

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

Case PGR2026-00031
Patent 12,349,941

**DECLARATION OF STEVEN K. NEUFELD, M.D.
IN SUPPORT OF PETITION FOR POST-GRANT REVIEW OF
U.S. PATENT NO. 12,349,941**

<p><i>Paragon 28 v. Treace Medical Concepts</i> PGR2026-00031 Paragon Ex. 1003</p>

I. BACKGROUND AND QUALIFICATIONS.....	3
A. Experience and Qualifications	3
B. Relevant Legal Standards.....	5
1. Claim Construction	6
2. Obviousness	7
C. Person of Ordinary Skill in the Art	10
II. OVERVIEW OF THE PRIOR ART	14
A. Relevant Human Foot Anatomy.....	14
B. Instrumented Bunion Correction.....	18
C. Dayton’s Bunion Correction Procedure	21
D. Known Bone Positioning Devices.....	24
E. Known Bone Cutting Guides	29
III. THE ’941 PATENT	32
A. Overview	32
1. Bone Positioning Device.....	33
2. Bone Cutting Guide	34
3. Bone Connector.....	34
B. Prosecution History	35
IV. CLAIM CONSTRUCTION	35
A. “bone positioning device”	35

B.	“bone connector”	36
C.	“cutting tool”	37
V.	THE PRIOR ART	38
VI.	GROUND 2: CLAIMS 1-27 WOULD HAVE BEEN OBVIOUS OVER DAYTON, WAISMAN, AND PALMER.....	39
A.	Claim 1	39
1.	Preamble.....	40
2.	Limitation 1[a]	41
3.	Limitation 1[b]	51
4.	Limitation 1[c]	59
5.	Limitation 1[d]	62
6.	Limitation 1[e]	64
7.	Limitation 1[f].....	65
B.	Claim 2	67
C.	Claim 3	68
D.	Claim 4	68
E.	Claim 5	71
F.	Claim 6	73
G.	Claim 7	75
H.	Claim 8	77
I.	Claim 9	80
J.	Claim 10	82

K.	Claim 11	84
L.	Claim 12	85
M.	Claim 13	86
N.	Claim 14	87
O.	Claim 15	88
P.	Claim 16	89
Q.	Claim 17	90
R.	Claim 18	92
	1. Preamble.....	92
	2. Limitation 18[a]	93
	3. Limitation 18[b]	93
	4. Limitation 18[c]	94
	5. Limitation 18[d]	94
	6. Limitation 18[e]	94
	7. Limitation 18[f].....	95
	8. Limitation 18[g]	95
S.	Claim 19	95
T.	Claim 20	96
U.	Claim 21	96
V.	Claim 22	96
W.	Claim 23	97

X.	Claim 24	97
Y.	Claim 25	97
Z.	Claim 26	98
AA.	Claim 27	98
VII. GROUND 3: CLAIMS 1-27 WOULD HAVE BEEN OBVIOUS		
	OVER DAYTON, TAYLOR, AND PALMER	98
A.	Claim 1	99
1.	Preamble.....	99
2.	Limitation 1[a]	99
3.	Limitation 1[b].....	105
4.	Limitation 1[c]	106
5.	Limitation 1[d].....	107
6.	Limitation 1[e]	107
7.	Limitation 1[f].....	108
B.	Claims 2-5	108
C.	Claim 6	109
D.	Claims 7-15	110
E.	Claim 16	110
F.	Claim 17	111
G.	Claim 18	113
1.	Preamble and Limitations 18[a]-18[d].....	113
2.	Limitation 18[e]	113

3.	Limitations 18[f]-18[g]	114
H.	Claims 19-27	114
VIII.	GROUND 4: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, ORSAK, AND PALMER.....	114
A.	Claim 1	115
1.	Preamble.....	115
2.	Limitation 1[a]	115
3.	Limitation 1[b]	124
4.	Limitation 1[c]	125
5.	Limitation 1[d]	125
6.	Limitation 1[e]	128
7.	Limitation 1[f].....	128
B.	Claims 2-5	129
C.	Claim 6	129
D.	Claims 7-15	130
E.	Claim 16	131
F.	Claim 17	133
G.	Claim 18	135
1.	Preamble and Limitations 18[a]-18[d].....	135
2.	Limitation 18[e]	135
3.	Limitations 18[f]-18[g]	135
H.	Claims 19-27	135

IX. GROUNDS 5-6: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, ORSAK, PALMER, AND WAISMAN/TAYLOR.....	136
X. GROUNDS 7-11: CLAIMS 1-27 ARE OBVIOUS OVER THE GROUNDS 2-6 COMBINATIONS WITH ORBAY SUBSTITUTED FOR PALMER	137
A. Claim 1	138
1. Preamble.....	138
2. Limitation 1[a]	138
3. Limitation 1[b].....	139
4. Limitation 1[c]	144
5. Limitations 1[d]-1[f]	145
B. Claims 2-4	146
C. Claim 5	146
D. Claim 6	148
E. Claim 7	149
F. Claim 8	151
G. Claim 9	153
H. Claim 10	155
I. Claim 11	157
J. Claim 12	158
K. Claim 13	159
L. Claim 14	160
M. Claims 15-17	160

N.	Claim 18	160
1.	Preamble.....	160
O.	Claims 19-27	162
XI.	GROUND 12-16: CLAIMS 1-27 WOULD HAVE BEEN OBVIOUS OVER ANY OF GROUNDS 2-6 IN COMBINATION WITH ORBAY	162
XII.	CONCLUSION.....	164

I, Steven K. Neufeld do hereby declare:

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

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

3. In preparing this Declaration, I considered the following materials:

Exhibit No.	Description
1001	U.S. Patent No. 12,349,941 to Dayton, et al. (“the ’941 patent”)
1002	File History of U.S. Patent Application No. 18/615,875
1003	This exhibit number is not used in this Declaration
1004	Curriculum Vitae of Steven K. Neufeld, M.D.
1005	Dayton, Paul, Mindi Feilmeier, Merrell Kauwe, and Jordan Hirschi, “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,” Journal of Foot and Ankle Surgery, Vol. 52, No. 3 (May-June 2013): 348-354 (“Dayton”)
1006	International Appl. Publ. No. 2012/004798 to Waisman (“Waisman”)
1007	U.S. Patent No. 5,702,389 to Taylor, et al. (“Taylor”)
1008	U.S. Publication No. 2012/0029575 to Orsak, et al. (“Orsak”)
1009	International Appl. Publ. No. 2012/103335 to Palmer, et al. (“Palmer”)
1010	U.S. Publication No. 2011/0288550 to Orbay, et al. (“Orbay”)

Exhibit No.	Description
1011	<i>McGlamry's Comprehensive Textbook of Foot and Ankle Surgery</i> , 4th ed. 2 vols. Edited by E. Dalton McGlamry, Joe T. Southerland, and Daniel F. Vickers. Chapters 1, 31, 34, 36, and 55. Philadelphia, PA: Wolters Kluwer Health, 2013 (“McGlamry”)
1012	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
1013	Declaration of Michelle L. Warmath for Translation of European Patent App. Publ. No. 1508316 (“Augoyard”)
1014	English Translation of Augoyard from Ex. 1013
1015	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1016	Cottom, James M. and Anand M. Vora. “Fixation of Lapidus Arthrodesis with a Plantar Interfragmentary Screw and Medial Locking Plate: A Report of 88 Cases.” <i>The Journal of Foot and Ankle Surgery</i> , Vol. 52, No. 4 (July-August 2013): 465-469 (“Cottom”)
1017	Baravarian, Babak, Gary B. Briskin, and Patrick Burns, “Lapidus Bunionectomy: Arthrodesis of the First Metatarsocunieiform Joint,” <i>Clinics in Podiatric Medicine and Surgery</i> , Vol. 21, No. 1, (January 2004): 97-111 (“Baravarian”)
1018	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 Clin. Orthopaedics 119-135 (1960)
1019	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. Surgery Gynecology & Obstetrics 183–191 (1934)
1020	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) Clinics Podiatric Med. & Surgery 486–496 (1996)
1021	Declaration of Sylvia Hall-Ellis, Ph.D.
1022	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1023	U.S. Patent No. 4,988,349 to Pennig (“Pennig”)

Exhibit No.	Description
1024	U.S. Patent App. Publ. No. 2009/0118733 to Orsak et al. (“Orsak-733”)
1025	U.S. Patent App. Publ. No. 2009/0198279 to Zhang et al. (“Zhang”)
1026	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)

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 correction and foot & ankle fusion.

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 U.S. Patent No. 12,349,941 (“the ’941 patent”, Ex.1001) would have been obvious

to a person of ordinary skill in the art (“POSA”) at the time of the alleged invention, in view of the prior art.

17. The opinions I am expressing in this Declaration are based on the application of my training and technical knowledge and experience to the evaluation of certain prior art to the ’941 patent.

18. I am not an expert in patent law. Attorneys from Morgan, Lewis & Bockius, LLP have provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of how I must apply current principles related to my analysis.

1. Claim Construction

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

20. 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 its ordinary and customary meaning ascribed to it by a POSA 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.

2. Obviousness

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

22. In determining the scope and content of the prior art, I understand that a reference is considered analogous prior art if it falls within the field of the inventor’s endeavor.¹ In addition, a reference is relevant prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A

¹ The ’941 patent specification defines the “TECHNICAL FIELD” as “devices and methods for positioning and cutting bones.” Ex.1001, 1:22-25. The ’941 patent claims are directed to “method[s] of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform. *Id.*, 6:24-26, 7:42-44.

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.

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 is 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 reference 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 skill 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 '941 patent, I must do so based on the perspective of a POSA as of the relevant priority date. As

discussed below, I understand that the earliest possible priority date for the '941 patent is July 15, 2014.

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 '941 patent describes “devices and methods for positioning and cutting bones,” including “temporarily fixing bones in a desired position during a surgical procedure, such as a bone alignment, osteotomy, and/or fusion procedure.” Ex.1001, 1:24-25, 2:63-66. Based on my review of the specification and claims of the '941 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 have had a medical degree and at least 3 years of surgical experience with foot surgery. Such a person would also work as part of a team or consult with an engineer having a bachelor's degree in biomedical engineering, mechanical engineering, or a closely related

discipline with experience designing surgical instrumentation, and who has at least three years of experience learning from these doctors about the use of such devices in foot and ankle surgeries.

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

33. Because the '941 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 would provide surgical know-how, and the engineer would provide the 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 '941 patent would have been obvious to any reasonably defined POSA.

35. I was at least a POSA by July 2014 because by that time, I was an orthopedic surgeon with at least three years of experience performing foot and ankle surgery, and I knew of and interacted with many other POSAs and worked with many surgeons and engineer developers. Further, by July 2014, I had performed

numerous surgeries (including bunion correction surgeries) and worked with many surgeons and engineer developers. Further, by July 2014, I had supervised and trained many surgeons in the field of orthopedic and podiatric surgery, including bunion surgery. By July 2014, the surgeons I worked with had the requisite knowledge to and did use the surgical methods and instruments as described in the specification and claims of the '941 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 2014, how those surgeons and engineers would interpret and understand the '941 patent and claims, and how they would understand the disclosures in the prior art discussed herein. Additionally, by July 2014, I helped design implants for bunion surgeries.

36. Although my own experience may have exceeded that of a POSA, the opinions expressed herein are from the perspective of the POSA as of July 2014.

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 '941 patent to be obvious in view of the prior art. My conclusions that the claims of the '941 patent would have been obvious would remain the same even if the invention date, field of endeavor, or level of ordinary skill were slightly different.

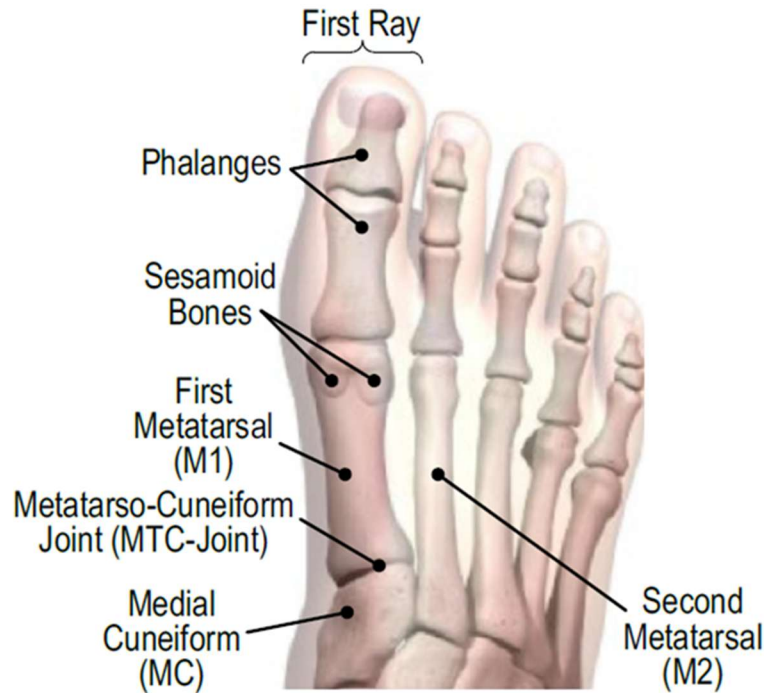
II. OVERVIEW OF THE PRIOR ART

38. The disclosure of the '941 patent relates to devices and methods for positioning and cutting bones. The '941 patent claims methods for performing bunion surgery.

39. Before July 2014, 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 of the '941 patent.

A. Relevant Human Foot Anatomy

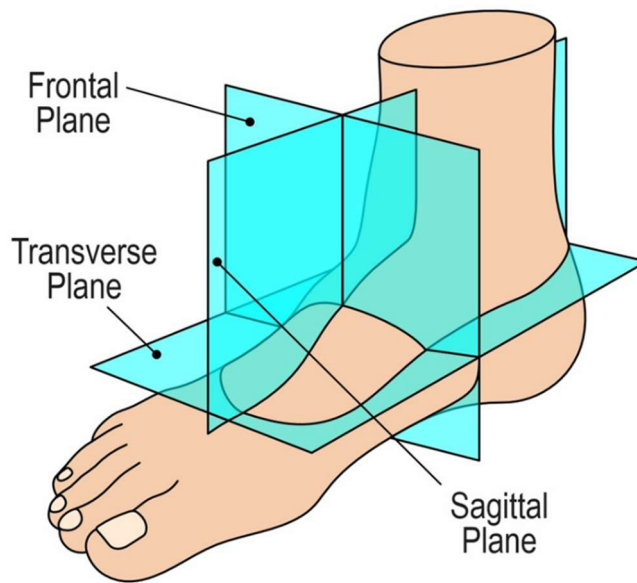
40. The human foot has 26 bones, including the bones of the first ray—the first metatarsal, medial cuneiform, and associated joints. The below image depicts the bones of the human foot, with annotations identifying the relevant bones and joints:



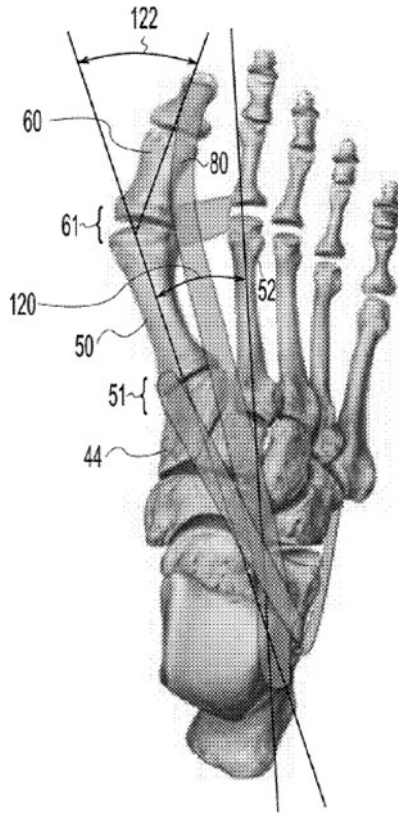
41. In a healthy foot, the bones of the first ray are anatomically positioned in three-dimensional alignment from the first/medial cuneiform² to first metatarsal through the hallux (“big toe”), which promotes normal function of the foot. The first metatarsal and medial cuneiform meet to form the metatarsal-cuneiform 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:

² The terms “medial cuneiform” and “first cuneiform” have the same meaning.



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.1026, 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.1026, [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.1011, 323 (describing use of McGlamry’s procedure to “moderate or severe” bunion deformities with an IMA “from 14 to 30 degrees”). Such 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.

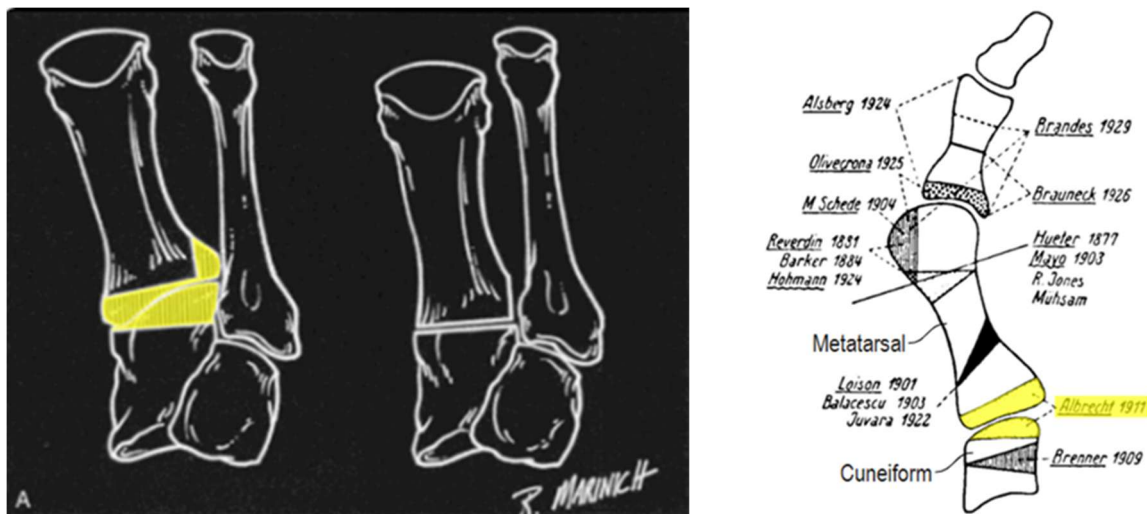
B. Instrumented Bunion Correction

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

46. One procedure for treatment of a bunion is a metatarsocuneiform arthrodesis, which Dr. Paul Lapidus popularized a version of in 1934. *See generally* Ex.1019. An arthrodesis is a surgical procedure in which the bones of a joint are permanently joined together through fusion. Ex.1011, 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.

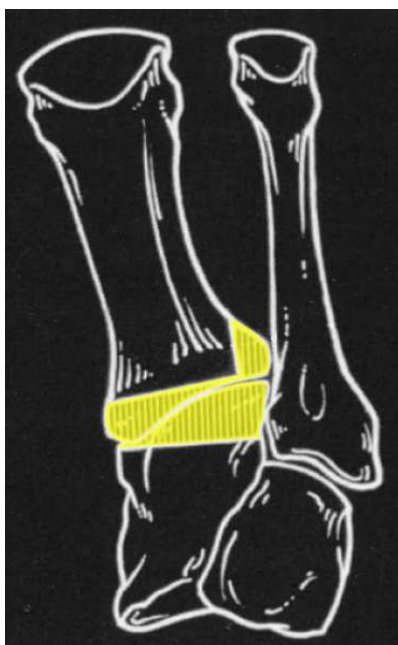
47. In a metatarsocuneiform arthrodesis procedure, the first metatarsal and medial cuneiform are realigned in their natural positions, and fixed together for fusion. Ex.1011, 322 (“While many techniques have been described modifying the original Lapidus procedure, all use arthrodesis of the of the metatarsal-cuneiform

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.1020, Fig.1A (color added); Ex.1016, Fig.3 (color added). The cutting of bones is called an osteotomy.

48. In one exemplar procedure for preparation of the joint, a surgeon cuts facing surfaces of the first metatarsal and cuneiform, as indicated by hatched areas below (left), creating space for repositioning the first metatarsal as shown below (right):



Before Correction



After Correction

Ex.1020, Fig.1A (excerpt) (colorized).

49. 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.1019, 187–88 (“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.1020, 493 (“Inherent to this procedure is the ability to correct deformity in three planes.”); *see generally* Ex.1005, 348 (describing frontal plane rotation as “third plane of deformity”); Ex.1011, 324-27; Ex.1016, 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.1011, 324-26 (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).

50. Another step in the procedure is the use fixation devices—for example, a screw or plate—to fix the bones in their corrected position. Ex.1005, 349; Ex.1011, 326-27; Ex.1020, 486-87, 490.

51. The body will heal and form bone between the cut bone surfaces (referred to as bone “fusion”) in the corrected orientation. Ex.1011, 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.”).

C. Dayton’s Bunion Correction Procedure

52. I understand that Dayton is an article from the Journal of Foot & Ankle Surgery and lists a publication date of 2013. *See generally* Ex.1005. For the

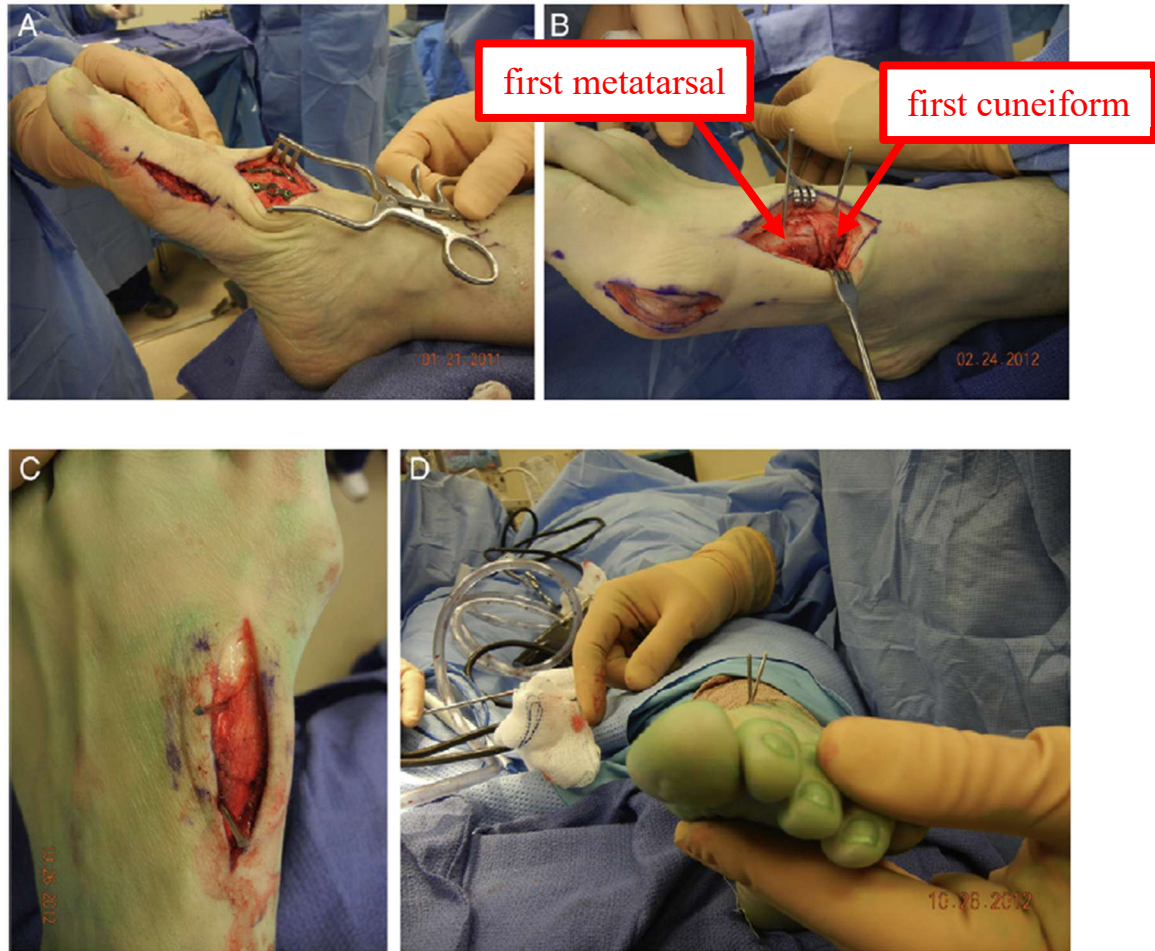
purposes of this Declaration, I have been asked to assume that Dayton qualifies as prior art to the '941 patent. In Dayton, the authors describe the history of identifying the center of angular rotation for a hallux abducto valgus deformity. *Id.*, 350-53.

53. Dayton describes a “surgical procedure,” specifically a “modified Lapidus procedure,” for bunion correction that emphasizes alignment of the first metatarsal in the transverse, frontal, and sagittal planes. Ex.1005, 348-49. Dayton’s bunion correction procedure is a “TMTJ arthrodesis.”³ *Id.*, 349-50. Dayton’s procedure “result[s] in anatomic alignment of [the] first metatarsophalangeal joint without distal procedures or medial eminence resection.” *Id.*, 353, Fig.5.

54. Dayton describes the traditional steps of a Lapidus procedure with a frontal plane correction, including (1) preparation of the metatarsal-cuneiform joint via 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 first cuneiform to promote fusion and healing of the bones. *See generally* Ex.1005, 349. Dayton provides

³ The TMTJ, or tarsometatarsal joint, is the joint of the first cuneiform and first metatarsal. It is also referred to as the “tarsal-metatarsal” joint, first metatarsal-cuneiform joint, or metatarsocuneiform joint.

figures to guide the surgeon through the steps of a bunion correction procedure, including the figures below:



Id., 349, Figs.1A (“Two-incision approach with medial midline first metatarsal phalangeal incision and 2-plate fixation technique”), 1B (“positioning of reference wires to observe rotation (1 wire in metatarsal base and 1 parallel wire in first cuneiform)”) (annotated), 1C (“Varus or inversion rotation of metatarsal indicated by reference wire position after anatomic alignment of first metatarsal and first metatarsal phalangeal joint”), 1D.

D. Known Bone Positioning Devices

55. Based on my experience and review of materials for this Declaration, I am aware that surgeons used bone positioning devices before July 2014 to precisely reposition bones of a joint relative to one another. Bone positioning devices allow a surgeon to precisely reposition bones such that the bones of a joint can be aligned and prevent recurrence of the deformity via underlying imperfections of the alignment of a joint's bones.

56. McGlamry describes a bunion correction procedure that involves repositioning the bones in one or more planes (e.g., transverse, frontal, sagittal) via, *inter alia*, a bone positioning device. Ex.1011, 324-27. McGlamry further discloses “bone-holding clamps and reduction forceps” for grasping and manipulating foot bones. Ex.1011, 10. Some clamps and forceps disclosed include Lewin, ASIF double-sharp, Verbrugge, and Lowman devices. *Id.*, 11. McGlamry's textbook method for a Lapidus procedure describes using self-retaining retractors, such as with a Weintraub retractor or AO mini distractor connectable to bone via pins. *Id.*, 7-8, 803, 806, 809. Images of a Weintraub retractor and AO mini-distractor in use during foot surgery as shown below:

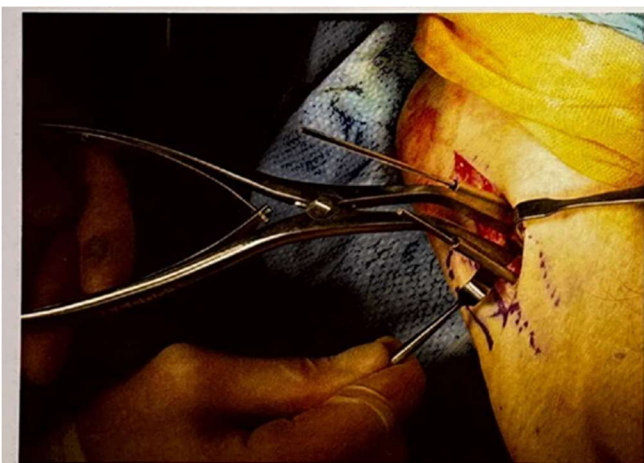
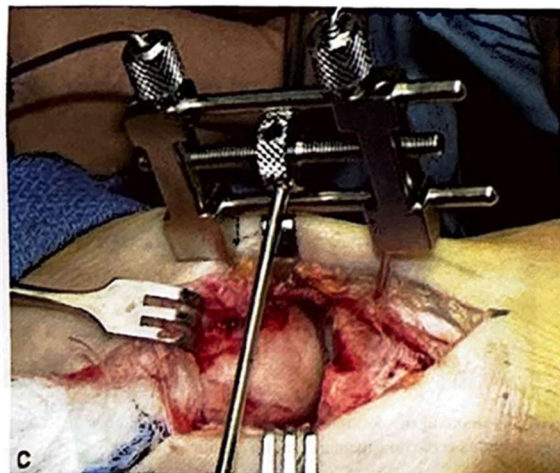


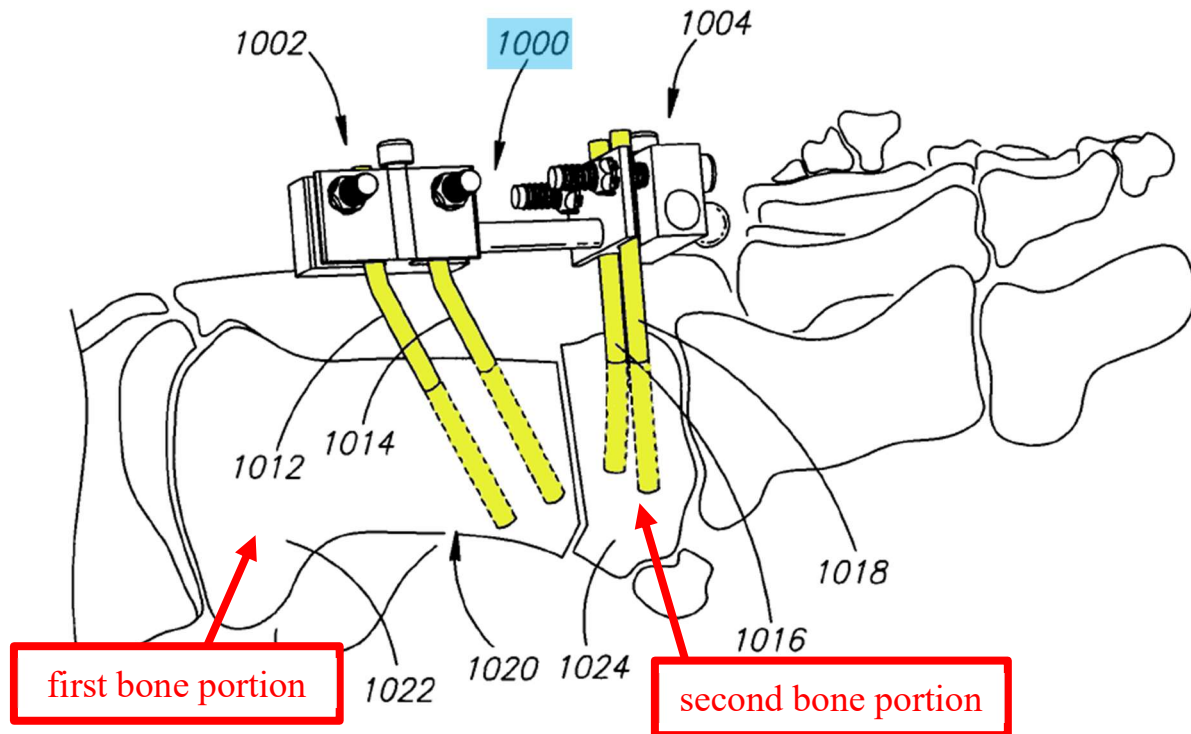
Figure 1.20 The Weinraub retractor affixed to joint margins via 0.045-inch K-wires and used to distract the osseous segments.



