

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

Case PGR2026-00022
Patent 12,274,481

**DECLARATION OF STEVEN K. NEUFELD, M.D.
IN SUPPORT OF PETITION FOR POST-GRANT REVIEW OF
U.S. PATENT NO. 12,274,481**

<i>Paragon 28 v. Treace Medical Concepts</i> PGR2026-00022 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:

Exhibit No.	Description
1001	U.S. Patent No. 12,274,481 to Santrock, et al. (“the ’481 patent”)
1002	File History of the ’481 patent
1003	This exhibit number is not used in this Declaration
1004	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4 th Edition, 2013 (“McGlamry”)
1005	U.S. Patent No. 8,882,816 to Kartalian et al. (“Kartalian”)
1006	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1007	U.S. Patent No. 8,328,806 to Tyber et al. (“Tyber”)
1008	RESERVED
1009	Paul Dayton, et al., <i>Relationship of Frontal Plane Rotation of First Metatarsal to Proximal Articular Set Angle and Hallux Alignment in Patients Undergoing Tarsometatarsal Arthrodesis for Hallux Abducto Valgus: A Case Series and Critical Review of the Literature</i> , 52(3) J. Foot & Ankle Surgery 348–354 (May-June 2013)

Exhibit No.	Description
1010	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. Surgery Gynecology & Obstetrics 183–191 (1934)
1011	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 Clin. Orthopaedics 119-135 (1960)
1012	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) Clinics Podiatric Med. & Surgery 486–496 (1996)
1013	Babak Baravarian, et al., <i>Lapidus bunionectomy: arthrodesis of the first metatarsocunieform [sic] joint</i> , 21 Clinics in Podiatric Med. & Surgery 97–111 (2004)
1014	Brian C. Toolan, <i>Surgical Strategies: The Lapidus Procedure</i> , 28 Foot & Ankle Int'l 1108-1114 (2007)
1015	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) Foot & Ankle Clinics 223–233 (June 2014)
1016	Nathan J. Young & Charles M. Zelen, <i>New techniques and alternative fixation for the lapidus arthrodesis</i> , 30(3) Clinics Podiatric Med. & Surgery 423–434 (July 2013)
1017	Lawrence A. DiDomenico, et al., <i>Correction of Frontal Plane Rotation of Sesamoid Apparatus During the Lapidus Procedure: A Novel Approach</i> , 53 J. Foot & Ankle Surgery 248–251 (Mar.-Apr. 2014)
1018	James M. Cottom & Anand M. Vora, <i>Fixation of lapidus arthrodesis with a plantar interfragmentary screw and medial locking plate: a report of 88 cases</i> . 52(4) J. Foot & Ankle Surgery 465–469 (July-Aug. 2013)
1019	Bas B.G.M. Franssen, et al., <i>One century of Kirschner wires and Kirschner wire insertion techniques: A historical review</i> , 76 Acta Orthopedic Belgium 1–6 (2010)
1020	File History for U.S. Provisional Application No. 62/108,936 (“the ’936 application”)

Exhibit No.	Description
1021	Curriculum Vitae of Steven K. Neufeld, M.D.
1022	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1023	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein (“Weinstein”)
1024	RESERVED
1025	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1026	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
1027	U.S. Patent No. 9,220,518 to Neal et al. (“Neal”)
1028	U.S. Patent App. Publ. No. 2014/0031882 to Schmuck et al. (“Schmuck”)
1029	RESERVED
1030	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1031	RESERVED
1032	RESERVED
1033	RESERVED
1034	RESERVED
1035	U.S. Design Patent No. D695,402 to DaCosta et al. (“DaCosta”)
1036	Declaration of Sylvia Hall-Ellis, Ph.D.
1037	U.S. Patent App. Publ. No. 2009/0036893 to Kartalian et al.

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 1021.

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 '481 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 '481 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 person of ordinary skill in the art (“POSITA”) 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.

2. Obviousness

20. 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.

21. 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.

22. In determining the scope and content of the prior art, I understand that a reference is considered 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.

23. 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 a whole. This “as a whole” assessment requires showing that a POSA at the time of

¹ The ’481 patent specification defines the “TECHNICAL FIELD” as “devices and methods for positioning and cutting bones.” Ex.1001, 1:27-28. The ’481 patent claims are directed to “[a]n instrumented surgical technique ... to correct a bunion deformity.” *Id.*, 18:4-7, 19:47-50, 21:43-45, 22:25-29.

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.

24. 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.

25. 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.

26. 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.

27. I also understand that when a claim element construed as a means-plus-function element, the construction includes both the function of the element and corresponding structure disclosed in the specification of the patent that performs that structure. I understand that a prior art references that discloses the performance of the claimed function by any of the structures recited in the specification therefore discloses the limitation. I further understand that the limitation may be disclosed by prior art that discloses an equivalent structure for performing the claimed function. I understand that a structure in the prior art is considered equivalent if a person of ordinary skilled in the art would consider the difference between the prior art structure and the corresponding structure described in the patent specification to be insubstantial. I further understand that one way of showing that the prior art structure

is only insubstantially different is to show that it performs the claimed function in substantially same way to achieve substantially the same result as the structure of the specification.

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 '481 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 '481 patent is August 15, 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 '481 patent describes “devices and methods for positioning and/or preparing bones,” specifically the first metatarsal and medial cuneiform. Ex.1001, 1:28-29, 1:51-62. Based on my review of the specification and claims of the '481 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 would 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 '481 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 '481 patent would have been obvious to any reasonably defined POSA.

35. I was at least a POSA by August 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 and interacted with many other POSAs and 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 '481 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 '481 patent and its claims, and how they would understand the disclosures in the prior art discussed herein. Additionally, by August 2015, I helped design implants for bunion surgeries.

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 '481 patent to be obvious in view of the prior art. My conclusions that the claims of the '481 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. OVERVIEW OF PRIOR ART

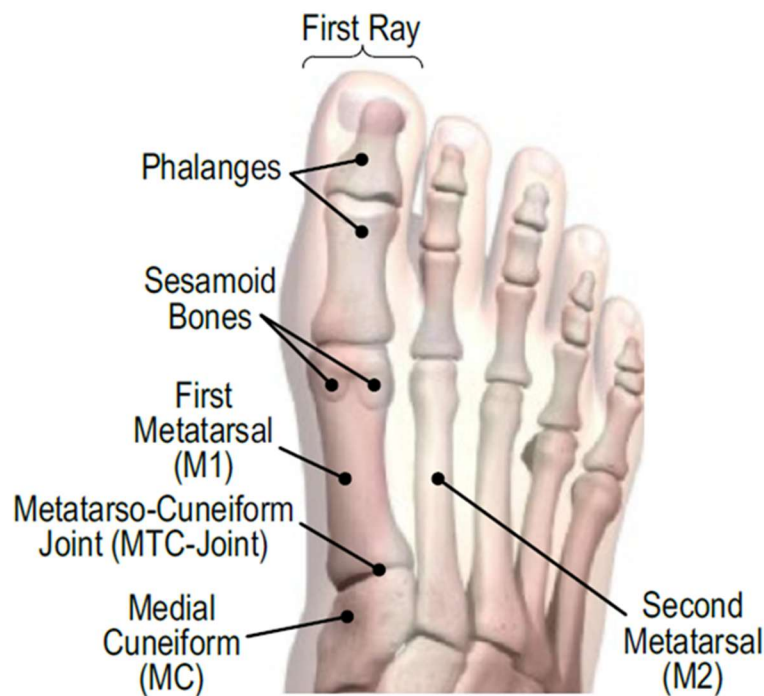
38. The disclosure of the '481 patent relates to devices and methods for positioning and cutting bones, and claims systems for performing bunion surgery.

39. Before August 2015, bunion surgery—including techniques to move the position of the metatarsal then fuse it relative to the cuneiform bone, known as the Lapidus procedure or metatarsal-cuneiform arthrodesis—and instruments for carrying out these surgeries were very well known. As described below, various

instruments and methods for correcting bunion deformities were very well known prior to the earliest priority date afforded to the '481 patent.

A. Relevant Human Foot Anatomy

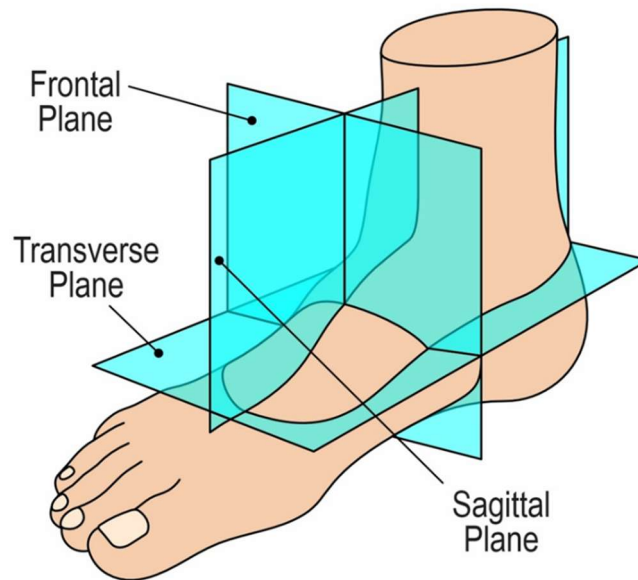
40. The human foot has 26 bones, including the bones of the first ray—the first metatarsal, medial cuneiform, and associated joints. The below image depicts the bones of the human foot, with annotations identifying the relevant bones and joints:



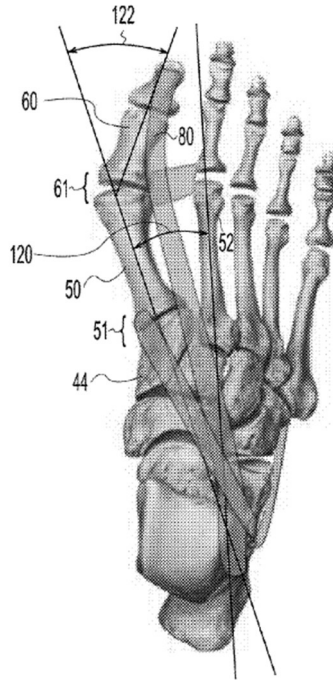
41. In a healthy foot, the bones of the first ray are anatomically positioned in three-dimensional alignment from the medial cuneiform to first metatarsal through the hallux (“big toe”), which promotes normal function of the foot. The first metatarsal and medial cuneiform meet to form the metatarsal-cuneiform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

42. 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:



43. One common deformity of the foot is known as a “bunion.” In a bunion deformity, the bones of the first metatarsal, medial cuneiform, and associated joints are misaligned in one or more planes as shown below:



Ex.1006, Fig.11. A bunion presents as a bump on the medial side of the foot.

44. The angle between the first metatarsal and the second metatarsal is referred to as the intermetatarsal angle (“IMA”). In most cases, bunions present as a shift of the distal head of the first metatarsal away from the second metatarsal, which forms an IMA relative to a normal IMA. In a healthy foot, the IMA is less than 9 degrees. Ex.1006, [0047] (describing an “abnormal” IMA as “9 degrees or greater”). In a severe bunion deformity, the IMA is greater than 15 degrees. *Id.*; *see also* Ex.1004, 323 (describing use of McGlamry’s procedure to “moderate or severe” bunion deformities with an IMA “from 14 to 30 degrees”).

45. Another common characteristic of a bunion is the first metatarsal being rotated in the frontal/coronal plane such that the sesamoid bones are no longer under on the bottom of the first metatarsal. *See* Ex.1006, [0043].

46. A bunion impacts the function of the foot. As explained above, with a bunion, the sesamoid bone are often out of position. Normal sesamoid positioning is a principal factor contributing to normal gait, and a less optimal alignment of the sesamoid can result in adverse retrograde forces that exacerbate the severity of the bunion deformity. Ex.1006, [0048]; Ex.1017, 250. Further, a bunion deformity can cause pain and an inability to wear shoes without discomfort. In extreme bunion cases, a patient may not be able to wear shoes at all.

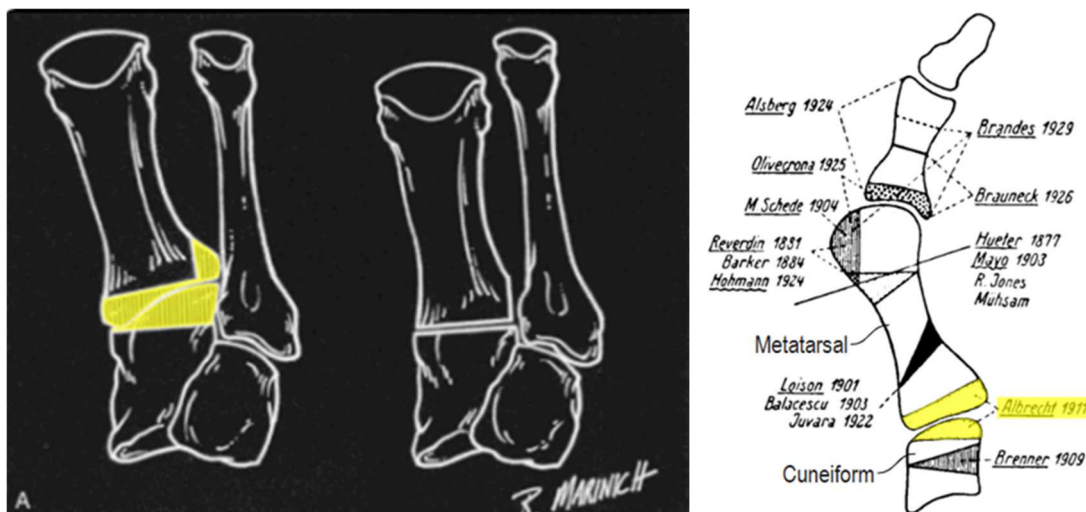
B. Bunion Correction

47. There are numerous surgical methods for treating bunions, the selection of which may depend on a variety of factors.

48. One procedure for treatment of a bunion is a metatarso-cuneiform arthrodesis, which Dr. Paul Lapidus popularized a version of in 1934. *See generally* Ex.1010. An arthrodesis is a surgical procedure in which the bones of a joint are permanently joined together through fusion. Ex.1004, 803 (referring to the “principles of arthrodesis” as the “principles for the fusion of joints”). An arthrodesis 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.

49. In a metatarso-cuneiform arthrodesis procedure, the first metatarsal and medial cuneiform are realigned in their natural positions, and fixed together for fusion. Ex.1004, 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.1012, Fig.1A (color added); Ex.1011, Fig.3 (color added). The cutting of bones is called an osteotomy.

50. 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.1010, 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.”); Ex.1012, 493 (“Inherent to this procedure is the ability to correct deformity in three planes.”); *see generally* Ex.1004, 324-327; Ex.1018, 466 (describing correction of the first metatarsal’s position in the transverse and sagittal planes). The purpose of this repositioning of the first metatarsal is to return the bone to its anatomically normal position. Ex.1004, 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).

51. 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.1004, 326-327; Ex.1012, 486-487, 490.

52. The body will heal and form bone between the cut bone surfaces (referred to as bone “fusion”) in the corrected orientation. Ex.1004, 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.”); *see also* Ex.1016, 429.

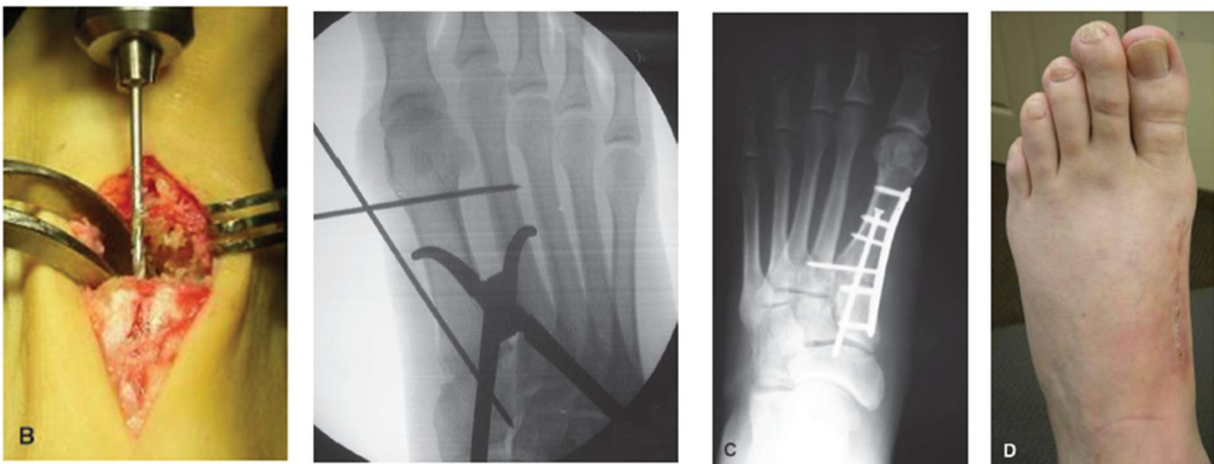
C. McGlamry’s Bunion Correction Procedure

53. I understand that McGlamry is the fourth edition of “McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery” and lists a publication date of 2013. *See generally* Ex.1004. 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.1004, xviii (Preface) (emphasis in original). In Chapter 31 of McGlamry, the textbook describes a “Lapidus Bunionectomy”—also known as “First Metatarsal-Cuneiform Arthrodesis”—including the history of the Lapidus procedure. 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.1004, 322.

54. The bunion correction procedure described by McGlamry is a “versatile procedure that can correct numerous pathologies,” as it “allows for triplanar

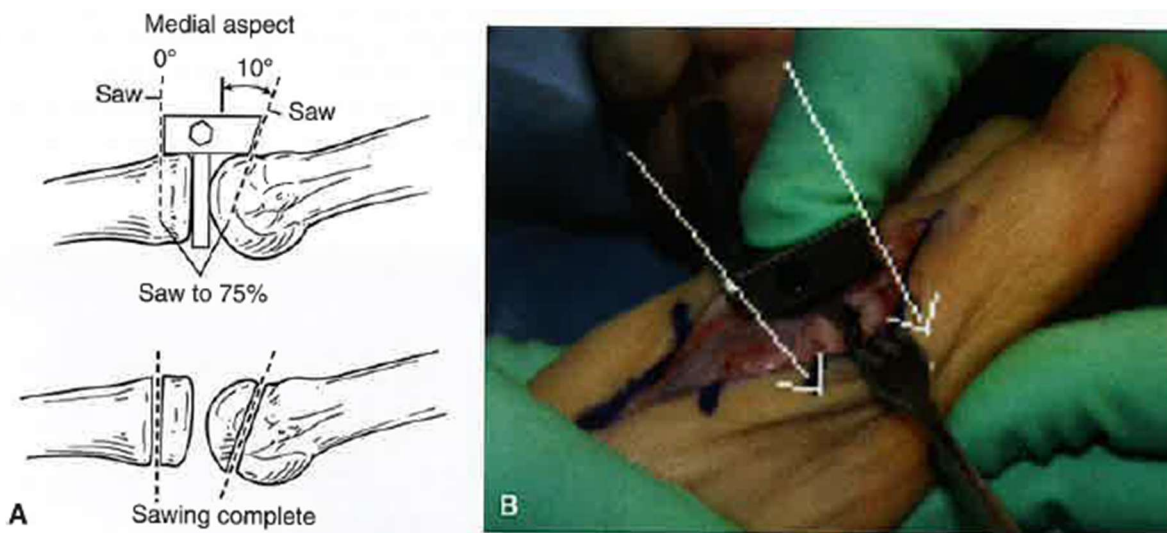
correction of the first metatarsal pathology, increases the biomechanical advantage of the peroneus longus, and has the ability to stabilize the medial column.” *Id.* McGlamry’s bunion correction procedure is generally used to correct moderate to severe bunion deformities caused by a hypermobile first ray, including IMAs ranging from 14 to 30 degrees. *Id.*, 322-323.

55. McGlamry describes in detail the traditional steps of the Lapidus 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 a bunion correction procedure, including the figures below:



Id., Figs.31.3B (“preparing the tarsal–metatarsal joint prior to fixation”), 31.5 (repositioning and temporary fixation of the first metatarsal), 31.9C (fixation, such as via screws and plate), 31.9D (foot after procedure showing absence of bunion deformity) (left to right).

56. Other chapters of McGlamry (such as Chapter 55) describe foot and ankle arthrodesis in more detail, and Chapters 1 and 34 of McGlamry identify instrumentation used in foot and ankle surgery. 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.1004, 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”).

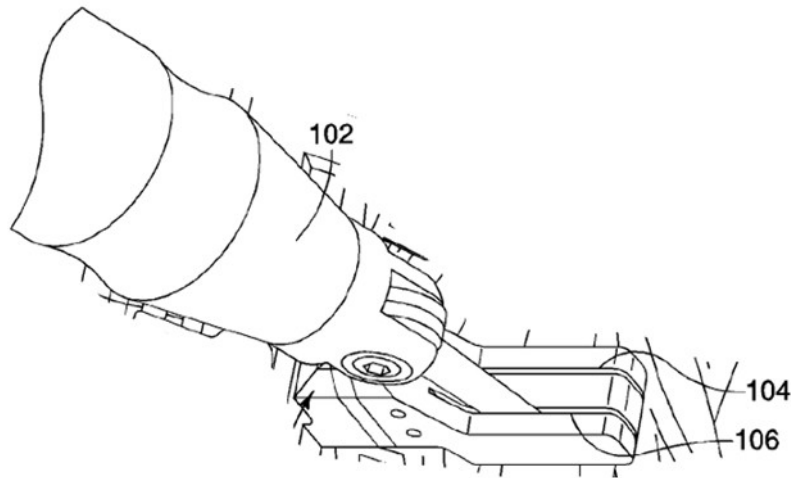
D. Known “Bone Preparation Guides” (Bone Cutting Guides)

57. Based on my experience and review of materials for this Declaration, I am aware that surgeons used bone preparation guides before July 2015 to ensure the accuracy and repeatability of cuts to bones. One form a bone preparation guide is a bone cutting guide. *See, e.g.*, Ex.1001, 7:26-44, 8:58-64, 12:5-22 (describing bone preparation guides used with a “tissue removing instrument”). Bone cutting guides allow bones to repeatably be cut such that the cut bone can fit together with other bones and help avoid resections of bone beyond what is required for correction of the targeted deformity.

58. Bone cutting guides existed and were well-known before July 2015 for bunion correction, and more specifically bunion correction via metatarso-cuneiform arthrodesis. U.S. Patent Publication No. 2013/0150900 to Haddad describes a bone cutting guide specifically for performing a metatarso-cuneiform arthrodesis—i.e., a Lapidus procedure. Haddad’s bone cutting guide and associated positioning jig can be used “for a fusion application [wherein] the jig likely would be secured to a metatarsal distally and a cuneiform proximally.” Ex.1022, [0058]. In a fusion application, two guide slots 104 and 106 cut the facing ends of the metatarso-cuneiform joint, which “create[s] two complimentary surfaces that will easily and effectively achieve a union through normal biological healing.” *Id.* [0068]. A surgeon can then use the jig to cause the cut bones of the metatarso-cuneiform joint

to “come into contact with each other, and potentially promote biological healing.”

Id., [0059].



Id., Fig.9 (excerpt).

59. U.S. Patent Publication No. 2007/0265634 to Weinstein similarly discloses a bone cut guide for a wedge osteotomy. Ex.1023, [0007] (“[E]mbodiments of the present invention provide one or more saw guides for facilitating a linear cut or a wedge shaped cut in an item which address deficiencies in the art, some of which are discussed above.”). According to Weinstein, certain prior art methods require a surgeon to “free hand[]” the cuts, which creates “a potential for significant misalignment of the cut surfaces when the bone ends are reapproximated.” *Id.*, [0005] (collecting references indicating the desirability of precision in osteotomy procedures). The below figures show Weinstein’s cut guides and resulting bone cuts to the first metatarsal and cuneiform.

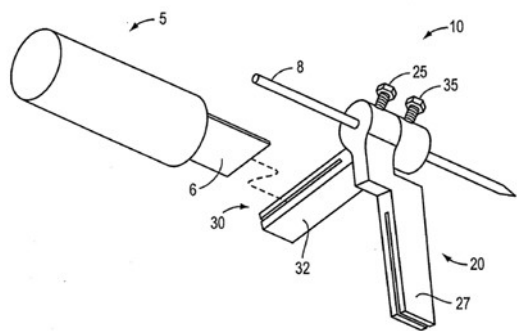


FIG. 3

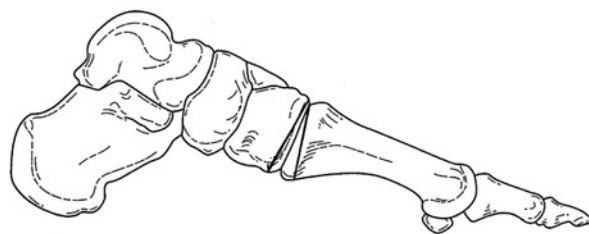


FIG. 13

Id., Figs.3, 13.

60. DaCosta is a design patent for a “LAPIDUS CUT GUIDE,” which states it issued in 2013. Ex.1035, Front Page. Images of DaCosta’s guide are below:

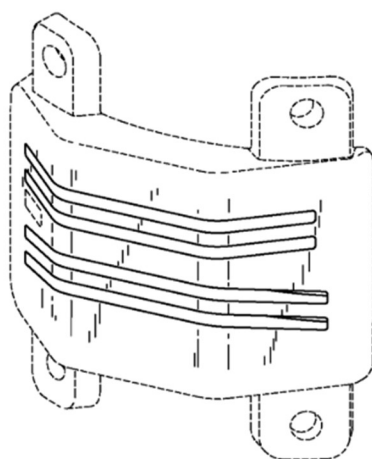


FIG. 1

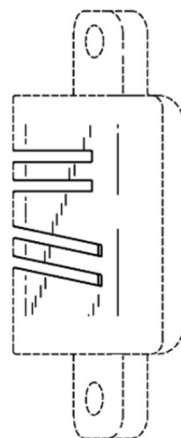
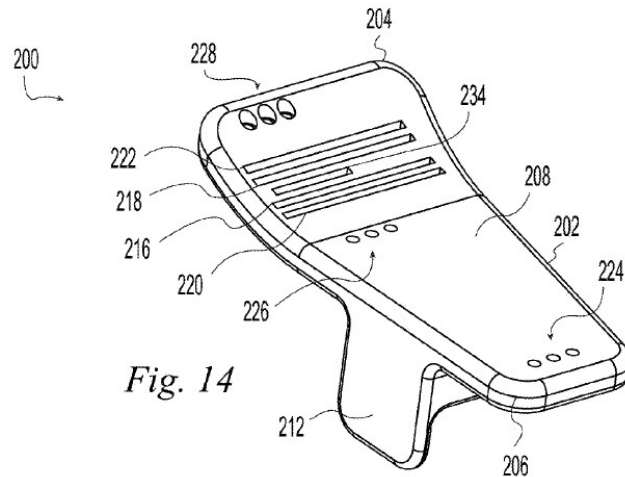


FIG. 5

Id., Figs.1, 5.

61. Fallin also discloses a bone cutting guide for use in a bunion correction surgery, such as a Lapidus procedure. Fallin discloses “[m]ethods and devices for performing an osteotomy,” including “forming a fusion osteotomy at a metatarsocuneiform joint on the first ray of a human foot.” Ex.1006, Abstract.

Fallin discloses an “an osteotomy guide 200” that achieves “more precision and repeatability in the relative orientation of the cuts” to the metatarsal and cuneiform. Ex.1006, [0062]. Figure 14 of Fallin below shows one embodiment of Fallin’s osteotomy guide:



Ex.1006, Fig.14.

62. Fallin’s osteotomy guide 200 includes multiple slots (216, 220) for cutting the first metatarsal bone, as well as multiple slots (218, 222) for cutting the medial cuneiform bone. *Id.*, [0052]; *see also id.*, [0065]-[0067] (describing use of slots for cutting bones). Fallin’s guide also includes holes (224, 226, 228) for receiving pins to attach the guide to the metatarsal and/or cuneiform. *Id.*, [0053]; *see also id.*, [0064], [0067] (describing use of holes to fix the guide to metatarso-cuneiform joint bones). Fallin’s guide also has a joint alignment feature to position the guide relative to the joint such that a predetermined amount of bone will be removed. *Id.*, [0055].

E. Known Bone Positioning Guides

63. As disclosed in McGlamry, one step in a bunion correction procedure involves repositioning the first metatarsal in one or more planes (e.g., transverse, frontal, sagittal). Ex.1004, 324-27. Bone positioning guides to assist with this movement are not new, and I have been aware of surgeons using bone positioning guides prior to July 2015.

64. For example, in 2013, McGlamry's textbook method for a Lapidus procedure disclosed the use of a Weber clamp and K-wires for repositioning the first metatarsal. Figure 31.5 below shows the Weber clamp positioned on the first and second metatarsal:



Ex.1004, Fig.31.5 (“Intraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle.”).

