Filed December 19, 2025

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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 PGR2026-00017
Patent 12,268,397

PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 12,268,397

TABLE OF CONTENTS

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF AUTHORITIES

Page No(s).

Cases

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

Statutes

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

Other Authorities

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,268,397 to Dayton et al. ("the '397 Patent")
1002	Declaration of Steven K. Neufeld, M.D.
1003	Curriculum Vitae of Steven K. Neufeld, M.D.
1004	File History of the '397 Patent
1005	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 ("McGlamry")
1006	Declaration of Michelle L. Warmath for Translation of European Patent App. Publ. No. 1508316 ("Augoyard")
1007	English Translation of Augoyard from Ex. 1006
1008	Paul W. Lapidus, *Operative correction of the metatarsus varus primus in hallux valgus*, 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)
1009	Mark H. Hofbauer & Jordan P. Grossman, *The Lapidus Procedure*, 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)
1010	RESERVED
1011	James M. Cottom & Anand M. Vora, *Fixation of lapidus arthrodesis with a plantar interfragmentary screw and medial locking plate: a report of 88 cases*. 52(4) J. FOOT & ANKLE SURGERY 465–469 (July-Aug. 2013)
1012	U.S. Patent No. 5,601,565 to Huebner ("Huebner")
1013	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. ("Haddad")
1014	U.S. Design Patent No. D695402 to DaCosta et al. ("DaCosta")

Exhibit No.	Description
1015	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein ("Weinstein")
1016	U.S. Patent No. 4,349,018 to Chambers ("Chambers")
1017	U.S. Patent No. 9,220,518 to Neal et al. ("Neal")
1018	U.S. Patent No. 5,935,128 to Carter et al. ("Carter")
1019	U.S. Patent No. 6,030,391 to Brainard et al. ("Brainard")
1020	Paul W. Lapidus, *The author's bunion operation from 1931 to 1959*, 16 CLIN. ORTHOPAEDICS 119-135 (1960).
1021	U.S. Patent No. 5,350,382 to Armstrong et al. ("Armstrong")
1022	U.S. Patent No. 5,947,973 to Masini ("Masini")
1023	U.S. Patent No. 5,112,334 to Alchermes et al. ("Alchermes")
1024	Timo Schmid & Fabian Krause, *The modified Lapidus fusion*, 19(2) FOOT & ANKLE CLINICS 223–233 (June 2014)
1025	U.S. Patent App. Publ. No. 2016/0175089 to Fallin
1026	Lawrence A. DiDomenico, et al., *Correction of Frontal Plane Rotation of Sesamoid Apparatus During the Lapidus Procedure: A Novel Approach*, 53 J. Foot & Ankle Surgery 248–251 (Mar.-Apr. 2014)
1027	Bun-Yo-Matic™ Lapidus Clamp System - Surgical Technique Guide
1028	U.S. Patent No. 5,722,978 to Jenkins ("Jenkins")
1029	U.S. Patent App. Publ. No. 2012/0078258 to Lo et al. ("Lo")
1030	International App. Publ. No. 2015/123270 to Sachin et al. ("Sachin")

Exhibit No.	Description
1031	Declaration of Sylvia Hall-Ellis, Ph.D.

Petitioner Paragon 28, Inc. requests post grant review ("PGR") of claims 1-30 of U.S. Patent 12,268,397 ("the '397 patent," Ex.1001).

I. INTRODUCTION

The claims of the '397 patent are directed to surgical methods for correcting bunions. Accounting for the permissive language in the specification, the '397 patent ultimately describes a single device (a bone cutting guide) and a general method for using that device in a surgical procedure (bunion correction surgery). The device described in the '397 patent is shown below in Figures 1 and 2.[1]

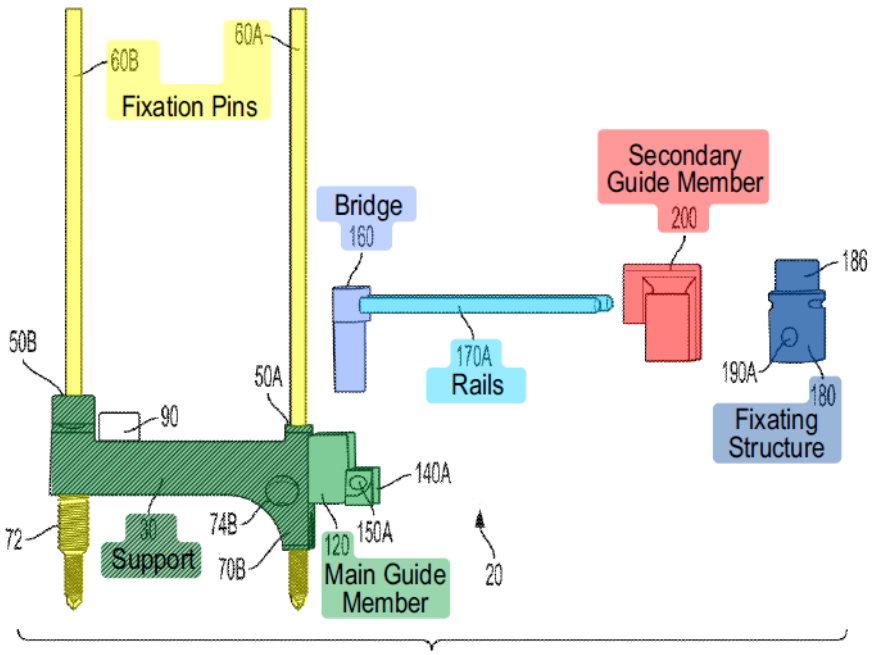


FIG. 1

[1] Annotations and highlighting added to figures unless otherwise noted. Emphasis added unless otherwise noted.

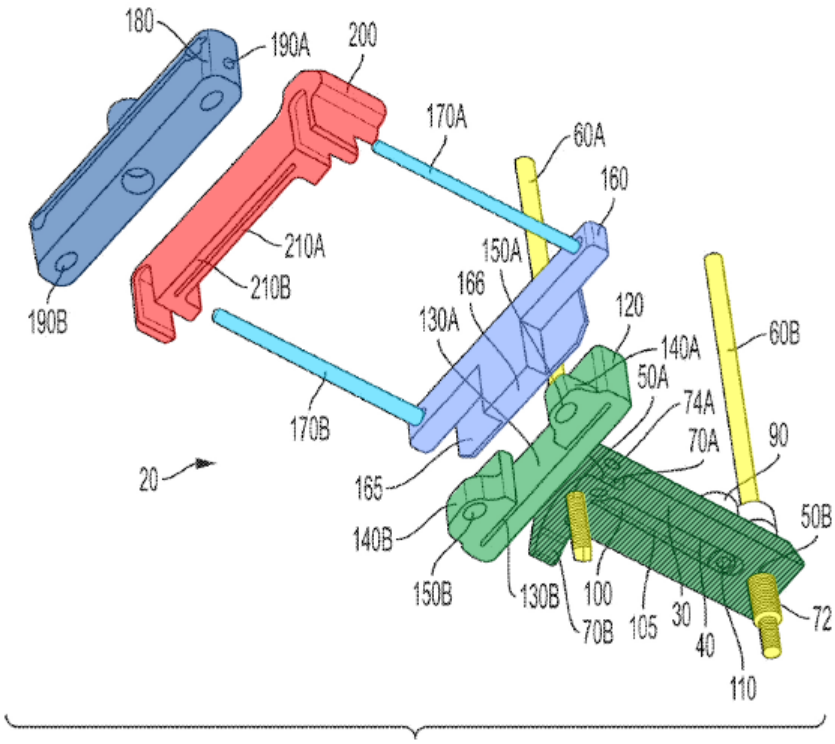


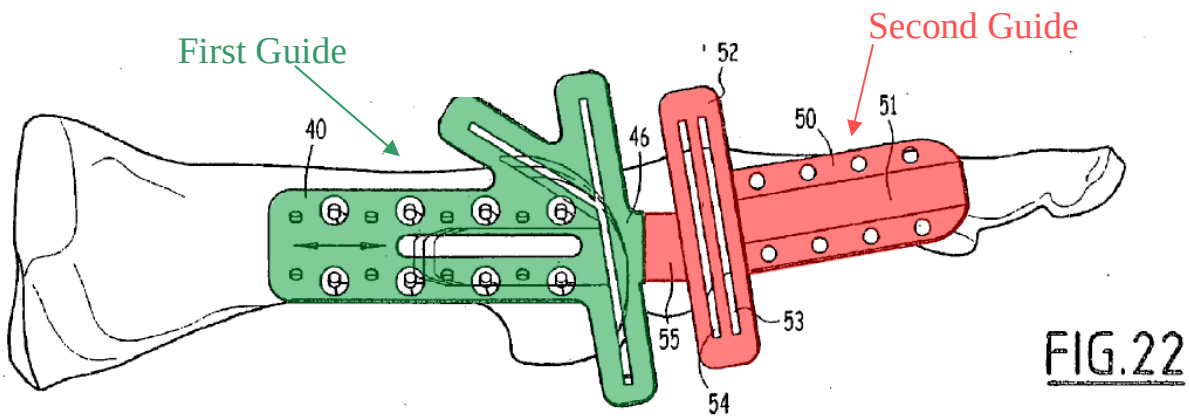
FIG. 2

The device includes a support 30 (teal), first guide 120 (green), a bridge 160 with rails 170 (light blue), a second guide 200 (red) and a fixating structure 18 (dark blue). The support 30, including the first cut guide 120, is positioned and used to cut a first bone (e.g., the proximal end of the metatarsal bone of the foot). Ex.1001, 7:64-8:17, 8:40-44. After the first cut, the bridge 160 can be inserted into the first cut guide 120. Ex.1001, 9:8-22. The bridge can include rails 170. Ex.1001, 6:26-30, 9:16-20. The rails 170 can be used to support the second cut guide 200, which can then be used to cut a second bone (e.g., the distal end of the cuneiform bone of a foot). Ex.1001, 6:49-55, 9:20-22, 9:63-10:3. The result is a device built on a series of

connections like railcars, with each component being an additional car added to the series (e.g., first guide 120, bridge 160, bridge rails 170, and second guide 200).

Treace wrote the claims of the ’397 patent to try to cover aspects of Petitioner’s Bun-Yo-Matic™ Lapidus Clamp product and quickly prosecuted them as a Track One application to file its infringement action. However, in its attempt to cover the Petitioner’s Bun-Yo-Matic, Treace’s claims are divorced from the devices and methods disclosed in the ’397 patent. Unlike the specification of the ’397 patent, the Bun-Yo-Matic uses a Metatarsal Cut Guide that is completely distinct from the Cuneiform Cut Guide. Ex.1027, 3. In fact, when the Bun-Yo-Matic is used, the Metatarsal Cut Guide must be fully removed before the Cuneiform Cut Guide is used. *Id.*, 11-16. Treace drafted claims targeting the use of two separate cutting guides using the language “the second guide being attached to the metatarsal by at least the first fixation pin … and the second fixation pin inserted into the metatarsal.” *See* Ex.1001, claim 1[e]. But that embodiment is neither described in nor enabled by the ’397 patent. Rather, as shown above, the ’397 patent discloses a second guide only as resting on rails 170, which are themselves connected to the bridge 160. The ’397 patent never describes nor enables a second guide as “attached to the metatarsal by at least the first fixation pin … and the second fixation pin.”

Moreover, the claimed methods recite nothing more than using a known cutting guide in a known procedure for bunion correction. By 2015, bunion correction was commonly performed using a procedure referred to as "metatarso-cuneiform joint arthrodesis," or more simply, a Lapidus procedure. That procedure is described in detail in a medical school textbook for foot surgery, McGlamry. Ex.1005. The surgical steps disclosed in McGlamry align with the steps claimed in the '397 patent, but McGlamry's procedure does not use a bone cutting guide. However, bone cutting guides and their benefits were well-known by 2015, for use Lapidus procedures. Moreover, the multi-part, serially connected cutting guides in the '397 patent are disclosed by Augoyard, as illustrated below:



Ex.1007, Fig.22. The use of a known cutting guide in a known procedure is obvious. The claims of the '397 patent recite nothing more and would have been obvious as set forth herein.

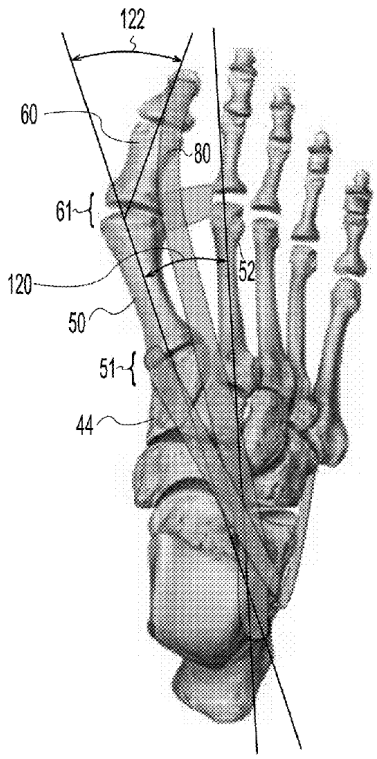
All claims of the '397 patent should be found unpatentable and cancelled.

II. STATE OF THE ART

Bunion correction procedures and the use of bone cutting guides were well-known by January 2015. The '397 patent does not acknowledge the well-developed state of the art, including bunion correction procedures that used bone cutting guides.

A. Bunion Deformity

In a healthy foot, the bones of the first ray are anatomically positioned in three-dimensional alignment from the medial cuneiform – first metatarsal-hallux ("big toe") to permit normal function of the foot. Ex.1002, ¶¶43-45. The first metatarsal and cuneiform meet to form the metatarsal and cuneiform joint. *Id.* A bunion can result when these bones become misaligned in one or more planes, as shown below:

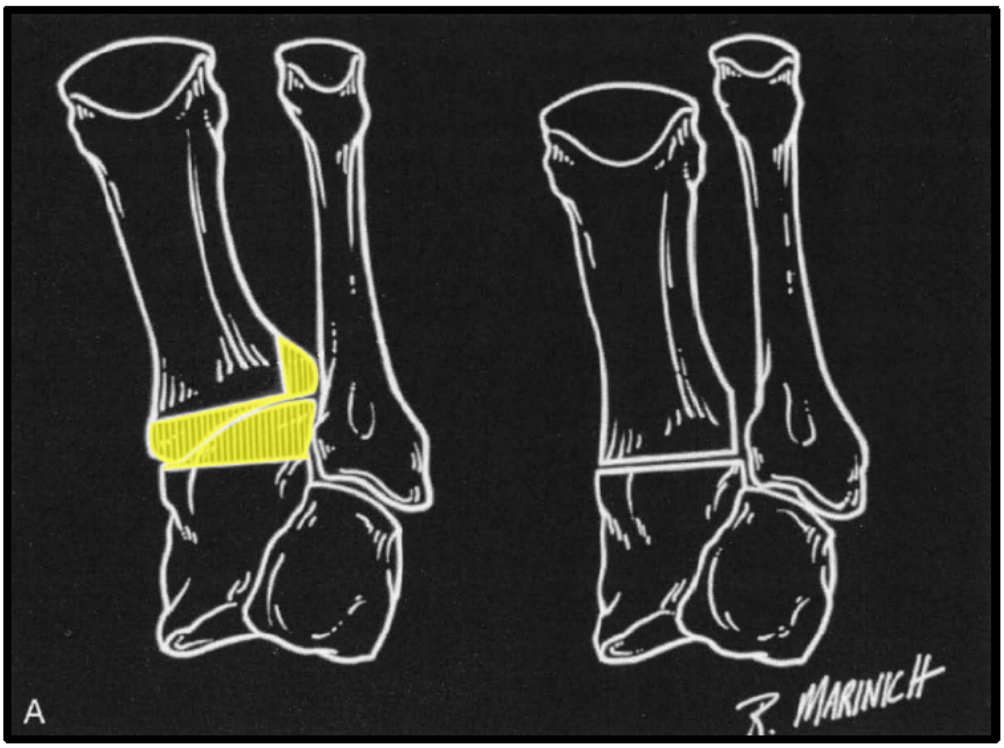


Ex.1002, ¶46. For example, bunions often present as a shift of the first metatarsal away from the second metatarsal resulting in an increased intermetatarsal angle ("IMA") between the bones. Further, the first metatarsal may be rotated in the frontal plane and the big-toe angled inward (known as "hallux valgus"). The result is a bump (or "bunion") on the inner part of the foot. Ex.1002, ¶¶46-49. Bunions impact the function of the foot, and can cause pain and the inability to wear shoes. *Id.*

B. <u>Bunion Correction - Metatarso-Cuneiform Joint Arthrodesis</u>

There are many methods for treating bunions depending on the severity of the deformity. One such procedure is metatarso-cuneiform arthrodesis,[2] which was developed in 1934 by Dr. Paul Lapidus and is now commonly referred to as a "Lapidus" procedure. Ex.1002 ¶¶50-51; Ex.1008, 183-191. The goal of Lapidus procedures is to fix the metatarsal and cuneiform in the corrected position to promote fusion of those bones. Ex.1002 ¶52; Ex.1008, 186, 189. The surgeon prepares the joint for correction by cutting the facing surfaces of the bones, as shown below. Ex. 1002 ¶52.

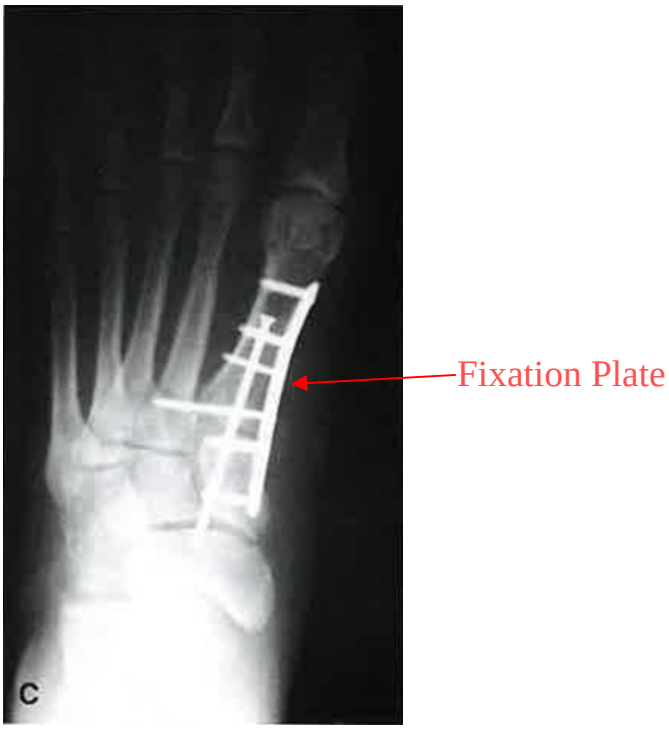
[2] Arthrodesis refers to a surgical procedure where two bones in a joint are mechanically joined together, with the goal that the body will heal (fuse) the bones together. Ex.1002, ¶51; Ex.1005, 803.



Ex. 1002 ¶52; Ex.1009, Fig.1A. The surgeon adjusts the alignment of the metatarsal relative to the cuneiform to establish a moved position of the metatarsal. Ex. 1002 ¶¶52-53; Ex.1008, 187-188; Ex.1009, 493; Ex.1005, 324-327; Ex.1011, 466. Adjusting the alignment of the metatarsal relative to the cuneiform corrects the bunion by returning the first metatarsal to an anatomically correct position. Ex.1005, 324-327.

Finally, the surgeon fixes the bones in the corrected position using, for example, fixation devices (e.g., screw or plate). The body will heal and form bone between the cut bone surfaces (bone fusion) in the corrected orientation. Ex.1002, ¶¶52-55. Ex.1009, 486-487, 490. For example, in 2012, McGlamry described using

three cortical screws to fix the metatarsal and cuneiform (shown below) and alternatively described the use of a fixation plate:

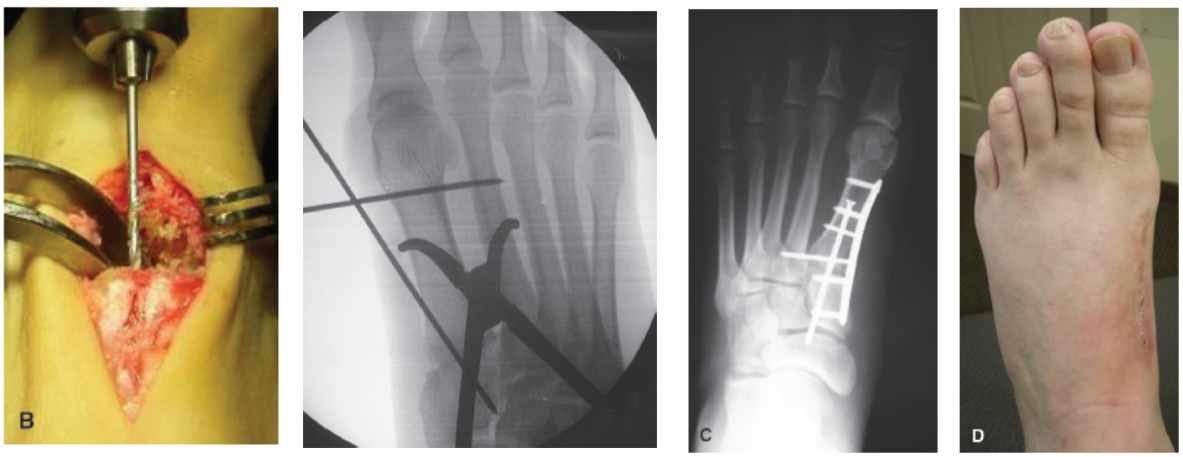


Ex.1005, 326 (disclosing "three solid cortical screws or … cortical screw along with a medial based locking plate"), Fig 31.9; *see also* Ex.1011, Figs.4, 5; Ex.1002, ¶56.

C. Overview of McGlamry

McGlamry is the fourth edition of "McGlamry's Comprehensive Textbook of Foot and Ankle Surgery." Ex.1005. McGlamry "encompasses all facets of foot and ankle surgery," and the fourth edition "places greater emphasis on an instructional approach so as to better help the surgeon, resident, or student *see* how the procedures are done." Ex.1005, xviii (Preface) (emphasis in original). Chapter 31 of McGlamry is titled "Lapidus Bunionectomy: First Metatarsal-Cuneiform Arthrodesis" and was

authored by Lawerence DiDomenico and Mari Wargo-Dorsey. Ex.1005, 322-330. In Chapter 31, McGlamry describes Lapidus procedures, including their history, development, and use. Ex.1005, 322; Ex.1002, ¶57. McGlamry explains that the Lapidus surgery is a "versatile procedure that can correct numerous pathologies," including bunions. Ex.1005, 322, 324; Ex.1002, ¶58. Lapdius procedures "allow[] for triplanar correction of first metatarsal pathology, increase[] the biomechanical advantage of the peroneus longus, and…stabilize the medial column." *Id.* McGlamry walks through the steps of the Lapidus surgery, including cutting and preparation of the bones, reorientation of the first metatarsal, and fixation of the first metatarsal and cuneiform to promote bone fusion.



Ex.1005, Figs. 31.3B (preparation of the bones), 31.5 (repositioning and temporary fixation of the first metatarsal), 31.9C (plate fixation), 31.9D (healed foot with corrected bunion) (left to right); Ex.1002, ¶¶55-60.

D. Known Use of Bone Cutting Guides

Well before 2015, surgeons recognized that bone cutting guides can ensure that the cuts are made accurately (so the bones fit together in a corrected position) and help avoid unnecessary resections, e.g. resections that unnecessarily shorten bones.