Id., Fig.1.20, Fig.55.5C. These devices “free the assistant to perform duties that may expedite the procedure” and “prepar[e] for fusion.” *Id.*, 7.

57. Based upon my experience and interactions with other surgeons, medical devices existed and were commercially available prior to July 2014 that surgeons used for the purpose of repositioning the first metatarsal in a bunion correction procedure. For example, a Hintermann distractor may be used to reposition the first metatarsal and reduce an abnormal IMA by pinning prongs of the distractor to the first metatarsal and the second metatarsal. See https://web.archive.org/web/20091122183715/http://www.ilstraining.com/idrt/brochures/ns1006_recon_catalog.pdf, 26 (last visited January 13, 2026) (showing Hintermann retractor available before July 2014). The surgeon would then adjust the distance between the two pinned prongs of the distracting end of the Hintermann device to correct the IMA.

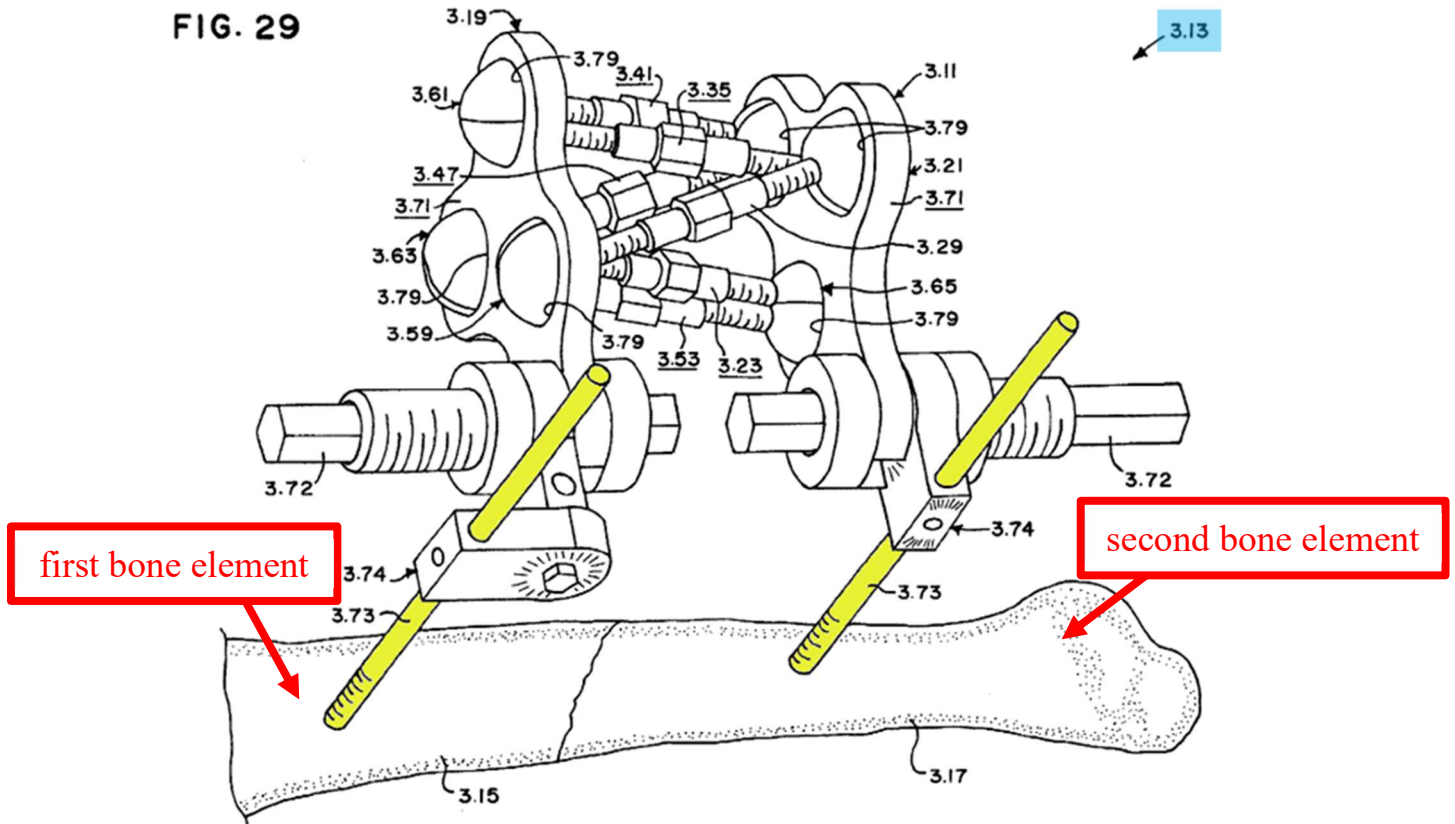
58. Waisman also discloses a bone positioning device (blue) that is connected to bones via pins (yellow), as shown below:



Ex.1006, Fig.2F (annotated). This device can be “applied to a human foot for fixing an osteotomy (hallux valgus surgery) of first metatarsus deformity.” *Id.*, 26:21-24. Waisman’s device performs “holding fixation possibilities” such as “compression,” “distraction,” “[c]lockwise motion,” and “translation.” *Id.*, 6:7-13.

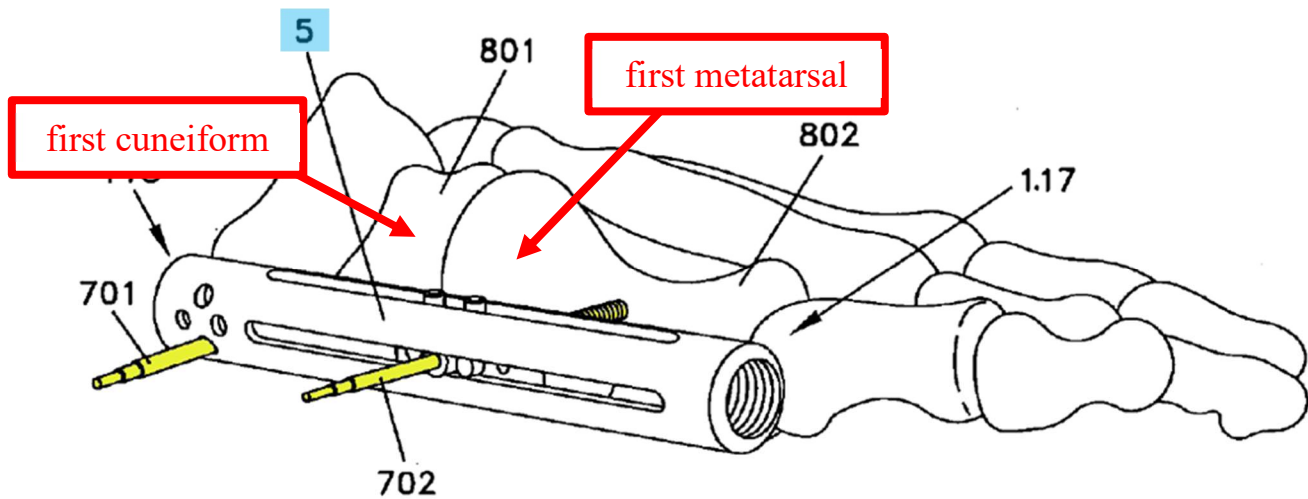
59. Taylor likewise discloses a bone positioning device (blue) attached to bones with pins (yellow), as shown below:

FIG. 29



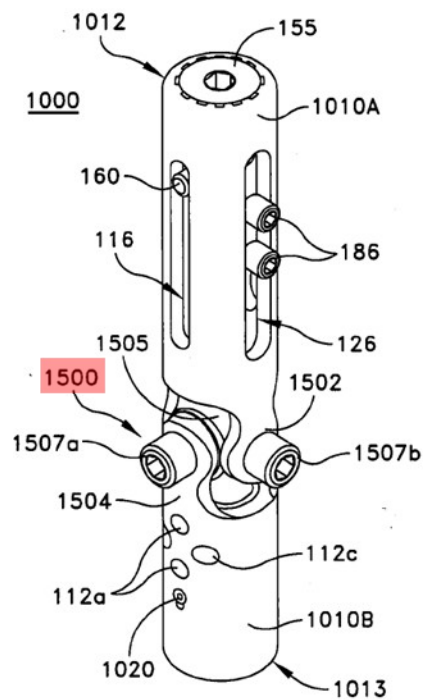
Ex.1007, Fig.29 (annotated). Taylor's bone positioning device may "move one fragment with respect to the other in six orthogonal degrees of freedom." *Id.*, 5:26-33. This device is "used for any situation requiring relative motion between elements including compression (shortening), distraction (lengthening), translation, angulation, or rotation and any combination of such movements." *Id.*, 5:37-42.

60. Orsak further discloses a bone positioning device usable to "adjust the relative orientation and spacing of the bone parts on opposing sides of a bone repair site." Ex.1008, [0003]. As shown below, Orsak's device (blue) may engage with the first metatarsal and first cuneiform using pins (yellow):



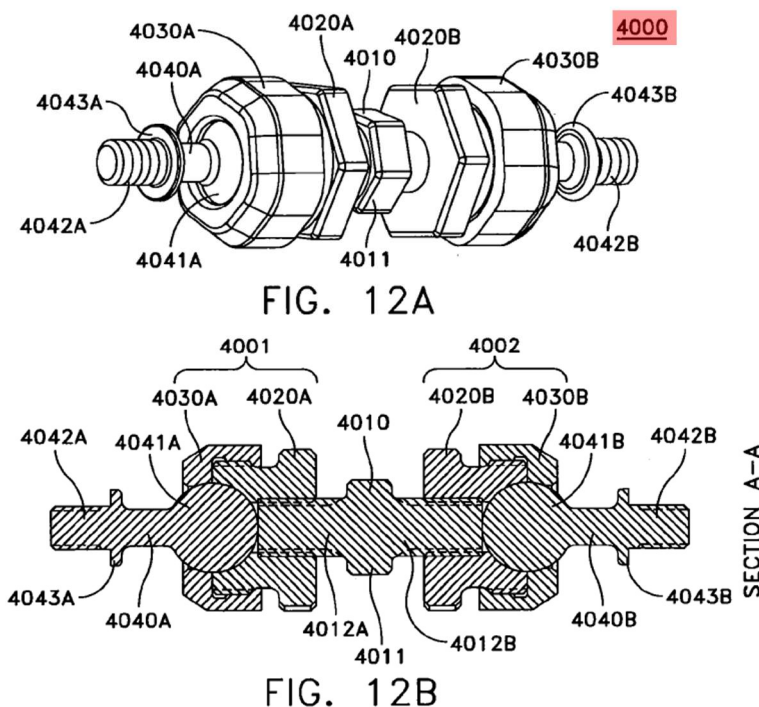
Id., Fig.5C (annotated).

61. Orsak also discloses embodiments facilitating movement in multiple axes with a universal joint (red), including one example below:



Id., Fig.8A (annotated); *see also id.*, [0094].

62. In addition, Orsak describes joint embodiments (red) that facilitate multiplanar movement with two ball joints, including one example below:



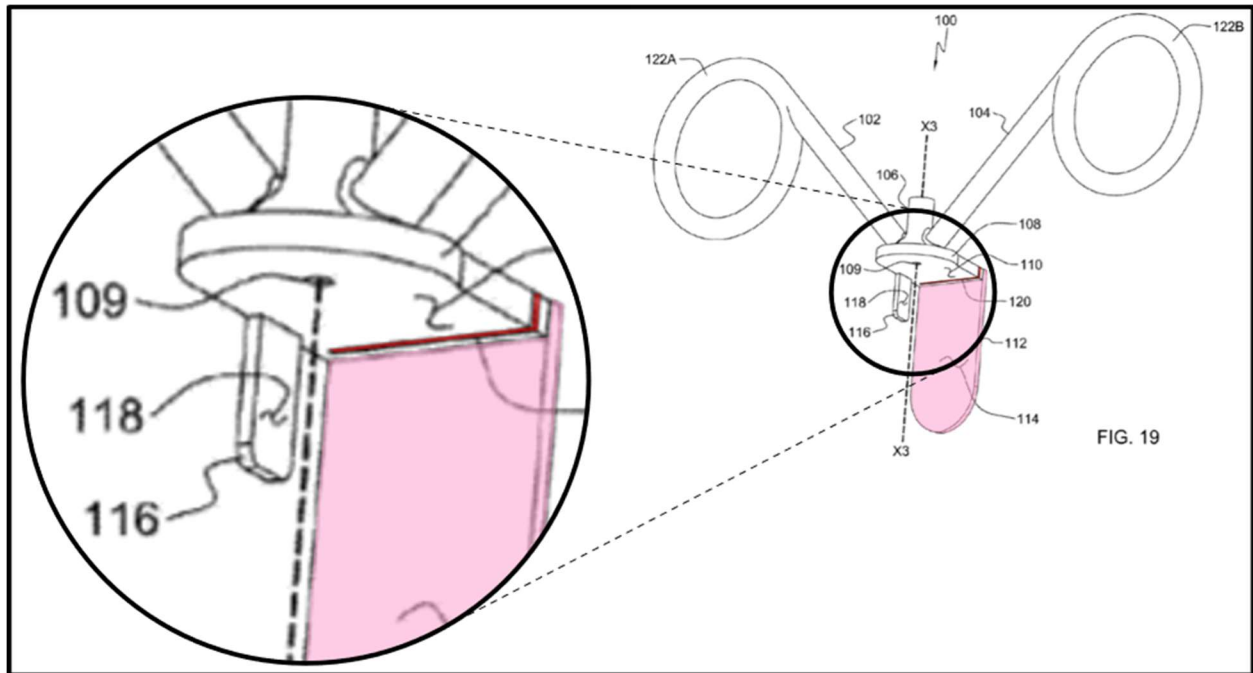
Ex.1008, Figs.12A-12B (annotated); *see also id.*, [0118]-[0125].

E. Known Bone Cutting Guides

63. Based on my experience and review of materials for this Declaration, I am aware that surgeons used bone cutting guides before July 2014 to ensure the accuracy and repeatability of cuts to bones. Bone cutting guides allow bones to be cut such that they can fit together with other bones and help avoid resections of bone beyond what is required for correction of the targeted deformity.

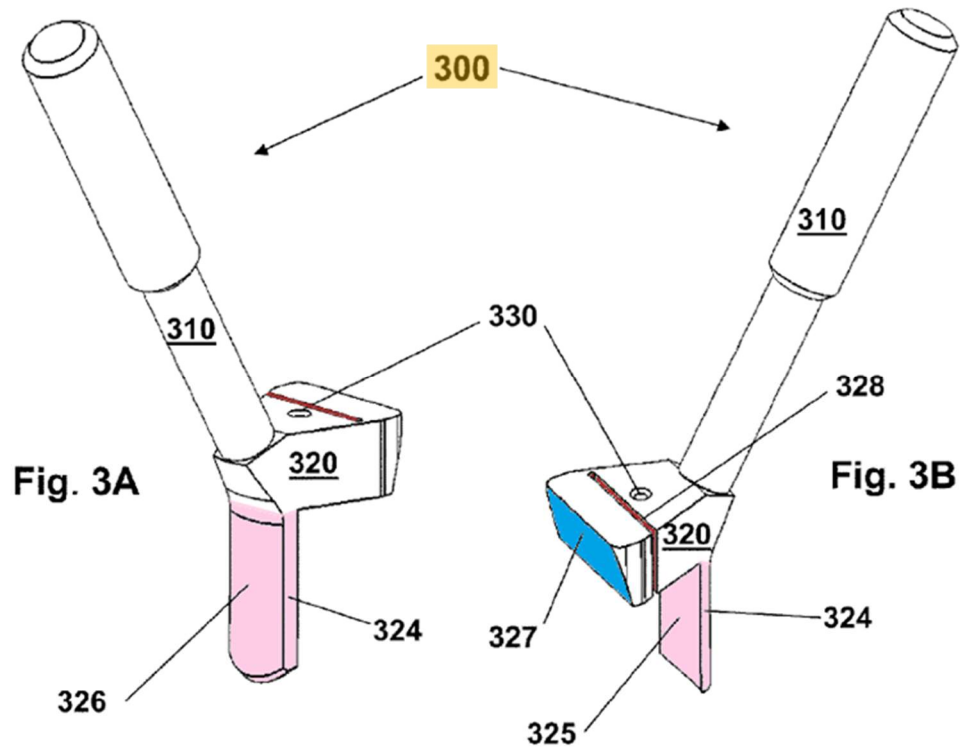
64. Bone cutting guides existed and were well-known before July 2014 for bunion correction. For example, Palmer discloses a cutting guide “for preparing one

of the target fusion bones for fusion thereof.” Ex.1009, Abstract. This guide includes a resection slot 120 (red) and positioning tab 112 (pink), as shown below:

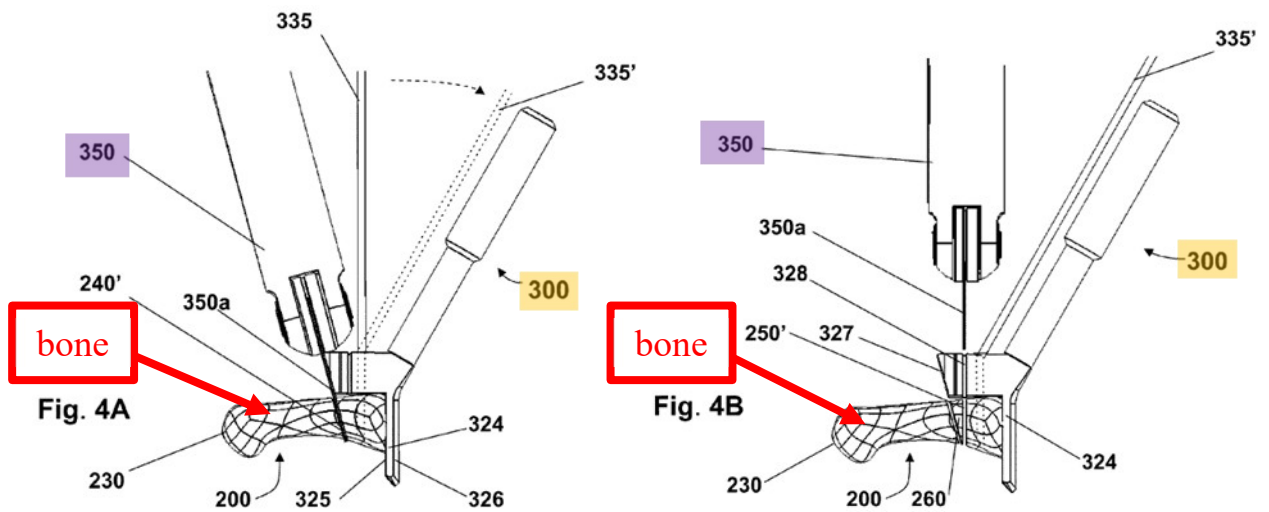


Id., Fig.19 (annotated). Palmer identifies the medial/first cuneiform as an example bone that is cut using its guide and fused with the first metatarsal. *Id.*, [00139]-[00140].

65. Orbay describes “[a] cutting guide 300 for performing small bone osteotomy.” Ex.1010, [0037]. This guide’s “body portion 320 includes an angled plane surface 327 [(blue)], adapted to align a cutting blade along the angled line 240, and a vertical slot 328 [(red)], adapted to align a cutting blade along cutting line 250.” *Id.* The guide 300 (orange) includes a divider piece 324 (pink) for placing into the joint. *Id.* These structures are shown in the figures below:



Id., Figs.3A-3B (color added). Using Orbay's guide, a surgeon makes cuts using an oscillating saw 350 (purple), as shown below:



Id., Figs.4A-4B.

III. THE '941 PATENT

A. Overview

66. I have reviewed the '941 patent and its prosecution history.

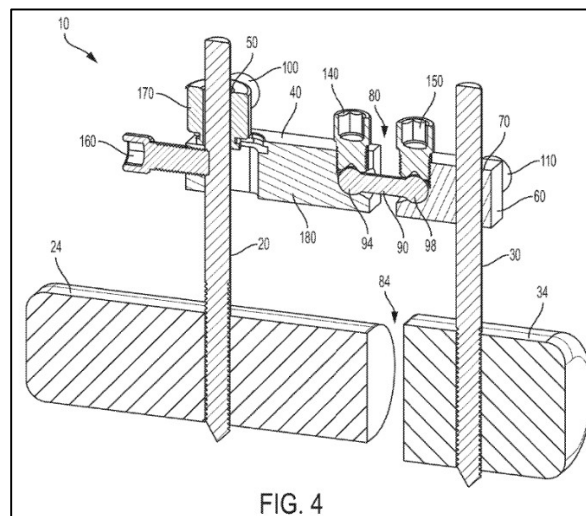
67. The '941 patent states that it relates generally to “devices and methods for positioning and cutting bones.” Ex.1001, 1:24-25. The specification of the '941 patent discloses embodiments of a bone positioning device for “temporarily fixing ones in a desired position during a surgical procedure, such as a bone alignment, osteotomy, and/or fusion procedure.” *Id.*, 2:63-66.

68. Each of the '941 patent's claims encompasses “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” *Id.*, claims 1-27. The claimed methods generally involve: engaging a positioning device with the first metatarsal and cuneiform using fixation pins, using a cutting guide to guide a cutting tool to cut the leading edge of one or both bones, adjusting bone alignment using the positioning device, and compressing the bone ends together and fixing them with a bone connector. *Id.*

69. The '941 patent describes using three surgical instruments in the claimed method: a bone positioning device, a bone cutting guide, and a bone connector.

1. Bone Positioning Device

70. Figure 4 of the '941 patent shows a bone positioning device 10 spanning the joint 84 between a first bone 24 and a second bone 34 using fixation pins 20, 30, respectively. Ex.1001, 3:10-15, Fig.4. The specification discloses that the bone positioning device “can be used in a procedure to correct an alignment between a metatarsal (e.g. a first metatarsal) and a cuneiform (e.g., a first cuneiform), such as a bunion correction. An example of such a procedure is a Lapidus procedure.” Ex.1001, 3:2-6.

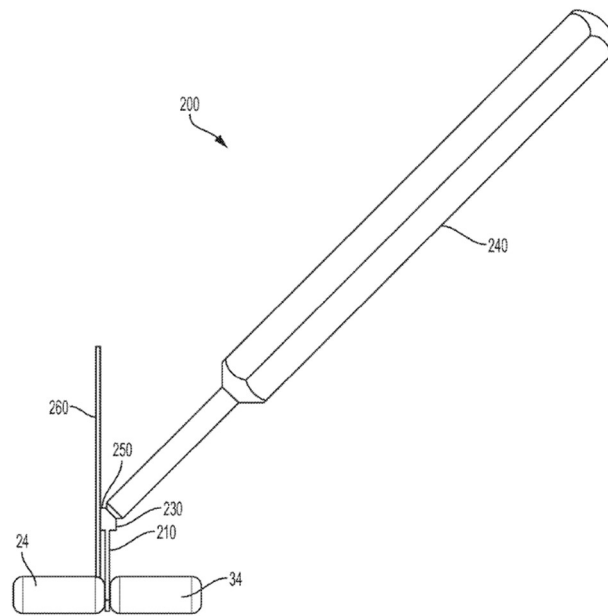


Id., Fig.4.

71. The bone positioning device 10 includes a multi-axis joint 80. Ex.1001, 3:37-40. The multi-axis joint 80 allows “angulation in all directions and rotation” between the first and second blocks 40, 60 of the bone positioning device 10. Ex.1001, 3:40-48. However, the '941 patent does not explain how this bone positioning device is used to correct a bunion.

2. **Bone Cutting Guide**

72. The '941 patent discloses a bone cutting guide 200. Ex.1001, 4:66-5:2. The bone cutting guide 200 has a plate 210, a block 230, and a handle 240. *Id.*, 5:6-9. The plate 210 can be placed such that it extends into a joint space or resected portion between the first bone 24 and second bone 34. *Id.*, 5:22-24.



Id., Fig.11. The surface 250 acts to guide a cutting tool 260 to cut a leading edge of a bone parallel to plate 210 and surface 250. *Id.*, 5:24-27.

3. **Bone Connector**

73. The '941 patent discloses that the first and second bones may be stabilized by attaching “a bone connector (e.g., a plate, pin, screw, wire, or staple) to connect and fix the first bone and the second bone.” Ex.1001, 5:62-66.

B. Prosecution History

74. During prosecution of the application that issued as the '941 patent, the examiner rejected claims over Pennig (Ex.1023), Orsak (Ex.1024), and/or Zhang (Ex.1025). Ex.1002, 67-76. In response, the applicant canceled all pending claims and presented new claims. *Id.*, 48-52. The examiner subsequently allowed the new claims. *Id.*, 10-14.

IV. CLAIM CONSTRUCTION

75. 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 '941 patent throughout my analysis unless otherwise noted.

A. “bone positioning device”

76. The term “bone positioning device” appears in multiple claims of the '941 patent.

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

78. A POSA would understand that “moving” a bone, or movement of a bone in the context of the ’941 patent would encompass either translational movement or rotation of the bone, or a combination of the two.

79. 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 device” if the term is construed as a means-plus-function limitation under Section 112(f).

Function: The claimed function of the “bone positioning device” is adjust[ing] an alignment of the first metatarsal in multiple planes to correct a bunion.” Ex.1001, claims 1, 18.

Corresponding Structure: An example of a corresponding structure includes a multi-axis joint with ball-and-socket ends. *Id.*, 3:55-67.

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

B. “bone connector”

81. The term “bone connector” appears in multiple claims of the ’941 patent.

82. A POSA would understand that a “bone connector” is a “a device for connecting bone” under the plain and ordinary meaning of this term.

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

Function: The claimed function of the “bone connector” is “fixing a position of the first metatarsal relative to the first cuneiform.” Ex.1001, claims 1, 5, 18, 21.

Corresponding Structure: Examples of a corresponding structure include a plate, pin, screw, wire, or staple. *Id.*, 5:62-66.

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

C. “cutting tool”

85. The term “cutting tool” appears in multiple claims of the ’941 patent.

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

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

Function: The claimed function of the “cutting tool” is “cut a leading edge of the first metatarsal/cuneiform.” Ex.1001, claims 1, 5, 18, 21.

Corresponding Structure: An example of a corresponding structure includes a saw blade. *Id.*, 5:17-21.

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

V. THE PRIOR ART

89. In this Declaration, I rely on several references that I understand are prior art to the '941 patent claims. These references include:

- Dayton (Dayton, *et al.*, *Relationship of Frontal Plane Rotation of First Metatarsal to Proximal Articular Set Angle and Hallux Alignment in Patients Undergoing Tarsometatarsal Arthrodesis for Hallux Abducto Valgus: A Case Series and Critical Review of the Literature*, Journal of Foot and Ankle Surgery, Vol. 52, No. 3 (May-June 2013): 348-354) (Ex.1005);
- Waisman (International App. Publ. No. 2012/004798) (Ex.1006);
- Taylor (U.S. Patent No. 5,702,389) (Ex.1007);
- Orsak (U.S. Patent App. Publ. No. 2012/0029575) (Ex.1008);
- Palmer (International App. Publ. No. 2012/103335) (Ex.1009); and
- Orbay (U.S. Patent App. Publ. No. 2011/0288550) (Ex.1010).

90. These references are from the same field as the '941 patent, e.g., surgical procedures involving bone. Ex.1001, 1:24-30. These references are

pertinent to a problem focused on by the inventors, e.g., cutting, repositioning, and fixating bone during a surgical procedure. *Id.*; *see also id.*, claims 1, 18.

**VI. GROUND 2: CLAIMS 1-27 WOULD HAVE BEEN OBVIOUS OVER
DAYTON, WAISMAN, AND PALMER**

91. It is my opinion that claims 1-27 of the '941 patent would have been obvious to a person of ordinary skill in the art as of July 14, 2014 in view of Dayton, Waisman, and Palmer.

A. Claim 1

92. Claim 1 in the '941 patent covers a method of correcting a bunion that includes cutting a first metatarsal and first cuneiform using a bone cutting guide, adjusting first-metatarsal alignment in multiple planes using a bone positing device, compressing the first metatarsal and first cuneiform, and fixing them with a bone connector. Ex.1001, claim 1. Dayton's method is similar and includes cutting, adjusting, compressing, and fixing the first metatarsal and first cuneiform with a bone connector. Ex.1005, 349.

