

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

Case IPR2026-00194
Patent 12,102,368

**DECLARATION OF DR. STEVEN K. NEUFELD, MD,
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 12,102,368**

<i>Paragon 28 v. Treace Medical Concepts</i> IPR2026-00194 Paragon Ex. 1003

I. BACKGROUND AND QUALIFICATIONS	1
A. Experience and Qualifications	1
B. Relevant Legal Standards	3
1. Claim Construction	4
2. Obviousness	4
C. Person of Ordinary Skill in the Art	8
II. OVERVIEW OF PRIOR ART	11
A. Relevant Human Foot Anatomy	12
B. Bunion Correction	15
C. McGlamry’s Bunion Correction Procedure	18
D. Known “Bone Preparation Guides” (Bone Cutting Guides)	20
E. Known Bone Positioning Guides	25
F. Known Fixation Devices	31
III. THE ’368 PATENT	32
A. Specification	32
B. Claims	34
IV. CLAIM CONSTRUCTION	34
A. “bone positioning guide”	35
B. “fixation device”	36
C. “temporary fixation device”	37
D. “tissue removing instrument”	38

E.	“a mechanism configured to move the bone engagement member and the tip relative to each other”	39
V.	THE PRIOR ART	40
VI.	GROUND 1 MCGLAMRY AND FALLIN RENDER CLAIMS 1–2 AND 4–20 OF THE ’368 PATENT OBVIOUS	40
A.	Claim 1	41
1.	Preamble	41
2.	Limitation 1[a].....	51
3.	Limitation 1[b]	56
4.	Limitation 1[c].....	61
B.	Claim 2	63
C.	Claim 4	64
D.	Claim 5	66
E.	Claim 6	70
F.	Claim 7	72
G.	Claims 8-9	74
H.	Claim 10	76
I.	Claim 11	78
J.	Claim 12	78
K.	Claim 13-14.....	79
L.	Claims 15-16	80
M.	Claim 17	83
N.	Claim 18	84

O.	Claim 19	86
P.	Claim 20	89

**VII. GROUND 2 MCGLAMRY, FALLIN, AND KARTALIAN
RENDER CLAIMS 1–30 OF THE '368 PATENT OBVIOUS** 89

A.	Claim 1	89
1.	Preamble.....	89
2.	Limitation 1[a].....	90
3.	Limitation 1[b]	90
4.	Limitation 1[c].....	94
B.	Claim 2	95
C.	Claim 3	95
D.	Claim 4	99
E.	Claim 5	99
F.	Claim 6	99
G.	Claim 7	100
H.	Claims 8-9	100
I.	Claim 10	100
J.	Claim 11	101
K.	Claim 12	102
L.	Claims 13-14	104
M.	Claims 15-16	104
N.	Claim 17	107

O.	Claim 18	108
P.	Claim 19	108
Q.	Claim 20	109
R.	Claim 21	109
1.	Limitation 21[pre]	109
2.	Limitation 21[a].....	110
3.	Limitation 21[b]	111
4.	Limitation 21[c].....	112
5.	Limitation 21[d]	112
S.	Claim 22	112
T.	Claim 23	113
U.	Claim 24	114
V.	Claim 25	114
W.	Claim 26	114
X.	Claim 27	115
Y.	Claim 28	115
Z.	Claim 29	115
AA.	Claim 30	116
VIII. GROUND 3 MCGLAMRY, FALLIN, AND SCHMUCK RENDER CLAIMS 3 AND 21–30 OF THE '368 PATENT OBVIOUS.....		116
A.	Claim 3	117

B.	Claim 21	120
C.	Claim 22	120
D.	Claim 23	120
E.	Claim 24	120
F.	Claim 25	121
G.	Claim 26	121
H.	Claim 27	121
I.	Claim 28	121
J.	Claim 29	122
K.	Claim 30	122

IX.	GROUND 4 MCGLAMRY, FALLIN, KARTALIAN, AND SCHMUCK RENDER CLAIMS 3 AND 21–30 OF THE '368 PATENT OBVIOUS	122
A.	Claim 3	122
B.	Claim 21	124
C.	Claim 22	124
D.	Claim 23	125
E.	Claim 24	125
F.	Claim 25	125
G.	Claim 26	126
H.	Claim 27	126
I.	Claim 28	126

J.	Claim 29	126
K.	Claim 30	127
X.	GROUND 5 CLAIM 7 WOULD HAVE BEEN OBVIOUS OVER THE GROUND 1 OR 2 COMBINATIONS FURTHER IN VIEW OF JENKINS	127
XI.	GROUND 6 CLAIM 23 WOULD HAVE BEEN OBVIOUS OVER THE GROUND 2-4 COMBINATIONS AND JENKINS	131
XII.	CONCLUSION	131

I, Steven K. Neufeld, do hereby declare:

1. I am making this declaration at the request of Paragon 28, Inc.
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. 12,102,368 to Smith et al. (“the ’368 patent”)
1002	File History of the ’368 Patent
1003	Exhibit not used in this declaration
1004	Curriculum Vitae of Steven K. Neufeld, M.D.
1005	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1006	U.S. Patent No. 8,882,816 to Kartalian, et al. (“Kartalian”)
1007	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 (“McGlamry”)
1008	James M. Cottom & Anand M. Vora, <i>Fixation of lapidus arthrodesis with a plantar interfragmentary screw and medial locking plate: a report of 88 cases</i> . 52(4) J. FOOT & ANKLE SURGERY 465–469 (July-Aug. 2013)
1009	RESERVED

Exhibit No.	Description
1010	Paul Dayton, et al., <i>Relationship of Frontal Plane Rotation of First Metatarsal to Proximal Articular Set Angle and Hallux Alignment in Patients Undergoing Tarsometatarsal Arthrodesis for Hallux Abducto Valgus: A Case Series and Critical Review of the Literature</i> , 52(3) J. FOOT & ANKLE SURGERY 348–354 (May-June 2013)
1011	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)
1012	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 CLIN. ORTHOPAEDICS 119-135 (1960)
1013	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)
1014	Babak Baravarian, et al., <i>Lapidus bunionectomy: arthrodesis of the first metatarsocunieform [sic] joint</i> , 21 CLINICS IN PODIATRIC MED. & SURGERY 97–111 (2004)
1015	Brian C. Toolan, <i>Surgical Strategies: The Lapidus Procedure</i> , 28 FOOT & ANKLE INT’L 1108-1114 (2007)
1016	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) FOOT & ANKLE CLINICS 223–233 (June 2014)
1017	Nathan J. Young & Charles M. Zelen, <i>New techniques and alternative fixation for the lapidus arthrodesis</i> , 30(3) CLINICS PODIATRIC MED. & SURGERY 423–434 (July 2013)
1018	U.S. Design Patent No. D695,402 to DaCosta et al. (“DaCosta”)
1019	Lawrence A. DiDomenico, et al., <i>Correction of Frontal Plane Rotation of Sesamoid Apparatus During the Lapidus Procedure: A Novel Approach</i> , 53 J. FOOT & ANKLE SURGERY 248–251 (Mar.-Apr. 2014)
1020	RESERVED
1021	RESERVED

Exhibit No.	Description
1022	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1023	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein (“Weinstein”)
1024	File History for U.S. Provisional Application No. 62/108,936 (“the ’936 application”)
1025	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1026	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
1027	U.S. Patent No. 9,220,518 to Neal et al. (“Neal”)
1028	U.S. Patent App. Publ. No. 2014/0031882 to Schmuck et al. (“Schmuck”)
1029	U.S. Patent No. 5,722,978 (“Jenkins”)
1030	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1031	U.S. Patent App. Publ. No. 2012/0078258 to Lo et al. (“Lo”)
1032	International App. Publ. No. 2015/123270 to Sachin et al. (“Sachin”)
1033	U.S. Patent App. Publ. No. 2013/0030438 to Fox (“Fox”)
1034	U.S. Patent App. Publ. No. 2011/0186456 to Bertazzoni et al.
1035	Bas B.G.M. Franssen, et al., <i>One century of Kirschner wires and Kirschner wire insertion techniques: A historical review</i> , 76 ACTA ORTHOPEDIC BELGIUM 1–6 (2010)
1036	Declaration of Sylvia Hall-Ellis, Ph.D.
1037	U.S. Patent App. Publ. No. 2009/0036893 to Kartalian et al.

I. BACKGROUND AND QUALIFICATIONS

A. Experience and Qualifications

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

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

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

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

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

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

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

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

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

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

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

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

B. Relevant Legal Standards

16. I have been asked to provide my opinion as to whether the claims of the '368 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, technical knowledge, and experience to the evaluation of certain prior art to the '368 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 patent validity to my analysis.

1. Claim Construction

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

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

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 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.

¹ The '368 patent specification defines the "TECHNICAL FIELD" as "devices and techniques for positioning bones." Ex.1001, 1:27-28. The '368 patent claims are directed to "metatarsal bunion correction system[s]." *Id.*, 18:43, 20:4.

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 '368 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 claimed priority date for the '368 patent is July 14, 2015.

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

31. The '368 patent describes devices and methods for positioning and cutting bones, and claims systems for correcting a first metatarsal bunion. Ex.1001, 1:27-28, claim 1. The '368 patent thus includes both surgical procedures and mechanical devices for use in such procedures. Based on my review of the specification and claims of the '368 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 educational backgrounds, a person could still be of ordinary skill in the art provided that person's additional experience, such as experience designing medical devices, compensates for any differences in that person's education.

33. Because the '368 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 '368 patent would have been obvious to any reasonably defined POSA.

35. I can make this assessment because I was at least a POSA by July 2015. 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 had worked with many surgeons and engineer developers. Further, by July 2015, I had performed numerous surgeries (including bunion correction surgeries) and worked with many surgeons and engineer developers. Further, by July 2015, I had supervised and trained many surgeons in the field of orthopedic and podiatric surgery, including bunion surgery. By July 2015, the surgeons I worked with had the requisite knowledge to and did use the instruments and surgical methods as described in the specification and claims of the '368 patent. Because I have worked with and supervised surgeons and engineers in the field, I know very well what their capabilities were prior to July 2015, how those surgeons and

engineers would interpret and understand the '368 patent and its claims, and how they would understand the disclosures in the prior art discussed herein.

36. Although my own experience may have exceeded that of a POSA, the opinions expressed herein are from the perspective of the POSA as of July 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 '368 patent to be obvious in view of the prior art. My conclusions that the claims of the '368 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.

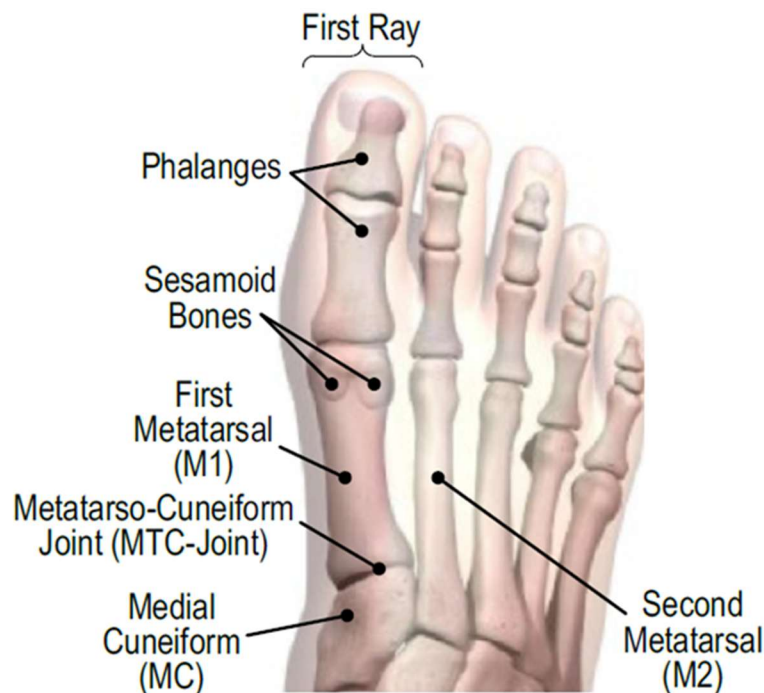
II. OVERVIEW OF PRIOR ART

38. The disclosure of the '368 patent relates to devices and methods for positioning and cutting bones, and claims systems for performing bunion surgery.

39. Before July 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 '368 patent.

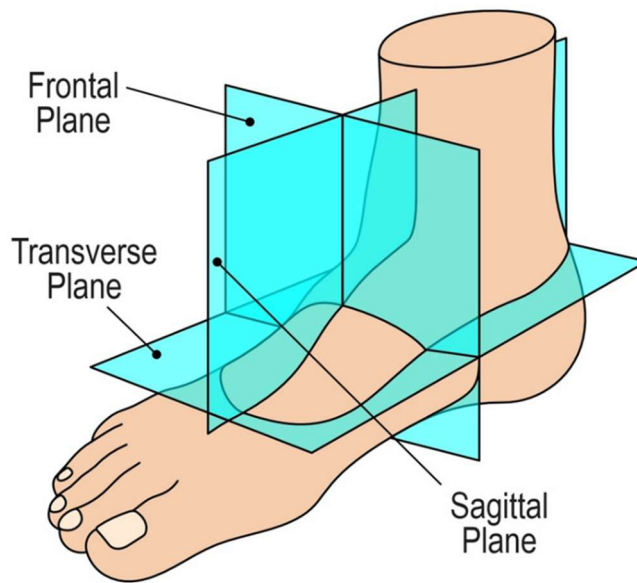
A. Relevant Human Foot Anatomy

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:

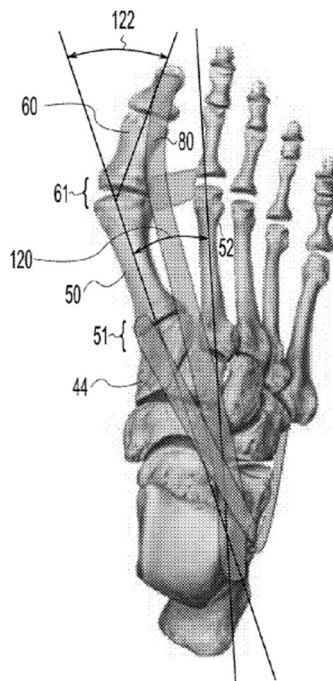


41. In a healthy foot, the bones of the first ray are anatomically positioned in three-dimensional alignment from the medial cuneiform to first metatarsal through the hallux (“big toe”), which promotes normal function of the foot. The first metatarsal and medial cuneiform meet to form the metatarsal-cuneiform 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.1005, 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.1005, [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.1007, 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.1005, [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.1005, [0048]; Ex.1019, 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.

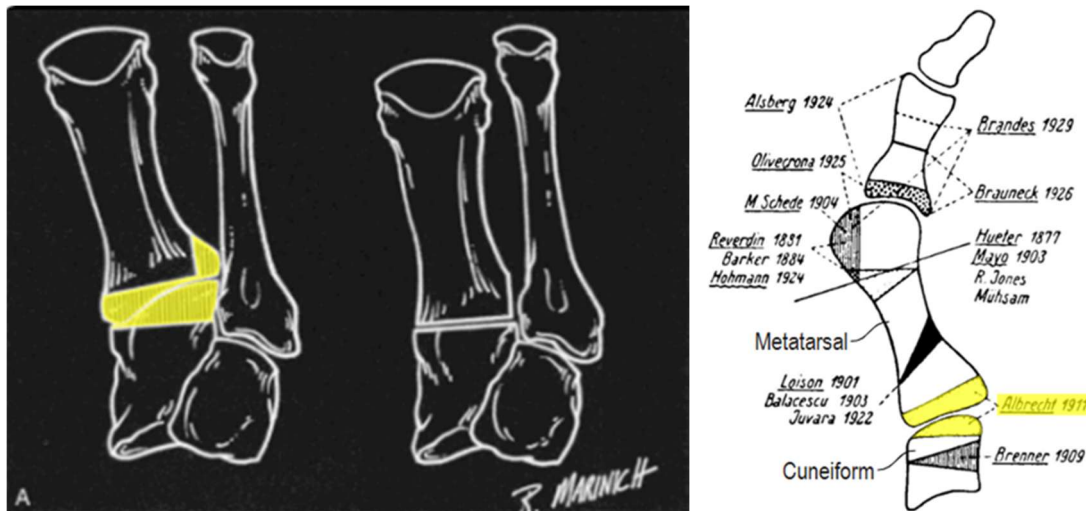
B. Bunion Correction

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.1013. An arthrodesis is a surgical procedure in which the bones of a joint are permanently joined together through fusion. Ex.1007, 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.1007, 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.1011, Fig.1A (color added); Ex.1012, 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. 1013, 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.1011, 493 (“Inherent to this procedure is the ability to correct deformity in three planes.”); *see generally* Ex.1007, 324-327; Ex.1008, 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.1007, 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.1007, 326-327; Ex.1011, 486-487, 490.

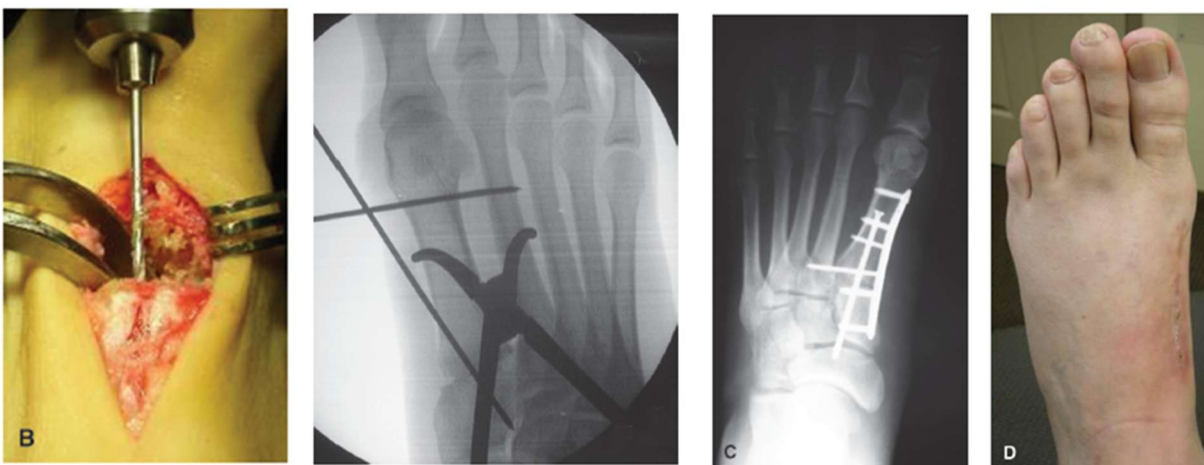
52. The body will heal and form bone between the cut bone surfaces (referred to as bone “fusion”) in the corrected orientation. Ex.1005, 808. The body treats the cut bones as a fracture and fuses them through the fracture healing process. In the weeks following the procedure, chondrogenesis takes places, creating a fibrocartilaginous network that spans the joint and links the two bones. Slowly the cartilage is ossified, transforming the soft cartilage into bone that fuses the first metatarsal and cuneiform. The fixation devices ensure that the two bones are maintained in the realigned position and facilitate fusion of the metatarsal and cuneiform in the corrected position. *Id.* (“While there are many different types of fixation that may be applied to the arthrodesis site (wire, screws, plates, etc.), it must be emphasized that the fixation is only to stabilize the arthrodesis site while the bone heals.”); *see also* Ex.1017, 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.1007. 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.1007, 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.1007, 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.

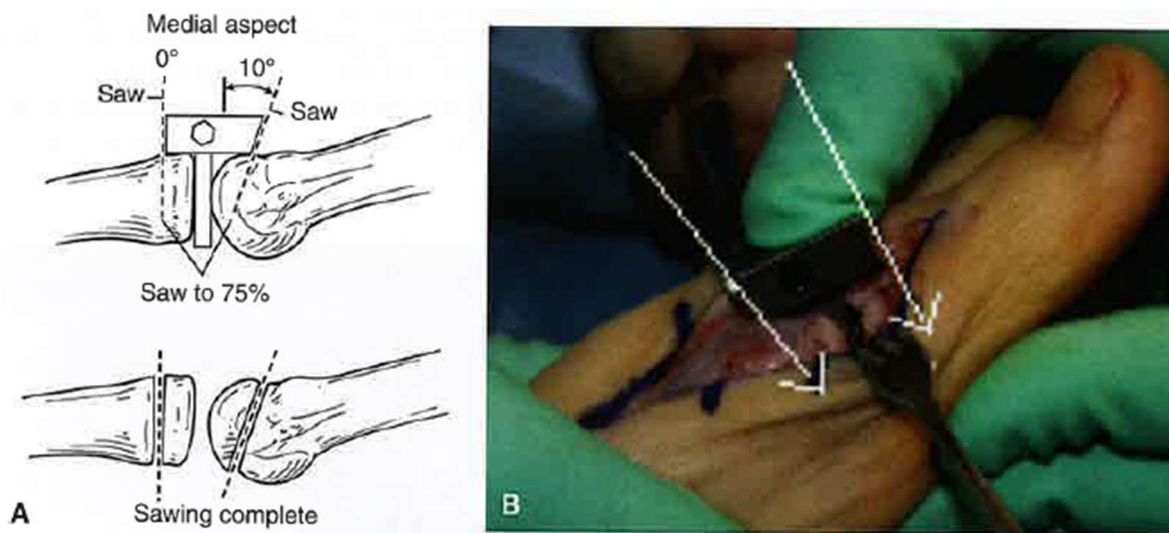
55. McGlamry describes in detail the traditional steps of the Lapidus procedure, including (1) preparation of the metatarsal-cuneiform joint via the resection of the joint and cutting of the bones, (2) repositioning of the first metatarsal in each of the frontal, sagittal, and transverse planes, and (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.1007, 381-383. The below image from McGlamry shows the bone cutting guide in use for resecting articular surfaces of a joint:



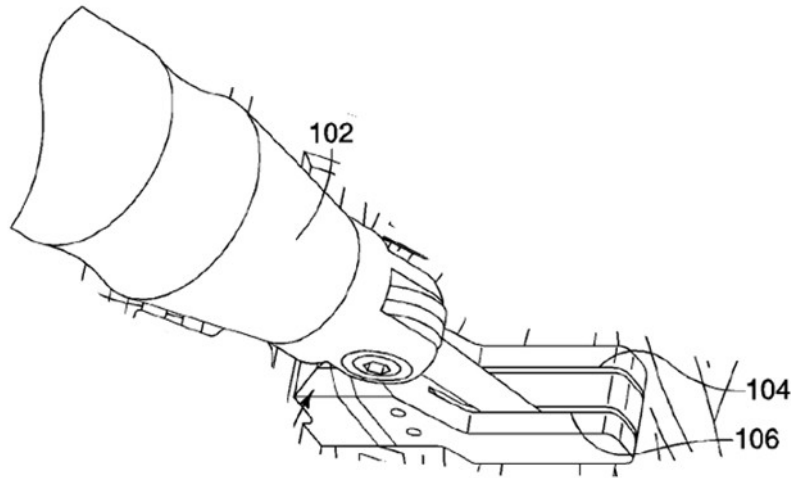
Id., Figs.34.27 (A and B) (describing “[i]nsertion of [a] primary resection guide [that] provides for a cutting guide for resection of the articular surfaces”).