For example, in 1980, Chambers disclosed a bone cutting guide system for total knee replacements and proximal tibia osteotomies. Ex.1016, 1:5-9.

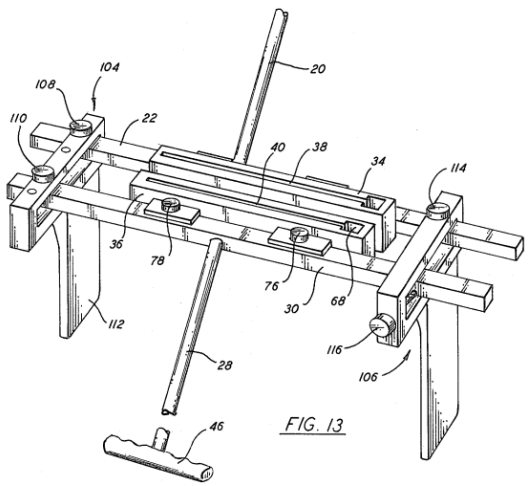


FIG. 13

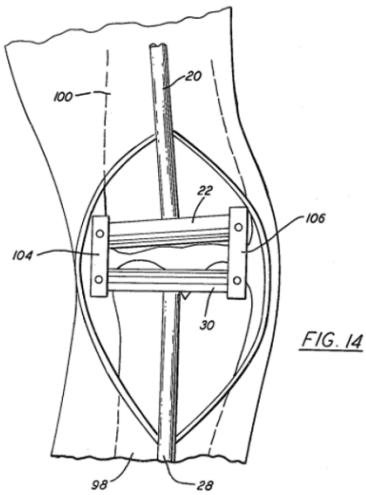


FIG. 14

Ex.1016, Figs.13-14.

Chambers' cutting guide "remove[s] the necessity of clinical judgement and guess work." Ex.1016, 3:1-5. The cutting guide "precisely maintain[s] a cutting plane" and "precisely determin[es] the necessary amount of bone to be removed." *Id.*, 1:8-13. Bone cutting guides have been used in a variety of surgical procedures, including ankle and wrist procedures. Ex.1017 (ankle); Ex.1018 (wrist); Ex.1002, ¶¶61-63.

More specifically, bone cutting guides for foot surgery, including metatarso-cuneiform arthrodesis were also well known by 2015. Ex.1002, ¶¶64-68. For example, Brainard discloses a cutting guide that creates "bone cuts [] through the heads of the metatarsal and base of the phalangeal bones that assures a predetermined orientation of the bones of the toe following attachment and fusion thereof." Ex.1019, 1:23-28.

In 1995, Huebner disclosed a cut guide for bunion-correction surgery. Ex.1012, 1:23-25, 4:8-67. Heubner's guide is for a wedge osteotomy—a procedure in which a wedge of bone is removed from the shaft of the metatarsal so that the remaining bone can be repositioned. *Id.*, 4:63-67. Cutting guides for metatarso-cuneiform arthrodesis (e.g., a Lapidus procedure) were also known by January 2015. For example, Haddad discloses a cutting guide and a positioning jig that can be used "for a fusion application, … [wherein] the jig likely would be secured to a metatarsal distally and a cuneiform proximally." Ex.1013, [0058]. The cutting guide includes two slots (104, 106) that allow a surgeon to "create two complimentary surfaces that will easily and effectively achieve a union through normal biological healing." *Id.*, [0068].

DaCosta and Weinstein similarly disclose cut guides for use in bunion correction surgeries. Ex.1014, Figs.1-7; Ex.1015, [0051], Fig.13.

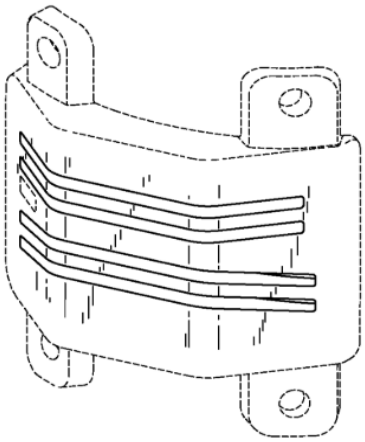


FIG. 1

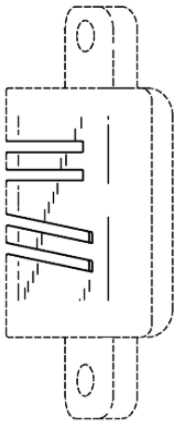


FIG. 5

Ex.1014, Figs.1, 5.

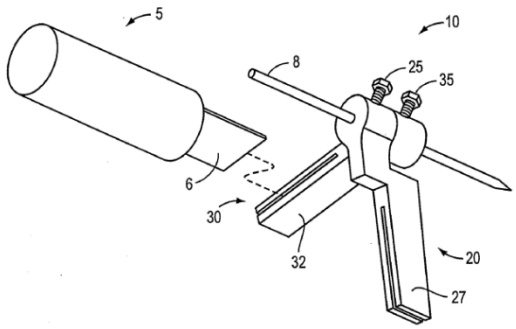


FIG. 3

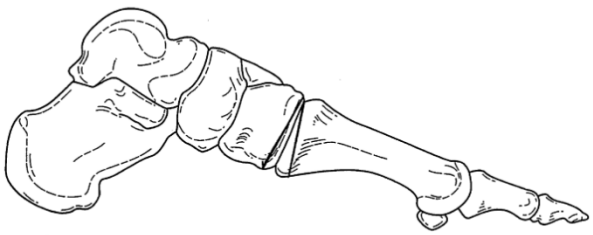


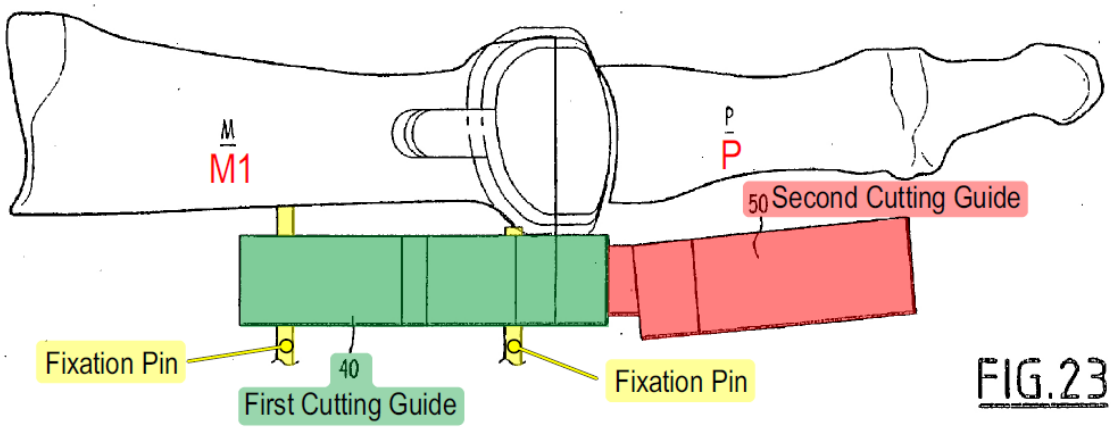
FIG. 13

Ex.1015, Figs.3, 13 (showing cuts to be made on the metatarsal and cuneiform); Ex.1002, ¶¶66, 68.

Similarly, Augoyard also discloses a metatarsophalangeal cutting guide that allows the surgeon to make corresponding cuts to the first metatarsal and the phalanx. Ex.1007, [0034]. Augoyard discloses a prothesis for replacing the metatarsophanageal joint and instruments for preparing the bones and placing the prosthesis. Ex.1007, [0001], [0004]. Augoyard also discloses instruments,

including cutting guides used to prepare the bone surfaces. *Id.*, [0034], [0059]-[0071]; Ex.1002, ¶¶69-73.

Augoyard further discloses a metatarsal cutting guide positioned along the longitudinal axis of a metatarsal to cut an end of the metatarsal. *Id.*, [0034], [0063]-[0066], Figs.20-23. As shown below, a first cutting guide (green) is attached to the metatarsal (M1) with a plurality of fixation pins (yellow). *Id.*, [0064], [0066].



Id., Fig.23; Ex.1002, ¶¶69-73.

The first cutting guide (green) includes a first slot. Augoyard discloses a second cutting guide (red) that attaches to a recess in the first cutting guide. *Id.*, [0034], [0064], [0070]-[0071]. The second cutting guide may be additionally secured to the phalanx with pins and have a second guide slot (purple). *Id.*, [0070]. Augoyard's interlocking cutting guides ensure precise orientation of the cuts to the metatarsal and phalanx. *Id.*, [0070]; Ex.1002, ¶71.

In operation, the surgeon cuts the distal end of the metatarsal by inserting a saw through the first slot of the first cutting guide (40). *Id.*, [0067]. The surgeon then attaches the second cutting guide to the first cutting guide, using it to cut the bone opposite the metatarsal. *Id.*, [0068]-[0071].

The configuration of Augoyard's guide slots is nearly identical to the configuration of the guide slots disclosed in the '397 patent, with both disclosing a first guide pinned to and for cutting the metatarsal and indirectly connected to a second guide for cutting a second bone on the opposite side of the joint. Ex.1002, ¶73. Ex. 1001, 6:23-28, 6:49-51.

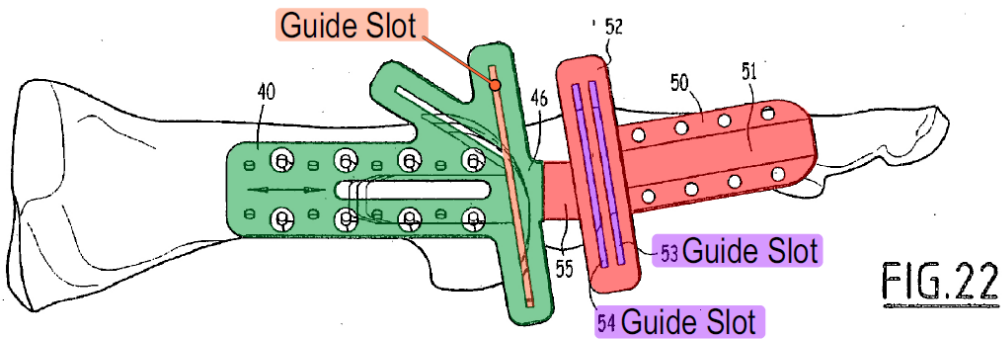
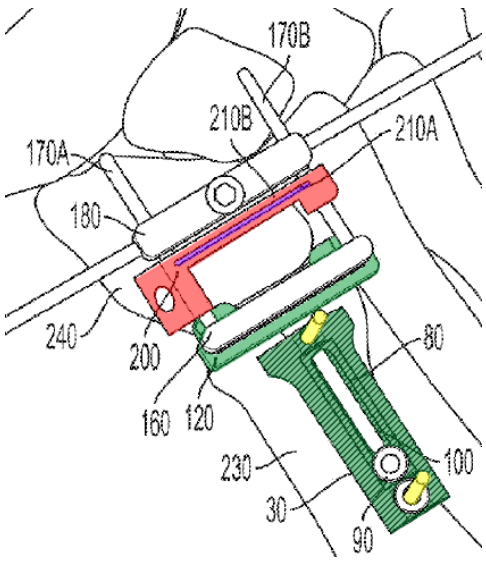


FIG.22



Ex.1007, Fig.22; Ex.1001, Fig.13 (excerpt).

III. THE ’397 PATENT

A. Specification

The ’397 patent purports to relate “generally to devices and methods for positioning and cutting bones” and describes a “bone cutting guide 20” having several components:

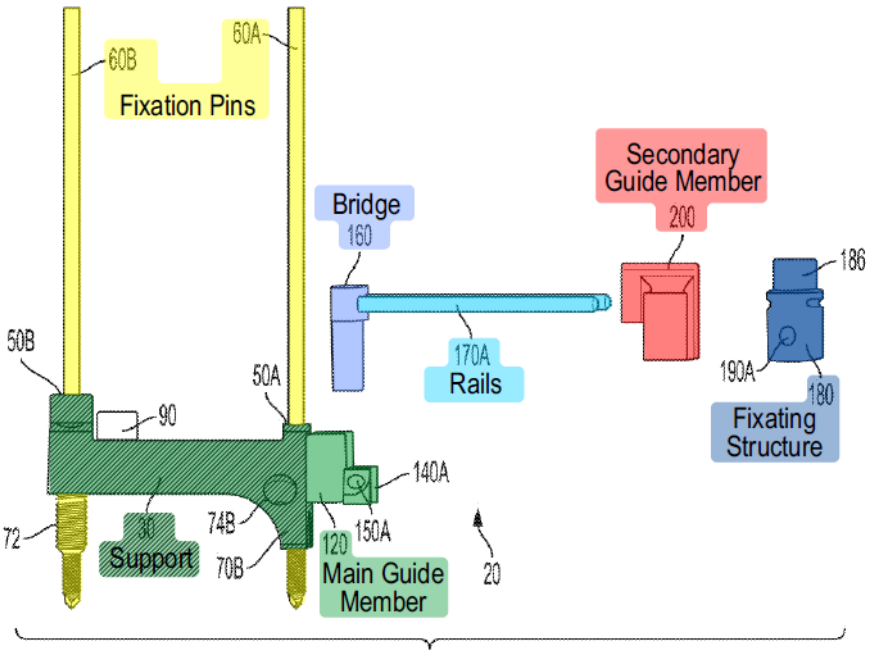


FIG. 1

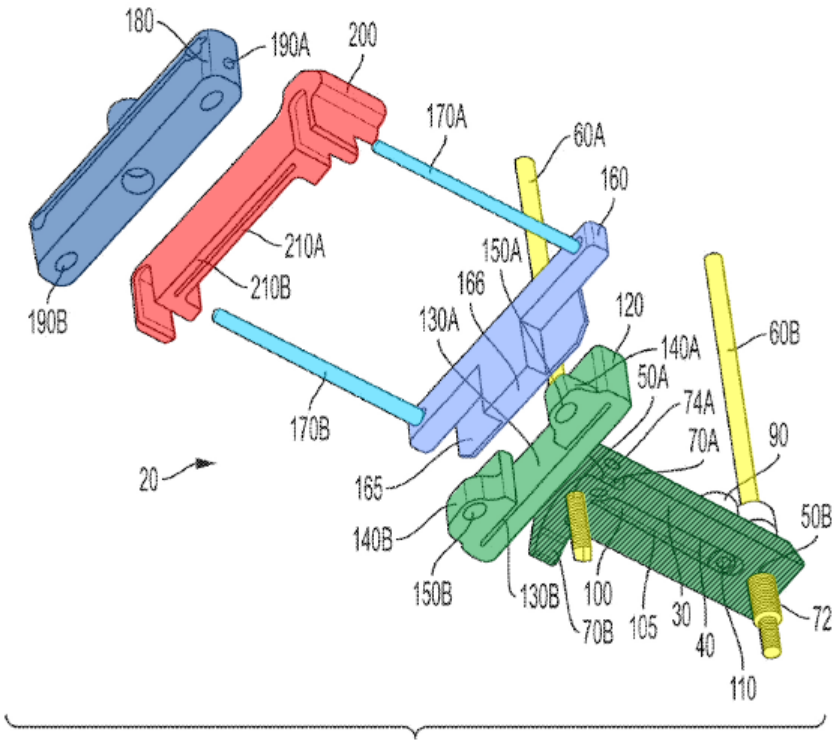
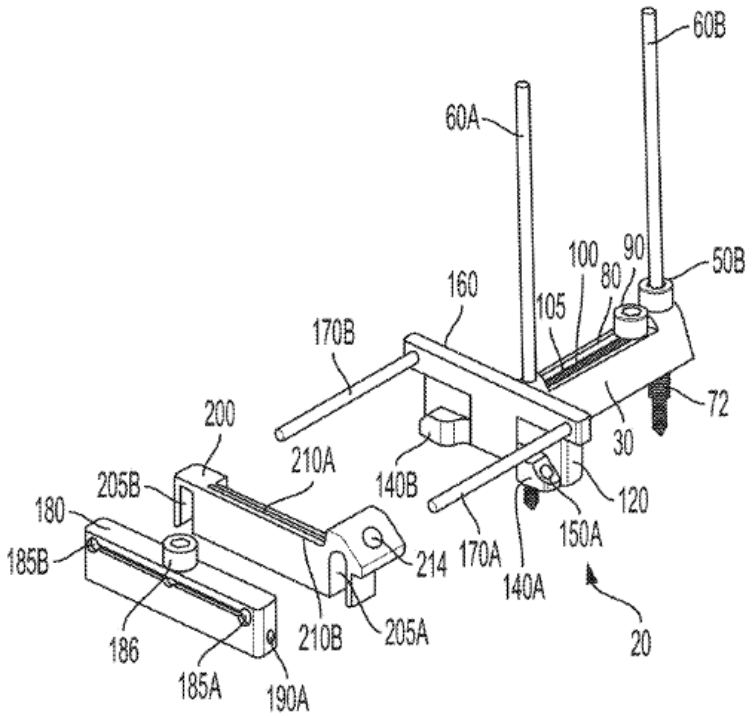


FIG. 2

Ex.1001, 1:27-28, Figs.1, 2. The bone cutting guide 20 includes a "support 30" with "apertures" 50A/B through which "pins" 60A/B can be inserted to attach the bone cutting guide to a bone. Ex.1001, 3:64-4:10.

"Main guide member 120" is located on one end of the support 30. *See* Ex.1001, 5:4-5. The main guide member includes "first and second guide surfaces 130A and 130B," which together can define a slot. Ex.1001, 5:8-28, Fig.2. A "cutting member (e.g., a saw blade) can be inserted through the space defined by the first guide surface 130A and the second guide surface 130B to cut" a bone. Ex.1001, 8:40-44.

A bridge component 160 can be added to the main guide member 120 by placing it into the slot defined by guide surfaces 130A/B in an interference fit, as shown in Figure 3A. Ex.1001, 6:10-16, 9:8-16.



Ex.1001, Fig.3A. Rails 170A/B can extend from the bridge component 160, Ex.1001, 6:26-30, 9:16-20. A "secondary guide member 200" can be added by placing it onto the rails. Ex.1001, 6:49-55, 9:20-22. The secondary guide member 200 can be "locked to" the rails or can translate along the rails, but the rails are the only structure described in the specification for accommodating the secondary guide member 200. Ex.1001, 7:8-12, 9:55-59. The secondary guide member 200 can include additional guide surfaces 210A/0B that define a slot. Ex.1001, 6:55-7:1. A saw can be placed through the slot in the secondary guide member to cut a second

bone. Ex.1001, 9:63-10:3. After the bones "have been cut and positioned as desired, the bone cutting guide 20 can be removed." Ex.1001, 10:26-28.

B. Claims

The claims of the '397 patent recite "bunion correction method[s]." The claims are listed in the Appendix to this Petition. Claims 1, 20, and 29 are independent claims. Claims 20 and 29 differ slightly from claim 1, and incorporate features of various claims that depend from claim 1.

C. Prosecution History

The application leading to the '397 patent was filed as a Track One Application with claims 1-30 on April 24, 2024. Ex.1004, 19. The Patent Office granted this request and issued a first action allowance of all claims. *Id.*, 164, 256-262, 274-276. Although Treace submitted over five hundred references, including Augoyard and Chapter 31 of McGlamry, during prosecution, not one was substantively applied to the claims of the '397 patent. *See generally* Ex.1004, Ex.1001, references cited p.1-9.

IV. LEVEL OF ORDINARY SKILL

The '397 patent relates to "devices and methods for positioning and cutting bones." Ex.1001, 1:27-28. The claims of the '397 patent recite "bunion correction method[s]" utilizing various instrumentation that is described in the specification. *See, e.g.*, Ex.1001, Claim 1. Thus, the patent includes both surgical procedures and

mechanical devices. Ex.1002, ¶¶31-33. A hypothetical person of ordinary skill in the art would have a combination of these two skill sets. *Id.*. Thus, a hypothetical person of ordinary skill in the art ("POSA") would have had medical degree and at least 3 years of surgical experience with foot surgery. *Id.* Such person would have worked as part of a team and collaborated with a person having a degree in mechanical engineering or a similar engineering discipline, and experience with the design of surgical instrumentation. *Id.* For individuals with different engineering backgrounds, a person could still be of ordinary skill in the art provided that person's additional experience compensates for any differences in that person's education as stated above. *Id.*

This Petition does not turn on this specific definition of the level of ordinary skill. The claims would been obvious from the perspective of any reasonable definition of a POSA. Ex.1002, ¶34.

V. CLAIM CONSTRUCTION

In a post grant review, a claim "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b). Under this standard, claims "are generally given their ordinary and customary meaning," as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation omitted).

A. "attached/attaching"

The term "attached" (and its variants "attaching" and "attached to") should be construed to require a direct connection between the recited structures, not merely an indirect or functional association through intervening components. The intrinsic record supports only this usage of "attached," and consistently employs the term to describe two components that are physically joined—such as by pins, screws, clamps, interference fits, or analogous mechanisms—such that they are directly connected. The patent does not use "attached" to refer to indirect associations, such as situations in which one component is merely supported by or held in place through another, separate part of the assembly.

1. The Specification Uses "Attached" for Direct Connections

Claims must be interpreted in light of the specification. *Phillips*, 415 F.3d at 1313. Here, the specification demonstrates that, in the '397 patent, "attached" and its variants refer to direct connections between components, not indirect relationships. Every instance of "attached" in the specification describes one structure being physically connected to another through a direct connection. Where a patent "repeatedly and consistently characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization." *See, e.g.*, *Wis. Alumni Res. Found. v. Apple Inc.*, 905 F.3d 1341, 1351 (Fed. Cir. 2018) (internal quotes omitted).

For example, the specification describes a bridge component 160 (purple below) that is physically joined, i.e., attached, to a main guide member 120 (orange below):

> [O]nce the bone 230 has been cut the bridge component 160 can optionally be attached to the main guide member 120. In one embodiment, the bridge component 160 can have a geometry that allows ***the bridge component 160 to attach to the main guide member 120 … through an interference fit***, while in other embodiments the bridge component 160 can attach to the main guide member 120 by other attachment means.

Ex.1001, 9:8-16. This is shown in Figure 2.

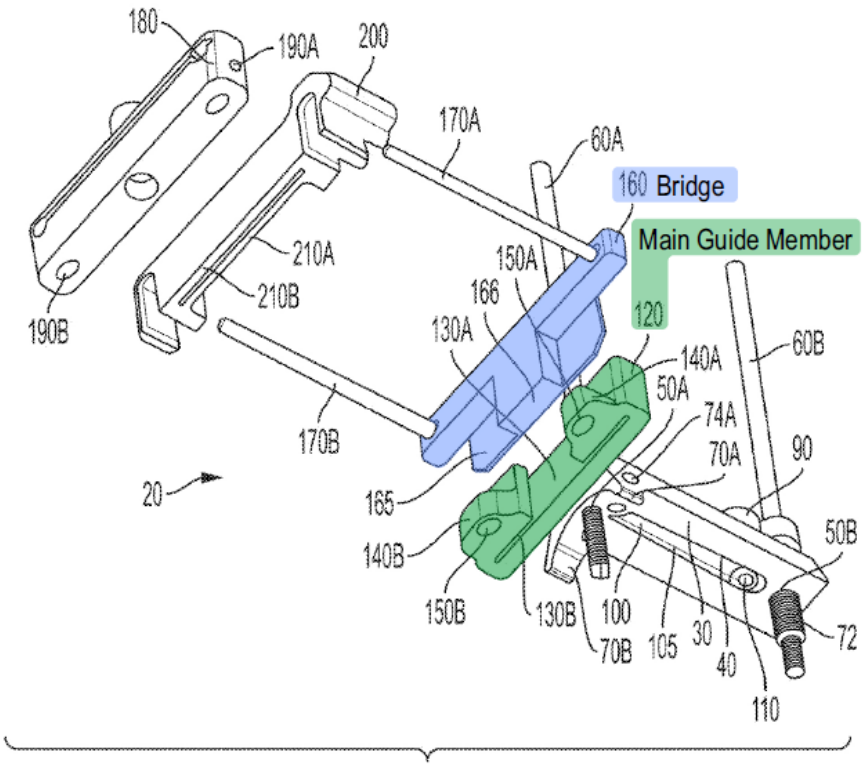


FIG. 2

Id., Fig.2.