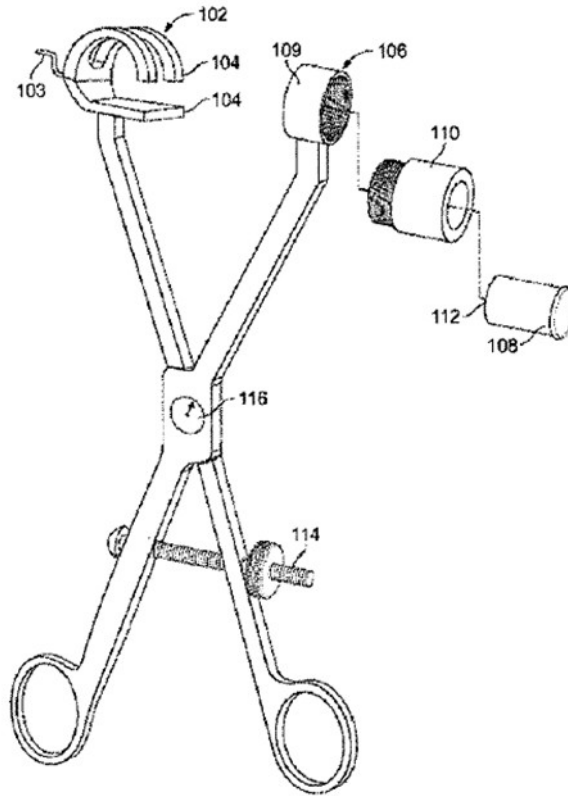
65. Based upon my experience and interactions with other surgeons, medical devices existed and were commercially available prior to July 2015 that surgeons used for the purpose of repositioning the first metatarsal in a bunion correction procedure. For example, a Hintermann distractor may be used to reposition the first metatarsal and reduce an abnormal IMA by pinning prongs of the distractor to the first metatarsal and the second metatarsal. *See* https://web.archive.org/web/20091122183715/http://www.ilstraining.com/idrt/brochures/ns1006_recon_catalog.pdf, 26 (last visited January 13, 2026) (showing Hintermann retractor available before July 2015). The surgeon would then adjust the distance between the two pinned prongs of the distracting end of the Hintermann device to correct the IMA.

66. Other known devices for repositioning a first metatarsal include Weber clamps (Ex.1004, 325-326), reduction forceps/clamps (Ex.1005; Ex.1018, 466), periarticular clamps, and joint distractors (<https://www.arthrex.com/resources/AN1-0437-EN/comprehensive-foot-system>) (last visited January 13, 2026). For example, surgeons have used clamps like the one below for positioning a first metatarsal for over two decades:



https://web.archive.org/web/20091122183715/http://www.ilstraining.com/idrt/brochures/ns1006_recon_catalog.pdf, 26 (last visited January 13, 2026); <https://www.youtube.com/watch?v=mLH4s96dErI>, 0:12 (last visited January 13, 2026).

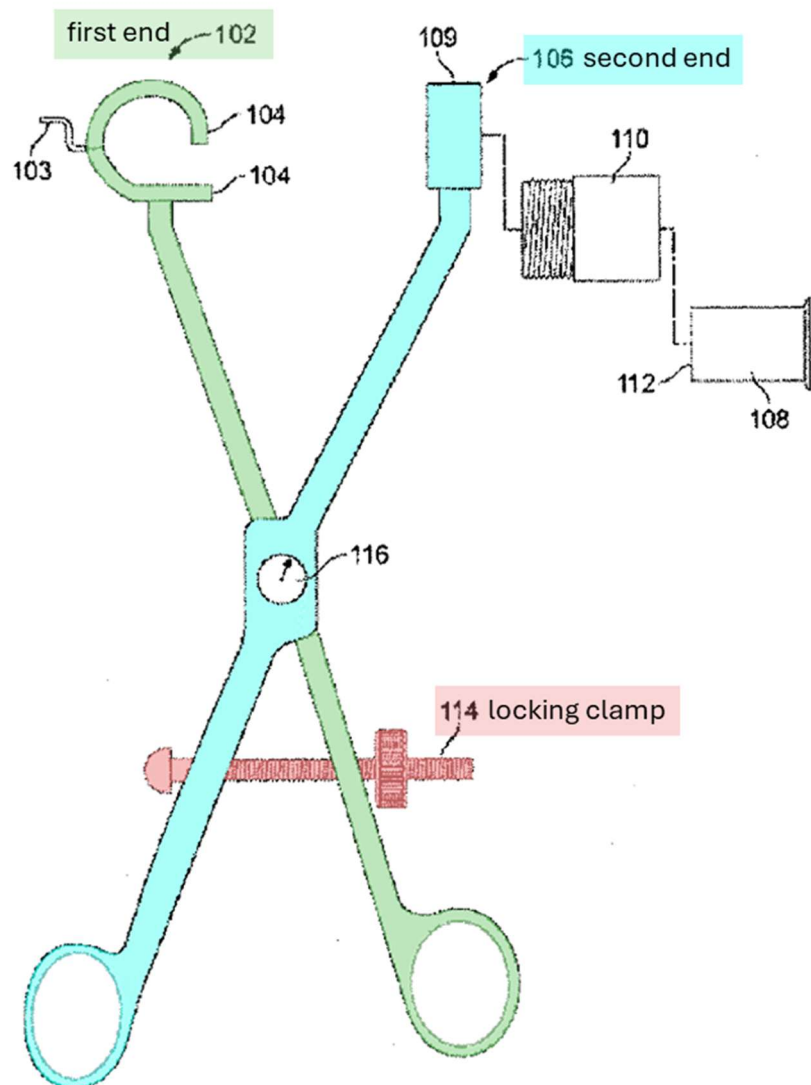
67. As another example, Kartalian discloses an “instrument”—a bone positioning guide—used to reposition the first metatarsal during a bunion correction surgery. Ex.1005, 9:16-18 (“More particularly, the ... instrument may be suitable for surgical repair of hallux valgus”), 10:19-22; *see also id.*, 9:24-45 (describing use of instrument 100 for correction of a bunion deformity), 9:66-10:3 (describing movement of first metatarsal in multiple places). Figure 1, Panel I of Kartalian shown below depicts an embodiment of Kartalian’s surgical instrument 100:



Ex.1005, Fig.1 (excerpt).

68. The surgical instrument 100 “act[s] as reduction forceps to align two bones or reduce the distance between the bones.” Ex.1005, 9:66-10:3. Specifically, Kartalian discloses that its instrument can be used to reduce the distance between the first and second metatarsal, thus reducing the IMA, and to rotate the first metatarsal in a frontal plane to correct any rotational deformities. *Id.*; *see also id.*, 10:46-49 (describing use of angle indicator 116 of instrument 100 to guide “reduction or realignment” of the first and second metatarsals “to the desired angle”).

69. Kartalian's instrument includes a first end/arm 102 (green) for engagement with the second metatarsal and a second end/arm 106 (blue) for engagement with the first metatarsal. *Id.*, 10:46-51. Kartalian's instrument also includes a "locking clamp 114" (red) comprising a threaded shaft and knob. *Id.* Figure 1, Panel II of Kartalian below shows an embodiment of these structures:



Id., Fig.1 (excerpt).

70. The first end/arm 102 of the instrument 100 can be configured in a variety of ways, including, for example, as a “caliper,” “towel clip,” or “vertically spaced plates.” *Id.*, 9:33-45. In a plate configuration, the first end/arm 102 may have “plated” that can be “curved or other shape[d]” to engage with the second metatarsal. *Id.*; *see also id.* 10:46-51 (describing engagement of the first arm with the second metatarsal). In one embodiment of the instrument 100, “once the plates have been placed around the bone, the position of the plates may be secured by a locking mechanism 103.” *Id.*, 9:42-45.

71. In contrast, the second end/arm 106 can be used to engage the first metatarsal. *Id.*, 10:46-51. The second end/arm can move the first metatarsal can be used when engaging the first metatarsal to achieve reduction or realignment of the first metatarsal to a desired position, including a reduction of the IMA in the transverse plane and correcting rotational deformity in the frontal plane. *Id.*, 9:66-10:3 (describing the instrument 100 as acting “as reduction forceps to align two bones or reduce the distance between the bones, as desired. Moreover, instrument 100 allows for correction of any rotational deformity (pronation) when used for surgical correction of a bunion”), 10:46-51 (describing reduction of the IMA).

72. Bone positioning guides, like those described above, allow a surgeon to precisely and reliably orient a bone relative to other bones, oftentimes in multiple planes, to correct positioning deformities of the bone. These bone positioning guides

prevent a surgeon from having to reposition bones by hand, which can result in imprecise movement, slippage of the bone from the surgeon's grasp during movement, excess movement resulting in damage to surrounding tissues and bone, and other problems associated with freehand bone repositioning.

F. Known Fixation Devices

73. One of the final steps in a bunion correction surgery is fixation of the first metatarsal and medial cuneiform to achieve a bony fusion in the corrected position. Fixation devices for fixing the corrected position of the first metatarsal and medial cuneiform have been known since at least the 1970s when surgeons were using screws and plates to maintain this corrected position. Ex.1012, 486-487, 490; Ex.1018, 467-468. Numerous fixation devices have been used in bunion correction procedures in the decades since, including one that I helped develop.

74. For example, in 1996, Hofbaur described the use of numerous fixation devices, such as K-wires, Steinman pins, compression screw(s), plate/screw, for use in fixing the moved position of the metatarso-cuneiform joint bones. Ex.1012, 486-487, 490.

75. In 2013, McGlamry's described using three cortical screws, and a "locking plate," as fixation devices (shown below):



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



Ex.1004, 326, Fig.31.7, Fig.31.8; *see also* Ex.1018, 467, Figs. 5A and 5B (showing use of screws and plate to fixate metatarso-cuneiform joint after preparation and repositioning).

III. THE '481 PATENT

A. Overview

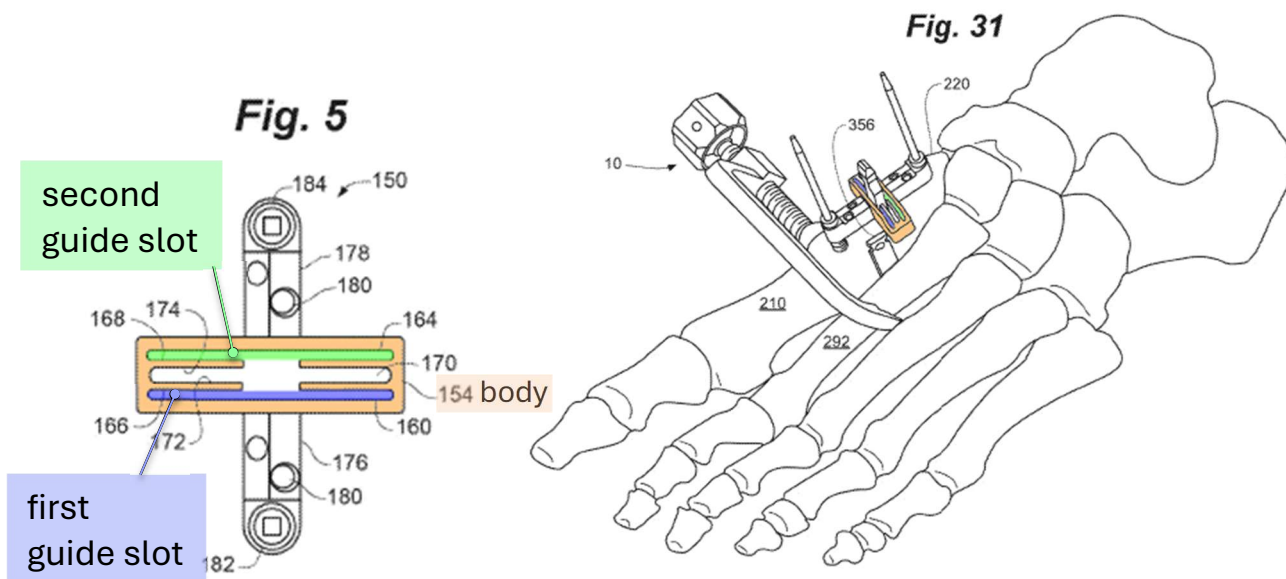
76. I have reviewed the '481 patent and its prosecution history.

77. The '481 patent states that it relates generally to "devices and techniques for positioning bones." Ex.1001, 1:28-29. The specification of the '481 patent discloses surgical instruments and techniques for bone positioning, including bunion correction surgery. Ex.1001, 1:28-29, 4:35-40.

78. The '481 patent describes performing a bunion correction procedure using (1) a bone positioning guide with a tip, bone engagement member, and a mechanism for urging the bone engagement member and tip towards each other (*id.*,

4:46-56), (2) a bone preparation guide for preparing the bones of the metatarsocuneiform joint (*id.*, 7:26-30), (3) a tissue removing instrument (*id.*, 7:34-38), (4) pin(s) inserted into the first metatarsal for rotating the first metatarsal in the frontal plane (*id.*, 11:29-34), and (5) fixation device(s) for fixating the moved position of the first metatarsal and medial cuneiform (*id.*, 10:44-51).

79. The “bone preparation guide” is identified by the ’481 patent. Ex.1001, 7:26-30, 8:58-64. An example of a bone preparation guide is shown Figures 5 and 31 (below). This “bone preparation guide” (150) includes a body (154 – orange) with a first guide slot (160 to 166 – blue) and second guide slot (164 to 168 – green) separated by a distance. Ex.1001, 7:30-52.



Ex.1001, Figs.5, 31 (annotated). In a bunion correction surgery, the bone preparation guide may be used to guide the cutting of the ends of the facing surfaces of the first metatarsal and medial cuneiform. *Id.*, 12:23-54.

80. The '481 patent also identifies a “bone preparation guide.” In one embodiment, the bone positioning guide is “a tenaculum or tong structure,” which can include a “first shaft pivotally connected to a second shaft,” “[a] first end of each shaft can include an actuator, such as a handle,” “[a] second end of the shaft can include a bone engagement member.” Ex.1001, 6:44-58. In another embodiment, the bone positioning guide is “[a] generally C-shaped configuration” that includes a main body member 20, a shaft 30, a bone engagement member 40, a first end 60, and a second end 70. Ex.1001, 4:63-5:10, Figs. 1, 3B, 3C, 9A.

81. The '481 patent also discloses various means of fixating the moved position of the first metatarsal and cuneiform. The specification states: “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) prior to a closing of the surgical access to the joint.” *Id.*, 10:46-51.

B. Claims

82. The claims of the '481 patent are directed to “[a]n instrumented surgical technique” to correct a bunion deformity.” *See* Ex.1001, Claims 1-30. Generally, the claimed methods include various combinations of making an incision on the foot, cutting the metatarsal and/or cuneiform, moving the metatarsal in multiple planes, compressing the metatarsal and cuneiform, and fixating the metatarsal and cuneiform for fusion. *Id.* To perform these methods, the '481 patent claims various

combinations of surgical instruments as part of the claimed surgical technique. These include, for example: a “bone positioning guide” to move the first metatarsal; a “pin” to rotate the first metatarsal in the frontal plane; a “bone preparation guide,” which is a bone cutting guide, to guide a cutting instrument to cut the metatarsal and/or cuneiform; a “fixational device,” for example a screw or plate to fixate a moved position of the first metatarsal for fusion. *Id.*

IV. CLAIM CONSTRUCTION

83. I have not been asked to opine on claim construction in this proceeding and 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 ’481 patent throughout my analysis unless otherwise noted.

A. “bone positioning guide”

84. The term “bone positioning guide” appears in multiple claims of the ’481 patent.

85. A POSA would understand that a “bone positioning guide” is a “device that is designed to move bone(s)” under the plain and ordinary meaning of this term.

86. A POSA would understand that “moving” a bone, or movement of a bone in the context of the ’481 patent would encompass either translational movement or rotation of the bone, or a combination of the two.

87. I understand that terms may also be construed as “means-plus-function” terms under 35 U.S.C. § 112(f). I further understand that if a term is construed as a means-plus-function term under Section 112(f), the law requires identifying the corresponding structure and function. I have been asked to assume the following function and corresponding structure(s) for the term “bone positioning guide” if the term is construed as a means-plus-function limitation under Section 112(f).

Function: The claimed functions of the “bone positioning guide” are:

- “causing the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity” (Ex.1001, claims 1, 14, 27);
- “reducing a distance between the bone engagement member and the contact surface, thereby reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity” (*Id.*, claim 30).

Corresponding Structure: Examples of a corresponding structure 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, 6:44-58);
- “[a] generally C-shaped configuration” that includes a main body member 20, a shaft 30, bone engagement member 40, a first end 60, and a second end 70, Ex.1001, 4:63-5:10, Figs.1, 3B, 3C.

88. I have analyzed obviousness under both constructions, and my conclusion would not change based on which construction is adopted.

B. “fixation device”

89. The term “fixation device” appears in multiple claims of the ’481 patent.

90. A POSA would understand that a “fixation device” is a “device that connects bones for fusion” under the plain and ordinary meaning of this term.

91. I have been asked to assume the following function and corresponding structure(s) for the term “fixation device” if the term is construed as a means-plus-function limitation under Section 112(f):

Function: The claimed functions of the “fixation device” are:

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

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

Corresponding Structure: Examples of a corresponding structure include:

- “compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail” (Ex.1001, 10:46-51);
- “two bone plates positioned in different planes” (*Id.*, 13:23-27).

92. I have analyzed obviousness under both constructions, and my conclusion would not change based on which construction is adopted.

C. “tissue removing instrument”

93. The term “tissue removing instrument” appears in multiple claims of the ’481 patent.

94. A POSA would understand that a “tissue removing instrument” is a “device for cutting tissue” under the plain and ordinary meaning of this term.

95. I have been asked to assume the following function and corresponding structure(s) for the term “fixation device” if the term is construed as a means-plus-function limitation under Section 112(f):

Function: The claimed function of the “tissue removing instrument” is cutting bone. Ex.1001, claim 1;

Corresponding Structure: Examples of a corresponding structure include: a saw blade, rotary bur, and osteotome. *Id.*, 7:34-38.

96. I have analyzed obviousness under both constructions, and my conclusion would not change based on which construction is adopted.

V. THE PRIOR ART

97. In this Declaration, I rely on several references that I understand are prior art to the '481 patent claims. These references include:

- McGlamry (McGlamry's Comprehensive Textbook of Foot and Ankle Surgery (4th Edition)) (Ex.1004);
- Kartalian (U.S. Patent No. 8,882,816 (Ex.1005));
- Fallin (U.S. Patent App. Publ. No. 2016/0213384 (Ex.1006));
- Tyber (U.S. Patent No. 8,328,806 (Ex.1007));

98. These references are from the same field as the '481 patent, e.g., devices and techniques for positioning and cutting bones. Ex.1001, 1:32-42. These references are pertinent to a problem focused on by the inventors, e.g., cutting, repositioning, and fixating bone during a surgical procedure. *Id.*

VI. GROUND 1: CLAIMS 1, 3-8, 10, 11, 13, 27, AND 29 WOULD HAVE BEEN OBVIOUS OVER MCGLAMRY AND KARTALIAN

99. It is my opinion that claims 1, 3-8, 10, 11, 13, 27, and 29 of the '481 patent would have been obvious to a person of ordinary skill in the art as of August 14, 2015 in view of McGlamry and Kartalian.

A. Claim 1

1. Preamble

100. The preamble of claim 1 recites “[a]n instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.”

101. McGlamry discloses an instrumented surgical technique for preparing a tarsal-metatarsal joint² for fusion and for repositioning a first metatarsal to correct a bunion deformity. Ex.1004, 324-328. Chapter 31 of McGlamry—“Lapidus Bunionectomy: First Metatarsal-Cuneiform Arthrodesis”—describes a surgical method for cutting the proximal end of the first metatarsal, cutting the distal end of the medial cuneiform, correcting the position of the metatarsal in the transverse plane and frontal plane, and fixing the moved first metatarsal to the medial cuneiform. *Id.* McGlamry discloses the use of instruments during its surgical procedure, including (1) an osteotome to cut the first metatarsal and medial cuneiform, Ex.1007, 324 (“The recommended joint preparation techniques consist of the use of an osteotome....”); (2) Weber clamps and/or K-wires to reposition the first metatarsal and/or temporarily stabilize the first metatarsal relative to the medial cuneiform prior to fixation, *id.*, 325-326, Fig.31.5; and (3) various combinations of

² A “tarsal-metatarsal joint,” “metatarsal-cuneiform joint,” “metatarso-cuneiform joint,” and “metatarsocuneiform joint” each refer to the same joint between the first metatarsal and medial cuneiform.

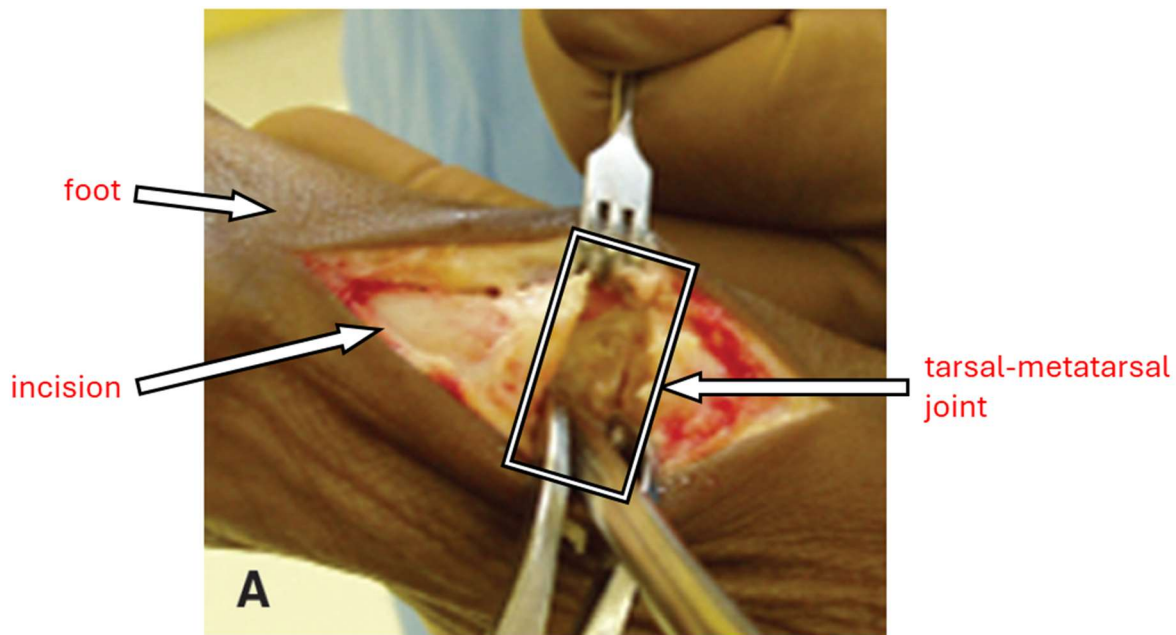
screws and plates which, in combination with a drill, fix the first metatarsal to the medial cuneiform, *id.*, 326-329.

2. **Limitation 1[a]**

102. Limitation 1[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” McGlamry discloses this limitation.

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

104. Figure 31.3A of McGlamry depicts an example of this incision as shown below:



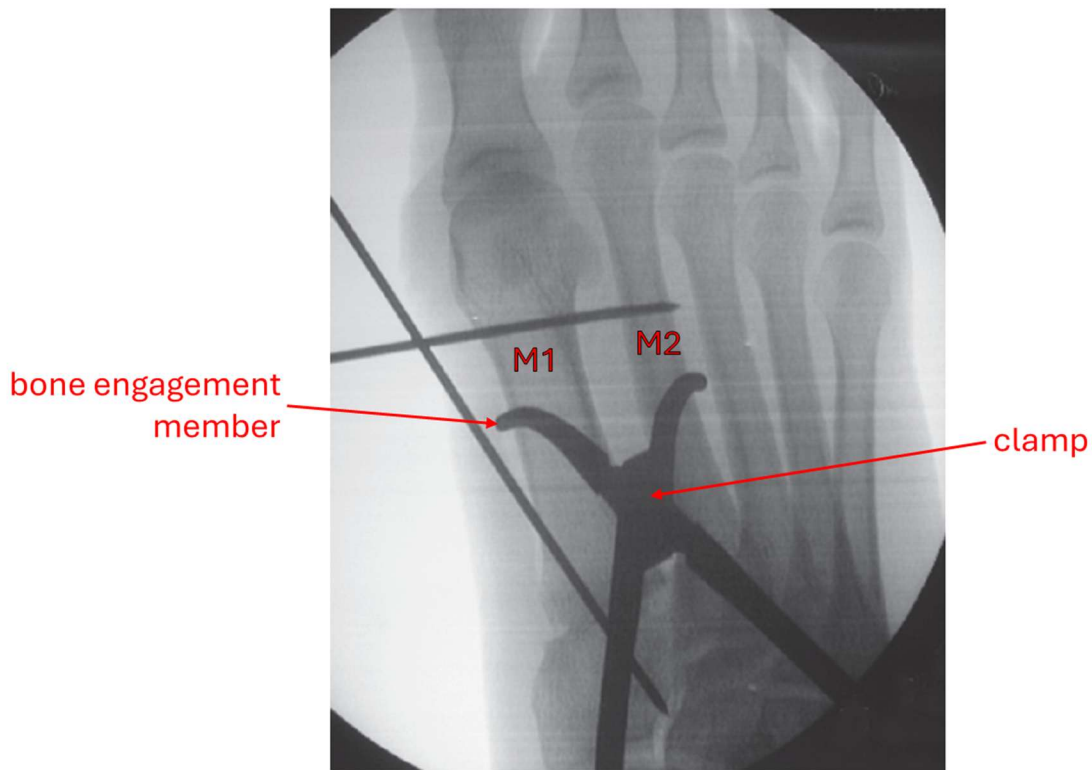
Ex.1004, Fig.31.3A (annotated). This incision provides access to the tarsal-metatarsal joint.

3. **Limitation 1[b]**

105. Limitation 1[b] recites “engaging the first metatarsal with a bone engagement member of a bone positioning guide.” McGlamry in combination with Kartalian renders obvious limitation 1[b].

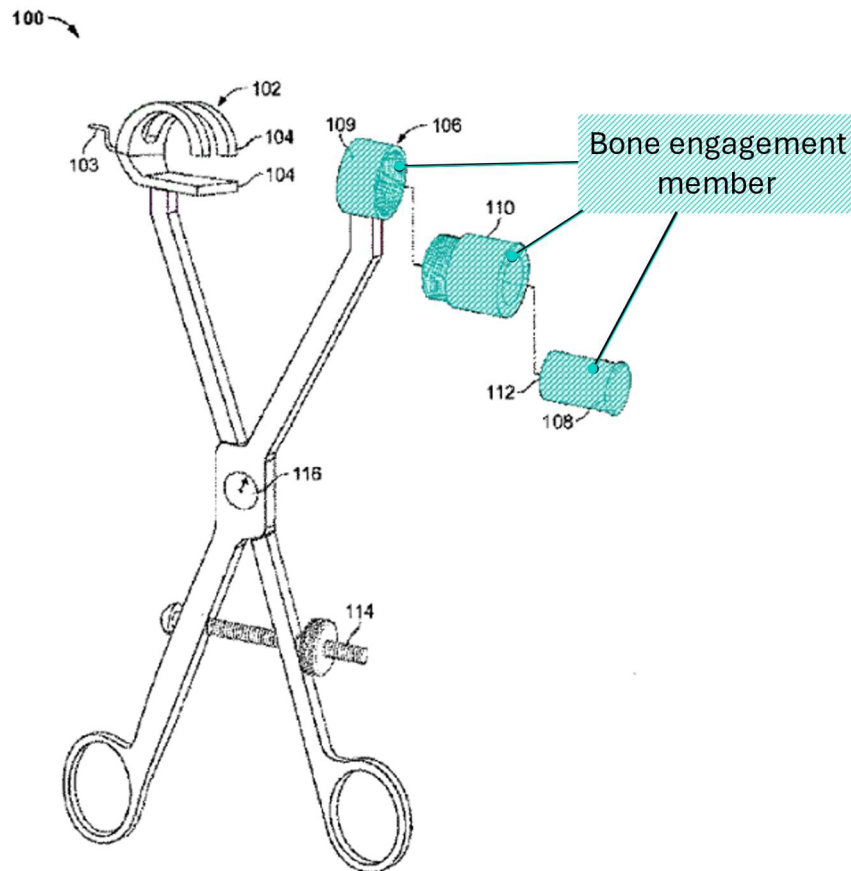
106. McGlamry discloses using a Weber clamp to move the metatarsal in the transverse plane. Ex.1004, 325-326. This movement of the first metatarsal in the transverse plane occurs, at least in part, by engaging the first metatarsal. *Id.*

107. McGlamry discloses that “a large Weber clamp may be used to assist, increase, or maintain the reduction.” *Id.*, 325; *see also id.*, 325-326; Ex.1014, 1112 (disclosing a lateral force applied to the first metatarsal that both reduces the IMA and corrects a hallux valgus deformity); Ex.1018, 466 (“The first IMA was then reduced with a large, pointed, bone reduction clamp” and Fig. 2 showing use of clamp). This reduction treats the bunion deformity. *See* Ex.1004, 322-329. McGlamry’s Weber clamp engages the first metatarsal (M1) as shown below:



Ex.1004, Fig.31.5 (annotated).