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, 8:1-19, 9:33-39, 12:46-13:27 (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 unions through 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.

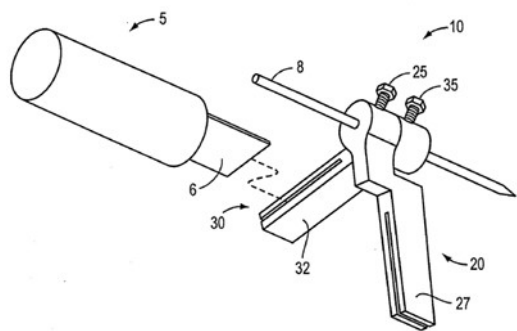


FIG. 3

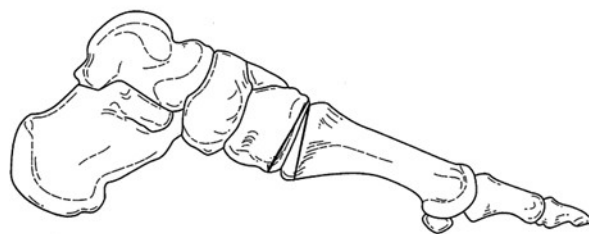


FIG. 13

Id., Figs.3, 13.

60. DaCosta is a design patent for a “LAPIDUS CUT GUIDE,” which states it issued in 2013. Ex.1014, Front Page. Images of DaCosta’s guide are below:

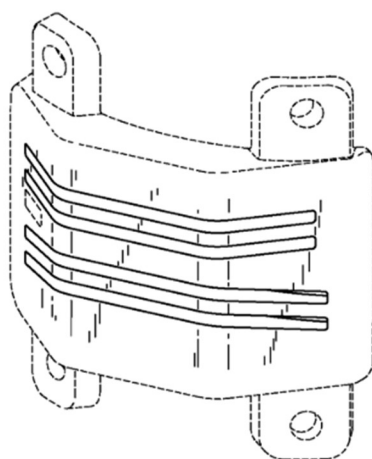


FIG. 1

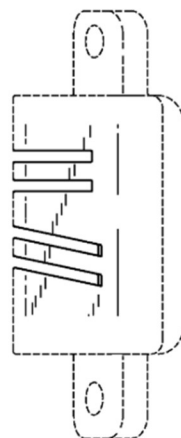
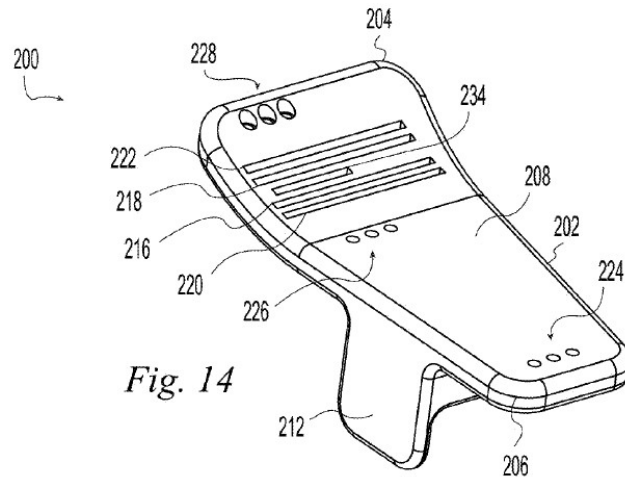


FIG. 5

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.1005, 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.1005, [0062]. Figure 14 of Fallin below shows one embodiment of Fallin’s osteotomy guide:



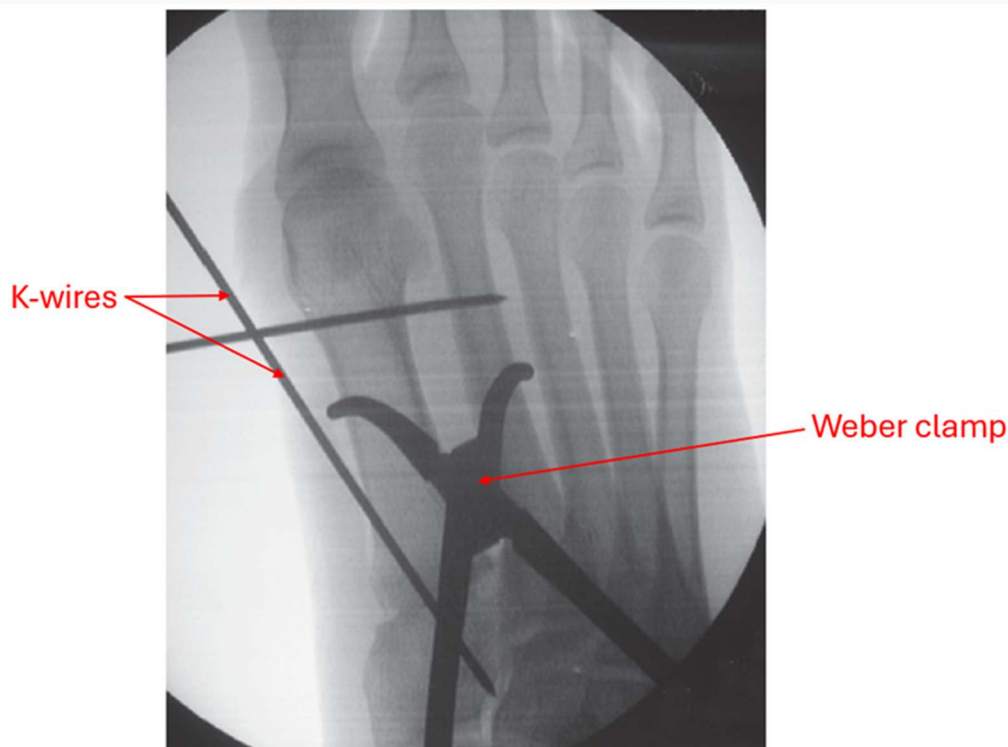
Ex.1005, Fig.14.

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.1007, 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.1007, Fig.31.5 (“Intraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle.”).

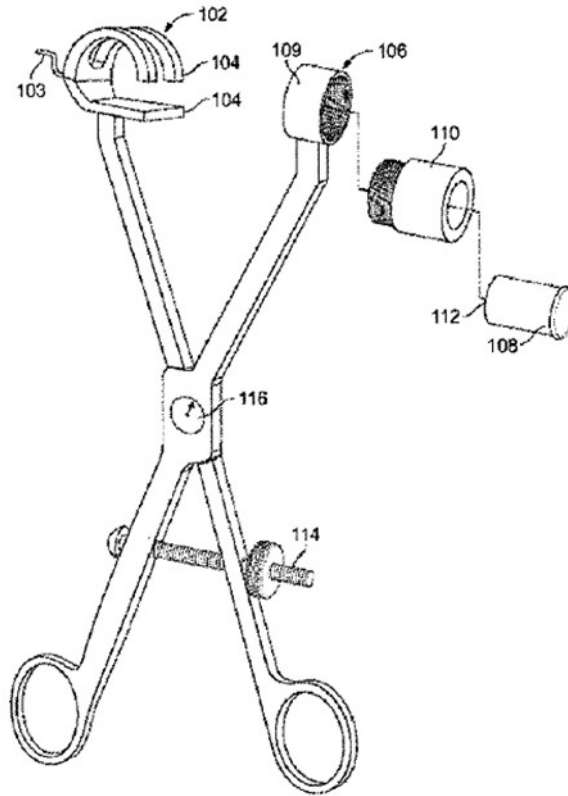
65. Based upon my experience and interactions with other surgeons, medical devices existed and were commercially available prior to July 2015 that surgeons used for the purpose of repositioning the first metatarsal in a bunion correction procedure. For example, a Hintermann distractor may be used to 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 December 31, 2025) (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.1007, 325-326), reduction forceps/clamps (Ex.1006; Ex.1008, 466), periarticular clamps, and joint distractors (<https://www.arthrex.com/resources/AN1-0437-EN/comprehensive-foot-system>) (last visited December 31, 2025). 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 December 31, 2025); <https://www.youtube.com/watch?v=mLH4s96dErI>, 0:12 (last visited December 31, 2025).

67. As another example, Kartalian discloses an “instrument”—a bone positioning guide—used to reposition the first metatarsal during a bunion correction surgery. Ex.1006, 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:



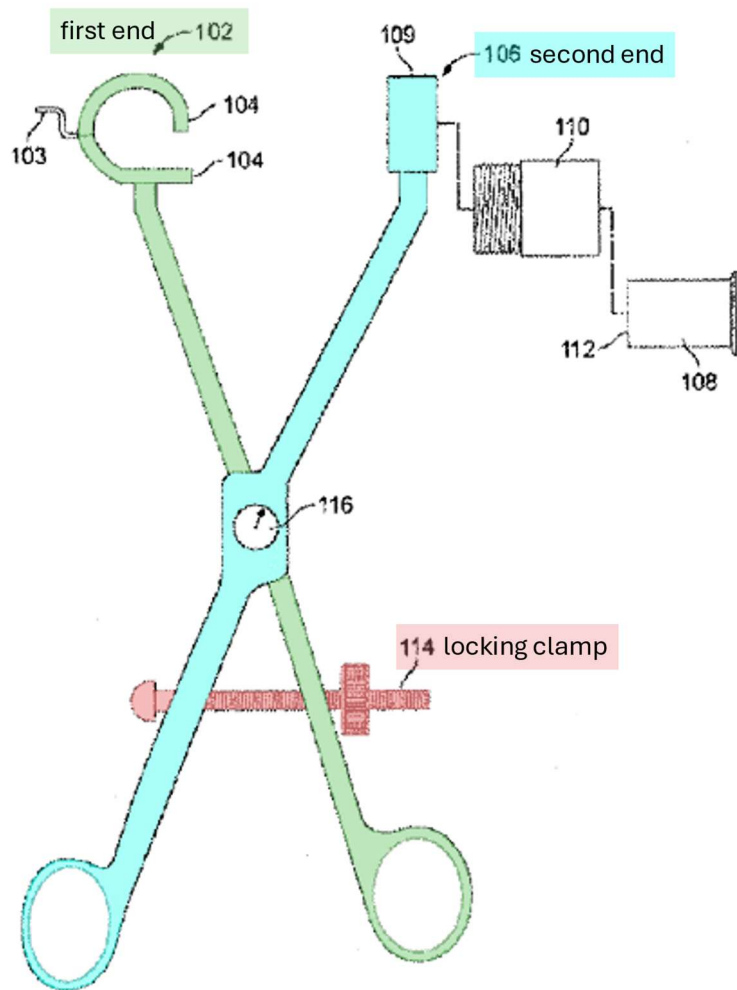
Ex.1006, Fig.1 (excerpt).²

68. The surgical instrument 100 “act[s] as reduction forceps to align two bones or reduce the distance between the bones.” Ex.1006, 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

² I use herein Figure 1 from one of Kartalian’s priority applications (U.S. Patent App. Publ. No. 2009/0036893, Ex. 1037) in place of Kartalian’s Figure 1 because it is identical and higher resolution.

“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.1011, 486-87, 490; Ex.1008, 467-468. Numerous fixation devices have been used in bunion correction procedures in the decades since.

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.1011, 486-87, 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.1005, 326, Fig.31.7, Fig.31.8; *see also* Ex.1008, 467, Figs. 5A and 5B (showing use of screws and plate to fixate metatarso-cuneiform joint after preparation and repositioning).

III. THE '368 PATENT

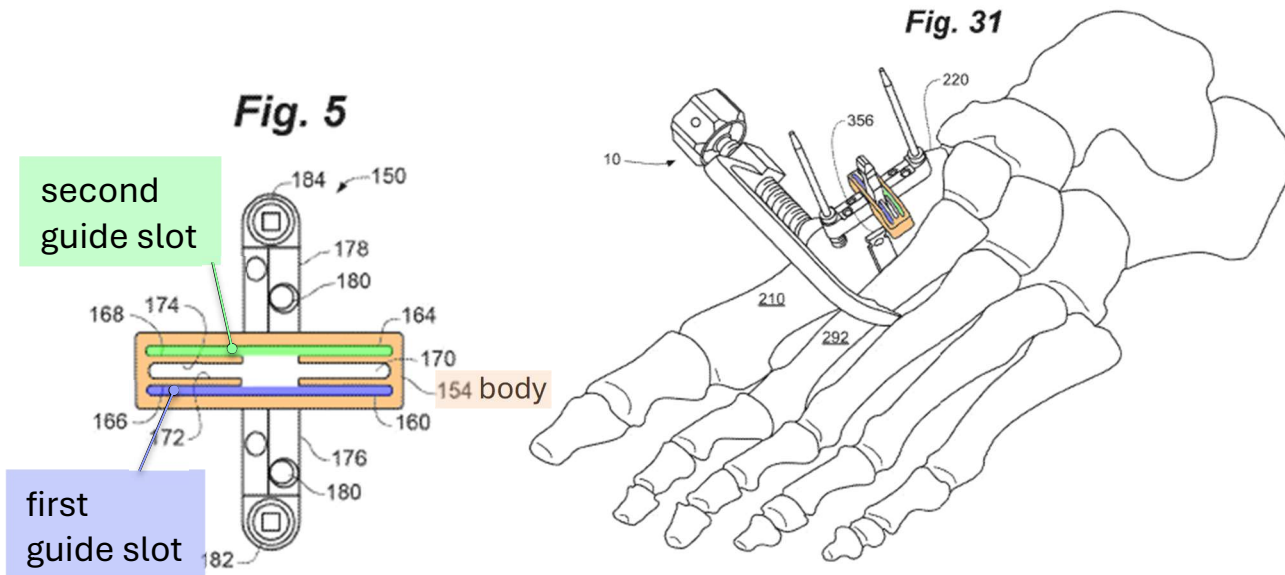
A. Specification

76. I have reviewed the '368 patent and its prosecution history.

77. The '368 patent states that it relates generally to "devices and techniques for positioning bones." Ex.1001, 1:27–28. The specification of the '368 patent discloses surgical instruments and techniques for bone positioning, including bunion correction surgery. Ex.1001, 1:46-48, 5:10-16.

78. One instrument identified in the '368 patent is a "bone preparation guide." Ex.1001, 8:1-5, 9:33-39. 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, 8:5-27.



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.*, 12:63-13:27.

79. Another instrument disclosed in the '368 patent is a “bone positioning 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, 7:20-34. 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, 5:38-46, Figs. 1, 3B, 3C, 9A.

80. The '368 patent also discloses a fixation device. 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.*, 11:20-25.

B. Claims

81. The claims of the '368 patent are directed to a “metatarsal bunion correction system.” Ex.1001, Claims 1-30. Generally, the claimed system comprises a collection of instruments for bunion correction, including: a “bone preparation guide,” a “bone positioning guide to move the first metatarsal in the transverse plane and rotate it in the frontal plane,” and a “fixation device” for fixing the first metatarsal in the moved position for fusion. *Id.*

IV. CLAIM CONSTRUCTION

82. 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 '368 patent throughout my analysis unless otherwise noted.

A. “bone positioning guide”

83. The term “bone positioning guide” appears in multiple claims of the '368 patent.

84. 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.

85. A POSA would understand that “moving” a bone, or movement of a bone in the context of the '368 patent would encompass either translational movement or rotation of the bone, or a combination of the two.

86. 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 function of the “bone positioning guide is “treating a bunion deformity by moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between a first metatarsal and a second metatarsal, and rotating the first metatarsal in a frontal plane.” Ex.1001, claims 1, 21.

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, 7:20-34);
- “[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, 5:38-46, Figs.1, 3B, 3C.

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

B. “fixation device”

88. The term “fixation device” appears in multiple claims of the ’368 patent.

89. 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.

90. 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 “fixation device” is “to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.”

Ex.1001, claims 1, 21.

Corresponding Structure: Examples of a corresponding structure include:

- “compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail” (Ex.1001, 11:20-25); and
- “two bone plates positioned in different planes” (*Id.*, 13:63-67).

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

C. “temporary fixation device”

92. The term “temporary fixation device” appears in two dependent claims of the ’368 patent.

93. A POSA would understand that a “temporary fixation device” is a “removable device that maintains the relative position of bones” under the plain and ordinary meaning of this term.

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

Function: the claimed function of the “fixation device” is “temporarily fixate a moved position of the first metatarsal relative to the medial cuneiform.”

Ex.1001, claims 1, 21.

Corresponding Structure: Examples of a corresponding structure include: a wire, such as a K-wire. *Id.*, 7:1-10.

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

D. “tissue removing instrument”

96. The term “tissue removing instrument” appears in multiple claims of the ’368 patent.

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

98. I have been asked to assume the following function and corresponding structure(s) for the term “tissue removing instrument” 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, claims 1, 21.

Corresponding Structure: Examples of a corresponding structure include: a saw blade, rotary burr, and osteotome. *Id.*, 8:9-13.

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

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

100. The term “a mechanism configured to move the bone engagement member and the tip relative to each other” appears in claim 15 of the '368 patent.

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

Function: The claimed function is moving the bone engagement member and the tip relative to each other. Ex.1001, claim 15.

Corresponding Structure: Examples of a corresponding structure include:

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

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

V. THE PRIOR ART

103. In this Declaration, I rely on several references that I understand are prior art to the '368 patent claims. These references include:

- McGlamry (McGlamry's Comprehensive Textbook of Foot and Ankle Surgery (4th Edition)) (Ex.1007);
- Fallin (U.S. Patent App. Publ. No. 2016/0213384 (Ex.1005));
- Kartalian (U.S. Patent No. 8,882,816 (Ex.1006));
- DaCosta (U.S. Design Patent No. D695,402 (Ex.1018));
- Schmuck (U.S. Patent App. Publ. No. 2014/0031882 (Ex.1028));
- Jenkins (U.S. Patent No. 5,722,978 (Ex.1029)).

104. These references are from the same field as the '368 patent, e.g., devices and techniques for positioning bones. Ex.1001, 1:27-28. These references are pertinent to a problem focused on by the inventors, e.g., cutting, repositioning, and fixation of bone during a surgical procedure. Ex.1001, 1:32-47, 4:66-5:20.

VI. GROUND 1 **MCGLAMRY AND FALLIN RENDER CLAIMS 1-2 AND 4-20 OF THE** **'368 PATENT OBVIOUS**

105. It is my opinion that claims 1-2 and 4-20 of the '368 patent would have been obvious to a person of ordinary skill in the art as of July 14, 2015 in view of McGlamry and Fallin.

A. Claim 1

1. Preamble

106. The preamble of claim 1 recites “[a] metatarsal bunion correction system.”

107. McGlamry discloses an instrumented method for performing a bunion correction surgery. Ex.1007, 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 screws and plates which, in combination with a drill, fix the first metatarsal to the medial cuneiform, *id.*, 326-329.

108. Fallin also discloses a system for correcting a metatarsal bunion. *See* Ex.1005, [0003] (“The present invention provides improved osteotomy and

arthrodesis methods, implants, and instruments.”); *see also id.*, [0047]-[0049] (describing deformities of the first ray of the human foot, including a bunion), [0057]-[0068] (describing method and associated instrumentation for correcting deformities of the human foot, including a bunion).

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

110. By July 2015, it would have been obvious to incorporate Fallin’s osteotomy³/cutting guide into McGlamry’s procedure. McGlamry discloses a joint preparation step wherein the first metatarsal base and the distal end of the cuneiform are prepared (cut) along with a medial aspect of the second metatarsal. Ex.1007, 324. McGlamry describes this preparation step as a “vital portion of the procedure,” since “[j]oint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion.” *Id.* McGlamry states that a surgeon should

³ “Osteotomy” refers to cutting bones.

