UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.
Petitioner

v.

WRIGHT MEDICAL TECHNOLOGY, INC.
Patent Owner

U.S. PATENT NO. 10,888,336

Case IPR2022-____

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Page(s)

Statutes

Rules

INDEX OF EXHBITS

Exhibit No.	Description
1001	U.S. Patent No. 10,888,336 to McGinley et al.
1002	U.S. Patent No. 9,907,561 to Luna et al.
1003	Declaration of Dr. Bruce Werber
1004	Prosecution History of U.S. Patent No. 10,888,336 to McGinley et al. (Excerpted)
1005	U.S. Patent No. 9,186,154 to Li
1006	U.S. Patent No. 8,002,841 to Hasselman
1007	US. Patent No. 7,763,027 to Irving
1008	U.S. Patent No. 7,648,508 Lutz et al.
1009	U.S. Patent Publication No. 2009/0054992 to Landes et al.
1010	U.S. Patent No. 8,652,180 to Federspiel et al.
1011	U.S. Patent No. 5,364,402 to Mumme et al.
1012	U.S. Patent No. 5,683,470 to Johnson et al.
1013	U.S. Patent No. 8,114,091 to Ratron et al.
1014	U.S. Patent No. 7,744,601 to Rosa et al.
1015	U.S. Patent No. 8,337,503 to Lian
1016	U.S. Patent No. 8,808,303 to Stemniski et al.
1017	U.S. Patent No. 9,326,780 to Wong et al.
1018	WO 2011/072249 to Richter et al.
1019	U.S. Patent Publication No. 2005/0004676 to Schon et al.
1020	Laurence W. McKeen, Handbook of Polymer Applications in Medicine and Medical Devices (2014).
1021	Bonasia, D. E. et al., *Total ankle replacement: Why, When and How?,* The Iowa Orthopaedic J., 30, (2010).
1022	Clare, Michael P. et al., *Preoperative Considerations in Ankle Replacement Surgery*, Foot and Ankle Clinic, Vol. 7 (2002).
1023	Cenni, Francesco et al., *Position of the Prosthesis Components in Total Ankle Replacement and the Effect on Motion at the Replaced Joint*, Int'l Orthopaedics, Vol. 36(3) (2012).
1024	U.S. Patent No. 5,688,279 to McNulty et al.

Exhibit No.	Description
1025	Steeves, Mark et al., *How Pilot-Hole Size Affects Bone-Screw Pullout Strength in Human Cadaveric Cancellous Bone,* Canadian J.of Surgery, Vol. 48(3) (2005).
1026	Howell, Joel D., *Early Clinical Use of the X-Ray*, Transactions of the Am. Clinical and Climatological Ass'n, Vol. 127 (2016)
1027	Hofstetter, R. et al., *Fluoroscopy as an Imaging Means for Computer-Assisted Surgical Navigation*, Computer Aided Surgery, Vol. 4 (1999).
1028	Jennings, John D. et al., *Intraoperative Fluoroscopy Improves Component Position During Anterior Hip Arthroplasty*, SLACK Inc., Vol. 38(11) (2015).
1029	Roberts, Timothy T. et al., *History of the Orthopedic Screw*, ORTHOPEDICS, Vol. 36(1) (2013).
1030	Definition of "Fluoroscopy", U.S. Food and Drug Admin., https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/fluoroscopy.
1031	Definition of "Dovetail Joint", https://en.wikipedia.org/wiki/Dovetail_joint
1032	*Wright Medical Tech., Inc. v. Paragon 28, Inc.,* No. 21-1809-MN (Apr. 13, 2022) at Dkt 16 ("Scheduling Order").
1033	June 30, 2022 Federal Court Statistics, https://www.uscourts.gov/sites/default/files/fcms_na_distcomparison0630.2022_0.pdf
1034	USPTO Mem. re "Interim Procedure for Discretionary Denial in AIA Post-Grant Proceedings with Parallel District Court Litigation", June 21 2022, https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf
1035	U.S. Patent No. 9,775,639 to Hanson et al.
1036	U.S. Patent No. 9,675,471 to Bojarski et al.
1037	Wright Medical Proposed Claim Constructions (Sept. 30, 2022)
1038	Paragon 28 Proposed Claim Constructions (Sept. 30, 2022)

Petitioner Paragon 28, Inc. ("Petitioner") requests *inter partes* review of Claims 1-6, 8-11, 20-24, and 26-27 (the "Challenged Claims") of U.S. Patent No. 10,888,336 ("the '336 Patent") (Ex. 1001).