108. Kartalian also discloses using a bone positioning guide with a bone engagement member to engage a first metatarsal. Kartalian discloses an “instrument 100” that “may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1005, 9:66-67. As shown below, Kartalian’s instrument is a tenaculum (forceps):



Ex.1005, Fig.1 (excerpt) (annotated).

109. Kartalian's instrument 100 functions to position the bones by moving the first metatarsal in the transverse plane. Ex.1005, 9:66-67. Accordingly, Kartalian's instrument is a bone positioning guide under the plain and ordinary meaning of that term discussed above. Further, it is identical or at least equivalent to the structures identified in the '481 patent for the claimed bone positioning guide because it is a tenaculum or structure that performs the same function (positioning metatarsals including through IMA reduction), in substantially the same way (e.g., opposed bone-engaging ends/arms of a tenaculum (forceps) or C-shaped frame)

manipulated by the surgeon to apply controlled corrective forces and hold alignment), to achieve the same result (moving the bones to the desired alignment and stabilizing them while fixation is performed).

110. Kartalian's bone positioning guide includes an end 106 that is a bone engagement member. Kartalian discloses that end 106 "may be placed on the proximal first bone (first metatarsal)." Ex.1005, 10:49-51. Accordingly, Kartalian's end 106 is a bone engagement member under the plain and ordinary meaning of that term discussed above.

111. A POSA would have been motivated to use Kartalian's bone positioning guide in McGlamry's procedure.

112. Kartalian has features that are specifically designed for bunion correction procedures and would have been desirable for use in McGlamry's procedure. Ex.1005, 9:58-10:15. For example, Kartalian includes a feature for locking bones during movement of the first metatarsal. *Id.*, 10:4-6 (describing structure to "hold the instrument 100 in position once the final alignment of the bones has been achieved"). This locking feature would prevent unwanted transverse plane movement after repositioning of the first metatarsal.

113. Kartalian's instrument 100 also includes "an automatic angle indicator 116 to provide the surgeon with an estimate of the angle of the bones requiring correction." *Id.*, 10:8-16. Kartalian explains that "one skilled in the art appreciates

that trigonometry may be used to estimate the angle between the two bones using known data regarding the length of the bones from x-rays or from anthropomorphic averages along with the final distance between the instrument arm 118 and instrument arm 120 to estimate the [IM] angle. The instrument 100 then may be suitably calibrated to show the angle between the bones.” *Id.*, 10:8-18. This feature would provide the surgeon with additional guidance on the final position of the bone, which could improve the success rate of a surgery that was known, in 2015, for having a relatively high failure rate. Ex.1005, 2:30-39.

114. Kartalian’s instrument also includes a sleeve that would have been useful for inserting the K-wires that McGlamry uses for temporary fixation. *See infra*, §VI.G. (Claim 10).

115. This would have been nothing more than the substitution of one known element (McGlamry’s Weber clamp) for another (Kartalian’s instrument), and the results would have been predictable. Both Kartalian’s instrument and McGlamry’s clamp are a form of a tenaculum/tongs. Kartalian’s instrument and McGlamry’s clamp are both disclosed as engaging the first and second metatarsals for the purpose of moving the first metatarsal during a bunion correction procedure. Ex.1005, 9:66-10:3, 10:43-51; Ex.1004, 325-326, Fig.31.5.

116. A POSA would have also reasonably expected to succeed in using Kartalian’s instrument in McGlamry’s procedure. Kartalian’s instrument was

designed for a bunion correction procedure that is, in many respects, similar to McGlamry's procedure. Ex.1005, 9:58-10:18, 10:29-62. The operational principles of Kartalian's instrument would not be changed when used in McGlamry's procedure given the similarities between the procedures described in McGlamry and Kartalian.

117. Given these similarities in structure and use, a POSA would have recognized that substituting Kartalian's instrument for McGlamry's clamp would have been nothing more than the substitution of one known instrument for another. The results of this substitution would have been predictable as both instruments perform the function of moving and maintaining the position of bones, and Kartalian's instrument is described for use in procedures like McGlamry's.

118. A POSA likely would not need to modify Kartalian's instrument for McGlamry's procedure. However, to the extent any modification would need to be made to Kartalian's instrument for use in McGlamry's procedure, such modification(s) would have been within the skill of a POSA capable of modifying basic surgical equipment. McGlamry's clamp and Kartalian's instrument are each simple mechanical tools, and thus any modification, if needed, would only involve easy-to-implement dimensional modifications.

4. Limitation 1[c]

119. Limitation 1[c] recites “engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle.”

McGlamry and Kartalian render obvious limitation 1[c].

120. McGlamry discloses a step for reducing the IMA:

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

Ex.1004, 325-326.

121. McGlamry further depicts its Weber clamp engaged with the first (M1) and second (M2) metatarsals, which are separated by the IMA.

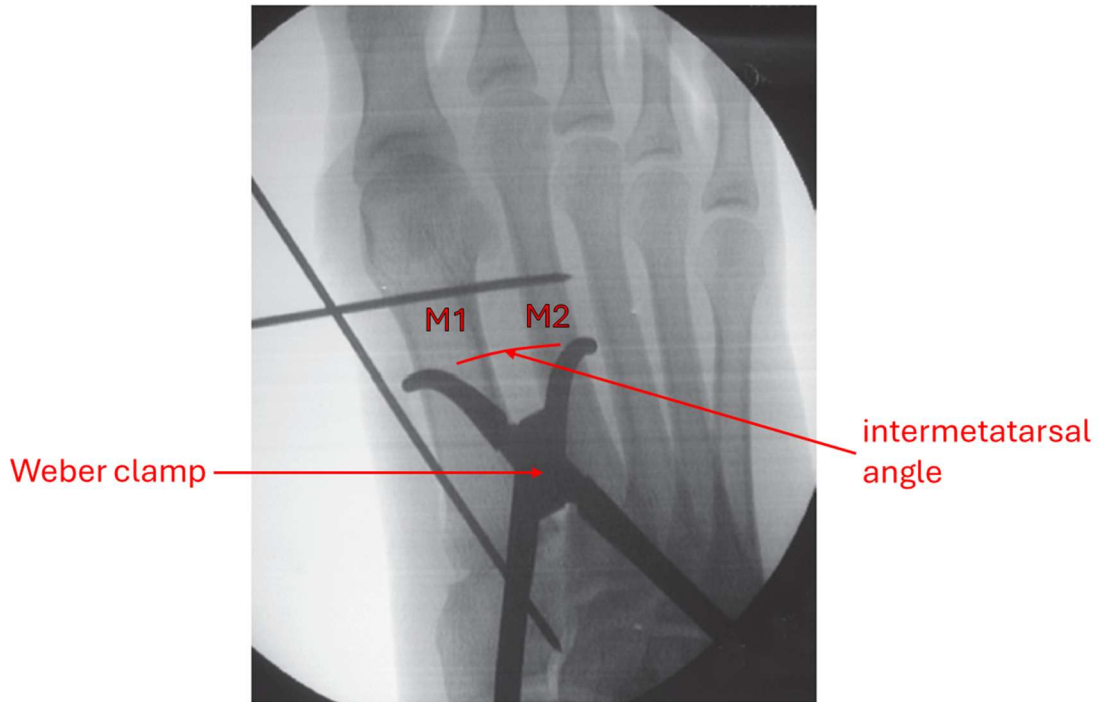


Figure 31.5 Intraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle.

Ex.1004, Fig.31.5 (annotated).

122. Kartalian’s instrument 100 includes an end 102 that engages with the second metatarsal: “first end 102 [(tip)] may be placed on the distal second bone (second metatarsal)” Ex.1005, 10:49-51. Kartalian describes various embodiments of the end 102 for engagement with the second metatarsal, including as a “caliper,” “towel clip,” or “two vertically spaced plates” that “may function to center instrument 100 on the desired bone, such as a metatarsal.” *Id.*, 9:31-38.

123. With the end 102 engaged to the second metatarsal, the arm 106 can be used to engage the first metatarsal and move it toward the second metatarsal to

reduce the intermetatarsal angle between the metatarsals. Ex.1005, 9:66-10:3, 10:46-51.

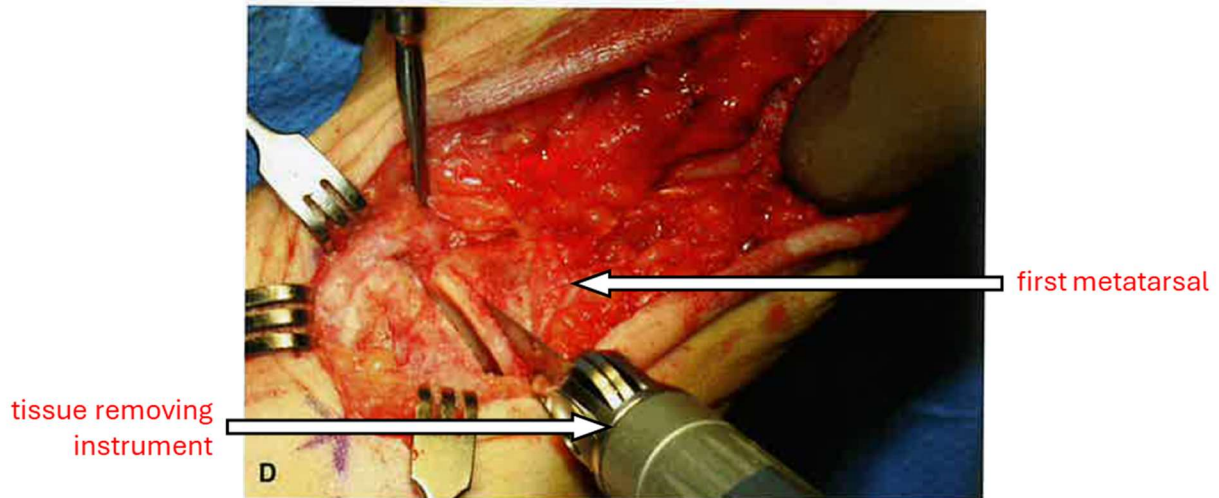
124. Thus, when Kartalian’s instrument is used in McGlamry’s procedure to reduce an IMA, the instrument would engage the second metatarsal while it is separated from the first metatarsal by the IMA. This would be consistent with McGlamry’s disclosure of using the Weber clamp.

5. Limitation 1[d]

125. Limitation 1[d] recites: “cutting an end of the first metatarsal with a tissue removing instrument.” McGlamry discloses limitation 1[d].

126. For example, McGlamry states that “[t]he initial joint resection is performed on the first metatarsal articular surface” and that the “resection is made perpendicular to the long axis of the first metatarsal and parallel to the existing metatarsal base.” Ex.1004, 324.

127. McGlamry describes the use of an “osteotome” to cut bone, including the articulating ends of the first metatarsal and medial cuneiform, in its Chapter 31 metatarsocuneiform arthrodesis. *Id.* (“The recommended joint preparation techniques consist of the use of an osteotome and mallet ...”). McGlamry teaches the use of a “sagittal saw”—a saw blade—for performing a metatarsocuneiform arthrodesis in Chapter 55, including cutting the end of the first metatarsal.



Ex.1004, Fig.55.7D (annotated) (“Removal of the articular surface of the base of the first metatarsal.”); *see also id.*, 807-808.

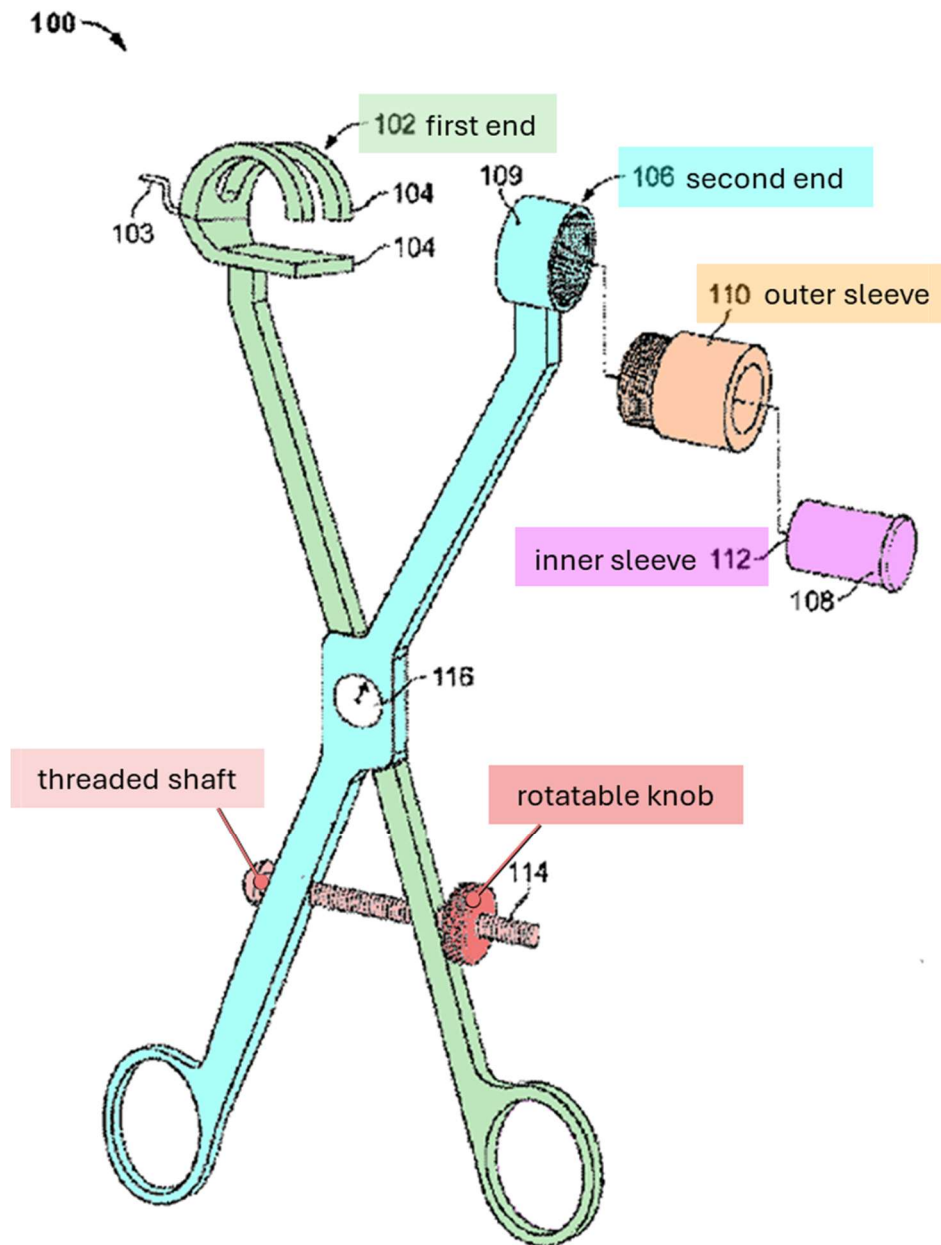
128. McGlamry’s use of an osteotome and mallet or saw satisfies the “tissue removing instrument” limitation under its plain meaning. If the means-plus-function construction were applied, each such instrument is a corresponding structure (or an equivalent thereof) to the saw/osteotome/bur-type tissue removal instruments described in the ’481 patent. For example, each instrument disclosed in McGlamry is insubstantially different from the instruments in the ’481 patent and performs the same function of cutting bone in substantially the same way with the same result.

6. Limitation 1[e]

129. Limitation 1[e] recites “rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to

correct the bunion deformity.” McGlamry in view of Kartalian renders obvious limitation 1[e].

130. Kartalian’s instrument 100 has a rotatable knob connected to a threaded shaft, as shown in Figure 1, Panel I below:



Ex.1005, Fig.1 (excerpt) (annotated).

131. A POSA would understand that rotation of the knob would cause the knob to move down the threaded shaft, thereby causing a reduction of the distance between the first end 102 and the second end 106. This would move the bone engagement member and the tip relative to one another. Accordingly, Kartalian's IMA reduction mechanism includes a knob connected to a threaded shaft.

132. When Kartalian's instrument is used in McGlamry's procedure and engaged with the first and second metatarsals, the surgeon would rotate the threaded knob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102. Kartalian explains that the movement of the arm 106 toward end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the IMA between the two metatarsals. Ex.1005, 9:66-67 ("The instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired."), 10:8-18 (describing operation of the "automatic angle indicator 116" for estimating the IMA between the "bones requiring correction" (the first and second metatarsals)), 10:46-62 ("After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by angle indicator 116."). This IMA reduction corrects the bunion deformity.

7. **Limitation 1[f]**

133. Limitation 1[f] recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” McGlamry discloses limitation 1[f].

134. McGlamry discloses:

If the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal medial and lateral cortex with the K-wire in the direction of the inferior medial to superior lateral. 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

Ex.1004, 326. Because the K-wire serves as a “rotation device” for rotating the first metatarsal in the frontal plane, the surgeon performing McGlamry’s method imparts a force on the pin, which is “inserted into the first metatarsal,” to rotate the first metatarsal in the frontal plane (i.e., adjust the alignment of the first metatarsal in the frontal plane).

135. A K-wire, also known as a Kirschner wire, is a type of pin. *See, e.g.*, Ex.1019, 1 (describing history of “a smooth pin, presently known as the Kirschner wire (K-wire)”); Ex.1009, 349, Fig.1 (interchangeably using pins and wires terminology). K-wires could be used interchangeably in a Lapidus procedure with other pins, including Steinman pins. *See* Ex.1012, 487 (disclosing temporary fixation by K-wire or Steinman pin in a Lapidus procedure).

136. McGlamry's K-wire "rotation device" is disclosed as being used in addition to (not instead of) other means of rotating the first metatarsal in the frontal plane. Ex.1004, 324-326 (describing use of K-wire as a rotation device for "further" frontal plane correction). The K-wire would be used with the bone positioning guide to correct frontal plane mispositioning of the first metatarsal. *See* Ex.1004, 326 (a "K-wire can be used as a rotation device" when "the surgeon feels a need to obtain *more* correction in the frontal plane") (emphasis added).

8. Limitation 1[g]

137. Limitation 1[g] recites "cutting an end of a medial cuneiform with the tissue removing instrument." McGlamry discloses limitation 1[g].

138. As I discussed regarding limitation 1[d], McGlamry discloses a tissue removing instrument for cutting an end of a first metatarsal. *See supra* §VI.A.5. McGlamry also teaches using a tissue removing instrument for cutting an end of a medial cuneiform. *See* Ex.1004, 324 (disclosing use of osteotome and a mallet for cutting an end of the medial cuneiform). For example, McGlamry states that "[t]he corrective articular resection is made at the distal aspect of the convex shaped cuneiform." *Id.*; *see also id.*, 807-808 (disclosing use of a sagittal saw for cutting an end of a medial cuneiform in Chapter 55 of McGlamry), Fig.55.7C ("Resection of the articular surface of the medial cuneiform with the sagittal saw.").

9. Limitation 1[h]

139. Limitation 1[h] recites “compressing the first metatarsal together with the medial cuneiform.” McGlamry discloses limitation 1[h].

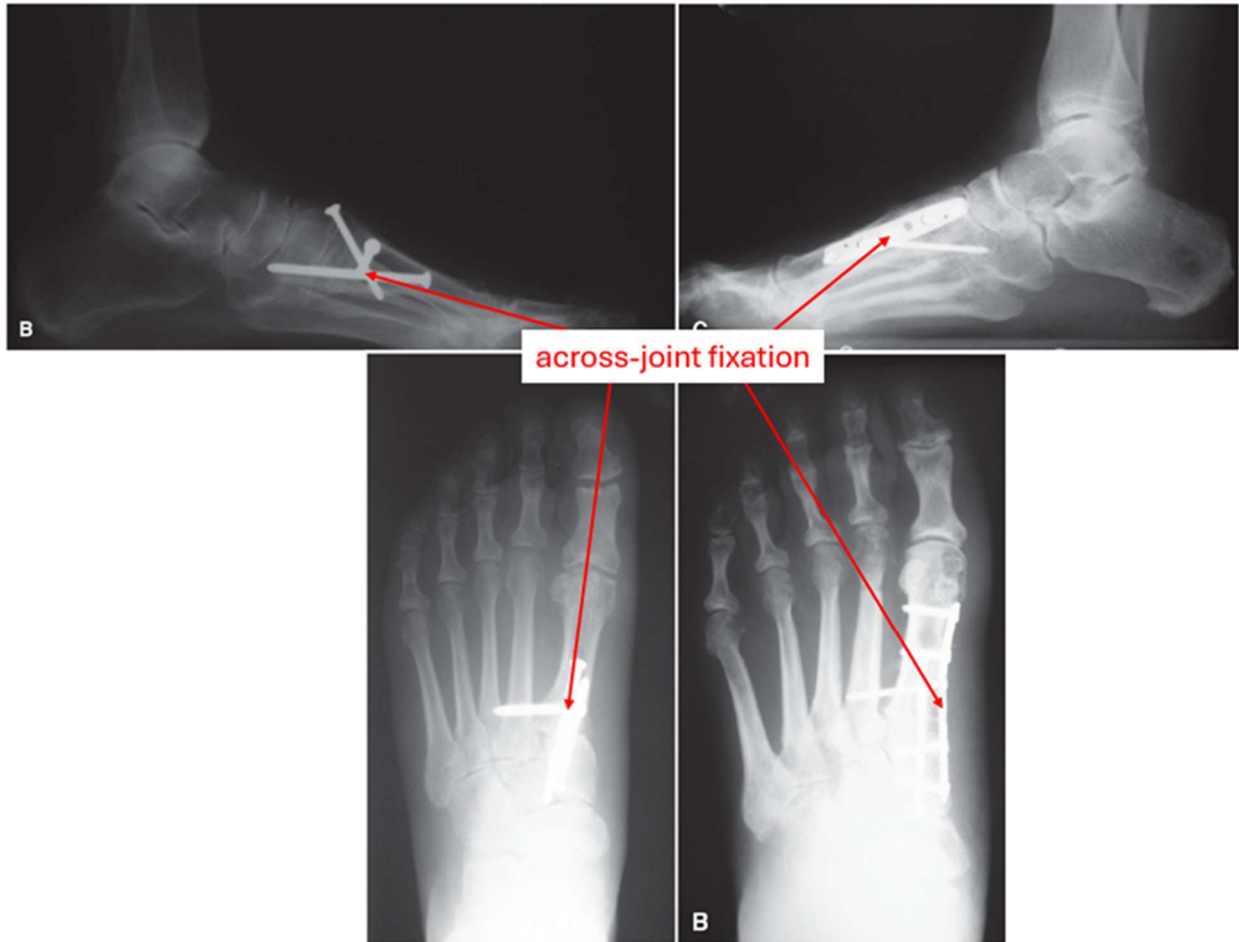
140. The '481 patent describes compressing the first metatarsal and medial cuneiform by moving them toward each other. Ex.1001, 14:64-15:3. In one example, the '481 patent describes “a compression pin, such as a threaded olive pin 300” to create compression. *Id.*, 13:11-14.

141. McGlamry’s procedure includes a surgeon using a screw to compress the first metatarsal and medial cuneiform. Ex.1004, 326 (describing that its “homerun screw” “provides interfragmentary compression and leverage. The interfragmentary compression will create an excellent reduction at the base of the tarsal-metatarsal joint...”), 328 (“If a plantar ledge remains following the osteotomy, correction will be impeded as proper placement and compression across the arthrodesis site will not be achieved.”); *see also id.*, Fig.55.7G (“Note the close apposition of the fusion surfaces.”).

10. Limitation 1[i]

142. Limitation 1[i] recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.” McGlamry discloses limitation 1[i].

143. McGlamry describes applying fixation “across the first metatarsal-cuneiform joint” using one or more screws and/or a plate that span the metatarsal-cuneiform joint. These screws and/or plate each serve as a “fixation device” fixing the first metatarsal in corrected alignment to the medial cuneiform for fusion. Ex.1004, 326 (“The recommended fixation techniques consist of interfragmentary compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate.”), 327-329. Figures 31.6B, 31.7, and 31.8B-C below show the placement of these fixation devices across the tarsal-metatarsal joint—the joint between the first metatarsal and medial cuneiform.



Id., Figs.31.6B, 31.7, 31.8B-C (annotated). This across-joint fixation fixes the first metatarsal relative to the medial cuneiform for fusion of the arthrodesis site. *Id.*, 324, 808-09 (describing fixation for fusion, and further stating that, “[w]hile there are many different types of fixation that may be applied to the arthrodesis [sic] site (wires, screws, plates, etc.), it must be emphasized that the fixation is only utilized to stabilize the arthrodesis site while the bone heals”).

144. McGlamry discloses a “fixation device” under either construction discussed above. McGlamry’s screws and plates discussed above are the same kinds of fixation devices identified by the ’481 patent, which identifies, for example,

screws and plates. Ex.1001, 10:46-51. Thus, they are a corresponding structure, or at least an equivalent structure, for fixing the moved position of the metatarsal for fusion.

B. Claim 3

145. Claim 3 depends from claim 1 and recites “further comprising removing the bone positioning guide from the first metatarsal and the second metatarsal with the moved position of the first metatarsal remaining fixated relative to the medial cuneiform by the at least one bone fixation device.” McGlamry in view of Kartalian renders obvious claim 3.

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

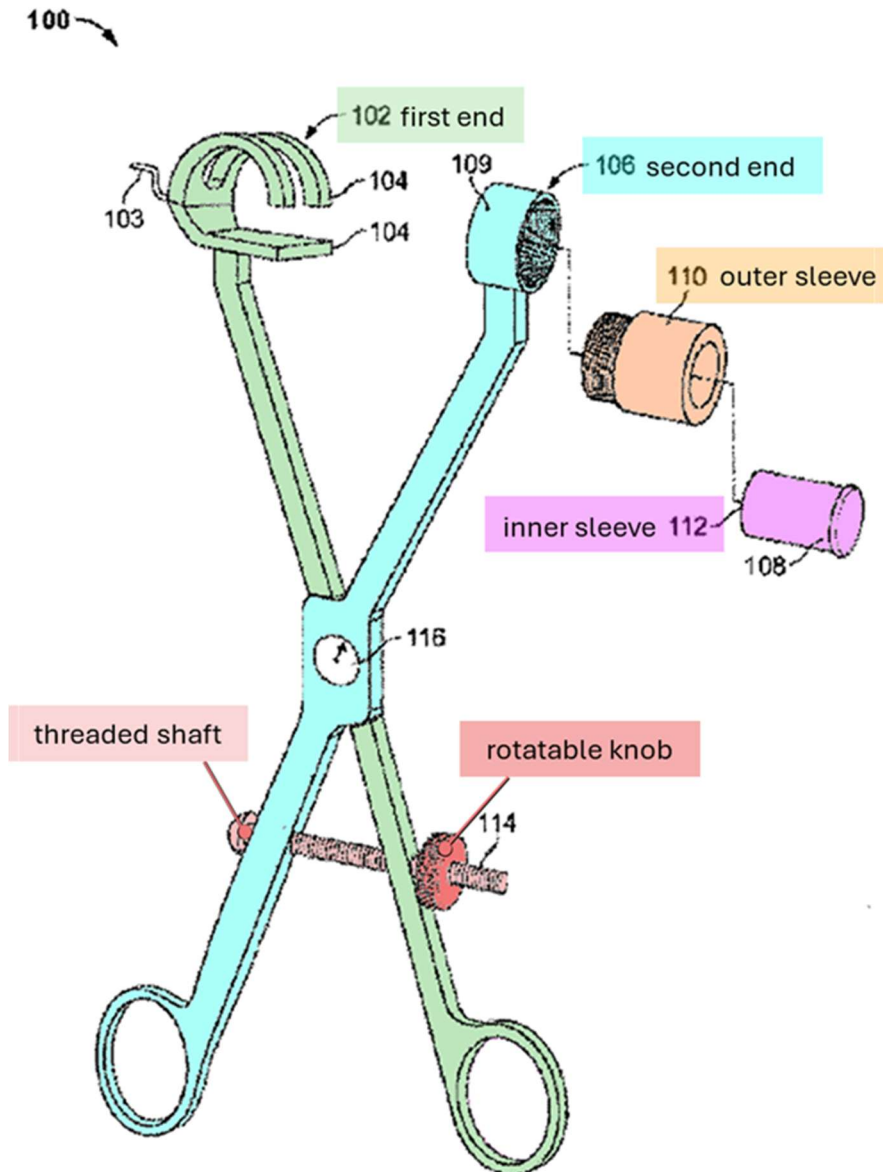
147. A POSA would have recognized that it would have been obvious to maintain this sequence for removing Kartalian’s instrument when using Kartalian’s instrument in McGlamry’s procedure. A POSA would have recognized that Kartalian’s instrument would remain in place during the installation of the bone fixation device in McGlamry’s procedure, as this would maintain the moved position of the first metatarsal until it is secured with the bone fixation device. This is

consistent with McGlamry's fixation techniques. *See* Ex.1004, 326. After fixation, the instrument would be removed, with the moved position of the first metatarsal remaining fixed relative to the medial cuneiform, consistent with Kartalian's disclosure.