Further, "[t]he bridge component 160 is attached to the main guide member 120." *Id*., 7:15-17. Figure 3A is likewise described as showing "a bridge component ***attached*** to a main guide member," which is a direct connection. Ex.1001, 2:61-63.

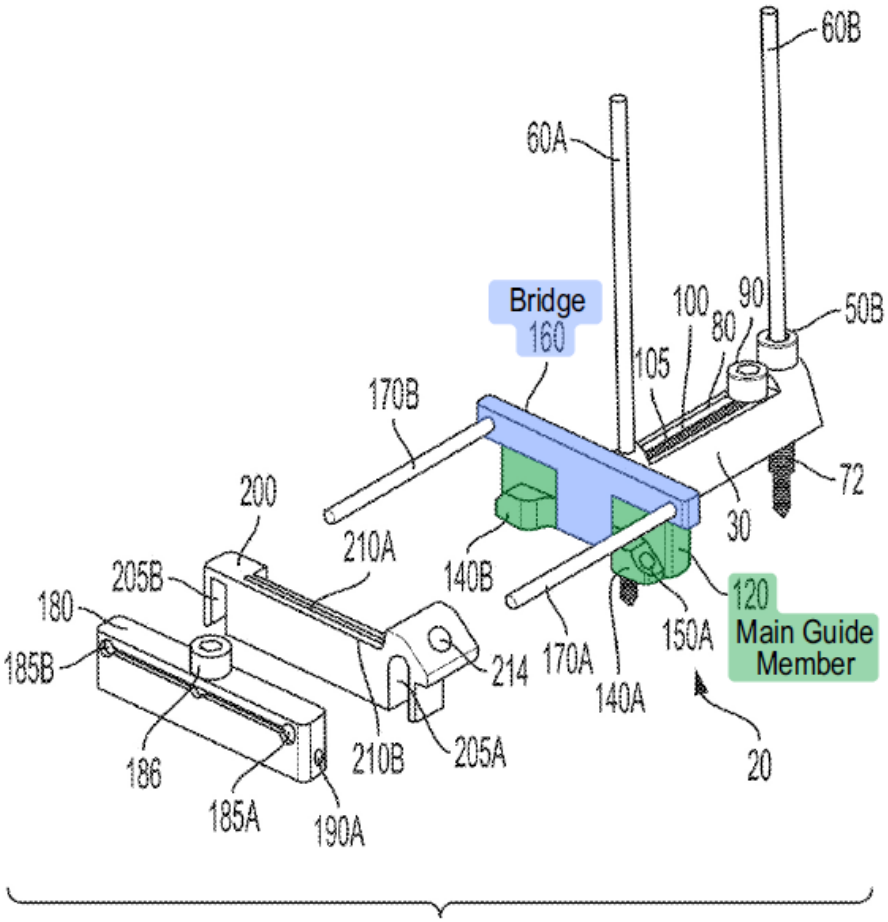


FIG. 3A

Ex.1001, Fig.3A. Likewise, the specification states: "the bridge component 160 can be coupled to the main guide member 120 by any ***attachment mechanism, such as screws or clamps***." *Id*., 6:23-26. These passages give concrete examples of "attachment" and "attachment mechanism[s]": interference fits, screws, clamps. Each of these is a direct connection between two structures.

The specification provides additional examples of attachment, i.e., direct physical connection, including the fixating structure 180 (yellow below):

> One such component of the bone cutting guide 20 that can be supported on the rails 170A and 170B [green below] is the fixating structure 180. FIG. 10 shows ***the fixating structure 180 attached to the rails 170A and 170B***.

Id., 9:23-26.

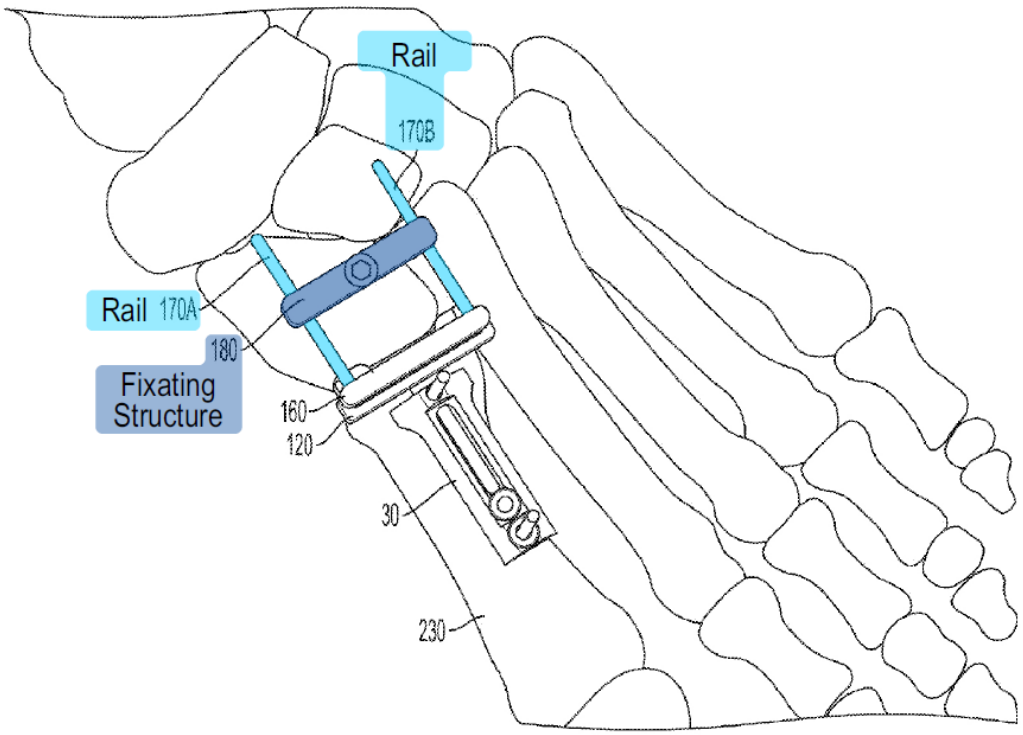


FIG. 10

Ex.1001, Fig.10; *see also id.*, 3:14-16 ("FIG. 10 is a perspective view of a bridge component ***attached*** to the main guide member of the support of FIG. 7 with a fixation structure ***attached*** to the bridge component."). As illustrated in Figures 10, 11, and 12, the described attachments are direct connections.

In contrast, the specification does not use "attached" to describe indirect connections made through intermediate components. For example, the specification describes a secondary guide member 200 (red below) that can "receive" the "rails 170A and 170B" (blue below). *Id*., 9:54-59. This is shown in Figure 2.

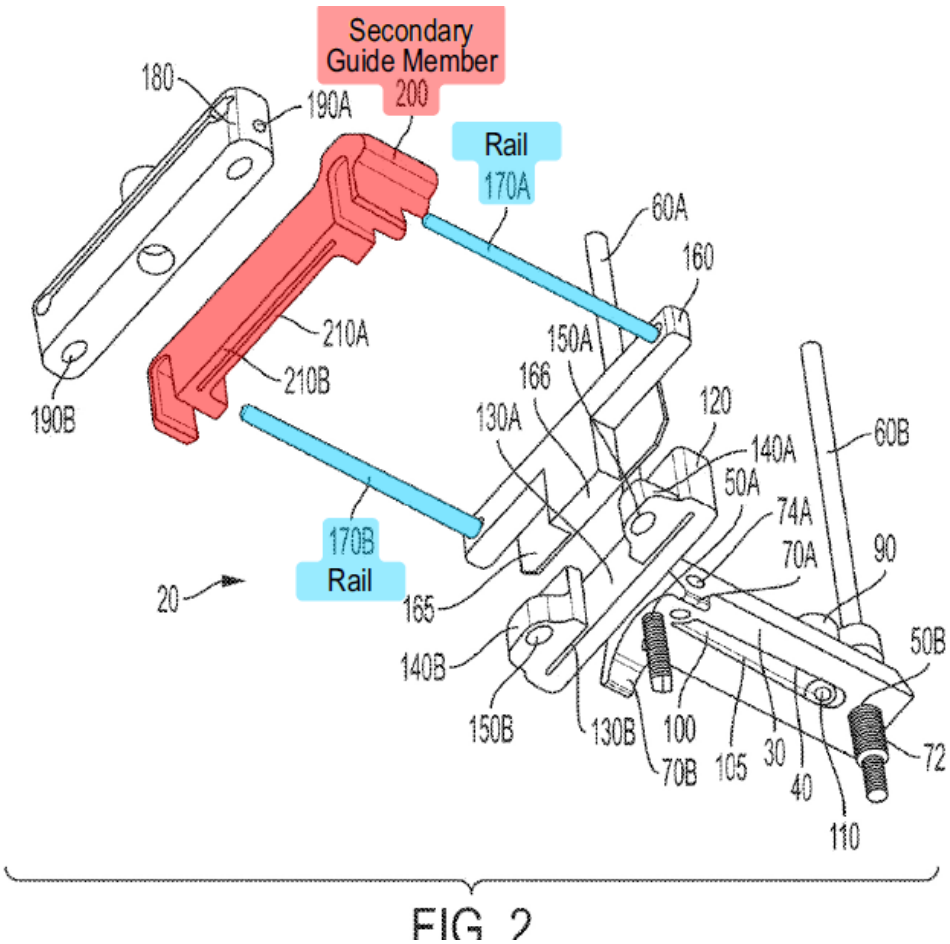


FIG. 2

Id., Fig.2. The specification never describes the secondary guide member 200 as "attached to" a bone. Instead, the fixation structure 180 is attached to the bone 240 (the cuneiform) by inserting pins 220A and 220B (yellow below) through fixation apertures in the fixation structure 180 (blue below) and into the cuneiform:

> FIGS. 11 and 12 illustrate perspective views of the fixating structure 180 with the fixation pins 220A and 220B received through the fixation apertures 190A and 190B …. Fixation pins 220A and 220B can be fixed to a bone 240 (e.g. a first cuneiform as illustrated) to provide stability for the bone cutting guide 20 and/or to position the bone 240.

Id., 9:34-42. This is shown in Figure 12.

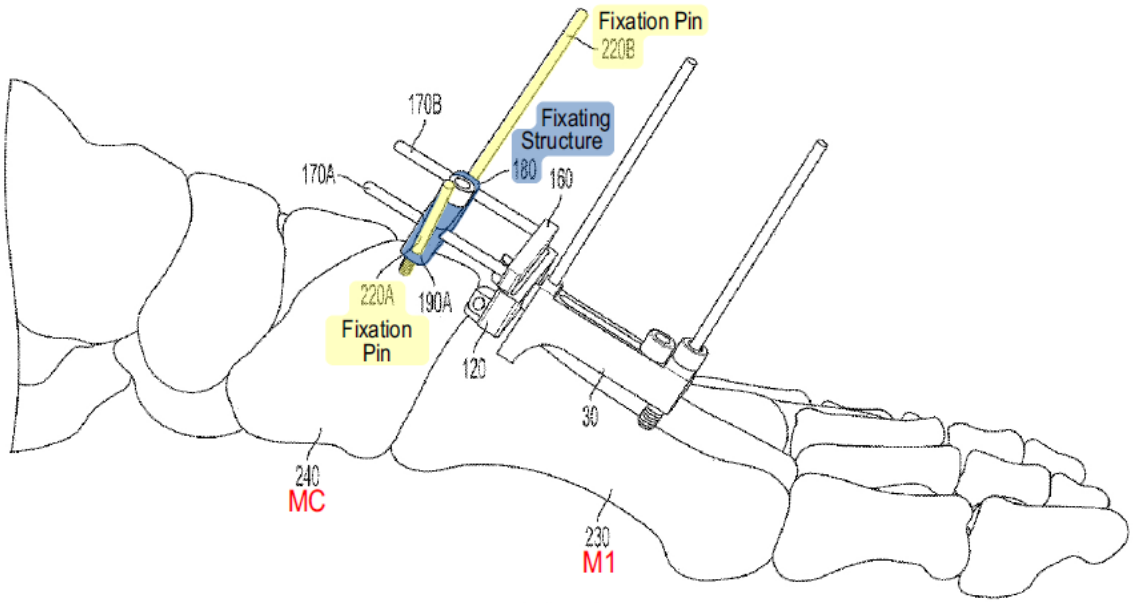


FIG. 12

Id., Fig.12. A POSA would understand, in the context of a surgical method as claimed in the '397 patent, that "attached" refers to a direct physical connection, not an attenuated series of indirect relationships. *See* Ex.1002, ¶40. Indeed, '397 patent never uses the word "attached" to describe an indirect relationship, for example the relationship disclosed by the between the secondary guide member 200 and the bone 230 or 240, through the train-like configuration where the assembly of the main guide member 120, shaft 100, and support 30 is attached to the bone 230, a bridge component 160 is added to the main guide member 120, rails 170 protrude from the

bridge component 160, and the secondary guide member 200 rests on the rails 170. This reinforces that "attached" requires a direct connection. *See, e.g.*, *Wis. Alumni Res. Found.*, 905 F.3d at 1351-52.

Within the context of the specification, if "attached" were interpreted to encompass any indirect connection, there would be no reason for the specification to use other terms such as "supported," because virtually every component in the assembly would qualify as "attached to" every other component or to the bone. The specification's consistent use of "attached" to describe direct connections—and not indirect ones—confirms this is the proper construction.

2. <u>The Claim Language is Consistent with the Specification</u>

The claims of the '397 patent are consistent with the specification's use of "attached" to refer to direct connections. For example, claim 1 uses "attaching" in the context of directly connecting the claimed guide slot to a bone via fixation pins. The relevant portions recite:

> attaching the first bone cutting guide slot to the metatarsal with a first fixation pin inserted into the metatarsal and a second fixation pin inserted into the metatarsal

and later:

> the second bone cutting guide slot being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal.

Ex.1001, claim 1; *see also id*., claims 20 and 29 (reciting similar language). Dependent claim 9 similarly recites:

> attaching the second bone cutting guide slot to the cuneiform with a third fixation pin inserted into the cuneiform.

Id., claim 9.

In each instance, the claim identifies which two components are "attached" and how: i.e., the claimed guide slot is connected to the bone "with a [first/second/third] fixation pin." The claimed phrase "attaching … with … a fixation pin" further demonstrates that the claims recite a direct attachment. For example, if a hook was attached to a wall with a nail, placement of a hanger on that hook would not be referred to as "attaching" the hanger to the wall with the nail. Rather, the hanger is on the hook. Consistent with that basic example, in the specification, components are directly attached to a bone ***with*** a fixation pin—a direct connection between a component and the bone. *See, e.g.*, *id*., 4:1-10, 9:34-42. Nothing in the claims suggests that "attached" or its variants should be construed more broadly than the direct connections described in the specification.

3. Proper Construction

In view of the intrinsic record, "attached/attaching" should be construed to mean "directly connected/connecting." This construction accords with Federal Circuit precedent construing this term when faced with analogous intrinsic records.

For example, in *Jurgens v. McKasy*, the court construed a claim with limitations reciting a hoop "attached" to a neck and a spike "attached" to the hoop to "literally require a direct series connection between neck, hoop, and spike," where neither the specification nor the prosecution history suggested any broader meaning for "attached." 927 F.2d 1552, 1560-61 (Fed. Cir. 1991).

Likewise, in *Searfoss v. Pioneer Consolidated Corp.*, the court affirmed a construction of "connecting"—treated as synonymous with "attaching"—as requiring only "direct, rigid, pivotal connections" between the recited parts, based on the specification and figures, notwithstanding general-purpose dictionary definitions that encompassed indirect connections. 374 F.3d 1142, 1149-50 (Fed. Cir. 2004).

The construction proposed by Petitioner is thus driven by the intrinsic record of the '397 patent, which consistently and exclusively uses "attached/attaching" to refer to direct connections. Given this record, the proper construction of "attached/attaching" is "directly connected/connecting."

B. <u>"moved position"</u>

Claim 1 recites "adjusting an alignment of the metatarsal to establish a moved position of the metatarsal." Ex.1001, claim 1. Later in the same claim, the method requires "causing the metatarsal to fuse to the cuneiform in the moved position." *Id.*

The term "moved position" (and its variant "moved position of the metatarsal") should be construed to mean the position of the metatarsal relative to the cuneiform that is established by the recited adjusting step and in which the metatarsal is eventually fused to the cuneiform.

The only "moved position" identified in the claim is the one established by the adjusting step, and that is the same position in which fusion occurs. Claim 20 uses identical language. Claim 29 uses the similar language, requiring "adjusting an alignment of the metatarsal relative to a first cuneiform … to establish a moved position of the first metatarsal" and then "causing the first metatarsal to fuse to the first cuneiform in the moved position." *Id*., claim 29. The claims thus treat "moved position" as a single, defined position: the alignment created by the adjusting step and later maintained for fusion.

This reading is consistent with the specification's description of positioning the bones "as desired" and then holding that position while a plate is applied across the joint. *See, e.g.*, Ex.1001, 7:46-50 (explaining that "cuts are made to bone with respect to the cutting guide, and the bones can be positioned for an additional surgical step, such as bone plating, after the cuts have been made"), *id*. 10:26-39 (describing translating the shaft "to adjust the relative position of the bones (e.g., to compress them together)" while a bone plate is applied across the joint).

C. Other Terms

Petitioner submits that the Board need not specially construe any other claim terms. *Toyota Motor Corp. v. Cellport Sys., Inc.*, IPR2015-00633, Paper No. 11 at 16 (P.T.A.B. Aug. 14, 2015); *see also Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

VI. RELIEF REQUESTED

PGR is requested for the following grounds of unpatentability:

Ground	Reference(s)	Basis	Challenged Claims
1	N/A	§112[3]	1-30
2	McGlamry and Augoyard	§103	1-2, 4-10, 12-20, 22-30
3	McGlamry, Augoyard, and DaCosta	§103	11

[3] The '397 patent claims a priority date of January 7, 2015. Accordingly, all references herein to 35 U.S.C §§ 102, 103, and 112 refer to the section in effect after the implementation of the America Invents Act.

The ’397 patent claims priority to a provisional application filed on January 7, 2015. Ex.1001, 1:6-22.

McGlamry’s Foot and Ankle Surgery, 4th edition, (“McGlamry”) is a textbook published by Wolters Kluwer Health in 2013.[4] Ex.1005. It is prior art to the ’397 patent under 35 U.S.C. § 102(a).

European Patent Application Publication No. 1508316A1 (“Augoyard”) published on February 23, 2005. Ex.1007[5], Front Page. Augoyard is titled “Total metatarsophalangeal prosthesis and ancillary instruments for fitting this prosthesis” and describes surgical instruments. *Id.* Augoyard is prior art to the ’397 patent under 35 U.S.C. § 102(a).

U.S. Design Patent No. D695,402S1 (“DaCosta”) issued on December 10, 2013, and is titled “LAPIDUS CUT GUIDE”, and depicts cut guides for use in Lapidus surgery. Ex.1014; Ex.1002, ¶68. DaCosta is prior art to the ’397 patent under 35 U.S.C. § 102(a).

[4] A declaration from a professional librarian is submitted to support the publication date and public accessibility of certain cited references. Ex.1031.

[5] Ex.1006 provides the translator’s declaration accompanying the English translation submitted as Ex.1007.

The references are analogous art because they are from the same field as the '397 patent, e.g., devices and methods for positioning and cutting bones. Ex.1002, ¶81; Ex.1001, 1:25-29, 3:44-61; *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). They are also pertinent to a problem the inventors were focused on, e.g., bone cutting guides used to cut the bones of a joint. Ex.1001, 3:44-61, 7:36-50; Ex.1002, ¶81.

This Petition is supported by the Declaration of Steven K. Neufeld, M.D. (Ex.1002). *See* Ex.1002, ¶¶1-28; *see also* Ex.1003.

VII. GROUND 1: CLAIMS 1-30 ARE UNPATENTABLE UNDER 35 U.S.C. § 112

A. Claims 1-30 are Unpatentable for Lack of Written Description

Section 112(a) "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" to determine whether the inventor had possession of the claimed subject matter as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The Federal Circuit has made clear that "claims may be no broader than the supporting disclosure" and are invalid if they attempt to cover subject matter not described in the specification. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-81 (Fed. Cir. 1998); *ICU Medical, Inc., v. Alaris Medical Sys., Inc.*, 558 F.3d 1368, 1378-1379 (Fed. Cir. 2009). Moreover, "a description that merely renders the invention obvious does not satisfy the

requirement." *Ariad Pharms.*, 598 F.3d at 1352 (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)). The written description requirement is not satisfied merely because the specification describes each individual step in isolation; it must also demonstrate possession of the particular combination and arrangement of steps that the claims now recite. *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005).

1. All Claims Lack Written Description for Requiring Direct Attachment of the Second Cutting Guide Slot

Every claim of the '397 patent requires, *inter alia*, "the second cutting guide slot being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal" (claim 1); "the second guide being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal" (claim 20); or "the second guide being attached to the first metatarsal by at least the first fixation pin and the second fixation pin" (claim 29). Ex.1001, claims 1, 20, and 29. These limitations lack written description support.[6]

[6] Claims 20 and 29 further require "the second guide being attached to the [first] cuneiform by at least a third fixation pin inserted into the cuneiform." This limitation lacks written description support for the same reasons.

Under the proper construction of "attached/attaching" in Section V.A, the independent claims require that the second bone cutting guide slot be directly connected to the metatarsal by the same first and second fixation pins that directly attach the first bone cutting guide slot to the first metatarsal. *See* Ex.1001, claims 1, 20, 29.[7] The claims therefore require (i) a direct connection of the second bone cutting guide slot to the metatarsal (not merely an indirect relationship through intermediate structures) (ii) using the same first and second fixation pins inserted into the metatarsal that attached the first bone cutting guide slot.

Nothing in the '397 patent describes such an arrangement. The only structure identified as defining the claimed second bone cutting guide slot is the secondary guide member 200. However, the secondary guide member 200 is never described as being attached to a bone in any manner. In fact, the secondary guide member 200 is not described as having any fixation apertures or other features that would allow it to be connected to bone. Instead, the specification explains that "[t]he secondary guide member 200 can be supported on the rails 170A and 170B" and that its slots

[7] To the extent the claims of the '397 patent are not invalid for failing one or more requirements of 35 U.S.C. § 112 under the proper construction of "attached," they are nonetheless invalid as obvious under any construction, as explained in subsequent grounds.