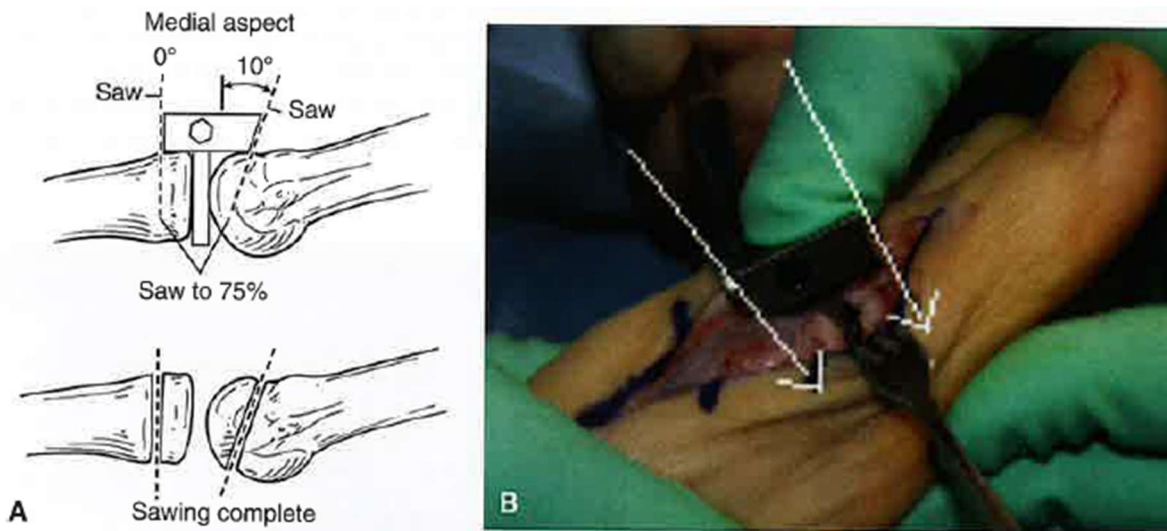
spend a “substantial period of time ... preparing the [metatarso-cuneiform] joint” to prevent issues with bony union. *Id.* McGlamry also describes complications that could arise from mistakes in cutting the first metatarsal and medial cuneiform, including “significant shortening” of the first metatarsal, delayed unions, nonunions, and malunions. *Id.*, 329; *see also* Ex.1017, 424 (describing nonunion issues associated with metatarsocuneiform arthrodesis). 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.1014, 186; Ex.1016, 230.

111. McGlamry’s bunion correction procedure involves a surgeon performing freehand resection of the metatarsal and cuneiform. Ex.1007, 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.

112. 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 judgment 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).

113. 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.1007, 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”).

114. 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.1005, [0062] (describing how Fallin’s cut guide “results in more precision and repeatability in the relative orientation of the cuts” “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.1005, [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.1005, [0062]; Ex.1007, 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. *Id.*, *see also id.*, [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).

115. Reducing the time spent for joint preparation benefits the patient by reducing the time the patient spends under anesthesia. *See* Ex.1005, 803 (describing proper anesthesia as being "of paramount importance" for arthrodesis procedures). Lengthier periods of anesthesia can increase the risk of anesthesia-related complications. 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.

116. 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.

117. 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.1007, 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.1007, 329; Ex.1013, 186; Ex.1016, 230. These changes to the biomechanics of the foot can cause pain in addition to the deformities mentioned and unmentioned.

118. 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.1005, [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.

119. Fallin’s cutting guide would also reduce the risk of delayed unions, nonunions, and malunions identified by McGlamry. Ex.1007, 324. Delayed unions, nonunions, and malunions can occur in a bunion correction procedure when the cut ends of the metatarsal and cuneiform, do not form a proper fit after the first metatarsal is repositioned. *See* Ex.1007, 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.1005, [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”).

120. Using Fallin’s cutting guide in McGlamry’s procedure would have been desirable because using Fallin’s cutting guide would have been nothing more than the use of a known technique for cutting bones to improve McGlamry’s known technique in the same way that the guides improved Fallin’s technique. For example, as I discussed in detail above, Fallin’s cutting guide would improve

McGlamry's cutting steps by precisely defining the cuts of the first metatarsal and medial cuneiform. Ex.1005, [0062].

121. 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.1007, 324-330; Ex.1005. 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.

122. A POSA would have recognized by July 2015 that implementing Fallin's known bone cutting guide and technique utilizing such a guide (cutting the facing surfaces of a metatarsocuneiform joint) would improve a substantially identical procedure (McGlamry's metatarsocuneiform arthrodesis) in the same way, by, for example, reducing the likelihood of complications.

123. 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.

124. 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.1015, [0046], [0051] (describing disclosed cutting guides' use in five "angular osteotomy procedures," including for use in a "Lapidus-type procedure"), Fig.13.

125. 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.1005, [0056]-[0058], [0065]-[0068]; Ex.1007, 324-26. 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.

2. Limitation 1[a]

126. Limitation 1[a] recites “a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform.” McGlamry in combination with Fallin renders obvious limitation 1[a].

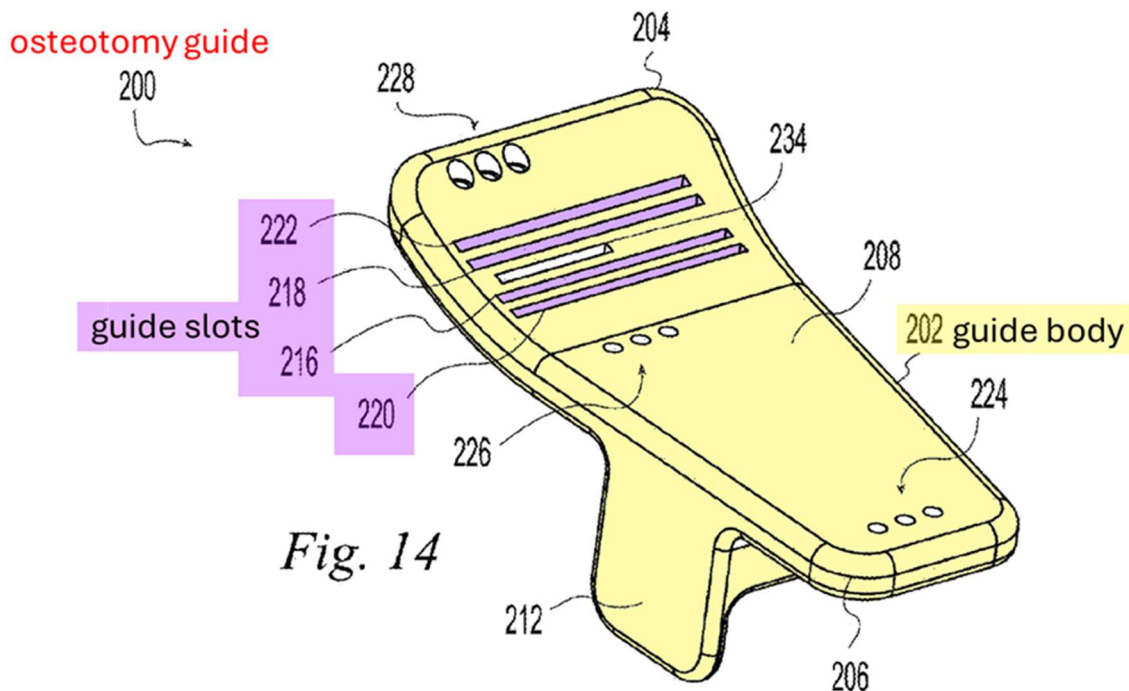
127. McGlamry describes cutting of the first metatarsal. Ex.1007, 324 (describing cutting of the metatarsal base). As I discussed regarding the Preamble of Claim 1 in Section VI.A.1. above, it would have been obvious to use a cutting guide like the one disclosed by Fallin to perform McGlamry’s resection by positioning Fallin’s bone cutting guide defining a guide slot over the proximal end of the first metatarsal that McGlamry discloses should be cut.

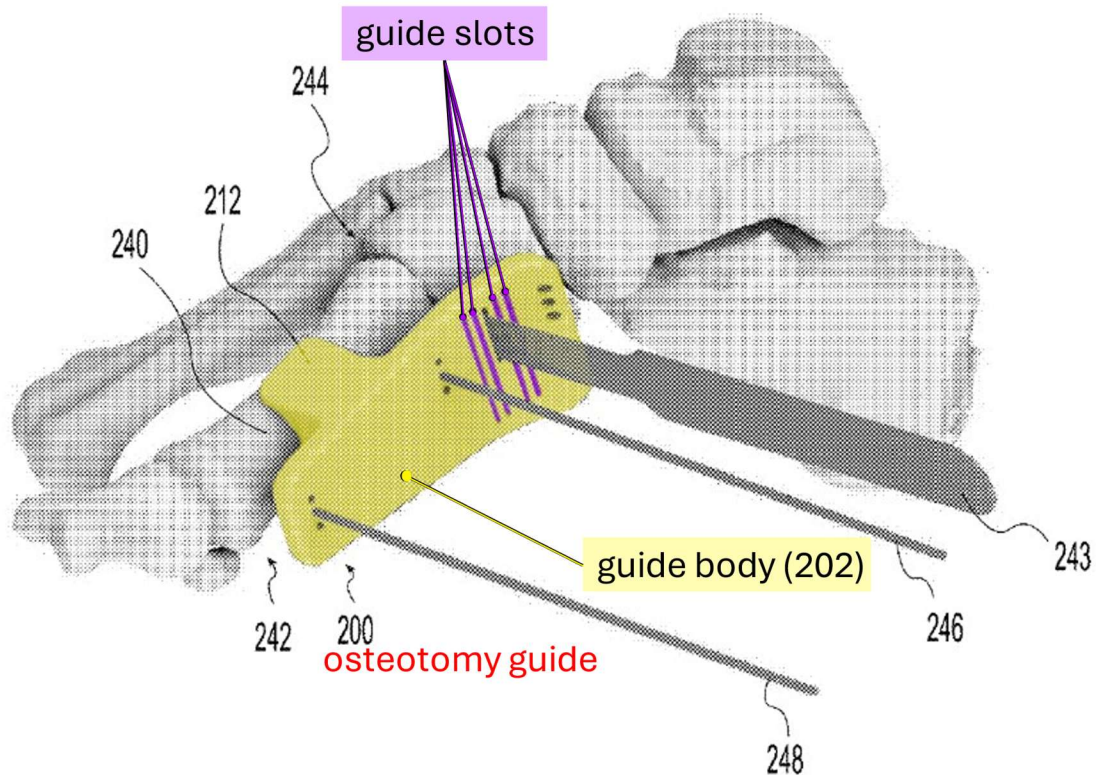
128. Fallin discloses a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform.

129. Fallin describes an “osteotomy guide [that] includes a first guide feature operable to guide a cutter to cut the metatarsus and a second guide feature operable

to guide a cutter to cut the cuneiform.” Ex.1005, claim 24; *see also 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.

130. Fallin discloses that its osteotomy guide includes a **guide body 202** having guide slots 216, 218, 220, 222, which are positioned for receiving and guiding a tissue removing instrument (e.g., a “cutter”). *Id.*, [0055]. Figures 14 and 21 of Fallin below depict the osteotomy guide, its body, and guide slots:





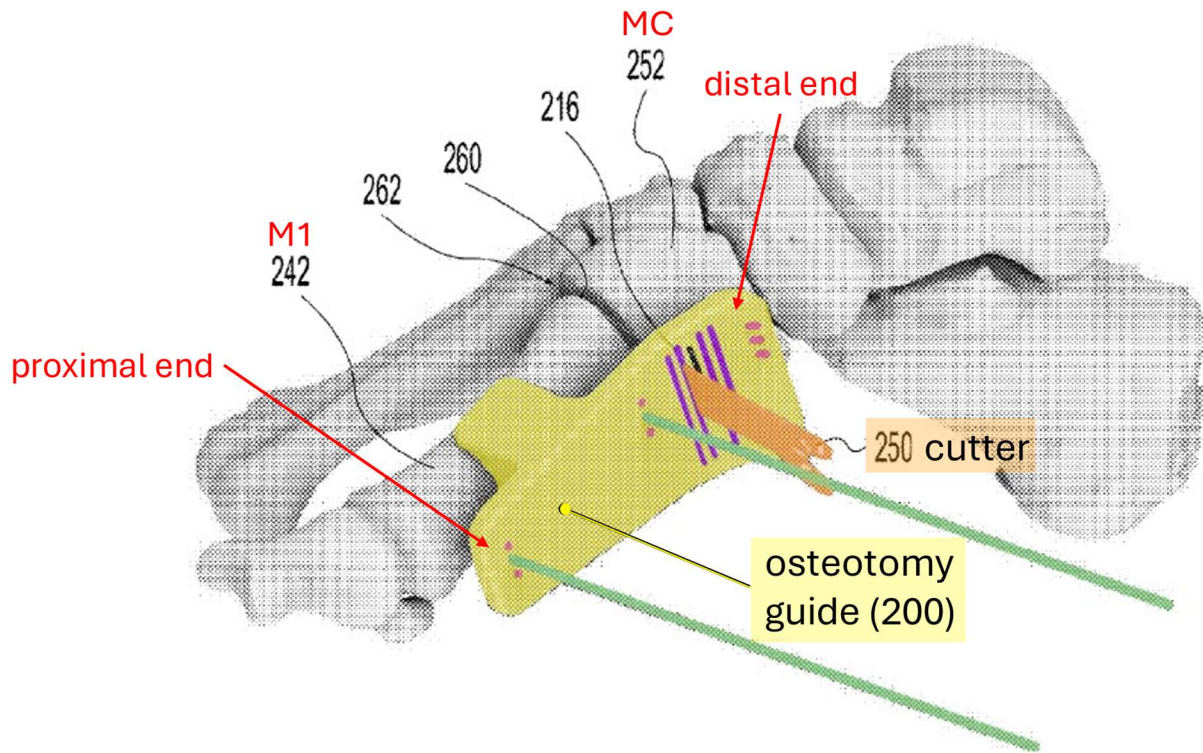
Id., Figs.14 and 21 (annotated).

131. As illustrated, for example, in the figures above, each of Fallin’s guide slots includes at least one plane that is the claimed guide surface.

132. Fallin’s description and illustration of its osteotomy guide is consistent with how the ’368 patent describes a guide surface. For example, the ’368 patent describes the bone preparation guide 150 as including “a body 154 defining a first guide surface to define a first preparing plane” Ex.1001, 8:6-9. The ’368 patent further describes each guide slot as formed by a guide surface and a facing surface. *Id.*, 8:20-27.

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

134. Fallin also depicts its osteotomy guide being positioned over the proximal end of the first metatarsal (M1) and the distal end of the medial cuneiform (MC), as shown in Figure 22 below:



Id., Fig.22 (annotated).

135. Fallin further describes using the bone preparation guide 200 to guide a cutter (e.g., a tissue removing instrument or saw) for cutting the proximal end of the metatarsal and distal end of the cuneiform using the guide slots. Ex.1005, [0065], [0067].

136. Fallin’s guided “cutter” satisfies the “tissue removing instrument” limitation under the plain meaning. If a means-plus-function construction were applied, the cutter is corresponding structure (or an equivalent) to the saw/osteotome/bur-type tissue removal instruments described in the ’368 patent. Fallin’s cutter would be insubstantially different from the structures described in the

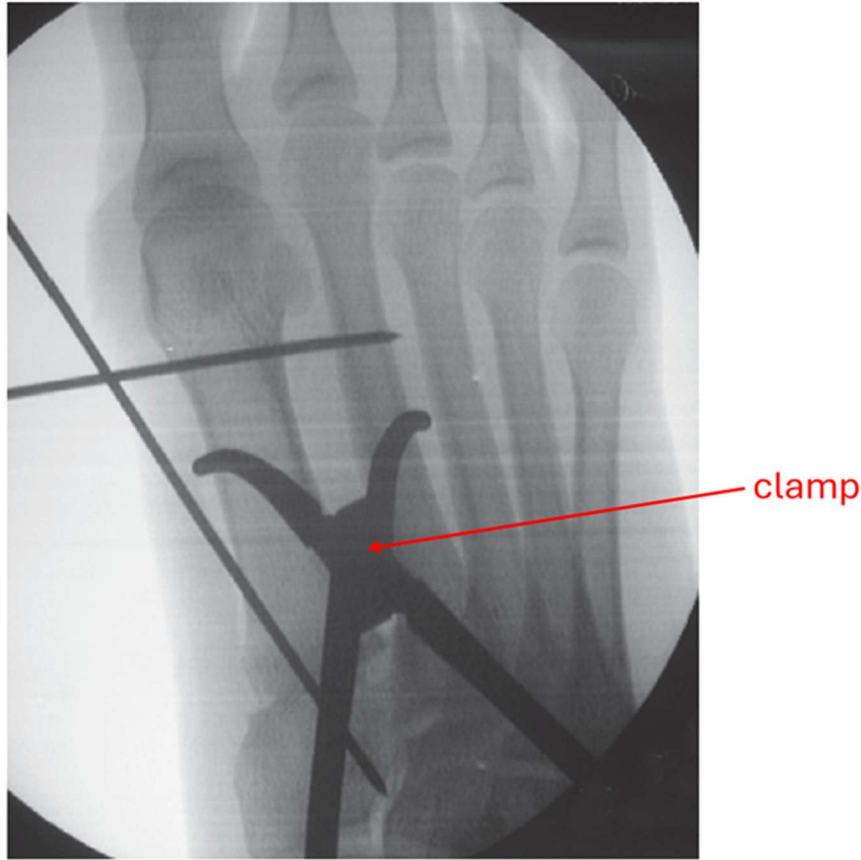
'368 patent as it performs the same function, in substantially the same way, with the same result as the tissue removal instruments in the '368 patent.

3. Limitation 1[b]

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

138. McGlamry discloses repositioning the first metatarsal in multiple planes as part of its procedure, including the transverse plane, frontal plane, and sagittal plane, to treat a bunion deformity. Ex.1007, 325-326.

139. McGlamry discloses a Weber clamp for moving the first metatarsal in the transverse plane and rotating the first metatarsal in the frontal plane. *Id.* 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.1015, 1112 (disclosing a lateral force applied to the first metatarsal that both reduces the IMA and corrects a hallux valgus deformity). This reduction treats the bunion deformity. Ex.1007, 322-29. McGlamry's Weber clamp is shown below:



Ex.1007, Fig.31.5 (annotated).

140. McGlamry's Weber clamp is a bone positioning guide under either construction of that term discussed above. A Weber clamp is a type of tenaculum and is used to position bones. In McGlamry's procedure, that positioning includes moving the metatarsal and the transverse and frontal planes.

141. For the transverse plane movement, McGlamry's Figure 31.5, shown above, shows an "[i]ntraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle." *Id.*, 326. McGlamry's Weber clamp is identical, or at least equivalent to the structures identified in the '368 patent for the claimed bone positioning guide. McGlamry's Weber clamp is at least an equivalent

of the '368 patent's bone positioning structure (e.g., tenaculum/tong/reduction forceps-type instrument) because it uses opposing jaws/arms that engage bones (the first and second metatarsal) that are actuated through a pivot/handle/screw mechanism. This mechanism allows a surgeon to apply controlled corrective forces and hold the first and second metatarsal in a corrected relationship. Ex.1007, 325-326. McGlamry's Weber clamp therefore performs the same function, in the same way (opposing jaws that apply/maintain a corrective clamping force), to achieve the same result of controlling the repositioning and maintenance of the correction during fixation.

142. The Weber clamp was a well-known and widely adopted surgical instrument, and it was known for use in bunion correction procedures as McGlamry describes. *See* Ex.1007, 325-326, Fig. 31.5; *see also* Ex.1008, 466 ("The first IMA was then reduced with a large, pointed, bone reduction clamp" and Fig. 2 showing use of clamp). A pointed bone reduction clamp is a Weber clamp.

143. Even if McGlamry does not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to use the Weber clamp to rotate the metatarsal in the frontal plane. A POSA would have recognized that a Weber clamp engaged across adjacent metatarsals (as shown by McGlamry) not only transmits compressive forces (for transverse plane correction) but also torsional

movement (frontal plane derotation) as part of a controlled reduction. *See* Ex.1006, 9:66-10:3.⁴

144. The first metatarsal is not cylindrical and has an asymmetric cross-section. The medial side of the first metatarsal has a ridge, which is referred to as the “metatarsal ridge.” *See, e.g.*, Ex.1001, Fig.15B, 11:14-17. The Weber clamp in McGlamry is illustrated as being placed in the region of the metatarsal ridge. Ex.1005, Fig.31.5. A POSA would have recognized that, because the first metatarsal is not symmetrical (e.g., has the ridge on the medial side), when a bone positioning device like a Weber clamp engages the first metatarsal as shown in McGlamry, the force from the clamp would generate rotation of the first metatarsal in the frontal plane when the force is not in line with the metatarsal’s center of mass. The surgeon could increase or decrease the amount of this rotation either through the positioning of the Weber clamp or by pulling/pushing on the Weber clamp as desired when moving the first metatarsal.

145. In McGlamry’s procedure, before using the Weber clamp, the surgeon resects the connective tissue from the metatarso-cuneiform joint. Ex.1005, 324. The first metatarsal can thus rotate in the frontal plane when the surgeon uses the Weber

⁴ I note that the ’368 patent does not explain how the linear movement of the disclosed bone positioning guides would cause rotation of the first metatarsal in the frontal plane. Rather, it simply states that such rotation occurs. *See, e.g.*, Ex.1001, 11:64-12:3.

clamp. *Id.*, 328 (“Once the ligamentous structures of the tarsal–metatarsal joint [are] free of soft tissue attachments, rotation of the first metatarsal from a valgus position in the direction of varus and into a neutral position can demonstrate the frontal plane motion associated with the pathological hallux valgus deformity.”).