The Challenged Claims relate to surgical guides that help ensure cuts or holes made to a bone during surgery are made in the proper location. The Challenged Claims take known guides and add a "cue," generally of radiopaque material (i.e., material visible using X-Ray or fluoroscopy). But using radiopaque material to position medical devices has been known for decades and adding them to guides is neither novel nor non-obvious. As the Challenged Claims are nothing more than obvious modifications of known surgical guides, this Board should institute *inter partes* review and find the Challenged Claims unpatentable.

I. BACKGROUND OF THE '336 PATENT

A. Technology Overview

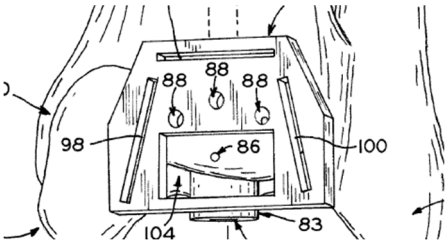
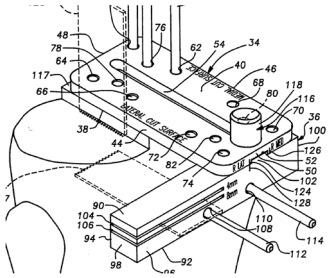
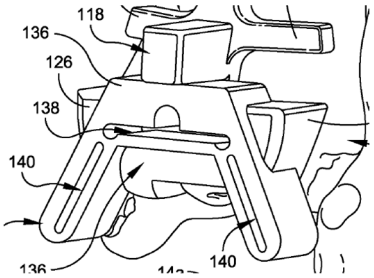
The '336 Patent discloses purportedly "improved systems and methods of providing ankle replacement surgery" to address "[a]rthritis, bone degeneration, and/or injury can cause ankle joint deterioration resulting in pain, reduced range of motion, and decreased quality of life." Ex. 1001, 1:32-38. Prostheses for ankle replacement have been FDA-approved since at least 1992, and were well-known to persons of ordinary skill in the art ("POSITAs"). Ex. 1003 ¶28; *see generally* Ex. 1021; Ex. 1015. Ankles, like knees and elbows, are a "joint that acts much like a hinge." Ex. 1001, 1:28. Typically, in a joint replacement surgery (one form of

arthroplasty, a surgical procedure to restore joint function), physicians replace a joint by removing or resecting portions of the bones that form the hinge (in ankle replacement, the tibia and talus bones), implanting prostheses in the portion of the bone that was removed, and inserting a spacer that sits between implants to restore mobility. Ex. 1003 ¶¶27, 29; Ex. 1005, 1:12-23; Ex. 1006, 1:56-65; Ex. 1015, 1:35-43, 2:21-22; 2:37-39.

Joint replacement implants were shaped in a variety of configurations to permit the implant to attach to the bone in an advantageous manner during joint replacement surgery. Ex. 1003 ¶30; Ex. 1015, 1:35-45, 2:18-41. Physicians chose the implant type and size based on the patient's bone size, bone shape, age, activity level, joint problems, health, and other factors. Ex. 1003 ¶30; Ex. 1021, 119; Ex. 1022, 710-719. To optimize the replaced joint's function, cuts made to the bone must be accurate so the implants are properly aligned. Ex. 1003 ¶31. Accordingly, surgeons' bone cuts reflect the geometry of the design and size of the implants used, accounting for differences in bone shape, density, and damage. *Id.*