C. Claim 4

148. Claim 4 depends from claim 1 and further recites "further comprising, prior to engaging the first metatarsal with the bone engagement member of the bone positioning guide and engaging the bone positioning guide with the second metatarsal, joining at least three components together, including the threaded shaft and the bone engagement member, to form the bone positioning guide." McGlamry in view of Kartalian renders obvious claim 4.

149. Kartalian discloses that its instrument 100 (bone positioning guide) comprises at least three components: (i) a first end 102 (green), (ii) a second end 106 (blue), (iii) an outer sleeve 110 (orange) of the cannulated sleeve 108 removably attached to ring 109 of the second end 106, (iv) an inner sleeve 112 (purple) of the cannulated sleeve 108, (v) a rotatable knob (dark red), and (vi) a threaded shaft (light red). Figure 1, Panel I below depicts each of the above-identified components of Kartalian's instrument 100.



Ex.1005, Fig.1 (excerpt) (annotated); *see also id.*, 8:12-14, 8:38-55. These components are joined prior to use so that the instrument may engage the first metatarsal with the arm 106 and engage the end 102 with the second metatarsal during a bunion correction procedure.

150. A POSA would understand that Kartalian's instrument is assembled from at least three joinable components (e.g., the threaded shaft, rotatable knob,

cannulated sleeves, and forceps). This assembly would necessarily occur prior to engaging the first metatarsal with the bone engagement member of the bone positioning guide and engaging the bone positioning guide with the second metatarsal to achieve the described instrument 100 for use, as Kartalian describes using the assembled bone positioning guide to perform bunion corrections. *See* Ex.1005, 9:66-67, 10:22-28, 10:43-51. Such an assembly was commonplace for surgical instruments enabled the pivoting/clamping function. It also would have provided benefits in ease of maintenance, cleaning, and sterilization through the ability to assemble and disassemble the clamp as needed. As such, the results of using a multi-component clamp would have been predictable.

D. Claims 5 and 6

151. Claim 5 depends from claim 1 and recites “further comprising making a second incision on the foot to provide access to the second metatarsal, wherein engaging the bone positioning guide with the second metatarsal comprises positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal.” Claim 6 depends from claim 5 and recites “wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal comprises inserting the tip through the second incision.” McGlamry in view of Kartalian renders obvious claims 5 and 6.

152. The '481 patent describes that its tip is the portion of the bone positioning guide that is meant to engage a metatarsal other than the first metatarsal (e.g., the second metatarsal). Ex.1001, 6:6-11. The tip can have various shapes and can be, for example, straight or have a non-linear orientation, for example a tip that is angled or curved. *Id.*, 6:6-22.

153. Kartalian's end 102 is a tip that engages the second metatarsal. Ex.1005, 9:24-57 (describing construction of end 102). Like in the '481 patent, Kartalian describes its end 102 of instrument 100 having various shapes, including "curved or other shape[d]" plates to engage the bone. *Id.*, 9:33-45. Kartalian explains that its tips are "placed around the bone." *Id.*, 9:42-45, 10:49-51 ("end 102 may be placed on the distal second bone (second metatarsal)"). Thus, end 102 is a tip for engaging the second metatarsal. *Id.*, 9:24-57.

154. Kartalian further discloses making a second incision to provide access to the second metatarsal for its tip: "[t]he surgical repair of hallux valgus may commence with a medial incision at the first metatarsal and an incision lateral to the second metatarsal at its distal portion ... followed by placement of instrument 100." Ex.1005, 10:29-33. This second incision is used to insert the instrument's tip so that the bone contacting surface is in contact with the second metatarsal. *See, e.g., id.*, 10:34-51.

155. A POSA would understand from Kartalian’s disclosure that the tip (end 102) is placed through this second incision and in contact with the second metatarsal. For example, Kartalian discloses that its tip is “placed on” the second metatarsal. Ex.1005, 10:46-51 (emphasis added); *see also id.*, 10:46-51 (“first end 102 may be placed on the distal second bone (second metatarsal)”).

156. When using Kartalian’s instrument as part of McGlamry’s procedure, making a second incision to access the second metatarsal for placement of the tip would have been a straightforward and predictable application of Kartalian’s technique. The second incision optimizes the use of Kartalian’s instrument, particularly on the second metatarsal. *Id.*; *see also supra* §VI.A.4. (limitation 1[c]). For example, Kartalian discloses that its end 102 of instrument 100 is designed to contact the second metatarsal, which allows the instrument to act of a “reduction forceps to align two cones or reduce the distance between two bones.” Ex.1005, 9:66-67; *see also id.*, 10:43-51. Implementing Kartalian’s second incision in McGlamry’s procedure would have been nothing more than the use of Kartalian’s known technique for providing an incision for placement of a bone positioning guide to improve McGlamry’s known bunion correction procedure in the same way that the second incision is used in Kartalian’s method, and yield the predictable result of a second incision for inserting a bone positioning guide. Ex.1005, 10:29-33; *see*

also Ex.1004, 325-326 (showing the Weber clamp placed on the first and second metatarsals).

157. A POSA would have recognized that the second incision was a predictable option for use in McGlamry's procedure, as the first incision in McGlamry's procedure is made over the first metatarsal, not the second metatarsal where Kartalian's bone contacting surface is described as being placed. Making an incision for placement of an instrument is a routine surgical technique and would have been predictable.

E. Claim 7

158. Claim 7 depends from claim 1 and recites "wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal." McGlamry in view of Kartalian renders obvious claim 7.

159. In short, this claim requires that the step of imparting the force to the pin (limitation 1[f]) occurs after the step of rotating the knob to laterally reposition the first metatarsal (limitation 1[e]).

160. McGlamry describes moving the first metatarsal using a Weber clamp in the transverse plane, including to reduce the IMA. Ex.1004, 325-26; *see also supra* §VI.A.4. (limitation 1[c]). After this disclosure, McGlamry describes, “[i]f the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal [T]he K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position....” Ex.1004, 326. Thus, in McGlamry’s procedure, the force is applied to the pin after the metatarsal has been laterally repositioned.

161. The substitution of Kartalian’s bone positioning guide for McGlamry’s Weber clamp would not change the order of steps disclosed by McGlamry. For example, when used in McGlamry’s procedure, Kartalian’s bone positioning guide would take the place of the Weber clamp and the function and timing of the use of a pin for rotation of the first metatarsal would not be altered.

F. Claim 8

162. Claim 8 depends from claim 1 and recites: “further comprising moving the first metatarsal in the sagittal plane.” McGlamry in view of Kartalian renders obvious claim 8.

163. McGlamry teaches that its “procedure allows for triplanar correction of first metatarsal pathology”— including the frontal, sagittal, and transverse planes. Ex.1004, 322. McGlamry describes that “[t]he correction is made in the transverse plane and the frontal and sagittal planes are later corrected via reduction and appropriate positioning of the tarsal-metatarsal joint.” *Id.*, 324. Specifically, McGlamry describes:

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

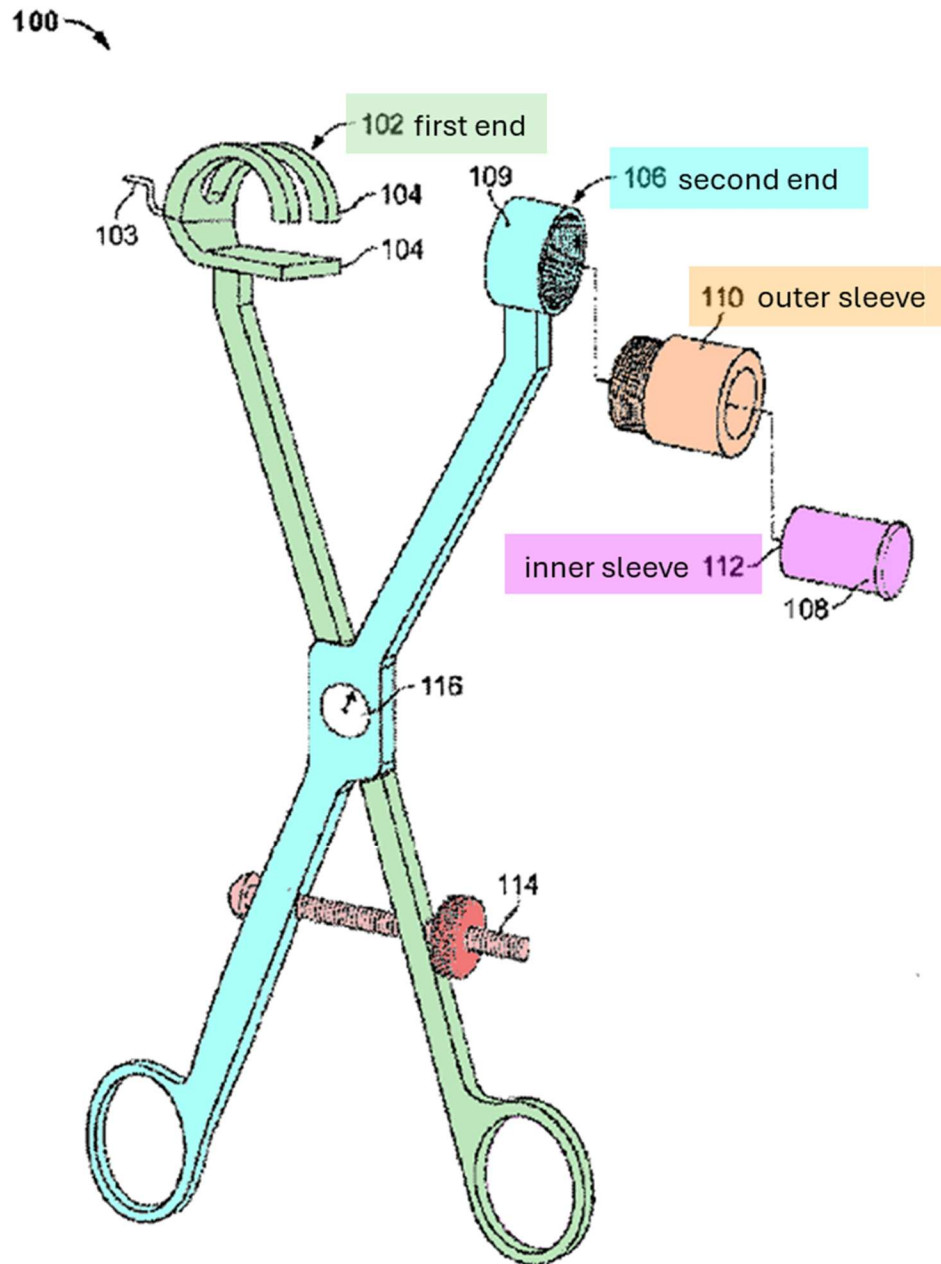
Id., 325. McGlamry further discloses that “[t]he primary surgeon must ensure that the first metatarsal is in the desired position, which is ... parallel with the second metatarsal in both the transverse and sagittal planes.” *Id.*

G. Claim 10

164. Claim 10 depends from claim 1 and recites “wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.” McGlamry in view of Kartalian renders obvious claim 10.

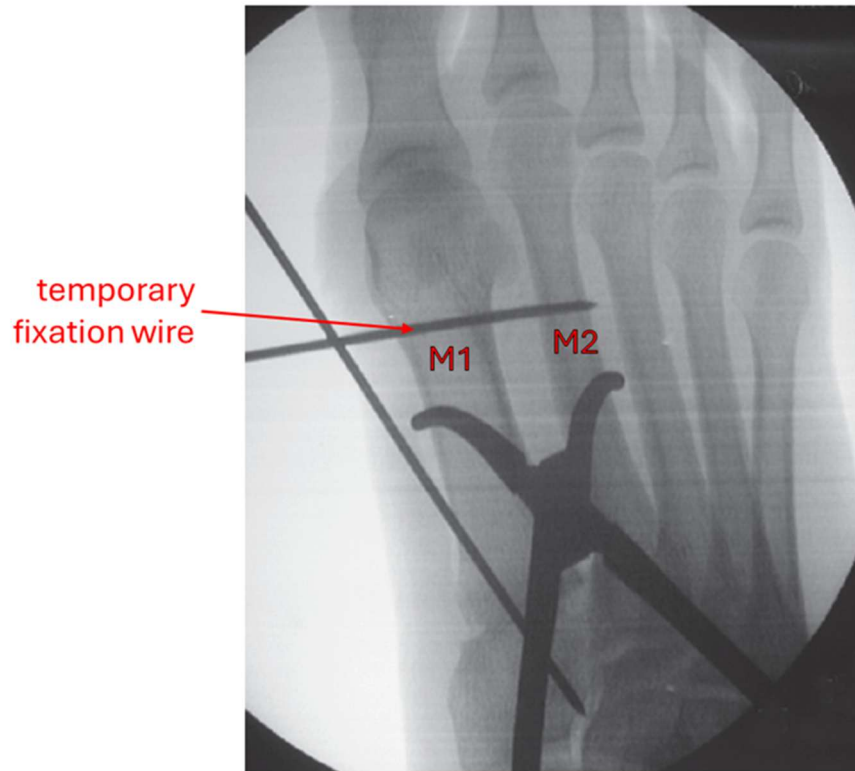
165. Kartalian discloses that the second end 106 of its bone positioning guide is “configured as a cannulated sleeve 108.” Ex.1005, 9:58-60, Fig.1. The sleeve “may be used as a drill guide” and can have a sleeve with a diameter of between

1mm and 4mm. *Id.*, 10:46-62. Kartalian also describes that this sleeve can be used as a guide for drilling through both the first and second metatarsals. *Id.* Figure 1 below shows the sleeve 108 with an outer sleeve 110 and inner sleeve 112, which are sized based on the object for insertion through the sleeve:



Id., Fig.1 (excerpt) (annotated). Thus, Kartalian discloses the bone positioning guide comprising a cannulation.

166. McGlamry discloses temporary fixation of the corrected position of the metatarsal using a K-wire inserted through the first and second metatarsals. Ex.1004, 325-326 (“[W]hile maintaining position in all three planes a ... K-wire is inserted into the medial first metatarsal head and into the lesser metatarsals; this serves to prevent derotation in the frontal plane and maintains reduction in the transverse plane.”); *see also* Ex.1013, 101 (describing K-wire for temporary fixation of first metatarsal in a Lapidus procedure). This K-wire serves to temporarily fixate the moved position of the first metatarsal relative to the medial cuneiform—and is thus a fixation wire—before final fixation. *Id.*, 326-327. Figure 31.5 below depicts the temporary fixation wire:



Ex.1004, Fig.31.5 (annotated).

167. When Kartalian’s bone positioning guide is used in McGlamry’s procedure, it would have been obvious to use Kartalian’s sleeve as a guide to place a fixation wire (e.g., a K-wire) through the cannulation into the first and second metatarsals and to temporarily fix the corrected relationship between the first and second metatarsal for final fixation. Using Kartalian’s sleeve would permit precise positioning of the K-wire while maintaining transverse plane reduction, as required by McGlamry. Ex.1004, 326 (describing insertion of K-wire “while maintaining position in all three planes,” including the transverse plane), 325 (describing bone positioning guide as “maintain[ing]” transverse plane reduction); *see also* Ex.1005, 10:4-8 (describing use of locking mechanism to hold the instrument 100 in the

position correcting the first metatarsal's alignment). Using Kartalian's cannulated sleeve to guide and place McGlamry's temporary fixation wire would allow the wire to be placed at a precise trajectory while the bone positioning guide was holding the alignment of the first metatarsal. Such a use would avoid the K-wire potentially interfering with the placement of permanent fixation devices.

168. This modification would have been a routine and predictable use of Kartalian's cannulated sleeve. Kartalian contemplates the use of wire-based components with guides, and discloses passing wire limbs through cannulated guides on its instrument for secure fixation while centralizing the instrument along the second metatarsal. Ex.1005, 8:26-37. Kartalian's cannulated sleeve is also described as being used to locate, drill holes for, and place anchors. *Id.*, 10:46-11:14. In view of this disclosure and McGlamry's use of K-wires to stabilize the correction, a POSA would have had a reasonable expectation of success in using Kartalian's cannulated sleeve to place a temporary fixation wire into the second metatarsal for the same stabilizing purpose with predictable results. *See, e.g.*, Ex.1028, [0028]-[0030].

169. A POSA would also reasonably expect to succeed in using Kartalian's cannulated sleeve to place a temporary fixation device, such as a K-wire. Kartalian's cannulated sleeve structures allow for the receipt of structures of different sizes. *See* Ex.1005, 10:52-62 (describing receipt of 1mm to 4mm drill bits through sleeve 108).

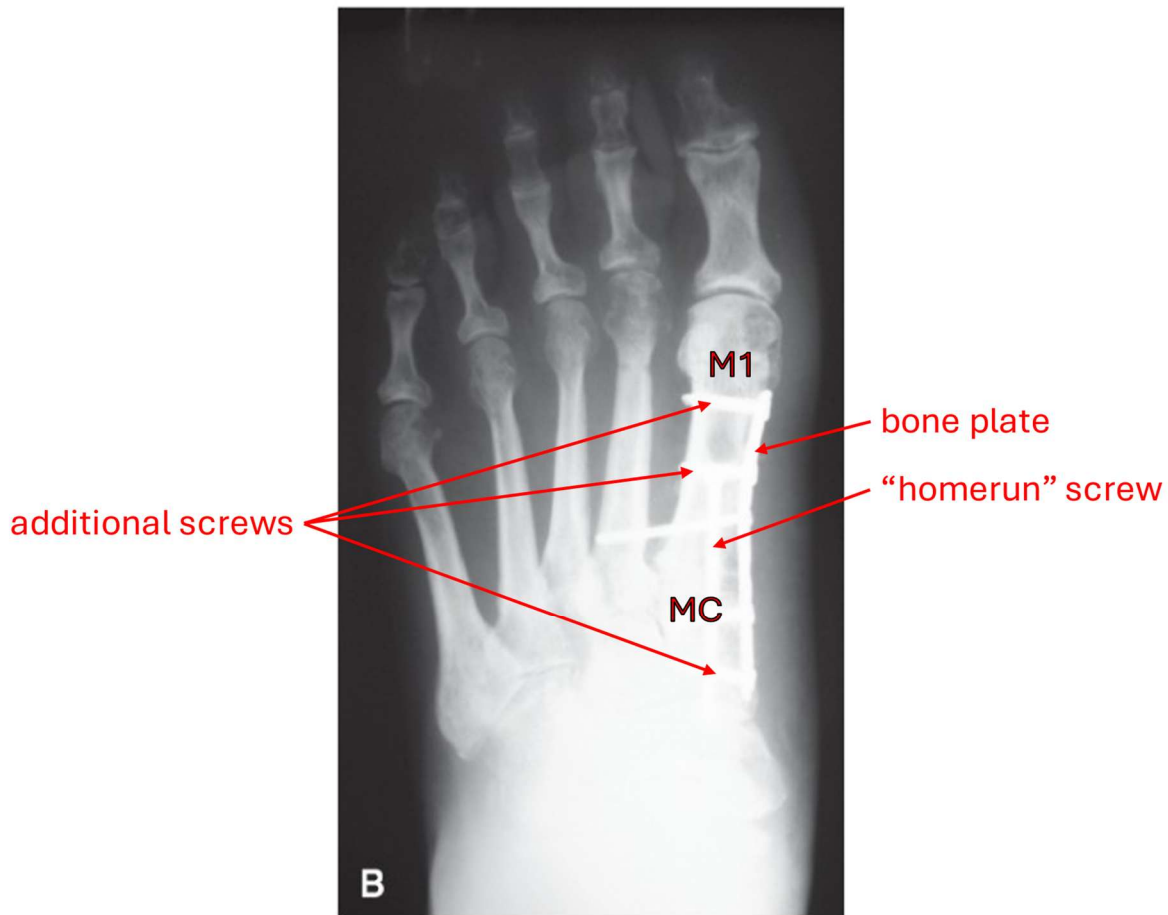
K-wires generally have a diameter within this range of acceptable insertable structures. Ex.1019, 2-3 (describing 0.7-1.5mm diameter K-wires).

H. Claims 11 and 13

170. Claim 11 depends from claim 1 and recites “wherein the at least one bone fixation device comprises at least one of a screw and a plate.” Claim 13 depends from claim 1 and recites “wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.” McGlamry in view of Kartalian renders obvious claims 11 and 13.

171. As I discussed with respect to limitation 1[i], McGlamry discloses fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device. *See supra* §VI.A.10. McGlamry discloses fixation devices including screws, plates, or a combination thereof. Ex.1004, 326 (“The recommended fixation techniques consist of interfragmentary compression of three solid cortical screws or an interfragmentary compression of

solid cortical screw along with a medial based locking plate.”), 327-328. Figure 31.8B below shows an exemplary placement of these fixation devices:



Id., Fig.31.8B (annotated).

172. McGlamry further describes that, “[f]ollowing the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate” and “the distal screws are placed into the metatarsal” *Id.*, 327. Thus, McGlamry discloses placing a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the

bone plate to the first metatarsal. Thus, McGlamry discloses the fixation steps of claims 11 and 13.

I. Claim 27

173. For the reasons described below, McGlamry in view of Kartalian renders claim 27 obvious.

1. Preamble

174. The preamble of claim 27 recites “[a]n instrumented surgical technique for correcting a bunion deformity.” McGlamry renders obvious this preamble.

175. As I explained above with respect to 1[pre], the McGlamry discloses an instrumented surgical technique. *See supra* §VI.A.1. McGlamry’s instrumented technique corrects a bunion deformity. *See generally* Ex.1004, 322-330 (Chapter 31 of McGlamry describing a “Lapidus Bunionectomy: First Metatarsal-Cuneiform Arthrodesis”).

2. Limitation 27[a]

176. Limitation 27[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” This limitation is substantively identical to limitation 1[a] and is rendered obvious by McGlamry for the same reasons. *See supra* §VI.A.2.

3. Limitation 27[b]

177. Limitation 27[b] recites “engaging the first metatarsal with the bone engagement member of the bone positioning guide.” This limitation is substantively

identical to limitation 1[b] and is rendered obvious by McGlamry in view of Kartalian for the same reasons. *See supra* §VI.A.3. The reasons why a POSA would have been motivated to combine McGlamry and Kartalian and would have had a reasonable expectation of success in do so are the same as discussed above for claim 1. *See id.*

4. Limitation 27[c]

178. Limitation 27[c] recites “engaging the bone positioning guide with the second metatarsal separated from the first metatarsal by an intermetatarsal angle.” This limitation is substantively identical to limitation 1[c] and is rendered obvious by McGlamry in view of Kartalian for the same reasons. *See supra* §VI.A.4.

5. Limitation 27[d]

179. Limitation 27[d] recites “preparing an end of the first metatarsal for fusion.” McGlamry discloses this limitation because it discloses cutting the end of the first metatarsal in preparation for fusion, as I explained in limitation 1[d].

180. As I explained above with respect to limitation 1[d], McGlamry discloses cutting an end of the first metatarsal with a tissue removing instrument. *See supra* §VI.A.5. This cutting prepares the end of the first metatarsal for fusion. *See Ex.1004, 324* (“Prior to reducing the joint... a significant amount of time should be spent with joint preparation. The metatarsal base and the distal cuneiform ... are prepared. It is imperative that the surgeon is diligent to ensure the subchondral plate

is penetrated demonstrating good bleeding at both the metatarsal and cuneiform.”). This preparation of both an end of the metatarsal and an end of the cuneiform is shown in Figure 31.3 below:



Id., Fig.31.3 (“Intraoperative clinical view demonstrating the use of a 2-mm drill preparing the tarsal-metatarsal joint prior to fixation.”).

181. McGlamry further discloses that “[a] substantial period of time is spent preparing this joint as this is a vital portion of the procedure to ensure good bony healing.” *Id.*, 324. This “bony healing” in an arthrodesis procedure refers to fusion. *See id.*, 808-09; *see also id.*, 803 (describing principles of arthrodesis for achieving fusion, including removal of material that prevent close approximation of “raw bone surfaces that will comprise the fusion mass”). Thus, McGlamry discloses limitation 27[d].

6. Limitation 27[e]

182. Limitation 27[e] recites “rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct a bunion deformity.” This limitation is substantively identical to limitation 1[e] and is rendered obvious by McGlamry in view of Kartalian for the same reasons. *See supra* §VI.A.6.

7. Limitation 27[f]

183. Limitation 27[f] recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” This limitation is substantively identical to limitation 1[f] and is rendered obvious by McGlamry in view of Kartalian for the same reasons. *See supra* §VI.A.7.

8. Limitation 27[g]

184. Limitation 27[g] recites “preparing an end of a medial cuneiform for fusion.” As I explained above for limitation 27[d], McGlamry discloses preparing an end of the medial cuneiform for fusion. *See supra* §VI.I.5. Thus, McGlamry discloses limitation 27[g].

9. Limitation 27[h]

185. Limitation 27[h] recites “installing at least one fixation device through the incision to fixate a moved position of the first metatarsal relative to the medial cuneiform.” McGlamry in view of Kartalian renders obvious limitation 27[h].

186. As I explained above regarding limitation 1[i], McGlamry discloses using fixation device(s) to fixate a moved position of the first metatarsal relative to the medial cuneiform. *See supra* §VI.A.10.

187. McGlamry discloses that when screws are used, “[t]he drill is aimed for the inferior, medial aspect of the cuneiform.” Ex.1004, 326. Thus, a POSA would have understood that the cuneiform is exposed via the incision, and the incision would allow a surgeon to place the screw through the incision into the drill hole. *Id.*

188. As demonstrated in Figures 31.6, 31.7, 31.8, and 31.9, the fixation devices in McGlamry’s procedure are installed through the incision. Ex.1004, Figs.31.6-31.9. For example, Figure 31.9 illustrates a radiograph illustrating the fixation device(s) next to an image of the foot; the side-by-side with the scar on the foot shows that the plate was installed through the incision, as shown below:



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

Ex.1004, Fig.31.9C-D (annotated). McGlamry further refers to suturing a single wound closed after the fixation devices are installed. *Id.*, 327. Thus, McGlamry in view of Kartalian renders limitation 27[h] obvious.

J. Claim 29

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

1. Limitation 29[a]

190. As I explained above regarding limitation 1[h], McGlamry discloses compressing the metatarsal and the cuneiform together. *See supra* §VI.A.9.

191. In McGlamry's procedure, this compression occurs after the preparation of the first metatarsal and medial cuneiform, and prior to the installation of the fixation device. Specifically, McGlamry describes compression occurring via the compression occurs via the "homerun screw," which is placed into the metatarsal and cuneiform after they are prepared. *See* Ex.1004, 324 (describing joint preparation), 326-327 (describing compression after preparation). A POSA would understand that the homerun screw alone does not fixate a moved position of the first metatarsal relative to the medial cuneiform, and thus the additional screws/plates with the homerun screw are installed subsequent the compression. *See id.*, 326-327.

192. McGlamry describes installing these plate/screws (fixation devices) after the placement of the "homerun screw": "Following the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate in combination of lock and nonlocking screws. The distal screws are placed into the metatarsal with a combination of locking and nonlocking screws." Ex.1004, 327.

2. Limitation 29[b]

193. Limitation 29[b] is substantively the same as the limitations of claim 3. McGlamry in view of Kartalian renders obvious limitation 29[b] for the same reasons as claim 3. *See supra* §VI.B.

VII. GROUND 2: CLAIMS 2, 9, 14-24, 26, 28, AND 30 WOULD HAVE BEEN OBVIOUS OVER MCGLAMRY, KARTALIAN, AND FALLIN

194. It is my opinion 2, 9, 14-24, 26, 28, and 30 of the '481 patent would have been obvious to a person of ordinary skill in the art by August 14, 2015 in view of McGlamry, Kartalian, and Fallin.