146. A POSA would have been motivated to use the Weber clamp to correct the frontal plane rotation of the first metatarsal due to the problems McGlamry discusses with failing to correct the position of the first metatarsal. Ex.1007, 322-329. McGlamry describes that maintaining the corrected position “in all three planes” is important during temporary fixation and further provides guidance for additional frontal plane rotation: “[a] K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position.” Ex.1007, 326, 328-329. Fallin likewise discloses that, after creating increased mobility, the metatarsus and cuneiform may be freely repositioned in a “new relative orientation” and “in one or more planes” before fusion. Ex.1005, [0057]-[0058]. Selecting a familiar reduction clamp already used in McGlamry’s procedure, such as the Weber clamp, to transmit controlled corrective forces (including a rotational component) during repositioning would have been desirable to a POSA, since such use of McGlamry’s clamp would improve control and stability (e.g., freeing the surgeon’s hands during temporary fixation) without modification of the clamp. A POSA would expect McGlamry’s

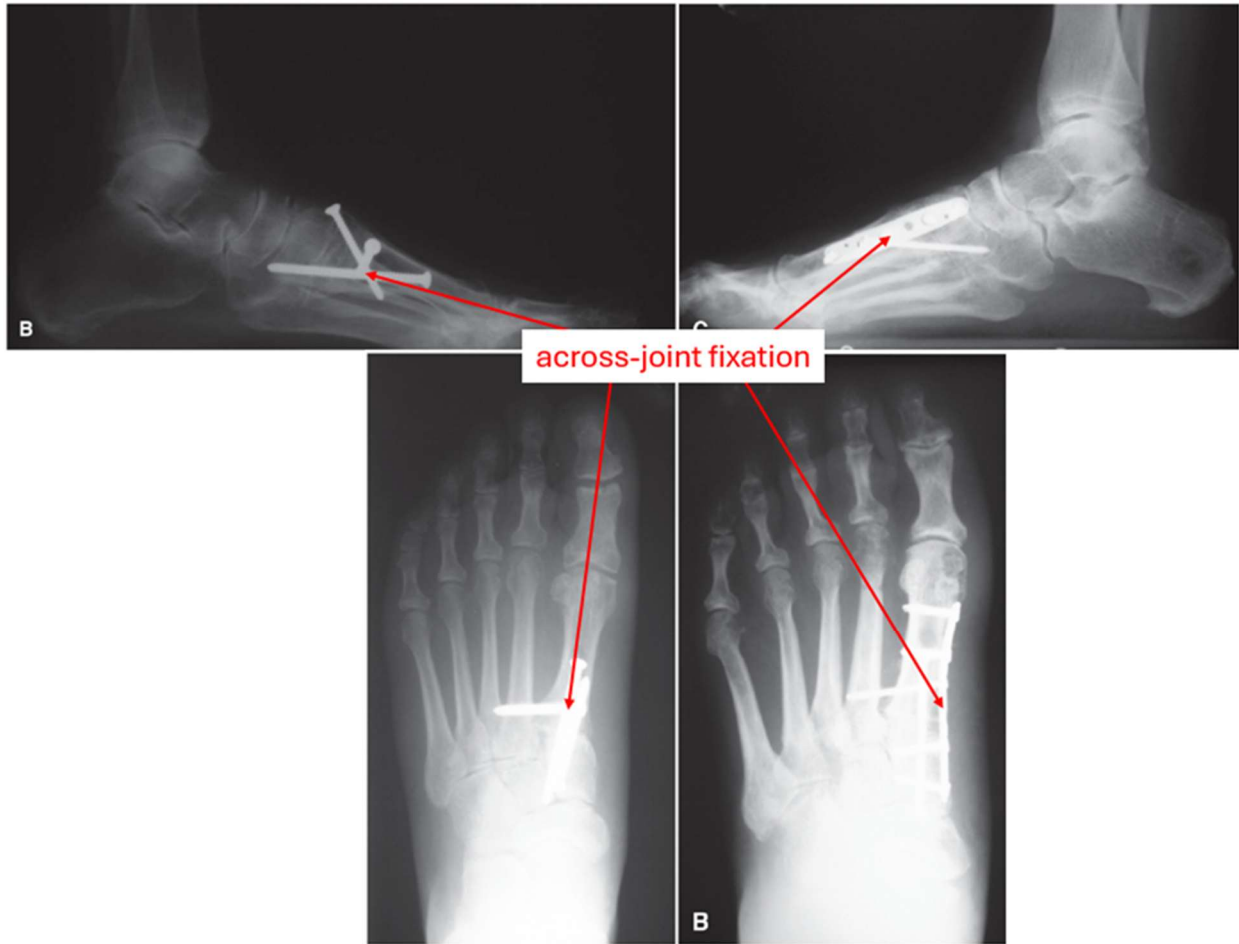
clamp to perform such a torsional rotation in the frontal plane as explained above while leaving the overall surgical approach of McGlamry's procedure unchanged.

4. Limitation 1[c]

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

148. 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.⁵ 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.1007, 329, 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.”). Figures 31.6B, 31.7, and 31.8B-C below show the placement of these fixation devices across the tarsal-metatarsal joint:

⁵ A “metatarsocuneiform joint,” “metatarsal-cuneiform joint,” and “tarsal-metatarsal joint” each refer to the same joint between the first metatarsal and medial cuneiform.



Id., Figs.31.6B, 31.7, 31.8B-C (annotated).

149. 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 ’368 patent, which identifies, for example, screws and plates. Ex.1001, 11:18-25. Thus, they are a corresponding structure, or at least an equivalent structure, for fixing the moved position of the metatarsal for fusion.

B. Claim 2

150. Claim 2 depends from claim 1 and recites “further comprising a pin configured to be inserted into the first metatarsal, the pin being configured to receive a force to rotate the first metatarsal in the frontal plane.” The McGlamry-Fallin combination renders this claim obvious.

151. Specifically, McGlamry discloses: “If the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal ... [and] can be used as a rotation device and rotate the metatarsal” in the frontal plane. Ex.1007, 326. Because the K-wire serves as a “rotation device” for rotating the first metatarsal in the frontal plane, the pin would be configured to receive a force from the surgeon in effectuating a frontal plane rotation.

152. A K-wire, also known as a Kirschner wire, is a type of pin. *See, e.g.*, Ex.1035, 1 (describing history of “a smooth pin, presently known as the Kirschner wire (K-wire)”); Ex.1010, 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.1011, 487 (disclosing temporary fixation by K-wire or Steinman pin in a Lapidus procedure).

153. 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.1007, 324-326 (describing use of K-wire as a rotation device for “further”

frontal plane correction). As I explained above regarding limitation 1[b] in Section VI.A.3., McGlamry describes a Weber clamp applied to the first and second metatarsals for reducing the IMA and rotating the first metatarsal in the frontal plane. The K-wire would be used with the bone positioning guide to correct frontal plane mispositioning of the first metatarsal. *See* Ex.1007, 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).

C. Claim 4

154. Claim 4 depends from claim 1 and recites “wherein the bone preparation guide further comprises a spacer extending downwardly from the body and configured to be placed into the tarsal-metatarsal joint.” The McGlamry-Fallin combination renders obvious the additional limitations of claim 4.

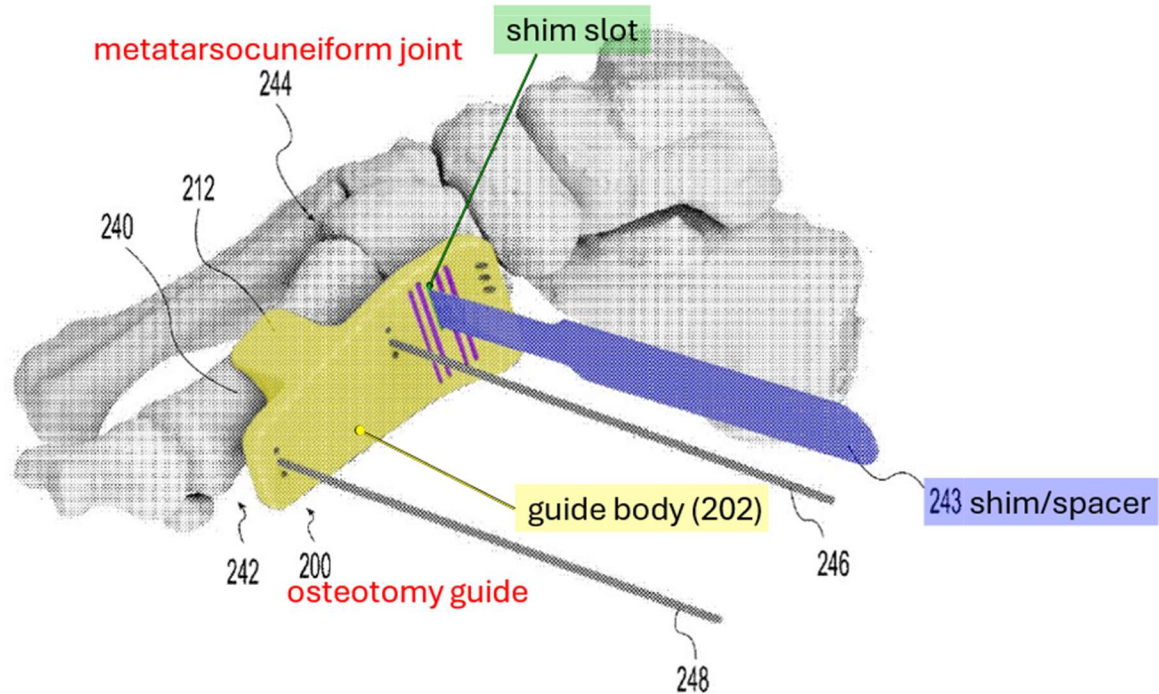
155. Fallin’s guide body 202 of its osteotomy guide 200 “may include a joint alignment feature to aid in positioning the guide body 202 relative to a joint.” Ex.1005, [0055]. One embodiment of this joint alignment feature is a “projection from the guide body 202 engageable with the joint.” *Id.* “The joint alignment feature allows a user to position the guide relative to the joint.” *Id.*

156. The joint referenced in Fallin is the tarsal-metatarsal (first metatarsal-medial cuneiform) joint. Ex.1005, [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).

157. Fallin’s “projection from the guide body 202 engageable with the joint” is a spacer that extends downwardly from the body and is configured to be placed into the tarsal-metatarsal joint. 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 ’368 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, 8:63-9:10. The joint alignment feature (spacer) of Fallin performs the same function.

158. 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:

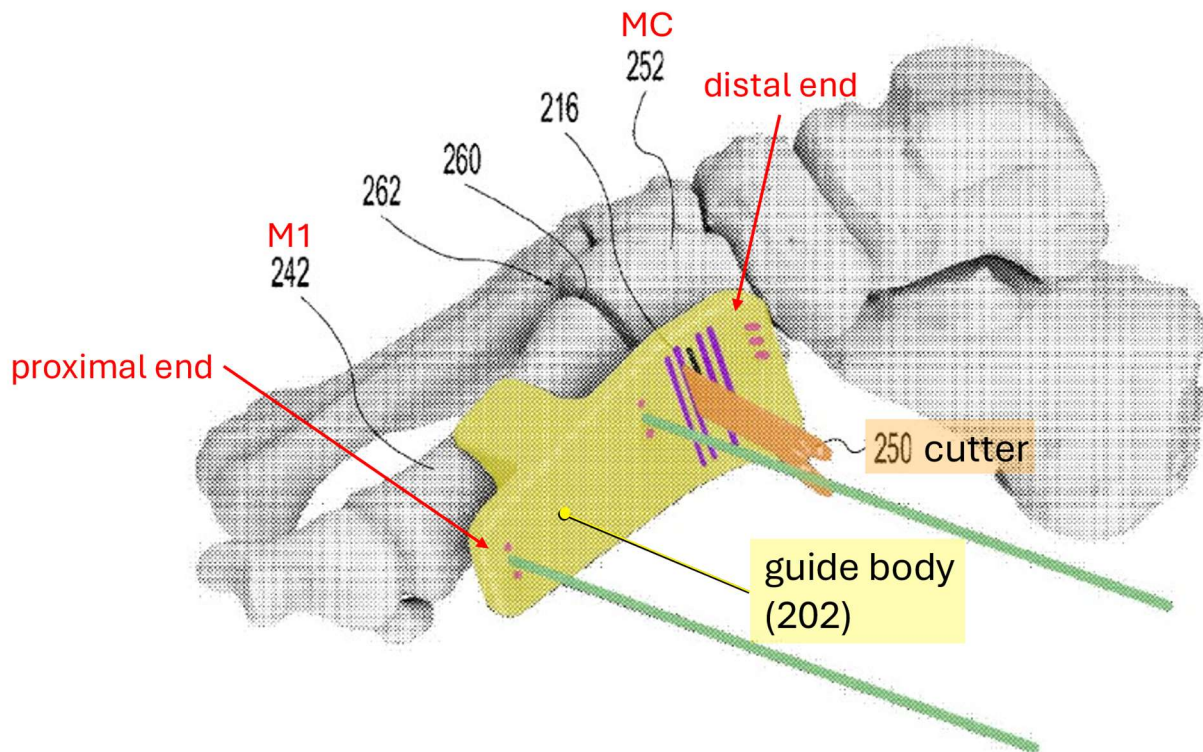


Ex.1005, Fig.21 (annotated); *see also id.*, [0055], [0056] (“A feeler gauge 243, or shim, is inserted through the joint alignment slot 234 and used to align the guide 200 with the metatarsocuneiform joint 244.”), Fig.21. The placement of this shim illustrates where a POSA would understand the projection would be placed.

D. **Claim 5**

159. Claim 5 depends from claim 1 and recites “wherein the body extends from a first end configured to be positioned over the first metatarsal to a second end configured to be positioned over the medial cuneiform, the body including a first fixation aperture configured to receive a first fixation pin and a second fixation aperture configured to receive a second fixation pin.” The McGlamry-Fallin combination renders obvious claim 5.

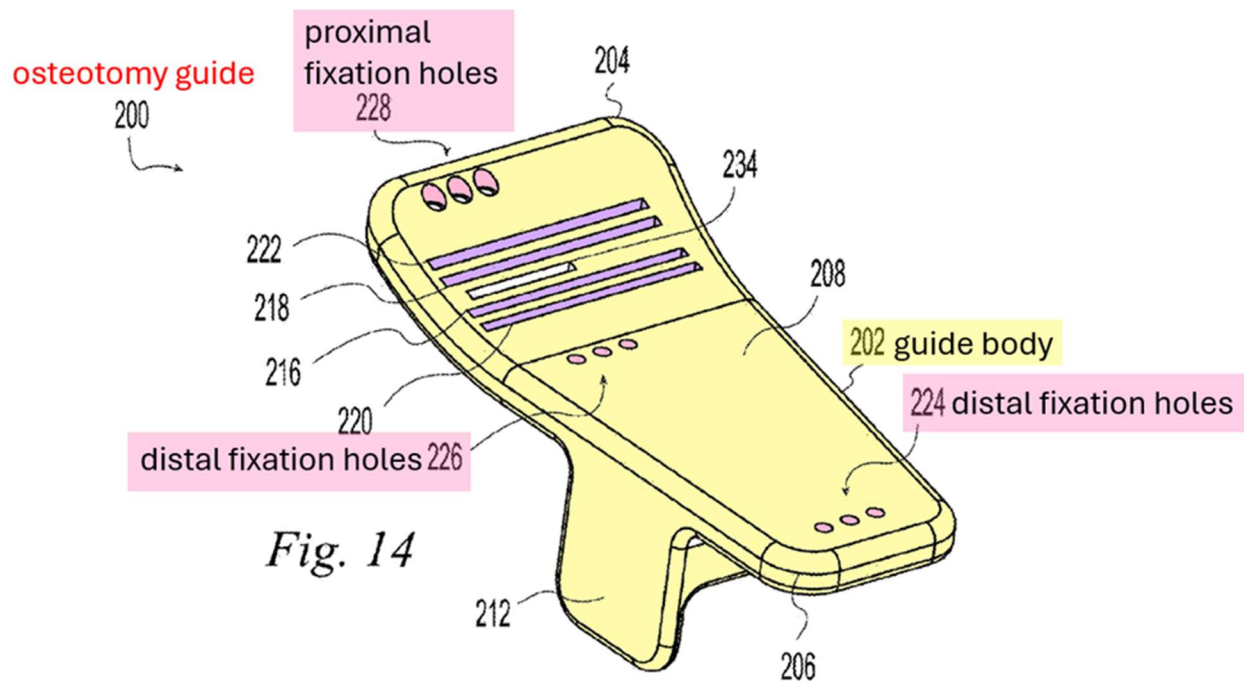
160. As explained regarding limitation 1[a], Fallin discloses a bone preparation guide with a body positioned over the proximal end of the first metatarsal and the distal end of the medial cuneiform. *See supra* §VI.A.2. Fallin’s osteotomy guide 200 “includes a guide body 202 having a proximal end 204...[and] a distal end 206.” Ex.1005, [0051]. These ends are located over the medial cuneiform and first metatarsal, respectively, as shown in Figure 22 below. *See id.*, [0053], [0056], Figs.21-24.



Id., Fig.22 (annotated). As depicted in Figure 22 above and Figure 23, the osteotomy guide’s ends maintain this position when a surgeon cuts the first metatarsal and medial cuneiform. *Id.*, Figs.22-24, [0051]; *see also id.*, [0064]-[0067] (describing

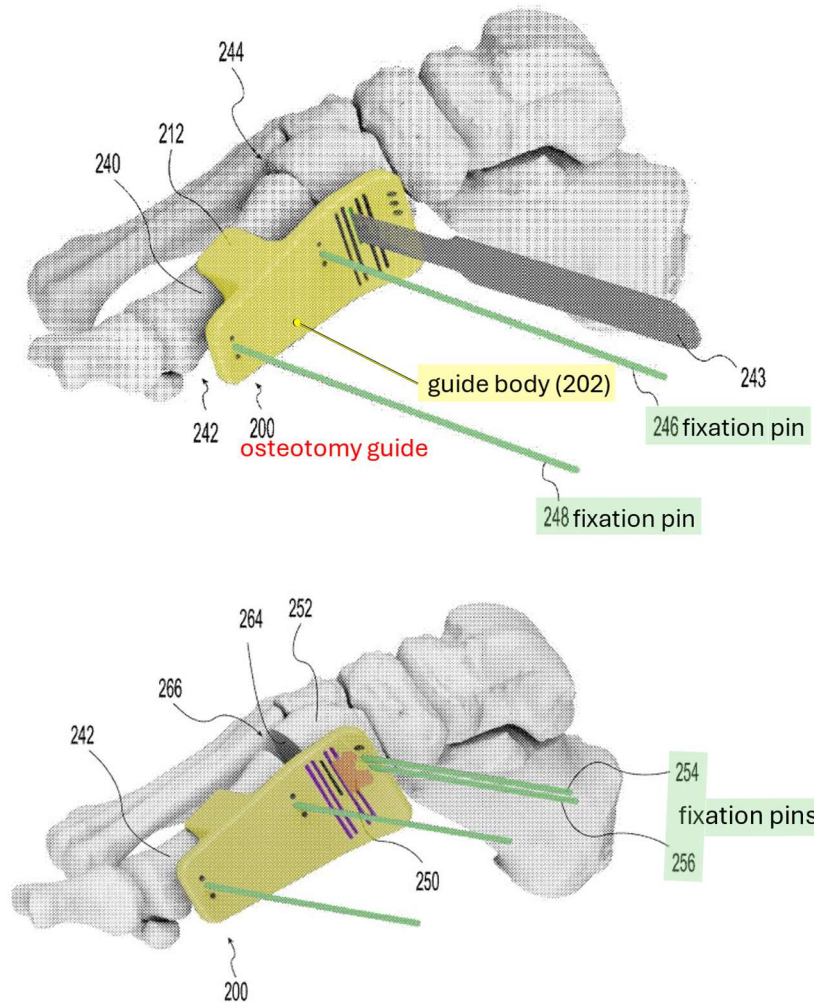
position of bone preparation guide (and thus its ends) during cutting of first metatarsal and medial cuneiform).

161. Fallin's guide body also "includes fixation elements in the form of holes operable to receive pins or screws to attach the guide 200 to bone." *Id.*, [0053], [0067]. A POSA would understand that the openings of these holes are fixation apertures for receiving fixation pins. Figure 14 below shows the configurations of these holes on the guide body:



Id., Fig.14 (annotated).

162. Fallin further discloses that each pin is placed in a different aperture, and that at least two pins are used in the surgical procedure. *Id.*, [0064], [0067]. Figures 21 and 24 below depict at least two fixation apertures (holes) receiving fixation pins for attaching the guide to the metatarsocuneiform joint bones:



Id., Figs.21, 24 (annotated).

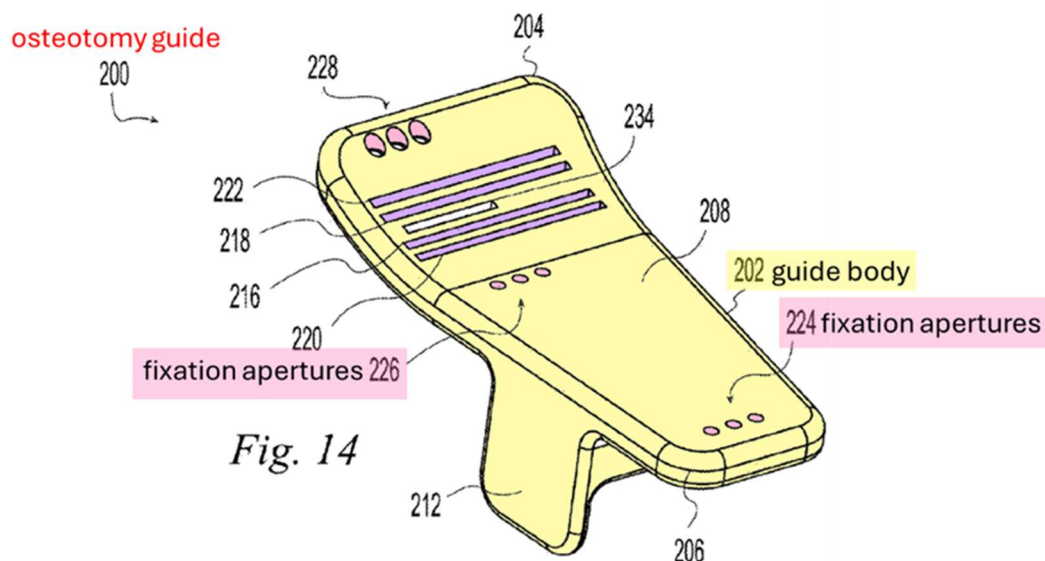
163. Any of the holes 224 and pin 248 inserted into such holes correspond to the first fixation aperture and first fixation pin, respectively. Any of the holes 226 and pin 246 inserted into such holes correspond to the second fixation aperture and second fixation pin, respectively.