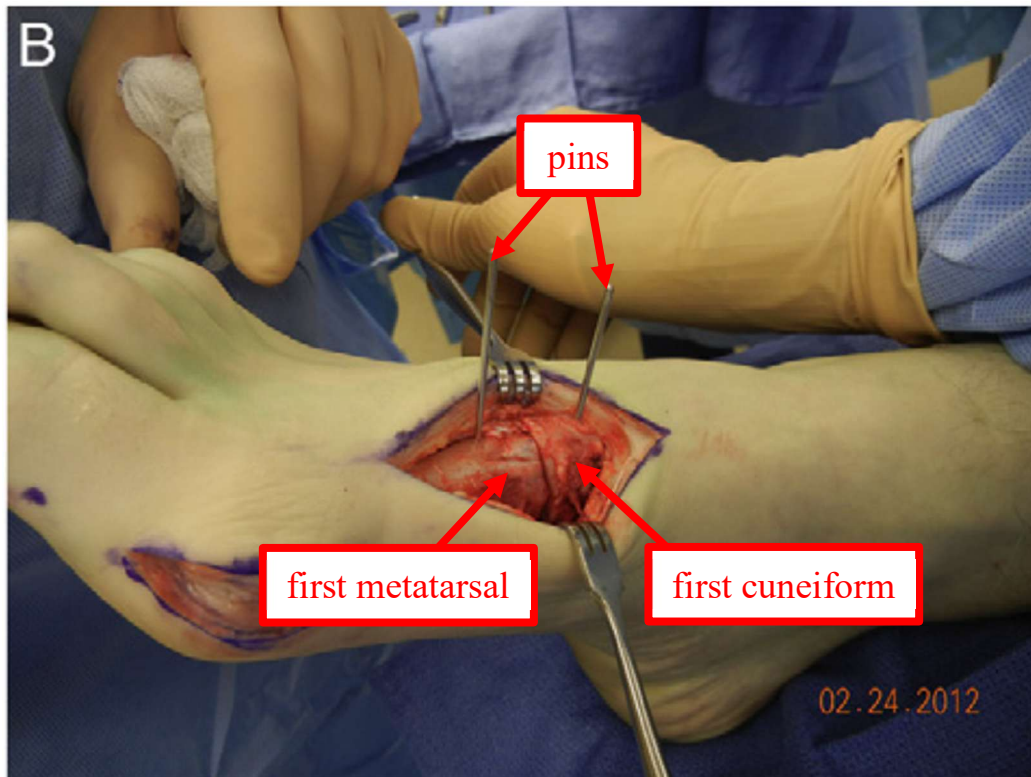
93. Palmer describes bone cutting guides for foot surgery (Ex.1009, [00139]-[00140]), and Waisman describes a bone positioning device for foot surgery and multi-planar alignment adjustment (Ex.1006, 27:4-7, 6:7-13). As I explain further below, a POSA would have been motivated and had a reasonable expectation of success to use these known cutting guides and positioning devices in performing Dayton's method.

1. Preamble

94. The preamble of claim 1 recites “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” To the extent the preamble is limiting, Dayton discloses the preamble

95. Dayton discloses “hallux valgus corrective procedures” that correct a “hallux abducto valgus [HAV] deformity.” Ex.1005, Abstract. A HAV deformity is the clinical term for a bunion.

96. In Dayton’s procedure, “pins were placed directly in the sagittal plane and parallel, 1 in the base of the metatarsal and 1 in the cuneiform.” Ex.1005, 349. The surgeon uses these pins “as a reference to more easily visualize the rotation of the metatarsal in the frontal plane.” *Id.* Dayton depicts these pins in the first metatarsal and first cuneiform.



Id., Fig.1B (annotated). Dayton further describes its bunion correction surgery as a “modified [L]apidus procedure” with specific attention given to the “reduction of the frontal plane rotation of the first metatarsal during correction.” *Id.*, 348. Dayton explains “the rotation of the metatarsal was addressed by rotating the bone in a varus, or inverted, direction until congruous alignment of the first MTPJ and sesamoids was observed.” Ex.1005, 349; *see also id.*, 348, 350.

2. Limitation 1[a]

97. Limitation 1[a] recites “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform.” A POSA would have been motivated to

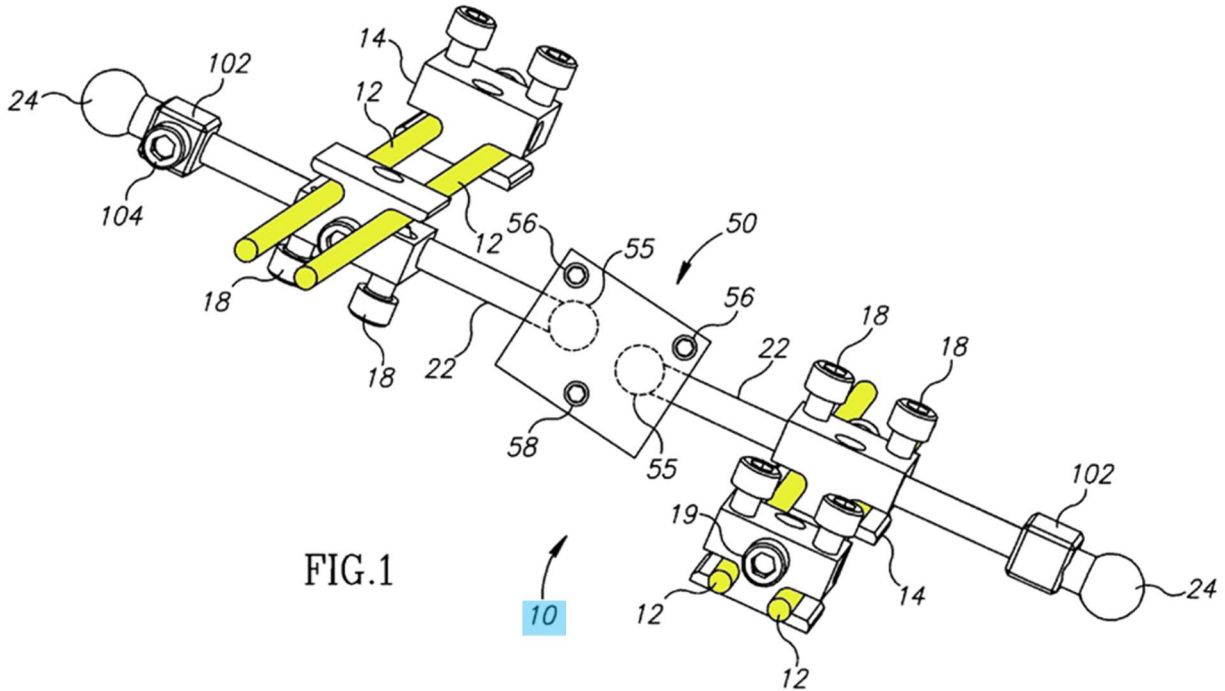
combine Dayton, Waisman, and Palmer, and the resulting combination would meet this limitation.

98. As explained above regarding claim 1's preamble, Dayton discloses repositioning the first metatarsal relative to the first cuneiform. *See* §VI.A.1, *supra*. Dayton discloses inserting pins into the first metatarsal and cuneiform for assisting visualization of the first metatarsal's rotation and temporarily stabilizing the first metatarsal relative to the first cuneiform. Ex.1005, 349 (“These pins were used as a reference to more easily visualize the rotation of the metatarsal in the frontal plane” and “[t]he segments were next temporarily stabilized with smooth wires”). Dayton achieves its movement through a surgeon manually manipulating the first metatarsal.

99. A POSA would have been motivated to use a bone positioning device like Waisman's in Dayton's procedure to reposition bone.

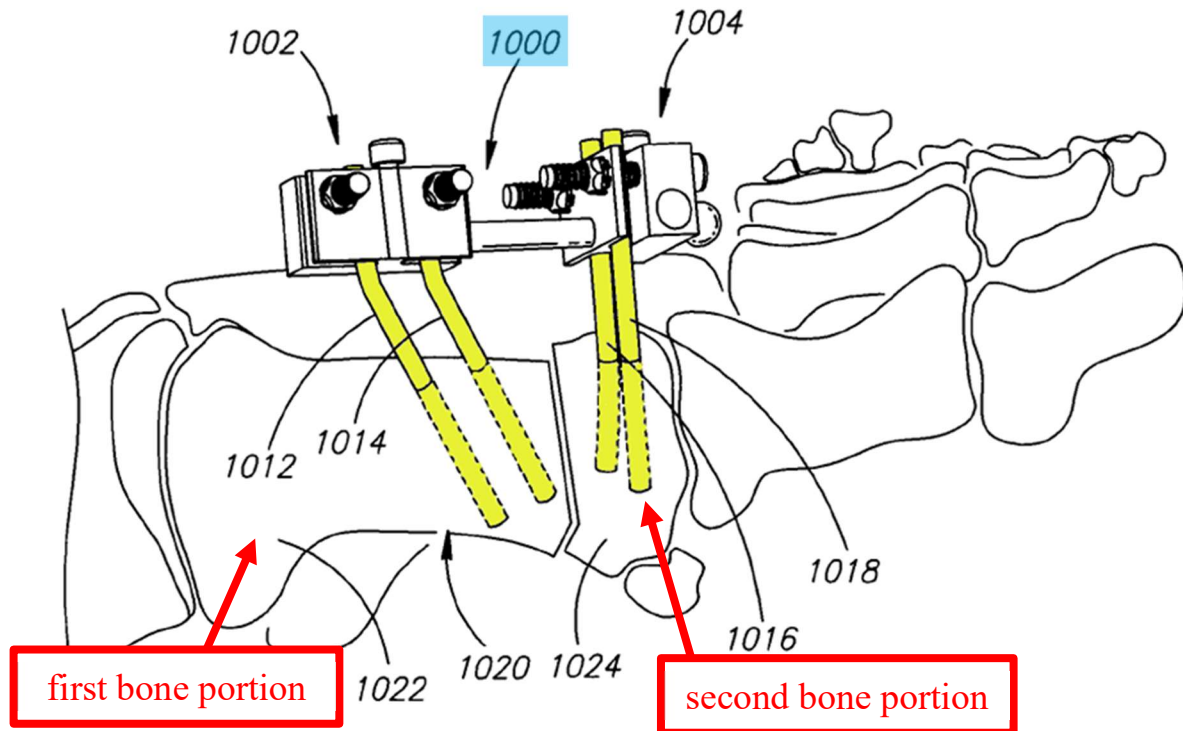
100. Waisman describes a “[p]olyaxial external fixator [(PEF)] 10” that includes “bone penetrating elements 12 such as K-wires, pins or screws.” Ex.1006, 15:4-5.⁴ One embodiment of Waisman's bone positioning device 10 (blue) with pins 12 (yellow) is shown in Figure 1:

⁴ K-wires, or “Kirschner wires (KW)” are “sterilized, sharpened, smooth stainless steel pins widely used today in orthopedic surgery.” Ex.1006, 5:10-12.



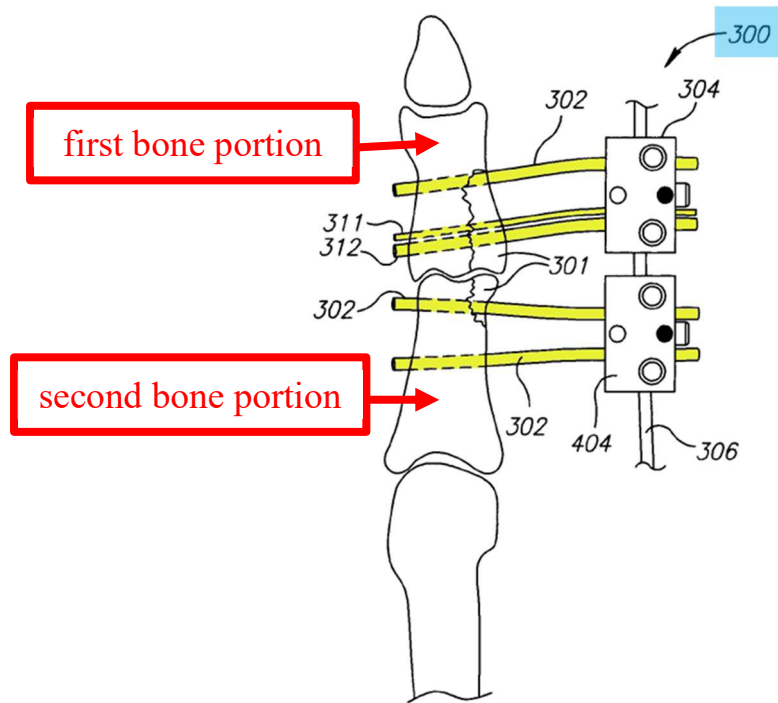
Id., Fig.1. Waisman explains that the pins 12 in each of the first and second bones are “flexibly joined” via connecting rods 22 with spheres 24 and are “capable of fixing the spatial orientation” of the rods. *Id.*, 8:15-20; *see also id.*, 8:20-9:12, 23:6-28 (describing capability of spheres and rods). “By sliding and/or rotating the lateral cages 14 along rods 22, and by changing the relative positions of rods 22 using central cages 50, the bone fragments may be held in desired position relative to each other.” *Id.*, 24:23-25.

101. In one embodiment, Waisman describes a fixator 100 that is “applied to a human foot for fixing an osteotomy (hallux valgus surgery) of a first metatarsus deformity.” Figure 10 below shows the K-wires/pins 1016 (yellow) in bone connected to the fixator 100 (blue).



Id., Fig.10 (annotated); *see also id.*, 26:21-30.

102. Waisman's fixator is further illustrated as applied across a joint, as shown below:



Id., Fig.9B; *see also id.*, 24:29-25:16 (describing above fixator).

103. Waisman explains that its “inventive PEF system and method may be used in a plurality of other surgical procedures, including ... orthopedic surgery such as but not limited to ... foot surgeries.” *Id.*, 27:4-7. Further, Waisman states “[its] invention may be used as temporary or final fixation.” *Id.*, 27:7-9. According to Waisman, its fixator is used with “osteotomized bones” (*id.*, 8:7-14), where such bones are ones that have been surgically cut.

104. Waisman’s fixator provides “different holding fixation possibilities based on the polyaxial device: 1) compression 2) distraction 3) abduction 4) adduction 5) flexion 6) extension 7) Clockwise motion 8) anti-clockwise motion 9) upper translation 10) lower translation 11) All of above combinations 12) Multiple

transverse connections between two or more devices, and 13) Custom modular device elongation, unilateral or bilateral frame construction.” Ex.1006, 6:7-13; *see also id.*, 2:30-3:1 (“Fixators are being used for positioning two or more bone portions They are often used in the course of...surgical procedures such as reduction, realignment and correction.”). According to Waisman, “[i]t is an object of [its] invention to provide an external fixator of different sizes for fixating bones of any size ... during ... reduction, realignment and correction surgery.” *Id.*, 4:25-27.

105. A POSA would have been motivated to incorporate a bone positioning device like Waisman’s fixator into Dayton’s procedure and would have done so by engaging the positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, so that this positioning device extends across the joint separating the first metatarsal and cuneiform. This engagement would facilitate use of the positioning device to both reposition and stabilize the bones during Dayton’s procedure.

106. A bone positioning device like Waisman’s polyaxial fixation system, including its fixator, has features useful for bunion correction procedures and would have been desirable for use in Dayton’s procedure. *Id.*, 13:17-20, 26:21-27. For example, Waisman includes features for repositioning and fixing bones, including the first metatarsal. *See id.* (describing use of fixator in correction of hallux valgus deformity of first metatarsal), Fig. 10; *see also id.*, 8:15-9:12, 15:4-5, 23:6-28, 24:23-

25. This system design would allow for precise correction of the first metatarsal-first cuneiform alignment and fixation of the corrected positions after alignment.

107. The combination of Waisman's bone positioning device and Dayton's procedure would have been a combination of familiar elements according to their known functions and yielded predictable results. Rather than pins serving primarily as visual references for manual manipulation or temporary stabilization, as disclosed by Dayton, a POSA would have recognized and been motivated to place pins in the first metatarsal and first cuneiform to couple them to a known frame to provide controlled and maintainable triplanar correction for final fixation. Ex.1005, 349; Ex.1006, 26:21-24, Fig.10; *see also* Ex.1006, 6:7-13 (describing triplanar correction, including "compression," "[c]lockwise motion," and/or "anti-clockwise motion" (transverse plane); "abduction" or "adduction" (frontal plane); and "flexion," "upper translation," and/or "lower translation" (sagittal plane)). Waisman functions in the same operative scale and environment as Dayton's procedure. *See* Ex.1005, 349; Ex.1006, Abstract, 4:25-5:9, 27:4-7.

108. The combination of a bone positioning device like Waisman's and a correction procedure like Dayton's would be a straightforward modification within the POSA's skill. Dayton describes anchoring the first metatarsal and cuneiform with pins and relies on achieving, visualizing, and maintaining a corrected rotational relationship between those bones while later steps proceed. Ex.1005, 349. Waisman

describes a fixator which is “suitable for fixation using K-wires, pins or screws.” Ex.1006, 5:3-4. Waisman’s fixator is the type of device a POSA would select for adjusting and maintaining relative alignment between adjacent bones during corrective surgery like Dayton’s.

109. A POSA would therefore have been motivated to incorporate fixation such as Waisman’s in Dayton’s procedure—such as, in place of, or adjunct to, manual manipulation—because such a fixator affords greater precision, controlled incremental correction, and improved maintenance of alignment compared to freehand manipulation, while not changing Dayton’s fundamental surgical goals or anatomical anchoring strategy. *See also* Ex.1011, 7 (describing devices that “free the assistant to perform duties that may expedite the procedure” and “prepar[e] for fusion.”).

110. Dayton’s procedure involves placing pins in the first metatarsal and cuneiform to visualize rotation, rotating the metatarsal by hand until alignment is achieved, and temporarily stabilizing the bones. Ex.1005, 349. Waisman discloses a polyaxial fixator for reduction/realignment/correction, uses K-wire/pins held by cages/rods, and is used on small bones such as those of the foot. Ex.1006, Abstract, 4:25-5:9 (describing objects of Waisman’s disclosure), 27:4-7 (describing use of polyaxial external fixator in foot surgeries, including orthopedic surgeries).

111. A POSA would have considered the combination as using a known technique to improve a similar method in the same way. Dayton explains hallux valgus is a triplanar deformity, and its procedure operationalizes this understanding by observing and manually correcting rotation (along with sagittal and transverse plane misalignments). Ex.1005, 348-349. Waisman's fixator supports reduction/realignment/correction and provides multiple fixation modes, including clockwise/anti-clockwise motion (rotation) and translation. Ex.1006, 6:7-13. These are the same degrees of freedom a surgeon performs for repositioning while correcting triplanar deformity and holding the corrected relationship. A POSA would have viewed engaging a positioning device like Waisman's to the first metatarsal and cuneiform in Dayton's procedure as an obvious way to improve intraoperative control and retention compared to manual manipulation, because it applies a known bone repositioning technique to the same corrective alignment task and predictably achieves controlled movement and stable maintenance of two bone portions.

112. A POSA would have had a reasonable expectation of success in combining Waisman's fixator with Dayton's procedure because the modification is consistent with the references' disclosures and relies on predictable mechanics. Waisman explains its polyaxial system may be used in "orthopedic surgery such as but not limited to hand and foot surgeries," including on the first metatarsal for

hallux valgus (bunion) correction. *Id.*, 27:4-7, 13:17-20, 26:21-27, Fig.10. Dayton's procedure is an orthopedic surgery of the foot involving, *inter alia*, the first metatarsal. Ex.1005, 348-49. As disclosures concerning the same kinds of procedures, a POSA would reasonably expect to succeed in placing Waisman's device in Dayton's procedure across the first metatarsal and first cuneiform.

113. A POSA would expect that engaging a bone positioning device like Waisman's to pins placed in the first metatarsal and first cuneiform would provide precise repositioning and stability of the corrected alignment during Dayton's procedure. Moreover, Waisman explicitly addresses small foot bones and hallux valgus-related use. Ex.1006, 5:18-20, 26:21-24. Waisman's fixator further "allows for optimal alignment and reduction," and Waisman provides its method "may be forgiving, allowing an improved degree of freedom for K-wire insertion." *Id.*, 7:9-10, 7:2-4; *see also id.*, 6:21-23, 7:1-2.

114. A device like Waisman's fixator in the combination satisfies "bone positioning device" under the plain and ordinary meaning because it is a structure for positioning bones in multiple planes. *See supra* §IV.A. Under § 112(f), such a device is identical or at least equivalent to structures identified in the '941 patent for the claimed positioning device identified in the claim construction section above. *See id.* This bone positioning device is at least an equivalent of the disclosed bone positioning structures in the '941 patent (i.e., multi-axis joint with ball-and-socket

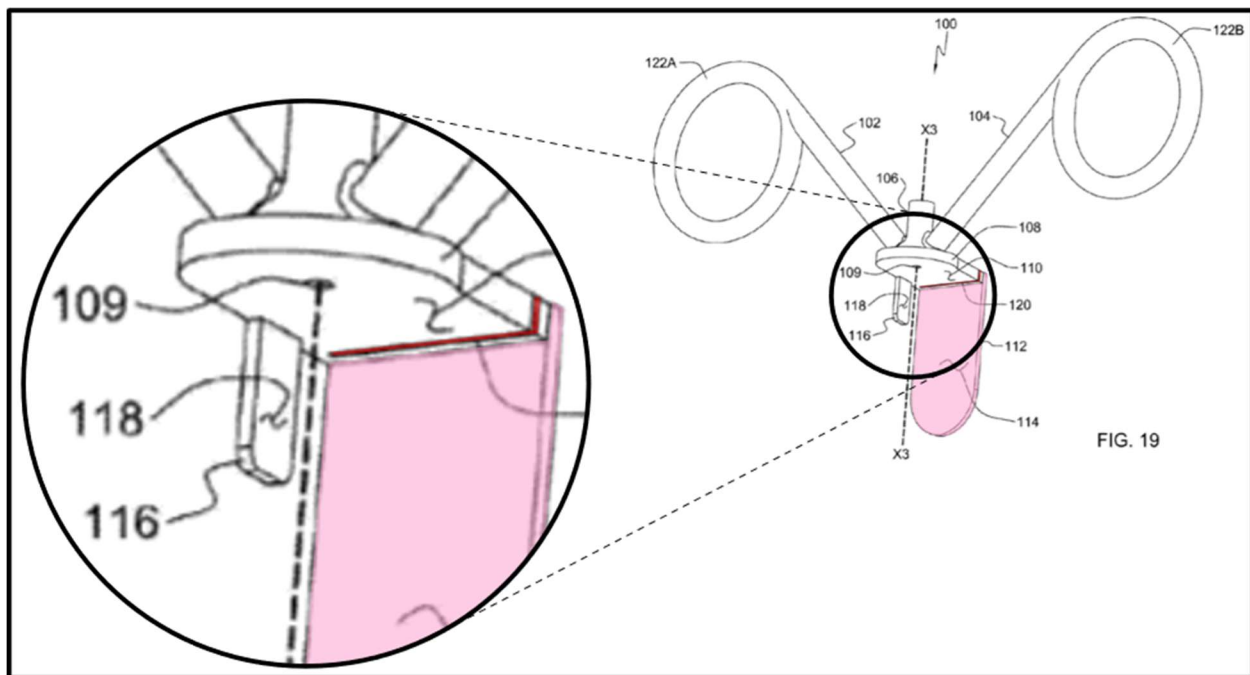
ends) because it performs the same function (i.e., adjusts first metatarsal alignment in multiple planes), in substantially the same way (i.e., spheres confined in central cage joint fixing rod angles), to achieve the same result (i.e., move and hold bones in intended position). *See* Ex.1005, 18:17-30, 19:22-31, Figs. 1, 10.

3. Limitation 1[b]

115. Limitation 1[b] recites “aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform, the bone cutting guide comprising a joint plate offset from a guide feature of the bone cutting guide, the joint plate extending downwardly relative to the guide feature, wherein aligning the bone cutting guide with the joint comprises inserting the joint plate into the joint.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would meet this limitation.

116. In Dayton’s procedure, the surgeon prepares the first metatarsal-cuneiform joint for arthrodesis by “resection of the articular surfaces” (which involves cutting the opposing joint surfaces) of the first metatarsal and first cuneiform. Ex.1005, 349; *see also id.*, 348 (referring to its procedure as a “tarsal metatarsal corrective arthrodesis”), 349 (“The joint surfaces were next resected, including the cartilage and all subchondral bone,” and describing a “first metatarsal cut” and “cuneiform cut.”).

117. Palmer describes “[a] guide instrument (100) for preparing one of the target fusion bones for fusion thereof.” Ex.1009, Abstract. Palmer explains that its instrument 100 “include[s] a resection slot 120 extending in a medial-lateral direction from a lateral side of the base member 120.” *Id.*, [00140]. “The guide instrument 100 may also include an exemplary distal positioning tab 112.” *Id.*, [00135]. Figure 19 below shows this positioning tab 112 (pink) and resection slot 120 (red) of Palmer:



Id., Fig.19 (annotated).

118. Palmer states that “[t]he medial-lateral width, proximal-distal length and dorsal-plantar height of the distal positioning tab 112 should be configured such that distal abutment surface 114 of the distal positioning tab 112 can abut or engage a distal facing surface of the target bone when the dorsal abutment surface 110 abuts

or engages a dorsal surface of the target bone.” *Id.*, [00137]; *see also id.*, [00138] (“the distal positioning tab 112 can be effective in positioning”). Accordingly, “[w]hen the bone anchor is received within the longitudinally extending aperture 109 and coupled to the target bone, the resection slot 120 can be utilized to resect a distal portion of the target bone.” *Id.*, [00140]. One of the target bones in Palmer is the medial cuneiform, which is the same as the first cuneiform. *Id.*, [00139]; *see also id.*, [00162] (explaining “the generic term ‘first target fusion bone’ or simply ‘first target bone’ may be used hereinafter to refer to the medial or transverse cuneiform bone, or any other bone that includes similar features, positioning, orientation, function or the like”).

119. Palmer’s instrument 100 is a bone cutting guide, as it is a guide for cutting bone. Ex.1009, [00140] (“the resection slot can be utilized to resect a distal portion of the target bone,” and “[s]uch resection of the target bone may facilitate fusion of the target bone with an adjacent second target bone”). The portion of Palmer’s base member 108 which structurally defines the resection slot 120 is a guide feature, and Palmer’s distal positioning tab 112 is a joint plate because it extends into the joint during use. *See id.*, [00131]-[00132] (describing structure of base member 108), [00135], [00137] (describing structure of the distal positioning tab 112), Figs.19-20. According to Palmer, the distal positioning tab 112 extends downwardly relative to the resection slot 120. *Id.*, [00135], [00137], Figs.19-20.

Palmer describes that “the resection slot 120 is preferably spaced from the distal abutment surface 114 in the proximal direction.” Ex.1009, [00140]. This means that the distal positioning tab 112—which includes the distal abutment surface 114 (*id.*, [00137])—is offset from the portion of Palmer’s base member 108 that structurally defines the resection slot 120.

120. A POSA would have been motivated to incorporate a bone cutting guide like Palmer’s instrument in Dayton’s procedure and in combination with Waisman’s bone positioning device. The instrument like Palmer’s would permit a surgeon to align the bone cutting guide with the first metatarsocuneiform joint (also referred to as metatarsal-cuneiform joint) between the first metatarsal and the first cuneiform. In this configuration, the bone cutting guide would include a joint plate (such as Palmer’s distal positioning tab) offset from a guide feature (such as Palmer’s bone cutting guide portion structurally defining a resection slot), with the joint plate extending downwardly relative to the guide feature and being inserted into the joint during the alignment of the bone cutting guide. A POSA would have recognized that bone cutting guides, like Palmer’s, simplify and standardize the cutting in a bunion correction procedure like Dayton’s and reduce the risk of complications.

121. Dayton’s procedure involves a surgeon performing freehand resection. Ex.1005, 349. A POSA would have understood by July 2014 that freehand resection of bones may be “very difficult to perform and can be rather imprecise.” Ex.1022,

1:31-37. This would have been known to a POSA at least as early as 1994, when Armstrong (Ex.1022) issued. *See generally id.* As Armstrong explains, inaccuracies during freehand resection “lead to complications such as nerve damage, poor quality bone healing, bone resorption, ... increased operating time and increased blood loss.” *Id.*, 1:45-50. Although Armstrong discusses difficulties of freehand cutting in the context of facial bones, its rationale also applies to freehand cuts of foot bones.

122. Additional prior art warns that errors in first metatarsal cutting may cause complications, including “[s]ignificant shortening,” delayed unions, non-unions, and malunions. Ex.1011, 329; *see also* Ex.1005, 349 (noting the “distal medial portion of the cuneiform [is] left intact” to avoid “sacrificing the length of the first ray”). Dayton advises to avoid damaging blood supply and unnecessary tissue disruption. Ex.1005, 349. These risks are increased during freehand resection compared to guided resection.

123. A POSA would have understood that incorporating a cutting guide like Palmer’s into Dayton’s procedure would reduce the risk of such complications. Ex.1022, 1:50-54 (“These significant disadvantages could be reduced or overcome with precise, quick and efficient bone cuts. It is therefore surprising that there has been no known cutting guide developed....”). The prior art provides that “[t]here are numerous prior art devices for precision cutting of bones in the appendicular skeleton,” including the feet. *Id.*, 1:55-58. Commercially available cutting guides

were understood to “help the surgeon resect the proper amount of bone and at the proper angles,” including when resecting the joint surface. Ex.1011, 381-83. Such cutting guides “remove the necessity of clinical judgement and guess work.” Ex.1012, 3:1-5; *see also* Ex.1014, [0034], [0070] (describing how the cut guides “precisely determine[]” the positions of the cuts). Palmer itself also explains that its “instrument 100 can provide for accurate and repeatable placement.” Ex.1009, [00139].

124. A cutting guide like Palmer’s instrument 100 with its distal positioning tab 112 would therefore make cutting predictable and repeatable, simplifying and shortening the procedure. Reducing the time spent on joint preparation benefits the patient by reducing the time the patient spends under anesthesia. *See* Ex.1011, 803 (describing proper anesthesia as being “of paramount importance” for arthrodesis procedures). Lengthier periods of anesthesia can increase the risk of anesthesia-related complications.

125. Incorporating a bone cutting guide like Palmer’s into Dayton’s procedure would reduce the risk of delayed unions, non-unions, and malunions. These occur in a bunion correction procedure when the cut bone ends do not form a proper fit after the first metatarsal is repositioned. *See* Ex.1011, 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 incorporation of a cutting guide into Dayton’s procedure would “easily and effectively achieve a union through normal biological healing.” *See* Ex.1015, [0068]. Palmer’s cutting guide with its joint plate and guide feature further promotes effective unions through “form[ing] a substantially planar prepared bone surface.” Ex.1009, [0042]; *see also id.*, [0031], claim 21.

126. Incorporating a bone cutting guide like Palmer’s into Dayton’s procedure would have been nothing more than the use of a known technique for cutting bones to improve Dayton’s known technique in the same way that the guide improved Palmer’s technique. As I explained above, Palmer’s bone cutting guide would improve Dayton’s cutting steps by precisely defining Dayton’s cuts, including of the first metatarsal and first cuneiform, via accurate and repeatable placement of the guide. *See* Ex.1009, [00139].