205A and 205B "receive the rails 170A and 170B such that the secondary guide member 200 is supported thereon." Ex.1001, 6:50-55. The specification further states that "the secondary guide member 200 can be locked to the rails 170A and/or 170B with a locking screw, cam, pin, etc." *Id*., 7:8-10. The cited "locking screw, cam, pin, etc." is expressly described only as a mechanism for locking the secondary guide member 200 to the rails—not to any bone. Nowhere does the '397 patent describe attaching the secondary guide member 200 to a bone.

Furthermore, the '397 patent discloses no embodiment in which the secondary guide member 200 is attached to a bone using the same pins that attached the first cutting guide slot to the metatarsal. Instead, as referenced above, the secondary guide member 200 rests on rails 170A/B that protrude from the bridge component 160, which, in turn, is connected to the sole structure connected to the metatarsal—the assembly of the main guide member 120, shaft 100, and support 30. Ex.1001, 6:9-30, 3:66-4:14. The patent similarly contains no description of the bridge component 160 being attached directly to a bone.

By contrast, when the '397 patent describes a structure that attaches to bone by fixation pins, it does so explicitly. For example, it states that "blocks 140A and 140B can provide a means for additionally positioning the bone 230" because "[f]ixation pins can be inserted through the fixation aperture 150A and/or 150B and into the bone 230." *Id*., 9:1-6 (referring to Fig.9). Likewise, a support 30 includes

fixation apertures 156A and 156B "formed in its side to receive fixation pins," which can secure the support to the bone. *Id*., 5:60-62, 6:2-8 (referring to Fig.3E). In each instance, the patent expressly describes fixation apertures extending through the structure and pins inserted "into the bone." No analogous disclosure exists for the secondary guide member 200.

The '397 patent never describes the claimed configuration: a second bone cutting guide slot that is attached to the metatarsal with the same first and second fixation pins inserted into that metatarsal. As an example, if a hook is attached to a wall with a first nail, the act of hanging a second hook from the first hook does not mean the second hook is attached to the wall with the first nail. A POSA, reading the '397 patent, would recognize (i) a first guide assembly that can be attached to bone (*id*., 7:64-8:7), and (ii) a separate secondary guide member 200 that sits on rails and may be locked to those rails (*id.*, 6:50-51, 7:8-10). In contrast, the patent contains no disclosure that the secondary guide member 200—and therefore the second bone cutting guide slot—is directly attached to the metatarsal, let alone by the same metatarsal fixation pins that attached the first bone cutting guide slot. The specification therefore lacks written description support for this limitation, and the independent claims and their dependents are invalid under 35 U.S.C. § 112.

2. Claims 3 and 21 Lack Written Description for Reciting The Negative Limitations "without the first bone cutting guide slot being positioned over the portion of the metatarsal to be cut"

Claim 3 further limits claim 1 by requiring, *inter alia*, that the cuneiform is cut only if the first bone cutting guide is no longer in its original claimed position:

> without the first bone cutting guide slot being positioned over the portion of the metatarsal to be cut and configured to receive the cutting instrument therethrough.

Id., claim 3. Claim 21, which depends from claim 20, requires a substantively identical limitation. *Id*., claim 21.

As written, this negative limitation requires that, at the time the cutting member is inserted through the second bone cutting guide slot to cut the cuneiform, the first bone cutting guide slot is (1) no longer positioned over the portion of the metatarsal to be cut ***and*** (2) not configured to receive the cutting instrument.

The '397 patent, however, never describes any device or method embodying both aspects of this negative limitation. The specification only describes that after the first bone cutting guide slot is used to help cut the first metatarsal, it remains in the same position over the metatarsal when the second bone cutting guide slot is used. *See, e.g.*, Ex.1001, 9:8-22.

Indeed, the '397 patent states that the second bone cutting guide is attached to the first bone cutting guide by inserting "the bridge component 160" into the first bone cutting guide slot:

> the bridge component 160 can have a geometry that allows the bridge component 160 to attach to the main guide member 120 between the first and second guide surfaces 130A and 130B[8] through an interference fit.

Id., 9:10-16. With the bridge component 160 inserted, the first bone cutting guide slot is no longer configured to receive a cutting instrument, but remains positioned over the portion of the metatarsal. Indeed, the specification contains no embodiment in which the position of the first cutting guide relative to the metatarsal changes after the metatarsal is cut.

Accordingly, the specification does not reasonably convey to a POSA that the inventors had possession of the claimed method limitation. Claims 3 and 21 therefore lack written description support and are unpatentable under §112(a).

3. Claim 14 Lacks Written Description for Encompassing Cutting the Metatarsal after the Cuneiform

Claim 14 further limits claim 1 by requiring "inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal ***after***

[8] As described above, the first bone cutting guide slot is defined between the first and second guide surfaces 130A and 130B, with a "space defined between the first guide surface 130A and the second guide surface 130B" through which "a cutting member (e.g. a saw blade) can be inserted … to cut, for example, the bone 230." *Id*., 8:40-44.

inserting the cutting member through the second bone cutting guide slot to cut the portion of the cuneiform." Ex.1001, claim 14. The specification, however, only describes the opposite sequence: the metatarsal is always cut ***before*** the cuneiform.

The specification repeatedly describes using the first bone cutting guide slot to cut the metatarsal as the initial cutting step. *Id*., 9:8-22, 9:52-10:11. Only after that first cut is completed does the patent explain that "the bridge component 160 can optionally be attached to the main guide member 120" (*id*., 9:8-10), after which the secondary guide member 200 is added on the rails of the bridge component 160 (*id*., 6:26-28, 6:51-55). The specification then teaches that the cuneiform cut is performed using that newly added secondary guide member 200. This is the only sequence of operations disclosed in the '397 patent.

Because the '397 patent does not describe performing the metatarsal cut after the cuneiform cut, as required by claim 14, the claim lacks written description. *LizardTech*, 424 F.3d at 1346 (rejecting argument that "section 112 requires only that each individual step in a claimed process be described adequately").

B. Claims 1-30 are Unpatentable for Lack of Enablement

To satisfy § 112(a), the specification must "describe the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art' to 'make and use' the invention." *Amgen v. Sanofi*, 598 U.S. 594, 612 (2023) (quoting 35 U.S.C. § 112(a)). This statutory standard requires that the disclosure "enable the

full scope of the invention as defined by its claims," not merely a subset of preferred embodiments. *Id*. at 610. In *Amgen*, the Supreme Court held that when "a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class," cautioning that "[t]he more one claims, the more one must enable," and rejecting an approach that left skilled artisans with "little more than advice to engage in 'trial and error.'" *Id*. at 610, 615.

Accordingly, the specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1365 (Fed. Cir. 2023). Whether the specification enables the full scope of the claims without undue experimentation is evaluated under the *Wands* factors, which include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

1. <u>The '397 Patent Does not Enable Disassociated First and Second Guides</u>

Independent claims 1, 20, and 29 broadly recite methods of cutting the metatarsal and cuneiform using, respectively, a "first" guide and a "second" guide defining respective bone cutting guide slots. Ex.1001, claims 1, 20, 29. But the '397

patent's written description only teaches a single species in which both cuts are provided by multiple bone cutting guides connected to each other through a bridge and rails. The patent nowhere discloses, or even meaningfully contemplates, an embodiment in which the claimed "first guide" and "second guide" are not associated with each other through other components and are independently attachable to and removable from the metatarsal at separate times.

Under § 112, the specification must teach the POSA how to make and use the entire scope of the claimed invention without undue experimentation. *Amgen* confirms that this requirement applies with full force to genus claims and that a patentee may not claim an entire class while disclosing only a limited subset and leaving the remainder to trial-and-error experimentation. *Amgen*, 598 U.S. at 610-11, 613-15. As explained below, the challenged claims encompass a broad genus of methods using any "first" and "second" guides, while the specification teaches at most a narrow, integrated species where a first guide is serially connected to a second guide, like a train car. The specification provides no guidance commensurate with the breadth of the claims.

a. <u>The Challenged Claims Recite a Broad Genus of Methods Using First and Second Guides</u>

Claim 1 recites a bunion correction method in which a surgeon: (1) positions "a first bone cutting guide slot" over a metatarsal; (2) attaches that slot to the metatarsal using first and second fixation pins; (3) cuts the metatarsal through the

first slot; (4) adjusts the alignment of the metatarsal relative to a cuneiform; (5) positions "a second bone cutting guide slot" over the cuneiform, with the second slot attached to the metatarsal "by at least the first fixation pin … and the second fixation pin" and those pins positioned distally of the second slot; and (6) cuts the cuneiform through the second slot and causes fusion in the moved position.

Dependent claim 16 further clarifies that the "first bone cutting guide slot" and "second bone cutting guide slot" of claim 1 are defined by respective "first" and "second" guides: "a first guide defining the first bone cutting guide slot; and a second guide defining the second bone cutting guide slot." Thus, read in light of claim 16, claim 1 necessarily encompasses any method that employs two structurally separate guide components—however configured—so long as they include the claimed slots and pin attachments.

Independent claims 20 and 29 repeat this structure in slightly different wording. Both are framed expressly in terms of "a first guide" and "a second guide," each defining a respective bone cutting guide slot and each attached to bone using fixation pins in the manner recited. For example, claim 29 recites attaching the first guide to the metatarsal with two parallel fixation pins and then, after cutting and repositioning, attaching a second guide to both the metatarsal (via those same pins) and the cuneiform (via a third, skewed pin) before cutting the cuneiform.

Nothing in claims 1, 20, or 29 requires that the first and second guides be part of a single, connected system or to share any particular structural relationship beyond their use of the same pair of metatarsal fixation pins. As drafted, the claims encompass a broad genus of methods in which the "first guide" and "second guide" can be completely distinct devices—for example, devices from different manufacturers, with different rails or no rails at all, and with any conceivable geometry so long as they can be attached to the metatarsal via the claimed pins and include a cutting slot.

b. The '397 Patent's Specification Describes a Single Embodiment

In contrast to the broad genus claimed, the '397 patent's specification describes and illustrates only a single system and method of using that system. *See, e.g.*, Ex.1001, 3:62-64, 7:13-15, 7:51-53. That system includes: (i) a support 30 fixed to bone (*id.*, 3:66-4:14); (ii) a shaft 100 translatable within the support 30 (*id.*, 4:49-54); (iii) a main guide member 120 carried on the shaft 100 and providing opposed "first" and "second" guide surfaces 130A and 130B that define a first cutting guide slot (*id.*, 5:4-34, 8:40-44); and (iv) optional additional components

including a bridge component 160, rails 170A, 170B, a fixating structure 180, and a secondary guide member 200 (*id*., 6:9-10, 6:31-32, 6:49-50).[9]

The main guide member 120's first and second guide surfaces 130A, 130B are described as opposing surfaces of the same guide member that together define a space (a first cutting guide slot) through which a cutting member is inserted. *Id*., 5:8-15, 8:40-47. The specification explains that these surfaces define parallel planes and may optionally be skewed relative to one another (*id*., 5:28-34), but they are both parts of a single "main guide member 120," not two separate guides.

Where, as in the claims, a second cutting guide is used, the patent describes adding the bridge component 160 that attaches between the first and second guide surfaces 130A, 130B of the main guide member 120—"between the first and second guide surfaces 130A and 130B through an interference fit"—and that carries rails 170A, 170B. *Id*., 6:9-30. The secondary guide member 200 is then slidably supported on those rails via slots 205A, 205B and includes third and fourth guide surfaces 210A, 210B that define a second cutting channel for the second bone cut. *Id*., 6:49-7:8.

[9] Although the specification contains various permissive statements regarding potential variations of the single disclosed embodiment, those minor variations do not affect the present analysis given the breadth of the claims.

In all described embodiments, both cuts are thus provided by components of a single connected system, with the main and secondary guide members 120, 200 rigidly linked through the bridge component 160 and rails 170A, 170B. When the cuts are complete, the specification explains that "the bone cutting guide 20 can be removed" (*id*., 10:26-28), which includes removing the support 30, bridge component 160, fixating structure 180, and secondary guide member 200 together.

The written description does not describe any embodiment in which the main and secondary guide members 120, 200 are physically separate instruments that can be independently attached to the metatarsal solely by the claimed fixation pins.

c. <u>The Narrow Specification Does Not Enable the Claimed Genus</u>

The narrow disclosure in the '397 patent does not enable the broad genus of claimed methods recited by the independent claims, which encompass any configuration of a "first guide" and a "second guide" that satisfy the claimed structural limitations (i.e., providing cutting slots and being pinned as recited). This includes, for example, a species in which the two guides are entirely distinct devices with no structural relationship to one another.

For such a species, a POSA would need to design at least two separate guide devices that (1) can each be independently mounted to the metatarsal using the claimed configuration of two pins positioned distally of the respective cutting slots; and (2) when separately pinned (at different times) to the metatarsal and cuneiform,

will generate cuts that align appropriately for the intended bunion correction and fusion geometry. Yet the specification provides no teaching or general design rules for how to do this outside the context of the integrated bone cutting guide 20. All of its guidance on relative positioning between the first and second cuts derives from the structural relationships imposed by the bridge component 160, rails 170A, 170B, and secondary guide member 200—features that are absent from the broad claim language. *See, e.g.*, Ex.1001, 6:49-7:8.

In a system where the first and second guides are completely separate devices (for example, individual blocks or jigs that are keyed only to the pin locations), none of these structural relationships or adjustment mechanisms are available. The specification does not disclose how to determine, for example:

- what geometry and slot orientation the second guide must have, relative to the first, so that using the same pair of fixation pins will locate the second cut appropriately after the bones are realigned;
- how to design multiple distinct second guides for different correction magnitudes or angles; or
- how to design distinct first and second guides that are compatible with each other across a range of bunion deformities, foot sizes, and surgeon preferences encompassed by the claims.

Absent the rails-and-bridge architecture, a POSA would have to engage in iterative trial-and-error—re-engineering first and second guides geometries, re-pinning bones, and testing whether resulting cuts produce the desired correction—for each new combination of metatarsal/cuneiform anatomy and correction angle. The ’397 patent provides no guidance on how to perform this work other than the single species where the relative positions are fixed by the integrated bone cutting guide 20.

Under *Amgen*, that is precisely the type of impermissible “research assignment” that cannot satisfy enablement for broad genus claims. *See Amgen*, 598 U.S. at 614. The ’397 patent claims every bunion correction method in which two generic guides, having the claimed structural features, are used to cut the metatarsal and cuneiform—yet it disclosed only an integrated species in which those cuts are coordinated through a particular structure. The specification neither discloses a representative range of structurally distinct “first guide / second guide” pairs, nor sets out any generalizable design principles that would allow the POSA to realize the full breadth of the genus without substantial experimentation.

d. Conclusion

By claiming methods that encompass any arrangement of a “first guide” and “second guide” satisfying generic pin and slot limitations, the ’397 patent asserts a genus far broader than the single species it teaches. For a POSA, practicing

embodiments in which the first and second guides are completely distinct devices would require substantial, case-by-case experimentation to determine appropriate geometries and relationships—precisely the sort of undue experimentation that *Amgen* holds cannot substitute for an enabling disclosure.

Accordingly, claims 1, 20, 29, and their dependents are invalid for lack of enablement under § 112.

2. The ’397 Patent Does Not Enable The Order Of The Claimed Procedure

Independent claims 1, 20, and 29 recite methods the include, *inter alia*, (1) “inserting the saw blade through the first bone cutting guide slot to cut the portion of the metatarsal,” (2) “adjusting an alignment of the metatarsal relative to a cuneiform … to establish a moved position of the metatarsal,” and (3) “inserting the saw blade through the second cutting slot to cut the portion of the cuneiform.” *Id*., claim 20; *see also id*., claims 1 and 29 (reciting similar limitations). The claims do not specify an order for these steps. *See Interactive Gift. Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) (“Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one”). However, the specification of the ’397 patent does not enable any order of the above cutting and adjusting steps.

The specification only describes that both cutting steps occur ***before*** the adjusting step. It explains that “cuts are made to bone with respect to the cutting

guide, and the bones can be positioned for an additional surgical step, such as bone plating, after the cuts have been made." Ex.1001, 7:46-50. Consistent with that passage, the '397 patent's detailed embodiment provides that "[w]hen the bone 230 and/or bone 240 have been cut and positioned as desired, the bone cutting guide 20 can be removed," and that the guide may then be reset so that "the shaft 100 can be translated within the cavity to adjust the relative position of the bones (e.g., to compress them together)" while a bone plate is applied across the joint. *Id*., 10:26-39. In short, the only described "adjust[ment of] the relative position of the bones" occurs after the relevant cuts have been made, not between them.

Although the specification also describes translational (axial along the first ray) movement of the fixating structure 180 and shaft 100—for example, "compress[ing] or expand[ing] the space between the bones 230 and 240 as needed" once fixation pins 220A, 220B are seated in the cuneiform and before the secondary guide member 200 is used—those passages describe temporary manipulations to facilitate cutting, not the final "moved position" in which fusion occurs. *Id*., 9:39-51, 9:63-64, 7:46-50. Nowhere does the '397 patent characterize the bones as being moved to their final position for fusion between the first (metatarsal) and second (cuneiform) cuts, as claims 20 and 29 require.

The '397 patent claims surgical methods. *See* Ex.1001, Claims 1-30. Yet, there is nothing in the specification that would even suggest to a surgeon how to

perform the claimed cutting and adjusting steps in the ’397 patent in any order other than the one described in the specification. For example, there is nothing in the ’397 patent that enables a method wherein the adjustment step occurs between the two cutting steps (i.e., in the order that every independent claim is written). As a result, the specification does not disclose how to determine:

- how the metatarsal should be adjusted relative to the cuneiform prior to cutting the cuneiform;
- how to align the cut on the cuneiform after the metatarsal has been adjusted; or
- how to design and implement a guide capable that cuts the cuneiform after the metatarsal has been adjusted.

Similarly, nothing in the ’397 patent discloses how to align either the metatarsal or the cuneiform cut where the adjusting step occurs prior to either cutting step. Yet, the claim facially encompasses such a procedure.

These details are not tangential. Each claim recites a “bunion correction method.” Ex.1001, Claims 1, 20, 29. As McGlamry explains, it was known that bunion correction methods that involved cutting both the metatarsal and cuneiform, and adjusting the metatarsal, were subject to significant complications, including shortening the metatarsal and “[d]elayed unions and nonunions” of metatarsal and cuneiform. Ex.1005, 329. The specification of the ’397 patent does nothing to

enable a POSA to successfully perform the claimed methods in any order except that described in the specification (i.e., with both cutting steps occurring before the adjusting step).

The '397 patent describes performing the cuneiform cut only before the bones are finally positioned for fusing. Claims 1, 20, and 29 and their dependents lack written description support as they claim methods in which the bones are moved to the fused "moved position" before the cutting the cuneiform cut. Accordingly, the claims are unpatentable under § 112.

VIII. GROUND 2: CLAIMS 1-2, 4-10, 12-20 AND 22-30 WOULD HAVE BEEN OBVIOUS OVER MCGLAMRY AND AUGOYARD

A. It Would Have Been Obvious to Use A Cutting Guide Like Augoyard's In McGlamry's Procedure

1. A POSA Would Have Had Reason To Use a Cutting Guide Like Augoyard's in McGlamry's Procedure

It would have been obvious by 2015 to use cutting guides like Augoyard's as part of the cutting steps in McGlamry's procedure. Ex.1002, ¶¶82-92. McGlamry emphasizes that cutting the bones of the foot is a "vital portion of the procedure." Ex.1005, 324. "[J]oint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion," and McGlamry therefore recommends that surgeons spend a "substantial period of time…preparing this [metatarsal-cuneiform] joint." *Id.* McGlamry also warns that mistakes in cutting the bones can

cause complications, including "[s]ignificant shortening" of the first metatarsal, delayed unions, non-unions, and malunions. *Id.*, 329; Ex.1002, ¶82.

McGlamry discloses freehand resection of bones which relies on the surgeon's technical capability to avoid complications. Ex.1005, 324-329; Ex.1021, 1:31-34; Ex.1002, ¶83. A POSA would recognize that freehand resection of bones can be "very difficult to perform and can be rather imprecise." *Id.*, 1:31-37. Inaccuracies during freehand resection "lead to complications such as nerve damage, poor quality bone healing, bone resorption,…increased operating time and increased blood loss." *Id.*, 1:45-50; Ex.1002, ¶83.

A POSA would have recognized that cutting guides, like Augoyard discloses, reduce the risk of such complications in McGlamry's procedure. Ex.1002, ¶¶84-92; *supra* §II.D; Ex.1021, 1:50-54 ("These significant disadvantages could be reduced or overcome with precise, quick and efficient bone cuts. It is therefore surprising that there has been no known cutting guide developed…."). "There are numerous prior art devices for precision cutting of bones in the appendicular skeleton," including the feet. *Id.*, 1:55-58. For example, in another chapter, McGlamry discloses that commercially available cutting guides "help the surgeon resect the proper amount of bone and at the proper angles," including when resecting the joint surface. Ex.1005, 381-83. Cutting guides "remove the necessity of clinical judgement and guess work" and make procedures simpler and repeatable. Ex.1002,

¶¶84-85; Ex.1016, 3:1-5; *see also* Ex.1007, [0034], [0070] (describing how the cut guides "precisely determine[]" the positions of the cuts). A POSA would also have recognized that using a cutting guide like Augoyard's would simplify McGlamry's cutting steps and shorten the procedure time. Ex.1002, ¶85. Rather than spending "a substantial amount of time" on freehand joint preparation (Ex.1005, 324), a cutting guide like Augoyard's would make preparation predictable and repeatable, which would simplify and shorten the procedure. Ex.1002, ¶85. Shorter and simpler surgical procedures typically mean less time under anesthesia, which benefits the patient. Ex.1002, ¶85. Simplifying surgical procedures also can make them accessible to a broader population of surgeons, which in turn makes them available to more patients. *Id.*

As another example, such a cutting guide would reduce the risk of the potential complications McGlamry identifies. McGlamry first identifies "[s]ignificant shortening" of the metatarsal as a potential complication. Ex.1005, 329. Shortening refers to excessive removal of bone that leads to changes in the biomechanics of the foot that can cause pain, deformities, and other complications. Ex.1002, ¶86. Cutting guides like Augoyard's "precisely define[s] the relative positions of the two cutting assemblies" and relative position of the cutting slots to the joint. Ex.1007, [0034]; Ex.1002, ¶85. By "precisely defin[ing]" the guide positions, and thereby the location of the cuts, these cutting guides allow the surgeon

to visualize the cuts before making them. Ex.1002, ¶87. This planning reduces the risk of "significant shortening." Ex.1002, ¶¶86-87.

Second, using a cutting guide like Augoyard's would reduce the risk of delayed unions, non-unions, and malunions identified by McGlamry. Ex.1005, 324, 329. Delayed unions, non-unions, and malunions occur when the metatarsal and cuneiform either do not fuse or fuse in an undesirable manner. Ex.1002, ¶88. This can occur when the cut ends of the metatarsal and cuneiform do not correctly fit together when the metatarsal is repositioned. *Id.* The use of cutting guides in metatarsal-cuneiform fusion procedures was a known technique for "easily and effectively achiev[ing] a union through biological healing." Ex.1013, [0068]. Such a cut guide promotes these effective unions because it is designed for preparing complementary joint surfaces. *See id.*; Ex.1007, [0034], [0070] (describing the two complementary cuts made by Augoyard's guides). Thus, a POSA would have recognized that the use of a cutting guide like Augoyard's reduces a known risk identified by Dr. DiDomenico in McGlamry. Ex.1002, ¶88. Thus, its use would have been nothing more than the use of a known technique to solve a known problem using prior art elements according to their established functions. Ex.1002, ¶¶89; *NuVasive, Inc. v. Hirshfeld*, 2021 WL 3661208, at *4-5 (Fed. Cir. Aug. 18, 2021) (use of a known nerve-monitoring technology to avoid a known surgical complication was nothing "more than the predictable use of prior art elements

according to their established functions”)*; see also Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023); *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”).