E. Claim 6

164. Claim 6 depends from claim 5 and recites “wherein the first fixation aperture and the second fixation aperture are generally parallel to each other.” McGlamry in view of Fallin renders obvious claim 6.

165. As I explained for claim 5 above, Fallin discloses an osteotomy guide including first and second fixation apertures for receiving first and second fixation pins, respectively. *See supra* §VI.D.

166. The fixation apertures of Fallin's bone preparation guide are circular openings. *See* Ex.1005, Figs.14, 19. These apertures correspond to cylindrical bones that extend through the thickness of the guide body, thus allowing for the passage of fixation pins. Figures 14, 18, and 19 below depict fixation apertures, as well as the surfaces on which these apertures reside:



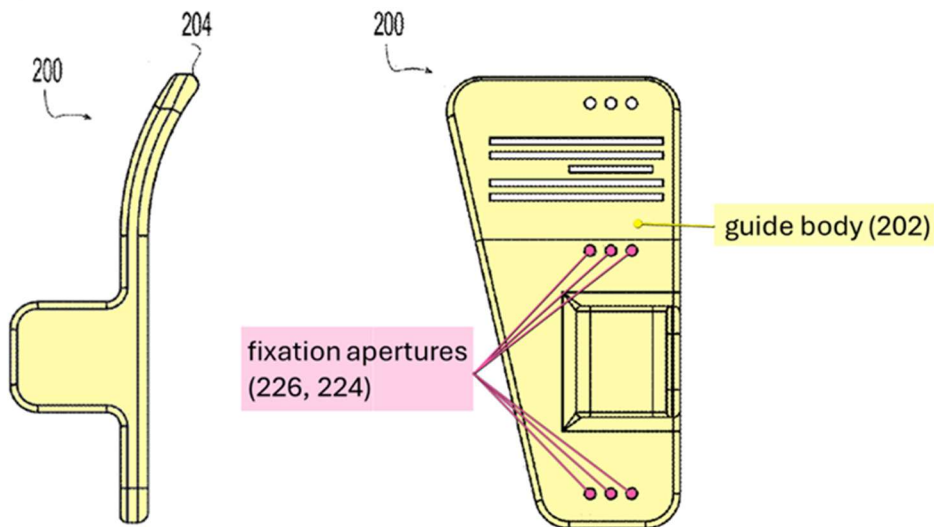
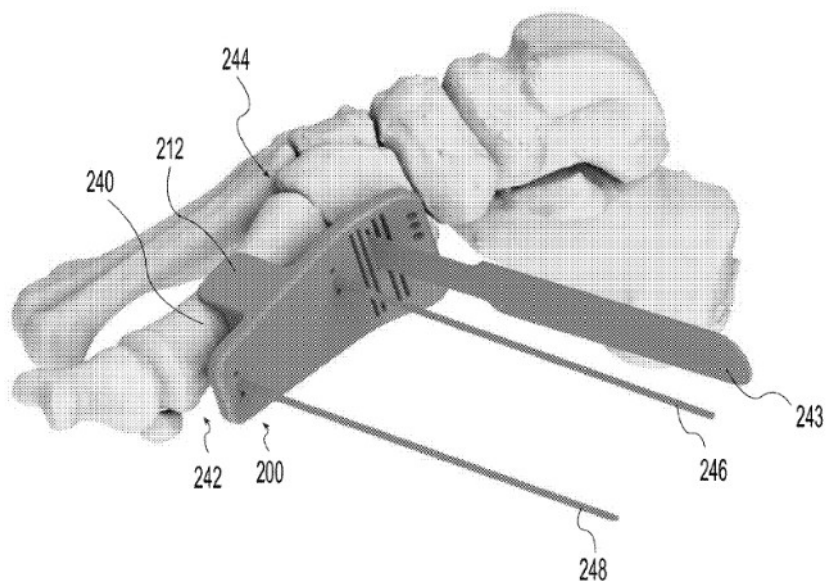


Fig. 18

Fig. 19

Id., Figs.14, 18-19 (annotated).

167. As illustrated by Figure 21 below, the bores of fixation apertures 224 and 226, and thus the fixation pins passed through such bores, are generally parallel.



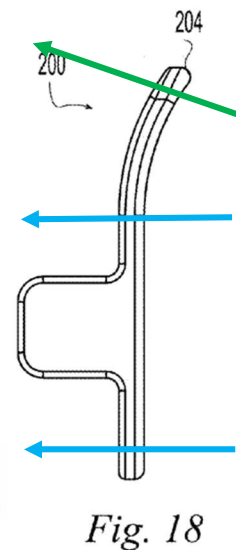
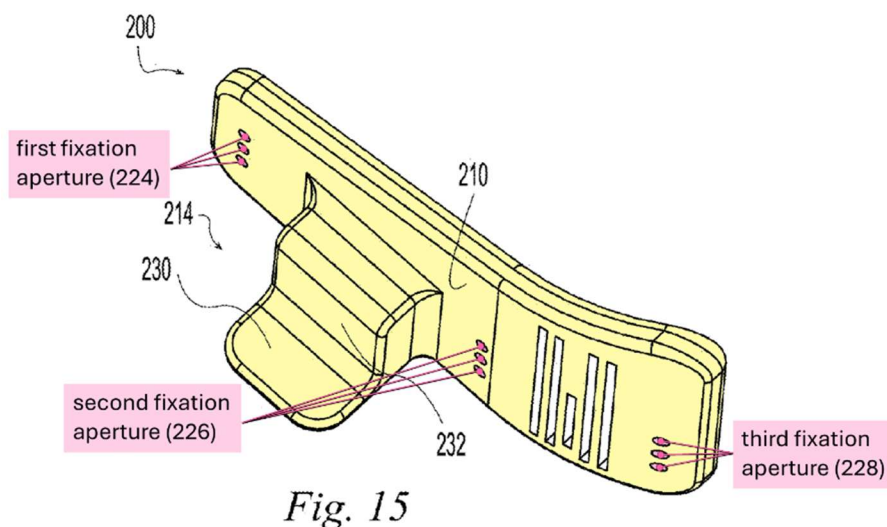
Id., Fig.21. Because the straight pins placed through the fixation apertures are generally parallel, a POSA would have recognized that the fixation apertures are also generally parallel to each other.

F. Claim 7

168. Claim 7 depends from claim 6 and recites “wherein the body further comprises a third fixation aperture that is skewed relative to the first fixation aperture and the second fixation aperture, the third fixation aperture being configured to receive a third fixation pin.” The McGlamry-Fallin combination renders obvious claim 7.

169. As I explained above for claims 5 and 6, Fallin discloses a guide body with fixation apertures in different regions, including distal apertures 224, 226 for fixing the guide over the metatarsal and proximal apertures 228 for fixing the guide over the cuneiform, all of which receive pins. *See supra* §§VI.D. and VI.E.

170. Fallin’s proximal apertures 228 have corresponding bores for receiving a fixation pin for fixing the osteotomy guide to the medial cuneiform. The figures below depict Fallin’s osteotomy guide defining first, second, and third fixation apertures, with arrows added to Figure 18 perpendicular to the fixation apertures (blue for first and second fixation apertures; green for third fixation aperture):



Ex.1005, Figs.15, 18, [0056].

171. The '368 patent uses “skewed” to distinguish “parallel.” Ex.1001, 8:28-29 (“The first and second slots may be parallel or skewed.”). The openings of holes 228 (any of which are a third fixation aperture) are oriented in a different direction—skewed—relative to the openings of holes 224/226. *Id.*, Figs.14, 18-19, [0056].

172. Even if Fallin does not disclose a third fixation aperture that is skewed relative to the first fixation aperture and the second fixation aperture, that feature would have been obvious. A POSA would have recognized that there were only two options for the orientation of a third fixation aperture relative to a first and second fixation aperture: skewed or parallel. Both options would have been known to a POSA and would have been a matter of designer preference and the desired goals of the designer. *See* Ex.1029, Abstract (“At least two fixation holes are formed through

the osteotomy guide in directions which are non-parallel to the guide holes so that additional fixation pins may be placed into the tibia for more stable positioning of the osteotomy guide.”); Ex.1031, [0071] (“Other features include a minimum of two non-parallel pin holes for additional stability of the block to the proximal humerus.”); Ex.1032, [0030] (“The non-parallel axes of the holes may provide an advantage ... of more positively coupling the cutting block 1 to a femur or a tibia in view of the fact that nonparallel axes prevent sliding of the cutting block 1 in a common direction along two or more fasteners placed in nonparallel holes.”), [0048].

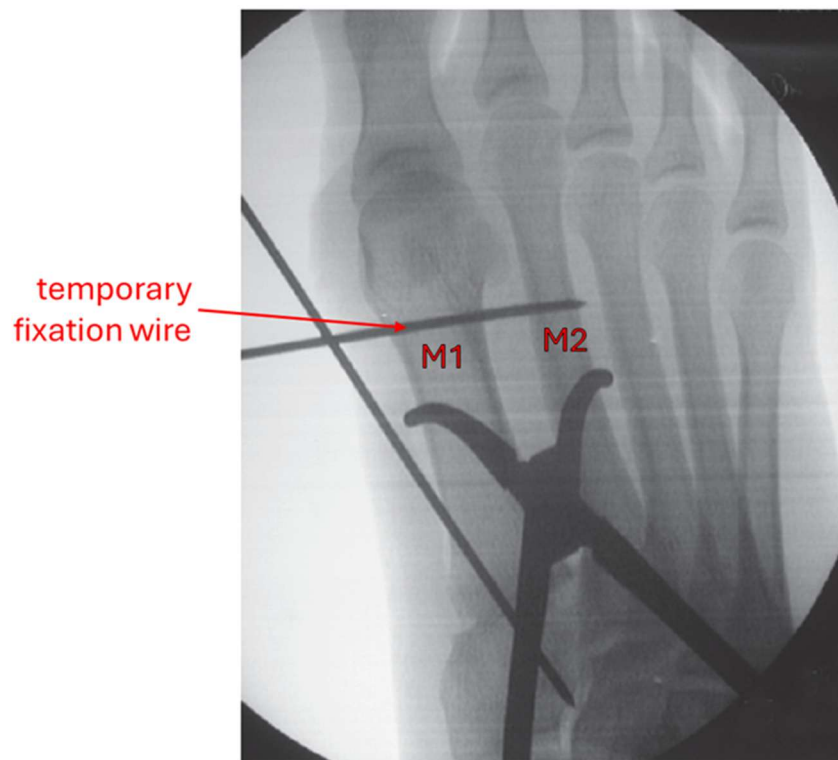
173. For example, a POSA would have recognized that it was routine to orient one fixation aperture at a different angle from others so that the fixation pin would provide additional stabilization and security by preventing the guide from being moved/removed without the pin being removed. In contrast, when all the apertures/pins are parallel, a surgeon can move or remove the guide even if the pins are present.

G. Claims 8-9

174. Claim 8 depends from claim 1 and recites “a temporary fixation device configured to be applied to the first metatarsal to temporarily fixate the moved position of the first metatarsal prior to permanent fixation using the at least one fixation device.” Claim 9 depends from claim 8 and recites “wherein the temporary

fixation device comprises a fixation wire.” The McGlamry-Fallin combination renders these claims obvious.

175. McGlamry discloses that, in its bunion correction procedure, once the hallux, sesamoids, and first metatarsal are aligned in three planes, the surgeon inserts a “K-wire is used to stabilize the reduction and position” of the metatarsal. Ex.1007, 326. This insertion of a K-wire serves to “prevent derotation in the frontal plane and maintain[] reduction in the transverse plane” while the final fixation device is applied. *Id.* This temporary fixation is shown below:



Ex.1005, Fig.31.5.

176. Under either the plain meaning or the Section 112(f) meaning of “fixation device,” McGlamry’s k-wire/fixation wire is the claimed temporary

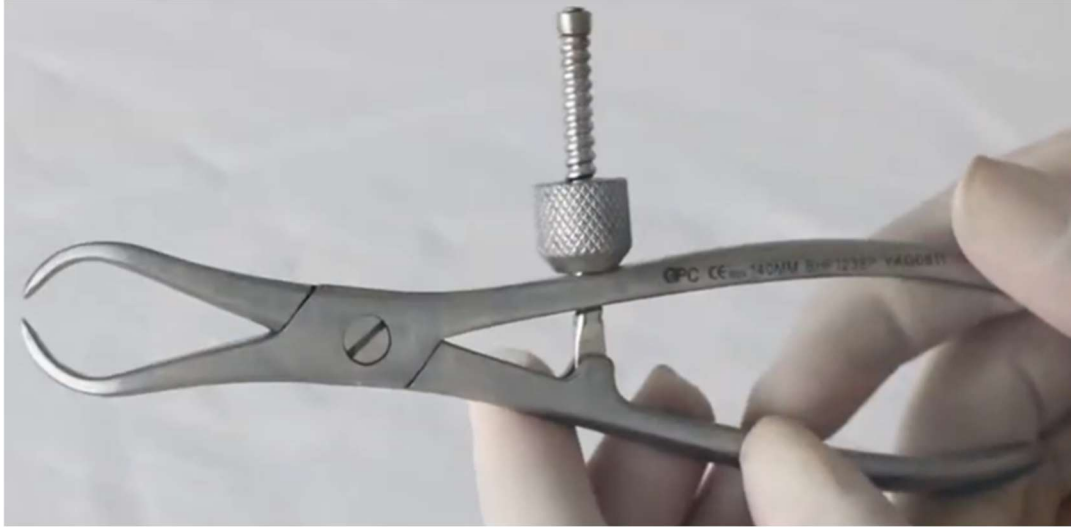
fixation device because it temporarily stabilizes the moved position of the metatarsal prior to final fixation.

177. McGlamry discloses the subsequent use of permanent fixation devices as discussed regarding limitation 1[c]. *See supra* §VI.A.4. McGlamry therefore describes a temporary fixation device, specifically a fixation wire, that is applied to the first metatarsal to hold its corrected, moved position until permanent fixation is completed.

H. Claim 10

178. Claim 10 depends from claim 1 and recites: “wherein the bone positioning guide comprises a rotatable knob connected to a threaded shaft.” McGlamry in view of Fallin renders obvious claim 10.

179. A POSA would have recognized that a “Weber clamp” as disclosed in McGlamry encompasses clamps with threaded shafts. For example, by July 2015, a known type of Weber clamp was the GPC Medical bone reduction forceps. An image (below) of a video dated September 2014 shows the GPC Medical bone reduction forceps with a threaded shaft that moves the ends of the clamp:



<https://www.youtube.com/watch?v=mLH4s96dErI> at 0:12, 0:54 (last visited December 31, 2025); *see also* Ex.1006, Fig.1 (illustrating bunion reduction instrument with rotatable knob and threaded shaft), 8:51-53.

180. Weber clamps/bone reduction clamps such as the one shown above were commercially available and in use by surgeons before July 2015. This includes configurations of the Weber clamp with a rotatable knob connected to a threaded shaft for incrementally moving the jaws and holding the reduction hands-free during subsequent fixation.

181. A POSA would understand that the threaded shaft could be used to incrementally move the arms of the clamp closer together, thereby moving the metatarsal in the transverse plane and rotating it in the frontal plane. The Weber clamp with a threaded shaft would allow a surgeon to hold the position of the metatarsal while inserting temporary fixation (e.g., a K-wire). Ex.1007, 325-326.

182. Selecting a screw adjustable (e.g., rotatable knob and threaded shaft) Weber clamp for McGlamry's bone reduction step would have been an obvious choice. A POSA would not need to modify such a knob-and-thread configuration for moving the first metatarsal in the transverse and frontal plane, and such a clamp would predictably result in finely controlled movement of the first metatarsal when implemented in McGlamry's bunion correction procedure.

I. Claim 11

183. Claim 11 depends from claim 1 and recites "wherein the at least one fixation device comprises one or more of a bone plate, a screw, a staple, and an intramedullary implant." As explained in limitation 1[c], McGlamry discloses that its fixation devices include one or more screws or a plate. *See supra* §VI.A.4.; Ex.1005, 325-27. The McGlamry-Fallin combination thus renders obvious claim 11.

J. Claim 12

184. Claim 12 depends from claim 1 and recites: "wherein the bone positioning guide is formed of at least three components joinable together to form the bone positioning guide." The McGlamry-Fallin combination renders obvious claim 12.

185. A POSA would have understood that a Weber clamp of the type used in McGlamry is a multi-part instrument assembled from at least (i) a first arm, (ii) a second arm, and (iii) a pivot/hinge member (e.g., a screw/bolt/pin) that join the arms

together and permit the arms to pivot to apply and maintain clamping force. These three components are joined at some point between each component's manufacture and the surgeon's use of the instrument as a whole in a bunion correction procedure.

186. Even if McGlamry did not spell out the internal construction of a Weber clamp, a POSA would have recognized it was obvious to use a Weber clamp having a conventional multi-component construction (e.g., two arms joined by a pivot/fastener). Such an assembly was commonplace for surgical instruments such as McGlamry's Weber clamp and enabled the pivoting/clamping function. It also would have provided benefits in ease of manufacture, 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.

K. Claim 13-14

187. Claim 13 depends from claim 1 and recites "further comprising the tissue removing instrument." Claim 14 depends from claim 13 and recites "wherein the tissue removing instrument comprises a saw blade." The McGlamry-Fallin combination renders obvious claims 13 and 14.

188. McGlamry describes the use of an "osteotome" to cut bone, including the first metatarsal and medial cuneiform, in its Chapter 31 metatarsocuneiform arthrodesis. Ex.1007, 324 ("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. *See id.*, 807-808.

189. As I explained above with respect to limitation 1[a], Fallin discloses its osteotomy guide receiving “a cutter, such as a saw blade.” Ex.1005, [0052]; *see supra* §VI.A.2. A cutter/saw blade removes the articulating bones of the metatarsocuneiform joint. Ex.1005, [0052], [0065], [0067]; *see also* Ex.1014, 99.

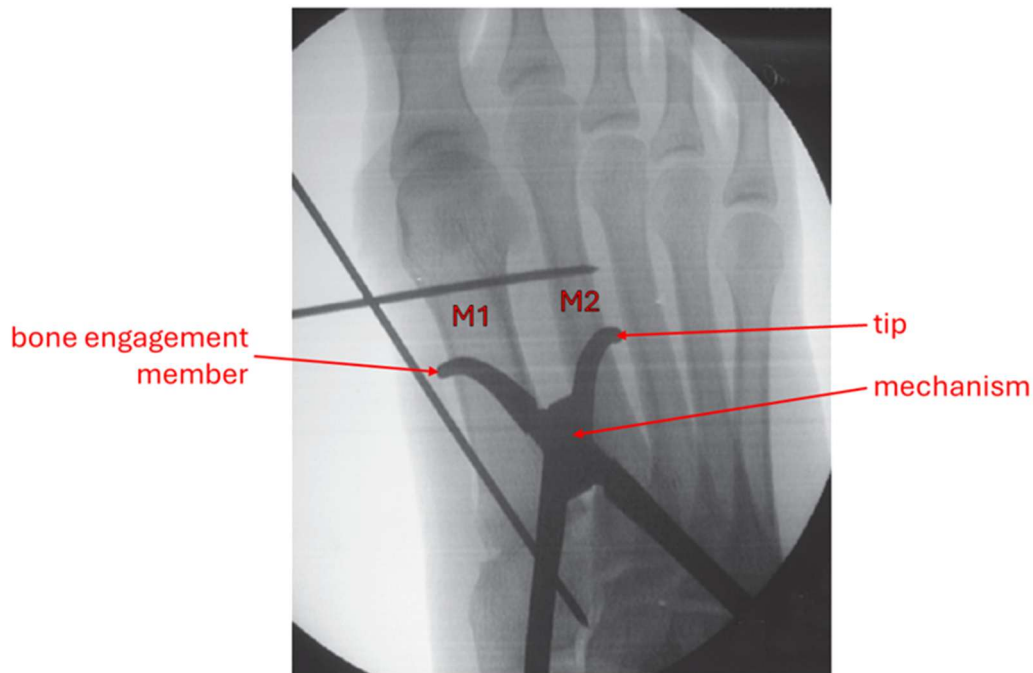
190. A POSA would understand that Fallin’s saw blade is interchangeable with McGlamry’s osteotome. Both tools cut bones and can be received by bone preparation guides. *See* Ex.1005, [0052], [0065], [0067] (use of osteotomy guide with a saw blade); Ex.1026, Abstract (use of cutting guide with osteotome). A POSA would recognize that use of an osteotome or a saw blade is a matter of surgeon preference in McGlamry’s procedure.