127. Further, a POSA would have recognized that incorporating a cutting guide like Palmer’s into Dayton’s procedure would have been nothing more than the application of a known technique to improve a similar method in a similar way. Palmer improves resection via use of a bone cutting guide that precisely defines cuts, as I described above. *See* Ex.1009, [00139]-[00140]; *see also* Ex.1011, 381-83; Ex.1012, 3:1-5; Ex.1014, [0034], [0070] (prior art describing benefits of cutting guides). A POSA would have looked to cutting guides used in other surgical

procedures, such as Palmer's, to improve Dayton's procedure given the potential risks associated with freehand resection. Dayton's procedure is similar in many respects to Palmer's, including that both procedures address the same first metatarsal-cuneiform joint. *Compare* Ex.1005, 349 (Dayton's procedure) *with* Ex.1009, [00138] (Palmer describing placement of bone cutting guide). This would reinforce to a POSA that Palmer's cutting guide is directly applicable to Dayton's procedure concerning the first metatarsal-cuneiform joint.

128. A POSA would have had a reasonable expectation of success in implementing a bone cutting guide like Palmer's as part of Dayton's procedure. Dayton describes cutting steps that would benefit from using such a cutting guide, as I explained above. Using the bone cutting guide with the joint plate and guide feature in the procedure would not have required changing the operational principles of Palmer's device, as Palmer discloses alignment of the bone cutting guide with the joint between the first metatarsal and first cuneiform by inserting the joint plate into the joint, and for subsequent cutting of a target bone, such as the first metatarsal or first cuneiform. *See* Ex.1009, [00140], [00162] (identifying exemplary target bones).

129. A POSA would have known how to modify the dimensions or feature spacing in a cutting guide like Palmer's, such as for accommodating smaller/larger feet. The POSA would have been capable of modifying this basic surgical

equipment in a simple mechanical manner, as adjusting dimensions to accommodate patient anatomy was a routine and predictable design consideration.

130. Moreover, a bone cutting guide like Palmer's would operate compatibly with a bone positioning device like Waisman's because a POSA would arrange the respective instruments to permit their use without interference.

4. Limitation 1[c]

131. Limitation 1[c] recites "using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal." A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would meet this limitation.

132. As I explained above regarding limitation 1[b], Dayton's procedure prepares the articulating ends of the metatarsocuneiform joint for arthrodesis by resecting (cutting) these opposing joint surfaces, including a "first metatarsal cut." Ex.1005, 349; *see supra* §VI.A.3; *see also* Ex.1011, 8, 324, 803, 806-808 (describing various metatarsocuneiform joint arthrodesis procedures); Ex.1010, [0039]. This resection/cutting of the first metatarsal involves cutting the first metatarsal's "leading edge," which is the articulating end of the first metatarsal. *See* Ex.1001, 5:2-5, Figs.9-11. Further, a POSA would understand that performing Dayton's disclosed resections/cuts necessarily involves use of a cutting tool given the level of precision demanded from Dayton's procedure. *See* Ex.1005, 349 ("The cuts were

oriented to correct the transverse and sagittal components, as needed, with the first metatarsal cut perpendicular to the long axis of the metatarsal.”).

133. Palmer’s bone cutting guide includes a “resection slot 120” that “can be utilized to resect a distal portion of the target bone.” Ex.1009, [00140]; *see also id.*, [0042], [00166], claim 21; *see also* Ex.1011, 382 (“primary resection guide provides for a cutting guide for resection of the articular surfaces”). As I explained above regarding limitation 1[b], this resection slot is formed by the bone cutting guide’s guide feature. *See supra* §VI.A.3. A POSA would have understood that the resection slot necessarily constrains and directs a cutting tool that performs resection through the slot: it is “utilized” to perform the resection. *See* Ex.1009, [00140] (“In the illustrated embodiment, a resection slot 120 is provided on the medial side of the base member 120 and extends in a medial-lateral direction towards the lateral side of the base member 120.”), Figs.19-20 (depicting a resection slot 120 bounded on three sides).

134. Palmer explains that its identification of “first” and “second” target bones (which are exemplified as first cuneiform and metatarsal) is not limiting, and the terms can refer to “any other bone that includes similar features, positioning, orientation, function or the like.” *Id.*, [00162]. A POSA would have understood the guide feature in Palmer as applicable to bone resections at the fusion interface, such as the first metatarsal resection (e.g., Palmer’s “second target bone”).

135. A POSA would have been motivated to use a guide feature like Palmer's to guide a cutting tool while performing the first-metatarsal cut in Dayton's procedure, thereby guiding the cutting tool to cut the articulating end of the first metatarsal (the "leading edge"). Dayton discloses that the first metatarsal cut is "oriented to correct the transverse and sagittal components, as needed" with the first metatarsal cut "perpendicular to the long axis of the metatarsal." Ex.1005, 349. A POSA would have recognized that a guide feature like Palmer's would allow for easier and repeatable perpendicular cuts to the first metatarsal for correcting transverse and sagittal deformities. *See* Ex.1009, [0042] (describing a slot to "resect a portion of the first bone to form a substantially planar prepared bone surface adjacent the second bone"). Further, Dayton describes its first metatarsal cut being made for the purpose of "fusion" of the metatarsocuneiform joint. Ex.1005, 349. Palmer's guide feature promotes fusion of the target bone. Ex.1009, [00140] ("the resection slot can be utilized to resect a distal portion of the target bone," and "[s]uch resection of the target bone may facilitate fusion of the target bone with an adjacent second target bone"); *see* Ex.1015, [0068] (describing guided cuts to "easily and effectively achieve a union through normal biological healing."); *see also* Ex.1022, 1:45-50 (describing "complications," including "poor quality bone healing" [fusion] more likely to occur during freehand resection).

136. Such a cutting tool in the combination meets the claimed “cutting tool” limitation under the plain and ordinary meaning. *See supra* §IV.C. Under §112(f), such a cutting tool is identical or at least equivalent to structures identified in the ’941 patent for the cutting tool—a saw—discussed in the claim construction section above. *See id.*

5. Limitation 1[d]

137. Limitation 1[d] recites “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would meet this limitation.

138. As I discussed regarding claim 1’s preamble, Dayton discloses repositioning the first metatarsal relative to the first cuneiform. *See supra* §VI.A.1. Dayton also describes that an HAV (bunion) deformity is “triplane” and that “each of these planes should be addressed in the corrective operation.” Ex.1005, 353. Dayton discloses this “triplane correction” occurring at the metatarsal-cuneiform joint for correcting a bunion deformity. *Id.* (“Unlike most head, shaft, and base osteotomy procedures, TMTJ arthrodesis [like Dayton’s procedure] allows triplane correction at the deformity’s [center of angular rotation].”); *see also id.*, 349 (describing procedure as an arthrodesis of the tarsal-metatarsal joint (TMTJ)).

139. Dayton identifies the planes of correction (transverse, sagittal, and frontal) and “reduction that resulted from attention to frontal plane rotational correction in addition to transverse plane and sagittal plane correction.” *Id.*, 348. Dayton explains multi-planar alignment adjustment is performed on the first metatarsal, stating that placement of pins in the first metatarsal and cuneiform to visualize first metatarsal movement. Ex.1005, 349.

140. As I explained regarding limitation 1[a], a POSA would have been motivated and had a reasonable expectation of success in using a bone positioning device like Waisman’s to facilitate Dayton’s repositioning and correction of the first metatarsal. *See supra* §VI.A.2. Waisman also provides its device can perform “compression,” “Clockwise motion,” and “translation.” Ex.1006, 6:7-13; *see also* Ex.1006, 2:30-3:1 (describing fixators used “in the course of ... surgical procedures” for “reduction, realignment and correction”), 4:25-27 (describing object of present invention to, *inter alia*, provide an external fixator for use during reduction, realignment and corrective surgery). Compression (transverse plane), clockwise motion (frontal plane), and translation (sagittal and/or transverse planes) would facilitate using the bone positioning device like Waisman’s to adjust first metatarsal alignment in multiple planes, as required by Dayton’s triplanar bunion correction.

141. For the reasons I explained for limitations 1[a]-1[b] (*supra* §§VI.A.2-3), a POSA would have been motivated to incorporate a positioning device like

Waisman's and would have reasonably expected success when using it in Dayton's procedure, including for controlling Dayton's repositioning of the first metatarsal in three planes. As a result, in the combination of Dayton in view of both Waisman and Palmer, the bone positioning device like Waisman's is used to adjust the first metatarsal alignment in multiple planes to correct a bunion, consistent with Dayton's disclosure of triplanar correction of an HAV deformity.

6. Limitation 1[e]

142. Limitation 1[e] discloses "compressing the first metatarsal and the first cuneiform together." A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would meet this limitation.

143. Dayton explains that, once the joint surfaces are resected and the first metatarsal is repositioned, "[t]he fusion site was positioned with the dorsal and medial cortices flush." Ex.1005, 349. Achieving and maintaining such a flush, gap-free fusion interface for arthrodesis involves pressing the first metatarsal and first cuneiform toward each another across the interface (applying compression) to close the fusion site and maintain contact, as the resection of the bone surfaces creates a gap that requires compression to achieve a "flush" fusion interface. *See* Ex.1016, 466 ("surgeon was able to compress the fusion site and manipulate the base of the first metatarsal"); Ex.1009, Abstract ("targeting instrument providing both distraction and compression to the joint between the target fusion bones"); *see also* Ex.1011,

808 (describing “the arthrodesis site must be held in close, stable apposition until full healing across the fusion site has occurred.”), 809 (“Final appearance of the first metatarsal cuneiform joint after planar resection. Note the close apposition of the fusion surfaces”), Fig.55.7G.

144. Dayton further discloses that its “final fixation” can include an “anatomic locking plate with compression screw.” Ex.1005, 349. This “compression screw” additionally shows that compression is applied across the metatarsal-cuneiform fusion site to press the bones together.

145. This compression in the combination would be achieved, for instance, using the bone positioning device like Waisman’s, consistent with Waisman’s disclosure that its holding/fixation possibilities include “compression.” *See* Ex.1006, 6:7-13.

7. Limitation 1[f]

146. Limitation 1[f] recites “fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would meet this limitation.

147. Dayton explains that, once the first metatarsal is repositioned, “[t]he segments were [] temporarily stabilized with smooth wires.” Ex.1005, 349. Dayton also provides that “[t]he final fixation ... consisted of multiple methods, including 2

small, flexible, locking plates ..., single- and double-screw fixation, and anatomic locking plate with compression screw.” *Id.*

148. This disclosure meets the “bone connector” limitation under its plain and ordinary meaning discussed in the claim construction section above. *See supra* §IV.B. Dayton’s wires, plates, and screws are bone connectors that fix the first metatarsal’s position relative to the first cuneiform and thus are devices for connecting bone. Under §112(f), these wires, plates, and/or screws are the same types of connector structures identified in the ’941 patent (e.g., plate/pin/screw/wire/staple) and thus constitute the corresponding structure (or at least an equivalent) for fixing the first metatarsal’s position relative to the first cuneiform. *See id.*

149. In the combination, the bone positioning device like Waisman’s is used for manipulating and maintaining the first metatarsal relative to the first cuneiform during repositioning. *See supra* §§VI.A.2, VI.A.5 (limitations 1[a], 1[d]). After this repositioning, Dayton’s wires and/or plates/screws are used to stabilize and maintain the achieved position. As a result, Dayton’s temporary and final fixation are both compatible with and complementary to incorporating a bone positioning device like Waisman’s.

B. Claim 2

150. Claim 2 depends from claim 1 and recites “further comprising, prior to fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, temporarily fixing the position of the first metatarsal relative to the first cuneiform.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 2.

151. As I explained above explained regarding limitation 1[f], Dayton describes a temporary fixation step prior to final fixation. *See supra* §VI.A.7. Dayton specifically explains “[t]he segments were [] temporarily stabilized with smooth wires,” and then describes “final fixation” using plates and/or screws. Ex.1005, 349. As a result, Dayton describes temporarily fixing the first metatarsal’s position relative to the first cuneiform (e.g., with wires) before fixing that position with a bone connector (e.g., plates/screws). *Id.*

152. Further, in the combination, the bone positioning device is used to temporarily hold the first metatarsal relative to the first cuneiform during repositioning prior to application of Dayton’s temporary wires and/or final fixation. *See* Ex.1006, 4:25-28, 27:7-8 (describing use of polyaxial external fixator system, including fixator, for “temporary or final fixation”). This disclosure also meets the claimed “temporarily fixing ... prior to fixing ... with the bone connector” sequence.

C. Claim 3

153. Claim 3 depends from claim 1 and recites “further comprising cutting a leading edge of the first cuneiform.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 3.

154. As I explained above regarding limitation 1[b], Dayton discloses “resection of the articular surfaces” at the metatarsal-cuneiform joint, such as resecting/cutting the first cuneiform’s articulating joint surface where it meets the first metatarsal. *See supra* §VI.A.3; Ex.1005, 349. The “leading edge” of a bone, such as the first cuneiform, is the articulating or opposing surface (in other words, surface of the bone facing the joint), satisfying this claim’s the cutting-leading-edge limitation.

D. Claim 4

155. Claim 4 depends from claim 3 and recites “wherein cutting the leading edge of the first cuneiform comprises cutting the leading edge of the first cuneiform after using the bone positioning device to adjust the alignment of the first metatarsal.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 4.

156. Dayton describes that achieving corrected alignment is an intraoperative objective, noting that surgeons assess alignment clinically and under

fluoroscopy during the procedure. Ex.1005, 349. Dayton further describes positioning the dorsal and medial cortices of the first metatarsal and first cuneiform “flush” to promote fusion. *Id.*

157. Dayton’s disclosed procedure performs the “cuneiform cut” before rotation of the first metatarsal (Ex.1005, 349), yet a POSA would have understood that the order of resection (including the cuneiform cut) and frontal-plane rotational correction is not critical to achieving Dayton’s objective of congruent, fluoroscopically confirmed reduction and a flush fusion interface. Indeed, finalizing the cuneiform cut after establishing the intended reduction promotes the “flush” cortices Dayton seeks and reduces the likelihood of recuts or rework that can result if the cut is finalized before the intended alignment is established. Ex.1005, 349. This congruency reduces the likelihood that a cut made before adjustment will require rework or recutting, thereby risking “[s]ignificant shortening” of the first metatarsal. *See* Ex.1011, 324 (describing importance of joint preparation for fusion and describing risk of significant shortening).

158. The ’941 patent itself confirms that the claimed step order is exemplary (“need not be performed in the order stated”) and that cutting is optionally performed “after a position of the bone has been fixed.” Ex.1001, 5:52-53, 4:66-5:2. Such a selection of step order, as recited in claim 4, reflects a routine sequencing alternative to Dayton’s disclosed order.

159. A POSA would have recognized that a finite number of sequencing options exist for repositioning the first metatarsal and cutting the first metatarsal and cuneiform. For example, a surgeon could: (1) realign the first metatarsal before cutting the metatarsocuneiform joint bones, (2) cut both bones and then reposition the first metatarsal, (3) cut the first metatarsal, realign it, and then cut the cuneiform, or (4) cut the cuneiform, realign the first metatarsal, and then cut the first metatarsal. Options (1) and (3) satisfy this limitation. In contrast, options (2) and (4) would require precise orientation of the cuneiform cut to achieve a “flush” interface because the cuneiform remains stationary during a metatarsocuneiform arthrodesis. Any deviation from a perfectly corresponding metatarsal cut may result in gapping—thereby increasing the risk of delayed union or nonunion—or necessitate a recut, further risking shortening of the first metatarsal. *See* Ex.1011, 446 (describing delayed union and nonunion issues with gapping); *see also id.*, 324 (describing importance of joint preparation/resection in “efforts to obtain a bony union and avoid a delayed and nonunion” in a metatarsocuneiform arthrodesis).

160. There would have been a reasonable expectation of success for a POSA because Dayton describes achieving and confirming the desired reduction and then stabilizing the segments to obtain flush cortices at the fusion site. Ex.1005, 349. A POSA would expect that performing the cuneiform cut after establishing the intended reduction would yield the flush apposition Dayton seeks.

E. Claim 5

161. Claim 5 depends from claim 3 and recites “wherein cutting the leading edge of the first cuneiform comprises using the guide feature of the bone cutting guide to guide the cutting tool to cut the leading edge of the first cuneiform.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 5.

162. As I explained above regarding limitation 1[b] and claim 3, Dayton describes preparing the metatarsal-cuneiform joint by resecting/cutting the opposing joint surfaces, and Dayton further expressly calls out a “cuneiform cut.” Ex.1005, 349; *see also supra* §§VI.A.3, VI.C.

163. As I also explained above regarding limitations 1[b]-1[c], Palmer describes a cutting guide having a guide feature (e.g., cutting guide portion structurally defining resection slot) that is used to guide a cutting tool during resection. *See supra* §§VI.A.3-4. According to Palmer, an “illustrated embodiment of the guide instrument 100 is particularly well suited for use with the medial or transverse cuneiform bone.” Ex.1009, [00136]; *see also id.*, [00135], [00138]-[00139], [00162] (describing use of Palmer’s instrument at metatarsocuneiform joint).

164. A POSA would have been motivated to use a cutting guide like Palmer’s with its guide feature to guide the cutting tool while performing Dayton’s

cuneiform cut at the first metatarsal-first cuneiform interface. As I explained above regarding limitation 1[c], A POSA would have recognized that a guide feature like Palmer's would allow for easier and repeatable cuts to the first cuneiform for correcting transverse deformities, including reduction of the IMA. *See* Ex.1009, [0042] (describing a resection guide surface of a cutting guide to "resect a portion of the second bone to form a substantially planar prepared bone surface adjacent the first bone"); Ex.1005, 349; *see also* §VI.A.4. A cutting guide like Palmer's would also help prevent excessive removal of cuneiform bone to accomplish Dayton's goal of allowing transverse plane correction "without sacrificing the length of the first ray." Ex.1009, 349; *see also* Ex.1011, 329 (warning that errors in cutting, *inter alia*, the first cuneiform may result in "[s]ignificant shortening" of the first ray). Further, Dayton describes its first cuneiform cut being made for the purpose of "fusion" of the metatarsocuneiform joint. Ex.1005, 349. Palmer's guide feature promotes fusion of the target bone. Ex.1009, [00140] ("the resection slot can be utilized to resect a distal portion of the target bone," and "[s]uch resection of the target bone may facilitate fusion of the target bone with an adjacent second target bone"); *see* Ex.1015, [0068] (describing guided cuts to "easily and effectively achieve a union through normal biological healing."); *see also* Ex.1022, 1:45-50 (describing "complications," including "poor quality bone healing" [fusion] more likely to occur during freehand resection).

165. Further, a POSA would have found using a cutting guide like Palmer's to cut the leading edge of the first cuneiform to be a predictable, routine design choice. A surgeon using such a cutting guide in Dayton's procedure would use the same cutting guide (and its guide feature) to guide the cutting tool during resections of each of the two bones forming the fusion interface—the first metatarsal and first cuneiform—rather than requiring separate guides for different bones. Doing so would reduce instrument changes and inventory usage, simplify operative workflow, and promote consistent preparation of complementary planar bone surfaces for apposition at the fusion interface.

166. There would have been a reasonable expectation of success for a POSA in using such a cutting guide to cut the leading edge of the first cuneiform because a guide feature like Palmer's is intended to guide resection for creating a prepared surface for fusion with another bone. Ex.1009, [0042], [00132], [00140]. This is the same joint preparation objective in Dayton. Ex.1005, 349 (describing procedure for using metatarsocuneiform joint, including the disclosed cuneiform cut).

F. Claim 6

167. Claim 6 depends from claim 1 and recites “further comprising, after fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, removing the first fixation pin from the first metatarsal and removing the second fixation pin from the first cuneiform.” A POSA would have been motivated

to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 6.

168. As I explained above regarding limitation 1[a], Waisman describes using fixation pins/K-wires to engage its bone positioning device with the first metatarsal and first cuneiform during reduction/realignment/correction and explains that “[its] invention may be used as temporary ... fixation.” Ex.1006, 15:4-5, 4:25-27, 27:7-9; *see also supra* §VI.A.2. Waisman also describes that its pins/K-wires are easily removable (e.g., by “just pull[ing] out applying a gentle rotation”). Ex.1006, 7:5.

169. Fixation pins like Waisman’s are used in the combination to achieve and maintain the desired repositioning during the correction steps, as I explained above regarding limitations 1[a] and 1[d]. *Supra* §§VI.A.2, VI.A.5. After the corrected relationship between the first metatarsal and cuneiform is fixed with the bone connector (e.g., Dayton’s disclosed fixation using wires and/or plates/screws as I explained above regarding limitation 1[f] (*supra* §VI.A.7)), the bone connector maintains the corrected alignment independent of the fixation pins. *See* Ex.1005, Fig.5B (depicting fixed first metatarsal and first cuneiform with fixation structures and without pins). Accordingly, the pins are no longer needed to maintain alignment.

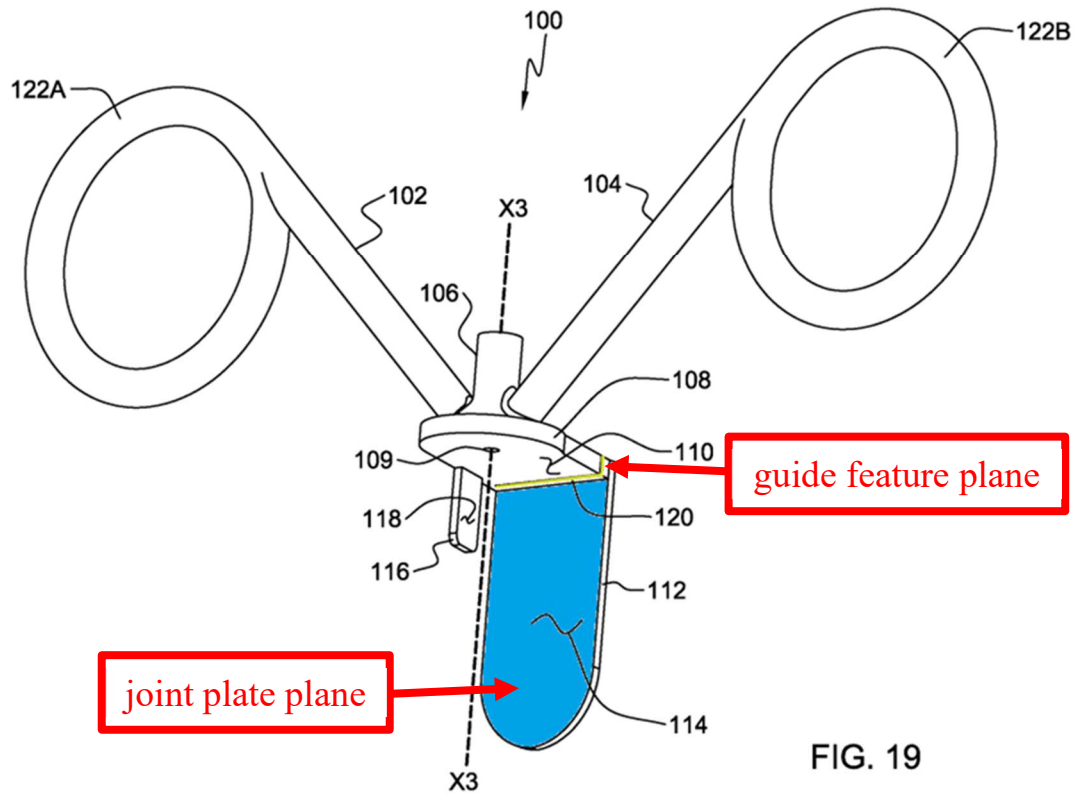
170. A POSA would have known to remove the first and second fixation pins after the corrected position of the metatarsocuneiform bones are fixed with the bone connector, consistent with Waisman's disclosure. After fixation with the bone connector, there would no longer be a purpose for keeping the pins in the bones, and the surgeon would not leave unnecessary hardware at the operative site that might interfere with the function of the bone connector.

G. Claim 7

171. Claim 7 depends from claim 1 and recites "wherein the joint plate defines a plane, the guide feature defines a plane, and the plane defined by the joint plate is parallel to the plane defined by the guide feature." A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 7.

172. Palmer's joint plate (distal positioning tab) "may define a substantially planar member." Ex.1009, [00137]; *see also id.*, Figs.19-20. A POSA would have understood that a "substantially planar" tab defines a plane, and that Palmer's resection slot, given its slot walls/slot-defining structure that guides the cutting tool, likewise defines a plane corresponding to the guided cutting direction. *Id.*, Figs.19-20, [00140]. Consistent with the configuration shown in Palmer's Figures 19-20, a POSA would have been motivated to orient the slot-defined cutting plane (yellow

below) parallel to the tab-defined plane (blue below) so that the guided resection is aligned to the reference plane established by the tab.



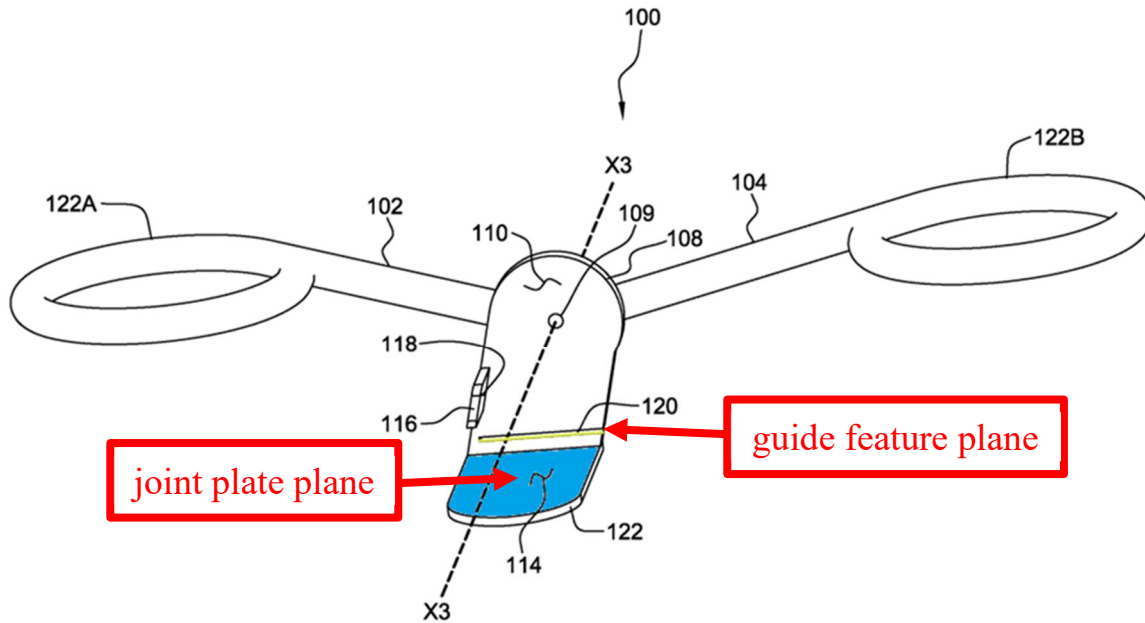


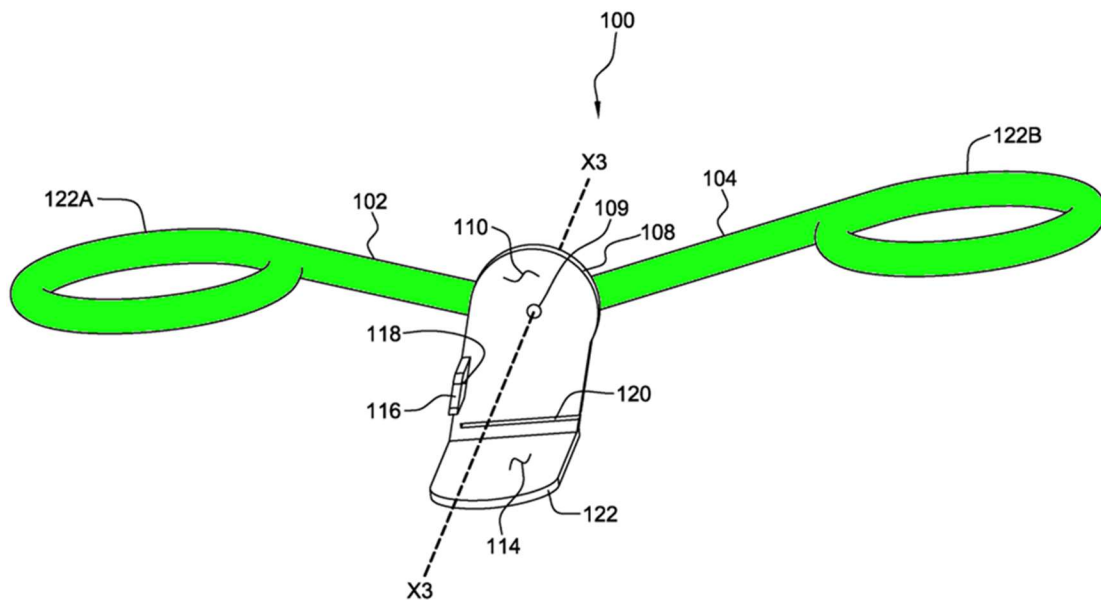
FIG. 20

Id., Figs.19-20 (annotated); *see also id.*, [00137] (describing joint plate—and thus joint plate plane—extending perpendicularly from slot-defining structure). This configuration would yield predictable and repeatable planar bone preparation. *See* Ex.1009, [0042].

H. Claim 8

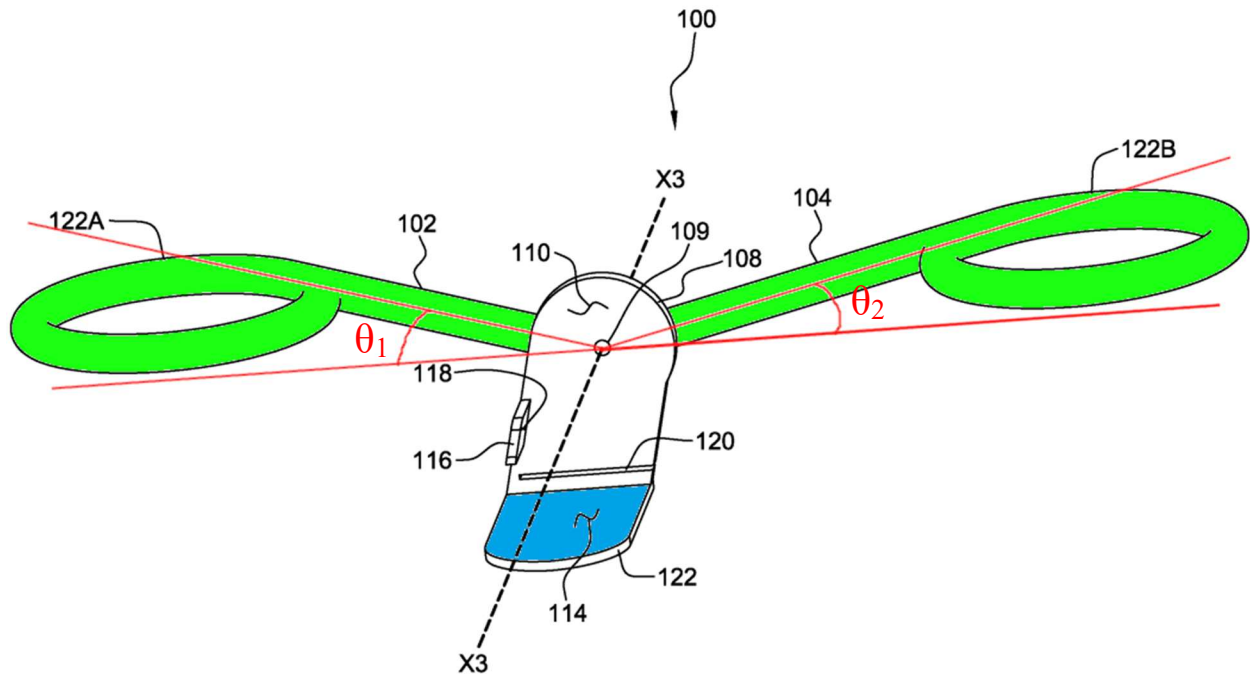
173. Claim 8 depends from claim 7 and recites “wherein the bone cutting guide comprises a handle extending away from the joint plate at an angle between 30 degrees and 60 degrees with respect to the plane.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 8.