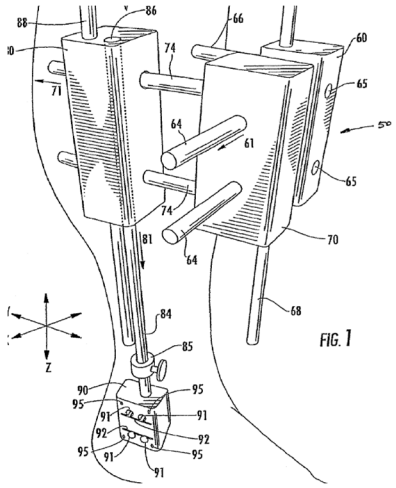
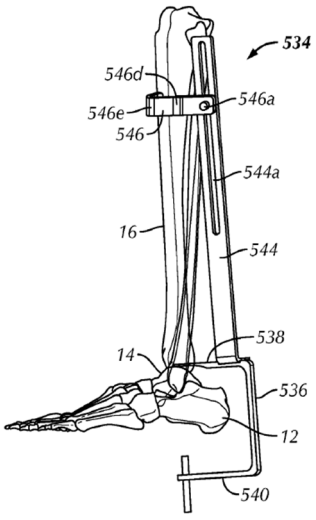
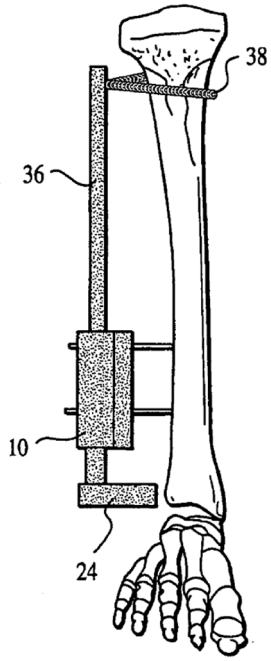
Because the positioning of prosthesis components affects the range of motion, joint replacement systems included surgical guides and/or implant alignment systems. *Id.* ¶32; Ex. 1005, 4:22-35. Physicians rely on these to aid in resecting the appropriate portion of patient bone and preparing the remaining bone for receiving an implant. Ex. 1003 ¶32. Guides may include slots designed to locate cuts to be made in the bone using saws or other cutting instruments, and holes to locate drills

or other surgical instruments. *Id.*; Ex. 1016, 1:25-28. Following the slots and holes in a guide helps ensure that cuts and holes made to the bone are located so that an implant can be attached in the desired position and orientation. Ex. 1003 ¶¶33-38. Different guides have different placements of holes and slots based on the implant design and size, as shown in the prior art examples below. *Id.* ¶38.

Li (Ex. 1005)	**Mumme (Ex. 1011)**	**Steminski (Ex. 1016)**
		

It was known that properly aligning guides were critical to ensuring cuts made to the bone were at the appropriate location, as the alignment of the guide dictates where the slots and holes of the guide—and thus the cuts and holes in the bone—were located. Ex. 1003 ¶¶39-41. As a result, joint replacement systems commonly included alignment systems that temporarily coupled to the patient during surgery to provide a static frame of reference, allowing for surgical guides and other instrumentation to be consistently placed and aligned throughout a procedure. Ex. 1003 ¶39; Ex. 1006, 1:25-34, Figs. 1, 7, 9, 7:19-27. These alignment systems permit surgeons to adjust the position of the surgical guide (or other instrument) at the

appropriate location, and ensure that instrument remains at that location throughout surgery. *Id*. Example prior art alignment guides are depicted below:

Hasselman (Ex. 1006)	Richter (Ex. 1018)	Schon (Ex. 1019)
 FIG. 1	 FIG. 8A	

Accurate implantation of prostheses is paramount to long-term success of joint replacements, and thus POSITAs understood that the cuts and holes made in the bone should be as accurate as possible. Ex. 1003 ¶45; Ex. 1028, 974. Although bones are located underneath the skin, not visible to the naked eye, they are radiopaque and appear white or light gray on X-rays, whereas muscle and skin are radiolucent and appear black or dark gray. Ex. 1003 ¶46. Thus, physicians used pre-operative and intraoperative fluoroscopy to view bone and other radiopaque materials within a patient, relatively unencumbered by interceding flesh. *Id*., ¶¶45-

47. Pre-operative imaging occurs prior to surgery, and is useful to determine the type of repair needed and perform an initial evaluation of protheses that may be available for the patient. Ex. 1003 ¶47. Intraoperative imaging occurs during surgery, allowing physicians to confirm the placement of bone resection cuts, components used to position implants (sometimes known as "trial components"), the implants, and other elements. *Id*.