L. Claims 15-16

191. Claim 15 depends from claim 1 and recites “wherein the bone positioning guide comprises: a bone engagement member; a tip; and a mechanism configured to move the bone engagement member and the tip relative to each other.” Claim 16 depends from claim 15 and recites: “wherein the mechanism comprises a threaded shaft.” The McGlamry-Fallin combinations renders obvious claims 15 and 16.

192. As explained in limitation 1[b], McGlamry's Weber clamp is a bone positioning guide. *See supra* §VI.A.3.

193. McGlamry's Weber clamp also meets each of the structural limitations of claim 15. Figure 31.5 below shows each of these features present on McGlamry's Weber clamp:



Ex.1007, Fig.31.5 (annotated).

194. Specifically, the structure of the Weber clamp that is engaged with the first metatarsal is the claimed “bone engagement member.” The portion of the Weber clamp that contacts the first metatarsal engages that bone.

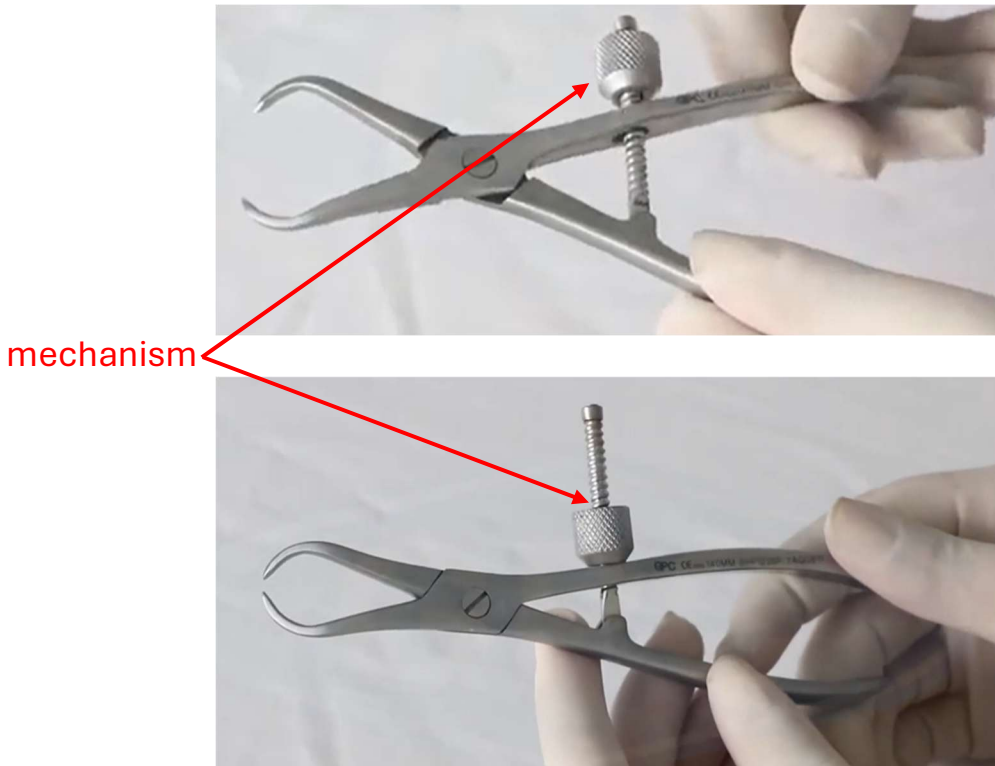
195. The '368 patent describes a tip of the bone positioning guide as the portion of the bone positioning guide that is meant to engage a metatarsal other than the first metatarsal (e.g., the second metatarsal). Ex.1001, 6:46-67. The '368 patent

describes a tip having various shapes and can be, for example, straight or have a non-linear orientation, for example, angled or curved. *Id.*, 6:48-64.

196. The end of the Weber clamp/bone reduction clamp that contacts the second metatarsal is a tip. As can be seen from Figure 31.5 of McGlamry and the example pointed bone reduction clamp above, these clamps have a tip engaging the second metatarsal. Ex.1007, Fig.31.5.

197. A Weber clamp is a type of tenaculum/tong structure where the ends of the shafts are urged together when the handles are squeezed. Thus, it is the claimed mechanism under either construction of “mechanism.” McGlamry’s Weber clamp is identical to or at least equivalent to the structures identified in the ’368 patent for the claimed mechanism. McGlamry’s Weber clamp is at least an equivalent of the “mechanism[s]” disclosed in the ’368 patent because its clamp actuation/adjustment structure moves the opposing bone engagement member and tip relative to one another, thereby performing the same function in substantially the same way to achieve the same result as the ’368 patent’s disclosed structures. Thus, claim 15 would have been obvious.

198. As explained for claim 10, POSA would have recognized that a “Weber clamp” as disclosed by McGlamry encompasses clamps with threaded shafts. Such clamps were commonly available (and used by surgeons) before July 2015. One example of such a clamp is shown below:



<https://www.youtube.com/watch?v=mLH4s96dErI>, 0:12, 0:54 (last visited December 31, 2025).

199. For the reasons discussed for claim 10, it would have been obvious to select a screw-adjustable Weber clamp for McGlamry's reduction step. *See supra* §VI.H. This would have been an obvious implementation of the Weber clamp disclosed in McGlamry that would yield predictable results.

M. Claim 17

200. Claim 17 depends from claim 15 and recites “wherein the bone engagement member is configured to engage the first metatarsal and the tip is configured to engage the second metatarsal.” As explained for claim 15, McGlamry

discloses these limitations. Thus, the McGlamry-Fallin combination renders claim 17 obvious.

N. Claim 18

201. Claim 18 depends from claim 1 and recites “further comprising a sterile kit containing at least the bone preparation guide and the bone positioning guide.” The McGlamry-Fallin combination renders obvious claim 18.

202. As I explained with respect to claim 1, McGlamry discloses an instrumented surgical procedure for correcting a bunion. *See supra* §§VI.A.1. and VI.A.2. These surgical instruments are commonly arranged in sterile instrument kits, or “packs,” that are opened in the operating room. Ex.1007, 12. The selection of a particular kit depends on the surgery being performed; McGlamry discloses surgical kits for, *inter alia*, forefoot surgery and rearfoot/ankle surgery. *Id.*, 12-13.

203. McGlamry describes the use of pre-arranged trays of reduction clamps, forceps, K-wires, screws, and related instruments for foot and ankle surgery, and further explains that these sets are sterilized and maintained as a kit so the surgeon has all of the instruments and implants for the procedure. *Id.*, 12-14.

204. It would have been obvious to a POSA to include the bone positioning guide and the bone preparation guide in a sterile kit for McGlamry’s procedure. With a sterile kit, both tools would have been readily available, sterile, and ready for use at the start of the procedure. Having a kit with these instruments would reduce

operating room set up time, simplify hospital inventory procedures, and reduce the risk of contamination by minimizing the number of separate packages introduced into the operating room. Ex.1034, [0010] (“Sterilising and packaging each instrument separately is impractical because of the need to maintain organisation, minimise packaging cost and waste and avoid use of excessive space in the operating room.”). This arrangement of instruments would also simplify hospital inventory. Ex.1034, [0002] (“Any surgical procedure typically requires a number of instruments. In order to simplify inventory and procedure in the operating room it is known to group the instruments required in a surgical procedure together in one or more trays.”); Ex.1033, [0266] (“This pre-sterilized combination instrument, cartridge and implant can be packaged with a drill and drill guide so that the medical procedure kit fully supports the surgical technique. Hospital costs savings are achieved because there is no hospital cleaning or sterilization required and the patients and hospital benefit from fewer infections and patient complications.”). This would have been nothing more than the use of known elements according to known methods. The result of a sterile kit would have been predictable and common.

205. A POSA would have reasonably expected to succeed in including a bone preparation guide and bone positioning guide in a sterile kit. Kits of varying sizes would have been known to a surgeon, and thus the size of a kit sufficient to

house such guides would not be a limiting factor. Indeed, McGlamry discloses a kit that includes a bone preparation guide for a forefoot surgery procedure. *See* Ex.1007, Fig.34.3B (showing a kit that includes a bone cutting guide), 381 (“The implant tray has an instrument guide to help the surgeon resect the proper amount of bone and at the proper angles.”). McGlamry also discloses a kit that includes bone reduction clamps for a forefoot surgery such as a metatarsocuneiform arthrodesis, *id.*, 13 (describing a Lewin bone reduction clamp in an example forefoot surgery kit); a Weber clamp is a bone positioning device. *See supra* §VI.A.2. Indeed, in my own experience, it was common, well before 2015, for hospitals to prepare sterile trays with all the tools I needed for a particular surgery. A “sterile kit” would have been consistent with this pre-existing common practice. Thus, this would have been nothing more than the use of a known technique (packaging instruments in a sterile kit) to a known method (McGlamry’s procedure) that was ready for improvement by packaging the instruments in a sterile kit.

O. Claim 19

206. Claim 19 depends from claim 1 and recites “wherein the bone positioning guide is configured to move the first metatarsal in the transverse plane to reduce the intermetatarsal angle to 10 degrees or less and to rotate the first metatarsal in the frontal plane to position sesamoid bones generally parallel to

ground and positioned under the first metatarsal.” The McGlamry-Fallin combination renders obvious claim 19.

207. McGlamry discloses its procedure uses the Weber clamp to “restore first metatarsophalangeal joint congruency and realign[] the sesamoid apparatus in addition to correction of the IM angle.” Ex.1007, 323.

208. McGlamry also explains that the first metatarsal is repositioned in the transverse plane such that it is “parallel with the second metatarsal.” Ex.1007, 325. When the first and second metatarsals are parallel, the IMA is less than 10 degrees.

209. Fallin states that an IMA of “9 degrees or greater” is considered “abnormal.” Ex.1005, [0047]. Accordingly, it would have been obvious to a POSA to correct an IMA in a bunion correction procedure to 10 degrees or less by moving the metatarsal in the transverse plane. *See* Ex.1007, 325 (“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.”).

210. For rotating the metatarsal in the frontal plane, McGlamry discloses that “[t]he surgeon derotates the hallux out of valgus in order to get the nail plate to be parallel with the ground. This derotation allows for the entire hallux, sesamoid, and first metatarsal complex to be rotated from a position of valgus and into a neutral position as one unit.” Ex.1007, 324. When the nail plate is parallel with the ground

and the first metatarsal complex is in a neutral position, the sesamoid bones are generally parallel to the ground and positioned under the first metatarsal as shown in McGlamry's post-operative radiographs:



Id., Figs.31.7, 31.8B.

211. McGlamry teaches correcting a frontal plane malposition such that the “hallux, sesamoid, and metatarsal [are] rotated to a neutral desirable position.” *Id.*, 325. A POSA would recognize that this “neutral desirable position” involves positioning the sesamoid bones generally parallel to ground and positioned under the first metatarsal. Fallin confirms this teaching, as it shows sesamoid bones generally parallel to ground and positioned under the first metatarsal. Ex.1005, Fig.8.

P. Claim 20

212. Claim 20 depends from claim 1 and recites “wherein the guide surface defined by the body of the bone preparation guide comprises a first guide surface configured to be positioned over the proximal end of the first metatarsal and a second guide surface configured to be positioned over the distal end of a medial cuneiform, the first guide surface being configured to guide the tissue removing instrument for cutting the proximal end of the first metatarsal and the second guide surface being configured to guide the tissue removing instrument for cutting the distal end of the medial cuneiform.” Fallin discloses the additional limitations of claim 20 as explained for limitation 1[a]. *See supra* §VI.A.2. Thus, the McGlamry-Fallin combination renders obvious claim 20.

VII. GROUND 2
MCGLAMRY, FALLIN, AND KARTALIAN RENDER CLAIMS 1–30 OF
THE ’368 PATENT OBVIOUS

213. It is my opinion that claims 1–30 of the ’368 patent would have been obvious to a person of ordinary skill in the art by July 14, 2015 in view of McGlamry, Fallin, and Kartalian.

A. Claim 1

1. Preamble

214. As I discussed with respect to Ground 1, both McGlamry and Fallin disclose the preamble of claim 1. *See supra* §VI.A.1.

2. Limitation 1[a]

215. As I discussed with respect to Ground 1, Fallin discloses this limitation.

See supra §VI.A.2.

3. Limitation 1[b]

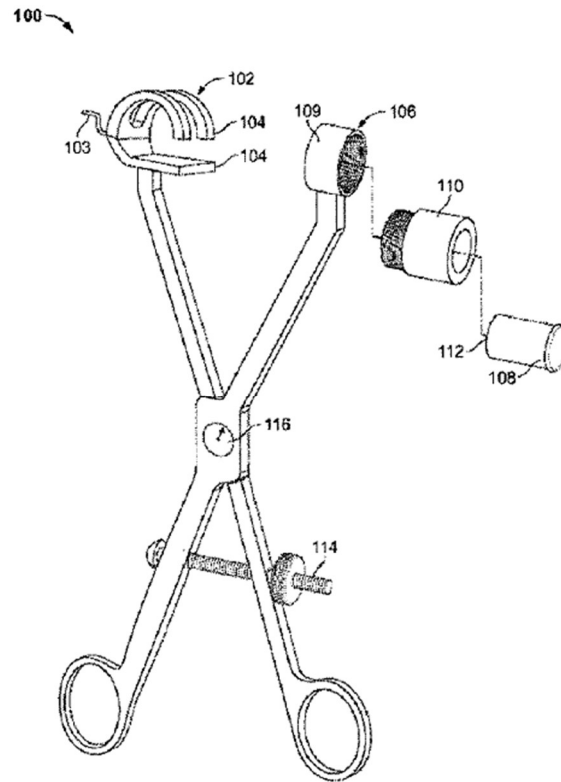
216. As I discussed with respect to Ground 1, McGlamry discloses this limitation. However, if it is found that McGlamry alone does not disclose limitation 1[b], Kartalian does disclose this limitation.

217. As I discussed regarding Ground 1, limitation 1[b] in Section VI.A.3. above, McGlamry discloses moving the metatarsal in the transverse plane to reduce the IMA and rotating it in the frontal plane to correct the bunion deformity. Ex.1007, 324-326.

218. Kartalian also discloses correction of a bunion deformity by moving the first metatarsal in the transverse plane (Ex.1006, 10:46-51 (describing reduction of the IMA via Kartalian's instrument 100)) and rotating the first metatarsal in the frontal plane. *Id.*, 9:66-10:3 (Kartalian's instrument 100 "correcti[ng] ... any rotational deformity (pronation)" of the first metatarsal). In the context of a bunion and a bunion correction procedure, "pronation" refers to a rotation of the metatarsal in the frontal plane.

219. Kartalian further discloses an "instrument 100" that "may act as reduction forceps to align two bones or reduce the distance between the bones, as

desired” and that “allow[s] for correction of any rotational deformity (pronation) when used for surgical correction of a bunion.” *Id.*, 9:66-10:3. As shown below, Kartalian’s instrument is a tenaculum (forceps):



Id., Fig.1 (excerpt).

220. Kartalian’s instrument 100 functions to position the bones by moving the metatarsal in the transverse plane and rotating it in the frontal plane. Ex.1006, 9:66-10:3, 10:46-51. 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 ’368 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 the transverse plane and rotational correction in the frontal plane), in substantially the same way (opposed bone-engaging ends/arms of a tenaculum (forceps) 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).

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

222. Kartalian has features that are specifically designed for bunion correction procedures and would have been desirable for use in McGlamry's procedure. Ex.1006, 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.

223. 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.1006, 2:30-39.

224. 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*, VII.C. (Claim 3).

225. A POSA would have also reasonably expected to succeed in using Kartalian’s instrument in McGlamry’s procedure. 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.1006, 9:66-10:3, 10:43-51; Ex.1007, 325-26, Fig.31.5.

226. Kartalian’s instrument was designed for a bunion correction procedure that is, in many respects, similar to McGlamry’s procedure. Ex.1006, 9:58-10:18,

10:29-62. 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.

227. Given these similarities in structure and use, a POSA would 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.

228. 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 tooling modifications.

4. Limitation 1[c]

229. As I discussed with respect to Ground 1, McGlamry discloses this limitation. *See supra* §VI.A.4.

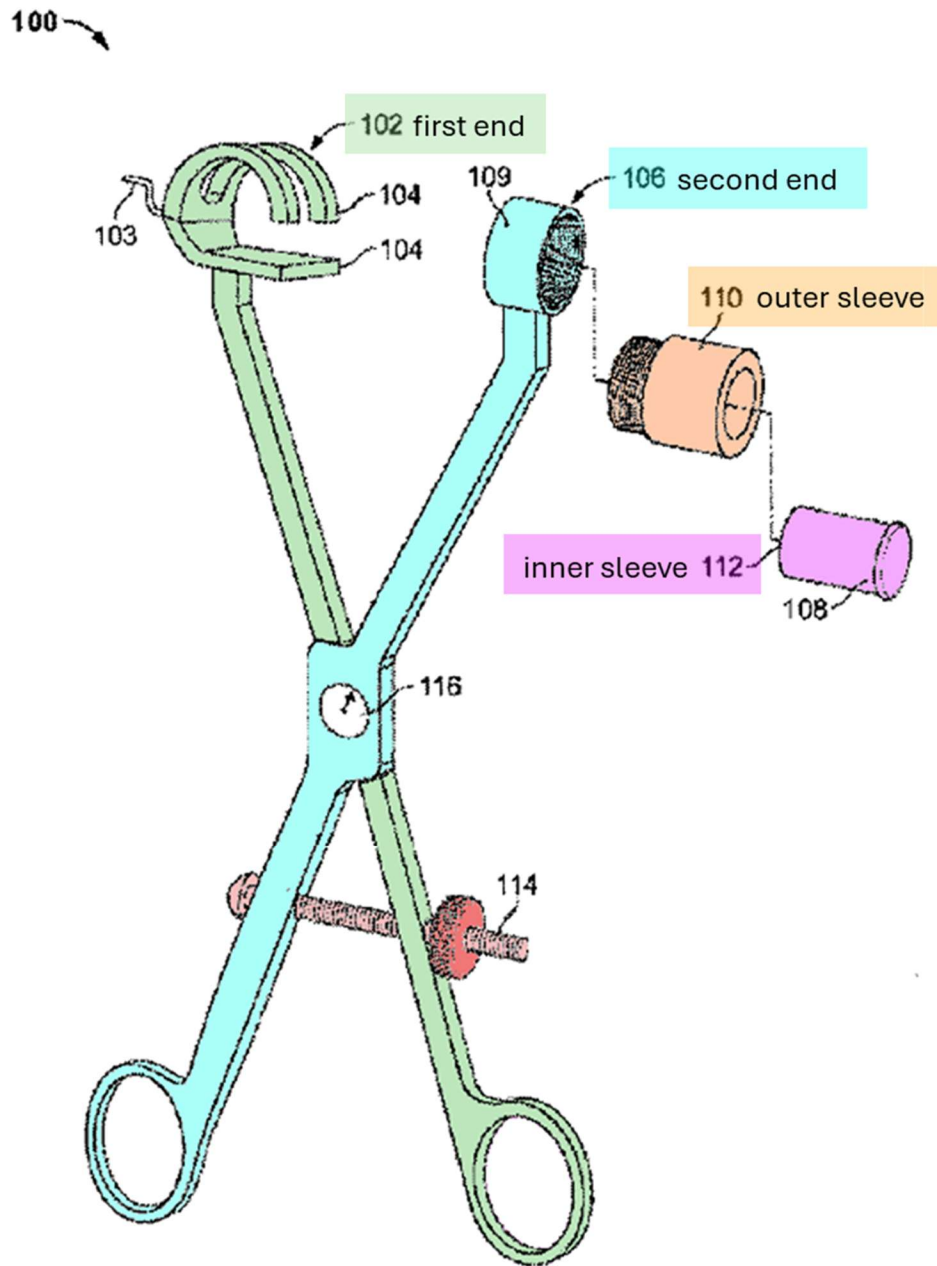
B. Claim 2

230. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 2. *See supra* §VI.B. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

C. Claim 3

231. Claim 3 depends from claim 1 and recites: “wherein the bone positioning guide comprises an opening, and further comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening.” The McGlamry-Fallin-Kartalian combination renders this claim obvious.

232. Kartalian discloses that its instrument 100 (bone positioning guide) has a second end 106 “configured as a cannulated sleeve 108.” Ex.1006, 9:58-60, Fig.1. The sleeve “may be used as a drill guide” and can have a diameter of between 1mm and 4mm. *Id.*, 10:46-62. Kartalian describes using this sleeve 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:

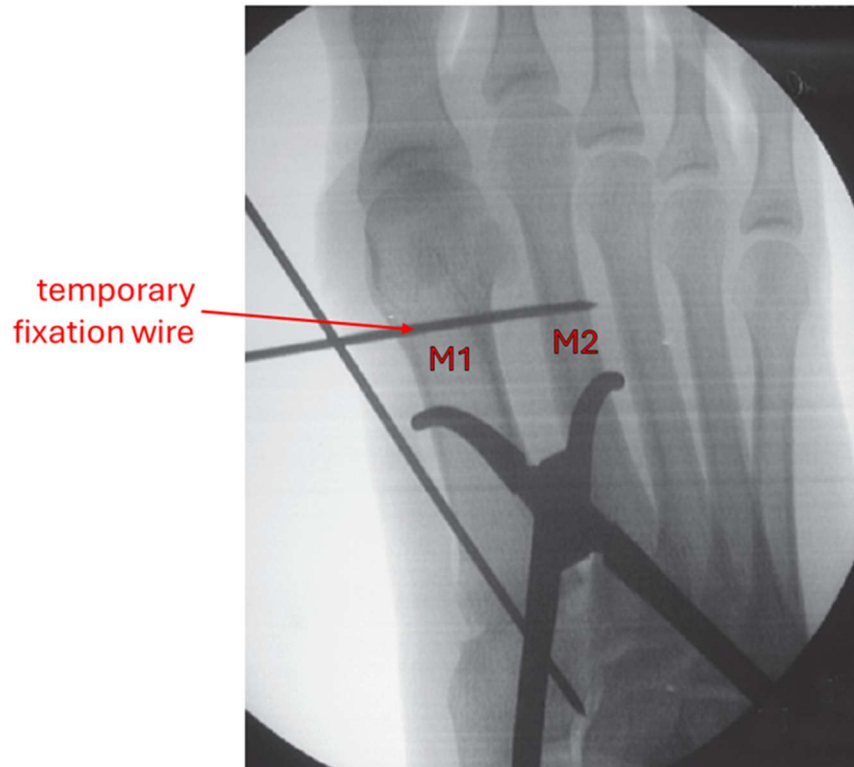


Id., Fig.1 (excerpt) (annotated).