It also would have been obvious to use a cutting guide like Augoyard’s in McGlamry’s procedure because this would have been nothing more than using a known technique used to improve a similar method in the same way. Ex.1002, ¶90; *KSR*, 550 U.S. at 417. As explained above, Augoyard improves resection of the distal metatarsal joint by providing a cut guide that precisely defines the metatarsal and phalangeal resections. Ex.1007, [0034]. A POSA would have looked at cutting guides from other joint replacement or arthrodesis surgeries to improve McGlamry’s procedure. Ex.1002, ¶90. McGlamry’s procedure is similar in many respects to Augoyard’s, including that both procedures involve a joint between the first metatarsal and adjacent bone. *See generally* Ex.1005, 324-330; *see also infra* §VIII.A.2. Using a cutting guide like Augoyard’s in McGlamry’s procedure would have improved McGlamry’s procedure in the same way as Augoyard’s procedure and reduced the likelihood of the complications as explained above. Ex.1002, ¶91. Thus, using a cutting guide like Augoyard’s in McGlamry’s procedure would have been nothing more than use of a known technique used to improve a similar surgical procedure in the same way. Ex.1002, ¶92.

2. A POSA Would Have Had a Reasonable Expectation of Success Using a Cutting Guide Like Augoyard's In McGlamry's Procedure

A POSA would have recognized that Augoyard's cut guide would have been adaptable for use with McGlamry's procedure with only minor modifications that were within the skill of a POSA.

A POSA would recognize that cutting guides and their associated functionalities are readily adapted across procedures and anatomies. Ex.1002, ¶¶93-99; *see, e.g.*, Ex.1022, 1:66-2:2 (describing a knee cutting guide that "is applicable to any bone-cutting procedure which might benefit from improved accuracy"). In particular, small bone cutting guides like Augoyard's were known to be adaptable to other procedures and anatomies with small bones. Ex.1002, ¶93; Ex.1013, [0057]-[0058] (describing how the jig and guide can be used in multiple metatarsal procedures and other anatomies, such as the hand); Ex.1023, 7:41-48. (describing a wedge osteotomy cutting guide that is "not only…applicable [to the toe], but rather, is [also] applicable to such cutting as related to any skeletal elements of the body"). Indeed, Weinstein confirms that its cut guides were known for use in Lapidus procedures. Ex.1015, [0051], Fig.13.

Additionally, the relevant portions of the surgical procedures described in Augoyard and McGlamry have many similarities. Ex.1002, ¶¶94-96. Both describe procedures involving a joint between first metatarsal and one of the abutting bones

(the cuneiform or phalanx). *Id.*, ¶94; *see generally* Ex.1005, 324-330. Furthermore, both McGlamry and Augoyard describe cutting both sides of the joint to create two corresponding cuts. Ex.1005, 324; Ex.1007, [0064]-[0071]. The types of cuts made to the metatarsal in McGlamry and Augoyard are also similar. Ex.1002, ¶¶94-95. For example, both McGlamry and Augoyard disclose cuts made perpendicular to the longitudinal axis of the metatarsal. *Id.*; Ex.1005, 324 (describing cutting "perpendicular to the long axis of the first metatarsal and parallel to the existing metatarsal base."); Ex.1007, [0058]-[0066] (describing placement of the guide parallel with the longitudinal axis of the metatarsal), [0034] (describing the slot as being positioned "70°± 20°" (i.e., perpendicular) to the longitudinal axis).

There are additional similarities between McGlamry's cuneiform cutting step and Augoyard's second cut guide. Ex.1002, ¶96. For example, McGlamry explains that resections on the metatarsal and cuneiform "need[] to be kept consistent and parallel with the natural occurring anatomy." Ex.1005, 324. Augoyard describes and depicts its second cutting guide as "precisely" oriented in a position that is roughly parallel with the natural anatomy. Ex.1007, [0034], [0070]-[0071].

Given Augoyard's disclosure, a POSA would have recognized that adapting Augoyard's cutting guide for use in McGlamry's procedure would, at most, involve minor modifications. Ex.1002, ¶97. A POSA would recognize that no, or very minor, modifications would be needed to place Augoyard's first guide on the

proximal end of the metatarsal instead of the distal end. Ex.1002, ¶¶97-98. A POSA would have been capable of lining up the slot in Augoyard's first guide with the desired location for the metatarsal cut. *Id.* Any modifications would largely be limited to changes in the orientation of the second guide to address its placement on the cuneiform instead of the phalanx. *Id.* A POSA would have recognized that these geometric changes would have been informed by the natural anatomy of the human foot. *Id.* Such geometric changes would have been nothing more than ordinary design considerations for a POSA. *Id.* Other than steps associated with placing and using the cut guide, a POSA would have recognized that McGlamry's procedure would not need to be modified. *Id.*, ¶99. Thus, a POSA would have had a reasonable expectation of success. *See, e.g.*, *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2019-01110, Paper 30, 2020 WL 684908, at *13-14 (P.T.A.B. Nov. 20, 2020) (finding reasonable expectation of success to modify surgical instrumentation).

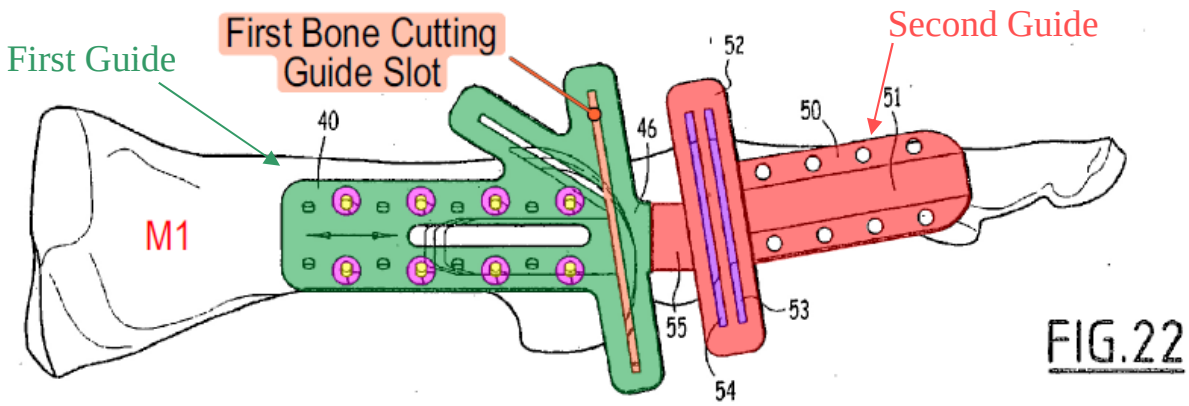
B. Claim 1

1. Preamble

Claim 1's preamble recites "a bunion correction method." To the extent the preamble is limiting, McGlamry discloses "a bunion correction method," describing a procedure to correct "hallux valgus"—also known as a bunion. Ex.1005, 322, 803-809; Ex.1002, ¶102.

2. Limitation 1[a]

Limitation 1[a] recites "positioning a first bone cutting guide slot over a portion of a metatarsal to be cut." McGlamry's procedure cuts a portion of the metatarsal. Ex.1005, 324. For the reasons explained in Section VIII.A, it would have been obvious to use a cutting guide like Augoyard's to perform McGlamry's bunion correction method by positioning the first bone cutting guide slot over the proximal portion of the first metatarsal that McGlamry discloses should be cut. Ex.1002, ¶¶103-105. In fact, Augoyard expressly discloses a first bone cutting guide slot (orange) disposed over a portion of a metatarsal to be cut. Ex.1007, [0034], [0063]-[0066].



Id., Fig.22; Ex.1002, ¶104.

Augoyard provides that "the body 41 [of the instrument 40] is rigidly attached to the metatarsal bone." Ex.1007, [0066]. Then, a "a vibrating saw is used to cut the end of the metatarsal bone, first through slot 44." *Id.*, [0067]; Ex.1002, ¶105.

3. Limitation 1[b]

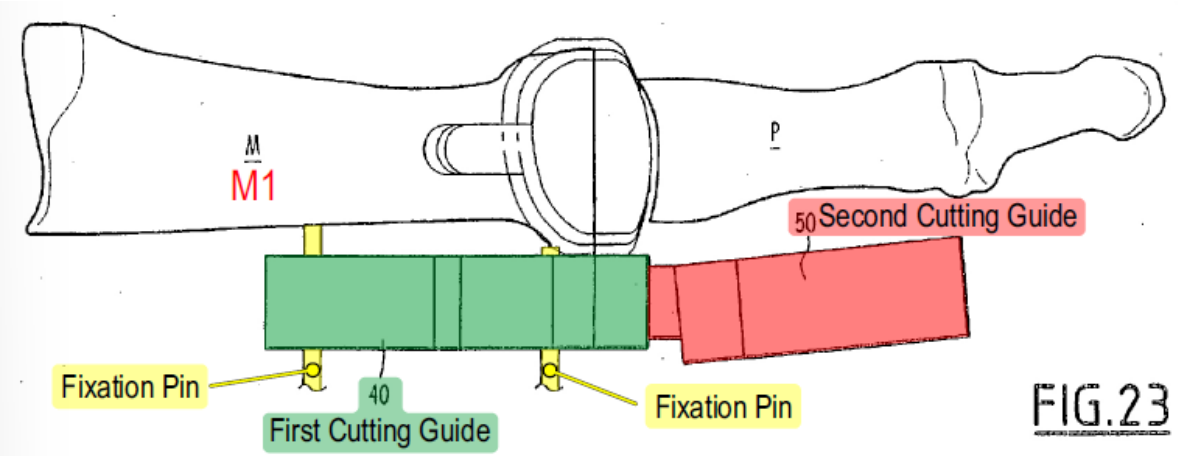
Limitation 1[b] recites "attaching the first bone cutting guide slot to the metatarsal with a first fixation pin inserted into the metatarsal and a second fixation pin inserted into the metatarsal, the first fixation pin and the second fixation pin being positioned distally of the first bone cutting guide slot."[10]

McGlamry discloses cutting the proximal end of the metatarsal during metatarso-cuneiform arthrodesis. Ex.1005, 324, 808; Ex.1002, ¶107. As discussed above, it would have been obvious to use a bone cutting guide like Augoyard's in McGlamry's procedure to perform the resections. *See supra* §VIII.A.

Augoyard discloses "attaching the first bone cutting guide slot to the metatarsal with a first fixation pin inserted into the metatarsal and a second fixation pin inserted into the metatarsal." Ex.1002, ¶108. For example, Augoyard discloses that "the body 41 [of the metatarsal cutting guide 40] has a plurality of transverse holes 42 through which small pins 43 can be inserted to secure the ancillary instrument 40 to the metatarsal bone M." Ex.1007, [0064]. Augoyard discloses that

[10] Petitioner's analysis of obviousness does not proceed under the construction of "attached"/"attaching" advocated in Section V.A. Rather, it proceeds under the broader construction seemingly applied by Treace that would encompass intermediate links between the second bone cutting guide and the metatarsal.

"the pins 43 are screwed in and the body 41 is rigidly attached to the metatarsal bone." *Id.*, [0066]; Ex.1002, ¶108.



Ex.1007, Fig.23.

In Augoyard, the first fixation pin and the second fixation pin are positioned proximally of the first bone cutting guide slot rather than distally as claimed. This is because Augoyard describes cutting the distal end of the metatarsal. Ex.1002, ¶109. However, McGlamry's procedure cuts the proximal end of the metatarsal. As such, a POSA would have recognized that, when used in McGlamry's procedure, a bone cutting guide like Augoyard's would have been placed over the proximal end of the metatarsal with the body extending over the metatarsal so as to not cover the joint to be resected. *Id.*, ¶109. In this placement, it would be obvious for the POSA to place the fixation pins of the bone cutting guide into the metatarsal, not the cuneiform, consistent with Augoyard's disclosure. *Id.*, ¶110. The metatarsal would have been a desirable location for the pins because it is longer than the cuneiform

and places the pins farther from the resected joint where they are less likely to interfere with the procedure. *Id.*, ¶111. As such, Augoyard in view of McGlamry renders limitation 1[b] obvious.

4. Limitation 1[c]

Limitation 1[c] recites "inserting a cutting member through the first bone cutting guide slot to cut the portion of the metatarsal." As discussed above, a POSA would be motivated to make the cuts disclosed by McGlamry using a bone cutting guide like Augoyard's, this includes cutting the portion of the metatarsal, as disclosed by McGlamry. Ex.1002, ¶113. In fact, Augoyard expressly discloses that "a vibrating saw is used to cut the end of the metatarsal bone…through slot 44." Ex.1007, [0067].

5. Limitation 1[d]

Limitation 1[d] recites "adjusting an alignment of the metatarsal relative to a cuneiform separated from the metatarsal by a joint to establish a moved position of the metatarsal." McGlamry discloses this. For example, McGlamry details how the metatarsal is corrected in three dimensions – "rotated out of valgus, and parallel with the second metatarsal in both the transverse and sagittal planes." Ex.1005, 325; *see also* Ex.1002, ¶¶115-116. This adjustment occurs after McGlamry's cutting steps. Ex.1005, 324-325; Ex.1002, ¶¶115-116. Thus, the metatarsal is adjusted relative to

the positions of the cuneiform. Ex.1002, ¶¶115-116. This movement establishes a moved position of the metatarsal. *Id.*

6. Limitation 1[e]

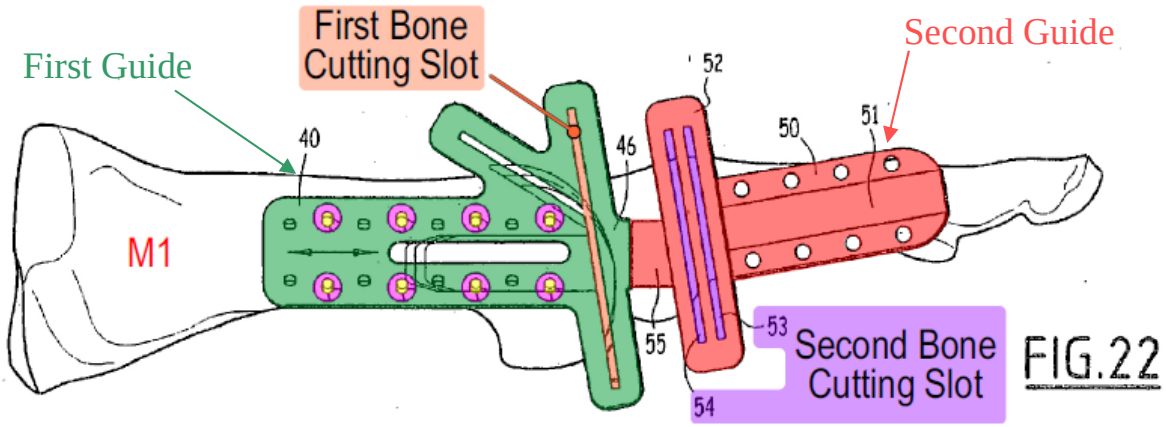
Limitation 1[e] recites "[i] positioning a second bone cutting guide slot over a portion of the cuneiform to be cut, [ii] the second bone cutting guide slot being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal, the first fixation pin and the second fixation pin being positioned distally of the second bone cutting slot."

a. Limitation 1[e][i]

McGlamry discloses cutting the cuneiform. Ex.1005, 324 ("The corrective articular resection is made at the distal aspect of the convex-shaped cuneiform."). McGlamry explains that "joint preparation is extremely important" and that the cuts on the cuneiform and metatarsal "need[] to be kept consistent and parallel with the natural occurring anatomy." *Id.* As discussed above, a POSA would have recognized that the use of a bone cutting guide like Augoyard's eliminates guess work and improves the repeatability of these cuts. Ex.1002, ¶¶117-118.

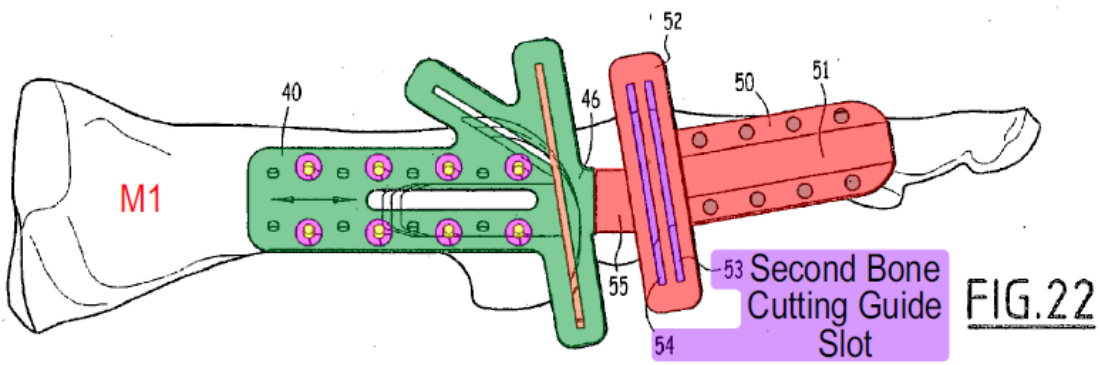
Accordingly, it would have been obvious to use a second bone cutting guide slot, like the one disclosed in Augoyard, to cut the distal aspect of the cuneiform as part of McGlamry's method. Ex.1002, ¶119. In Augoyard, the first cutting guide slot is formed in and defined by a first cutting guide (green), and Augoyard's second

cutting guide slot is formed in and defined by a second cutting guide (red) separate from the first cutting guide:



Ex.1007, Fig.22; Ex.1002, ¶119. The first cutting guide includes a recess 46 into which an extension 55 of the second cutting guide interlocks to form Augoyard's bone cutting guide. Ex.1007, [0034], [0065], [0070], Claim 19.

When using a guide like Augoyard's as part of McGlamry's method, it would have been obvious to position the second guide slot over a portion of the cuneiform to be cut. Ex.1002, ¶120. Augoyard discloses a second bone cutting guide slot (purple, below) over a portion of a second bone adjacent to portion of the metatarsal (M1) to be cut. Ex.1007, [0034], [0070].



Id., Fig.22. In Augoyard, the second bone is the phalanx. However, when used in McGlamry's procedure, that second bone would be the cuneiform. Ex.1002, ¶121.

The use of Augoyard's second cutting guide slot to cut the cuneiform, would have been consistent with how Augoyard describes using the second cutting guide slot and with how a POSA would have used it in McGlamry's procedure. *Id.*, ¶¶122-124. As explained in Section VIII.A, a POSA would have been motivated to use a guide like Augoyard's to cut the metatarsal and cuneiform in McGlamry's procedure for multiple reasons, including simplification of the procedure, patient safety, and increased repeatability. *Id.* Its use would have been nothing more than the use of a known technique to solve a known problem using prior art elements according to their established functions. *NuVasive*, 2021 WL 3661208, at *4-5. As such, McGlamry in combination with Augoyard renders limitation 1[e][i] obvious.

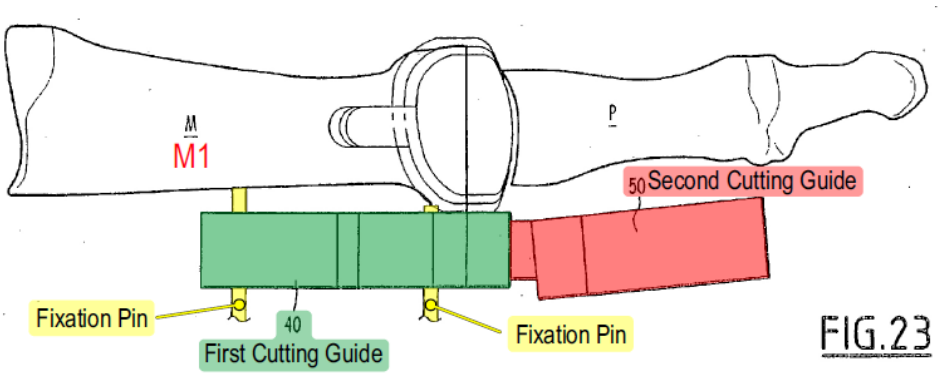
b. Limitation 1[e][ii]

As explained in Ground 1, the '397 patent does not sufficiently describe or enable limitation 1[e][ii]. Regardless, Augoyard discloses this limitation in the same way that the '397 patent discloses this limitation (e.g., neither discloses a second guide slot pinned to the metatarsal).

As discussed above, it would have been obvious to use a bone cutting guide like Augoyard's as part of McGlamry's method of bunion correction surgery. Ex.1002, ¶¶125-131. It would have been obvious to position the second cutting

guide over the cuneiform and proximal to the first cutting guide. *See supra* §VIII.A.2. Thus, the first cutting guide and the first and second fixation pins placed therein would be distal to the second cutting guide, and over the metatarsal. Ex.1002, ¶127. Placing a guide like Augoyard's in this configuration would be consistent with McGlamry's procedure and further the benefits of using such a guide in McGlamry's procedure that are explained in Section VIII.A. Ex.1002, ¶128.

Augoyard discloses a second guide (red) that includes "two parallel phalangeal cutting slots" and is attached to the first guide (green) via "an extension…to precisely define the relative positions of the two cutting assemblies." Ex.1007, [0034]. The first and second guides are show below:



Id., Fig.23; Ex.1002, ¶129. The extension 55 is "interlocking, to a corresponding end of the" first guide, which is attached to the metatarsal via the fixation pins. *Id.*, [0034]; *see also id.*, [0070] ("The proximal end of this enlargement continues with an end 55 that has a short tip enabling it to penetrate the small recess in the end 46

of the ancillary metatarsal instrument 40, which precisely determines the respective positions of the two ancillary instruments 40 and 50."); Ex.1002, ¶130.

Similarly, the '397 patent describes a "bridge component 160…attached to the main guide member 120." Ex.1001, 7:15-19. Rails 170A/B (light blue) are connected to the bridge component 160 (dark blue), and a secondary guide member 200 (red) "can be supported on the rails 170A and 170B…." Ex.1001, 7:15-22. These features are shown below:

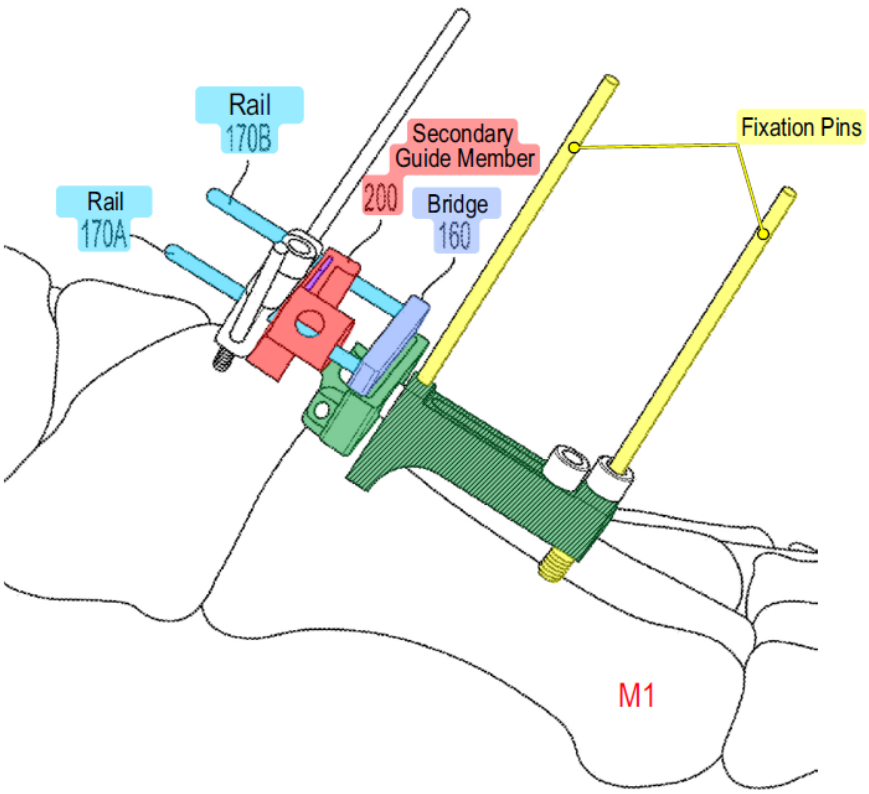


FIG. 14

Ex.1001, Fig.14 (unrelated reference numbers removed). Thus, both Augoyard and the '397 patent disclose a first guide attached to the metatarsal using the fixation

pins, and a second guide that is connected to the first guide through another component. Ex.1002, ¶131. As such, to the extent the '397 patent sufficiently describes limitation 1[e][ii], McGlamry in view of Augoyard renders the limitation obvious.