Prior to the '336 Patent, PHOSITAs knew to include radiopaque materials in surgical instruments because it permitted a physician to simultaneously view, via fluoroscopy, the patient's bone and the radiopaque component of the instrument to align and position them. Ex. 1003 ¶¶48, 52; Ex. 1007, 8:34-38, 9:24-33, 13:19-29, 15:33-41, 16:15-62. This is important in joint replacement surgeries because prostheses should be aligned correctly to achieve optimal patient results. Ex. 1003 ¶49. Prior art alignment and cutting guides for joint replacement systems included radiopaque markers to ensure proper alignment and positioning of these instruments prior to making a cut to the bone and permanently implanting a prosthesis. *Id.* ¶50. For example, one prior art reference depicts an "adjustable guide assembly" with a fluoroscopically visible guidewire target. Ex. 1018, [0077]; *see also id.*, [0090], Figs. 5, 7, 8, 10, 12; Ex. 1003 ¶51. Another describes joint replacement surgery methods using an alignment guide with radiopaque instrument references viewed fluoroscopically. Ex. 1007, Abstract; Ex. 1003 ¶50.

B. Alleged Invention of the '336 Patent

The '336 Patent relates to systems and methods for joint replacements. Ex. 1001, 1:20-25; Ex. 1003 ¶54. The Challenged Claims recite a "surgical guide" (Claims 1-6, 8-9) or an "adjustable guide assembly" (Claims 10-11, 20-24, 26-27), each of which includes either at least one "radiopaque line" or a "cue." Ex. 1001, Claims 1-6, 8-11, 20-24, 26-27.

The '336 Patent discloses an "adjustment block" used "as a fixed reference to associate all other instruments used for trial sizing and trials related to tibial side of the ankle replacement" and associated "guides." *Id.*, 21:1-4. One embodiment includes an "adjustment block" with a "drill guide" having "guide holes [] to be used to drill pilot holes in the tibia." *Id.*, 17:10-14. The drill guide has "sizing patterns 285 showing the size and location of one or more resectioning cuts corresponding to the holes to be drilled using the drill guide" and "reference lines [] that the physician optionally can use to position the drill guide." *Id.*, 17:19-23. Figure 35 depicts an adjustment block with a drill guide having guide holes (red) and a sizing pattern (green):

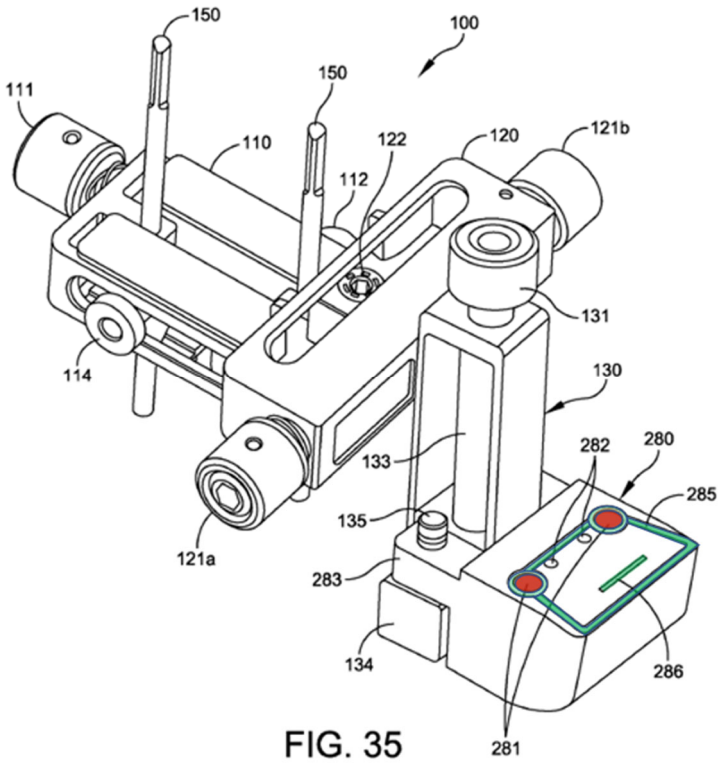


FIG. 35

Id., Fig. 35; Ex. 1003 ¶56.