233. Kartalian's sleeve is an opening in the bone positioning guide.

234. McGlamry discloses temporary fixation of the corrected position of the metatarsal using a K-wire inserted through the first and second metatarsals. Ex.1007, 325-26 (“[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.1014, 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 temporary fixation wire—before final fixation. *Id.*, 326-327. Figure 31.5 below depicts the temporary fixation wire.



Ex.1007, Fig.31.5 (annotated).

235. 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) into the second metatarsal and through the sleeve to

temporarily fix the corrected relationship between the first and second metatarsal for fixation. Using Kartalian's sleeve would permit precise positioning of the K-wire while maintaining transverse plane reduction, as required by McGlamry. Ex.1007, 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.1006, 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 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 as use would avoid the K-wire potentially interfering with the placement of permanent fixation devices.

236. This modification would have been a routine and predictable use of Kartalian's sleeve. Kartalian contemplate 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.1006, 8:26-37. 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 sleeve to place a temporary fixation wire into the second metatarsal for the same stabilizing purpose with predictable results. *See* Ex.1028,

[0028]-[0030] (disclosing an opening at a clamp's tip for accommodating a K-wire while the clamp maintains a reduction).

237. A POSA would also reasonably expect to succeed in using Kartalian's sleeve to place a temporary fixation device, such as a K-wire. Kartalian's sleeve structures allow for the receipt of structures of different sizes. *See* Ex.1006, 10:52-62 (describing receipt of 1mm to 4mm drill bits by sleeve 108). K-wires generally have a diameter within this range of acceptable insertable structures. Ex.1035, 2-3 (describing 0.7-1.5mm diameter K-wires).

D. Claim 4

238. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claim 4. *See supra* §VI.C. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

E. Claim 5

239. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claim 5. *See supra* §VI.D. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

F. Claim 6

240. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claim 6. *See supra* §VI.E. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

G. Claim 7

241. As I discussed with respect to Ground 1, Fallin renders the additional limitations of claim 7 obvious. *See supra* §VI.F. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

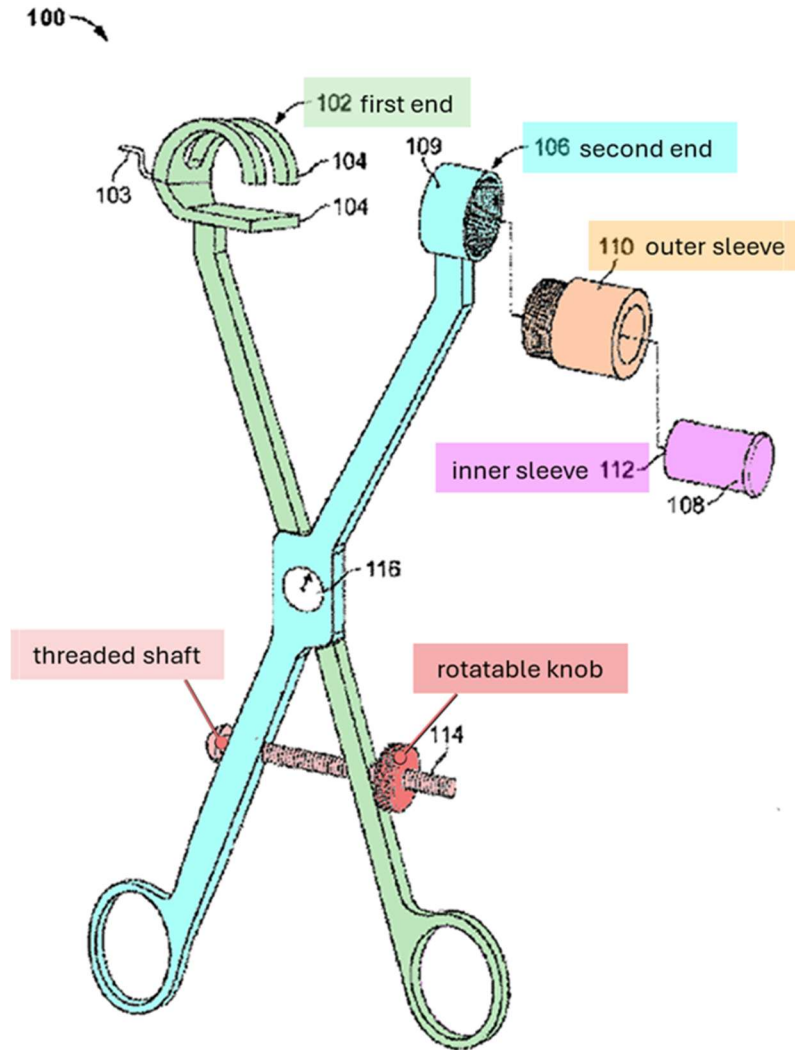
H. Claims 8-9

242. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 8-9. *See supra* §VI.G. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

I. Claim 10

243. The McGlamry-Fallin-Kartalian combination thus renders claim 10 obvious.

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



Ex.1006, Fig.1 (excerpt) (annotated), 8:51-53.

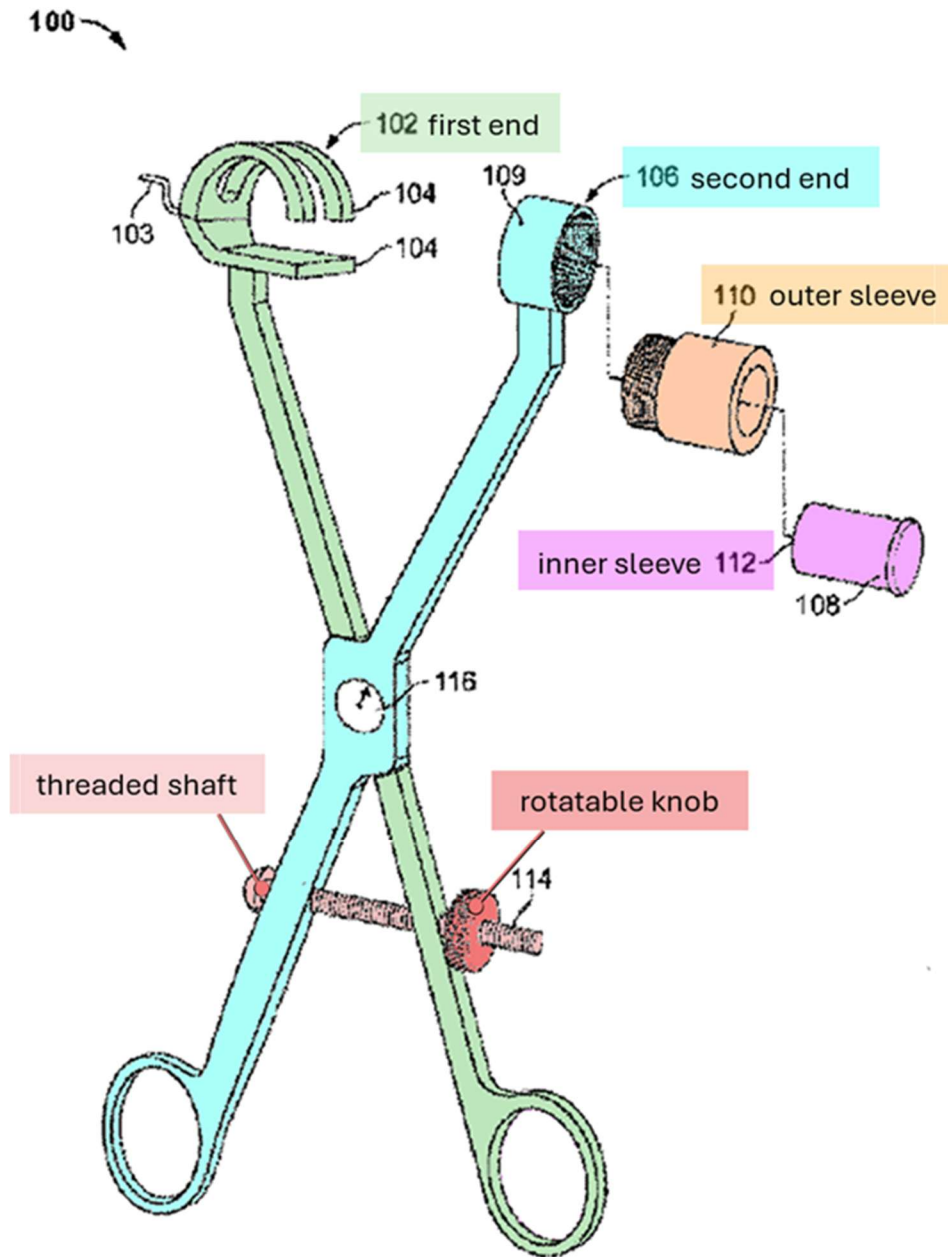
J. Claim 11

245. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 11. *See supra* § VI.I. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

K. Claim 12

246. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious.

247. 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.1006, Fig.1 (excerpt) (color added); *see also id.*, 8:12-14, 8:38-55.

248. A POSA would understand that, as a matter of routine design and manufacturing practice, that Kartalian's instrument is assembled from at least three joinable components (e.g., the threaded shaft, rotatable knob, cannulated sleeves, and forceps). Such an assembly was commonplace for surgical instruments enabled

the pivoting/clamping function. It also would have provided benefits in ease of manufacture, 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.

L. Claims 13-14

249. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claims 13 and 14. *See supra* §VI.K. The McGlamry-Fallin-Kartalian combination thus renders these claims obvious.

M. Claims 15-16

250. The McGlamry-Fallin-Kartalian combination renders claims 15 and 16 obvious.

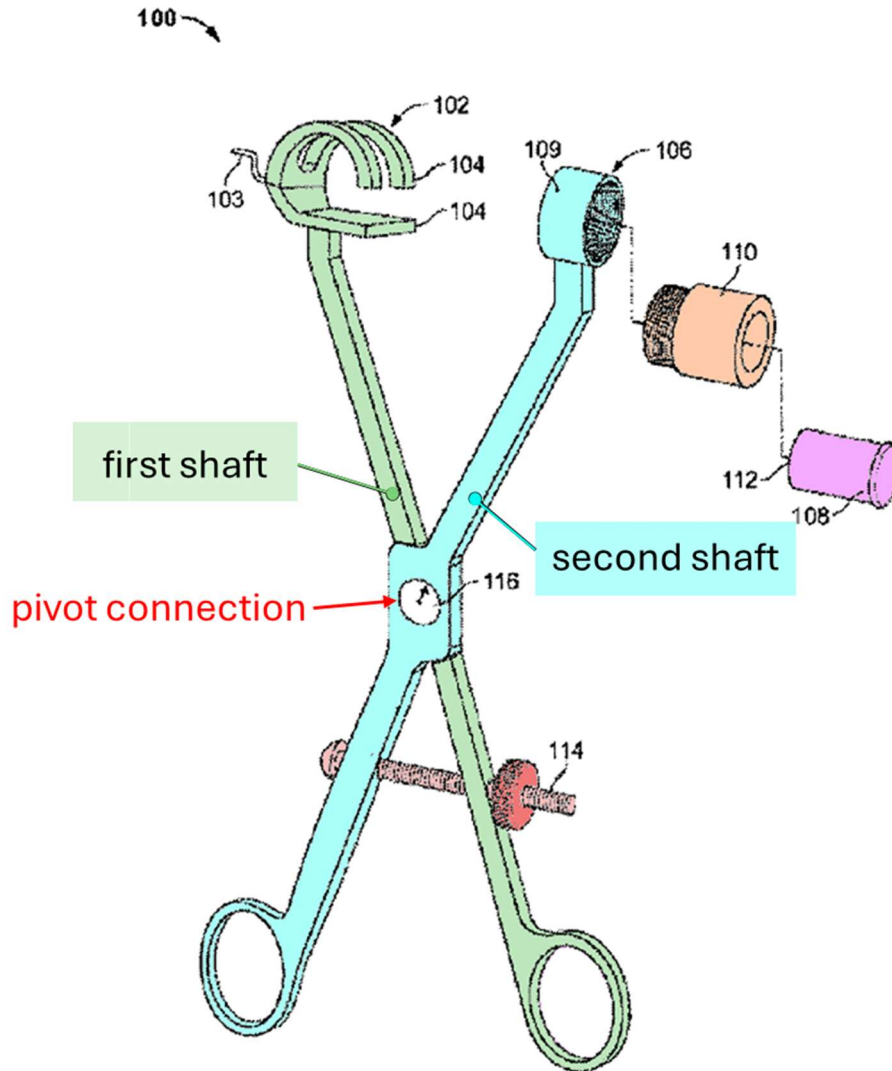
251. Kartalian's instrument (bone positioning guide) includes a bone engagement member, a tip, and a mechanism for moving the bone engagement member and tip relative to one another. For instance, Kartalian's end 106 is a bone engagement member, because this end "may be placed on the proximal first bone (first metatarsal)." Ex.1006, 10:49-51.

252. Kartalian's end 102 is a tip that engages the second metatarsal. *Id.*, 9:24-57 (describing construction of end 102). The '368 patent describes that 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. Ex.1001, 6:48-64. Kartalian

describes its end 102 of instrument 100 having various shapes, including “curved or other shape[d]” plates to engage the bone. Ex.1006, 9:33-45. Thus, end 102 is a tip for engaging the second metatarsal. *Id.*, 9:24-57.

253. Kartalian also discloses a mechanism configured to move the bone engagement member and the tip relative to each other under either construction. A POSA would understand that the shafts of ends 102 and 106 have handles, and when the surgeon moves the handles towards each other, the bone engagement member and tip move relative to one another to reduce the distance between the first metatarsal and second metatarsal. *See* Ex.1006, Fig.1, Panel I. Thus, “[t]he instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” *Id.*, 9:66-10:3.

254. As shown in Figure 1, Panel I below, Kartalian’s instrument 100 is a tenaculum/tong structure that includes pivotably connected first and second shafts:



Ex.1006, Fig.1 (excerpt) (annotated); *see also id.*, 8:51-53.

255. Kartalian also discloses a rotatable knob and threaded shaft as described in Ground 2, Claim 10 above. *See supra* §VII.I. 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 mechanism includes a threaded shaft.

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

N. Claim 17

257. The McGlamry-Fallin-Kartalian combination renders claim 17 obvious.

258. Kartalian’s instrument 100 has a first end 102 configured to engage the second metatarsal and a second end 106 configured to engage the first metatarsal: “first end 102 [tip] may be placed on the distal second bone (second metatarsal) and second end 106 [bone engagement member] may be placed on the proximal bone (first metatarsal).” Ex.1006, 10:49-51.

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

reduction and/or realignment of the first metatarsal to a desired position. *Id.*, 9:66-10:3, 10:46-51; *see also supra* §§VII.M. (discussing Ground 2, claims 15-16).

O. Claim 18

260. The McGlamry-Fallin-Kartalian combination renders claim 18 obvious. The placement of the bone preparation guide and bone positioning guide into a sterile kit would have been obvious for the same reasons explained with respect to the McGlamry-Fallin combination above. *See supra* §VI.N.

261. There are no unique obstacles posed by Kartalian's instrument that would impact its inclusion in a sterile kit, including when substituted for McGlamry's Weber clamp.

P. Claim 19

262. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 19. *See supra* §VI.O.

263. Using Kartalian's instrument as a bone positioning guide would not impact the final position of the metatarsal in McGlamry's procedure. Kartalian discloses an IM angle "in the range of about 6 degrees to about 9 degrees" "[u]nder normal conditions." Ex.1006, 2:3-4. This "normal" range is consistent with McGlamry's desired IMA between the first metatarsal in its corrected position and the second metatarsal. Ex.1007, 323, 325.

264. Further, Kartalian’s instrument corrects rotational mispositioning of the first metatarsal, such as pronation, in the frontal plane. *See supra* §VII.A.3. This is consistent with McGlamry’s procedure for “derotat[ing] the hallux out of valgus in order to get the nail plate to be parallel with the ground” as discussed regarding Ground 1, claim 19. *See supra* §VI.P. Thus, the McGlamry-Fallin-Kartalian combination renders this claim obvious.

Q. Claim 20

265. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claim 20. *See supra* §VI.Q. Thus, the McGlamry-Fallin-Kartalian combination renders claim 20 obvious.

R. Claim 21

266. I performed a comparison of claim 21 to independent claims 1 and dependent claims 2-4. Independent claim 21 recites all the limitations of claim 1 and further includes the limitations of claims 2-4. The McGlamry-Fallin-Kartalian discloses each of these limitations for the reasons I explained for claims 1-4 above.

1. Limitation 21[pre]

267. The preamble of claim 1 recites “[a] metatarsal bunion correction system.” This limitation is identical to claim 1[pre] and is rendered obvious by McGlamry-Fallin-Kartalian for the same reasons. *See supra* §VII.A.1. The reasons why a POSA would have been motivated to combine McGlamry-Fallin-Kartalian

and would have had a reasonable expectation of success in do so are the same as discussed above for claim 1. *See supra* §§VI.A.1. and VII.A.3.

2. Limitation 21[a]

268. Limitation 21[a] recites “a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform, wherein the bone preparation guide comprises a spacer extending downwardly from the body and configured to be placed into a tarsal-metatarsal joint separating the first metatarsal from the medial cuneiform.” The McGlamry-Fallin-Kartalian combination renders obvious limitation 21[a].

269. Fallin discloses “a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform.” *See supra* §VII.A.2 (discussing limitation 1[a] of Ground 2).

270. Fallin also discloses “wherein the bone preparation guide further comprises a spacer extending downwardly from the body and configured to be

placed into the tarsal-metatarsal joint separating the first metatarsal from the medial cuneiform.” *See supra* §VII.D. (discussing claim 4 of Ground 2). The tarsal-metatarsal joint separates the first metatarsal from the medial cuneiform. *See, e.g.*, Ex.1007, 324 (describing resection of tarsal-metatarsal (metatarsocuneiform) joint between articulating surface of first metatarsal and medial cuneiform bones); Ex.1005, Fig.4 (depicting metatarsocuneiform joint 51 between first metatarsal 50 and medial cuneiform 44), [0040] (“The first metatarsal 50 articulates with the first [medial] cuneiform 44 at a metatarsocuneiform (MTC) joint 51.”).

3. Limitation 21[b]

271. Limitation 21[b] recites “a bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal and rotating the first metatarsal in a frontal plane, wherein the bone positioning guide comprises an opening, and further comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening.” McGlamry-Fallin-Kartalian renders obvious limitation 21[b].

272. McGlamry in combination with Kartalian renders obvious “a bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least: moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal and

rotating the first metatarsal in a frontal plane.” *See supra* §VII.A.3. (discussing limitation 1[b] of Ground 2).

273. McGlamry in combination with Kartalian renders obvious “wherein the bone positioning guide comprises an opening, and further comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening.” *See supra* §VII.C. (discussing claim 3 of Ground 2).

4. Limitation 21[c]

274. Limitation 21[c] recites “a pin configured to be inserted into the first metatarsal, the pin being configured to receive a force to rotate the first metatarsal in the frontal plane.” McGlamry discloses limitation 21[c]. *See supra* §VII.B. (discussing claim 2 of Ground 2).

5. Limitation 21[d]

275. Limitation 21[d] recites “at least one fixation device positionable across the tarsal-metatarsal joint, the at least one fixation device being configured to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.” McGlamry discloses limitation 21[d]. *See supra* §VII.A.4 (discussing limitation 1[c] of Ground 2).

S. Claim 22

276. Claim 22 depends from claim 21 and recites “wherein the body extends from a first end configured to be positioned over the first metatarsal to a second end

configured to be positioned over the medial cuneiform, the body including a first fixation aperture configured to receive a first fixation pin and a second fixation aperture configured to receive a second fixation pin, wherein the first fixation aperture and the second fixation aperture are generally parallel to each other.” The McGlamry-Fallin-Kartalian combination renders claim 22 obvious.

277. Claim 22 recites substantively the same additional limitations as claims 5 and 6. Fallin discloses “wherein the body extends from a first end configured to be positioned over the first metatarsal to a second end configured to be positioned over the medial cuneiform, the body including a first fixation aperture configured to receive a first fixation pin and a second fixation aperture configured to receive a second fixation pin.” *See supra* §VII.E. (discussing claim 5 of Ground 2).

278. Fallin discloses “wherein the first fixation aperture and the second fixation aperture are generally parallel to each other.” *See supra* §VII.F. (discussing claim 6 of Ground 2).

T. Claim 23

279. Claim 23 depends from claim 22 and recites “wherein the body further comprises a third fixation aperture that is skewed relative to the first fixation aperture and the second fixation aperture, the third fixation aperture being configured to receive a third fixation pin.” Claim 23 recites the same substantive additional

limitations as claim 7. The McGlamry-Fallin-Kartalian combination renders claim 23 obvious. *See supra* §VII.G. (discussing claim 7 of Ground 2).