174. Palmer describes its guide as having first and second arms 102 and 104 that terminate in manually engageable members 122A and 122B (green). Ex.1009, [00131]. These members function as a handle for guide manipulation. *Id.* (describing user passing fingers through engageable members to “allow the guide instrument 100 to be manually applied to target fusion bones” and manual removal therefrom).



Ex.100, Fig.20 (color added).

175. Palmer describes its arms extending “vertically” from the guide’s top surface—away from the body/joint-plate rather than remaining coplanar with it. *Id.*; *see also id.*, [00137]. Palmer illustrates the members 122A, 122B as not extending parallel to one another, but instead extending away from a line parallel to the joint plate (blue) by acute “away” angles (θ_1 , θ_2):



Ex.1009, Fig.20 (annotated).

176. A POSA would have found selecting a specific acute angle for the handle extension (θ_1/θ_2) in the cutting guide—such as angle within the claimed range of 30°-60°—to be a routine design choice. A POSA would have understood the handle angle relative to the joint-plate plane is an ergonomic/clearance design parameter chosen to (i) provide handle clearance over the operative site, (ii) improve visibility and access for the cutting tool guided by the guide feature, and (iii) reduce interference between the user's grip and surrounding anatomy or instrumentation—while leaving the guide's cutting function unchanged. A handle like that in Palmer's cutting guide meets these objectives. The claimed range reflects a finite set of predictable acute-angle configurations used to balance access, clearance, and

control. Choosing a moderate “away” angle within 30°-60° would predictably preserve or improve access to the resection slot rather than obstruct it.

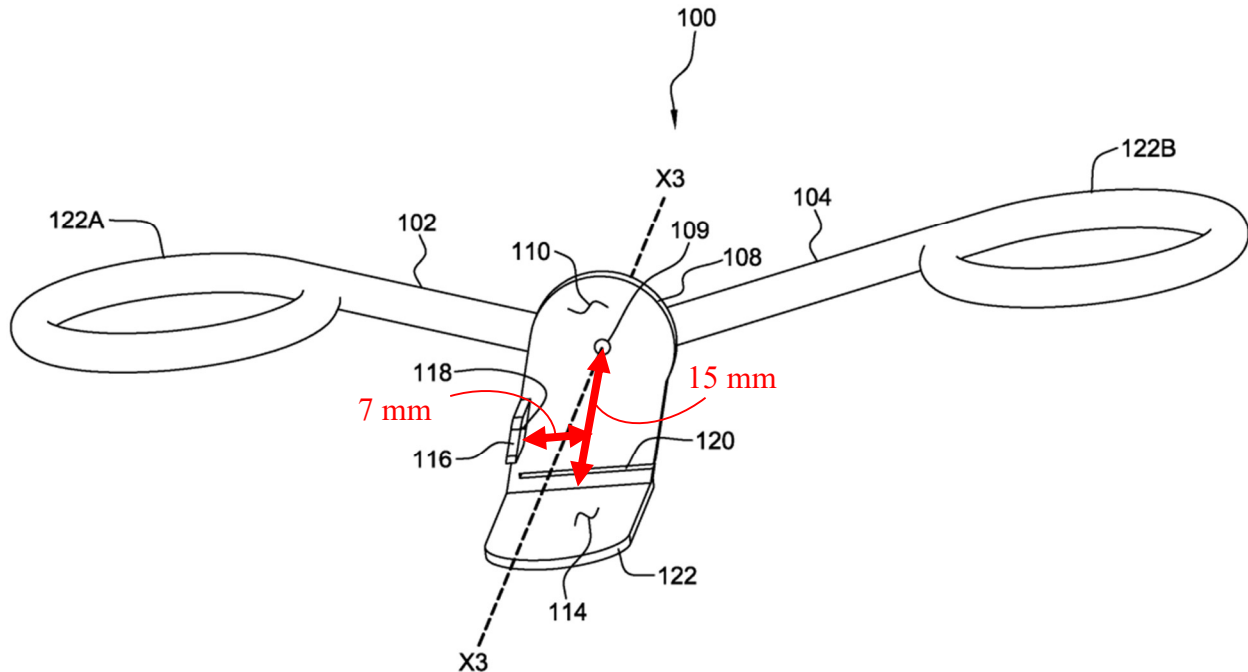
177. A POSA would have also had a reasonable expectation of success because selecting the handle angle between 30°-60° does not alter the guiding relationship between the guide feature, cutting tool, and cut plane, but instead relocates the grasp point.

I. Claim 9

178. Claim 9 depends from claim 1 and recites “wherein the joint plate is offset from the guide feature by being spaced laterally from the guide feature, and the guide feature defines a guiding surface that is offset from the joint plate a distance ranging from 1 millimeter to 20 millimeters.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 9.

179. Palmer describes its guide as having millimeter-scale geometric offsets between functional locating/abutment features and other structures, including providing that “the distal abutment surface 114 of the distal positioning tab 112 is spaced from the longitudinal X3-X3 of the longitudinally extending aperture 109 about 15 millimeters” and “the lateral abutment surface 118 of the lateral positioning tab 116 is spaced from the longitudinal X3-X3 of the longitudinally extending

aperture 109 about 7 millimeters” in an illustrative embodiment. Ex.1009, [00136]-[00138]. Figure 20 below depicts these offsets:



Ex.1009, Fig.20 (annotated).

180. These disclosures would show that Palmer contemplates and teaches dimensional offsets on the order of 1-20 mm between locating structures and guide structures on the cutting guide. Palmer’s positioning tabs are joint-locating structures, including being positioned between adjacent bones at the target joint (e.g., between first cuneiform and metatarsal, or between first and intermediate cuneiform). Ex.1009, [00135]-[00138] (describing use of positioning tabs). Accordingly, Palmer’s disclosure of 15 mm and 7 mm spacings from the tab abutment surfaces to the X3-X3 axis of aperture 109 evidence the type of millimeter-

scale offset between the joint-inserted locating structure and the guide structure that defines the guiding surface/slot required by claim 9.

181. A POSA would have been motivated to select a lateral spacing between the joint plate used to locate the cutting guide at the joint and the guiding surface of the guide feature within the claimed range of 1-20 mm. This selection would be based on ordinary considerations in the medical device design process, such as anatomical clearance, maintaining stable seating of the joint plate in the metatarsocuneiform joint while permitting the cutting tool to pass through and be constrained by the guide feature, and achieving the intended resection location at the fusion interface (for example, ensuring Dayton's objective of resecting "all subchondral bone" from the target bone's leading edge (Ex.1005, 349)).

182. There would have been a reasonable expectation of success for a POSA because changing the magnitude of the offset or selecting it to be within a millimeter scale range does not change the fundamental guiding function of the guide feature. Rather, it positions the guided cut relative to the locating/abutment structure used to position the guide on the bone.

J. Claim 10

183. Claim 10 depends from claim 1 and recites "wherein the joint plate is integral with the guide feature." A POSA would have been motivated to combine

Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 10.

184. Palmer describes its bone cutting guide 100 as including a distal positioning tab 112 that may define a “substantially planar member” and “extend[] from the dorsal abutment surface 110 of the base member 108.” Ex.1009, [00137]. Palmer further explains that the same guide can include “a resection slot 120 extending ... from a lateral side of the base member.” *Id.*, [00140]. As a result, Palmer the distal positioning tab 112 (joint plate) and structure defining the resection slot 120 (guide feature) as portions of the same guide/body which are integral with one another. A POSA likewise would have been motivated to make the joint place and the guide feature in the combination integral with each other.

185. If “integral” requires has a meaning beyond Palmer’s disclosure that both the guide feature and the joint plate be portions of the same bone cutting guide/body, a POSA would have been motivated to implement the distal positioning tab and slot-defining guide feature as integral in the bone cutting guide. Palmer explains that “particular aspects or features described or illustrated herein as individual separate components may be combined into an integral unit.” Ex.1009, [00177]. Adopting such an integrated unit for the bone cutting guide would have been a predictable implementation choice for a POSA to maintain rigidity and repeatable cut guidance (and avoids unnecessary interfaces/assembly) while leaving

the guiding and positioning functions unchanged. A POSA would further have had a reasonable expectation of success in implementing the joint plate and guide feature integrally based upon Palmer's disclosure.

K. Claim 11

186. Claim 11 depends from claim 1 and recites "wherein using the guide feature of the bone cutting guide to guide the cutting tool comprises placing the cutting tool in apposition to a guide surface defined by the guide feature of the bone cutting guide." A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 11.

187. As I explained above regarding limitation 1[c], a POSA would have been motivated to use a bone cutting guide like Palmer's, including its guide feature (e.g., resection slot), to guide the cutting tool for performing the first-metatarsal cut in Dayton's procedure. *See supra* §VI.A.4. In the combination, as I explained regarding limitation 1[c], the "guide surface defined by the guide feature" corresponds to a surface that defines the slot and provides the guiding constraint (e.g., interior wall surface forming the slot). *See supra* §VI.A.4; *see also* Ex.1009, [00140]; Ex.1011, 382 ("primary resection guide provides for a cutting guide for resection of the articular surfaces").

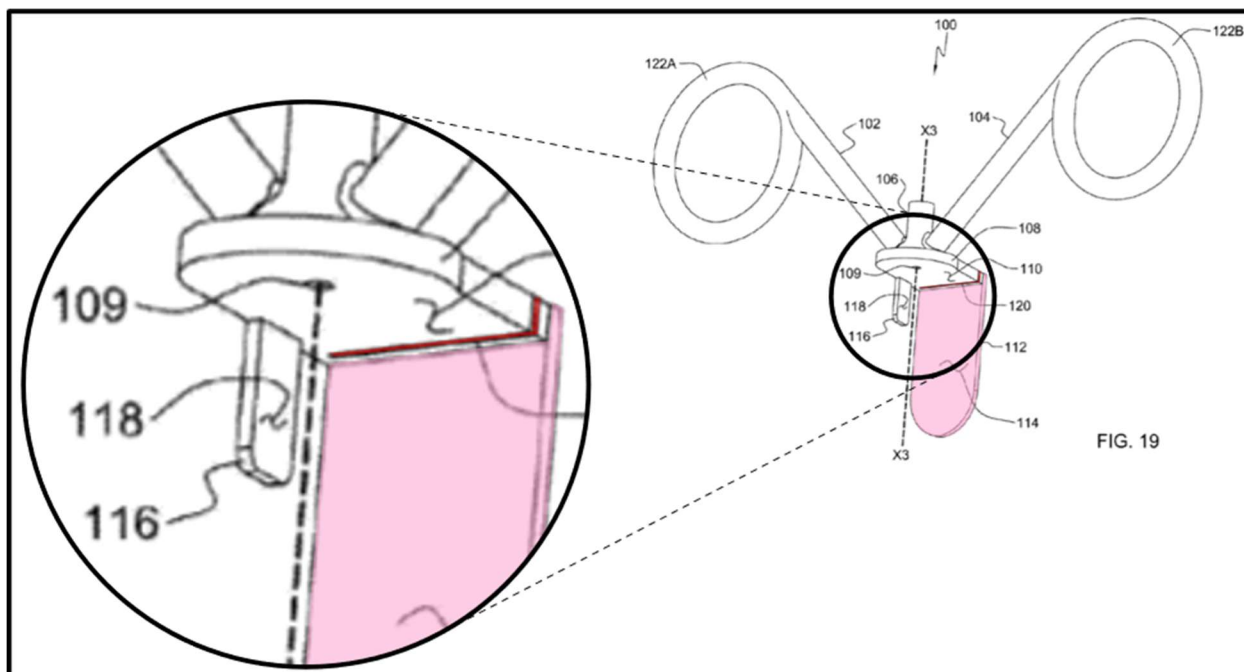
188. Thus, using the guide feature to guide the cutting tool comprises placing the cutting tool in apposition to that guide surface (i.e., positioned against the slot's

guiding surface) by positioning the cutting tool through and along the slot such that, as used, the tool is guided by the slot-defining guiding surface with the guide surface constraining and directing the tool's movement during the resection. The use of Palmer's resection slot in this manner would have been desirable to prevent cuts at an undesired angle. Ex.1009, [0042]; Ex.1005, 349 (describing "flush" orientation of cut surfaces). This reflects the routine, predictable operation of slot-based cutting guides and would have been implemented in ordinary course by a POSA. For example, McGlamry discloses a bone cutting guide that functions by placing a cutting tool in apposition to a guide surface. *See* Ex.1011, 382, Figs.34.27A-B.

L. Claim 12

189. Claim 12 depends from claim 11 and recites "wherein the guide surface is operable to guide the cutting tool in a plane parallel to the guide surface." A POSA would have been motivated to combine Dayton, Waisman, and Palmer to arrive at claim 12.

190. Palmer provides that its cutting guide includes the resection slot that "extend[s] in a medial-lateral direction" and is "utilized to resect a distal portion of the target bone." Ex.1009, [00140]. Figure 19 below depicts this resection slot (red):



Ex.1009, Fig.19 (annotated). Given that Palmer describes the slot as extending in a defined direction and being used to perform a resection, this slot-defining wall surface provides a straight guiding surface over that extent, which causes the tool path during resection to remain in a plane parallel to that surface.

191. When the cutting tool is placed in apposition to the slot's guide surface in the procedure in the combination, the guide surface guides the tool's movement in a plane parallel to the guide surface because the tool's permitted motion during resection is constrained to slide/translate along that surface.

M. Claim 13

192. Claim 13 depends from claim 1 and recites "wherein using the guide feature of the bone cutting guide to guide the cutting tool comprises placing the cutting tool in contact with a guide surface defined by the guide feature of the bone

cutting guide.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 13.

193. As I explained above regarding claim 11, a POSA would have been motivated to place the cutting tool in apposition to a guide surface defined by the guide feature. *See supra* §VI.K. Using the guide feature to guide the cutting tool requires the tool to contact that slot’s guide surface to constrain and direct the tool along the intended resection path. *See* Ex.1009, [0042]; Ex.1005, 349 (describing “flush” orientation of cut surfaces); *see also* Ex.1011, 382, Figs.34.27A-B.

N. Claim 14

194. Claim 14 depends from claim 1 and recites “wherein the cutting tool is a saw blade.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 14.

195. As I explained above regarding limitation 1[c], a POSA would have been motivated to use a cutting guide like Palmer’s, including its guide feature (e.g., resection slot), to guide the cutting tool while performing the first-metatarsal cut in Dayton’s procedure. *See supra* §VI.A.4. Such a saw blade is a conventional “cutting tool” used to performing controlled planar bone resections of the type described in Dayton and guided by a slot-type guide as described in Palmer. *See* Ex.1017, 99 (“It is the surgeon’s choice as to joint resection technique, though a saw is commonly

used.”); Ex.1011, 382 (describing use of resection guide with saw), 808 (same for a metatarsocuneiform arthrodesis procedure).

196. Further, using a saw blade with a guide slot is a predictable, routine option because the flat blade geometry is well-suited to the guide’s planar constraint, facilitating repeatable cuts and maintaining the intended resection plane. Ex.1009, [0042], [00139]; *see also supra* §§VI.A.3-4 (limitations 1[b] and 1[c]) (describing repeatability of cuts using a bone cutting guide like Palmer’s).

197. A POSA would have been motivated to implement the guided cutting in the combination using a saw blade with a reasonable expectation of success. Using one known bone-cutting implement (saw blade) in place of another generic cutting tool does not change the guide’s function and yields the predictable result of a guided resection, resulting in a cut surface as desired. *See* Ex.1009, [0042].

O. Claim 15

198. Claim 15 depends from claim 1 and recites “wherein the bone connector comprises one or more of a plate, screw, and pin.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 15.

199. As I explained above regarding limitation 1[f], Dayton discloses a bone connector comprising a plate, screw, or pin. *See supra* §VI.A.7.

P. Claim 16

200. Claim 16 depends from claim 1 and recites “wherein compressing the first metatarsal and the first cuneiform together comprises applying a force to press a first fixation pin inserted into the first metatarsal and a second fixation pin inserted into the first cuneiform toward one another.” A POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 16.

201. As I explained above regarding limitation 1[e], the first metatarsal and first cuneiform are compressed together in Dayton’s procedure and in the combination. *See supra* §VI.A.6; Ex.1005, 349. Additionally, as I explained above regarding limitation 1[a], Waisman describes engaging a positioning device with bones using fixation pins/K-wires and that its invention can be used as “temporary or final fixation” during reduction, realignment, and/or correction. *See supra* §VI.A.2.

202. Waisman moreover discloses its positioning device can perform various holding/fixation possibilities, such as “compression.” Ex.1006, 6:7-13. This compression function applies a compressive force through the bone positioning device (Waisman’s fixator) to the pins anchored in the bones to drive those pins toward one another, which diminishes the gap between the first metatarsal and first cuneiform and thus presses the bones together.

203. A POSA would have been motivated to use a positioning device like Waisman's in the combination with the first pin inserted into the first metatarsal and the second pin inserted into the first cuneiform not only to achieve and/or hold Dayton's corrected alignment, but further—consistent with Waisman's disclosure of “compression”—to apply a force that presses the pins in the first metatarsal and first cuneiform toward one another. This would compress the first metatarsal and cuneiform together at the fusion site, achieving Dayton's “flush” cortices. Ex.1005, 349.

204. This is a predictable and routine use of compression capability like Waisman's in the context of Dayton's procedure, since such compression across opposing joint surfaces is a known and expected objective at a fusion site. *See* Ex.1011, Fig.55.7F-G, 808 (“[T]he arthrodesis site must be held in close, stable apposition until full healing across the fusion site has occurred.”); Ex.1005, 349. Incorporating compression through actuating such a pin-based positioning device does not require alternations to Dayton's surgical goal or to Waisman's described mode of operation.

Q. Claim 17

205. Claim 17 depends from claim 1 and recites “wherein the bone positioning device comprises a sliding connection and a screw, and compressing the first metatarsal and the first cuneiform together comprises operating the screw.” A

POSA would have been motivated to combine Dayton, Waisman, and Palmer, and the resulting combination would satisfy claim 17.

206. As I explained above regarding limitation 1[e], the first metatarsal and first cuneiform are compressed together in Dayton's procedure and in the combination. *See supra* §VI.A.6; Ex.1005, 349. In addition, as I explained above regarding claim 16, a POSA would have been motivated to use a bone positioning device like Waisman's to apply a force pressing the first metatarsal and cuneiform toward one another, thereby compressing them together. *See supra* §VI.P.

207. Waisman describes a bone positioning device in which fixation pins are secured to "cages," and the cages are mounted to connecting rods via rod-receiving holes sized to fit the rods, enabling the cages to be positioned relative to the rod(s) before being locked and/or clamped in a selected position. Ex.1006, 16:15-17:8, 20:23-28. Waisman also describes that its cages' relative positioning on the rods may be maintained by one or more screws (e.g., screws received in tapped holes of the cage) that are tightened to fix (e.g., clamp or lock) the cage relative to the rod. *Id.*

208. A POSA would have been motivated to use a structure like Waisman's sliding cage/rod interface, together with its screw-based locking, for implementing compression across Dayton's metatarsal-cuneiform fusion site. A POSA would have been motivated to achieve this "compression" described by Waisman by (i)

sliding one or both cages along the rod(s) to reduce the spacing between the bone-anchored pins (bringing the first metatarsal and first cuneiform together), and then (ii) operating the screw (e.g., tightening the cage lock screw) to lock the cage(s), which would maintain the compression at the fusion site while fixation is completed. Such operation of a bone positioning device like Waisman's satisfies the requirement that "compression" comprises "operating the screw," since setting the cage position via the slidable connection and then operating the screw carries out the compression step in Waisman's screw/slide mechanism to secure the compression-setting configuration. A POSA would have a reasonable expectation of success in this routine use of Waisman's screw-actuated locking of a slidable connection to achieve and maintain compression for Dayton's procedure.

R. Claim 18

209. For the reasons I described below, Dayton in view of Waisman and Palmer renders obvious claim 18.

1. Preamble

210. The preamble of claim 18 recites "[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform." To the extent the preamble is limiting, and for the same reasons as I explained above regarding claim 1's preamble, a POSA would have been motivated to combine

Dayton, Waisman, and Palmer; the resulting combination would satisfy this preamble. *See supra* §VI.A.1.

2. Limitation 18[a]

211. Limitation 18[a] recites “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform.” For the same reasons as I explained above regarding limitation 1[a] (*see supra* §VI.A.2), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[a].

3. Limitation 18[b]

212. Limitation 18[b] recites “aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform, the bone cutting guide comprising a joint plate offset from a guide feature of the bone cutting guide, the joint plate extending downwardly relative to the guide feature, wherein aligning the bone cutting guide with the joint comprises inserting the joint plate into the joint.” For the same reasons as I explained above regarding limitation 1[b] (*see supra* §VI.A.3), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[b].

4. Limitation 18[c]

213. Limitation 18[c] recites “using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal.” For the same reasons as I explained above regarding limitation 1[c] (*see supra* §VI.A.4), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[c].

5. Limitation 18[d]

214. Limitation 18[d] recites “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” For the same reasons as I explained above regarding limitation 1[d] (*see supra* §VI.A.5), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[d].

6. Limitation 18[e]

215. Limitation 18[e] recites “after using the bone positioning device to adjust the alignment of the first metatarsal in multiple planes to correct the bunion, cutting a leading edge of the first cuneiform.” For the same reasons as I explained above regarding claims 3 and 4 (*see supra* §§VI.C-D), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[e].

7. Limitation 18[f]

216. Limitation 18[f] recites “compressing the first metatarsal and the first cuneiform together.” For the same reasons as I explained above regarding limitation 1[e] (*see supra* §VI.A.6), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[f].

8. Limitation 18[g]

217. Limitation 18[g] recites “fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.” For the same reasons as I explained above regarding limitation 1[f] (*see supra* §VI.A.7), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy limitation 18[g].

S. Claim 19

218. Claim 19 depends from claim 18 and recites “further comprising, prior to fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, temporarily fixing the position of the first metatarsal relative to the first cuneiform.” For the same reasons as I explained above regarding claim 2 (*see supra* §VI.B), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 19.

T. Claim 20

219. Claim 20 depends from claim 18 and recites “further comprising, after fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, removing the first fixation pin from the first metatarsal and removing the second fixation pin from the first cuneiform.” For the same reasons as I explained above regarding claim 6 (*see supra* §VI.F), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 20.

U. Claim 21

220. Claim 21 depends from claim 18 and recites “wherein cutting the leading edge of the first cuneiform comprises using the guide feature of the bone cutting guide to guide the cutting tool to cut the leading edge of the first cuneiform.” For the same reasons as I explained above regarding claim 5 (*see supra* §VI.E), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 21.

V. Claim 22

221. Claim 22 depends from claim 18 and recites “wherein the joint plate defines a plane, the guide feature defines a plane, and the plane defined by the joint plate is parallel to the plane defined by the guide feature.” For the same reasons as I explained above regarding claim 7 (*see supra* §VI.G), a POSA would have been

motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 22.

W. Claim 23

222. Claim 23 depends from claim 22 and recites “wherein the bone cutting guide comprises a handle extending away from the joint plate at an angle.” For the same reasons as I explained above regarding claim 8 (*see supra* §VI.H), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 23.

X. Claim 24

223. Claim 24 depends from claim 18 and recites “wherein the guide surface is operable to guide the cutting tool in a plane parallel to the guide surface.” For the same reasons as I explained above regarding claim 12 (*see supra* §VI.L), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 24.

Y. Claim 25

224. Claim 25 depends from claim 18 and recites “wherein the bone connector comprises one or more of a plate, a screw, and a pin.” For the same reasons as I explained above regarding claim 15 (*see supra* §VI.O), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 25.

Z. Claim 26

225. Claim 26 depends from claim 18 and recites “wherein compressing the first metatarsal and the first cuneiform together comprises applying a force to press the first fixation pin inserted into the first metatarsal and the second fixation pin inserted into the first cuneiform toward one another.” For the same reasons as I explained above regarding claim 16 (*see supra* §VI.P), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 26.

AA. Claim 27

226. Claim 27 depends from claim 18 and recites “wherein the bone positioning device comprises a sliding connection and a screw, and compressing the first metatarsal and the first cuneiform together comprises operating the screw.” For the same reasons as I explained above regarding claim 17 (*see supra* §VI.Q), a POSA would have been motivated to combine Dayton, Waisman, and Palmer; the resulting combination would satisfy claim 27.

VII. GROUND 3: CLAIMS 1-27 WOULD HAVE BEEN OBVIOUS OVER DAYTON, TAYLOR, AND PALMER

227. It is my opinion that claims 1-27 of the '941 patent would have been obvious to a POSA in view of Dayton, Taylor, and Palmer. The disclosures and my analysis of Dayton and Palmer set forth in Ground 2 (*supra* §VI) are adopted and

applied here for the same claims and corresponding limitations addressed in Ground 2, and may not be repeated in full for brevity.

A. Claim 1

1. Preamble

228. The preamble of claim 1 recites “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” To the extent the preamble is limiting and as I explained above regarding the preamble of claim 1 in Ground 2 (*see supra* §VI.A.1), Dayton discloses a method of performing bunion surgery to correct the alignment between the first metatarsal and the medical cuneiform.

2. Limitation 1[a]

229. Limitation 1[a] recites “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform.” A POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would meet limitation 1[a].

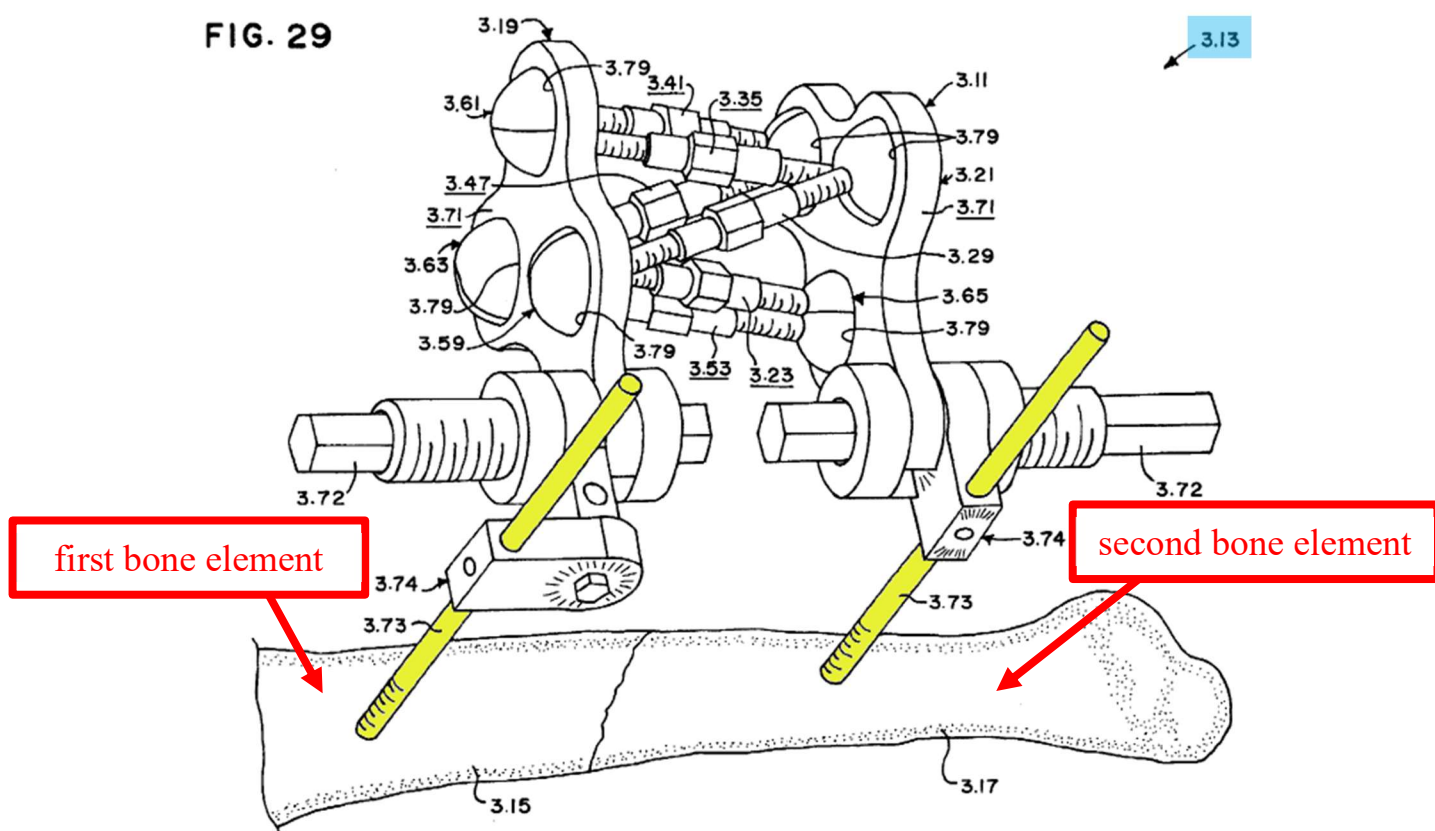
230. As I explained above regarding claim 1’s preamble and limitation 1[a] in Ground 2, Dayton discloses repositioning the first metatarsal relative to the first cuneiform. *See supra* §VI.A.1-2. Dayton further discloses inserting pins into the

first metatarsal and cuneiform for assisting in visualizing metatarsal rotation and temporarily stabilizing the first metatarsal relative to the first cuneiform. Ex.1005, 349. Dayton achieves its movement through manual manipulation. *Id.*; *see also* §VI.A.2 (limitation 1[a], Ground 2).