195. It would have been obvious by August 2015 to a POSA to implement Fallin's cutting guide in the McGlamry-Kartalian combination, and specifically during the procedure's cutting steps. McGlamry considers the cutting of bones of the foot a "vital portion of the procedure." Ex.1004, 324. "Joint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion," and McGlamry therefore recommends that surgeons spend a "substantial period of time ... preparing this [metatarsal-cuneiform] joint." *Id.* McGlamry warns of complications caused by mistakes in cutting the bones, including "[s]ignificant shortening" of the first metatarsal, delayed unions, non-unions, and malunions. *Id.*, 329. The shortening of the first metatarsal can lead to "transfer lesions plantar to the second metatarsal head as well as decreased hallux purchase," as well as functional

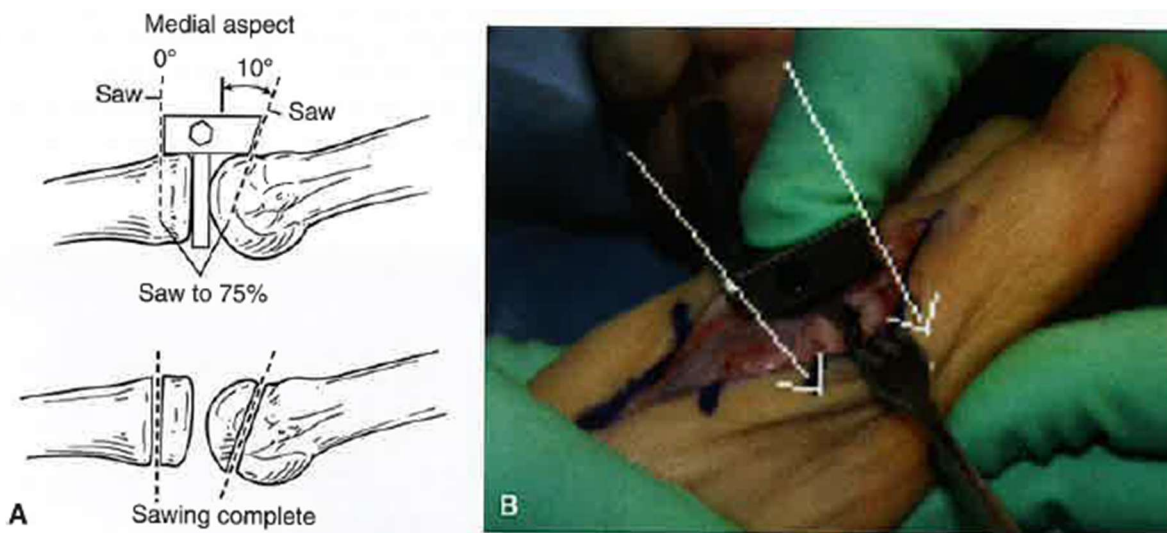
disturbance of the foot and transfer metatarsalgia of the second and/or third rays. *Id.*; Ex.1010, 186; Ex.1015, 230.

196. McGlamry's bunion correction procedure involves a surgeon performing freehand resection of the metatarsal and cuneiform. Ex.1004, 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.1025, 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.1023, [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.1025, 1:31-37, 1:45-50. Although Armstrong discusses difficulties of freehand cutting in the context of facial bones, its rationale applies to freehand cuts of foot bones.

197. 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. *See, e.g.*, Ex.1026, 1:9-14, 3:1-5 (describing a cutting guide that "remove[s] the necessity of clinical judgement and guess work" by "precisely maintaining a cutting plane,

precisely determining the necessary amount of bone to be removed, and ... guiding [an] osteotome blade for precisely removing such amount of bone.”); Ex.1025, 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).

198. Armstrong discloses that “[t]here are numerous prior art devices for precision cutting of bones in the appendicular skeleton,” including the feet. Ex.1025., 1:55-58. For example, Chapter 34 of McGlamry identifies a bone cutting guide in a podiatric surgery that “help[s] the surgeon resect the proper amount of bone and at the proper angles.” Ex.1004, 381-383. The below image from McGlamry shows the bone cutting guide in use for resecting articular surfaces of a joint.



Id., Fig.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”).

199. Cutting guides like those disclosed by Fallin “remove the necessity of clinical judgement and guess work” and make procedures simpler and repeatable. Ex.1026, 3:1-5; *see also* Ex.1006, [0062] (describing how Fallin’s cut guide “results in more precision and repeatability in the relative orientation of the cuts” and “facilitates providing preformed spacers that will fit the gap and lock in the new position of the bones”). Fallin’s cutting guide in particular can be used to “remove a predetermined, and relatively thin, portion of the articulating ends of the metatarsus and cuneiform.” Ex.1006, [0056]. A POSA would have recognized that using Fallin’s cutting guide in McGlamry’s cutting steps would simplify the procedure and shorten the “significant amount of time” spent preparing the metatarso-cuneiform joint. Ex.1006, [0062]; Ex.1004, 324. Rather than spending large amounts of time on freehand joint preparation, a POSA would have recognized that Fallin’s cutting guide would make preparation of the metatarso-cuneiform joint predictable and repeatable, which would simplify and shorten McGlamry’s procedure. Ex.1004, 324; *see also* Ex.1006, [0052] (describing provision of bone cutting guide slots), [0056] (describing use of cutting slots to “remove a predetermined, and relatively thin, portion of bone from the articulating ends of the [first metatarsal] and [medial] cuneiform”), [0065]-[0067] (describing method of cutting bones using guide slots).

200. Reducing the time spent for joint preparation benefits the patient by reducing the time the patient spends under anesthesia. *See* Ex.1004, 803 (describing

proper anesthesia as being “of paramount importance” for arthrodesis procedures). Lengthier periods of anesthesia can increase the risk of anesthesia-related 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.

201. 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.

202. Fallin’s cutting guide would also reduce the risk of potential complications identified by Dr. DiDomenico in Chapter 31 of McGlamry. One identified risk is “significant shortening” of the first metatarsal. Ex.1004, 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.1004, 329; Ex.1010, 186; Ex.1015, 230. These changes to the biomechanics of the foot can cause pain in addition to the deformities mentioned and unmentioned.

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.1006, [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.1004, 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 id.*, 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.1022, [0068]. Fallin’s cutting guide facilitates proper unions after osteotomy

because it prepares complementary joint surfaces. *Id.*; Ex.1006, [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 guide 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.1006, [0062].

206. Further, a POSA would recognize that McGlamry’s metatarso-cuneiform arthrodesis procedure is nearly identical to Fallin’s instrumented metatarso-cuneiform arthrodesis, as both procedures involve the same joint and cutting of the same bones for the same purpose: fusion of the metatarso-cuneiform joint. *See generally* Ex.1004, 324-330; Ex.1006. Both Fallin and McGlamry describe cuts to the proximal end of the first metatarsal and distal end of the medial cuneiform, repositioning of the first metatarsal relative to the cuneiform, and fixation—all part of correcting a bunion. A POSA would understand that Fallin’s cutting guide in McGlamry’s procedure would have improved McGlamry’s

procedure in the same way as Fallin's procedure (e.g., precisely defining the resecting cuts performed using the slots of a cutting guide) and reduced the likelihood of complications contemplated by McGlamry.

207. A POSA would have recognized by August 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.

208. A POSA would have had a reasonable expectation of success in implementing Fallin's cutting guide in McGlamry's procedure. Fallin's guide would have been adaptable to McGlamry's procedure with minimal or no modifications.

209. Bone cutting guides, such as the guide disclosed by Fallin, were routinely adapted across procedures and anatomical variations. *See* Ex.1022, [0057]-[0058] (describing a jig and associated bone cutting guide for use in multiple metatarsal procedures and in other anatomies, such as a human hand); Ex.1030, 7:41-48 (describing an osteotomy 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"). For example, Weinstein describes its cut guides as adaptable for numerous uses, including for use in bunion correction procedures. Ex.1023, [0046],

[0051] (describing disclosed cutting guides' use in five "angular osteotomy procedures," including for use in a "Lapidus-type procedure"), Fig.13.

210. Additionally, the relevant portions of the surgical procedures in McGlamry and Fallin are nearly identical. Both describe bunion correction procedures in which the proximal end of the first metatarsal the distal end of the cuneiform are cut, and the first metatarsal is repositioned relative to the cuneiform. Ex.1006, [0056]-[0058], [0065]-[0068]; Ex.1004, 324-326. Given the overlap between the procedures, a POSA would have had a reasonable expectation of success in implementing Fallin's cutting guide in McGlamry's procedure.

211. In the McGlamry-Kartalian-Fallin combination, Fallin's "cutter such as a saw blade" (Ex.1006, [0052]) would be selected as the tool to cut bones in the procedure. This would ensure that the cutter (or saw blade) fits with Fallin's guide. Fallin's cutter (and saw blade) satisfy the "tissue removing instrument" limitation under its plain meaning. If a means-plus-function construction were applied, Fallin's cutter (and saw blade) are a corresponding structure (or an equivalent thereof) to the saw/osteotome/bur-type tissue-removal instruments described in the '481 patent.

A. Claim 2

212. Claim 2 depends from claim 1 and recites: "wherein: [a] rotating the knob connected to the threaded shaft comprises rotating the knob connected to the

threaded shaft after cutting the end of the first metatarsal; [b] imparting the force to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after cutting the end of the first metatarsal; and [c] cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity.” McGlamry in view of Kartalian and Fallin renders obvious claim 2.

213. In summary, claim 2 requires that the steps of rotating the knob (limitation 1[e]) and imparting the force to the pin (limitation 1[f]) occur after cutting the end of the first metatarsal (limitation 1[d]) and before cutting the bend of the medial cuneiform (limitation 1[g]).

214. McGlamry discloses that preparing (e.g., cutting) the first metatarsal occurs before repositioning the first metatarsal using the Weber clamp. Ex.1004, 324-326 (“[P]rior to reducing the joint into the appropriate desired position, a significant amount of time should be spent with joint preparation.”). Thus, when Kartalian’s instrument is used in McGlamry’s procedure, it would have been obvious to maintain the sequence of steps disclosed by McGlamry. Kartalian provides instrumentation the repositioning steps already disclosed by McGlamry rather than change the order of the procedural steps.

215. As I explained above regarding limitation 1[f] for Ground 1, McGlamry discloses imparting a force to a pin inserted into the first metatarsal. *See supra* §VI.A.7. In McGlamry’s procedure, imparting a force to a pin occurs after cutting the first end of the metatarsal. Ex.1004, 324-325 (“Prior to reducing the joint into the appropriate desired position, a significant amount of time should be spent with joint preparation.”); *see also id.*, 326 (describing use of pin to rotate the first metatarsal in the frontal plane). As explained above, this would not change when using Kartalian’s instrument.

216. It would have been obvious to modify McGlamry’s procedure such that the step of cutting the medial cuneiform occurs after reducing the intermetatarsal angle using the rotating knob and after imparting force to the pin. Fallin discloses this order as a known option.

217. The ’481 patent acknowledges that the order of its cutting and moving steps can be performed is not critical, and does not identify any advantage of one order versus another. The ’481 patent also expressly states that “unless otherwise indicated, the steps described need not be carried out in the order described.” Ex.1001, 10:55-56; *see also id.*, 12:23-34, 12:42-54 (indicating the cutting can be performed before or after moving the metatarsal).

218. Similarly, McGlamry identifies certain steps that can be performed in different orders. *Compare* Ex.1004, 324 (describing resection of first metatarsal,

then medial cuneiform in metatarsocuneiform arthrodesis) *with* 808-809 (depicting, in Fig.55.7, resection of the medial cuneiform first, then the first metatarsal in metatarsocuneiform arthrodesis). Like the '481 patent, McGlamry does not identify an advantage to the order of its cutting and adjusting steps relative to each other.

219. Fallin discloses cutting the end of the medial cuneiform after adjusting the position of the first metatarsal to correct the bunion deformity. Ex.1006, [0006], [0065]-[0068]; *see also id.*, [0058] (describing cut to one of the metatarsal or cuneiform, and subsequent repositioning of the first metatarsal in multiple planes). A POSA would have found it obvious to cut the metatarsal, adjust the position of the metatarsal (including via imparting a force into a pin), and after those steps, cut the cuneiform. POSA using Kartalian's instrument in the McGlamry-Kartalian-Fallin combination would therefore have found it obvious to cut the metatarsal, adjust the metatarsal position, and then cut the cuneiform, as this sequence naturally accommodates Fallin's correction technique while achieving the same surgical endpoint.

220. Furthermore, there are only two options for the timing of cutting the cuneiform relative to adjusting the position of the metatarsal—before or after. Both options were known in the art prior to August 2015. *Compare* Ex.1004, 324-326 (describing cutting of cuneiform before repositioning) *with* Ex.1006, [0058], [0065]-[0068] (describing cutting of cuneiform after repositioning). Thus, selecting Fallin's

disclosed order would be nothing more than choosing between two known, predictable alternatives.

221. A POSA would reasonably expect to succeed in cutting the medial cuneiform after repositioning the first metatarsal, as Fallin teaches this order of steps. Ex.1006, [0058], [0065]-[0068]. Fallin's steps produce the same clinical and structural outcome as McGlamry's technique.

B. Claim 9

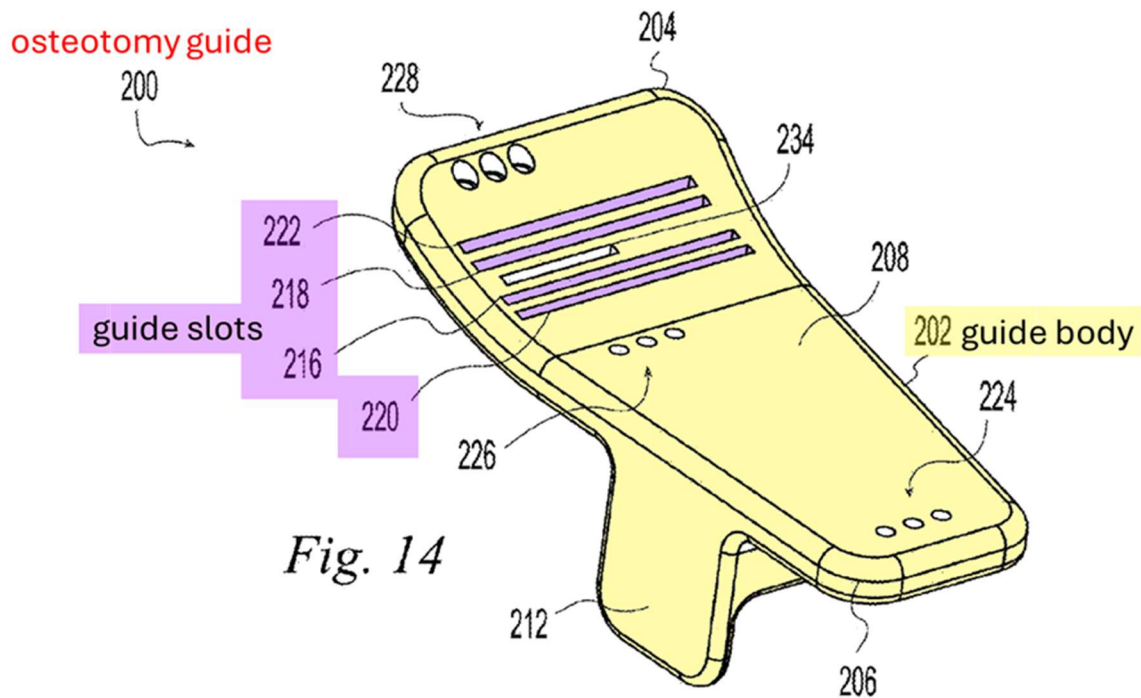
222. Claim 9 depends from claim 1 and recites "wherein: the tissue removing instrument is a saw blade; cutting the end of the first metatarsal comprises guiding the saw blade through a first bone preparation guide cutting slot; and cutting the end of the medial cuneiform comprises guiding the saw blade through a second bone preparation guide cutting slot." McGlamry in view of Kartalian and Fallin renders obvious claim 9.

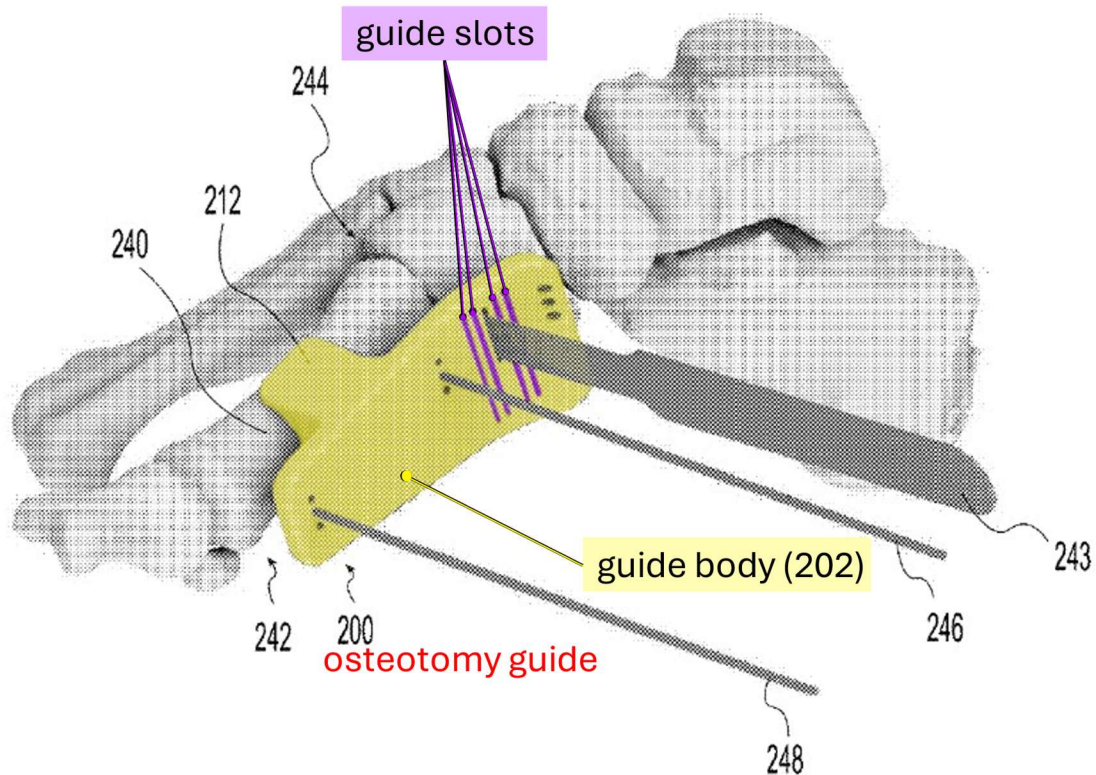
223. As discussed above regarding limitation 1[d] in Ground 1, McGlamry discloses a saw blade as a tissue removing instrument. *See supra* §VI.A.5.

224. Fallin describes an "osteotomy guide [that] includes a first guide feature operable to guide a cutter to cut the metatarsus and a second guide feature operable to guide a cutter to cut the cuneiform." Ex.1006, claim 24; *see also id.*, [0052] (describing slots 216, 218 and "cutter, such as a saw blade" for cutting of the first metatarsal and medial cuneiform), [0065], [0067] (describing use guide slots to cut

the metatarsocuneiform joint bones). An osteotomy guide and a bone preparation guide are each bone cutting guides.

225. Fallin discloses that its osteotomy guide includes a guide body 202 having guide slots 216, 218, 220, 222, which are positioned for receiving and guiding a saw blade. *Id.*, [0055]. Figures 14 and 21 of Fallin below depict the osteotomy guide, its body, and bone preparation guide cutting slots (guide slots):

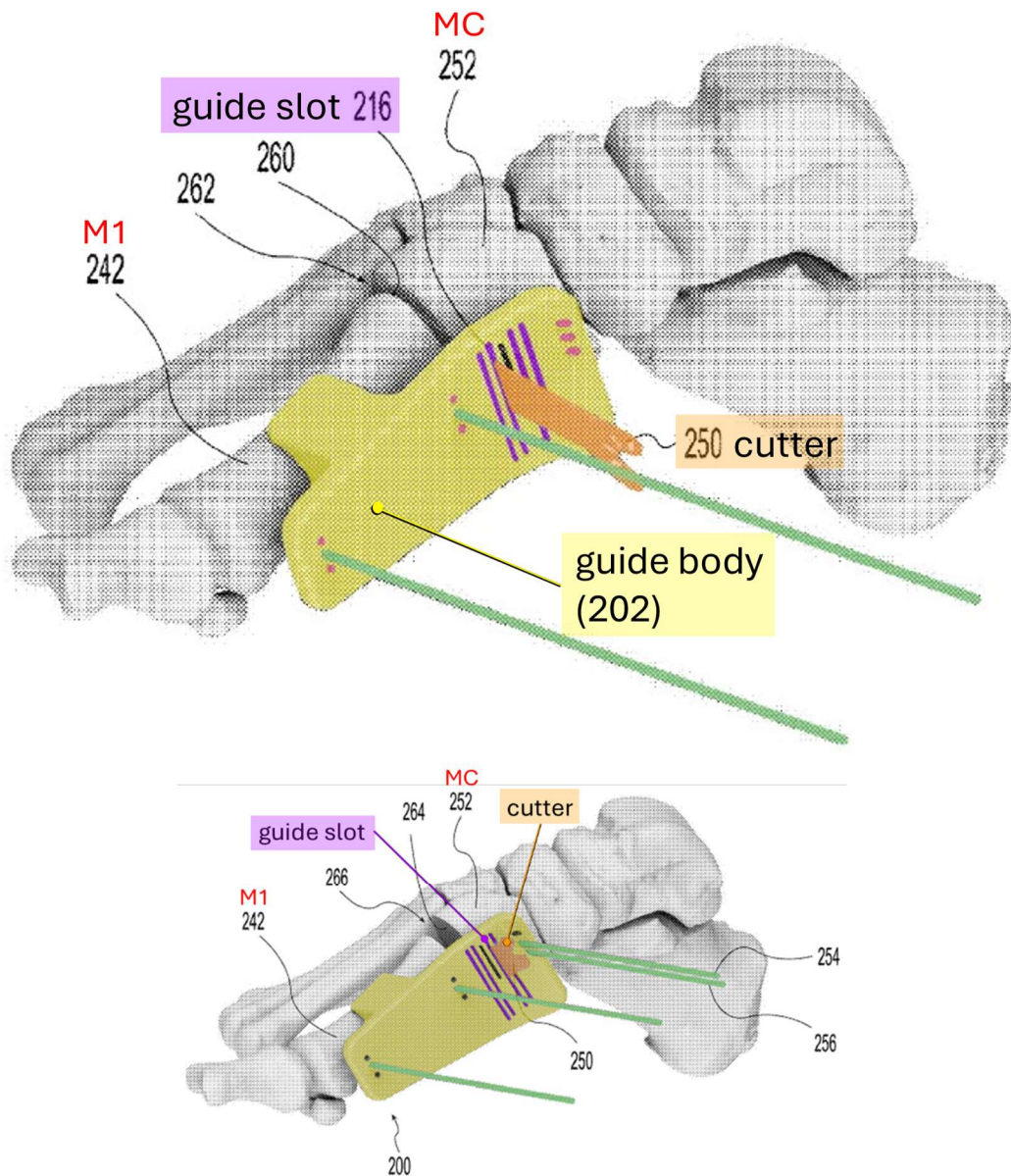




Id., Figs.14 and 21 (annotated).

226. Fallin also discloses positioning its osteotomy guide on the bones of the metatarsocuneiform joint—the first metatarsal and medial cuneiform. Fallin discloses “fixing an osteotomy guide to the metatarsus” by “abutting” indexing features against the metatarsus and separately teaches “guiding a cutter with the osteotomy guide to cut the metatarsus at a predetermined angle relative to the osteotomy guide to produce a first cut surface and remove a first portion of bone adjacent the joint.” Ex.1006, claims 14, 19; *see also id.*, [0056], [0064]-[0065], [0067]. Fallin also depicts its osteotomy guide being used to guide a saw blade through guide slots for cutting the first metatarsal and medial cuneiform. For

example, as shown in Figures 22 and 24 below, the saw blade goes through a first cutting guide slot to cut the first metatarsal (M1) and a second cutting guide slot to cut the medial cuneiform (MC):



Ex.1006, Figs. 22, 24.

C. Claim 14

227. I performed a comparison of claim 14 to independent claim 1 and dependent claims 2-10. Independent claim 14 recites many of the same limitations of claim 1. McGlamry in view of Kartalian and Fallin disclose each of these common limitations for the reasons I explained for claim 1 above.

1. Preamble

228. The preamble of claim 14 recites “[a]n instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.” This limitation is substantively identical to the preambles of claims 1 and 27. McGlamry in view of Kartalian and Fallin renders obvious the preamble for the same reasons. *See supra* §§VI.A.1., VI.I.1. (limitations 1[pre] and 27[pre] of Ground 1).

2. Limitation 14[a]

229. Limitation 14[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” This limitation is substantively identical to limitation 1[a] and would have been obvious over McGlamry, Kartalian, and Fallin for the same reasons as discussed in Ground 1. *See supra* §VI.A.2.

3. Limitation 14[b]

230. Limitation 14[b] recites “engaging the first metatarsal with the bone engagement member of a bone positioning guide.” This limitation is substantively

identical to limitation 1[b] and would have been obvious over McGlamry, Kartalian, and Fallin for the same reasons discussed in Ground 1. *See supra* §VI.A.3.

4. Limitation 14[c]

231. Limitation 14[c] recites “engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle.” This limitation is substantively identical to limitation 1[c] and would have been obvious over McGlamry, Kartalian, and Fallin for the same reasons discussed in Ground 1. *See supra* §VI.A.4.

5. Limitation 14[d]

232. Limitation 14[d] recites “cutting an end of the first metatarsal by guiding a saw blade through a first bone preparation guide cutting slot.” This limitation substantively recites the saw blade and first slot limitations from claim 9 that is discussed above. This limitation would have been obvious over McGlamry, Kartalian, and Fallin for the same reasons discussed in limitation 1[d] and claim 9. *See supra* §§VI.A.5., VII.B.

6. Limitation 14[e]

233. Limitation 14[e] recites “removing a cut portion of the first metatarsal from the tarsal-metatarsal joint.”

234. McGlamry discloses this limitation. For example, McGlamry discloses that “[t]he initial joint resection is performed on the first metatarsal articular

surface.” Ex.1004, 324. Performing that resection entails cutting and removing a portion of the first metatarsal at the tarsal-metatarsal joint. *See, e.g.*, Ex.1006, [0058] (“[A] first cut may be made on one of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface and a space resulting in increased mobility between the metatarsus and cuneiform to allow them to be freely repositioned.”), [0056]. McGlamry further explains that, during its procedure, “it is vital that the entire plantar ledge of the metatarsal base and the medial cuneiform are removed in entirety.” Ex.1004, 328. The plantar ledge is a portion of the first metatarsal at the tarsal-metatarsal joint. Its removal is an example of removing a cut portion of the first metatarsal from that joint. This portion of McGlamry’s procedure would not be altered by the use of Fallin’s guide as Fallin’s guide is simply an instrument for performing these steps.

7. Limitation 14[f]

235. Limitation 14[f] recites “after cutting the end of the first metatarsal, rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” This limitation substantively recites the rotating after cutting limitation of claim 2. The McGlamry, Kartalian, Fallin combination renders obvious limitation 14[f] for the same reasons

discussed with respect to limitation 1[e] and claim 2[a] above. *See supra* §§VI.A.6., VII.A.

8. Limitation 14[g]

236. Limitation 14[g] recites “after cutting the end of the first metatarsal, imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” This limitation substantively recites the imparting a force after cutting the metatarsal features from claim 2. The McGlamry, Kartalian, Fallin combination renders this limitation obvious for the same reasons discussed above. *See supra* §VII.A.

9. Limitation 14[h]

237. Limitation 14[h] recites “after rotating the knob and after imparting the force to the pin to correct the bunion deformity of the first metatarsal, cutting an end of a medial cuneiform by guiding the saw blade through a second bone preparation guide cutting slot.” This limitation substantively recites a combination of the cutting the cuneiform after rotating the knob and impart the force to the pin limitations from claim 2, and the saw blade and second slot limitations from claim 9. The McGlamry, Kartalian, Fallin combination renders obvious limitation 14[h] for the same reasons discussed above. *See supra* §§VII.A., VII.B.

10. Limitation 14[i]

238. Limitation 14[i] recites “removing a cut portion of the medial cuneiform from the tarsal-metatarsal joint.” McGlamry discloses limitation 14[i].

239. McGlamry discloses that “[t]he corrective articular resection is made at the distal aspect of the convex shaped cuneiform.” Ex.1004, 324. Resecting the distal aspect of the cuneiform involves cutting and removing a portion of the medial cuneiform from the tarsal metatarsal joint. *See, e.g., id.*, 328 (“[E]ntire plantar ledge of...medial cuneiform [is] removed in entirety.”); Ex.1006, [0067] (“A saw blade 250 is guided in one of the proximal guide slots 218 to remove bone from the distal end of the cuneiform.”). This would be a standard surgical step that would not be modified with the incorporation of Fallin’s guide.

11. Limitations 14[j] and 14[k]

240. Limitation 14[j] recites “fenestrating a cut end of the first metatarsal.” Limitation 14[k] “fenestrating a cut end of the medial cuneiform.” McGlamry discloses these limitations.

241. McGlamry describes and depicts preparing (e.g., fenestrating) the cut ends of the first metatarsal and medial cuneiform. For example, one of the steps in McGlamry’s procedure is to cut the articulating ends of the first metatarsal and medial cuneiform. Ex.1004, 324 (describing resections). After these resections, McGlamry discusses preparation of the joint. *Id.* For instance, McGlamry discloses,

when the “metatarsal base and distal cuneiform ... are prepared,” “the subchondral plate is penetrated demonstrating good bleeding at both the metatarsal and cuneiform.” Ex.1004, 324. In Chapter 55, McGlamry describes “fenestration with a Kirschner wire (K-wire)” to “break through the subchondral plate” in an arthrodesis procedure. *Id.*, 807. Figure 31.3 illustrates Figure this fenestration of the cut bone ends:



Id., Fig.31.3B (“Interoperative clinical view demonstrating the use of a 2-mm drill preparing the tarsal-metatarsal joint prior to fixation.”).