7. Limitation 1[f]

Limitation 1[f] recites "inserting the cutting member through the second cutting slot to cut the portion of the cuneiform."

As discussed above, McGlamry discloses cutting the cuneiform, and it would have been obvious to use a guide like Augoyard's to perform that cut. *See supra* §VIII.B.6. Augoyard discloses using a saw inserted through the second guide slot to cut the second bone. Ex.1007, [0071] ("The surgeon…uses one of the two slots 53 and 54 to make a straight cut through the end of the phalanx using an oscillating or vibrating blade."); Ex.1002, ¶¶132-133. When such a guide is used in McGlamry's procedure, it would have been obvious that this second bone is the cuneiform.

8. Limitation 1[g]

Limitation 1[g] recites "causing the metatarsal to fuse to the cuneiform in the moved position." After repositioning the metatarsal, McGlamry discloses multiple "fixation techniques" that "fix" the joint in the corrected, moved position. Ex.1005, 326 (disclosing for example, fixation through "interfragmentary compression of

three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate"). By fixing the resected portions of the first metatarsal and cuneiform in contact with one another, the surgeon positions the bones in the moved position for fusion through the body's natural healing processes. Ex.1002, ¶¶134-138.

Accordingly, McGlamry in view of Augoyard renders obvious each limitation of claim 1, and claim 1 would have been obvious.

C. Claim 2

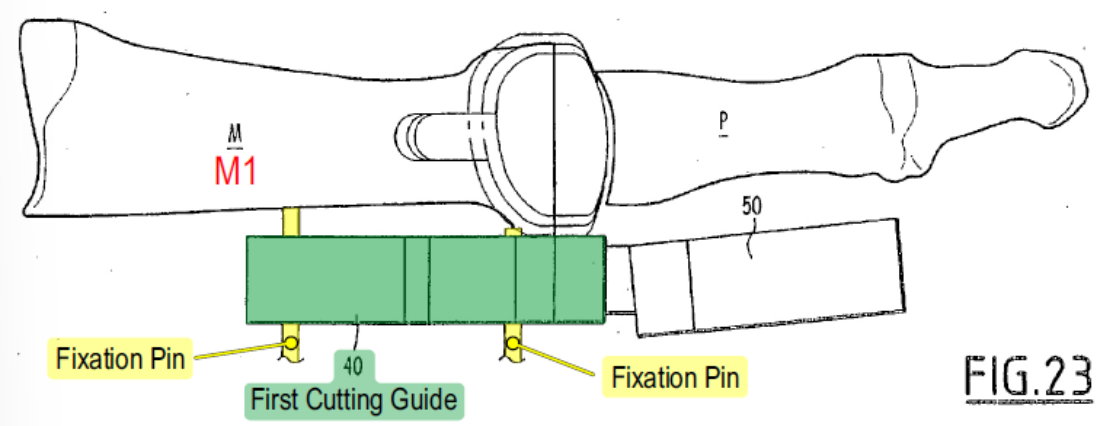
Claim 2 depends from claim 1 and recites: "further comprising, after adjusting the alignment of the metatarsal relative to the cuneiform to establish the moved position of the metatarsal, lifting the first bone cutting guide slot off the first fixation pin and the second fixation pin."

McGlamry and Augoyard render claim 2 obvious. Ex.1002, ¶¶139-145. In McGlamry, as in other instrumented bunion correction procedures, one obvious step is the removal of the surgical instruments used to perform the procedure, leaving only the fixation devices in the foot. *Id.*, ¶140. When a bone cutting guide, like Augoyard's, is used in McGlamry's procedure, it would have been obvious that the bone cutting guide would need to be removed before the procedure is complete. *Id.*

McGlamry discloses resecting the metatarsal relative to its longitudinal axis first, and then creating a corresponding, parallel cut in the cuneiform. Ex.1005, 324.

When a bone cutting guide like Augoyard's is used in McGlamry's procedure, there are only two options for when the guide is removed relative to the adjustment of the bones—before or after. Ex.1002, ¶141. Either option would have been obvious. *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1340 (Fed. Cir. 2020) (holding substitution of one of two alternatives for the other "is obvious because it would have been a 'predictable variation.'"). Augoyard discloses the claimed removal of the bone cutting guide after adjusting the alignment of the bones. Ex.1007, [0069], [0072] (explaining that, after cutting the first metatarsal, "the dislocation is reduced and the phalanx P is returned to its natural position" and "the two cutting implants 40 and 50 are…removed").

Augoyard also discloses a bone cutting guide configured to be lifted off the first and second fixation pins after adjusting the bones to a moved position. Ex.1007, [0072] (describing removal of guide and pins). For example, Augoyard discloses that the metatarsal cutting guide includes "transverse passages through which small lateral fixing pins can be inserted and screwed into the lateral cortical bone of the metatarsal bone," as shown below. *Id*., [0034].



Id., Fig.23. The fixation pins, as illustrated, are placed parallel to one another. Ex.1002, ¶¶142-143. Thus, Augoyard's guide is configured to be lifted off of the pins. *Id.*[11]; *see In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) ("[T]he law is, and long has been, that 'if a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented device.'").

Once the cutting guide and fixation pins are in place, a POSA would understand that there are a finite number of options for the order of the removal of

[11] Unlike a screw, fixation pins typically do not include a proximal retention means, such as a head, that could prevent removal of the guide. Ex.1002, ¶144; Ex.1005, 12 (discussing "Steinmann pins" as a fixation device); *see also* Ex. 1001, 4:7-10 (describing the fixation pins 60A and 60B), Figs.1-16 (depicting the fixation pins that do not include a retention means).

the pins and guides, including (1) removing the pins and then the guide or (2) removing the guide and then the pins. Ex.1002, ¶145. A POSA would recognize that either option was available for a guide like Augoyard's, and the order of operations was merely surgeon preference. *Id.* Adopting the claimed lifting approach would have been an obvious implementation choice. *See also Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1340 (Fed. Cir. 2020) (holding substitution of one of two alternatives for the other "is obvious because it would have been a 'predictable variation.'"). Moreover, the benefits of removing the guide before the pins would have been known to include: leaving the fixation pins in the bone as reference points for the surgeon, reducing the chance of the guide transmitting a torque to the recently cut bone (which would be more likely if the pins were removed first), and improving access and visibility to the pins for faster and safer removal. Ex.1002, ¶145. Thus, a POSA would have been motivated to adopt the claimed lifting approach. *Id.*

D. <u>Claim 4</u>

Claim 4 depends from claim 1 and recites: "wherein positioning the first bone cutting guide slot over the portion of the metatarsal to be cut comprises positioning a support extending perpendicularly from the first bone cutting guide slot over a dorsal surface of the metatarsal with the support extending substantially parallel to a longitudinal axis of the metatarsal."

McGlamry and Augoyard render claim 4 obvious. Ex.1002, ¶¶146-150. McGlamry discloses a dorsal surgical approach and cutting perpendicular to the longitudinal axis. Ex.1005, 324, 328; Ex.1002, ¶147. In view of McGlamry's dorsal approach, placing the first cutting guide slot over a dorsal surface of the metatarsal would have been obvious so as not to make addition incisions in the foot. Ex.1002, ¶148. Doing so would have further been consistent with the operational principles of using a bone cutting guide like Augoyard's in McGlamry's procedure. *Id.*, ¶148.

Augoyard discloses a support (green striped portion) extending perpendicular from the cut guide slot (orange) parallel to the longitudinal axis of the metatarsal.

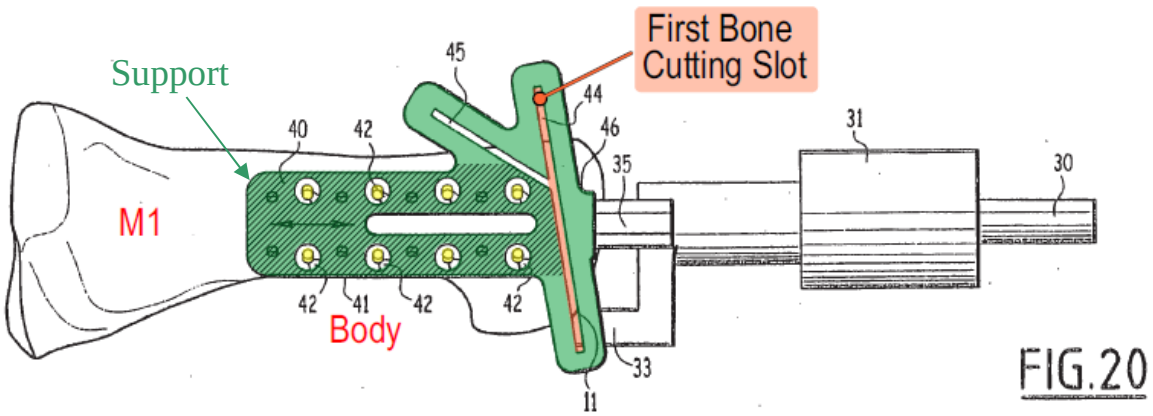


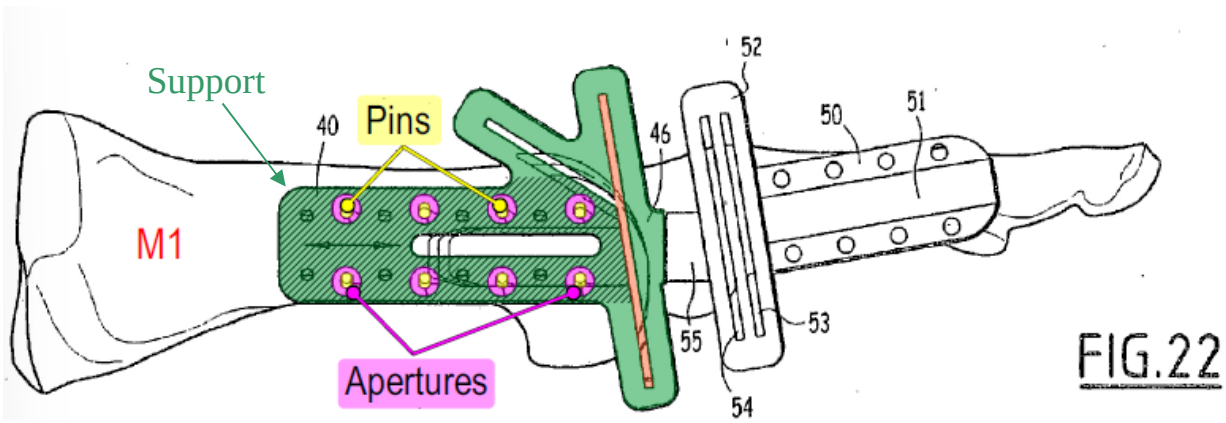
FIG.20

Id., Fig.20; Ex.1002, ¶149. Augoyard further discloses that the support (body 41) extends perpendicularly from the guide slot. Ex.1002, ¶150. As shown in Figure 20, the "slot 44 is formed, inclined at 70° to the body 40 [support] and to the arm 35 and therefore to the pin 30." Ex.1007, [0064]. Augoyard also discloses that the slot 44 can be "at an angle of 70°± 20° [i.e., 90° or perpendicular], relative to the axis of the pin," and therefore also to the support (body). *Id.*, [0034]; Ex.1002, ¶150.

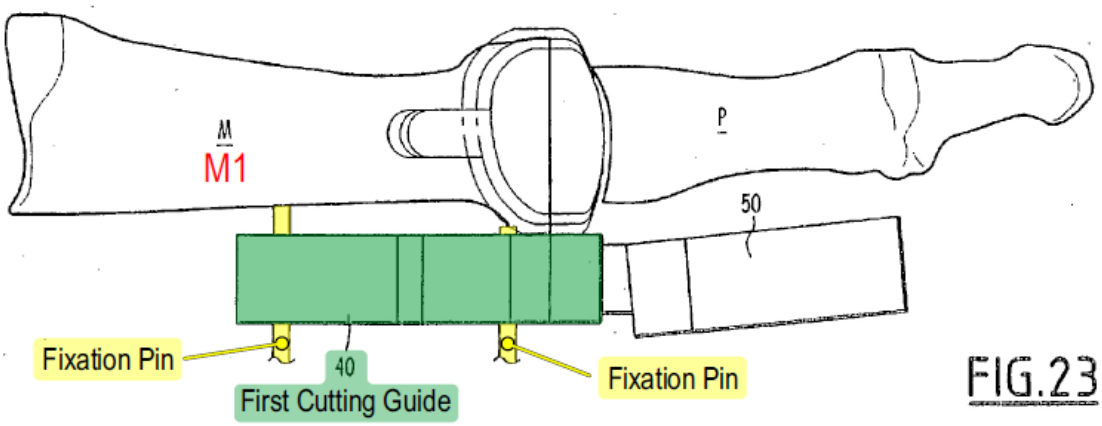
E. Claim 5

Claim 5 depends from claim 4 and recites: "wherein attaching the bone cutting guide slot to the metatarsal with the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal comprises inserting the first fixation pin through a first fixation aperture of the support into the metatarsal and inserting the second fixation pin through a second fixation aperture of the support into the metatarsal."

McGlamry and Augoyard render claim 5 obvious. Ex.1002, ¶¶151-153. Augoyard discloses that "[t]he body 41 has a plurality of transverse holes 42 through which small pins 43 can be inserted to secure the ancillary instrument 40 to the metatarsal bone M." Ex.1007, [0064]. "[T]he pins 43 are screwed in and the body 41 is rigidly attached to the metatarsal bone." *Id.*, [0066]. Figures 22-23 show that the first and second fixation pins (yellow) are inserted through the first and second fixation apertures (pink) in the support (green stripe) and into the metatarsal (M1).



Id., Fig.22.



Id., Fig.23.

It would have been obvious to use a bone cutting guide with these structural features in McGlamry's technique so that positioning the first bone cutting guide slot over the portion of the metatarsal to be cut involves positioning a support extending perpendicularly from the first bone cutting guide slot over a dorsal surface of the metatarsal with the support extending substantially parallel to a longitudinal axis of the metatarsal. Ex.1002, ¶¶152-153.

F. Claim 6

Claim 6 depends from claim 1 and recites: "wherein positioning the second bone cutting guide slot over the portion of the cuneiform to be cut comprises positioning a support extending perpendicularly from the second bone cutting guide slot over a dorsal surface of the metatarsal with the support extending substantially parallel to a longitudinal axis of the metatarsal." McGlamry and Augoyard render claim 6 obvious. Ex.1002, ¶¶154-158.

As explained for claim 4, it would have been obvious to place a bone cutting guide like Augoyard's over the dorsal surface of the metatarsal. *See supra* §VIII.D. Augoyard further discloses that the support (body 41) extends perpendicularly from the guide slot. Augoyard discloses that the slot 44 can be "at an angle of 70°± 20° [i.e., 90° or perpendicular], relative to the axis of the pin…," and therefore also to the support (body). Ex.1007, [0034]; Ex.1002, ¶156. Augoyard also discloses that the second guide slot (purple) is parallel to the first guide slot (orange). Ex.1007, [0070] ("[S]lots 53 and 54 are parallel to slot 44…."). Because the second guide slot is parallel to the first guide slot, it is also perpendicular to the support when the first guide slot is perpendicular to the support. Ex.1002, ¶157; *see also* Ex.1007, [0034], [0070]. These orientations would not change when a cutting guide like Augoyard's is used in McGlamry's procedure. Ex.1002, ¶158.

G. <u>Claim 7</u>

Claim 7 depends from claim 6 and recites: "wherein, when the second bone cutting guide slot is positioned over the portion of the cuneiform to be cut, the first fixation pin extends from the metatarsal through a first fixation aperture of the support and the second fixation pin extends from the metatarsal through a second fixation aperture of the support."

McGlamry and Augoyard render claim 7 obvious. Ex.1002, ¶¶159-161. As explained for limitation 1[b], Augoyard discloses that the first and second fixation

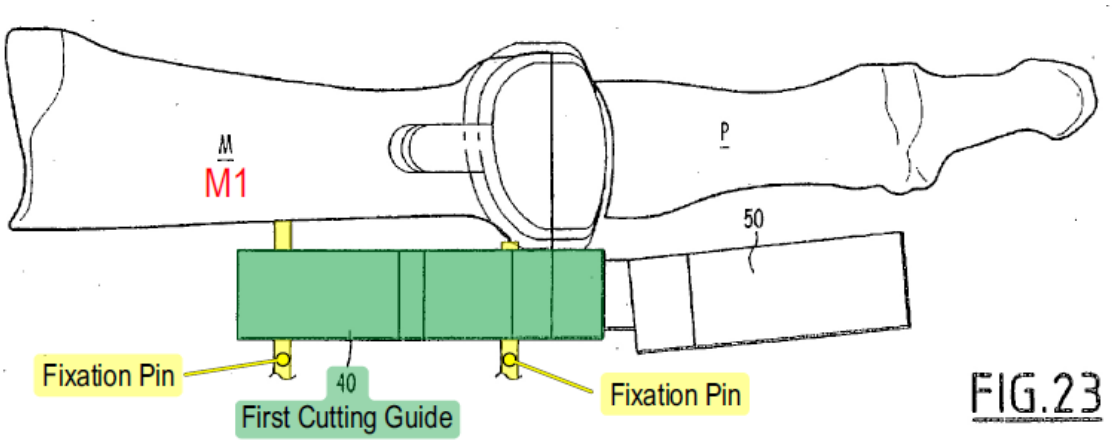
pins are placed in the body of the first metatarsal cutting guide through a first and second aperture, respectively. *See supra* §VIII.B.3. When the second bone cutting guide of Augoyard is attached and positioned over the second bone, the first and second fixation pins are disposed through their respective apertures and into the metatarsal. *Id.*; Ex.1002, ¶161. When using a guide like Augoyard's as part of McGlamry's procedure, the second bone cutting guide slot would be positioned over the portion of the cuneiform to be cut, with the first fixation pin extending from the metatarsal through a first fixation aperture of the support and the second fixation pin extending from the metatarsal through a second fixation aperture of the support. *Id.*

H. Claim 8

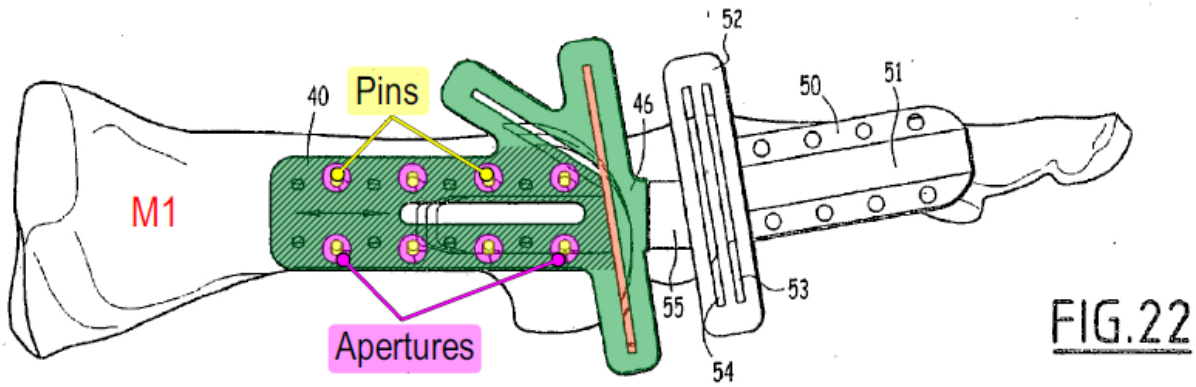
Claim 8 depends from claim 1 and recites: "wherein attaching the first bone cutting guide slot to the metatarsal with the first fixation pin and the second fixation pin comprises: [i] inserting the first fixation pin extending substantially perpendicular to a dorsal surface of the metatarsal; and [ii] inserting the second fixation pin extending substantially perpendicular to the dorsal surface of the metatarsal with the second fixation pin being substantially parallel to the first fixation pin."

McGlamry and Augoyard render claim 8 obvious. Ex.1002, ¶¶162-165. As explained with respect to claim 5, McGlamry in view of Augoyard render obvious inserting the first and second fixation into the dorsal surface of the metatarsal. *See*

§VIII.E, *supra*. Augoyard further discloses placement of pins that are "substantially perpendicular to the dorsal surface of the metatarsal" and parallel to one another. As shown in Fig.23, the pins (yellow) extend substantially perpendicular from the metatarsal (M1), and as shown in Fig.22 the apertures and consequently pins are parallel to one another. Ex.1002, ¶164.



Ex.1007, Fig.23.



Id., Fig.22. It would have been obvious to use a bone cutting guide with this orientation of the pins and dorsal surface of the metatarsal in McGlamry's procedure so that the inserted first fixation pin extends substantially perpendicular to a dorsal

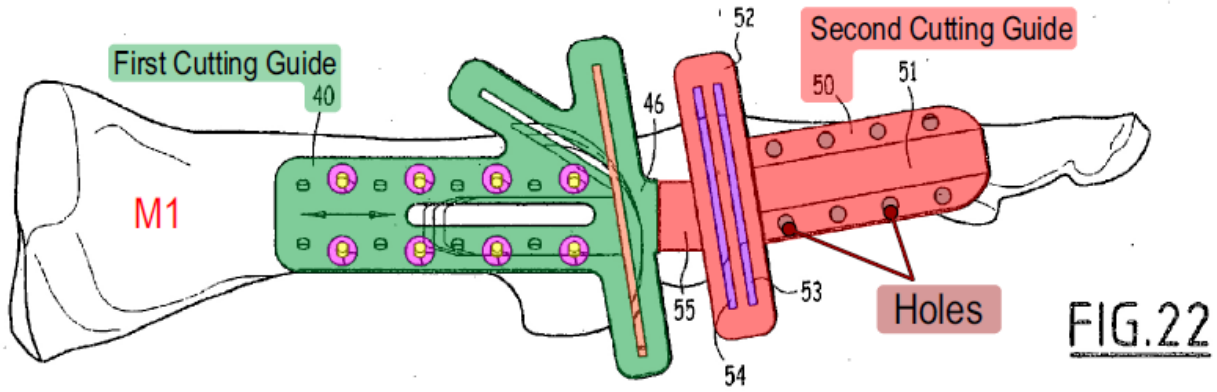
surface of the metatarsal and the inserted second fixation pin extends substantially perpendicular to the dorsal surface of the metatarsal, with the inserted second fixation pin being substantially parallel to the inserted first fixation pin. Ex.1002, ¶165.