U. Claim 24

280. Claim 24 depends from claim 21 and recites “wherein the bone positioning guide comprises a rotatable knob connected to a threaded shaft.” Claim 24 recites substantively the same additional limitations as claim 10. Kartalian discloses the additional limitations of claim 24. *See supra* §VII.I. (discussing claim 10 of Ground 2). The McGlamry-Fallin-Kartalian combination renders claim 24 obvious.

V. Claim 25

281. Claim 25 depends from claim 21 and recites “wherein the at least one fixation device comprises one or more of a bone plate, a screw, a staple, and an intramedullary implant.” Claim 25 recites substantively the same additional limitations as claim 11. McGlamry discloses the additional limitations of claim 25. *See supra* §VII.J. (discussing claim 11 of Ground 2). The McGlamry-Fallin-Kartalian combination renders claim 25 obvious.

W. Claim 26

282. Claim 26 depends from claim 21 and recites “further comprising the tissue removing instrument, wherein the tissue removing instrument comprises a saw blade.” Claim 26 recites substantively the same additional limitations as claims 13

and 14. Fallin discloses the additional limitations of claim 26. *See supra* §VII.L. (discussing claims 13 and 14 of Ground 2). The McGlamry-Fallin-Kartalian combination renders claim 26 obvious.

X. Claim 27

283. Claim 27 depends from claim 21 and recites “wherein the bone positioning guide comprises: a bone engagement member; a tip; and a mechanism configured to move the bone engagement member and the tip relative to each other.” Claim 27 recites substantively the same additional limitations as claim 15. Kartalian discloses the additional limitations of claim 27. *See supra* §VII.M. (discussing claim 15 of Ground 2). The McGlamry-Fallin-Kartalian combination renders claim 27 obvious.

Y. Claim 28

284. Claim 28 depends from claim 27 and recites “wherein the mechanism comprises a threaded shaft.” Claim 28 recites substantively the same additional limitations as claim 16. Kartalian discloses the additional limitations of claim 28. *See supra* §VII.M. (discussing claim 16 of Ground 2). The McGlamry-Fallin-Kartalian combination renders claim 28 obvious.

Z. Claim 29

285. Claim 29 depends from claim 21 and recites “further comprising a sterile kit containing at least the bone preparation guide and the bone positioning

guide.” Claim 29 recites substantively the same additional limitations as claim 18. The McGlamry-Fallin-Kartalian combination renders claim 29 obvious. *See supra* §VII.O. (discussing claim 18 of Ground 2).

AA. Claim 30

286. Claim 30 depends from claim 21 and recites “wherein the guide surface defined by the body of the bone preparation guide comprises a first guide surface configured to be positioned over the proximal end of the first metatarsal and a second guide surface configured to be positioned over the distal end of a medial cuneiform, the first guide surface being configured to guide the tissue removing instrument for cutting the proximal end of the first metatarsal and the second guide surface being configured to guide the tissue removing instrument for cutting the distal end of the medial cuneiform.” Claim 30 recites substantively the same additional limitations as claim 20. Fallin discloses the additional limitations of claim 30. *See supra* §VII.Q. (discussing claim 20 of Ground 2). The McGlamry-Fallin-Kartalian combination renders claim 30 obvious.

VIII. GROUND 3
MCGLAMRY, FALLIN, AND SCHMUCK RENDER CLAIMS 3 AND 21–30
OF THE ’368 PATENT OBVIOUS

287. It is my opinion that claims 3 and 21–30 of the ’368 patent would have been obvious to a person of ordinary skill in the art by July 14, 2015 in view of McGlamry, Fallin, and Schmuck.

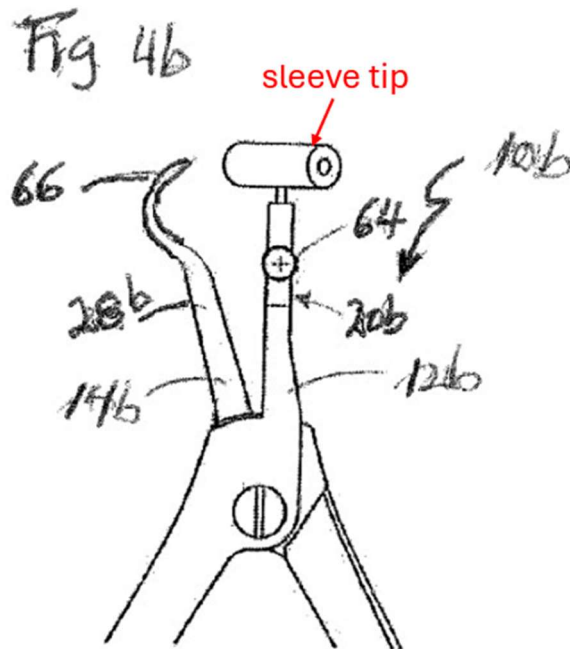
A. Claim 3

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

289. As I explained regarding limitation 1[b] in Ground 1, McGlamry discloses the use of a bone positioning guide—a Weber clamp—for the claimed movements of the first metatarsal. *See supra* §VI.A.3.

290. Schmuck also discloses a “surgical reduction clamp.” Ex.1028, Title, [0002]. A POSA would recognize that a reduction clamp like Schmucks could be used for the positioning of bones in an arthrodesis procedure. *See* Ex.1007, 325.

291. Schmuck describes a reduction clamp in which one arm of the clamp includes a tip “formed as a sleeve for accommodating a surgical wire, such as a k-wire.” Ex.1028, [0028]-[0029], [0011]. Figure 4b below shows one embodiment of Schmuck’s reduction clamp with a sleeve tip.



Ex.1028, Fig.4b; *see also id.*, [0056] (describing components of Figure 4b embodiment).

292. Schmuck's sleeve tip "accommodat[es] a surgical wire." *Id.*, [0028]. This wire extends through the sleeve while the clamp is used to reduce and hold bone fragments. *See id.*, [0030] (describing the capability of the sleeve to "allow[] the operating surgeon to align bone fragments in a surgical procedure with the help of, for example, k-wires."). Schmuck's sleeve is an "opening" configured to receive a fixation wire for passage into the underlying bone.

293. It would have been obvious to configure McGlamry's Weber clamp to include a sleeve/opening like in Schmuck's clamp for the insertion of a K-wire through that sleeve and into the second metatarsal while the clamp maintains the reduction. Schmuck's clamp and McGlamry's Weber clamp are both bone reduction

clamps. Ex.1028, [0002] (Schmuck); *see also supra* §§VI.A.3. and VI.L. (explaining McGlamry’s Weber clamp is a kind of bone reduction clamp).

294. McGlamry discloses inserting a second K-wire “into the lesser metatarsal” while maintaining the correction position “in all three planes,” including to “prevent derotation in the frontal plane and maintain[] reduction in the transverse plane.” Ex.1007, 326. The second metatarsal is the adjacent “lesser metatarsal” referred to in McGlamry for stabilizing the first metatarsal’s corrected relationship. This is also illustrated in Figure 31.5. Thus, a POSA would recognize that McGlamry’s disclosure encompasses placing a K-wire into the second metatarsal.

295. A POSA would be motivated to incorporate a sleeve into McGlamry’s Weber clamp through which a K-wire can be inserted. Adding Schmuck’s sleeve provides an opening that guides the K-wire along a controlled trajectory into the second metatarsal while the clamp shifts relative to the second metatarsal during temporary fixation. This was nothing more than the application of a known wire-guidance technique in a reduction clamp to McGlamry’s reduction clamp for a predictable improvement of interoperative stability. The use of temporary fixation like this addresses a known potential risk of clamp movement relative to the second metatarsal. This would have been nothing more than a routine design choice for which a POSA would have had a reasonable expectation of success.

B. Claim 21

296. Independent claim 21 recites all the limitations of claim 1 and further recites the limitations of claims 2-4. One of McGlamry or Fallin renders each of the limitations of claims 1-2 and 4 obvious as explained in Ground 1, and Schmuck discloses the additional limitations of claim 3 as explained immediately above. *See supra* §§VI.A., VI.B., VI.C., and VIII.A. Accordingly, the McGlamry-Fallin-Schmuck combination renders this claim obvious.

C. Claim 22

297. Claim 22 recites substantively the same additional limitations as claims 5-6. As I discussed with respect to Ground 1, Fallins discloses the limitations of claims 5-6. *See supra* §§VI.D. and VI.E. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

D. Claim 23

298. Claim 23 recites substantively the same additional limitations as claim 7. As I discussed with respect to Ground 1, Fallin renders obvious the additional limitations of claim 7. *See supra* §VI.F. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

E. Claim 24

299. Claim 24 recites substantively the same additional limitations as claim 10. McGlamry renders obvious the additional limitations of claim 10. *See supra*

§VI.H. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

F. Claim 25

300. Claim 25 recites substantively the same additional limitations as claim 11. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 11. *See supra* §VI.I. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

G. Claim 26

301. Claim 26 recites substantively the same additional limitations as claims 13-14. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claims 13-14. *See supra* §VI.K. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

H. Claim 27

302. Claim 27 recites substantively the same additional limitations as claim 15. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 15. *See supra* §VI.L. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

I. Claim 28

303. Claim 28 recites substantively the same additional limitations as claim 16. As I discussed with respect to Ground 1, McGlamry discloses the additional

limitations of claim 16. *See supra* §VI.L. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

J. Claim 29

304. Claim 29 recites substantively the same additional limitations as claim 18. As I discussed with respect to Ground 1, these limitations would have been obvious. *See supra* §VI.N. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

K. Claim 30

305. Claim 30 recites substantively the same additional limitations as claim 20. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claim 20. *See supra* §VI.P. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious.

IX. GROUND 4
MCGLAMRY, FALLIN, KARTALIAN, AND SCHMUCK RENDER
CLAIMS 3 AND 21–30 OF THE '368 PATENT OBVIOUS

306. It is my opinion that claims 3 and 21–30 of the '368 patent would have been obvious to a person of ordinary skill in the art by July 14, 2015 in view of McGlamry, Fallin, Kartalian, and Schmuck.

A. Claim 3

307. As I explain with respect to claim 3 in Ground 3, McGlamry in view of Schmuck discloses a bone positioning guide comprises an opening, and further

comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening. *See supra* §VIII.A.

308. Schmuck discloses a sleeve on a clamp that is used to accommodate a surgical wire. *See* Ex.1028, [0011], [0028]-[0029], Fig.4b. Further, Schmuck's K-wire extends through the sleeve while the clamp is used to reduce and hold bone fragments. *See id.*, [0030] (describing the capability of the sleeve to "allow[] the operating surgeon to align bone fragments in a surgical procedure with the help of, for example, k-wires.").

309. It would have been a known, predictable design choice to incorporate a wire-accommodating sleeve, like Schmuck's, into a bone reduction clamp such as Kartalian's bone reduction instrument (bone positioning guide). *See supra* §VIII.A. (discussing claim 3 of Ground 3). Kartalian discloses a bone positioning guide (instrument 100) with an opening (sleeve 108) of end 106 for receiving a fixation structure. *See supra* §VII.C. (discussing claim 3 of Ground 2). A POSA would have been motivated to modify Kartalian's opening to function as a wire guide for McGlamry's temporary fixation wire, as doing so would improve the accuracy of the fixation wire's placement and thus the stability of the moved position of the first metatarsal. *See* Ex.1007, 325-326. This configuration would allow the reduction instrument to hold alignment while the wire is placed along a controlled trajectory

without changing the underlying reducing and fixation techniques taught by Kartalian and McGlamry. *See* Ex.1005, 9:66-10:3, 10:46-51; Ex.1007, 325-326.

310. A POSA would reasonably expect to succeed in modifying Kartalian's instrument to include a wire guide like Schmuck's sleeve given the similarities between that structure and Kartalian's sleeve 108. *Compare* Ex.1005, Fig.1 with Ex.1028, Fig.4b. The use of a sleeve to place a K-wire would have been a routine process in view of Schmuck's disclosure. As such a POSA would have had a reasonable expectation of success in using the instrument.

311. Thus, the McGlamry-Fallin-Kartalian-Schmuck combination renders claim 3 obvious.

B. Claim 21

312. Independent claim 21 recites all the limitations of claim 1 and further recites the limitations of claims 2-4. One of McGlamry, Fallin, or Kartalian renders each of the limitations of claims 1-2 and 4 obvious as explained in Grounds 1 and 2, and Schmuck discloses the additional limitations of claim 3 as explained immediately above. *See supra* §§VII.R. and VIII.A. Accordingly, the McGlamry-Fallin-Kartalian-Schmuck combination renders this claim obvious.

C. Claim 22

313. Claim 22 recites substantively the same additional limitations as claims 5-6. As I discussed with respect to Ground 1, Fallin discloses the limitations of

claims 5-6. *See supra* §§VI.D. and VI.E. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

D. Claim 23

314. Claim 23 recites substantively the same additional limitations as claim 7. As I discussed with respect to Ground 1, Fallin renders obvious the additional limitations of claim 7. *See supra* §VI.F. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

E. Claim 24

315. Claim 24 recites substantively the same additional limitations as claim 10. As I discussed with respect to Grounds 1 and 2, McGlamry and Kartalian each renders obvious the additional limitations of claim 10. *See supra* §§VI.H and VII.I. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

F. Claim 25

316. Claim 25 recites substantively the same additional limitations as claim 11. As I discussed with respect to Ground 1, McGlamry discloses the additional limitations of claim 11. *See supra* §VI.I. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

G. Claim 26

317. Claim 26 recites substantively the same additional limitations as claims 13-14. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claims 13-14. *See supra* §VI.K. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

H. Claim 27

318. Claim 27 recites substantively the same additional limitations as claim 15. As I discussed with respect to Grounds 1 and 2, McGlamry and Kartalian each discloses the additional limitations of claim 15. *See supra* §§VI.L. and VII.M. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

I. Claim 28

319. Claim 28 recites substantively the same additional limitations as claim 16. As I discussed with respect to Grounds 1 and 2, McGlamry and Kartalian each discloses the additional limitations of claim 16. *See supra* §§VI.L. and VII.M. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

J. Claim 29

320. Claim 29 recites substantively the same additional limitations as claim 18. As I discussed with respect to Ground 1, these limitations would have been obvious. *See supra* §VI.N. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

K. Claim 30

321. Claim 30 recites substantively the same additional limitations as claim 20. As I discussed with respect to Ground 1, Fallin discloses the additional limitations of claim 20. *See supra* §VI.P. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious.

X. GROUND 5
CLAIM 7 WOULD HAVE BEEN OBVIOUS OVER THE GROUND 1 OR 2
COMBINATIONS FURTHER IN VIEW OF JENKINS

322. In view of the background provided above, and further in view of the reasons set forth below, it is my opinion that claims 7 and 23 of the '368 patent would have been obvious to a person of ordinary skill in the art as of July 14, 2015 in view of McGlamry, Fallin, and Jenkins, as well as McGlamry, Fallin, Kartalian, and Jenkins.

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

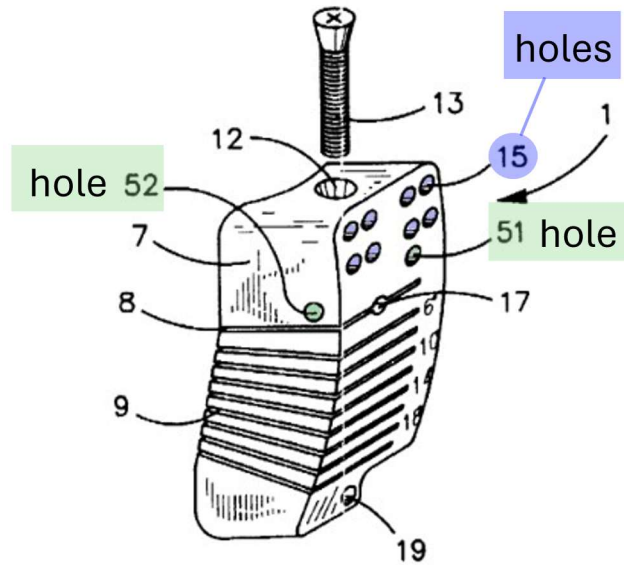
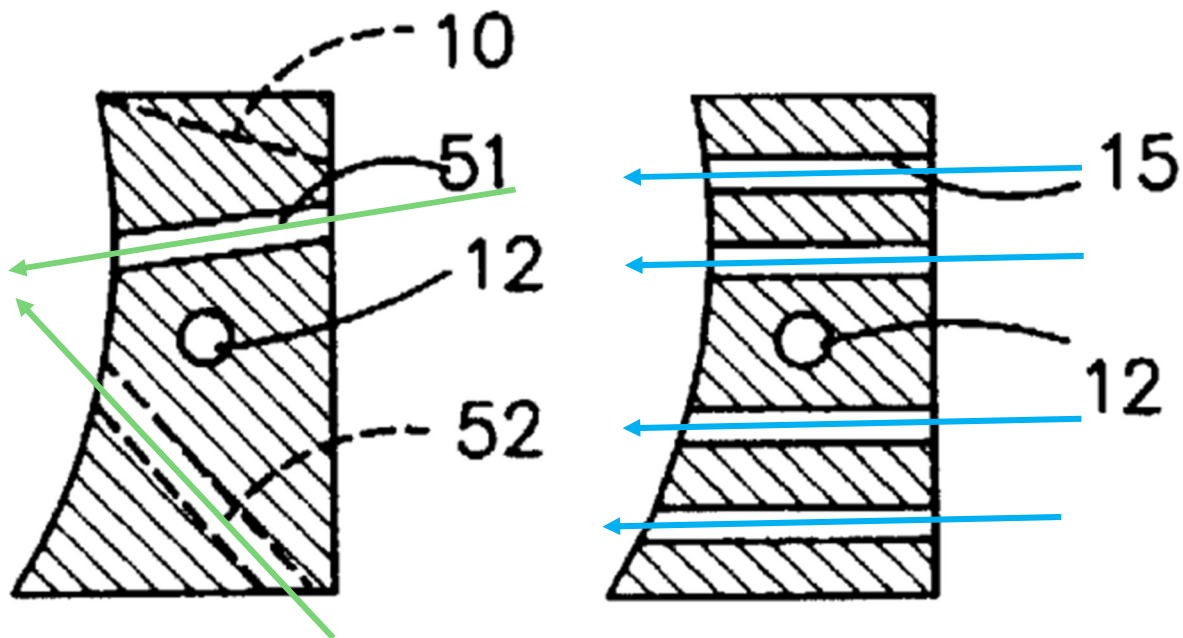


FIGURE 1A

Id., Fig.1A, 5:61-6:13, 7:20-40.

324. Jenkins describes that “pins [are] placed into guide holes 15” and “serve as the means for holding and stabilizing the osteotomy guide 1.” *Id.*, 6:3-13. Similarly, “an additional method of fixation for the osteotomy guide 1 is available through the use of one or more pins 22 placed through angular fixation holes 51,52.” *Id.*, 7:20-22. “Fixation holes 51,52 are formed through the body 7 of the osteotomy guide 1 in directions that are non-parallel to guide holes 15 and non-parallel to one another.” *Id.*, 7:22-25.



Id., Figs.1C-1D. The arrows in the above figure illustrate the angular orientation of the holes. “When a single pin 22 is used in either of fixation holes 51,52, the guide is prevented from sliding along the pins 22 in guide holes 15,” resulting in “more stable positioning of the osteotomy guide.” *Id.*, 7:30-32, Abstract.

325. Claim 7 of the ’368 patent depends from claim 6 and recites: “wherein the body further comprises a third fixation aperture that is skewed relative to the first fixation aperture and the second fixation aperture, the third fixation aperture being configured to receive a third fixation pin.”

326. As I explain with respect to claim 5 in Ground 1, Fallin discloses a guide body with distal apertures for fixing the guide over the metatarsal and proximal apertures for fixing the guide over the cuneiform, all of which receive pins. *See supra* §VI.D.

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

328. A POSA would have been motivated to modify Fallin’s osteotomy guide body to have its third fixation aperture be skewed relative to its first and second fixation apertures. This would achieve the same benefits described in Jenkins. For example, Jenkins’ identifies that the skewed fixation aperture provides stability. This would have desirable to a POSA using Fallin’s osteotomy guide, and would be consistent with Fallin’s goal of precise, repeatable cuts. Ex.1005, [0062]. Using a skewed aperture would prevent the guide from sliding off the other pins unintentionally.

329. Further, modifying Fallin’s osteotomy guide body to have a fixation aperture where its corresponding bore is skewed relative to the corresponding bore of other fixation apertures would be a simple design modification in the direction of the drill forming the fixation aperture bores. This kind of design modification would have been straightforward for a POSA in light of Jenkins’ disclosure.

XI. GROUND 6
CLAIM 23 WOULD HAVE BEEN OBVIOUS OVER THE GROUND 2-4
COMBINATIONS AND JENKINS

330. Any of the McGlamry-Fallin-Kartalian, McGlamry-Fallin-Schmuck, or McGlamry-Fallin-Kartalian-Schmuck combinations, in view of Jenkins, renders obvious the additional limitations of claim 23 for the reasons explained with respect to claim 7. *See supra* §IX (discussing Ground 5).

331. Implementing the skewed bore corresponding to a third fixation aperture to the osteotomy guide of Fallin would have been within the skill of a POSA as explained in Section VI.F. above.

XII. CONCLUSION

332. For the foregoing reasons, it is my opinion that, in July 2015, a POSITA would have found Claims 1–30 of the '368 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.

333. 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.

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

Executed: December 31, 2025 By: Steven Neufeld,
Dr. Steven K. Neufeld