231. A POSA would have been motivated to use a bone positioning device like Taylor's in Dayton's procedure to facilitate bone repositioning. Taylor discloses devices that include "a mechanism that allows two bone elements to be fixed relative to one another while allowing complete repositioning of the two bone elements or portions relative to one another." Ex. 1007, 1:9-15. Taylor explains "[i]t is often necessary to realign, reposition and/or securely hold two elements relative to one another," and that "bone fragments and the like must sometimes be aligned or realigned and repositioned to restore boney continuity and skeletal function." Ex.1007, 1:17-24. According to Taylor, its device "can move one fragment with respect to the other in six orthogonal degrees of freedom, a combination of three orthogonal translational axes (e.g., typical 'X,' 'Y' and 'Z' axes) and three orthogonal rotational axes (e.g., rotation about such typical 'X,' 'Y' and 'Z' axes)." *Id.*, 5:26-33; *see also id.*, 5:52-58 (explaining its device provides "a mechanism for producing a prescribed relative change in position between two bone fragments in conjunction with external fixation of the bone fragments for correction of angular

and translational displacements of acutely fractured fragments, correction of angular and translational deformities in nonunion and malunion, etc.”).

232. Taylor illustrates an embodiment of one such device 3.13 (blue), including a spatial frame 3.11, that engages a first bone element 3.15 with a pin 3.73 (yellow) and a second bone element 3.17 with a pin 3.73 (yellow):



Id., Fig.29 (annotated); *see also id.*, 18:56-19:52, Fig.28 (illustrating similar structure), 17:60-18:55. In this configuration, the spatial frame 3.11 spans the space between the engaged bone elements 3.15, 3.17 and provides a mechanism for controlled relative movement and stabilization between these bone elements. *Id.*,

Fig.29; *see also id.*, 18:56-19:52 (describing configuration of frame 3.11). According to Taylor, its device can be “universal” and “can be used for any situation requiring relative motion between elements including compression (shortening), distraction (lengthening), translation, angulation, or rotation and any combination of such movements.” *Id.*, 5:37-42. Its device may “be[] attached to either side of a skeletal joint” (*id.*, 6:54-62), “predictably and reproducibly cause small displacements between bone fragments” (*id.*, 7:58-60), and “be used in small sizes in situations where space is at a premium, for example, in external fixation of children’s bones” (*id.*, 8:45-48).

233. A POSA would have been motivated to incorporate a bone positioning device like Taylor’s into Dayton’s procedure and to engage it with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, so that the positioning device extends across the joint separating the first metatarsal and cuneiform. *See* Ex. 1007, 1:33-36, 5:4-8; 19:30-35; *see also* Ex. 1005, 349. This would, among other things, stabilize the first metatarsal and first cuneiform during the repositioning step, including during verification of the alignment of the bones. *See* Ex. 1005, 350 (discussing how the authors verified alignment of the bones intraoperatively). This engagement and positioning across the joint would permit the surgeon to use the positioning device to achieve bone repositioning and stabilizing during Dayton’s procedure.

234. A device like Taylor's in the combination satisfies the claimed "bone positioning device" under the plain and ordinary meaning because it is a structure for positioning bones in multiple planes. *See supra* §IV.A. Under §112(f), such a bone positioning device is identical or at least equivalent to structures identified in the '941 patent for the claimed bone positioning device discussed in the claim construction section above. *See id.* This bone positioning device is at least an equivalent of the disclosed bone-positioning structures (multi-axis joint with ball-and-socket ends) because it performs the same function (adjusts first metatarsal alignment in multiple planes), in substantially the same way (split-ball joints in spherical cavities), to achieve the same result (move and hold bones in intended position).

235. A POSA would have recognized that Taylor's device and Dayton's pins would be usable according to their known functions to yield a predictable advantage: a controlled, maintainable correction. Dayton discloses placing pins in the first metatarsal and first cuneiform as visual references for manual repositioning of the first metatarsal. Ex.1005, 349. Taylor discloses that the device can be coupled to pins (Ex. 1007, 19:30-35) and positioned across joints (Ex.1007, 6:54-62). A POSA would have recognized that Taylor's device would be readily coupled to metatarsal and cuneiform pins to provide controlled, maintainable correction instead of the pins primarily serving as visual references for manual manipulation. *Id.*, 5:37-42.

236. The combination represents a straightforward modification to Dayton's procedure. Taylor describes a device "securely attached to the bone fragments with skeletal pins or wires." Ex.1007, 20:54-56. This device is the type of known surgical instrument that a POSA would identify and select to adjust and maintain relative alignment between adjacent bones during corrective surgery. *Id.* A POSA would have been motivated to incorporate external fixation engagement like Taylor's in Dayton's procedure because such a repositioning device predictably facilitates improved control and stability of the achieved alignment compared to manual manipulation while not changing Dayton's goals or strategy. *See* Ex. 1007, 5:14-16, 6:15-21. That Taylor's device is referred to as an external fixation device does not undermine the combination. Taylor describes known multi-axis repositioning and stabilization mechanics that a POSA would have predictably used intraoperatively and temporarily to achieve/hold triplanar correction in Dayton's procedure before separate final fixation. *Id.*, 5:26-33.

237. A POSA would have understood the combination as using a known fixation-and-adjustment technique like Taylor's in order to improve a similar method like Dayton's. Taylor's device offers the same degrees of freedom (Ex.1007, 5:26-33, 5:37-42) a surgeon uses to correct triplanar deformity. Engaging a device like Taylor's with metatarsal and cuneiform pins in Dayton's procedure would have predictably improved intraoperative precision and retention compared

to freehand manipulation by providing controlled movement and stable maintenance of corrected alignment.

238. A POSA would have had a reasonable expectation of success because the modification is consistent with and applies the references' disclosures, relying on predictable mechanics. *See* Ex.1006, 26:21-24. Engaging a device like Taylor's with such pins would have provided controlled repositioning and stable maintenance of the corrected alignment. *See id.* Taylor discloses "reposition[ing] any two bodies relative to each other" (Ex.1007, 6:31-33) and constructing components in "various shapes and sizes" (Ex.1007, 19:24-26), including small bones (Ex.1007, 7:58-60, 8:45-48) like the bones of the foot. Since the same pin-coupled mechanics are incorporated to move and hold bone segments, a POSA would have reasonably expected an adjustment framework like Taylor's to operate successfully in Dayton's procedure. *See* Ex.1007, Fig.29, 18:56-19:52.

3. Limitation 1[b]

239. Limitation 1[b] recites "aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform, the bone cutting guide comprising a joint plate offset from a guide feature of the bone cutting guide, the joint plate extending downwardly relative to the guide feature, wherein aligning the bone cutting guide with the joint comprises inserting the joint plate into the joint."

A POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would meet this limitation.

240. As I discussed above regarding limitation 1[b] in Ground 2, Dayton discloses manual resection of the ends of the first metatarsal and first cuneiform. *See* §VI.A.3, *supra*. Further, a POSA would have been motivated to incorporate a bone cutting guide like Palmer’s into Dayton’s procedure to facilitate bone cutting with a reasonable expectation of success, for the reasons I explained. *See id.* (limitation 1[b], Ground 2), *supra*. Incorporating a bone positioning device like Taylor’s rather than Waisman’s would not change how Palmer’s cutting guide is used in Dayton’s procedure.

4. Limitation 1[c]

241. Limitation 1[c] recites “using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal.” For the same reasons I explained in Ground 2 for this limitation (*see supra* §VI.A.4), a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would meet this limitation. Using Taylor’s bone positioning guide would not change how a cutting guide like Palmer’s is used in Dayton’s procedure.

5. Limitation 1[d]

242. Limitation 1[d] recites “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” A POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would meet this limitation.

243. Dayton describes triplanar correction of the first metatarsal. Ex.1005, 349. Taylor discloses a device that provides multi-axis relative movement of two bones, including compression, translation (both transverse and/or sagittal plane movements), and rotation (frontal plane) of the bones. Ex.1007, 5:37-42. For the same reasons I discussed above regarding limitation 1[a] in this Ground, a POSA would have been motivated to use a bone positioning device like Taylor’s to control the triplanar repositioning of the first metatarsal and the first cuneiform in Dayton’s procedure, with a reasonable expectation of success. *See* §VII.A.2, *supra*.

6. Limitation 1[e]

244. Limitation 1[e] recites “compressing the first metatarsal and the first cuneiform together.” For the same reasons I explained above regarding limitation 1[e] of Ground 2 (*see supra* §VI.A.6), a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would meet this limitation. The substitution of a bone positioning device like Taylor’s for one like Waisman’s would not change a POSA’s motivation or expectation of success in the

combination. As I explained above regarding limitation 1[a] in this Ground, using Taylor's bone positioning device, rather than Waisman's, would not change how Palmer's bone cutting guide is used in Dayton's procedure. *See supra* §VII.A.2. Further, this compression in the combination would be achieved, for instance, using the bone positioning device like Taylor's, consistent with Taylor's disclosure that its facilitated relative motion includes "compression (shortening)." *See* Ex.1007, 5:37-42.

7. Limitation 1[f]

245. Limitation 1[f] recites "fixing a position of the first metatarsal relative to the first cuneiform with a bone connector." For the same reasons I explained above regarding limitation 1[f] of Ground 2 (*see supra* §VI.A.7), a POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would meet this limitation.

B. Claims 2-5

246. For the reasons I explained above in Ground 2 regarding these same claims (*see supra* §§VI.B-E), a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would satisfy these claims. The substitution of a bone positioning device like Taylor's for one like Waisman's would not change a POSA's motivation or expectation of success in the combination.

C. Claim 6

247. Claim 6 depends from claim 1 and recites “further comprising, after fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, removing the first fixation pin from the first metatarsal and removing the second fixation pin from the first cuneiform.” A POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would satisfy claim 6.

248. As I explained above regarding limitations 1[a] and 1[d] in this Ground, Taylor describes using pins to engage its bone positioning device with the first and second bone elements (Ex.1007, 20:54-56) and that, after performing controlled positioning, the device can be “replaced by other means of stabilization” (Ex.1007, 5:4-9). *See supra* §§VII.A.2, VII.A.5. Pins are used in the combination to achieve and maintain the desired repositioning during the procedure, and when the corrected metatarsal-cuneiform relationship is fixed with the bone connector (e.g., Dayton’s wires/plates/screws as I explained for limitation 1[f] in this Ground (*supra* §VII.A.7)), that fixation maintains alignment independently of the pins. *See* Ex.1005, Fig.5B (depicting fixed first metatarsal and first cuneiform with fixation structures and without pins). A POSA would have removed the first and second fixation pins after fixation with the bone connector, as this is consistent with the

disclosure in Taylor and because this would be a predictable, routine step for the reasons I explained for this claim in Ground 2. *See supra* §VI.F (claim 6).

D. Claims 7-15

249. For the reasons I explained above in Ground 2 regarding these same claims (*see supra* §§VI.G-O), a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would satisfy these claims. The substitution of a bone positioning device like Taylor’s for one like Waisman’s would not change a POSA’s motivation or expectation of success in the combination.

E. Claim 16

250. Claim 16 depends from claim 1 and recites “wherein compressing the first metatarsal and the first cuneiform together comprises applying a force to press a first fixation pin inserted into the first metatarsal and a second fixation pin inserted into the first cuneiform toward one another.” A POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would satisfy claim 16.

251. As I explained above for limitation 1[a] in this Ground, Taylor describes engaging a pin-based positioning device with bone elements and also describes relative motion including “compression (shortening).” *See supra* §VII.A.2; Ex.1007, 5:37-42. The compression force in Taylor is applied through the

bone positioning device to the bone-anchor pins, drawing the pins toward each other, which reduces the gap between bones and presses the bones together.

252. As a result, a POSA would have been motivated to use the bone positioning device like Taylor's with the first pin in the first metatarsal and the second pin in the first cuneiform to hold Dayton's correction and apply compressive force which presses the pins (and accordingly the metatarsal and cuneiform). This is a predictable and routine use of disclosed compression capability like Taylor's in Dayton's procedure. Compression across opposing joint surfaces is a known objective at a fusion site. *See* Ex.1011, Fig.55.7F-G; *see also id.*, 808 (“[T]he arthrodesis site must be held in close, stable apposition until full healing across the fusion site has occurred.”); Ex.1005, 349. Using a bone positioning device like Taylor's for compression involves using such a device according to its intended function without changing Dayton's surgical goal or Taylor's mode of operation.

F. Claim 17

253. Claim 17 depends from claim 1 and recites “wherein the bone positioning device comprises a sliding connection and a screw, and compressing the first metatarsal and the first cuneiform together comprises operating the screw.” A POSA would have been motivated to combine Dayton, Taylor, and Palmer, and the resulting combination would satisfy claim 17.

254. As I explained above for limitation 1[e] and claim 16 in this Ground, a POSA would have been motivated to compress the first metatarsal and cuneiform using a bone positioning device like Taylor's. *See supra* §§VII.A.6, VII.E. Taylor achieves "compression (shortening)" by changing struts (Ex.1007, 5:21-25, 5:37-42), including with a screw-based strut adjuster (*id.*, 6:1-9 ("screw and nut" configuration)) in which operating (e.g., rotating) a threaded coupling produces axial sliding/translation of rod components to change (including shorten) strut length. *See* Ex.1007, 10:64-12:7, 18:39-49, 19:36-46. Taylor explains that this strut structure is used, for instance, in the embodiments of Figures 28-29. Ex.1007, 18:39-49, 19:36-46. Such axial translation is a sliding connection between rod components and the coupling, and the threaded coupling functions as a screw that drives the sliding movement.

255. A POSA would have been motivated to use a structure like Taylor's screw-actuated, axially slidable strut structure to compress the metatarsal-cuneiform fusion site in Dayton's procedure by operating the screw to shorten the strut and draw the bone-mounted components together, thereby applying and maintaining compression. For example, a POSA would have been motivated to use a screw-actuated, axially slidable strut structure like Taylor's to provide the dual ability of (1) actuating compression between the target bone segments (e.g., the first metatarsal and first cuneiform) when desired, and (2) preventing movement of the target bone

segments once repositioned. Ex.1007, 6:1-5 (describing one object of Taylor’s invention to prevent “spontaneous slippage” when “loaded in tension or compression”); *see also id.*, 6:27-30 (describing another object of Taylor’s invention to securely hold bone fragments), 5:4-8.

256. This operation of a bone positioning device like Taylor’s satisfies the claim requirement that “compressing ... comprises operating the screw” because the bone positioning device includes a sliding connection and screw, and the compression step is carried out by operating the screw to produce the sliding movement that shortens the strut and generates compression. *See* Ex.1007, 10:64-12:7, 18:39-49, 19:36-46. This is a predictable and routine use of such a bone positioning device and would provide a reasonable expectation of success.

G. Claim 18

1. Preamble and Limitations 18[a]-18[d]

257. For the reasons I explained above regarding claim 1’s preamble and limitations 1[a]-1[d] in this Ground (*see supra* §§VII.A.2-5), a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would meet claim 18’s preamble and limitations 18[a]-18[d].

2. Limitation 18[e]

258. For the reasons I explained above regarding claims 3-4 in this Ground (*see supra* §VII.B; *see also* §§VI.C-D), a POSA would have been motivated to

combine Dayton, Taylor, and Palmer; the resulting combination would meet this limitation.

3. Limitations 18[f]-18[g]

259. For the reasons I explained above regarding limitations 1[e]-1[f] in this Ground (*see supra* §§VII.A.6-7), a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would meet limitations 18[f]-18[g].

H. Claims 19-27

260. For reasons I explained above regarding claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in this Ground (*see supra* §§VII.B-F), respectively, a POSA would have been motivated to combine Dayton, Taylor, and Palmer; the resulting combination would satisfy claims 19-27.

VIII. GROUND 4: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, ORSAK, AND PALMER

261. It is my opinion that Claims 1-27 of the '941 patent would have been obvious to a POSA in view of Dayton, Orsak, and Palmer. The disclosures and my analysis of Dayton and Palmer set forth in Ground 2 (*supra* §VI) are adopted and applied here for the same claims and corresponding limitations addressed in Ground 2, and may not be repeated in full for brevity.

A. Claim 1

1. Preamble

262. The preamble of claim 1 recites “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” To the extent the preamble is limiting and as I explained above regarding the preamble of claim 1 in Ground 2, Dayton discloses a method of performing bunion surgery to correct the alignment between the first metatarsal and the medical cuneiform. *See supra* §VI.A.1.

2. Limitation 1[a]

263. Limitation 1[a] recites “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform.” A POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet limitation 1[a].

264. As I explained above regarding claim 1’s preamble and limitation 1[a] in Ground 2, Dayton discloses repositioning the first metatarsal relative to the first cuneiform. *See supra* §§VI.A.1-2. Dayton further discloses inserting pins into the first metatarsal and cuneiform for assisting in visualizing metatarsal rotation and temporarily stabilizing the first metatarsal relative to the first cuneiform. Ex.1005,

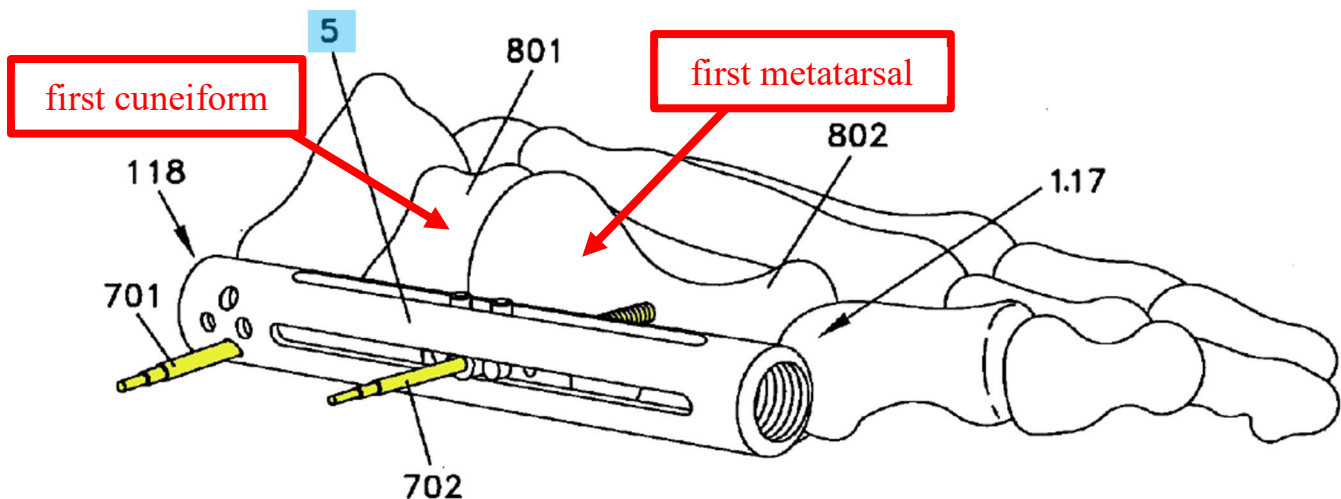
349. Dayton achieves its movement through manual manipulation. *Id.*; *see also* §VI.A.2 (limitation 1[a], Ground 2).

265. A POSA would have been motivated to incorporate a bone positioning device like Orsak's into Dayton's procedure to facilitate bone repositioning. According to Orsak, "[e]xternal orthopedic devices are used in many orthopedic treatments to fixate, distract, or reduce bone segments" and to "adjust the relative orientation and spacing of the bone parts on opposing sides of a bone repair site." Ex.1008, [0003]. Orsak describes "an external fixator device for fixating bone parts," including "in treating ... osteotomies." *Id.*, [0005]. A POSA would have understood that "osteotomies" refers to surgical procedures in which one or more bones are cut. Osteotomies include arthrodesis procedures, such as Dayton's procedure, where two adjacent bones are cut and fixed relative to one another with the goal of fusing the bones together.

266. Orsak discloses "placing a first fixation pin into a first bone piece [and] placing an external fixator over the first fixation pin by having the fixation pin go through a pin hole provided at one end of the external fixator's elongated body." Ex.1008, [0009]; *see also id.*, [0084] (describing "driving bone fixation pins into a bone piece"). In addition, Orsak provides that the "elongated body's second end is then positioned over a second bone piece," and "a second fixation pin is inserted

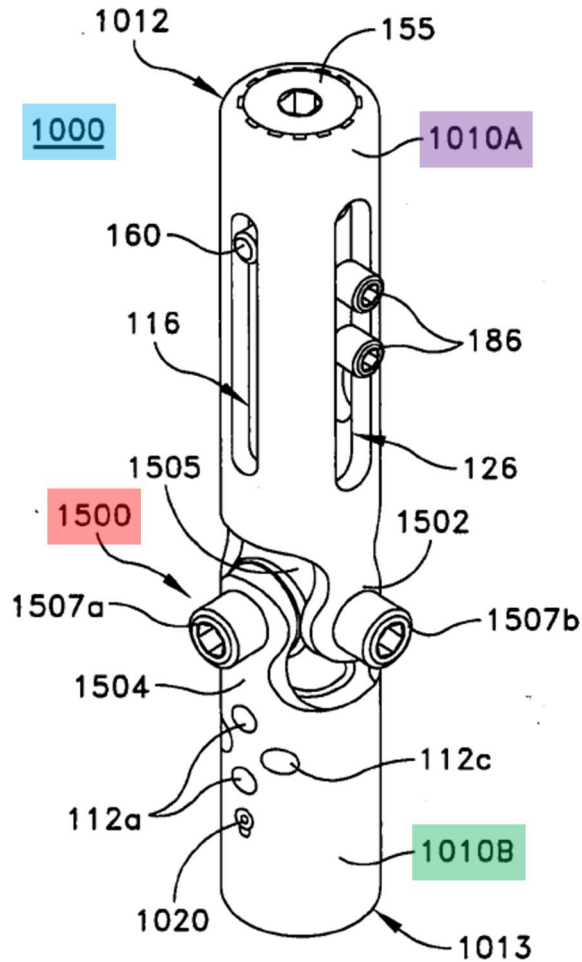
through a pin hole provided in the pin-holder [within the elongated body] and into the second bone piece.” *Id.*, *see also id.*, [0130]-[0131], claims 1, 7.

267. Orsak shows a fixator 5 (blue) engaged with the first metatarsal and the first cuneiform using fixation pins (yellow) and extending across the joint separating the first metatarsal and the first cuneiform:



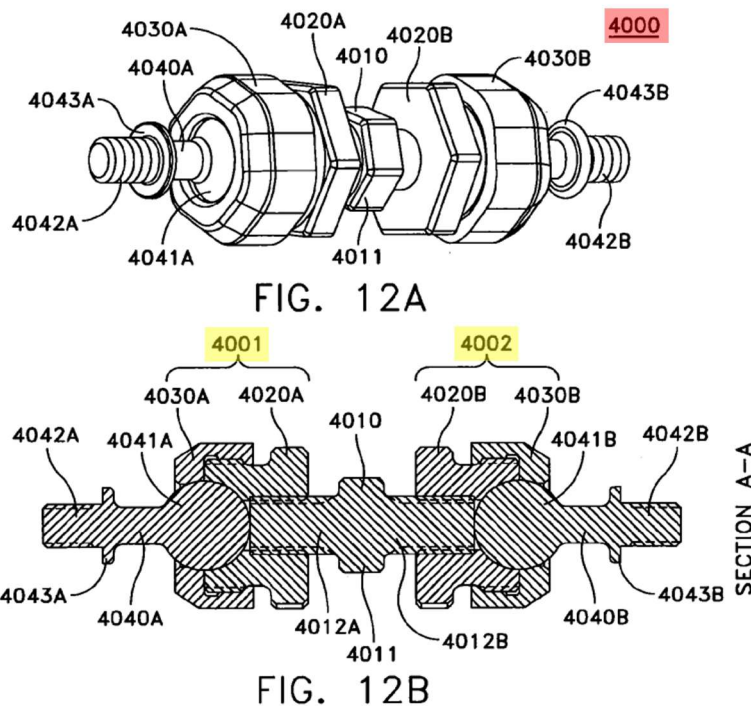
Id., Fig.5C (annotated); *see also id.*, Fig.5A (showing fixation pin 801 inserted into first cuneiform), [0088]-[0089].

268. The fixator in Orsak facilitates bone movement in multiple planes. In one example, Orsak discloses a fixator 1000 (blue) “includ[ing] a first portion 1010A [purple] and a second portion 1010B [green] that are linked by a universal joint 1500 [red]”:



Id., Fig.8A, [0094]. According to Orsak, “the universal joint 1500 allows the two portions 1010A and 1010B of the fixator body to be set at any desired angle, which in turn allows the fixation pins held in each of the two portions 1010A and 1010B of the fixator body to be arranged into a variety of angular configurations.” *Id.*, [0094]. “Similar to the external fixator 5, a set of fixation pins can be held in the first portion 1010A of the external fixator 1000 through the pin holes 142 in the pin-holder 143 and another set of fixation pins can be held in the second portion 1010B of the external fixator 1000 through the pin holes 112a, 112b, 112c and 112d.” *Id.*

Orsak also discloses a fixator with a double universal joint that makes the “angular adjustability” of its two portions even greater. *Id.*, [0115]; *see also id.*, Figs.11A-11F, 12A-12B, [0109]-[0111], [0116]-[0117]. Moreover, Orsak describes a joint system which facilitates multiplanar movement with two ball joints (yellow):



Ex.1008, Figs.12A-12B (color added); *see also id.*, [0118]-[0125].

269. A POSA would have been motivated to incorporate a bone positioning device like Orsak’s into Dayton’s procedure and to engage it with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, so that the positioning device extends across the joint separating the first metatarsal and cuneiform. *See id.*, [0094] (disclosing that Orsak’s device is attached to fixation pins like those disclosed by Dayton). This engagement and positioning across the joint

would permit the surgeon to use the positioning device to achieve bone repositioning and stabilizing during Dayton’s procedure. *See e.g.*, Ex.1008, [0003]-[0006].

270. This bone positioning device satisfies the “bone positioning device” limitation under the plain and ordinary meaning because it is a structure for positioning bones in multiple planes. *See supra* §IV.A. Under §112(f), such a bone positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed bone positioning device discussed in the claim construction section above. *See id.* This bone positioning device is at least an equivalent of the disclosed bone-positioning structures (multi-axis joint with ball-and-socket ends) because it performs the same function (adjusts first metatarsal alignment in multiple planes), in substantially the same way (two multiaxial ball joints linked by center piece), to achieve the same result (move and hold bones in intended position).

271. Orsak describes a device to reposition the first metatarsal relative to the first cuneiform with pins held by adjustable device portions (Ex.1008, Fig.5A-5D, [0088]-[0089], [0094], [0115]), which is a matching operative environment to Dayton’s procedure. A POSA would have recognized that a bone positioning device like Orsak’s and pins would be usable according to their known functions to yield a predictable advantage: a controlled, maintainable correction. Dayton discloses placing pins in the first metatarsal and first cuneiform as a visual reference for

manual repositioning of the first metatarsal. Ex.1005, 349. Orsak discloses that its device can be used in “treating ... osteotomies” to “hold the bone pieces in place [and] can be used for compression or distraction of the bone parts.” Ex.1008, [0005]; *see also* Ex.1006, 27:7-9 (explaining a fixator is “used as temporary or final fixation”), 6:7-13 (explaining a fixator “may perform one or few, or combination of thirteen different holding fixation possibilities,” such as clockwise/anti-clockwise motion and translation), 2:30-3:1, 4:25-27; Ex.1007, 5:26-33 (describing fixation device for “mov[ing] one fragment with respect to the other in six orthogonal degrees of freedom, a combination of three orthogonal translational axes...and three orthogonal rotational axes...”), 5:52-58 (describing fixation device providing “mechanism for producing a prescribed relative change in position between two bone fragments in conjunction with external fixation of the bone fragments”), 7:58-60 (using fixation device to “predictably and reproducibly cause small displacements between bone fragments”). A POSA would recognize that a bone positioning device like Orsak’s could be readily coupled to pins in the first metatarsal and first cuneiform to provide controlled, maintainable correction, instead of the pins primarily serving primarily as visual references for manual manipulation. Ex.1008, [0005].

272. The combination represents a straightforward incorporation of a bone positioning device like Orsak’s into Dayton’s corrective procedure. Orsak explains

its “device can be used for both compression as well as distraction of two bone pieces [with] one of the two bone pieces being affixed to the first set of fixation pins 5a and the second bone piece being affixed to the second set of fixation pins 5b.” Ex.1008, [0140]. This device is the type of known surgical instrument that a POSA would identify and select to adjust and maintain relative alignment between adjacent bones during corrective surgery. *See* Ex.1008, [0094]. Using fixation engagement like Orsak’s in Dayton’s procedure would have predictability improved control and stability compared to manual manipulation without changing Dayton’s goals or strategy. Although Orsak’s device is referred to as an external fixator, Orsak describes pin-holder/sliding/screw-driven positioning mechanics and controlled compression-distraction functionality that a POSA would have predictably used as an intraoperative positioning aid in Dayton’s procedure prior to final fixation.

273. A POSA would have understood the combination as using a known fixation-and-adjustment technique like Orsak’s in order to improve a similar method like Dayton’s. Orsak explains its device supports “many orthopedic treatments to fixate, distract, or reduce bone segments” (Ex.1008, [0003]) and can be “arranged into a variety of angular configurations” (Ex.1008, [0094], [0109], [0115]). The universal joint in Orsak allows Orsak’s device to perform the same motions and configurations that a surgeon uses to correct triplanar deformity. *See* Ex.1008, [0094]; *see also id.*, [0118]-[0125], Figs.12A-12B (describing and depicting dual

ball joint embodiment capable of triplanar correction). Indeed, Orsak discloses that the device may be used to reposition and stabilize the first metatarsal relative to first cuneiform. *See id.*, Figs. 5A-5H. Engaging a bone positioning device like Orsak's with metatarsal and cuneiform pins in Dayton's procedure would have predictably improved intraoperative precision and retention compared to freehand manipulation by providing controlled movement and stable maintenance of corrected alignment.

274. A POSA would have had a reasonable expectation of success because the modification is consistent with and applies the references' disclosures, relying on predictable mechanics. Orsak discloses the device can be used in osteotomies to reposition and stabilize bones. Ex.1008, [0005]. Orsak also specifically discloses that the device can be placed across the metatarsocuneiform joint and attached to the first metatarsal and first cuneiform. *See id.*, Figs. 5A-5H. Orsak further discloses that the device can be secured to the first metatarsal and first cuneiform using pins. *Id.*, [0094], Figs. 5A-5H; *see also* Ex.1005, 349. Using a bone positioning device like Orsak's with pins inserted into the first metatarsal and first cuneiform in Dayton's procedure would have provided controlled repositioning and stable maintenance of the corrected alignment. Orsak describes using such devices "in many orthopedic treatments to fixate, distract, or reduce bone segments" (Ex.1008, [0003]), including foot surgeries (Ex.1008, Figs.5A-5D).