I. Claim 9

Claim 9 depends from claim 1 and recites: "further comprising, after positioning the second bone cutting guide slot over the portion of the cuneiform to be cut, attaching the second bone cutting guide slot to the cuneiform with a third fixation pin inserted into the cuneiform."

McGlamry and Augoyard render claim 9 obvious. Ex.1002, ¶¶166-170. As explained with respect to limitation 1[b], when a bone cutting guide like Augoyard's is used in McGlamry's procedure, the second bone cutting guide slot would have been positioned over the cuneiform to be cut. *See supra* §VIII.B.3. In view of Augoyard's disclosure, it would have been obvious to also place a pin through the second cutting guide into the cuneiform. Ex.1002, ¶168; *see also* Ex.1007, [0070].

Augoyard teaches attaching the second bone cutting guide slot to the second bone with a third fixation pin inserted into the second bone. Specifically, Augoyard discloses that the second bone cutting guide (red) includes "a plurality of holes [(brown)] through which small pins can be inserted to secure the [guide to the] phalanx." Ex.1007, [0070].



Id., Fig.22. Once the second cutting guide in Augoyard is placed over the phalanx, pins are inserted through the holes into the bone. *See id.*, [0070]; Ex.1002, ¶168. When a guide like Augoyard's is used in McGlamry's procedure, it would have been obvious to place such additional pins into the cuneiform rather than the phalanx. Ex.1002, ¶¶169-170.

J. Claim 10

Claim 10 depends from claim 1 and recites: "wherein the first bone cutting guide slot and the second bone cutting guide slot are configured to result in a cut end of the metatarsal being substantially parallel to a cut end of the cuneiform."

McGlamry and Augoyard render claim 10 obvious. Ex.1002, ¶¶171-173. McGlamry discloses the claimed alignment of parallel cuts, explaining that the ends of the bones should be "kept consistent and parallel with the natural occurring anatomy." Ex.1005, 324. A POSA would have looked to maintain that alignment when using a bone cutting guide like Augoyard's in McGlamry's procedure. Ex.1002, ¶172. Augoyard likewise discloses "the metatarsal and phalangeal cutting

slots being substantially parallel when the two ancillary cutting instruments are joined." Ex.1007, [0034], Fig.22. Thus, the cut end of the metatarsal and the cut end of the cuneiform would have been substantially parallel in the combination's method. Ex.1002, ¶173.

K. Claim 12

Claim 12 depends from claim 1 and recites: "wherein the cutting member is a saw blade."

McGlamry and Augoyard render claim 12 obvious. Ex.1002, ¶¶174-175. Augoyard discloses using a saw blade to cut bones through the first and second cutting slots. Ex.1007, [0034], [0067], Claim 17. McGlamry likewise discloses a saw to cut the first metatarsal and the cuneiform. Ex.1005, 808; Ex.1002, ¶175.

L. Claim 13

Claim 13 depends from claim 1 and recites: "wherein inserting the cutting member through the first bone cutting guide slot and inserting the cutting member through the second bone cutting guide slot comprises inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal prior to inserting the cutting member through the bone cutting guide slot to cut the portion of the cuneiform."

McGlamry and Augoyard render claim 13 obvious. Ex.1002, ¶¶176-178. As discussed for limitations 1[c] and 1[f], McGlamry and Augoyard render obvious the

order of the insertion and cutting steps. *See supra* §§VIII.B.4, VIII.B.7. McGlamry also discloses the claimed cutting order, explaining "[t]he first metatarsal articular surface is denuded first," and then, "[t]he corrective articular resection is made at the distal aspect of the convex-shaped cuneiform." Ex.1005, 324; *see also* Ex.1007, [0067], [0070]-[0071] (disclosing cutting the metatarsal then the second bone).

M. Claim 14

Claim 14 depends from claim 1 and recites: "wherein inserting the cutting member through the first bone cutting guide slot and inserting the cutting member through the second bone cutting guide slot comprises inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal after inserting the cutting member through the second bone cutting guide slot to cut the portion of the cuneiform."

McGlamry and Augoyard render claim 14 obvious. Ex.1002, ¶¶179-181. Claim 14 recites the same two inserting steps as claim 13 but in a different order. But the order of cutting the first metatarsal and the cuneiform would have been a matter of surgeon preference. *Id.*, ¶180. The '397 patent discloses no advantage in cutting the bones in a particular order. *Id.* There are a finite number of options for the order of the claimed steps: either the cuneiform is cut first, or the metatarsal is cut first. *Id.*, ¶181. Where, as here, both are predictable, the ordering is obvious.

Uber Techs, 957 F.3d at 1340 (substitution of one of two alternatives for the other "is obvious because it would have been a 'predictable variation.'").

N. Claim 15

Claim 15 depends from claim 1 and recites: "wherein: [i] the first bone cutting guide slot is provided between a first guide surface defining a first plane and a second guide surface defining a second plane; and [ii] the second bone cutting guide slot is provided between a third guide surface defining a third plane and a fourth guide surface defining a fourth plane."

McGlamry and Augoyard render claim 15 obvious. Ex.1002, ¶¶182-184. Augoyard discloses that the first cutting guide slot (orange) is positioned between a first guide surface defining a first plane (blue) and a second guide surface defining a second plane (green); and the second cutting guide slot (purple) is positioned between a third guide surface defining a third plane (yellow) and a fourth guide defining a fourth plane (red):

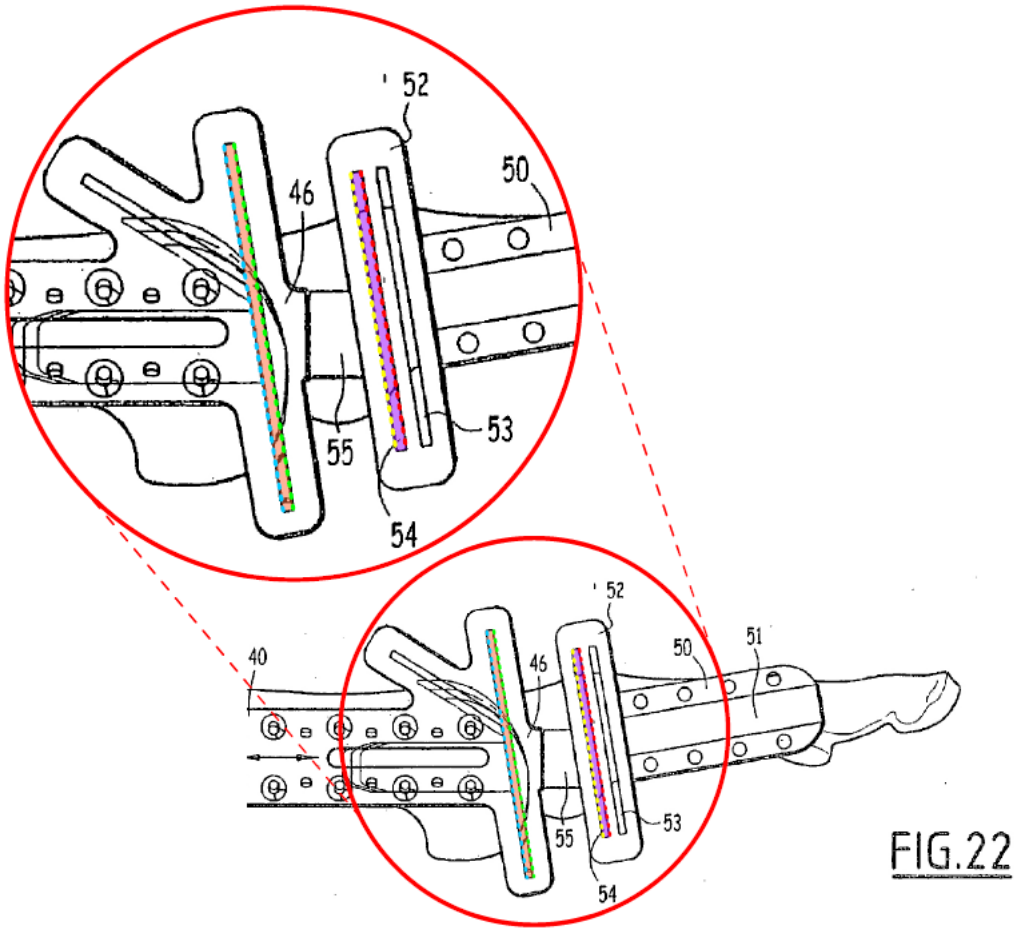


FIG.22

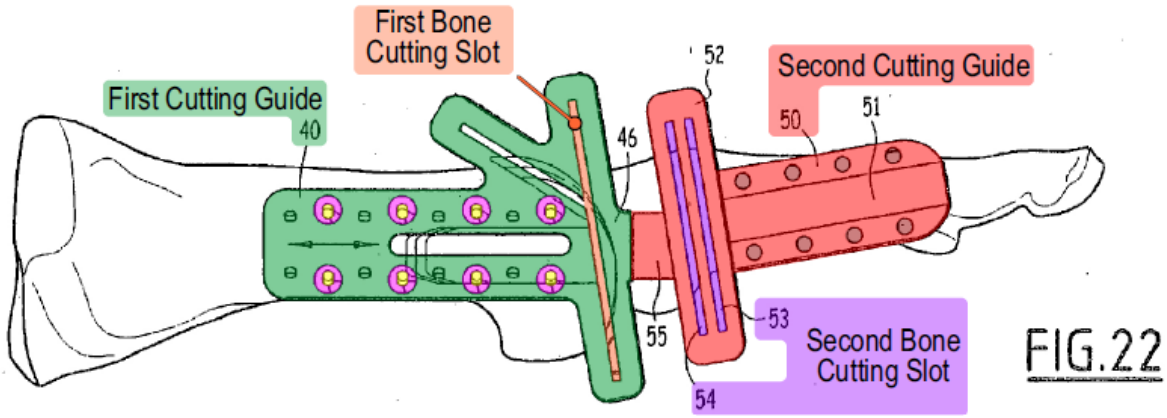
Ex.1007, Fig.22; Ex.1002, ¶183. It would have been obvious to use a bone cutting guide with these structural features in McGlamry's method. Ex.1002, ¶184.

O. Claim 16

Claim 16 depends from claim 1 and recites: "comprising: a first guide defining the first bone cutting guide slot; and a second guide defining the second bone cutting guide slot."

McGlamry and Augoyard render claim 16 obvious. As discussed for limitations 1[a] and 1[e], Augoyard discloses a first cutting guide (green) defining

the first bone cutting slot (orange) and a second cutting guide (red) defining the second bone cutting guide slot (purple). *Supra* §§VIII.B.2, VIII.B.6.

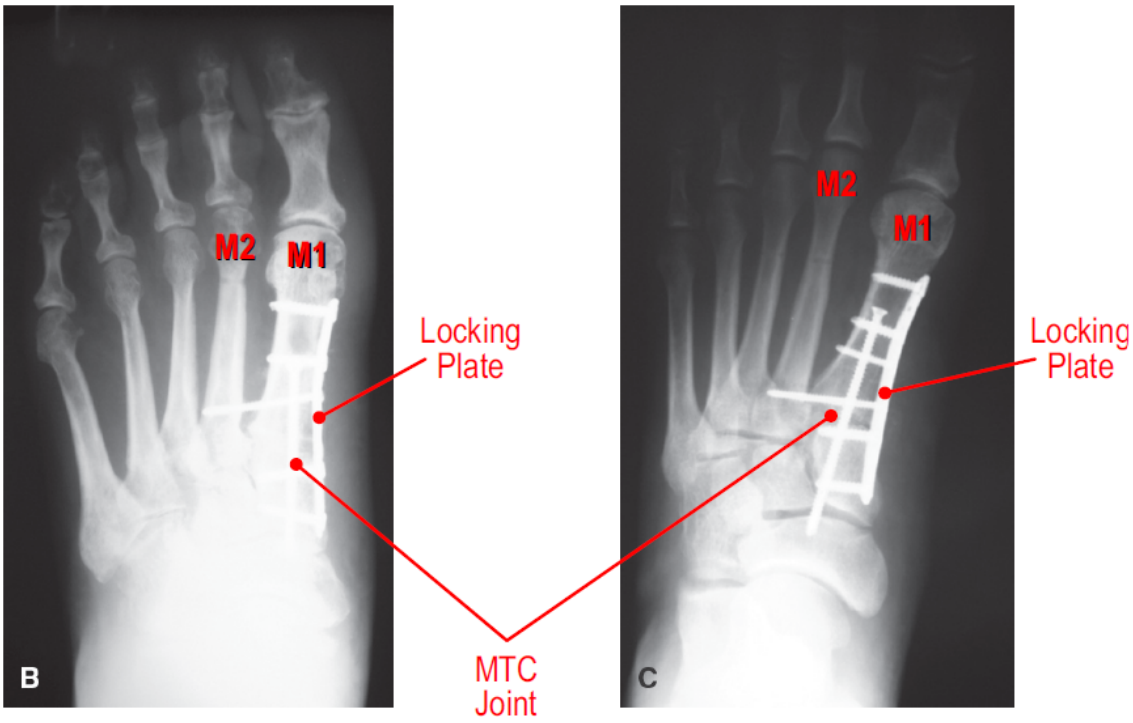


Id., Fig.22. It would have been obvious to use a bone cutting guide with these structural features in McGlamry's method. Ex.1002, ¶¶185-187.

P. Claim 17

Claim 17 depends from claim 1 and recites: "wherein causing the metatarsal to fuse to the cuneiform in the moved position comprises applying a bone plate across the joint."

McGlamry and Augoyard render claim 17 obvious. Ex.1002, ¶¶188-189. McGlamry discloses using a "a medial based locking plate" after the metatarsal is repositioned. Ex.1005, 326. The locking plate "is applied to the medial first metatarsal-cuneiform joint" (MTCJ) and used to fix the moved metatarsal to the cuneiform, such that the bone can fuse in the moved position. *Id.*, 327; Ex.1002, ¶189.



Ex.1005, Figs.31.8B, 31.9C. Such a locking plate is a bone plate applied across the joint for causing the metatarsal to fuse to the cuneiform in the moved position. Ex.1002, ¶189.

Q. <u>Claim 18</u>

Claim 18 depends from claim 1 and recites: "further comprising compressing the metatarsal and the cuneiform together."

McGlamry and Augoyard render claim 18 obvious. Ex.1002, ¶¶190-191. McGlamry discloses using a compression screw (i.e., "homerun screw") that "provides interfragmentary compression" as part of its bunion correction procedure. Ex.1005, 326. Interfragmentary compression is compression of the metatarsal and cuneiform. Ex.1002, ¶191.

R. Claim 19

Claim 19 depends from claim 1 and recites: "wherein the metatarsal is a first metatarsal and the cuneiform is a first cuneiform."

McGlamry and Augoyard render claim 19 obvious. Ex.1002, ¶¶192-193 McGlamry's procedure is performed on the first metatarsal and the medial cuneiform, i.e. the first cuneiform. *See generally* Ex.1005, 322-330 (titled "Lapidus Bunionectomy: First Metatarsal–Cuneiform Arthrodesis"); Ex.1002, ¶193.

S. Claim 20

1. Preamble

McGlamry discloses "a bunion correction method." *See supra* §VIII.B.1; Ex.1002, ¶195.

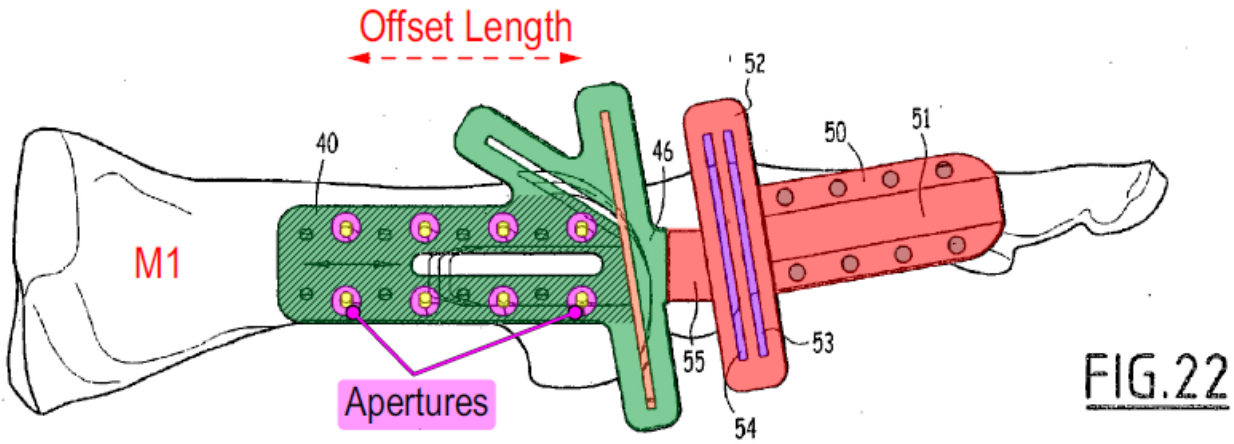
2. Limitation 20[a]

This limitation recites "positioning a first bone cutting guide slot over a portion of a metatarsal to be cut." *See* §VIII.B.2; Ex.1002, ¶196. For the reasons explained in Section VIII.A, it would have been obvious to use a cutting guide like Augoyard's to perform McGlamry's bunion correction method by positioning the first bone cutting guide slot over the portion of the metatarsal that McGlamry discloses should be cut. Ex.1002, ¶196.

3. Limitation 20[b]

Limitation 20[b] recites the same limitations as limitation 1[b] and claim 8, and further recites that "the first fixation aperture is offset a length of the metatarsal from the second fixation aperture." McGlamry in view of Augoyard renders obvious the limitations of limitation 1[b] and claim 8 as explained above. *See supra* §§VIII.B.3, VIII.H; Ex.1002, ¶¶197-198. Augoyard further discloses the remaining limitations.

Figure 22 shows that Augoyard's first and second fixation apertures (pink) are offset along the length of the cutting guide and metatarsal:



Ex.1007, Fig.22. It would have been obvious to use a bone cutting guide with this aperture positioning in McGlamry's technique. Ex.1002, ¶¶197-203.

4. Limitation 20[c]

This limitation recites "inserting a saw blade through the first bone cutting guide slot to cut the portion of the metatarsal." It would have been obvious to use

such a saw blade with a bone cutting guide like Augoyard's in McGlamry's technique, as explained in Section VIII.K. Ex.1002, ¶204.

5. Limitation 20[d]

This limitation recites "adjusting an alignment of the metatarsal relative to a cuneiform separated from the metatarsal by a joint to establish a moved position of the metatarsal." McGlamry discloses this limitation as explained in Section VIII.B.5. Ex.1002, ¶205.

6. Limitation 20[e]

This limitation recites "lifting the first guide off the first fixation pin and the second fixation pin." The limitation would have been obvious for the reasons discussed with respect to claim 2. *See* §VIII.C; Ex.1002, ¶206.

7. Limitation 20[f]

Limitation 20[f] recites the same limitations as limitation 1[e] and claim 9. These limitations would have been obvious for the same reasons explained for limitation 1[e] and claim 9. *See* §§VIII.B.6, VIII.I; Ex.1002, ¶207.

8. Limitation 20[g]

Limitation 20[g] recites the same limitations as limitation 1[f] and claim 12. These limitations would have been obvious for the same reasons explained for limitation 1[f] and claim 12. *See* §§VIII.B.7, VIII.K; Ex.1002, ¶208.

9. Limitation 20[h]

Limitation 20[h] recites the same limitations as limitation 1[g]. McGlamry discloses these limitations for the same reasons explained for limitation 1[g]. *See* §VIII.B.8; Ex.1002, ¶209.

Therefore, McGlamry and Augoyard render claim 20 obvious. Ex.1002, ¶¶194-209.

T. Claim 22

Claim 22 depends from claim 20 and recites: "wherein a support extends substantially perpendicularly from the first guide and defines the first fixation aperture and the second fixation aperture." These limitations would have been obvious for the same reasons explained for claims 4-5. *See* §§VIII.D, VIII.E; Ex.1002, ¶210.

U. Claim 23

Claim 23 depends from claim 20 and recites the same additional limitations as claim 8. These limitations would have been obvious for the same reasons explained for claim 8. *See* §VIII.H; Ex.1002, ¶211.

V. Claim 24

Claim 24 depends from claim 20 and recites the same additional limitations as claim 10. These limitations would have been obvious for the same reasons explained for claim 10. *See* §VIII.J; Ex.1002, ¶212.

W. Claim 25

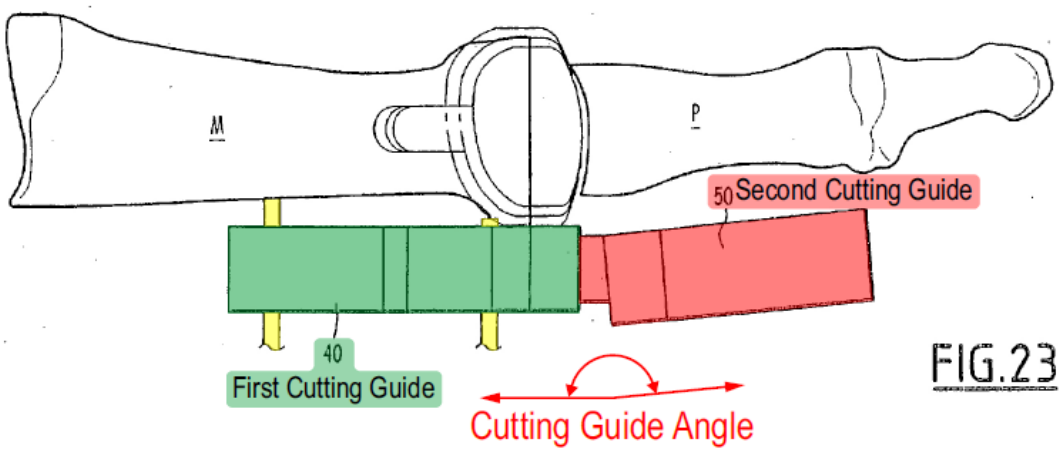
Claim 25 depends from claim 20 and recites the same additional limitations as claim 13. These limitations would have been obvious for the same reasons explained for claim 13. *See* §VIII.L; Ex.1002, ¶213.

X. Claim 26

Claim 26 depends from claim 20 and recites: "wherein the third fixation pin is at a skewed angle relative to the first fixation pin and the second fixation pin."