242. The surface of the bone visible in the image above has been fenestrated. Fenestration is a process for stimulating bony healing by penetrating the subchondral plate with small holes. These small holes serve as sites for regenerative bone growth, as the body interprets these holes as individual wounds requiring healing. The image above shows a drill being used to create these holes in both bones,

particularly after both articulating ends of the metatarsal and cuneiform are removed. As such, McGlamry discloses fenestrating the cut ends of both the first metatarsal and medial cuneiform.

243. A POSA would have recognized that the use of a drill to penetrate the subchondral plate of prepared bone surfaces, as disclosed in McGlamry, is a conventional fenestration technique. *See* Ex.1004, 449 (“When using a 1.5mm wire pass drill bit to generously fenestrate these surfaces, the bone will be excavated while creating recess for neovascularization and capillary ingrowths.”), 433 (Fig. 36.15C showing metatarsal head “fenestrated using a 2.0-mm wire pass drill bit”), 439 (Fig. 36.198 showing fenestration).

12. Limitation 14[l]

244. Limitation 14[l] recites “compressing the first metatarsal together with the medial cuneiform.” This limitation is substantively identical to limitation 1[h] and would have been obvious over the McGlamry, Kartalian, Fallin combination for the same reasons as discussed in Ground 1. *See supra* §VI.A.9.

13. Limitation 14[m]

245. Limitation 14[m] recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.” This limitation is substantively identical to limitation 1[i] and would have

been obvious over the McGlamry, Kartalian, Fallin combination for the same reasons as discussed in Ground 1. *See supra* §VI.A.10.

14. Limitation 14[n]

246. Limitation 14[n] recites “removing the bone positioning guide from the first metatarsal and the second metatarsal.” This limitation includes the removing the bone positioning guide features from claim 3, and the McGlamry, Kartalian, Fallin combination renders obvious limitation 14[n] for the same reasons discussed in Ground 1 above. *See supra* §VI.B.

D. Claim 15

247. Claim 15 recites “further comprising after cutting the end of the first metatarsal, moving the first metatarsal in a sagittal plane.” McGlamry in view of Kartalian and Fallin renders obvious claim 15 for the same reasons discussed above regarding claim 8 in Ground 1. *See supra* §VI.F.

E. Claims 16 and 17

248. Claim 16 depends from claim 14 and recites “further comprising positioning a joint spacer offset from the first bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the first bone preparation guide cutting slot over an end of the first metatarsal to be cut.” Claim 17 depends from claim 14 and recites “further comprising positioning a joint spacer offset from the second bone preparation guide cutting slot into the tarsal-metatarsal

joint simultaneous with positioning the second bone preparation guide cutting slot over an end of the medial cuneiform to be cut.” McGlamry in view of Kartalian and Fallin renders obvious claims 16 and 17.

249. Fallin’s guide body 202 of its osteotomy guide 200 “may include a joint alignment feature to aid in positioning the guide body 202 relative to a joint.” Ex.1006, [0055]. One embodiment of this joint alignment feature is a “projection from the guide body 202 engageable with the joint.” *Id.* “The joint alignment feature allows a user to position the guide relative to the joint.” *Id.*

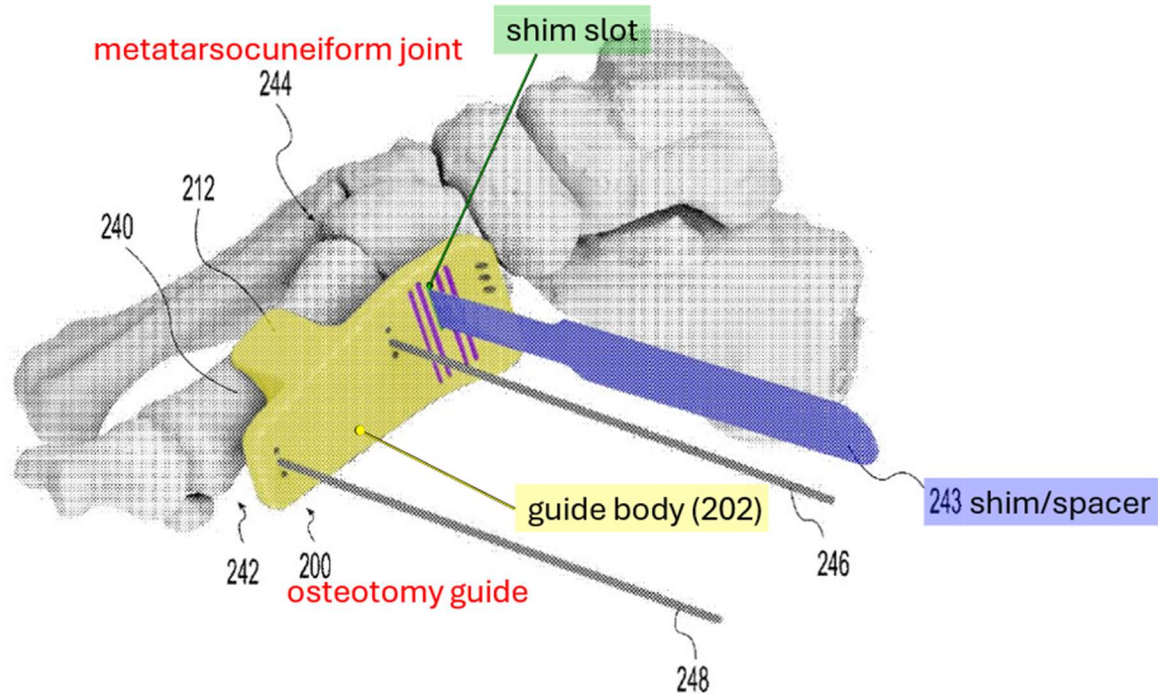
250. As this embodiment of the joint spacer is a projection from Fallin’s osteotomy guide 200 (bone preparation guide), it is placed into the joint simultaneous with the bone preparation guide being placed over the end of the metatarsal to be cut and over the end of the cuneiform to be cut. *See supra* §VII.B. (claim 9, Ground 2). As the joint spacer is a projection off of the osteotomy guide 200, a POSA would have understood that the joint spacer cannot occupy the same location as the cutting slots because the cutting slots must remain unobstructed to permit the insertion of the cutting instrument.

251. The joint referenced in Fallin is the tarsal-metatarsal (first metatarsal-medial cuneiform) joint. Ex.1006, [0064] (describing insertion of the joint alignment feature for use in aligning “the guide 200 with the metatarsocuneiform

joint 244”), Fig.21 (depicting insertion of a joint alignment feature into the tarsal-metatarsal joint).

252. Fallin’s “projection from the guide body 202 engageable with the joint” is a spacer that is configured to be placed into the tarsal-metatarsal joint. Because Fallin’s joint spacer is a projection from the osteotomy guide 200 (bone preparation guide), it is positioned into the joint simultaneously with positioning the bone preparation guide over the ends of the metatarsal and medial cuneiform to be cut. This is at least because a consistent way of aligning a bone preparation guide to a joint is to place the joint alignment feature in the joint itself. The ’481 patent describes its spacer for insertion into the metatarsocuneiform joint for positioning the body of a joint preparation guide on a joint and properly positioning the guide with respect to the bones to be cut. Ex.1001, 8:21-40. The joint alignment feature (spacer) of Fallin performs the same function.

253. In another embodiment, Fallin discloses its “joint alignment feature” being a shim 243 inserted through a slot 234 of the osteotomy guide into the metatarsocuneiform joint. This embodiment of Fallin’s spacer extending downwardly from the guide body is depicted in Figure 21 shown below:



Ex.1006, Fig.21 (annotated); *see also id.*, [0055], [0056] (“A feeler gauge 243, or shim, is inserted through the joint alignment slot 234 and used to align the guide 200 with the metatarsocuneiform joint 244.”). The placement of this shim illustrates where a POSA would understand the projection would be placed.

254. A POSA would recognize that, even in this embodiment, a surgeon could position the joint spacer (shim) into the metatarsocuneiform joint simultaneous with the bone preparation guide being placed over the ends of the metatarsal and cuneiform to be cut. For instance, a surgeon would understand that inserting the shim 243 into its joint alignment slot 234 prior to aligning the guide 200 over the metatarsocuneiform joint, thus resulting in simultaneous placement of the joint spacer in the metatarsocuneiform joint and placement of the bone preparation guide

cutting slots over the bones to be cut. *See* Ex.1006, [0064]. This configuration of the shim and guide would benefit the surgeon by ensuring immediate and accurate placement of Fallin's osteotomy guide over the bones to be cut.

F. Claim 18

255. Claim 18 depends from claim 14 and recites: “wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into the first metatarsal adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal.” Claim 18 recites the same features as claim 7, and McGlamry in view of Kartalian and Fallin renders obvious claim 18 for the same reasons discussed above regarding Ground 1. *See supra* §VI.E.

G. Claim 19

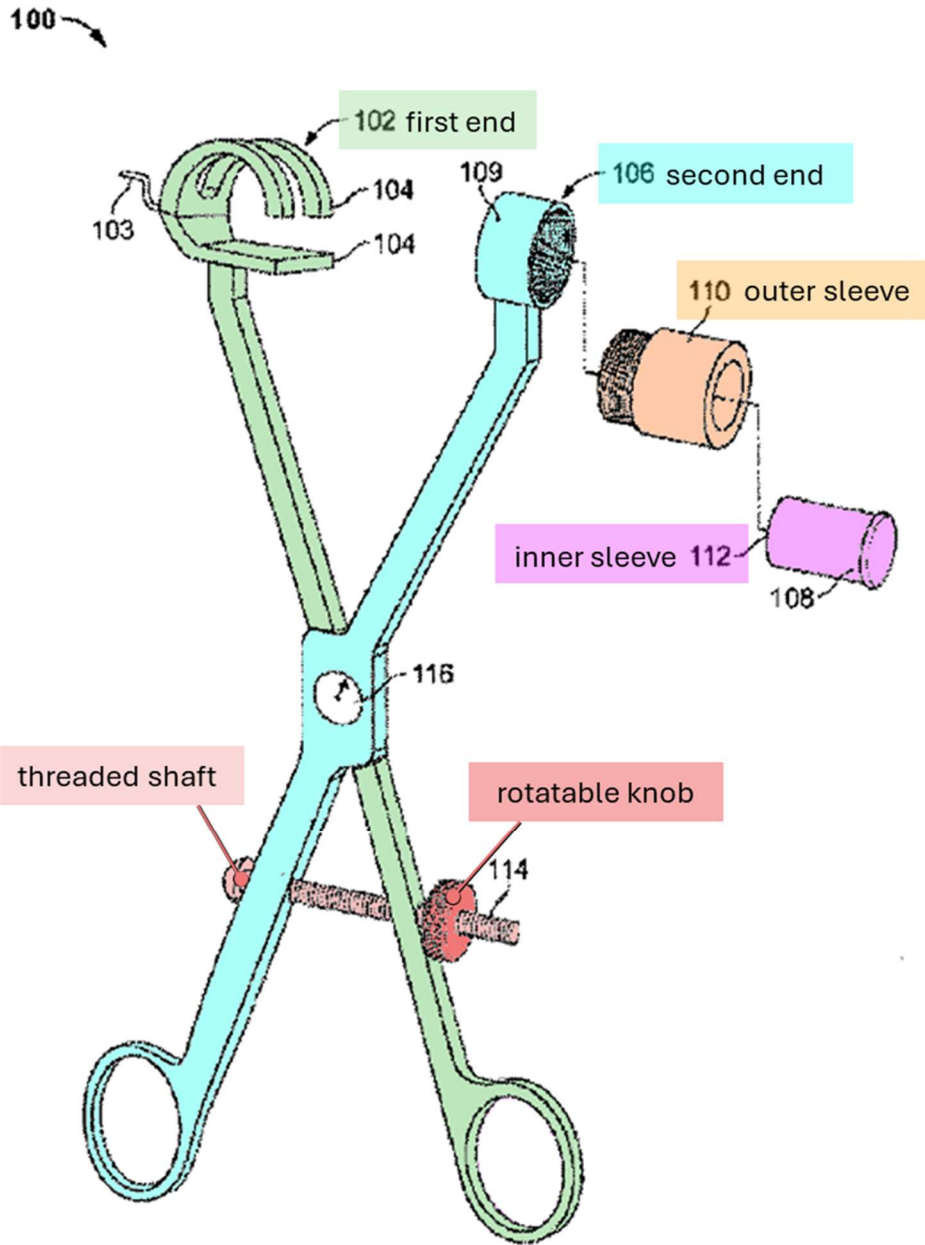
256. Claim 19 depends from claim 14 and recites “further comprising [a] making a second incision on the foot to provide access to the second metatarsal, wherein: engaging the bone positioning guide with the second metatarsal comprises positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal; [b] and rotating the knob connected to a threaded shaft of the

bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal comprises rotating the knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface.”

257. Limitation 19[a] recites the same substantive features as claim 5, and McGlamry in view of Kartalian and Fallin renders obvious limitation 19[a] for the same reasons discussed above regarding Ground 1. *See supra* §VI.D.

258. Regarding limitation 19[b], as I explained above regarding limitation 1[e] for Ground 1 above, rotating the knob connected to the threaded shaft of Kartalian’s bone positioning guide reduced the distance between first end 102 and second end 106. *See supra* §VI.A.6.

259. As I also explained above regarding limitation 1[b] and claim 5 for Ground 1 above, Kartalian’s bone positioning guide has the claimed contact surface on end 102 and the claimed bone engagement member on end 106. *See supra* §§VI.A.3., VI.D. Thus, rotating Kartalian’s knob will reduce the distance between the bone engagement member and the contact surface when correcting the bunion deformity. Figure 1, Panel I below depicts the ends 102 and 106, as well as the knob connected to the threaded shaft in its “reduction forceps”-like configuration effectuating the above-described reduction:



Ex.1005, Fig.1 (excerpt) (annotated).

H. Claim 20

260. Claim 20 depends from claim 19 and recites: “wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second

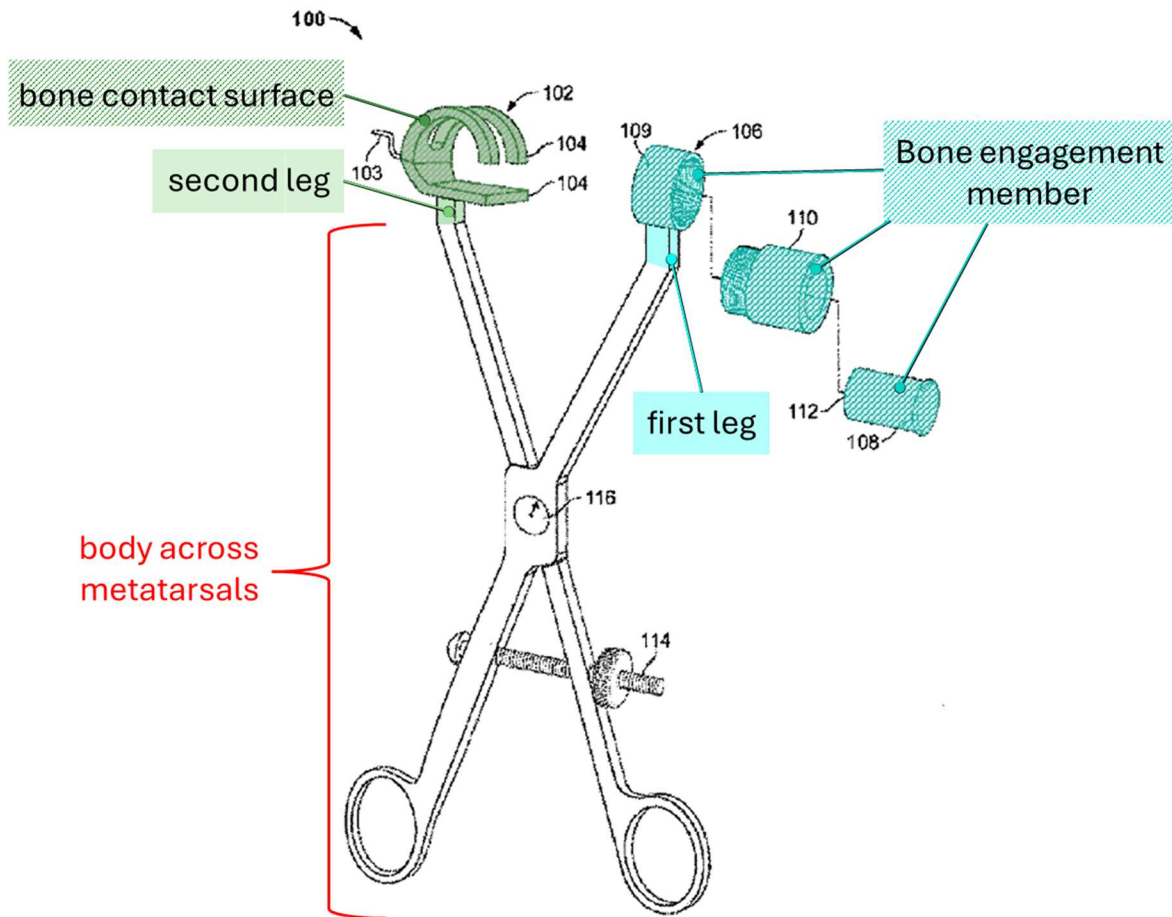
metatarsal comprises inserting the tip through the second incision.” Claim 20 recites the same substantive features as claim 6, and McGlamry in view of Kartalian and Fallin renders obvious claim 20 for the same reasons discussed above regarding Ground 1. *See supra* §VI.D.

I. Claim 21

261. Claim 21 depends from claim 19 and recites “[a] the bone positioning guide comprises a body, a first leg carrying the bone engagement member, and a second leg defining the bone contact surface; and [b] engaging the first metatarsal with the bone engagement member and positioning the bone contact surface in contact with the second metatarsal comprises positioning the body extending in a medial-to-lateral direction across the first metatarsal and across the second metatarsal with the first leg positioned on a medial side of the first metatarsal.” McGlamry in view of Kartalian and Fallin renders obvious claim 21.

1. Limitation 21[a]

262. As I explained above regarding limitation 1[b] and claims 5, 6, and 19, Kartalian’s bone positioning guide (instrument 100) includes a bone engagement member (end 106) and a bone contact surface (end 102). *See supra* §§VI.A.3., VI.D., VII.G. As shown below, Kartalian’s bone positioning guide also includes a body, a first leg carrying the bone engagement member, and a second leg defining the bone contact surface.



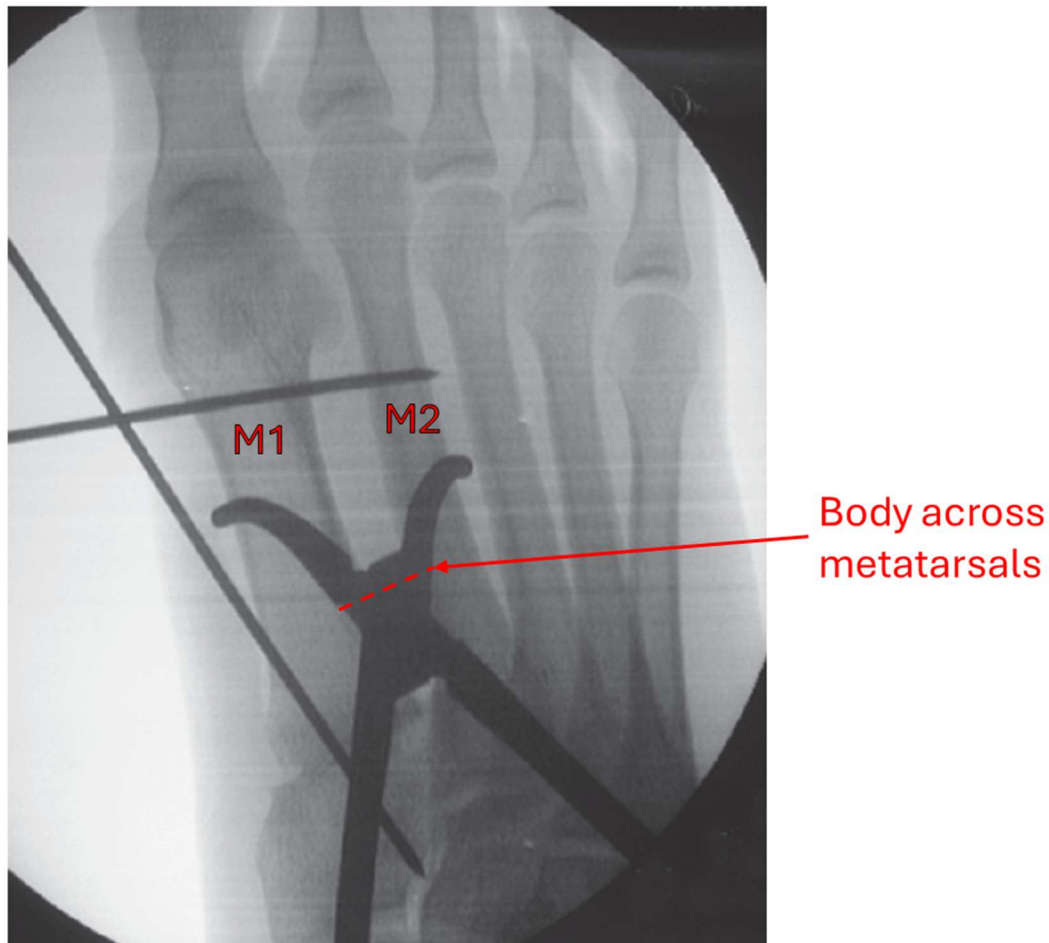
Ex.1005, Fig.1 (excerpt) (annotated).

2. Limitation 21[b]

263. Kartalian discloses second end 106 (bone engagement member) of its instrument is placed through “medial incision at the first metatarsal” such that it is placed on the first metatarsal. Ex.1005, 10:29-62. Similarly, the first end 102 (bone contacting surface) is placed through “an incision lateral to the second metatarsal at its distal portion” and onto the second metatarsal. *Id.* Thus, a POSA would recognize that the instrument 100 would be placed with its body extending in a medial to lateral direction across the first and second metatarsals, with the

instrument's first leg positioned on a medial side of the first metatarsal. This configuration corresponds to the claimed positioning of the bone positioning guide.

264. The positioning of Kartalian's instrument 100 would not change when used in McGlamry's procedure. As shown in Figure 31.5 below, McGlamry's Weber clamp is similarly placed over the first and second metatarsals in a medial-to-lateral position, where one end of the Weber clamp is on the first metatarsal (M1) and the other end is on the second metatarsal (M2):



Ex.1004, Fig.31.5 (annotated).

265. As I explained above for limitation 1[b] in Ground 1, a POSA would have reasonably expected to succeed in using Kartalian's instrument in McGlamry's procedure. *See supra* §VI.A.3. A POSA would understand Kartalian's instrument to be used in place of McGlamry's Weber clamp to engage the metatarsals in the same medial to later orientation, which is consistent with the positioning that Kartalian describes.

J. Claim 22

266. Claim 22 depends from claim 14 and recites “wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.” Claim 22 recites the same features as claim 10, and McGlamry in view of Kartalian and Fallin renders obvious claim 22 for the same reasons discussed above for Ground 1. *See supra* §VI.G.

K. Claim 23

267. Claim 23 depends from claim 14 and recites “wherein the bone positioning guide is formed by joining at least three components together, including the threaded shaft and the bone engagement member, to provide the bone positioning guide.” Claim 23 recites the same substantive features as claim 4, and McGlamry in view of Kartalian and Fallin renders obvious claim 23 for the same reasons discussed above for Ground 1. *See supra* §VI.C.

L. Claim 24

268. Claim 24 depends from claim 14 and recites “wherein the at least one bone fixation device comprises at least one of a screw and a plate.” Claim 24 recites the same features as claim 11, and McGlamry in view of Kartalian and Fallin renders obvious claim 24 for the same reasons discussed above for Ground 1. *See supra* §VI.H.

M. Claim 26

269. Claim 26 depends from claim 14 and recites “wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.” Claim 24 recites the same features as claim 13, and McGlamry in view of Kartalian and Fallin renders obvious claim 26 for the same reasons discussed above for Ground 1. *See supra* §VI.H.

N. Claim 28

270. Claim 28 depends from claim 27 and recites “wherein: [a] rotating the knob connected to the threaded shaft comprises rotating the knob connected to the threaded shaft after preparing the end of the first metatarsal; [b] imparting the force

to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after preparing the end of the first metatarsal; and [c] preparing the end of the medial cuneiform comprises preparing the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity.” McGlamry in view of Kartalian and Fallin renders obvious the additional limitations of claim 28.

271. The limitations of claim 28 are substantively the same as the limitations of claim 2, with the lone exception that claim 28 recites “preparing” rather than “cutting.” As explained for limitations 27[d] and 27[g] in Ground 1, cutting the end of the first metatarsal or the medial cuneiform constitutes preparing those bone ends for fusion. *Supra* §VI.I.5, VI.I.8.

272. Furthermore, even if “preparing” requires something akin to fenestration, it would have been obvious that this step follows the cutting. Fenestrating after cutting prepares the resected bone surfaces for fusion by promoting bleeding and healing, a well-known and conventional surgical technique. Ex.1004, 433, 439, 449.

O. Claim 30

273. I performed a comparison of claim 30 to independent claims 1 and 14. Independent claim 30 shares many of the same limitations of claims 1 and 14.

McGlamry in view of Kartalian discloses each of these common limitations for the reasons I explained for claims 1 and 14 above.

1. Preamble

274. The preamble of claim 30 recites “An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.” McGlamry in view of Kartalian and Fallin renders obvious this preamble. *See supra* §§VI.A.1., VII.C.1. (limitations 1[pre] and 14[pre]).

2. Limitation 30[a]

275. Limitation 30[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” This limitation is substantively identical to limitation 1[a] would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons as discussed in Ground 1. *See supra* §VI.A.2.

3. Limitation 30[b]

276. Limitation 30[b] recites “making a second incision on the foot to provide access to a second metatarsal separated from the first metatarsal by an intermetatarsal angle.” This limitation recites the same substantive features as claims 1[c], 5, and 19, and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. *See supra* §VI.A.4., VI.D., VI.G.

4. Limitation 30[c]

277. Limitation 30[c] recites “engaging the first metatarsal with the bone engagement member of a bone positioning guide.” This limitation is identical to limitation 1[c] and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons as discussed in Ground 1. *See supra* §VI.D.

5. Limitation 30[d]

278. Limitation 30[d] recites “positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal.” This limitation recites substantively the same features as claims 5 and 19 and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons as discussed above. *See supra* §VI.D., VII.G.

6. Limitation 30[e]

279. Limitation 30[e] recites “cutting an end of the first metatarsal by guiding a saw blade through a first bone preparation guide cutting slot.” This limitation recites substantively the same features as limitation 14[d] and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. *See supra* §VII.C.5.

7. Limitation 30[f]

280. Limitation 30[f] recites “rotating a knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface, thereby reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” This limitation recites substantively the same features as limitation 1[e] and claim 5 and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. *See supra* §VI.A.6., VI.D.

8. Limitation 30[g]

281. Limitation 30[g] recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” This limitation is substantively identical to limitation 1[g] and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. *See supra* §VI.A.8.

9. Limitation 30[h]

282. Limitation 30[h] recites “cutting an end of a medial cuneiform by guiding the saw blade through a second bone preparation guide cutting slot.” For the same reasons as I explained above regarding limitation 14[h], these features would have been obvious over the combination of McGlamry, Kartalian, and Fallin. *See supra* §VII.C.9.

10. Limitation 30[i]

283. Limitation 30[i] recites “compressing the first metatarsal together with the medial cuneiform.” This limitation recites the same substantive features as limitation 1[h] and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. *See supra* §VI.A.9.

11. Limitation 30[j]

284. Limitation 30[j] recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.” This limitation recites the same substantive features as limitation 1[i] and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. *See supra* §VI.A.10.

12. Limitation 30[k]

285. Limitation 30[k] recites “removing the bone positioning guide from the first metatarsal and the second metatarsal.” This limitation recites many of the same features as claim 3 and the same substantive features as limitation 14[n], and would have been obvious over the combination of McGlamry, Kartalian, and Fallin for the same reasons discussed above. §§VI.B., VII.C.14.

13. Limitation 30[l]

286. Limitation 30[l] recites “wherein one or both of the first metatarsal and the medial cuneiform is cut after reducing the intermetatarsal angle between the first

metatarsal and the second metatarsal to correct the bunion deformity and after adjusting the alignment of the first metatarsal in the frontal plane to correct the bunion deformity.” For the same reasons as I explained for limitations 1[e]-1[f], and the cutting the cuneiform after rotating and imparting force to a pin limitation of claim 2, these features would have been obvious over the combination of McGlamry, Kartalian, and Fallin. *See supra* §§VI.A.6-7., VII.A.