3. **Limitation 1[b]**

275. Limitation 1[b] recites “aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform, the bone cutting guide comprising a joint plate offset from a guide feature of the bone cutting guide, the joint plate extending downwardly relative to the guide feature, wherein aligning the bone cutting guide with the joint comprises inserting the joint plate into the joint.” For the same reasons I explained for limitation 1[b] in Ground 2 (*supra* §VI.A.3), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet this limitation: a POSA would have been motivated to incorporate a bone cutting guide like Palmer’s into Dayton’s procedure (where a bone positioning device like Orsak’s is substituted for one like Waisman’s) and align the bone cutting guide with the metatarsal-cuneiform joint.

276. As I explained above regarding limitation 1[b] in Ground 2, a bone cutting guide like Palmer’s includes a joint plate/tab offset from the resection-slot guide feature, extending downward and inserted into the joint during the alignment. *See supra* §VI.A.3. The substitution of a bone positioning device like Orsak’s for one like Waisman’s would not change a POSA’s motivation or expectation of success in the combination.

4. Limitation 1[c]

277. Limitation 1[c] recites “using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal.” For the same reasons I explained above regarding this limitation in Ground 2 (*supra* §VI.A.4), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet this limitation.

278. The substitution of a bone positioning device like Orsak’s for one like Waisman’s would not change a POSA’s motivation or expectation of success in the combination.

5. Limitation 1[d]

279. Limitation 1[d] recites “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” A POSA would have been motivated to combine Dayton, Orsak, and Palmer, and the resulting combination would meet this limitation.

280. As I explained above regarding limitation 1[a] in this Ground, a POSA would have been motivated to incorporate a bone positioning device like Orsak’s into Dayton’s procedure to facilitate manual repositioning and correction. *See supra* §VIII.A.2. According to Orsak, its fixators are used to “adjust the relative orientation and spacing of the bone parts on opposing sides of a bone repair site.” Ex.1008, [0003]. This adjusting spacing produces translational movement, and this

adjusting orientation produces angular movement, which together facilitate use of the bone positioning device to achieve and hold multiplanar movement for corrected positioning during surgery.

281. Orsak describes mechanisms that provide such adjustments. Orsak explains a “driving screw” moves a pin-holder “longitudinally,” pushing or pulling distal pins relative to proximal pins to adjust spacing. *Id.*, [0068], [0092]; *see also id.*, [0105]-[0107] (discussing driving screw 1125), [0115] (explaining “external fixator 3000 includes a first portion 1010A and a second portion 1010C having the same structures as the first portion 1010A and second portion 1010C of the external fixator 2000”). Such longitudinal push/pull adjustment corresponds to translational (spacing) adjustment between the bone parts. Orsak also discloses a “universal joint 1500 allows the two portions 1010A and 1010B of the fixator body to be set at any desired angle, which in turn allows the fixation pins held in each of the two portions 1010A and 1010B of the fixator body to be arranged into a variety of angular configurations.” *Id.*, [0094]; *see also id.*, [0109], [0115] (“[B]ecause the external fixator 3000 comprises two universal joints[,], the angular adjustability of the two portions 1010A and 1010C of the external fixator 3000 is greater.”). For example, a bone positioning device like Orsak’s facilitates correction of sagittal plane deformities through rotation about a first axis and transverse-plane deformities through rotation about a second axis. Ex.1008, [0110] (describing rotation of about

two axles of the universal joint 1500). Orsak's dual ball joint configuration further facilitates repositioning of the engaged bones in three anatomical planes, including frontal plane rotation. *See id.*, [0118]-[0125], Figs.12A-B. Such angular adjustability corresponds to angulation/rotation adjustment of alignment. These disclosures together support incorporating a bone positioning device like Orsak's into Dayton's procedure to perform multi-planar adjustment of the first metatarsal during bunion correction, consistent with Dayton's multiplanar correction objective.

282. Even if Orsak were considered to expressly describe using its positioning device to adjust first-metatarsal/first-cuneiform bone alignment in only one plane, a POSA still would have been motivated to use a bone positioning device like Orsak's with its multi-axis capabilities (translation/spacing and angulation/orientation) to perform the multi-planar adjustments Dayton identifies for its bunion correction procedure. According to Dayton, bunion correction requires addressing deformity in multiple planes. Ex.1005, 348-349. Adopting known translational and angular adjustment mechanisms like Orsak's to achieve the multiplanar correction in Dayton's procedure would have been a predictable use of such a device according to its intended purpose, which would yield controlled multi-planar repositioning and maintenance of alignment during Dayton's procedure.

283. For the reasons I explained for limitations 1[a]-1[b] in this Ground (*see supra* §§VIII.A.2-3), a POSA would have been motivated to use a bone positioning

device like Orsak's into Dayton's procedure to control multiplanar repositioning of the first metatarsal and would have reasonably expected success.

6. Limitation 1[e]

284. Limitation 1[e] recites “compressing the first metatarsal and the first cuneiform together.” For the same reasons I explained above regarding limitation 1[e] in Ground 2 (*see supra* §VI.A.6), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet this limitation.

285. The substitution of a bone positioning device like Orsak's for one like Waisman's would not change a POSA's motivation or expectation of success in the combination. As I explained above regarding limitation 1[a], using Orsak's bone positioning device, rather than Waisman's, would not change how Palmer's bone cutting guide is used in Dayton's procedure. *See supra* §VIII.A.2 (Ground 4). Further, this compression in the combination would be achieved, for instance, using the bone positioning device like Orsak's, consistent with Orsak's disclosure that its device is used for “compression ... of two bone pieces.” *See* Ex.1008, [0140].

7. Limitation 1[f]

286. Limitation 1[f] recites “fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.” For the same reasons I explained above in Ground 2 (*see supra* §VI.A.7 (limitation 1[f])), a POSA would have been

motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet this limitation.

B. Claims 2-5

287. For the same reasons I explained above in Ground 2 regarding these same claims (*see supra* §§VI.B-E), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would satisfy these claims. The substitution of a bone positioning device like Orsak’s for one like Waisman’s would not change a POSA’s motivation or expectation of success in the combination.

C. Claim 6

288. Claim 6 depends from claim 1 and recites “further comprising, after fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, removing the first fixation pin from the first metatarsal and removing the second fixation pin from the first cuneiform.” A POSA would have been motivated to combine Dayton, Orsak, and Palmer, and the resulting combination would satisfy claim 6.

289. As I explained above regarding limitations 1[a] and 1[d] in this Ground, Orsak describes using pins to engage its bone positioning device with the first metatarsal and cuneiform and to reposition the bones. *See supra* §§VIII.A.2, VIII.A.5. Orsak also describes “driving bone fixation pins into a bone piece and []

removing the bone fixation pins.” Ex.1008, [0084]; *see also id.*, [0085], [0006]-[0008].

290. Pins are used in the combination to achieve and maintain the desired repositioning during correction, and when the corrected metatarsal-cuneiform relationship is fixed with the bone connector (e.g., Dayton’s wires/plates/screws as I explained for limitation 1[f] in this Ground (*see supra* §VIII.A.7)), that fixation maintains alignment independently of the pins. *See* Ex.1005, Fig.5B (depicting fixed first metatarsal and first cuneiform with fixation structures and without pins).

291. A POSA would have removed the first and second fixation pins after fixation with the bone connector, as this is consistent with the disclosure in Orsak and as a predictable and routine step for the reasons I explained for this claim in Ground 2. *See supra* §VI.F.

D. Claims 7-15

292. For the same reasons I explained above in Ground 2 (*see supra* §§VI.G-O), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would satisfy these claims.

293. The substitution of a bone positioning device like Orsak’s for one like Waisman’s would not change a POSA’s motivation or expectation of success in the combination.

E. Claim 16

294. Claim 16 depends from claim 1 and recites “wherein compressing the first metatarsal and the first cuneiform together comprises applying a force to press a first fixation pin inserted into the first metatarsal and a second fixation pin inserted into the first cuneiform toward one another.” A POSA would have been motivated to combine Dayton, Orsak, and Palmer, and the resulting combination would satisfy claim 16.

295. As I explained above for limitation 1[e] in this Ground, a POSA would have been motivated to compress the first metatarsal and cuneiform together. *See supra* §VIII.A.6. In addition, as I explained for limitation 1[a] in this Ground, Orsak discloses engaging a bone positioning device with bones using pins and using the device to compress. *See supra* §VIII.A.2. For example, Orsak discloses that its bone positioning device can be used in “treating ... osteotomies” by “hold[ing] the bone pieces in place [and] can be used for **compression** or distraction of the bone parts.” Ex.1008, [0005] (emphasis added). Orsak describes its “device can be used for both compression as well as distraction of two bone pieces [with] one of the two bone pieces being affixed to the first set of fixation pins 5a and the second bone piece being affixed to the second set of fixation pins 5b.” Ex.1008, [0140]. Orsak depicts an embodiment for use on the first metatarsal and first cuneiform, where the first metatarsal and first cuneiform are compressed by turning a driving screw 155 in a

direction to drive pins in the first metatarsal (702, 704) towards the pins in the first cuneiform (701, 703). Ex.1008, [0092]; *see also id.*, Fig.5H. Orsak's multi-axis embodiments similarly allow for compression. *See id.*, [0114] ("As with the external fixator 1000, the external fixator can be used for both compression as well as distraction procedures."); *see also id.*, [0118] (describing incorporation of dual ball joint structures into fixators of other embodiments). A POSA would therefore have understood the compression in Orsak as applying compressive force through the device to the pinned bone interfaces, which drives the pins toward each other to reduce the inter-bone gap and presses the bones together.

296. As a result, a POSA would have been motivated to use the bone positioning device like Orsak's with the first pin in the first metatarsal and the second pin in the first cuneiform to hold Dayton's correction and apply compressive force which presses the pins (and accordingly the metatarsal and cuneiform). This is a predictable and routine incorporation of disclosed compression capability like Orsak's into Dayton's procedure because compression across opposing joint surfaces is a known objective at a fusion site. *See* Ex.1005, 349; Ex.1011, 808-09. The combination uses a bone positioning device for its intended compression function, without changing Dayton's surgical goal or Orsak's manner of operation.

F. Claim 17

297. Claim 17 depends from claim 1 and recites “wherein the bone positioning device comprises a sliding connection and a screw, and compressing the first metatarsal and the first cuneiform together comprises operating the screw.” A POSA would have been motivated to combine Dayton, Orsak, and Palmer, and the resulting combination would satisfy claim 17.

298. As I explained above for limitation 1[e] and claim 16 in this Ground, a POSA would have been motivated to compress the first metatarsal and cuneiform using a bone positioning device like Orsak’s. *See supra* §§VIII.A.6, VIII.E. Orsak describes that its positioning device’s pin-holder “threadably engages the internally threaded bore” and “[t]his configuration enables the pin-holder 143 to move longitudinally inside the first portion,” with longitudinal slots that “guide the longitudinal movement of the pin-holder 143.” Ex.1008, [0102]-[0103]. According to Orsak, a “threaded driving screw” is used such that “as the head portion is threaded in or out ... it pushes or pulls the pin-holder 143 longitudinally,” and that the driving screw “operates on the pin-holder 143 to move the pin-holder 143 back and forth ... in [a] longitudinal direction,” including “while the pin-holder 143 is holding the fixation pins.” *Id.*, [0068]-[0069]; *see also id.*, [0092], [0094] (“another embodiment of external fixator 5” describing use of a “driving screw” that, when turned in the correct direction, effectuates compression, particularly compression of

the first metatarsal and first cuneiform), [0105], [0114], Figs.5A-5H; *see also id.*, [0118] (describing incorporation of dual ball joint structures into fixators of other embodiments). Orsak describes that this repositioning “can be used for both compression as well as distraction procedures.” *Id.*, [0114].

299. A POSA would have been motivated to use a structure like Orsak’s sliding connection and screw to implement compression across the metatarsal-cuneiform fusion site in Dayton’s procedure. In such an arrangement, compressing the bones comprises operating (e.g., turning) the threaded driving screw to advance/retract the screw and thus pushing or pulling the pin-holder longitudinally and translating the fixation pins (and the attached bone segments) toward each another to apply compression. Ex.1008, [0068]-[0069], [0092], [0094], [0102]-[0103], [0105], [0114], Figs.5A-5H.

300. Such operation of a bone positioning device like Orsak’s satisfies the requirement that “compressing ... comprises operating the screw” because the bone positioning device includes a sliding connection (pin-holder’s longitudinal movement within fixator portion) and a screw (threaded driving screw) that drives that sliding movement. *See* Ex.1008, [0068]-[0069], [0092], [0094], [0105], [0114]. This is a predictable and routine use of such a bone positioning device and would provide a reasonable expectation of success.

G. Claim 18

1. Preamble and Limitations 18[a]-18[d]

301. For the reasons I explained above regarding claim 1's preamble and limitations 1[a]-1[d] in this Ground (*see supra* §§VIII.A.1-5), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet claim 18's preamble and limitations 18[a]-18[d].

2. Limitation 18[e]

302. For the reasons I explained above for claims 3-4 in this Ground (*see supra* §VIII.B; *see also supra* §§VI.C-D), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet this limitation.

3. Limitations 18[f]-18[g]

303. For the reasons I explained above for limitations 1[e]-1[f] in this Ground (*see supra* §§VIII.A.6-7), a POSA would have been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would meet limitations 18[f]-18[g].

H. Claims 19-27

304. For the reasons I explained above regarding claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in this Ground (*see supra* §§VIII.B-F), respectively, a POSA would have

been motivated to combine Dayton, Orsak, and Palmer; the resulting combination would satisfy claims 19-27.

IX. GROUNDS 5-6: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, ORSAK, PALMER, AND WAISMAN/TAYLOR

305. Even if the Ground 4 combination had not described or suggested using the bone positioning device to adjust the first metatarsal alignment in multiple planes to correct a bunion, a POSA would have been motivated—based on Waisman or Taylor—to use a bone positioning device like Orsak’s for that adjustment. *See* Ex.1001, claims 1 (limitation 1[d]), 4 (adding related timing limitation), 18 (reciting limitation 1[d] and claim 4 limitation).

306. As I explained for limitation 1[d] in Ground 4, Orsak describes a bone positioning device having multi-axis capabilities and using that device to perform bone alignment in at least one plane. *See supra* §VIII.A.5.

307. A POSA would have been motivated to use the bone positioning device like Orsak’s to perform the multi-planar adjustments Dayton identifies for bunion correction, in view of Waisman or Taylor, each of which describes using similar positioning devices to reposition and maintain bone alignment, as I explained for limitation 1[d] in Grounds 2-3. *See supra* §§VI.A.5, VII.A.5. For example, Orsak, Waisman, and Taylor each disclose a pin-based bone positioning device usable across a joint to reposition bone in multiple planes. *See supra* §§VI.A.5, VII.A.5, VIII.A.5 (limitation 1[d], Grounds 2-4). The multiplanar correction functionality in

Waisman or Taylor would have been desirable for use with a bone positioning device like Orsak's to correct misalignment of the first metatarsal relative to the first cuneiform in three planes (i.e., transverse, sagittal, and frontal planes), consistent with Dayton's procedure. Ex.1005, 348-50; *see also* Ex.1006, 6:7-13, Ex.1007, 5:37-42 (describing object of Taylor's invention to provide a device "that can be used for any situation requiring relative motion between elements," including "compression," "translation," and/or "rotation" and "any combination of such movements").

308. Incorporating a bone positioning device like Orsak's in this manner would have predictably provided controlled repositioning and maintenance of position, consistent with the reasons I explained for limitation 1[d] in Grounds 2-4. *See supra* §§VI.A.5, VII.A.5, VIII.A.5. Accordingly, a POSA would have had a reasonable expectation of successfully incorporating the triplanar adjustments described in Waisman and Taylor into a bone positioning device like Orsak's.

X. GROUND 7-11: CLAIMS 1-27 ARE OBVIOUS OVER THE GROUND 2-6 COMBINATIONS WITH ORBAY SUBSTITUTED FOR PALMER

309. A POSA would have been motivated to substitute a bone cutting guide like Orbay's for one like Palmer's in each combination set forth in Grounds 2-6. Orbay, like Palmer, includes cutting-guide disclosures that meet the cutting-guide claim limitations, and substituting Orbay for Palmer in each combination likewise would have led a POSA to arrive at claims 1-27, as I explain further below.

310. The disclosures and my analysis of Dayton, Waisman, Taylor, and Orsak set forth in Grounds 2-6 (*supra* §§VI-IX) are adopted and applied here for the same claims and corresponding limitations addressed in Grounds 2-6, and I do not repeat them in full for brevity.

A. Claim 1

1. Preamble

311. The preamble of claim 1 recites “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” To the extent the preamble is limiting, and as I explained above regarding the preamble of claim 1 in Ground 2, Dayton discloses such a method. *See supra* §VI.A.1.

2. Limitation 1[a]

312. Limitation 1[a] recites “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform.” For the reasons I explained above in Grounds 2-4 regarding these limitations (*see supra* §§VI.A.2, VII.A.2, VIII.A.2), a POSA would have been motivated to combine the references of each combination; the resulting combinations would meet this limitation.

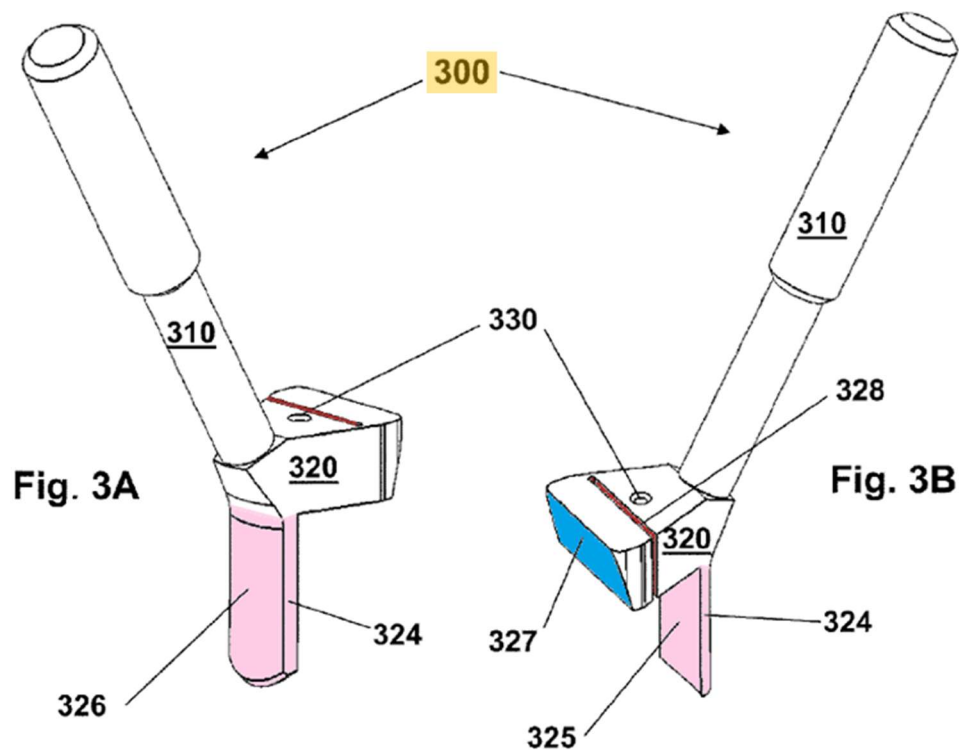
3. **Limitation 1[b]**

313. Limitation 1[b] recites “aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform, the bone cutting guide comprising a joint plate offset from a guide feature of the bone cutting guide, the joint plate extending downwardly relative to the guide feature, wherein aligning the bone cutting guide with the joint comprises inserting the joint plate into the joint.” A POSA would have been motivated to combine the references of each combination, and the resulting combinations would meet this limitation.

314. A POSA would have been motivated to use a bone cutting guide like Orbay’s in each combination’s procedure to facilitate bone cutting. Orbay describes using a vertical slot or planar surface to cut a distal portion of a bone. Ex.1010, [0037]. This is the same cutting of the first metatarsocuneiform joint’s articulating surfaces disclosed by Dayton. Ex.1005, 349.

315. Orbay describes “[a] cutting guide” for “performing small bone osteotomy.” Ex.1010, [0037]; *see also id.*, [0002] (“The invention is particularly useful in connection with surgical treatment of the carpo-metacarpal joint and other similarly configured joints.”). This guide’s “body portion 320 includes an angled plane surface 327, adapted to align a cutting blade along the angled line 240, and a vertical slot 328, adapted to align a cutting blade along cutting line 250.” *Id.*, [0037]; *see also id.*, [0033], [0040], claims 1, 5, 13-14, 18. The bone cutting guide includes

a divider piece 324 which is placed into the joint with “aligning surface 325 abutting the proximal articular surface 220 of [one bone] and its opposite surface 326 abutting the distal articular surface 120 of [another bone]” so that “[t]hese surfaces 325, 326 align the saw guide at a desired, relative cutting angle and position.” *Id.*, [0037]; *see also id.*, [0038]. Orbay’s guide 300 (orange), with the plane surface 327 (blue), vertical slot 328 (red), and divider piece 324 (pink), is shown in Figures 3A-3B:

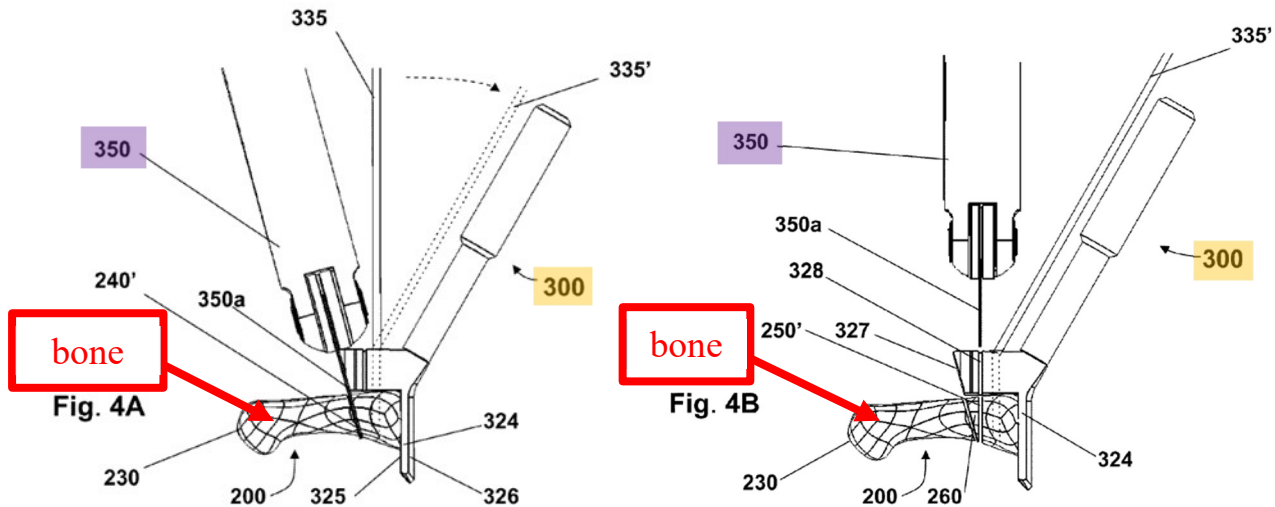


Id., Figs.3A-3B (color added).

316. According to Orbay, “an oscillating saw 350 [purple] may be used to make a first distal cut 240’ in the [one bone], by aligning the oscillating saw blade with angled plane surface 327” and further “the blade 350a of the oscillating saw 350 [is] inserted into the vertical slot 328 to make the proximal cut 250’,

substantially perpendicular to the longitudinal axis of [the one bone].” *Id.*, [0039].

Figures 4A and 4B depict the oscillating saw’s usage:



Id., Figs.4A-4B (annotated).

317. A bone cutting guide like Orbay’s satisfies the “bone cutting guide” limitation because it is a guide for cutting bone. The portions of a bone cutting guide like Orbay’s that structurally define the plane surface 327 and vertical slot 328 each constitutes a guide feature, and a divider piece like Orbay’s divider piece 324 constitutes a joint plate. The divider piece 324 extends downwardly relative to the plane surface 327 and vertical slot 328. *See* Figs. 3A-3B, 4A-4B. As shown in Figures 3A-3B and 4A-4B, the divider piece 324 is offset from the portions of Orbay’s guide that structurally define the plane surface 327 and vertical slot 328.

318. A POSA would have been motivated to use a bone cutting guide like Orbay’s in Dayton’s procedure and to align it with the joint between the first metatarsal and first cuneiform. In such an arrangement, this bone cutting guide

would include a joint plate (e.g., divider piece) offset from a guide feature (e.g., portion of cutting guide structurally defining the plane surface or vertical slot), with the joint plate extending downwardly relative to the guide feature and being inserted into the metatarsocuneiform joint during the alignment with said joint.

319. As I explained for limitation 1[b] in Ground 2, a POSA would understand the benefits of using a cutting guide over freehand resection. *See supra* §VI.A.3. Dayton explains that the first metatarsal cut is “oriented to correct the transverse and sagittal components, as needed,” with the first metatarsal cut being “perpendicular to the long axis of the metatarsal.” Ex.1005, 349. A POSA would have recognized that a guide feature like Orbay’s would facilitate easier and repeatable perpendicular cuts to the first metatarsal for correcting transverse and sagittal deformities. *See* Ex.1010, [0039] (describing a cut that is “substantially perpendicular to the longitudinal axis” of the target bone). Further, Dayton describes its first metatarsal cut being made for the purpose of “fusion” of the metatarsocuneiform joint. Ex.1005, 349. Further, a POSA would have recognized that a bone cutting guide like Orbay’s would promote fusion of the target joint. *See* Ex.1015, [0068] (describing guided cuts to “easily and effectively achieve a union through normal biological healing.”); *see also* Ex.1022, 1:45-50 (describing “complications,” including “poor quality bone healing” [fusion] more likely to occur during freehand resection).

320. Incorporating a cutting guide like Orbay's into Dayton's procedure would have been understood to reduce the risk of complications and delayed unions, non-unions, and malunions. *See* Ex.1011, 446 (describing delayed union and nonunion issues with gapping); *see also id.*, 324 (describing importance of joint preparation/resection in "efforts to obtain a bony union and avoid a delayed and nonunion" in a metatarsocuneiform arthrodesis). Deviation from a corresponding metatarsal cut may result in gapping—thereby increasing the risk of delayed union or nonunion—or necessitate a recut, further risking shortening of the first metatarsal.

321. A POSA would have been motivated to incorporate a bone cutting guide like Orbay's into Dayton's procedure because doing so would have been the application of a known technique to improve a similar method in the same way. As I explained, Orbay enhances resection with a cutting guide which precisely defines cuts. A POSA would have considered bone cutting guides used in other surgical procedures, such as Orbay's, to improve the procedure in Dayton. Dayton's procedure is similar in many respects to Orbay's, such as that both involve a joint between bones. Ex.1005, 349; Ex.1010, [0037]. Orbay explains that the aligning surface 325 of the divider piece 324 can abut the proximal surface a bone (Ex.1010, [0037]), which reinforces that a bone cutting guide like Orbay's is applicable to the metatarsal-cuneiform joint in Dayton's procedure. As a result, each combination

represents a predictable application of known cutting-guide to an analogous procedure.

322. A POSA would have had a reasonable expectation of success in using a bone cutting guide like Orbay's in Dayton's procedure. *See* Ex.1011, 382 (describing using a bone cutting guide similar to Orbay's on a foot bone). According to Orbay, that its guide can be adapted to use in different joints without departing from the invention, and such guides can be made in different sizes/scales to accommodate anatomy. Ex.1010, [0066], [0040]. Using Orbay's divider-piece alignment approach (joint insertion to register against opposing articular surfaces) in the metatarsal-cuneiform joint preparation in Dayton would not change Dayton's surgical objective or principle of operation. Rather, it would provide a predictable alignment/registration mechanism to guide the resection cuts at the same joint interface. Further, a POSA would have understood how to position and use the bone cutting guide and the bone positioning device in each combination so that both instruments could be used without undue interference.

4. Limitation 1[c]

323. Limitation 1[c] recites "using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal." A POSA would have been motivated to combine the references of each combination, and the resulting combinations would meet this limitation.

324. As I explained for limitation 1[c] in Ground 2, Dayton's resection/cutting of the metatarsal articular surface involves cutting that "leading edge" portion. *See supra* §VI.A.4. Incorporating the cutting guide like Orbay's into the joint-surface preparation in Dayton's procedure would involve using the cutting guide's guide feature (e.g., portion of cutting guide structurally defining plane surface or vertical slot) to guide a cutting tool, such as Orbay's disclosed saw (Ex.1010, [0039]), when making the metatarsal cut at the joint interface.

325. A cutting tool like Orbay's saw in these combinations satisfies "cutting tool" under its plain meaning discussed in the claim construction section above. *See supra* §IV.C. Under §112(f), a saw like Orbay's is corresponding structure (or an equivalent) to the saw instrument disclosed in the '941 patent. *See id.*

5. Limitations 1[d]-1[f]

326. For the reasons I explained above in Grounds 2-6 regarding these limitations (*see supra* §§VI.A.5-7, VII.A.5-7, VIII.A.5-7, IX), a POSA would have been motivated to combine the references of each combination; the resulting combinations would meet these limitations.

327. The substitution of a bone cutting guide like Orbay's for one like Palmer would not change a POSA's motivation or expectation of success in the combination. The structure of the bone cutting guide like Orbay's would not disrupt

the operation of a bone positioning device like Waisman's, Taylor's, and/or Orsak's in Dayton's procedure.

B. Claims 2-4

328. For the reasons I explained above in Grounds 2-6 regarding these claims (*see supra* §§VI.B-D, VII.B, VIII.B, IX), a POSA would have been motivated to combine the references of each combination; the resulting combinations would satisfy these claims.

329. The substitution of a bone cutting guide like Orbay's for one like Palmer's would not change a POSA's motivation or expectation of success in the combination. As discussed above with respect to claim 3 in Ground 2, Dayton's procedure calls for cutting the leading edge of the first cuneiform. *See supra*, §VI.C. Orbay discloses that the aligning surface 325 of the divider piece 324 of its bone cutting guide can abut the proximal surface a bone (Ex.1010, [0037]), confirming that a bone cutting guide like Orbay's would be suitable for use at the metatarsal-cuneiform joint in Dayton's procedure, including at the leading edge of the first cuneiform.