The reference lines are "visible under a fluoroscope, so [a] physician can view the position and size of the lines 285, 286 in situ, relative to [a] patient's bones," allowing "[a] physician view[ing] [an] X-ray of the tibia bone 260 and drill guide 280 [to determine] whether it is the optimum size and position for the patient." *Id.*, 17:24-49. The '336 Patent contends that the adjustment block configuration ultimately allows a physician to "assess the fit of the ankle replacement system, including size, anterior-posterior position, and whether the tibia has been sized, drilled and cut optimally." *Id.*, 20:29-36.

The '336 Patent also describes an "adjustment block" having "independently positionable frames" and a "tool holder [] … adapted to hold a drilling tool, a cutting

tool, or a tibia trial 210." *Id.*, 15:1-3, 15:42-44. The frames of the adjustment block adjust the position of a tool holder, and purport to permit "precise[] positioning [of the] tool holder [] adjacent the joint to be replaced." *Id.*, Fig. 29, 5:27-29, 15:1-3.

The Challenged Claims are set forth in Appendix A.

C. Prosecution History of the '336 Patent

U.S. Patent Appl. No. 16/047,425 ("the '425 application"), which led to the '336 Patent, was filed on July 27, 2018. Ex. 1001, Cover. Through a series of applications, the '336 Patent claims priority to a provisional application filed December 27, 2012. *Id.*[1]

Prior to action by the PTO, the applicant submitted a preliminary amendment cancelling all original claims and replacing them with claims 66-73 directed to a "surgical guide." Ex. 1004, 1-5. On November 11, 2019, the applicant submitted a second preliminary amendment, adding claims 74-87 directed to an "adjustable guide assembly." *Id.*, 6-12.

In an office action, the examiner rejected the pending "surgical guide" claims as either anticipated by U.S. Publication No. 2004/0039394 ("Conti") or obvious over Conti in view of U.S. Patent No. 8,911,444 ("Bailey"). *Id.*, 13-19. The pending

[1] For purposes of this IPR, Petitioner assumes the priority date is December 27, 2012, the earliest priority date on the face of the '336 patent. Petitioner reserves the right to challenge any claim of priority in the district court case.

"adjustable guide assembly" claims (74-87) were rejected as invalid in view of §101.[2] *Id.* In response, the applicant amended the independent "surgical guide" claim to recite "wherein the sizing pattern comprises at least two radiopaque lines each comprising a length dimension configured to provide a fluoroscopic cue for positioning the body" to address the anticipation and obviousness rejection of claims 66-68 and 70-73 and withdrew claim 69. *Id.*, 21-22, 30-32. The applicant also amended claims 74-87 to resolve the §101 objection and added new claims 88-93. *Id.*, 23-29. The examiner allowed the pending claims following applicant's amendment. *Id.*, 38-40. The examiner did not include a statement regarding the reasons for allowance.

II. IDENTIFICATION AND BASIS OF CHALLENGE

Petitioner requests IPR of the Challenged Claims in view of the following prior art and grounds:

- **Li**: U.S. Patent No. 9,186,154 (Ex. 1005), filed March 17, 2011 and issued November 17, 2015. Li is prior art under §102(e).[3]

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[2] The correlation between the application claim numbers and issued claim numbers can be found in the file history. Ex. 1004, 43.

[3] Cites to 35 U.S.C. §§102 and 103 are to the pre-AIA version applicable based on the claimed priority date of the '336 Patent.