VIII. GROUND 3: CLAIMS 1-11, 13-24, AND 26-30 WOULD HAVE BEEN OBVIOUS OVER FALLIN, KARTALIAN, AND MCGLAMRY

287. It is my opinion that claims 1-11, 13-24, and 26-30 of the ’481 patent would have been obvious to a person of ordinary skill in the art by August 14, 2015 in view of Fallin, Kartalian, and McGlamry.

A. Claim 1

1. Preamble

288. The preamble of claim 1 recites: “An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.”

289. Fallin discloses an instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity. *See* Ex.1006, [0047]-[0049] (describing deformities of the first ray, including a bunion).

290. 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]; *see also id.*, [0057], [0065]-[0068]. 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.

Ex.1006, [0058].

291. 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]. Fallin thus discloses an “instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.”

2. Limitation 1[a]

292. Limitation 1[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” Fallin in view in McGlamry renders obvious this limitation.

293. As discussed above, Fallin discloses a surgical method for correcting a bunion deformity that involves operating on (and in fact cutting) the first metatarsal and medial cuneiform. *See supra* §VIII.A.1. (1[pre] – Ground 3). The joint connecting the first metatarsal and medial cuneiform is the tarsal-metatarsal joint. Accessing that joint in Fallin’s procedure requires that making an incision on a foot to provide access to a tarsal-metatarsal joint to permit the disclosed surgical step (such as removal of the cut bone fragments from the operation site) to be performed.

294. Even if Fallin did not disclose an incision, it would have been obvious over McGlamry and Kartalian. McGlamry describes a bunion correction procedure that is nearly identical to Fallin’s. McGlamry’s procedure includes the steps of (a) cutting a first metatarsal and a medial cuneiform, (b) repositioning the first metatarsal in multiple planes, and (c) fixing the first metatarsal to the medial cuneiform to promote fusion of the arthrodesis site. Ex.1004, 324-327. McGlamry expressly discloses that “[a]n incision is made over the metatarsal-cuneiform joint approximately 4 to 6 cm in length.” *Id.*, 324.

295. Kartalian also describes “surgical repair of a hallux valgus” (bunion) by beginning with “a medial incision at the first metatarsal.” Ex.1005, 10:29-33. A POSA would recognize that a medial incision at the first metatarsal would provide access to the metatarsocuneiform joint when implemented in Fallin’s procedure.

296. A POSA would have been motivated to make an incision on the foot as disclosed, for example, by McGlamry and Kartalian to perform Fallin’s surgical procedure. Exposing the tarsal-metatarsal joint via an incision is a prerequisite to the cutting, moving, and fixation steps disclosed by Fallin.

3. Limitation 1[b]

297. Limitation 1[b] recites “engaging the first metatarsal with a bone engagement member of a bone positioning guide.” Kartalian discloses limitation 1[b] for the same reasons discussed in Ground 1 above. *See supra* §VI.A.3.

298. Fallin teaches bunion correction procedure that specifically includes cutting the proximal end of the first metatarsal, cutting the distal end of the medial cuneiform, correcting the position of the metatarsal in three planes, including the transverse plane and rotation in the frontal plane, compression of the metatarsal and cuneiform, then fixing the medial portion of the moved first metatarsal to the distal portion of the cuneiform. Ex.1006, [0057]-[0058].

299. Fallin discloses various tools for use in its bunion correction procedure but does not provide specific details on the tools that can be used to reposition the first metatarsal. Thus, a POSA would have been motivated to look to a known bone positioning guide, such as Kartalian’s instrument, for repositioning the first metatarsal in Fallin’s procedure.

300. A POSA would have been motivated to implement Kartalian's instrument into Fallin's bunion correction procedure for a number of reasons. First, Kartalian discloses an instrument that functions as a reduction forceps to engage bone and apply controlled force to align bones or reduce the distance between them, including by moving the first metatarsal in the transverse plane.

301. Kartalian's instrument also includes features specifically designed for correcting a bunion (e.g., a bone engagement member, locking mechanism, alignment indicator, and sleeve), which would have been well suited for reliably engaging and manipulating the first metatarsal during bunion correct like Fallin's procedure. Ex.1005, 9:58-10:15. These features would have made Kartalian's instrument a predictable and advantageous choice for use in Fallin's procedure.

302. For example, Kartalian includes a feature for locking bones during movement of the first metatarsal. *Id.*, 10:4-6 (describing structure to "hold the instrument 100 in position once the final alignment of the bones has been achieved"). This locking feature would prevent unwanted transverse plane movement after repositioning of the first metatarsal.

303. Kartalian's instrument 100 also includes "an automatic angle indicator 116 to provide the surgeon with an estimate of the angle of the bones requiring correction." *Id.*, 10:8-16. Kartalian explains that:

[O]ne skilled in the art appreciates that trigonometry may be used to estimate the angle between the two bones using known data regarding the

length of the bones from x-rays or from anthropomorphic averages along with the final distance between the instrument arm 118 and instrument arm 120 to estimate the [IM] angle. The instrument 100 then may be suitably calibrated to show the angle between the bones.

Id., 10:8-18. This feature would provide the surgeon with additional guidance on the final position of the bone, which could improve the success rate of a surgery that was known, in 2015, for having a relatively high failure rate. Ex.1005, 2:30-39.

304. Second, a POSA would have found it desirable to reliably engage and manipulate the first metatarsal while adjusting its position in multiple planes and maintaining that position during fixation, rather than relying on techniques such as manual adjustment of the metatarsal. Ex.1009, 353 (“If we can accept that HAV deformity is triplane, it follows that each of these planes should be addressed in the correction operation.”) Proper anatomical alignment in multiple planes is associated with more consistent and favorable patient outcomes. *See* Ex.1004, 328 (describing impedance of correction from McGlamry’s procedure as “proper placement and compression across the arthrodesis site will not be achieved”); Ex.1006, [0003] (“It is often desirable to change the angular alignment of a bone or a portion of a bone to restore function and/or reduce pain.”), [0048] (describing anatomical changes resulting from bunion deformity); Ex.1017, 250 (describing importance of frontal plane rotation for anatomic alignment of the first metatarsophalangeal joint, including “less than optimal realignment of the [first ray] apparatus can lead to retrograde forces, with the increased possibility of recurrence”).

305. As I explained above for limitation 1[b] in Ground 1, the structure disclosed regarding Kartalian's instrument for accomplishing this multiplanar movement is substantively identical, or at least equivalent, to the structure disclosed in the '481 patent's specification. *See supra* §VI.A.3. Further, Kartalian's instrument includes an end 106, which is a bone engagement member and may be placed on the first metatarsal as I explained above. *Id.*

306. A POSA would have also reasonably expected to succeed in using Kartalian's instrument in Fallin's procedure. Kartalian's instrument is designed for use in a bunion correction procedure like the procedure described by Fallin. *Compare* Ex.1005, 9:58-10:18, 10:29-62 *with* Ex.1006, [0057]-[0058], [0064]-[0068]. A POSA would understand that modifications to Kartalian's bone positioning guide would likely have been unnecessary given Kartalian's disclosure of using the instrument for bunion correction procedures. However, to the extent Kartalian's instrument would need any modification, it would have been within the skill of a POSA capable of modifying basic surgical equipment, as Kartalian's instrument is a simple mechanical tool that would only require easy-to-implement tooling modifications to make.

4. Limitation 1[c]

307. Limitation 1[c] recites "engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle."

Kartalian discloses limitation 1[c] for the same reasons discussed in Ground 1 above.

See supra §VI.A.4.

5. Limitation 1[d]

308. Limitation 1[d] recites “cutting an end of the first metatarsal with a tissue removing instrument.” Fallin discloses this limitation. Fallin explains that “a saw blade...is guided...to remove bone from the proximal end of the metatarsus.” Ex.1006, [0065]; *see also id.*, [0006] (“cutting one of the metatarsus and cuneiform to remove a first portion of bone adjacent the joint”), claim 14 (“guiding a cutter with the osteotomy guide to cut the metatarsus...and remove a first portion of bone adjacent the joint”). Fallin’s saw satisfies the “tissue removing instrument” limitation under its plain meaning; and if a means-plus-function construction were applied, each is corresponding structure (or an equivalent) to the saw/osteotome/bur-type tissue-removal instruments described in the ’481 patent.

6. Limitation 1[e]

309. Limitation 1[e] recites “rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” Kartalian discloses limitation 1[e] for the same reasons discussed in Ground 1 above. *See supra* §VI.A.6.

7. Limitation 1[f]

310. Limitation 1[f] recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” It would have been obvious to use McGlamry’s pin in the procedure in the combination of Fallin, Kartalian, and McGlamry for the reasons discussed in limitation 1[f] in Ground 1 above. *See supra* §VI.A.7.

311. McGlamry’s pin—as a “rotation device”—is a simple form of finetuning the rotational alignment of the first metatarsal, including after the use of a bone positioning guide. Ex.1004, 325-27 (“If the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the metatarsal ... [and] can be used as a rotation device and rotate the metatarsal” in the frontal plane). McGlamry’s disclosure directly corresponding to the limitation of imparting a force to a pin inserted into the first metatarsal to adjust alignment in the frontal plane to correct a bunion deformity. As I have previously explained, the use of McGlamry’s K-wire would be in addition to, rather than instead of, Kartalian’s instrument. *See supra* §VI.A.7.

312. Implementing McGlamry’s known method of imparting a force to a pin for correction of the first metatarsal in the frontal plane into Fallin’s method would have led to the predictable result of ensuring frontal plane correction of the first metatarsal into a desirable, neutral position. It was nothing more than the use of an

established, predictable technique for achieving or refining frontal-plane rotational alignment during bunion correction procedures. It was also compatible with the use of other instruments.

313. Further, a POSA would have a reasonable expectation of success because McGlamry expressly discloses the use of a K-wire to rotate the first metatarsal in the frontal plane. This rotational manipulation is performed during a bunion correction procedure that has many similarities to Fallin's. *See generally* Ex.1004, 324-330; Ex.1006, [0057]-[0068]. For example, both Fallin and McGlamry describe cuts to the proximal end of the first metatarsal and distal end of the medial cuneiform, repositioning of the first metatarsal relative to the cuneiform, and fixation—all part of correcting a bunion. Combining Kartlian's instrument with McGlamry's K-Wire in a technique like Fallin's would have predictably allowed for controlled correction of the first metatarsal in multiple planes, and would not have altered Fallin's underlying technique.

8. Limitation 1[g]

314. Limitation 1[g] recites "cutting an end of a medial cuneiform with the tissue removing instrument." Fallin discloses limitation 1[g] for the same reasons discussed in Ground 2 above. *See supra* §§VII.A., VII.B. (limitation 2[c] and claim 9). For example, Fallin explains that "[a] saw blade...is guided...to remove bone from the distal end of the cuneiform." Ex.1006, [0067]; *see also id.*, [0006] ("cutting

one of the metatarsus and cuneiform to remove a first portion of bone adjacent the joint”), claim 14 (“guiding a cutter with the osteotomy guide to cut the cuneiform...and remove a second portion of bone adjacent the joint”).

9. Limitation 1[h]

315. Limitation 1[h] recites “compressing the first metatarsal together with the medial cuneiform.” Fallin in view of McGlamry renders obvious limitation 1[h].

316. Fallin’s procedure involves “compression of the bone surfaces together”—compression of the first metatarsal and medial cuneiform at the tarsal-metatarsal joint. Ex.1006, [0075] (“[C]ompression may be facilitated... to press the bone portions together.”). Fallin also discloses bringing the cut surfaces of the metatarsocuneiform joint bones together after their cuts. *Id.*, [0058], [0060], [0065]-[0068].

317. However, to the extent that Fallin’s procedure does not explicitly include a step for compressing the first metatarsal and medial cuneiform, it would have been obvious to apply compression between the two bones in Fallin’s procedure. For example, McGlamry explains that “interfragmentary compression will create an excellent reduction at the base of the tarsal-metatarsal joint” and that “interfragmentary compression allows the surgeon to reduce the IM angle well.” Ex.1004, 326-327. As discussed above regarding limitation 1[h] in Ground 1, McGlamry provides compression via a “homerun screw.” *See supra* §VI.A.9. This

compression is a part of ensuring bony healing between the cut ends of the metatarsocuneiform joint, as the planar contact results in fusion of the bones in their corrected respective positions. Ex.1006, [0068].

318. Compressing the metatarsal and cuneiform together in Fallin's procedure would have been nothing more than the use of McGlamry's known compression technique for its known purpose to achieve the predictable result of bringing the prepared surfaces of the metatarsocuneiform joint in contact for fusion. Fallin describes final fixation of the repositioned metatarsocuneiform joint bones via "plates, screws, rods or other suitable fixation elements." Ex.1006, [0060]; *see also id.*, [0068]. Since compression in McGlamry's procedure may be achieved at least through a screw, a POSA would have understood that one of the fixation elements for use in Fallin's procedure could be an interfragmentary compression screw. A POSA would have had a reasonable expectation of success given that this was a use of a known technique in a similar bunion correction procedure.

10. Limitation 1[i]

319. Limitation 1[i] recites "fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device." Fallin discloses limitation 1[i].

320. Fallin discloses that, after the bones are brought together, "the guide 200 may be used to hold the bones in the desired orientation while ... additional

fixation in the forms of pins, plates, screws, rods or other suitable fixation is applied.” Ex.1006, [0067]-[0068], [0074]-[0075]; *see also id.*, [0060]. Applying such fixation devices fixates the moved position of the first metatarsal relative to the medial cuneiform so that the bones will remain immobilized and fuse. *Id.*, [0068]; *see also* Ex.1004, 808-09 (describing purpose of fixation devices in an arthrodesis procedure). Fallin’s method is an arthrodesis procedure. Ex.1006, [0003].

321. Thus, Fallin in view of McGlamry and Kartalian render obvious claim 1.

B. Claim 2

322. Claim 2 depends from claim 1 and recites “rotating the knob connected to the threaded shaft comprises rotating the knob connected to the threaded shaft after cutting the end of the first metatarsal; imparting the force to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after cutting the end of the first metatarsal; and cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity.” Fallin in view of McGlamry and Kartalian renders obvious claim 2.

323. It would have been obvious to use Kartalian’s instrument to move the first metatarsal in the order described by Fallin. Fallin discloses that the preparation (e.g., cutting) of the first metatarsal occurs before the metatarsal is repositioned.

Ex.1006, [0057]-[0062], [0065]-[0068]. As such, a POSA would understand that, when using Kartalian's bone positioning guide in Fallin's procedure, the step of rotating the knob connected to the threaded shaft for reducing the IMA and repositioning the first metatarsal would occur after the cutting of the proximal end of the first metatarsal. In Fallin's procedure, repositioning of the first metatarsal—including in the frontal plane—occurs after cutting the first metatarsal. Ex.1006, [0057]-[0062], [0065]-[0068]. As such, it would have been obvious to a POSA to impart a force on a pin, like McGlamry's "rotation device," to correct the frontal plane position of the first metatarsal after cutting the articulating end of the first metatarsal.

324. Kartalian's instrument and McGlamry's pin merely provide known tools for performing the repositioning step disclosed in Fallin and would not alter Fallin's disclosed sequence.

325. Fallin discloses cutting the end of the medial cuneiform after adjusting the position of the metatarsal in multiple planes to correct the bunion deformity. Ex.1006, [0006], [0057]-[0062], [0065]-[0068]. Because the bone positioning guide and pin would be used to reposition the first metatarsal when used in Fallin's procedure, the cutting of the medial cuneiform would occur after rotating the knob and after imparting the force to the pin to correct the bunion deformity.

C. Claim 3

326. Claim 3 depends from claim 1 and recites: “removing the bone positioning guide from the first metatarsal and the second metatarsal with the moved position of the first metatarsal remaining fixated relative to the medial cuneiform by the at least one bone fixation device.” Fallin in view of McGlamry and Kartalian renders obvious claim 3.

327. It would have been obvious to remove the surgical instruments used to perform the Fallin’s bunion correction procedure, leaving only fixation devices in the foot at the end of the procedure. Surgical instruments used to perform different steps of the surgery (like bone positioning guides) may be removed after final fixation because they no longer serve a purpose in maintaining the proper alignment of the moved bones. Further, instruments that are not designed for permanent implementation in the foot (e.g., bone positioning guides, like Kartalian’s “reduction forceps”-like instrument) are generally removed before closing the incision. If these instruments are not removed, they can impede the healing, may hinder the patient’s mobility, or prevent the patient from wearing certain footwear. Particularly for bone positioning guides like Kartalian, it would have been obvious to remove the guide by the end of the procedure. Indeed, Kartalian discloses the removal of its guide. Ex.1005, 10:23-28 (disclosing that its instrument 100 is removed after “insert[ing]

an anchoring and alignment system ... [and] properly aligning and securing the reduction of the IM angle of the first metatarsal”).

328. A POSA would have recognized that, when using Kartalian’s guide in Fallin’s procedure, it would have been obvious to maintain this sequence for the removal of Kartalian’s instrument. For example, Kartalian further describes that its instrument 100 includes “a locking clamp 114 to hold the instrument 100 in position once the final alignment of the bones has been achieved.” Ex.1005, 10:4-8. A POSA would have recognized that, in view of this disclosure, Kartalian’s instrument would remain in place during the installation of the bone fixation device in Fallin’s procedure, as this would maintain the moved position of the first metatarsal until it is secured with the bone fixation device.

329. The timing of the removal of Kartalian’s instrument is nothing more than the use of Kartalian’s known technique in Fallin’s method for repositioning, maintaining, and fixing the position of the metatarsocuneiform joint bones for the predictable result of proper alignment of the first metatarsal and medial cuneiform.

D. Claim 4

330. Claim 4 depends from claim 1 and recites “further comprising, prior to engaging the first metatarsal with the bone engagement member of the bone positioning guide and engaging the bone positioning guide with the second metatarsal, joining at least three components together, including the threaded shaft

and the bone engagement member, to form the bone positioning guide.” Fallin in view of Kartalian and McGlamry renders obvious claim 4. *See supra* §VI.C. (describing assembly of Kartalian’s bone positioning guide). The order of assembly and use of Kartalian’s instrument would not change when implemented in Fallin’s bunion correction procedure.

E. Claims 5 and 6

331. Claim 5 depends from claim 1 and recites “further comprising making a second incision on the foot to provide access to the second metatarsal, wherein engaging the bone positioning guide with the second metatarsal comprises positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal.” Claim 6 depends from claim 5 and recites “wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal comprises inserting the tip through the second incision.” Fallin in view of McGlamry and Kartalian renders obvious claims 5 and 6.

332. As I explained above in Ground 1, Kartalian discloses the features of claims 5 and 6. *See supra* §VI.D.

333. It would have been obvious to implement use a second incision in Fallin’s procedure to access the second metatarsal for placement of Kartalian’s tip. As I explained above regarding limitation 1[b], the use of Kartalian’s instrument in

Fallin's procedure would have been obvious for multiple reasons. A POSA would have been motivated to and had a reasonable expectation of success in implementing Kartalian's second incision in Fallin's procedure, as the second incision optimizes the use of Kartalian's instrument without unnecessarily increasing the size of the first incision to accommodate Kartalian's instrument on the second metatarsal.

334. For example, Kartalian's first end 102 is designed to contact the second metatarsal, which allows the instrument to act of a "reduction forceps to align two cones or reduce the distance between two bones." *See* Ex.1005, 9:66-67. Implementing Kartalian's second incision in Fallin's procedure would have been nothing more than the use of Kartalian's known technique of making and using a second incision to improve Fallin's known method of repositioning the first metatarsal in the same way that the second incision is made and used in Kartalian's method. The implementation of Kartalian's second incision in Fallin's method would yield the predictable result of allowing Kartalian's bone positioning guide to contact the second metatarsal and serve as a means for repositioning the first metatarsal in multiple planes.

F. Claim 7

335. Claim 7 depends from claim 1 and recites: "wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into

the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal.” Fallin in view of McGlamry and Kartalian renders obvious claim 7.

336. As I explained above regarding limitation 1[f], McGlamry discloses imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity, and a POSA would have found it obvious to apply this technique to Fallin’s method. *See supra* §VIII.A.7.

337. As I explained above regarding limitations 1[b] and 1[e], Kartalian discloses using a bone positioning guide (instrument 100), and more specifically, rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the IMA between the first metatarsal and the second metatarsal. *See supra* §§VIII.A.3., VIII.A.6. Kartalian’s instrument 100 would also be used to rotate the first metatarsal in the frontal plane. Ex.1005, 9:66-10:3. In McGlamry’s procedure, the use of a pin to adjust the alignment of the metatarsal in the frontal plane occurs after the reduction of the IMA, which in

McGlamry occurs via a Weber clamp. Ex.1004, 325-326 (“If the surgeon feels a need to obtain *more* correction in the frontal plane, the K-wire can be inserted into the first metatarsal [T]he K-wire can be used as a rotation device to rotate the metatarsal into more of a neutral position....”) (emphasis added).

338. In view of Kartalian’s explanation that its bone positioning guide reduces the IMA and rotates the first metatarsal in the frontal plane, McGlamry’s explanation that the pins can be used for *additional* rotation in the frontal plane after the reduction of the IMA, and Fallin’s silence as to an order of the triplanar corrective movements, it would have been obvious to maintain this order of steps disclosed in Fallin, Kartalian, and McGlamry. Using the rotation via the pins in this manner would permit the surgeon to finetune the rotational adjustment of the metatarsal in the frontal plane after the final IMA has been established using Kartalian’s instrument and account for the rotation from the use of Kartalian’s instrument, similar to how McGlamry describes using its pin “rotation device.”

G. Claim 8

339. Claim 8 depends from claim 1 and recites “further comprising moving the first metatarsal in a sagittal plane.” Fallin in view of McGlamry and Kartalian renders obvious claim 8.

340. Fallin discloses moving the first metatarsal in the sagittal plane. Ex.1006, [0058] (“[T]he metatarsus may be ... rotated in the sagittal plane to adjust plantar/dorsal flexion.”), [0066]. This rotation movement is in the sagittal plane.

H. Claim 9

341. Claim 9 depends from claim 1 and recites “wherein: the tissue removing instrument is a saw blade; cutting the end of the first metatarsal comprises guiding the saw blade through a first bone preparation guide cutting slot; and cutting the end of the medial cuneiform comprises guiding the saw blade through a second bone preparation guide cutting slot.” Fallin in view of McGlamry and Kartalian renders obvious claim 9. *See supra* §§VII.B. (claim 9, Ground 2 – describing Fallin disclosing the additional limitations of this claim).

I. Claim 10

342. Claim 10 depends from claim 1 and recites “wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.” Fallin in view of McGlamry and Fallin renders obvious claim 10.

343. As I explained for claim 10 in Ground 1, Kartalian and McGlamry renders obvious the limitations of claim 10. *Supra* §VI.G. My reasoning from Ground 1 applies equally to Fallin’s procedure as it is a very similar procedure, and the use of a fixation wire through Kartalian’s cannulation for temporary fixation

would provide the benefit of temporarily holding the position of the first metatarsal while permanent fixation is applied.

J. Claim 11

344. Claim 11 depends from claim 1 and recites “wherein the at least one bone fixation device comprises at least one of a screw and a plate.” Fallin in view of McGlamry and Kartalian renders obvious claim 11.

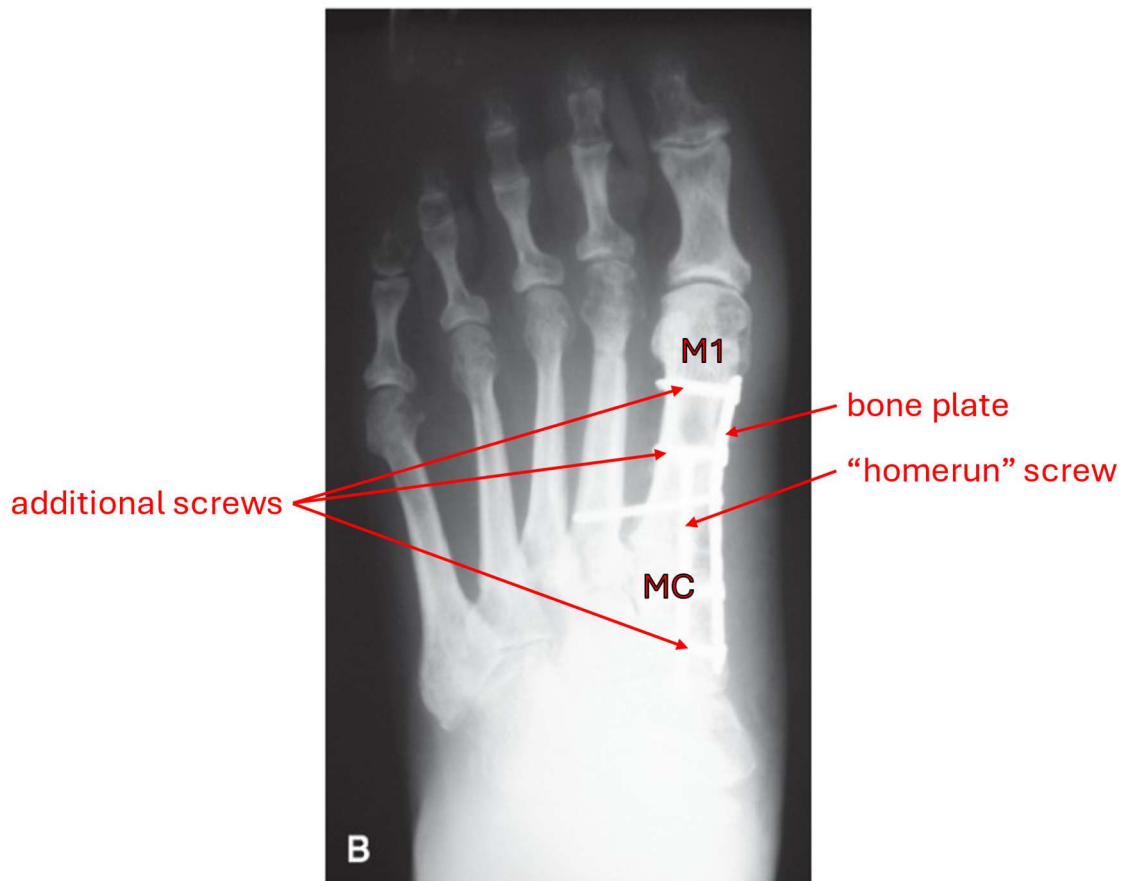
345. As I explained regarding limitation 1[i] above, Fallin discloses bone fixation devices. *See supra* §VIII.A.10. Fallin discloses that “[t]he bone portions may be fixed relative to one another to promote healing with fixation elements such as pins, plates, screws, rods or other suitable fixation elements.” Ex.1006, [0060], [0068].

K. Claim 13

346. Claim 13 depends from claim 1 and recites “wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.” Fallin in view of McGlamry and Kartalian renders obvious claim 13.

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

348. McGlamry discloses, similar to Fallin, bone fixation devices for use across the metatarsocuneiform joint of screws, plates, or a combination of the two. Ex.1004, 326 (“[t]he recommended fixation techniques consist of interfragmentary compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate”), 327-329. Figure 31.8B below shows an exemplary placement of these fixation devices:



Id., Fig.31.8B (annotated). McGlamry further describes that, “[f]ollowing the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate” and “the distal screws are placed into the metatarsal” *Id.*, 327. Thus, McGlamry discloses placing a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.

349. It would have been obvious to use McGlamry’s fixation devices and configuration the procedure in the combination of Fallin, Karatlian, and McGlamry because McGlamry’s plate and screw construct is designed for the same type of

tarsal-metatarsal fusion procedure performed in Fallin. Fallin does not provide any details, such as the specific kinds of screws used as fixation devices, beyond general categories of fixation hardware. Applying that known fixation configuration to stabilize the repositioned bones in Fallin's procedure would have been nothing more the predictable use of known fixation elements according to their established functions to achieve rigid fixation and compression for fusion. *See* Ex.1006, [0068].

350. A POSA would reasonably expect to succeed in implementing McGlamry's homerun screw and plate configuration in Fallin's procedure because McGlamry demonstrates that this construct reliably achieves interfragmentary compression and stabilization across the tarsal-metatarsal joint in an analogous bunion correction procedure. Using that same configuration in the combination's procedure would have produced the same fixation and fusion results as disclosed in McGlamry.

L. Claim 14

1. Preamble

351. The preamble of claim 14 recites "An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity." Fallin discloses this limitation as discussed regarding 1[pre] above. *See supra* §VIII.A.1.

2. Limitation 14[a]

352. Limitation 14[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” As I explained regarding limitation 1[a], Fallin in view of McGlamry and Kartalian discloses this limitation. *See supra* §VIII.A.2.

3. Limitation 14[b]

353. Limitation 14[b] recites “engaging the first metatarsal with the bone engagement member of a bone positioning guide.” As I explained above regarding limitation 1[b], Fallin in view of Kartalian renders obvious this limitation. *See supra* §VIII.A.3.