C. Claim 5

330. Claim 5 depends from claim 3 and recites "wherein cutting the leading edge of the first cuneiform comprises using the guide feature of the bone cutting guide to guide the cutting tool to cut the leading edge of the first cuneiform." A

POSA would have been motivated to combine the references of each combination, and the resulting combinations would satisfy claim 5.

331. As I explained above for limitations 1[b]-1[c] in these Grounds, Orbay describes a cutting guide with a guide feature (e.g., portion of cutting guide structurally defining plane surface or vertical slot) for use in guiding a cutting tool during bone resection. *See supra* §§X.A.3-4.

332. A POSA would have been motivated to use a cutting guide like Orbay's and its guide feature to guide the cutting tool when performing Dayton's disclosed "cuneiform cut" at the metatarsal-cuneiform interface. As I explained above regarding limitation 1[c], a POSA would have recognized that a guide feature like Orbay's would allow for easier and repeatable cuts to the first cuneiform for correcting deformities, including reduction of the IMA. *See* Ex.1010, [0039] (describing a resection guide surface of a vertical slot 328 of a bone cutting guide to make a cut "substantially perpendicular to the longitudinal axis" of a target joint); Ex.1005, 349; *see also supra* §X.A.4. A bone cutting guide like Orbay's would also help prevent excessive removal of cuneiform bone to accomplish Dayton's goal of allowing transverse plane correction "without sacrificing the length of the first ray." Ex.1009, 349; *see also* Ex.1011, 329 (warning that errors in cutting, among other things, the first cuneiform may result in "[s]ignificant shortening" of the first ray).

333. For the reasons I explained above for claim 5 in Ground 2, a POSA would have found using a bone cutting guide like Orbay’s to cut the leading edge of the first cuneiform to be a predictable and routine design choice. *See supra* §VI.E. A surgeon using such a cutting guide (and its guide feature) would use the same cutting guide and its guide feature to guide the cutting tool during resections of each of the two bones forming the fusion interface—i.e., the first metatarsal and cuneiform—rather than requiring separate guides for different bones. *See supra id.* (claim 5, Ground 2).

334. There would have been a reasonable expectation of success for a POSA in using such a bone cutting guide to cut the leading edge of the first cuneiform because a guide feature like Orbay’s is expressly intended to guide resection of a target bone, which is the same objective of the metatarsal-cuneiform joint preparation in each combination. *See* Ex.1010, [0037], [0039]; Ex.1005, 349 (describing a first cuneiform cut in a bunion correction procedure).

D. Claim 6

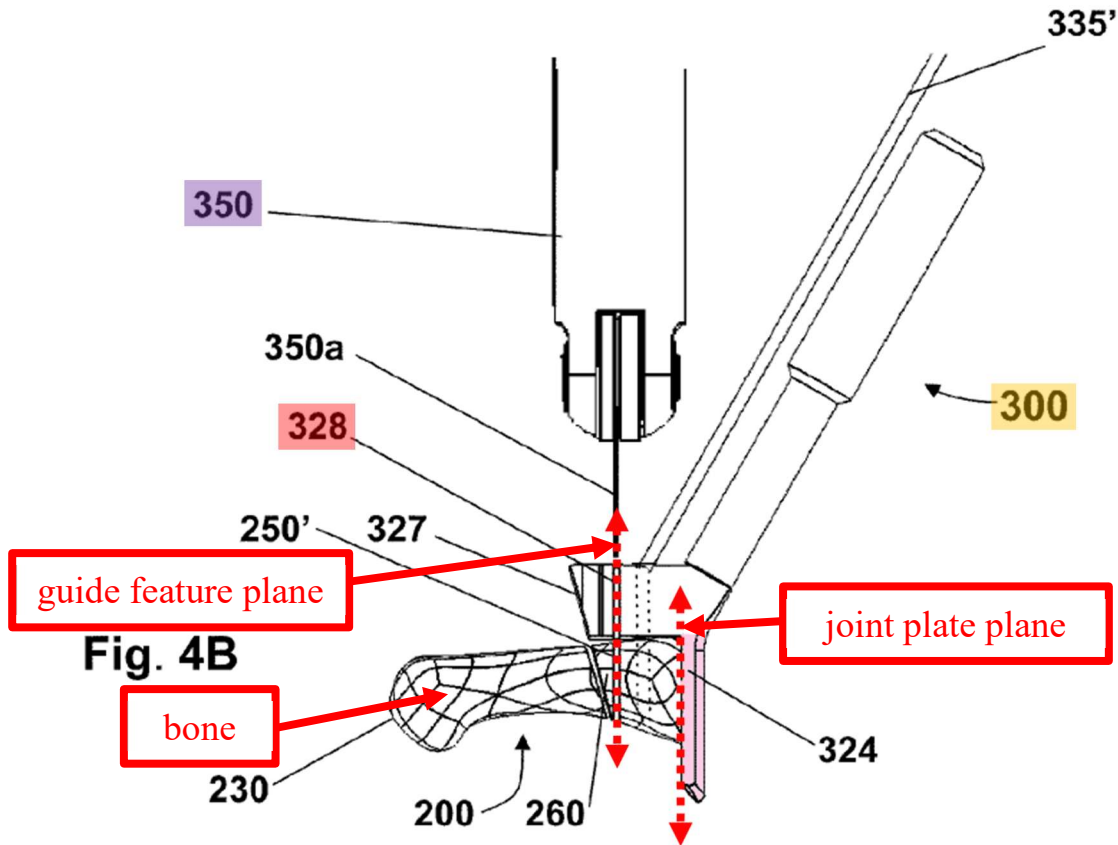
335. Claim 6 depends from claim 1 and recites “further comprising, after fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, removing the first fixation pin from the first metatarsal and removing the second fixation pin from the first cuneiform.” For the same reasons I explained above in Grounds 2-6 regarding this claim (*see supra* §§VI.F, VII.C, VIII.C, IX), a

POSA would have been motivated to combine the references of each combination; the resulting combination would satisfy claim 6. The substitution of a bone cutting guide like Orbay's for one like Palmer's would not change a POSA's motivation or expectation of success in the combination.

E. Claim 7

336. Claim 7 depends from claim 1 and recites “wherein the joint plate defines a plane, the guide feature defines a plane, and the plane defined by the joint plate is parallel to the plane defined by the guide feature.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 7.

337. Orbay explains its bone cutting guide's divider piece 324 can have “flat, planar surface[]” that faces the bone positioned for cutting. Ex.1010, [0037]. Orbay further describes that the guide's vertical slot 328 is “adapted to align a cutting blade along cutting line 250, substantially perpendicular the longitudinal axis of the [bone].” Ex.1010, [0037]. As a result, the divider piece's planar surface defines a joint plate plane, and the slot-defining structure defines a guide feature plane:



Ex.1010, Fig.4B (annotated); *see also* Ex.1010, Figs.3A-3B. As the figure above confirms, these planes are parallel to one another.

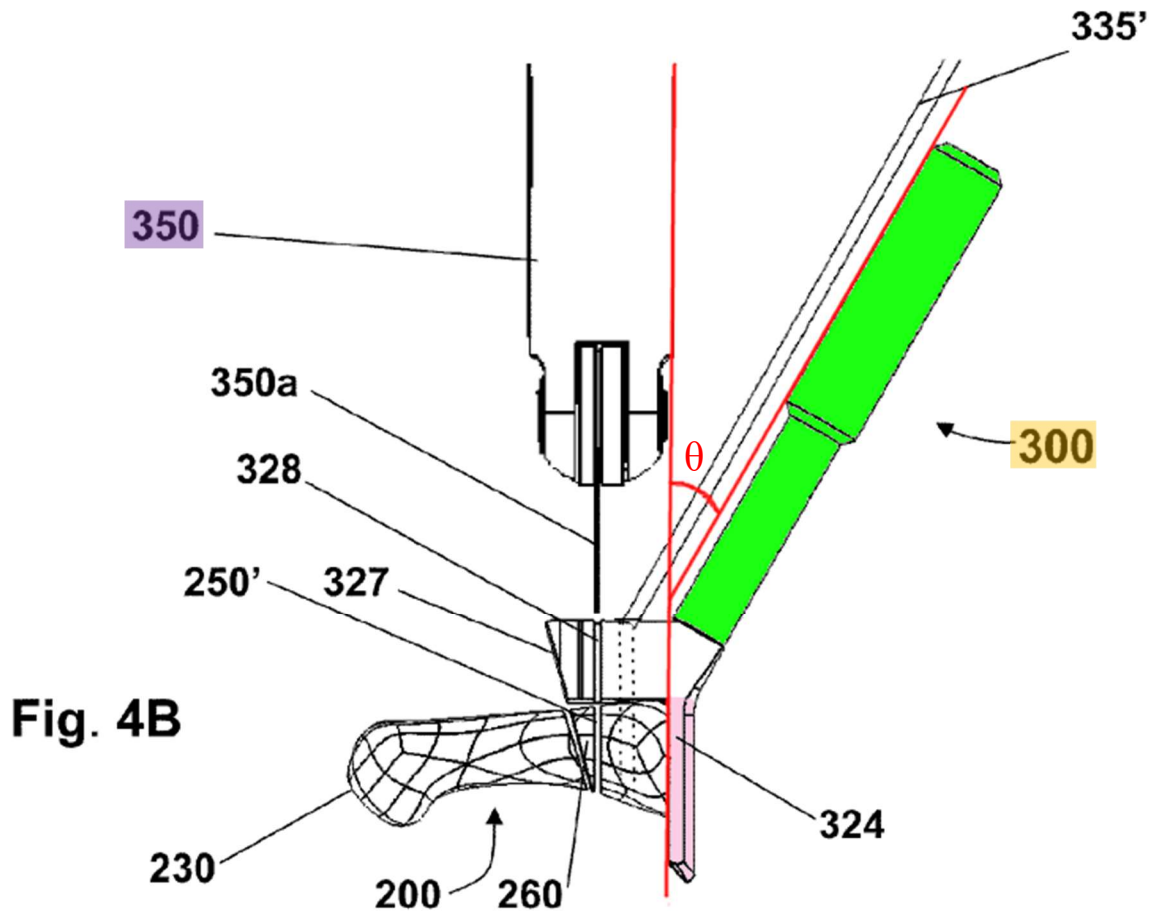
338. Consistent with Orbay's configuration, a POSA would have been motivated to use a guide feature like Orbay's (slot-defined) cutting plane parallel to the joint-plate (divider-defined) plane so that the guided cut is made in a plane aligned to the reference plane established by the divider piece when inserted into the joint. This configuration would yield predictable, repeatable planar bone preparation at the metatarsal-cuneiform interface. Ex.1010, [0037], [0039]; *see also* Ex.1022, 1:31-37 (describing potential difficulty and imprecision of freehand bone resection), Ex.1012, 3:1-5 (cutting guides "remove the necessity of clinical judgement and

guess work”); Ex.1014, [0034], [0070] (describing how the cut guides “precisely determine[]” the positions of the cuts).

F. Claim 8

339. Claim 8 depends from claim 7 and recites “wherein the bone cutting guide comprises a handle extending away from the joint plate at an angle between 30 degrees and 60 degrees with respect to the plane.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 8.

340. According to Orbay, its “cutting guide 300 includes a body portion 320 and a removable handle 310.” Ex.1010, [0037]. As Orbay depicts in its illustrated embodiments the handle (green) extending away from the joint-plate plane at an angle θ :



Ex.1010, Fig.4B (annotated); *see also* Ex.1010, Figs.3A-3B.

341. A POSA would have found selecting a specific acute angle for the handle extension (θ_1/θ_2) in the cutting guide—such as angle within the claimed range of 30° - 60° —to be a routine design choice. A POSA would have understood the handle’s angular orientation relative to the joint-plate plane is a routine ergonomic/clearance design parameter chosen for the reasons explained for claim 8 in Ground 2. *See supra* §VI.H. The claimed range reflects a finite set of predictable acute-angle configurations that balance access, clearance, and control, and choosing

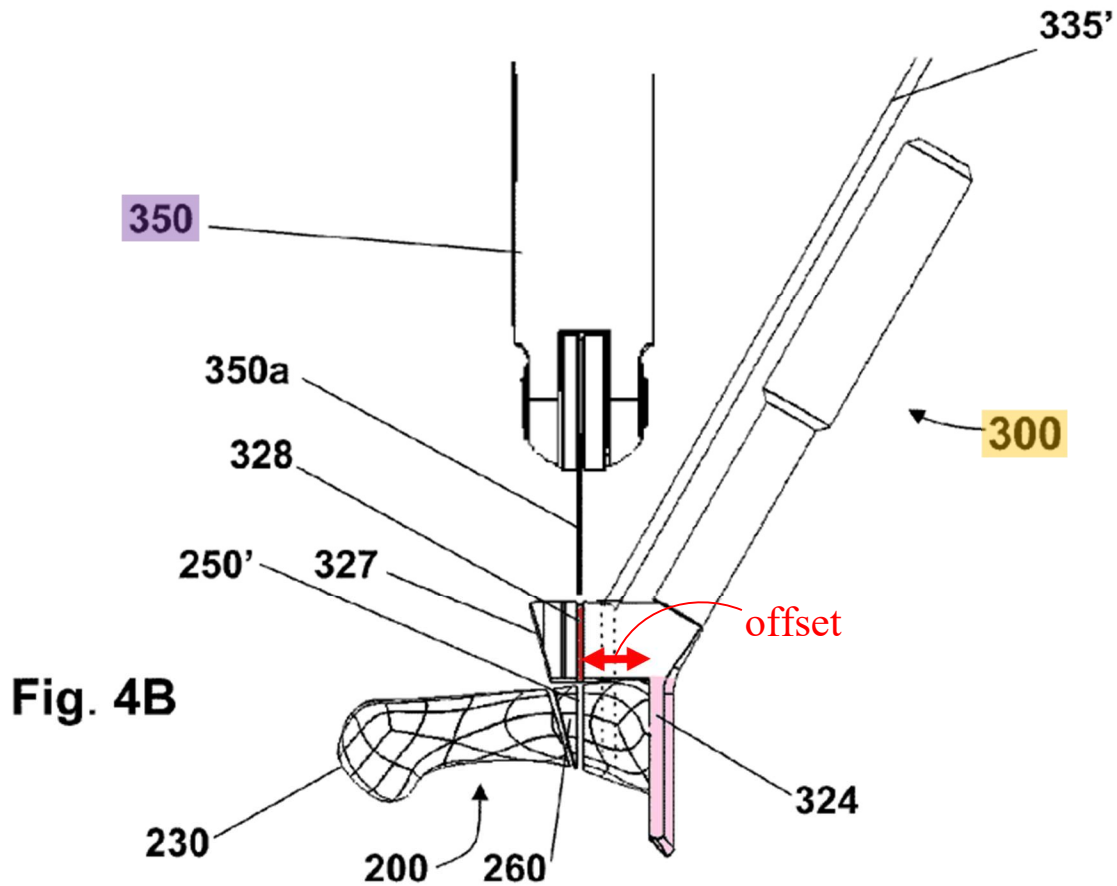
a moderate angle within 30°-60° would predictably preserve or improve access to the resection slot rather than obstruct it.

342. A POSA would have had a reasonable expectation of success because selecting such a handle angle between 30°-60° does not change the guiding relationship among the guide feature, cutting tool, and cut plane; rather, it relocates the grasp point.

G. Claim 9

343. Claim 9 depends from claim 1 and recites “wherein the joint plate is offset from the guide feature by being spaced laterally from the guide feature, and the guide feature defines a guiding surface that is offset from the joint plate a distance ranging from 1 millimeter to 20 millimeters.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 9.

344. Orbay illustrates that its cutting guide’s joint plate (pink) may be spaced laterally from the guide feature (portion of cutting guide structurally defining vertical slot (red)), so that the guide feature’s guiding surface is laterally offset from the joint plate:



Ex.1010, Fig.4B (annotated). The divider piece 324 in Orbay is positioned to be received at the joint when the slot-defined guiding surface is laterally displaced from that divider piece by a distance. Ex.1010, [0037] (describing insertion of divider piece 324 into the joint), Fig.4B. Orbay describes designing such an offset to be a “predetermined distance.” See Ex.1010, claims 1-3. Such disclosures underscore to a POSA that the lateral spacing between the joint-inserted divider piece and the slot-defined guiding surface in Orbay is an intentional and selectable geometric parameter.

345. A POSA would have been motivated to provide (and/or select) the magnitude of that lateral offset such that the guiding surface is offset from the joint plate by a distance within the claimed range of 1-20 mm. Such a lateral spacing is a predictable and result-effective design parameter: it would be chosen by a POSA based on ordinary surgical and anatomical considerations, including anatomical clearance, maintaining stable seating of the joint plate in the joint while permitting the cutting tool to pass through and be constrained by the guide feature, and achieving the intended resection location at the fusion interface (for example, ensuring Dayton’s objective of resecting “all subchondral bone” from the target bone’s leading edge (Ex.1005, 349)). Orbay further describes adapting bone cutting guides for “accommodate[ing] different patient anatomies” (Ex.1010, [0040]), confirming to a POSA that dimensional variations were expected and would have been routine.

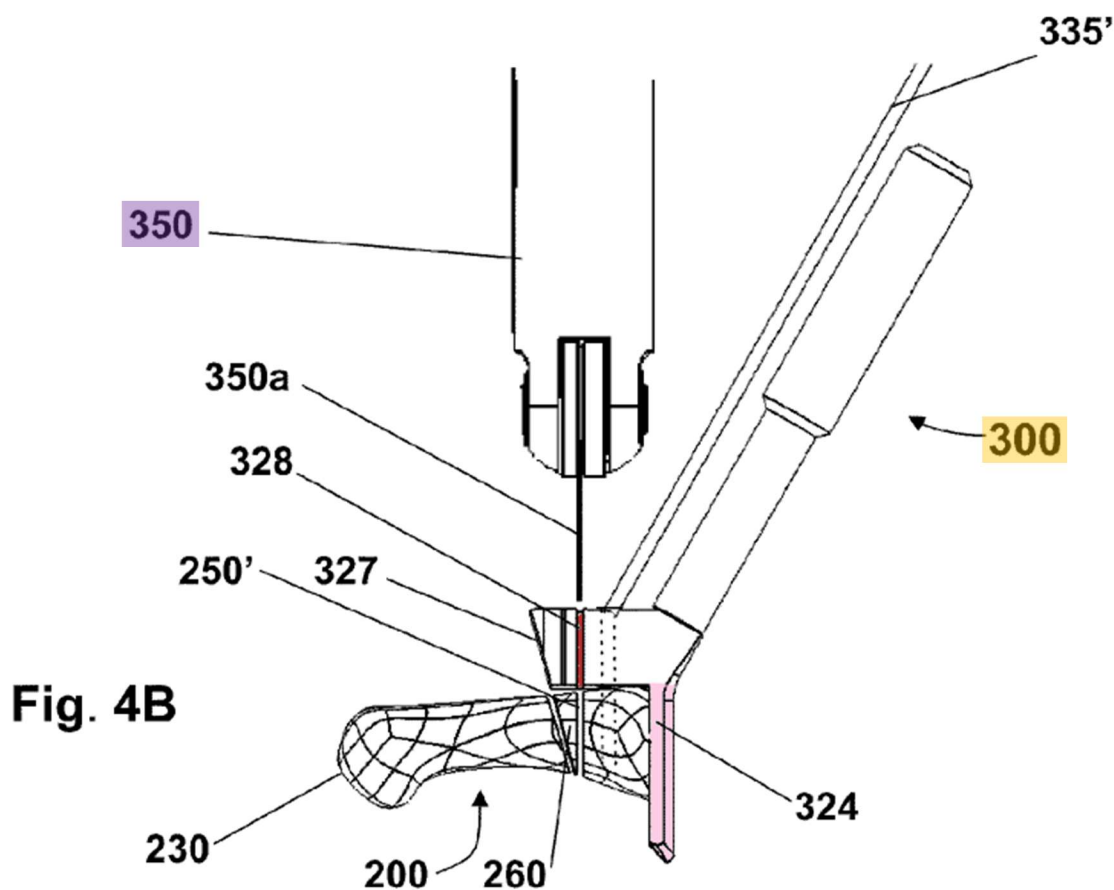
346. There would have been a reasonable expectation of success for a POSA because selecting the offset to be within a millimeter-scale range does not change the fundamental guiding function of the guide feature. Rather, it positions the guided cut relative to the locating/abutment structure used to position the guide on the bone.

H. Claim 10

347. Claim 10 depends from claim 1 and recites “wherein the joint plate is integral with the guide feature.” A POSA would have been motivated to combine

the references of each combination, and the resulting combination would satisfy claim 10.

348. Orbay illustrates its guide's joint plate (pink) as a unitary extension from the same cutting-guide body that defines the guide feature (portion of cutting guide structurally defining vertical slot (red)), so that the joint plate and guide feature form a single, undivided component rather than separate parts:



Ex.1010, Fig.4B (annotated). The claims in Orbay further recite “[a] surgical guide comprising ... a body portion ...; and a divider piece extending from the body portion.” Ex.1010, claim 1. A POSA would thus have understood that Orbay’s joint

plate (divider piece) is part of (i.e., integral with) the cutting guide body that provides the guiding surface. As a result, a POSA would have had a reasonable expectation of success to use such an integral cutting device like Orbay's with Dayton's procedure.

I. Claim 11

349. Claim 11 depends from claim 1 and recites “wherein using the guide feature of the bone cutting guide to guide the cutting tool comprises placing the cutting tool in apposition to a guide surface defined by the guide feature of the bone cutting guide.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 11.

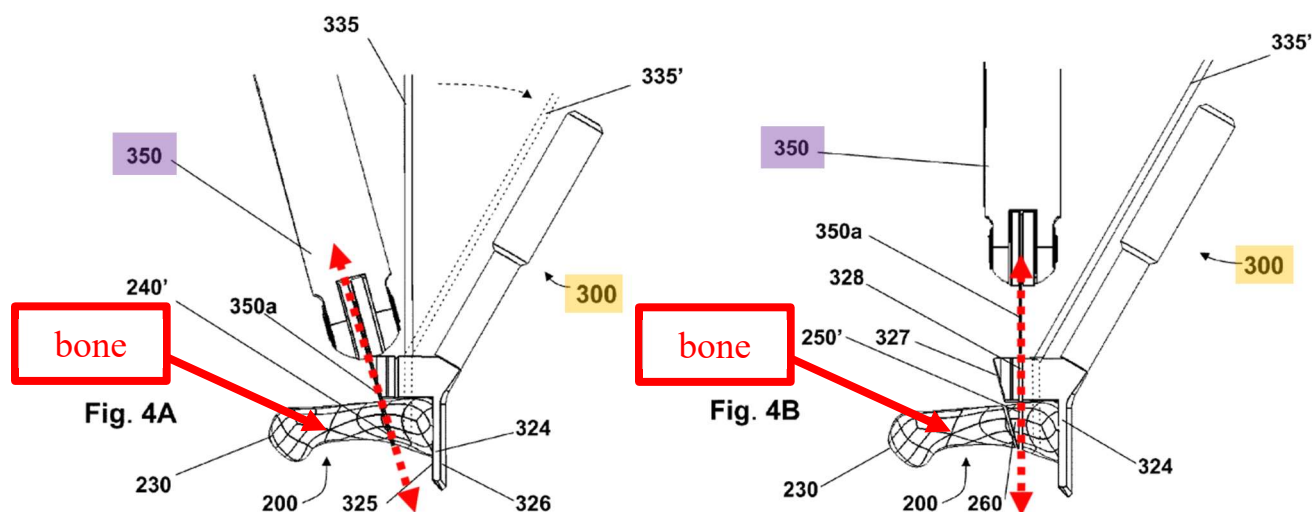
350. According to Orbay, its guide's “body portion 320 includes an angled plane surface 327, adapted to align a cutting blade along the angled line 240, and a vertical slot 328, adapted to align a cutting blade along cutting line 250.” Ex.1010, [0037]; *see also id.*, [0039] (“aligning the oscillating saw blade with angled plane surface 327”). The cutting blade during use is guided by its placement against the guide surface provided by the guide feature so that the guide constrains blade motion along the intended cutting path. *Id.*, [0037] (describing aligning cutting blade along by a guide surface to cut “along a cutting line,” which is “substantially perpendicular [to] the longitudinal axis” of the target joint). A POSA would have considered this

usage to be a routine and predictable manner in which slot-based cutting guides operate and would have been implemented in ordinary course.

J. Claim 12

351. Claim 12 depends from claim 11 and recites “wherein the guide surface is operable to guide the cutting tool in a plane parallel to the guide surface.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 12.

352. According to Orbay, its cutting guide’s “body portion 320 includes an angled plane surface 327, adapted to align a cutting blade along the angled line 240, and a vertical slot 328, adapted to align a cutting blade along cutting line 250.” Ex.1010, [0037]; *see also id.*, [0039]. I noted the angled line 240 and cutting line 250 with dotted lines on Figures 4A-4B, alongside the saw 250 (purple):



Id., Figs.4A-4B (annotated). These figures illustrate that the blade’s permitted motion during resection is guided along the corresponding guide surface, so that the

blade path lies in a plane parallel to the guide surface. *See* Ex.1010, [0037] (describing guidance of cutting blade along cutting lines 240 and 250).

353. As a result, when the cutting tool is placed in apposition to the guide surface, that guide surface is operable in each combination to guide the cutting tool in a plane parallel to the guide surface.

K. Claim 13

354. Claim 13 depends from claim 1 and recites “wherein using the guide feature of the bone cutting guide to guide the cutting tool comprises placing the cutting tool in contact with a guide surface defined by the guide feature of the bone cutting guide.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 13.

355. As I explained above regarding claim 11 in Grounds 2-6, a POSA would have been motivated to place the cutting tool in apposition to and against a guide surface defined by the guide feature. *See supra* §§VI.K, VII.D, VIII.D, IX. Such use of the guide feature to guide the cutting tool necessarily involves placing the cutting tool in contact with that guide surface—particularly during guided movement through the slot—because the guide’s function of constraining the tool’s path is achieved by contact between the tool and guide surface. *See supra*, §VI.M (claim 13, Ground 2).

L. Claim 14

356. Claim 14 depends from claim 1 and recites “wherein the cutting tool is a saw blade.” A POSA would have been motivated to combine the references of each combination, and the resulting combination would satisfy claim 14.

357. Orbay describes using a “saw blade” together with its cutting guide. Ex.1010, [0039]; *see also id.*, [0037]. As a result, a POSA would have been motivated to adopt a saw blade as the cutting tool when performing guided resection using the cutting guide in the combination.

M. Claims 15-17

358. For the reasons I explained above in Grounds 2-6 regarding these claims (*see supra* §§VI.O-Q, VII.D-F, VIII.D-F, IX), a POSA would have been motivated to combine the references of each combination; the resulting combination would satisfy these claims. The substitution of a bone cutting guide like Orbay’s for one like Palmer’s would not change a POSA’s motivation or expectation of success in the combination.

N. Claim 18

1. Preamble

359. The preamble of claim 18 recites “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” To the extent the preamble is limiting, and for the same reasons as I explained above

regarding claim 1's preamble (*see supra* §X.A.1), a POSA would have been motivated to combine the references of each combination; the resulting combination would meet claim 18's preamble.

a. Limitations 18[a]-18[d]

360. For reasons I explained above regarding limitations 1[a]-1[d] in these Grounds (*see supra* §§X.A.2-5), a POSA would have been motivated to combine the references of each combination; the resulting combination would meet limitations 18[a]-18[d].

b. Limitation 18[e]

361. Limitation 18[e] recites “after using the bone positioning device to adjust the alignment of the first metatarsal in multiple planes to correct the bunion, cutting a leading edge of the first cuneiform.” For the same reasons I explained above regarding claims 3-4 in these Grounds (*see supra* §X.B), a POSA would have been motivated to combine the references of each combination; the resulting combination would meet this limitation.

c. Limitations 18[f]-18[g]

362. For the reasons I explained above regarding limitations 1[e]-1[f] in these Grounds (*see supra* §X.A.5), a POSA would have been motivated to combine the references of each combination; the resulting combination would meet limitations 18[f]-18[g].

O. Claims 19-27

363. For the same reasons I explained above regarding claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in these Grounds (*see supra* §§X.B-F, X.J, X.M), respectively, a POSA would have been motivated to combine the references of each combination; the resulting combination would satisfy claims 19-27.

XI. GROUND 12-16: CLAIMS 1-27 WOULD HAVE BEEN OBVIOUS OVER ANY OF GROUNDS 2-6 IN COMBINATION WITH ORBAY

364. Even if the Ground 2-6 combinations had not disclosed or suggested the use of a cutting tool like a saw blade, a POSA would have been motivated based on Orbay to use a cutting tool, such as a saw blade, with each combination's cutting guide to cut using the guide feature. *See* Ex.1001, claims 1 (using cutting tool for metatarsal), 5 (using cutting tool for cuneiform), 11-13 (positioning of cutting tool), 14 (cutting tool is saw blade), 18 (using cutting tool for metatarsal), 21 (using cutting tool for cuneiform), 24 (positioning of cutting tool).

365. As I explained above regarding limitations 1[b] and 1[c] in Grounds 7-11, Orbay describes placing a cutting tool like a saw blade into its bone cutting guide's vertical slot for cutting of bone. *See supra* §§X.A.3-4.

366. A POSA would have been motivated to use such a saw blade with a cutting guide like Palmer's in each combination. As I explained above regarding claim 14 in Ground 2, using a saw blade with a guide slot is a predictable and routine choice because the flat blade geometry is well-suited to the guide's planar constraint,

facilitating repeatable cuts while maintaining the intended resection plane. *See supra* §VI.N. A bone cutting guide like Palmer’s is used to produce “substantially planar prepared bone surface[s],” which a saw blade like Orbay’s would accomplish. *See* Ex.1009, [0042], [00139].

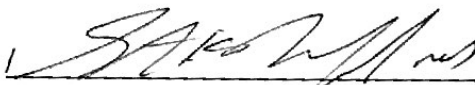
367. As I also explained above regarding claim 14 in Ground 2, a POSA would have been motivated to implement the guided cutting using a saw blade with a reasonable expectation of success. Substituting one known bone-cutting implement (saw blade) for another generic cutting tool does not change the guide’s function and yields the predictable result of a guided resection. *See* Ex.1009, [0042].

XII. CONCLUSION

368. For the foregoing reasons, it is my opinion that, by July 15, 2014, a POSA would have found claims 1-27 of the '941 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.

369. 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.

370. 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 on: March 3, 2026 By: 
Dr. Steven K. Neufeld