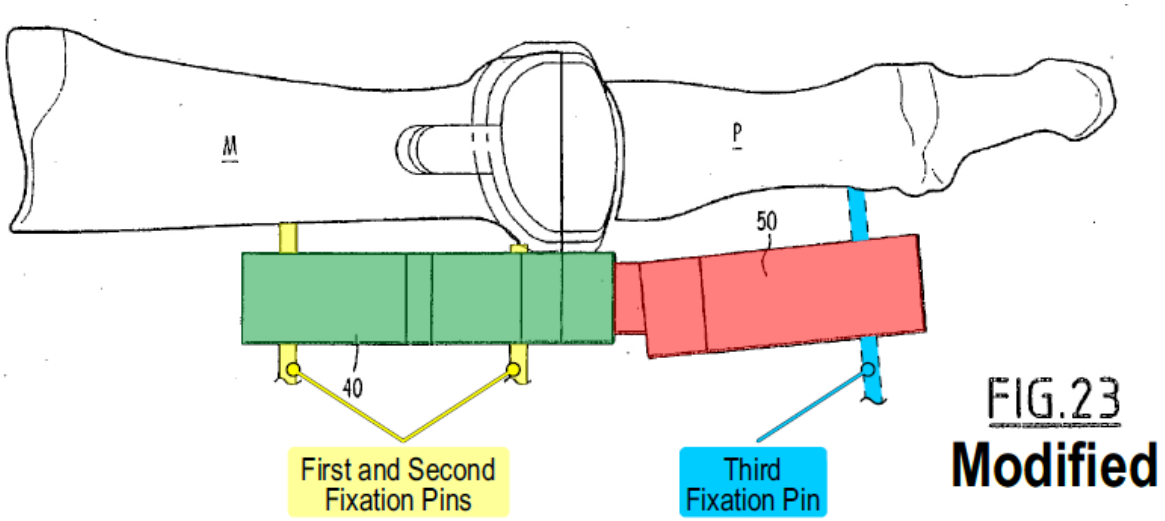
McGlamry and Augoyard render claim 26 obvious. Ex.1002, ¶¶214-219. As explained for claim 5, Augoyard discloses that the first and second fixation pins are positioned parallel to one another in the metatarsal. *See* §VIII.E. Augoyard also discloses that a third fixation pin may be placed in the second cut guide. *See* §VIII.I.

Augoyard further renders obvious placing the third fixation pin at a skewed angle relative to the first and second fixation pins. Ex.1002, ¶¶215-219. Augoyard discloses that the second cutting guide is angled relative to the metatarsal cutting guide, as shown in the figure below:



Ex.1007, Fig.23, [0070] ("As can be seen in Figure 23, in this position the body 50 is slightly inclined….").

Because the first and second guides are skewed relative to one another, a POSA would have recognized that the third pin placed through the second guide would be at a skewed angle relative to the first and second pins. Ex.1002, ¶217. The example placement of this added third pin (blue) is illustrated below.



Ex.1007, Fig.23 (modified); Ex.1002, ¶218. Furthermore, a POSA would have recognized that there are only two options for orienting the third pin relative to the

first and second pins: parallel or skewed. Ex.1002, ¶219; Ex.1001, 7:1-8. A skewed orientation of the third pin would prevent the cutting guide assembly from being unintentionally removed. Ex.1002, ¶219; Ex.1028, Abstract ("At least two fixation holes are formed through the osteotomy guide in directions which are non-parallel to the guide holes so that additional fixation pins may be placed into the tibia for more stable positioning of the osteotomy guide."); Ex.1029, [0071] ("Other features include a minimum of two non-parallel pin holes for additional stability of the block to the proximal humerus."); Ex.1030, [0030] ("The non-parallel axes of the holes may provide an advantage … of more positively coupling the cutting block 1 to a femur or a tibia in view of the fact that nonparallel axes prevent sliding of the cutting block 1 in a common direction along two or more fasteners placed in nonparallel holes."), [0048]. Thus, placing the third fixation pin at a skewed angle relative to the first and second fixation pins would have been obvious. *Uber Techs*, 957 F.3d at 1340.

Y. Claim 27

Claim 27 depends from claim 20 and recites the same additional limitations as claim 17. McGlamry discloses these limitations for the reasons discussed for claim 17. *See* §VIII.P; Ex.1002, ¶220.

Z. Claim 28

Claim 28 depends from claim 20 and recites the same additional limitations as claim 18. McGlamry discloses these limitations for the reasons discussed for claim 18. *See* §VIII.Q; Ex.1002, ¶221.

AA. Claim 29

Independent claim 29 recites all the limitations of claim 20 and further recites the additional limitations of claim 23, 26, and 28. These additional limitations would have been obvious for the same reasons as explained for claims 20, 23, 26, and 28. *See* §§VIII.S, VIII.U, VIII.X, VIII.Z; Ex.1002, ¶¶222-231.

BB. Claim 30

Claim 30 depends from claim 29 and further recites the additional limitations of claim 17. McGlamry discloses these limitations for the reasons discussed for claims 17 and 27. *See* §§VIII.P, VIII.X; Ex.1002, ¶232.

IX. GROUND 3: MCGLAMRY AND AUGOYARD IN VIEW OF DACOSTA RENDERS CLAIM 11 OBVIOUS

Claim 11 depends from claim 1 and recites: "wherein the first bone cutting guide slot and the second bone cutting guide slot are configured to result in a cut end of the metatarsal being angled relative to a cut end of the cuneiform." McGlamry and Augoyard in view of DaCosta render claim 11 obvious. Ex.1002, ¶¶233-240.

DaCosta is a design patent titled "LAPIDUS CUT GUIDE" and discloses a design for a cut guide. Ex.1014, Cover Page. Fig.1 is a "top perspective view of the

lapidus cut guide comprising the new design." *Id.* Figs.2-7 provide additional views of the design. *See id.*

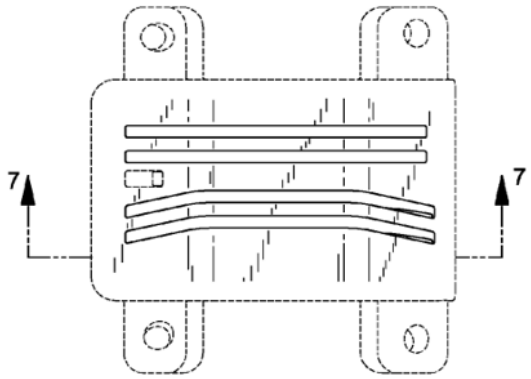


FIG. 2

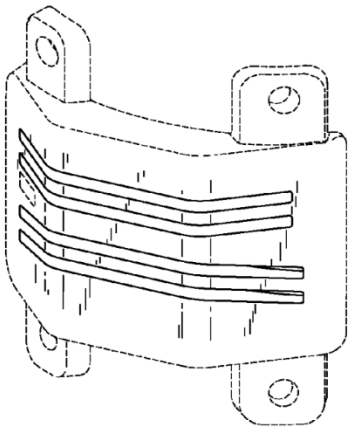


FIG. 1

Id., Figs.1-2; Ex.1002, ¶235.

DaCosta discloses two sets of slots that can be used in a bunion correction procedure. Ex.1002, ¶236. A distal first set of slots (purple) can be used to make a first bone resection (e.g. a resection of the first metatarsal), and a proximal second set of slots (orange) can be used to make a second bone resection (e.g. a resection of the cuneiform). *Id.*, ¶237.

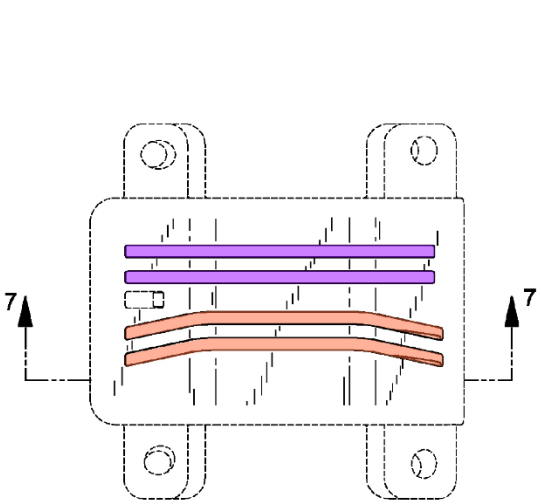


FIG. 2

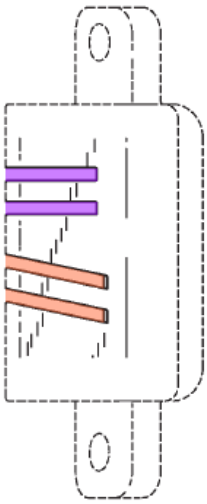


FIG. 5

Ex.1014, Figs.2, 5. The second set of slots include lateral portions (orange striped) that are angled relative to the first set of slots. Ex.1002, ¶237. When a surgeon uses one of the distal slots (orange), the resulting cut is angled relative to the cut produced by a cut made using one of the proximal slots (purple). *Id.*, ¶¶237-238.

In view of DaCosta, it would have been obvious to modify the shape of a cutting guide like Augoyard's to include guide slots with the first bone cutting guide slot angled relative to the second bone cutting guide slot. There are two options for the orientation of Augoyard's cut guide slots: parallel or angled.[12] Ex.1002, ¶239.

[12] The '397 patent explains: "components of the bone cutting guide 20 … can be configured such that the cut made using the secondary guide member 200 is ***an angular cut (i.e., not parallel)*** relative to the cut made using the guide member."

Both designs were known in the prior art. For example, Haddad and Augoyard disclose cutting guides that produced parallel cuts. Ex.1013, 9:28-29; Ex.1007, [0070]. Conversely, Weinstein and DaCosta disclose cut guides that produce angled cuts. Ex.1015, [0035]; *see* Ex.1014, Figs.1-6; Ex.1002, ¶240. It would have been obvious to substitute the parallel guide orientation in a bone cutting guide like Augoyard's for DaCosta's angled guide because the resulting guide is a "predictable variation" based on a design that was already known in the art. *KSR*, 550 U.S. at 417 ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability."); *see also Uber Techs.*, 957 F.3d at 1340 (holding substitution of one of two alternatives for the other "is obvious because it would have been a 'predictable variation.'").

X. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. If Patent Owner identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

Ex.1001, 10:6-11 (emphasis added). Thus, in the context of the intrinsic record, "angled" cuts are any two cuts that are not parallel.

XI. STIPULATION

Petitioner hereby stipulates that, in the event the Board institutes review, Petitioner will not pursue in *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.*, C.A. No. 1:25-cv-00592-GBW (Dist. Del), any invalidity ground against the challenged claims of the '397 patent that was raised or reasonably could have been raised in this Petition. This stipulation weighs strongly against discretionary denial under §314(a) (*Fintiv* factor 4). *Sotra Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (Dec. 1, 2020) (precedential as to §II.A).

XII. MANDATORY NOTICES AND FEE PAYMENT

Pursuant to 37 C.F.R. §42.8(a)(1), the mandatory notices identified in 37 C.F.R. § 42.8(b) are provided below as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Paragon 28, Inc. is the real party in interest for Petitioner. The parent company for Paragon 28, Inc. is Zimmer, Inc. whose parent company is Zimmer Biomet Holdings, Inc. Furthermore, in an abundance of caution and erring on the side of inclusivity, Petitioner identifies the following additional subsidiaries of Zimmer, Inc. as having a financial interest in, or potentially being affected by the outcome of, this proceeding: Zimmer US, Inc.; Paragon Advanced Technologies, Inc.; Disior Oy; Paragon 28 Italia SRL; Paragon 28 UK, LTD; Paragon 28 Medical Devices Trading

Limited; Paragon 28 Medical Devices Trading Limited – South African Branch; Paragon 28 Australia PTY LTD; Paragon 28 Japan K.K.; Paragon 28 DE Gmbh.

B. Related Matters (37 C.F.R. §42.8(b)(2))

The parties are currently engaged in district court litigation in the case captioned *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.*, C.A. No. 1:25-cv-00592-GBW (Dist. Del). Treace Medical Concepts, Inc. ("Treace" or "Patent Owner") has asserted the '397 patent against Petitioner in the district court litigation.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

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

Lead Counsel	**Back-up Counsel**
Ali S. Razai (Reg. No. 60,771) *ali.razai@morganlewis.com* Postal and Hand-Delivery Address: MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700	Jacob L. Peterson (Reg. No. 65,096) *jacob.peterson@morganlewis.com* Brandon G. Smith (provisionally recognized PTAB attorney) *brandon.g.smith@morganlewis.com* Zachary Messick (Reg. No. 77,839) *zachary.messick@morganlewis.com* Postal and Hand-Delivery Address: MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700

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

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to MLB-P28-PGR-397@morganlewis.com.

E. Standing

The ’397 patent is available for PGR and no bar or estoppel applies.

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

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

XIII. CONCLUSION

Petitioner respectfully requests that the Board institute a PGR and cancel claims 1–30 of the ’397 patent.

Dated: December 19, 2025 By: /Ali S. Razai/
Ali S. Razai (Reg. No. 60,771)
MORGAN, LEWIS & BOCKIUS, LLP

Attorney for Petitioner, Paragon 28, Inc.

APPENDIX

Listing of Claims from U.S. 12,268,397

Claim 1[13]

1[pre]	A bunion correction method comprising:
1[a]	positioning a first bone cutting guide slot over a portion of a metatarsal to be cut;
1[b]	attaching the first bone cutting guide slot to the metatarsal with a first fixation pin inserted into the metatarsal and a second fixation pin inserted into the metatarsal, the first fixation pin and the second fixation pin being positioned distally of the first bone cutting guide slot;
1[c]	inserting a cutting member through the first bone cutting guide slot to cut the portion of the metatarsal;
1[d]	adjusting an alignment of the metatarsal relative to a cuneiform separated from the metatarsal by a joint to establish a moved position of the metatarsal;
1[e]	positioning a second bone cutting guide slot over a portion of the cuneiform to be cut, the second bone cutting guide slot being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal, the first fixation pin and the second fixation pin being positioned distally of the second bone cutting guide slot;
1[f]	inserting the cutting member through the second cutting slot to cut the portion of the cuneiform; and

[13] Bracketed labels have been added for convenient referencing to the claim limitations.

Listing of Claims from U.S. 12,268,397	
1[g]	causing the metatarsal to fuse to the cuneiform in the moved position.
Claim 2	
--	The method of claim 1, further comprising, after adjusting the alignment of the metatarsal relative to the cuneiform to establish the moved position of the metatarsal, lifting the first bone cutting guide slot off the first fixation pin and the second fixation pin.
Claim 3	
3[a]	The method of claim 1, wherein: inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal comprises inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal without the second bone cutting guide slot being positioned over the portion of the cuneiform to be cut; and
3[b]	inserting the cutting member through the second bone cutting guide slot to cut the portion of the cuneiform comprises inserting the cutting member through the second bone cutting guide slot to cut the portion of the cuneiform without the first bone cutting guide slot being positioned over the portion of the metatarsal to be cut and configured to receive the cutting instrument therethrough.
Claim 4	
--	The method of claim 1, wherein positioning the first bone cutting guide slot over the portion of the metatarsal to be cut comprises positioning a support extending perpendicularly from the first bone cutting guide slot over a dorsal surface of the metatarsal with the support extending substantially parallel to a longitudinal axis of the metatarsal.

Listing of Claims from U.S. 12,268,397

Claim 5

-- The method of claim 4, wherein attaching the bone cutting guide slot to the metatarsal with the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal comprises inserting the first fixation pin through a first fixation aperture of the support into the metatarsal and inserting the second fixation pin through a second fixation aperture of the support into the metatarsal.

Claim 6

-- The method of claim 1, wherein positioning the second bone cutting guide slot over the portion of the cuneiform to be cut comprises positioning a support extending perpendicularly from the second bone cutting guide slot over a dorsal surface of the metatarsal with the support extending substantially parallel to a longitudinal axis of the metatarsal.

Claim 7

-- The method of claim 6, wherein, when the second bone cutting guide slot is positioned over the portion of the cuneiform to be cut, the first fixation pin extends from the metatarsal through a first fixation aperture of the support and the second fixation pin extends from the metatarsal through a second fixation aperture of the support.

Claim 8

8[a] The method of claim 1, wherein attaching the first bone cutting guide slot to the metatarsal with the first fixation pin and the second fixation pin comprises:

inserting the first fixation pin extending substantially perpendicular to a dorsal surface of the metatarsal; and

Listing of Claims from U.S. 12,268,397	
8[b]	inserting the second fixation pin extending substantially perpendicular to the dorsal surface of the metatarsal with the second fixation pin being substantially parallel to the first fixation pin.
Claim 9	
--	The method of claim 1, further comprising, after positioning the second bone cutting guide slot over the portion of the cuneiform to be cut, attaching the second bone cutting guide slot to the cuneiform with a third fixation pin inserted into the cuneiform.
Claim 10	
--	The method of claim 1, wherein the first bone cutting guide slot and the second bone cutting guide slot are configured to result in a cut end of the metatarsal being substantially parallel to a cut end of the cuneiform.
Claim 11	
--	The method of claim 1, wherein the first bone cutting guide slot and the second bone cutting guide slot are configured to result in a cut end of the metatarsal being angled relative to a cut end of the cuneiform.
Claim 12	
--	The method of claim 1, wherein the cutting member is a saw blade.

Listing of Claims from U.S. 12,268,397

Claim 13

-- The method of claim 1, wherein inserting the cutting member through the first bone cutting guide slot and inserting the cutting member through the second bone cutting guide slot comprises inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal prior to inserting the cutting member through the bone cutting guide slot to cut the portion of the cuneiform.

Claim 14

-- The method of claim 1, wherein inserting the cutting member through the bone cutting guide slot and inserting the cutting member through the second bone cutting guide slot comprises inserting the cutting member through the first bone cutting guide slot to cut the portion of the metatarsal after inserting the cutting member through the second bone cutting guide slot to cut the portion of the cuneiform.

Claim 15

15[a] The method of claim 1, wherein:

the first bone cutting guide slot is provided between a first guide surface defining a first plane and a second guide surface defining a second plane; and

15[b] the second bone cutting guide slot is provided between a third guide surface defining a third plane and a fourth guide surface defining a fourth plane.

Listing of Claims from U.S. 12,268,397	
Claim 16	
--	The method of claim 1, comprising: a first guide defining the first bone cutting guide slot; and a second guide defining the second bone cutting guide slot.
Claim 17	
--	The method of claim 1, wherein causing the metatarsal to fuse to the cuneiform in the moved position comprises applying a bone plate across the joint.
Claim 18	
--	The method of claim 1, further comprising compressing the metatarsal and the cuneiform together.
Claim 19	
--	The method of claim 1, wherein the metatarsal is a first metatarsal and the cuneiform is a first cuneiform.
Claim 20	
20[pre]	A bunion correction method comprising:
20[a]	positioning a first bone cutting guide slot defined by a first guide over a portion of a metatarsal to be cut;

Listing of Claims from U.S. 12,268,397

20[b] attaching the first guide to a dorsal surface of the metatarsal by inserting a first fixation pin through a first fixation aperture connected to the first guide and inserting a second fixation pin through a second fixation aperture connected to the first guide, wherein the first fixation aperture is offset along a length of the metatarsal from the second fixation aperture, and inserting the first fixation pin and inserting the second fixation pin comprises inserting the first fixation pin and inserting the second fixation pin extending substantially parallel to each other;

20[c] inserting a saw blade through the first bone cutting guide slot to cut the portion of the metatarsal;

20[d] adjusting an alignment of the metatarsal relative to a cuneiform separated from the metatarsal by a joint to establish a moved position of the metatarsal;

20[e] lifting the first guide off the first fixation pin and the second fixation pin;

20[f] positioning a second bone cutting guide slot defined by a second guide over a portion of the cuneiform to be cut, the second guide being attached to the metatarsal by at least the first fixation pin inserted into the metatarsal and the second fixation pin inserted into the metatarsal, and the second guide being attached to the cuneiform by at least a third fixation pin inserted into the cuneiform;

20[g] inserting the saw blade through the second cutting slot to cut the portion of the cuneiform; and

20[h] causing the metatarsal to fuse to the cuneiform in the moved position.

Listing of Claims from U.S. 12,268,397	
Claim 21	
21[a]	The method of claim 20, wherein: inserting the saw blade through the first bone cutting guide slot to cut the portion of the metatarsal comprises inserting the saw blade through the first bone cutting guide slot to cut the portion of the metatarsal without the second bone cutting guide slot being positioned over the portion of the cuneiform to be cut; and
21[b]	inserting the saw blade through the second bone cutting guide slot to cut the portion of the cuneiform comprises inserting the saw blade through the second bone cutting guide slot to cut the portion of the cuneiform without the first bone cutting guide slot being positioned over the portion of the metatarsal to be cut and configured to receive the saw blade therethrough.
Claim 22	
--	The method of claim 20, wherein a support extends substantially perpendicularly from the first guide and defines the first fixation aperture and the second fixation aperture.
Claim 23	
--	The method of claim 20, wherein inserting the first fixation pin and inserting the second fixation pin extending substantially parallel to each other comprises: inserting the first fixation pin extending substantially perpendicular to the dorsal surface of the metatarsal; and inserting the second fixation pin extending substantially perpendicular to the dorsal surface of the metatarsal.

Listing of Claims from U.S. 12,268,397	
Claim 24	
--	The method of claim 20, wherein the first bone cutting guide slot and the second bone cutting guide slot are configured to result in a cut end of the metatarsal being substantially parallel to a cut end of the cuneiform.
Claim 25	
--	The method of claim 20, wherein inserting the saw blade through the first bone cutting guide slot and inserting the saw blade through the second bone cutting guide slot comprises inserting the saw blade through the first bone cutting guide slot to cut the portion of the metatarsal prior to inserting the saw blade through the bone cutting guide slot to cut the portion of the cuneiform.
Claim 26	
--	The method of claim 20, wherein the third fixation pin is at a skewed angle relative to the first fixation pin and the second fixation pin.
Claim 27	
--	The method of claim 20, wherein causing the metatarsal to fuse to the cuneiform in the moved position comprises applying a bone plate across the joint.
Claim 28	
--	The method of claim 20, further comprising compressing the metatarsal and the cuneiform together.
Claim 29	
29[pre]	A bunion correction method comprising:

Listing of Claims from U.S. 12,268,397

29[a] positioning a first bone cutting guide slot defined by a first guide over a portion of a first metatarsal to be cut;

29[b] attaching the first guide to a dorsal surface of the first metatarsal by inserting a first fixation pin through a first fixation aperture connected to the first guide and inserting a second fixation pin through a second fixation aperture connected to the first guide, wherein the first fixation aperture is offset along a length of the first metatarsal from the second fixation aperture, and inserting the first fixation pin and inserting the second fixation pin comprises inserting the first fixation pin and inserting the second fixation pin extending substantially parallel to each other and substantially perpendicular to the dorsal surface of the first metatarsal;

29[c] inserting a saw blade through the first bone cutting guide slot to cut the portion of the first metatarsal;

29[d] adjusting an alignment of the metatarsal relative to a first cuneiform separated from the metatarsal by a joint to establish a moved position of the first metatarsal;

29[e] lifting the first guide off the first fixation pin and the second fixation pin;

29[f] positioning a second bone cutting guide slot defined by a second guide over a portion of the first cuneiform to be cut, the second guide being attached to the first metatarsal by at least the first fixation pin and the second fixation pin, and second guide being attached to the first cuneiform by at least a third fixation pin inserted into the first cuneiform at a skewed angle relative to the first fixation pin and the second fixation pin;

Listing of Claims from U.S. 12,268,397	
29[g]	inserting the saw blade through the second cutting slot to cut the portion of the first cuneiform;
29[h]	compressing the first metatarsal and the first cuneiform together; and
29[i]	causing the first metatarsal to fuse to the first cuneiform in the moved position.
Claim 30	
--	The method of claim 29, wherein causing the metatarsal to fuse to the cuneiform in the moved position comprises applying a bone plate across the joint.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 12,102,368 contains 17,855 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 18,700-word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: December 19, 2025

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

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 12,102,368, PETITIONER'S POWER OF ATTORNEY, AND EXHIBITS 1001-1009 AND 1011-1031**, are being served by FedEx on the Patent Owner at the correspondence address of record for the subject patent as follows:

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