4. Limitation 14[c]

354. Limitation 14[c] recites “engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle.” As I explained above regarding limitation 1[c], Fallin in view of McGlamry and Kartalian renders obvious this limitation. *See supra* §VIII.A.4.

5. Limitation 14[d]

355. Limitation 14[d] recites “cutting an end of the first metatarsal by guiding a saw blade through a first bone preparation guide cutting slot.” As I explained above regarding limitation 1[d] and claim 9, Fallin discloses this limitation. *See supra* §§VIII.A.5., VIII.H.

6. Limitation 14[e]

356. Limitation 14[e] recites “removing a cut portion of the first metatarsal from the tarsal-metatarsal joint.” As I explained above regarding limitation 14[e] for Ground 2, Fallin discloses this limitation. *See supra* §VII.C.6.

7. Limitation 14[f]

357. Limitation 14[f] recites “after cutting the end of the first metatarsal, rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” Fallin in view of McGlamry and Kartalian renders obvious limitation 14[f]. *See supra* §§VIII.A.6., VIII.B. (limitations 1[e] and 2[a]).

8. Limitation 14[g]

358. Limitation 14[g] recites “after cutting the end of the first metatarsal, imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” Fallin in view of McGlamry and Kartalian renders obvious limitation 14[g]. *See supra* §§VIII.A.7., VIII.B. (limitation 1[f] and Claim 2).

9. Limitation 14[h]

359. Limitation 14[h] recites “after rotating the knob and after imparting the force to the pin to correct the bunion deformity of the first metatarsal, cutting an end of a medial cuneiform by guiding the saw blade through a second bone preparation guide cutting slot.” Fallin in view of McGlamry and Kartalian renders obvious limitation 14[h]. *See supra* §§VIII.B., VIII.H. (Claims 2 and 9).

10. Limitation 14[i]

360. Limitation 14[i] recites “removing a cut portion of the medial cuneiform from the tarsal-metatarsal joint.” As I explained above regarding limitation 14[i] for Ground 2, Fallin discloses this limitation. *See supra* §VII.C.10.

11. Limitations 14[j] and 14[k]

361. Limitation 14[j] recites “fenestrating a cut end of the first metatarsal.” Limitation 14[k] recites “fenestrating a cut end of the medial cuneiform.” Fallin in view of McGlamry renders obvious this limitation.

362. One step in Fallin’s procedure is that “[t]he first and second surfaces may be brought together and fixed so that they heal together fusing the joint in the new position.” Ex.1006, [0058], [0060] (“fixed relative to one another to promote healing”); *see also id.*, [0078], [0084].

363. Fallin does not provide any detail on the preparation of the cut ends of the metatarsocuneiform joint bones after their cuts, and thus does not provide any

details on preparation techniques for promoting healing of the cut ends. However, a POSA would have recognized that Fallin could benefit from well-known techniques, such as fenestration, to achieve Fallin’s goal of fusion through healing.

364. McGlamry describes and depicts fenestration of the cut ends of the first metatarsal and medial cuneiform. For example, one of the steps in McGlamry’s procedure is to cut the articulating ends of the first metatarsal and medial cuneiform. Ex.1004, 324 (describing resections). After these resections, McGlamry discusses preparation of the joint. *Id.* For instance, McGlamry discloses, when the “metatarsal base and distal cuneiform ... are prepared,” “the subchondral plate is penetrated demonstrating good bleeding at both the metatarsal and cuneiform.” Ex.1004, 324. In Chapter 55, McGlamry describes “fenestration with a Kirschner wire (K-wire)” to “break through the subchondral plate” in an arthrodesis procedure. *Id.*, 807. Figure 31.3B illustrates this fenestration of the cut bone ends:



Id., Fig.31.3B (“Interoperative clinical view demonstrating the use of a 2-mm drill preparing the tarsal-metatarsal joint prior to fixation.”). As I explained above regarding limitations 14[j] and [k] for Ground 2, the image above shows fenestration of the cut bones. *See supra* §VII.C.11.

365. It would have been obvious to use McGlamry’s fenestration technique in Fallin’s bunion correction procedure. A POSA would have known that fenestration was ubiquitous as a means of promoting fusion of the metatarsocuneiform joint, which is one of Fallin’s goals. *See, e.g.*, Ex.1004, 324, 807; Ex.1012, 490 (“Once articular surfaces have been resected, numerous fenestrations are made on each side at the fusion site with a 1.5 mm drill bit to promote osseous bleeding and fusion.”); Ex.1014, 1111; Ex.1016, 430 (“Fenestrating the joint surface with a 1.5-mm drill is recommended after bone

resection to obtain further bleeding channels for healing.”). Thus, a POSA would have been recognized the desirability of using McGlamry’s well-known fenestration technique in Fallin’s procedure to promote bone fusion. Fallin already discloses preparing opposing cut bone surfaces for fusion. Fenestrating the cut ends of the bone would have been a predictable refinement to improve fusion at the joint. Thus, using McGlamry’s fenestration technique in Fallin’s procedure would have been a predictable application of a known bone-healing technique to a known fusion procedure. Further, a POSA would have reasonably expected to succeed in implementing McGlamry’s fenestration steps. It was a known technique for preparing bones for fusion that could be utilized in Fallin’s similar bunion correction procedure without modification.

12. Limitation 14[l]

366. Limitation 14[l] recites “compressing the first metatarsal together with the medial cuneiform.” For the same reasons I explained above regarding limitation 1[h], Fallin in view of McGlamry renders obvious limitation 14[l]. *See supra* §VIII.A.9.

13. Limitation 14[m]

367. Limitation 14[m] recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation

device.” For the same reasons I explained above regarding limitation 1[i], Fallin discloses limitation 14[m]. *See supra* §VIII.A.10.

14. Limitation 14[n]

368. Limitation 14[n] recites “removing the bone positioning guide from the first metatarsal and the second metatarsal.” For the same reasons I explained above regarding claim 3, Fallin in view of McGlamry and Kartalian renders obvious limitation 14[n]. *See supra* §VIII.C.

M. Claim 15

369. Claim 15 depends from claim 14 and recites “further comprising after cutting the end of the first metatarsal, moving the first metatarsal in a sagittal plane.” Fallin in view of McGlamry and Kartalian renders obvious claim 15 for the same reasons I discussed regarding claim 8. *See supra* §VIII.G.

N. Claims 16 and 17

370. Claim 16 depends from claim 14 and recites “further comprising positioning a joint spacer offset from the first bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the first bone preparation guide cutting slot over an end of the first metatarsal to be cut.” Claim 17 depends from claim 14 and recites “further comprising positioning a joint spacer offset from the second bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the second bone preparation guide cutting slot

over an end of the medial cuneiform to be cut.” As I discussed above regarding claims 16 and 17 for Ground 2, Fallin discloses the additional limitations of claims 16 and 17. *See supra* §VII.E. Therefore, Fallin in view of McGlamry and Kartalian renders obvious claims 16 and 17.

O. Claim 18

371. Claim 18 depends from claim 14 and recites “wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into the first metatarsal adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal.” Fallin in view of McGlamry and Kartalian renders obvious the additional limitations of claim 18 for the same reasons I discussed regarding claim 7. *See supra* §VIII.F.

P. Claim 19

372. Claim 19 depends from claim 14 and recites “further comprising making a second incision on the foot to provide access to the second metatarsal, wherein: [a] engaging the bone positioning guide with the second metatarsal comprises positioning a bone contact surface of the bone positioning guide in contact

with the second metatarsal; and [b] rotating the knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal comprises rotating the knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface.” As I discussed above regarding claim 19 for Ground 2, McGlamry in view of Kartalian discloses the additional limitations of claim 19. *See supra* §VII.G. Therefore, Fallin in view of McGlamry and Kartalian renders obvious claim 19.

Q. Claim 20

373. Claim 20 depends from claim 19 and recites “wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal comprises inserting the tip through the second incision.” Fallin in view of McGlamry and Kartalian renders obvious the additional limitations of claim 20 for the same reasons I discussed regarding claims 5 and 6. *See supra* §VIII.E.

R. Claim 21

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

contact with the second metatarsal comprises positioning the body extending in a medial-to-lateral direction across the first metatarsal and across the second metatarsal with the first leg positioned on a medial side of the first metatarsal.” Fallin in view of McGlamry and Kartalian renders obvious claim 21.

1. Limitation 21[a]

375. As I explained above regarding limitation 21[a] for Ground 2, Kartalian discloses limitation 21[a]. *See supra* §VII.I.1.

2. Limitation 21[b]

376. As I explained above regarding limitation 21[b] for Ground 2, Kartalian discloses placing its bone positioning guide in the claimed position. *See supra* §VII.I.2.

377. Using Kartalian’s bone positioning guide in Fallin’s procedure would not change when used in Fallin’s procedure would not alter that disclosed positioning because Fallin operates on the same bones and joint and uses the same access and working geometry. For example, both Fallin and Kartalian describe approaches of the first metatarsal from a medial direction. *See, e.g.,* Ex.1006, Figs.21-25, 28-31; Ex.1005, 9:66-67, 10:8-18, 10:43-51. Given Fallin’s medial approach, it would have been obvious to maintain the orientation of Kartalian’s instrument 100, including its own medial approach, when used in Fallin’s procedure. This positioning would be consistent with the use of Kartalian’s instrument to adjust

the IMA, as it functions “as reduction forceps” for moving the first metatarsal toward the second metatarsal. Ex.1005, 9:66-67.

378. A POSA would have recognized that the positioning of Kartalian’s bone positioning guide and associated components in Fallin’s procedure would be the use of a known method (Kartalian’s positioning of the bone positioning guide) in Fallin’s known method for the predictable result of operating Kartalian’s reduction forceps-like instrument for to move the position of the first metatarsal.

S. Claim 22

379. Claim 22 depends from claim 14 and recites “wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.” Fallin in view of McGlamry and Kartalian renders obvious the additional limitations of claim 22 for the same reasons I discussed regarding claim 10. *See supra* §VIII.I.

T. Claim 23

380. Claim 23 depends from claim 14 and recites “wherein the bone positioning guide is formed by joining at least three components together, including the threaded shaft and the bone engagement member, to provide the bone positioning guide.” Kartalian discloses the additional limitations of claim 23 for the same reasons I discussed regarding claim 4. *See supra* §VIII.D. Therefore, Fallin in view of McGlamry and Kartalian renders obvious claim 23.

U. Claim 24

381. Claim 24 depends from claim 14 and recites “wherein the at least one bone fixation device comprises at least one of a screw and a plate.” For the same reasons I explained above regarding claim 11, Fallin in view of McGlamry and Kartalian renders obvious claim 24. *See supra* §VIII.J.

V. Claim 26

382. Claim 26 depends from claim 14 and recite “wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.” For the same reasons I explained above regarding claim 13, Fallin in view of McGlamry and Kartalian renders obvious claim 26. *See supra* §VIII.K.

W. Claim 27

1. Preamble

383. The preamble of claim 27 recites “[a]n instrumented surgical technique for correcting a bunion deformity.” For the same reasons I explained above

regarding 1[pre] and 14[pre], Fallin discloses the preamble of claim 27. *See supra* §§VIII.A.1., VIII.L.1.

2. Limitation 27[a]

384. Limitation 27[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” As I explained regarding limitation 1[a], Fallin in view of McGlamry and Kartalian discloses this limitation. *See supra* §VIII.A.2.

3. Limitation 27[b]

385. Limitation 27[b] recites “engaging the first metatarsal with the bone engagement member of the bone positioning guide.” As I explained regarding limitation 1[b], Fallin in view of McGlamry and Kartalian renders obvious this limitation. *See supra* §VIII.A.3.

4. Limitation 27[c]

386. Limitation 27[c] recites “engaging the bone positioning guide with the second metatarsal separated from the first metatarsal by an intermetatarsal angle.” As I explained regarding limitation 1[c], Fallin in view of McGlamry and Kartalian renders obvious this limitation. *See supra* §VIII.A.4.

5. Limitation 27[d]

387. Limitation 27[d] recites “preparing an end of the first metatarsal for fusion.” Fallin in view of McGlamry renders obvious limitation 27[d].

388. As I explained regarding limitation 1[d], Fallin discloses cutting an end of the first metatarsal. *See supra* §VIII.A.5. As I explained regarding limitation 1[i], Fallin discloses fixating the cut ends of bones for fusion. *See supra* §VIII.A.10.

389. To the extent this preparation of an end of the first metatarsal for fusion requires something more than cutting of the end, McGlamry discloses further preparation of the cut end of the first metatarsal for fusion as I explained above regarding limitation 14[j]. *See supra* §VIII.L.11.

6. Limitation 27[e]

390. Limitation 27[e] recites “rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct a bunion deformity.” As I explained above regarding limitation 1[e], Fallin in view of Kartalian renders obvious limitation 27[e]. *See supra* §VIII.A.6.

7. Limitation 27[f]

391. Limitation 27[f] recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” For the same reasons I explained above regarding limitation 1[f], Fallin in view of McGlamry renders obvious limitation 27[f]. *See supra* §VIII.A.7.

8. Limitation 27[g]

392. Limitation 27[g] recites “preparing an end of a medial cuneiform for fusion.” Fallin in view of McGlamry renders obvious limitation 27[g].

393. As I explained regarding limitation 1[g], Fallin discloses cutting an end of the medial cuneiform. *See supra* §VIII.A.8. As I explained regarding limitation 1[i], Fallin discloses fixating the cut ends of bones for fusion. *See supra* §VIII.A.10.

394. To the extent this preparation of an end of the medial cuneiform for fusion requires something more than cutting of the end, McGlamry discloses further preparation of the cut end of the medial cuneiform for fusion as I explained above regarding limitation 14[k]. *See supra* §VIII.L.11.

9. Limitation 27[h]

395. Limitation 27[h] recites “installing at least one fixation device through the incision to fixate a moved position of the first metatarsal relative to the medial cuneiform.” Fallin in view of McGlamry renders obvious limitation 27[h].

396. As I explained above regarding limitation 1[i], both Fallin and McGlamry disclose using fixation devices to fixate the moved position of the first metatarsal relative to the medial cuneiform. *See supra* §§VI.A.10., VIII.A.10. (Grounds 1 and 3). As I explained above regarding limitation 1[a], Fallin requires making an incision on a foot to provide a surgeon with access to a tarsal-metatarsal

joint, and McGlamry expressly discloses making such an incision. *See supra* §VIII.A.2.

397. Even if Fallin did not disclose using an incision for installing a fixation device, McGlamry and Kartalian render this limitation obvious. A POSA would have found it obvious to install Fallin's fixation devices through the incision providing access to the metatarsocuneiform joint as illustrated by McGlamry. For example, McGlamry discloses using a drill "aimed for the inferior, medial aspect of the cuneiform" when using screws as fixation device(s). Ex.1004, 326. Thus, a POSA would have understood that the cuneiform is exposed via the incision, and the incision would allow a surgeon to place the screw through the incision into the drill hole. *Id.*

398. As demonstrated in Figures 31.6, 31.7, 31.8, and 31.9, the fixation devices in McGlamry's procedure are installed through the incision. Ex.1004, Figs.31.6-31.9. For example, Figure 31.9 illustrates a radiograph illustrating the fixation device(s) next to an image of the foot; the side-by-side with the scar on the foot shows that the plate was installed through the incision, as shown below:



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

Ex.1004, Fig.31.9C-D (annotated). McGlamry further refers to suturing a single wound closed after the fixation devices are installed. *Id.*, 327.

399. Fallin discloses the installation of the same kinds of fixation devices used in McGlamry's procedure, and a POSA would have understood that they would be installed in the same manner: through the incision. A POSA would recognize that Fallin's installation of fixation devices would necessarily occur through the incision, since installation of final fixation hardware elsewhere (e.g., at a different incision site) would increase the trauma inflicted on the foot without discernable benefit relative to fixation through the already-present incision, or (for external fixation devices) would increase the profile of the foot making wearing footwear painful and lead to higher rates of hardware failure prior to fusion.

400. To the extent Fallin does not explicitly teach the claimed installation, a POSA would have been motivated to install Fallin's fixation devices through the

incision as taught by McGlamry because of the similarity of their procedures and because access to the joint is a prerequisite to installing the disclosed fixation devices. Further, implementing McGlamry's explicit teachings of how to install its fixation devices into Fallin's installation step would have been nothing more than using McGlamry's known technique to make explicit what Fallin teaches, resulting in Fallin's already-disclosed final fixation of the metatarsocuneiform joint.

X. Claim 28

401. Claim 28 depends from claim 27 and recites "wherein: [a] rotating the knob connected to the threaded shaft comprises rotating the knob connected to the threaded shaft after preparing the end of the first metatarsal; [b] imparting the force to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after preparing the end of the first metatarsal; and [c] preparing the end of the medial cuneiform comprises preparing the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity." Fallin in view of McGlamry and Kartalian renders obvious claim 28.

402. For the same reasons I explained above regarding claim 2, Fallin in view of McGlamry and Kartalian renders obvious claim 28. *See supra* §VIII.B.

Y. Claim 29

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

1. Limitation 29[a]

404. As I explained above regarding limitation 1[h], Fallin discloses compressing the first metatarsal together with the medial cuneiform. *See supra* §VIII.A.9.

405. The compression step in Fallin’s procedure occurs after the preparation of the first metatarsal and medial cuneiform, but prior to the installation of the final fixation device(s). For example, Fallin discloses “compression of the bone surfaces together”—compression of the first metatarsal and medial cuneiform. Ex.1006, [0075]. Fallin also discloses bringing the cut surfaces of the metatarsocuneiform joint bones together after their cuts. *Id.*, [0065]-[0068] (“[T]he bones [are] brought together with their cut surfaces in planar contact so that the bones fuse together in

the new angular orientation” and subsequently disclosing fixation techniques); *see also id.*, [0058], [0060]. Thus, Fallin discloses this limitation.

406. Even if Fallin did not disclose the claimed sequence, it would have been obvious based on McGlamry. In McGlamry’s procedure, this compression occurs after the preparation of the first metatarsal and medial cuneiform, and prior to the installation of the fixation device. Specifically, McGlamry describes compression occurring via the compression occurs via the “homerun screw,” which is placed into the metatarsal and cuneiform after they are prepared. *See* Ex.1004, 324 (describing joint preparation), 326-327 (describing compression after preparation). A POSA would understand that the homerun screw alone does not fixate a moved position of the first metatarsal relative to the medial cuneiform, and thus the additional screws/plates with the homerun screw are installed subsequent the compression. *See id.*, 326-327.

407. McGlamry describes installing these plate/screws (fixation devices) after the placement of the “homerun screw”: “Following the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate in combination of lock and nonlocking screws. The distal screws are placed into the metatarsal with a combination of locking and nonlocking screws.” Ex.1004, 327.

408. For the reasons I explained above regarding limitation 1[h] and limitation 29[a] in Ground 1, a POSA would have been motivated to utilize this

compression in Fallin’s procedure in the order described in both Fallin and McGlamry and would have reasonably expected to succeed in implementing such an order. *See supra* §§VI.A.9., VI.J.

2. Limitation 29[b]

409. For the same reasons I explained above regarding claim 3, Fallin in view of McGlamry and Kartalian discloses limitation 29[b]. *See supra* §VIII.C.

Z. Claim 30

410. For the reasons I explain below, Fallin in view of McGlamry and Kartalian render obvious claim 30.

1. Preamble

411. The preamble of claim 30 recites “An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.” For the reasons I explained above regarding limitations 1[pre] and 14[pre], Fallin in view of McGlamry and Kartalian renders obvious this preamble. *See supra* §§VIII.A.1., VIII.L.1.

2. Limitation 30[a]

412. Limitation 30[a] recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” For the reasons I explained above regarding limitation 1[a], Fallin in view of McGlamry renders obvious this limitation. *See supra* §VIII.A.2.

3. Limitation 30[b]

413. Limitation 30[b] recites “making a second incision on the foot to provide access to a second metatarsal separated from the first metatarsal by an intermetatarsal angle.” For the reasons I explain above regarding claims 5 and 6, Fallin in view of Kartalian renders obvious limitation 30[b]. *See supra* §VIII.E.

4. Limitation 30[c]

414. Limitation 30[c] recites “engaging the first metatarsal with the bone engagement member of a bone positioning guide.” For the reasons I explain above regarding limitation 1[b], Kartalian discloses limitation 30[c]. *See supra* §VIII.A.3.

5. Limitation 30[d]

415. Limitation 30[d] recites “positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal.” For the reasons I explained above regarding claim 5, Kartalian discloses limitation 30[d]. *See supra* §VIII.E.

6. Limitation 30[e]

416. Limitation 30[e] recites “cutting an end of the first metatarsal by guiding a saw blade through a first bone preparation guide cutting slot.” For the reasons I explained above regarding limitation 14[d], Fallin discloses limitation 30[e]. *See supra* §VIII.L.5.

7. Limitation 30[f]

417. Limitation 30[f] recites “rotating a knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface, thereby reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” For the reasons I explained above regarding limitation 14[f] and claim 19 in this ground, Kartalian discloses limitation 30[f]. *See supra* §§VIII.L.7., VIII.P.

8. Limitation 30[g]

418. Limitation 30[g] recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” For the reasons I explained above regarding limitation 1[f], McGlamry discloses limitation 30[g]. *See supra* §VIII.A.7.

9. Limitation 30[h]

419. Limitation 30[h] recites “cutting an end of a medial cuneiform by guiding the saw blade through a second bone preparation guide cutting slot.” For the reasons I explained above regarding limitation 14[h], Fallin discloses limitation 30[h]. *See supra* §VIII.L.9.

10. Limitation 30[i]

420. Limitation 30[i] recites “compressing the first metatarsal together with the medial cuneiform.” For the reasons I explained above regarding limitation 1[h], Fallin in view of McGlamry renders obvious limitation 30[i]. *See supra* §VIII.A.9.

11. Limitation 30[j]

421. Limitation 30[j] recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.” For the reasons I explained above regarding limitation 1[i], McGlamry discloses limitation 30[j]. *See supra* §VIII.A.10.

12. Limitation 30[k]

422. Limitation 30[k] recites “removing the bone positioning guide from the first metatarsal and the second metatarsal.” For the reasons I explained above regarding claim 3, Fallin in view of McGlamry and Kartalian renders obvious limitation 30[k]. *See supra* §VIII.C.

13. Limitation 30[l]

423. Limitation 30[l] recites “wherein one or both of the first metatarsal and the medial cuneiform is cut after reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity and after adjusting the alignment of the first metatarsal in the frontal plane to correct the bunion deformity.” For the reasons I explained above regarding limitations 1[e]-

1[f] and claim 2, Fallin in view of McGlamry and Kartalian renders obvious limitation 30[l]. *See supra* §§VIII.A.6., VIII.A.7., and VIII.B. Specifically, the combination of Fallin, Katalian, and McGlamry renders obvious cutting the medial cuneiform after reducing the intermetatarsal angle and after adjusting the alignment of the first metatarsal in the frontal plane.

**IX. GROUNDS 4-6: CLAIMS 12 AND 25 WOULD HAVE BEEN OBVIOUS
OVER THE GROUNDS 1-3 COMBINATIONS IN FURTHER VIEW OF
TYBER**

424. In view of the background provided above, and further in view of the reasons set forth below, it is my opinion that claims 12 and 25 of the '481 patent would have been obvious to a person of ordinary skill in the art as of August 14, 2015 in view of McGlamry, Kartalian, and Tyber as well as Fallin, McGlamry, Kartalian, and Tyber.

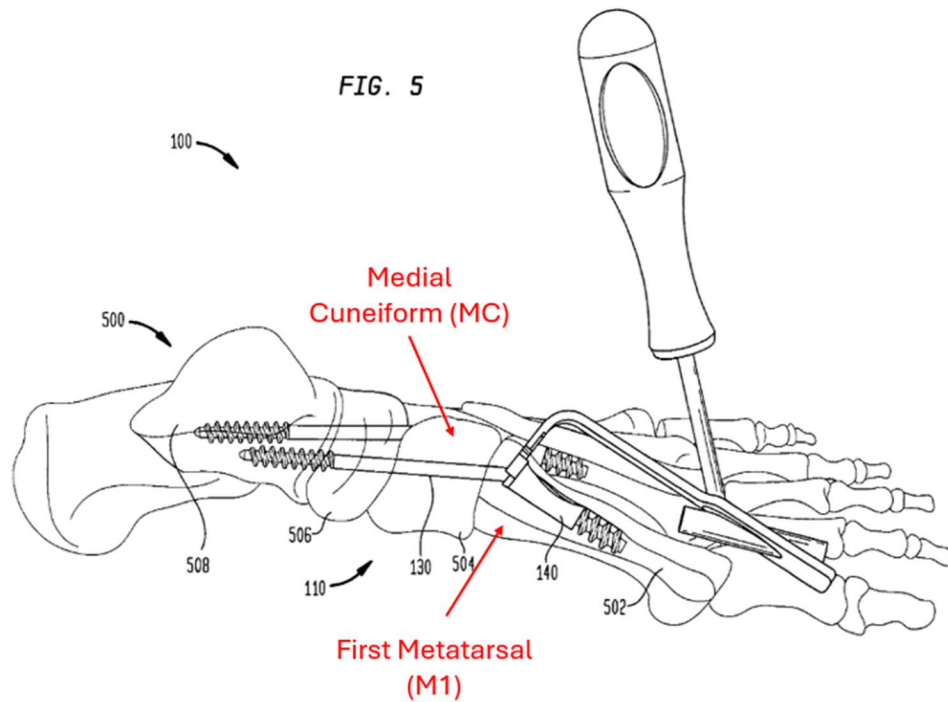
A. Claims 12 and 25

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

426. As I explained above, both McGlamry in view of Kartalian and Fallin, as well as Fallin in view of McGlamry and Kartalian, render obvious claims 1 and 14. *See supra* §§VI.A., VIII.A., VII.C., and VIII.L.

427. As I explained above regarding limitation 1[i] for both Grounds 1 and 3, Fallin and McGlamry each disclose fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device. *See supra* §§VI.A.10, VIII.A.10.

428. Tyber discloses an “intramedullary fixation assembly that may be utilized to treat bones in a mid-foot and forefoot regions.” Ex.1007, 2:27-29. Tyber discloses the use of its intramedullary implants 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 also depicted in Figure 5 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.



Ex.1007, Fig.5. This intramedullary assembly fixes the first metatarsal relative to the medial cuneiform. *Id.*, 7:36-39, 8:34-40. Tyber further teaches inserting the intermedullary fixation assembly through the joint selected for fusion, such that rigid coupling of the components maintains alignment of the bones during healing. Ex.1007, 1:42-46, 7:30-8:50, Claims 23 & 64-65 (describing a “method of compressing bone” and “thereby compressing the first bone to the second bone.”).

429. A POSA would have been motivated to modify Fallin’s procedure to use Tyber’s intramedullary implant as the fixation device. Fallin discloses that any “suitable fixation” device may be used to fixate the corrected position of the first metatarsal and medial cuneiform, Fallin and gives rods as an example. Ex.1006, [0060], [0068]. Tyber’s implant is a set of rods as suggested by Fallin. Ex.1007,

Fig.5; *see also id.*, 5:15-21, 5:32-34 (describing member 130 as “generally cylindrical in shape”), 6:8-12 (describing member 140 as a “generally tubular in shape”).

430. Tyber provides a known alternative fixation method (an intermedullary fixation configuration) that achieves the same objectives stated in Fallin, e.g., maintaining close, stable apposition across the fusion cite. Ex.1007, 1:44-46, Figs. 5-6. A POSA would have recognized that Tyber’s intermedullary fixation device was a suitable substitute for the fixation devices disclosed in McGlamry and Fallin for stabilizing the first metatarsal relative to the medial cuneiform. Substituting an intermedullary implant like Tyber’s for one of McGlamry’s or Fallin’s fixation devices therefore constitutes nothing more than the substitution of one known fixation element for another. These fixation elements perform their established function of stabilizing bones across a fusion site.

431. Like the fixation devices disclosed in McGlamry and Falin, Tyber’s intermedullary implant was designed for use in forefoot and midfoot fusion procedures, including bunion corrections. Thus, a POSA would have also reasonably expected to succeed in implementing Tyber’s intramedullary implant in the McGlamry, Kartalian combination and the Fallin, Kartalian, McGlamry combination.

432. When implementing an intermedullary implant like Tyber's, in the Ground 1, 2, or 3 combinations, a POSA would have recognized that such an implant would have satisfied limitations 1[h] and 14[l] ("compressing the first metatarsal together with the medial cuneiform"). As discussed above, Tyber's implant compresses the first metatarsal together with the medial cuneiform. *See, e.g.*, Ex.1007, 7:30-8:50, Claims 23 & 64-65.

X. CONCLUSION

433. For the foregoing reasons, it is my opinion that, by August 14, 2015, a POSA would have found Claims 1-30 of the '481 patent unpatentable as obvious 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.

434. 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.

Executed on: January 13, 2026

By: _____ / _____
Dr. Steven K. Neufeld