- **Hasselman**: U.S. Patent No. 8,002,841 (Ex. 1006), issued August 23, 2011. Hasselman is prior art under §§102(a) and (b).
- **Irving**: U.S. Patent No. 7,763,027 (Ex. 1007), issued July 27, 2010. Irving is prior art under §§102(a) and (b).
- **Lutz**: U.S. Patent No. 7,648,508 (Ex. 1008), issued January 19. 2010. Lutz is prior art under §§102(a) and (b).
- **Landes**: U.S. Pat. Pub. No. 2009/0054992 (Ex. 1009), published February 26, 2009. Landes is prior art under §§102(a) and (b).
- **Federspiel**: U.S. Patent No. 8,652,180 (Ex. 1010), filed September 27, 2011 and issued February 18, 2014. Federspiel is prior art under §102(e).

Ground	Claims	Statutory Basis	Description
1	1–4, 6, 8–9	§103	Li in view of Lutz
2	5	§103	Li in view of Lutz and Landes
3	10–11, 20–21, 23–24, 26–27	§103	Hasselman in view of Irving
4	22	§103	Hasselman in view of Irving and Federspiel

An Index of Exhibits is attached. Section VII details the statutory grounds of unpatentability for each of the Challenged Claims, including the relevance of the evidence and the specific portions of the evidence that support the challenge.

Petitioner submits a declaration of Dr. Bruce Werber (Ex. 1003) in support of this Petition in accordance with 37 C.F.R. §1.68.

III. THE ART AND ARGUMENTS IN THIS PETITION WERE NOT PREVIOUSLY BEFORE THE PATENT OFFICE.

The Board should exercise its discretion to institute review of the Challenged Claims. All six Becton Dickinson factors weigh in favor of institution. *Becton, Dickinson, & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017); *see also Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020).

The Board has consistently "held that a reference that 'was neither applied against the claims nor discussed by the Examiner' does not weigh in favor of exercising [] discretion under §325(d)." *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7-11 (PTAB Nov. 5, 2019). Here, prior art references Irving, Lutz, and Federspiel are not cited on the face of the '336 patent. While Patent Owner ("PO") did list Hasselman, Landes, and the published application that led to Li in an IDS, the Examiner neither applied those references against the claims nor discussed them. Thus, the arguments presented herein are not the same or substantially the same as those considered during prosecution, and none of the grounds in this Petition were evaluated during prosecution. The Examiner improperly concluded that the Challenged Claims were not obvious because the Examiner did not have the opportunity to consider the asserted prior art, particularly

in the combinations presented herein. *Bowtech Inc. v. MCP IP, LLC*, IPR2019-00383, Paper 14 at 5 (PTAB Aug. 6, 2019) (petitioner did not need to explain how the Examiner erred "because the Examiner did not consider the combinations of the references asserted in the Petition at all").

IV. CLAIM CONSTRUCTION

Claims in an IPR are construed under the claim construction principles set forth in *Phillips v. AWH Corp*., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). 37 C.F.R. §42.100(b). Petitioner does not believe any terms need be construed to resolve the prior art issues presented in this Petition, and thus identifies no terms for construction for the purpose of this IPR proceeding. In the District Court case, Petitioner and PO exchanged preliminary proposed constructions for some claim terms relevant to disputed issues in that forum. Exs. 1037-38. These constructions are preliminary, and the parties are not scheduled to exchange final proposed constructions until February 3, 2023. Ex. 1032, 7-8.

V. PERSON HAVING ORDINARY SKILL IN THE ART

A POSITA at the time of the alleged invention of the '336 patent would have had a degree in the field of mechanical engineering or bioengineering or a doctorate of medicine, and at least 2-3 years of experience in the design or use of prostheses and/or surgical instruments for use in joint replacement surgeries. Ex. 1003 ¶92. Additional education might compensate for a deficiency in experience, and vice versa. Dr. Werber has been a POSITA since at least December 2012. *Id.* ¶93.

VI. SUMMARY OF PRIOR ART REFERENCES

A. Li

Li is titled "Patient-Specific Instruments for Total Ankle Arthroplasty" and describes "patient-specific instruments for use in a total ankle arthroplasty procedure." Ex. 1005, 1:8-11. Li discloses a cutting guide with guide holes and cut slots that is designed to be inserted into a block and coupled to a bone. *Id.*, 8:24-34; *id.*, 7:49-57, 8:35-55, 11:21-32; 12:54-13:8, Figs. 6, 8-11. The cutting guide is shown below (slots in green and holes in red):

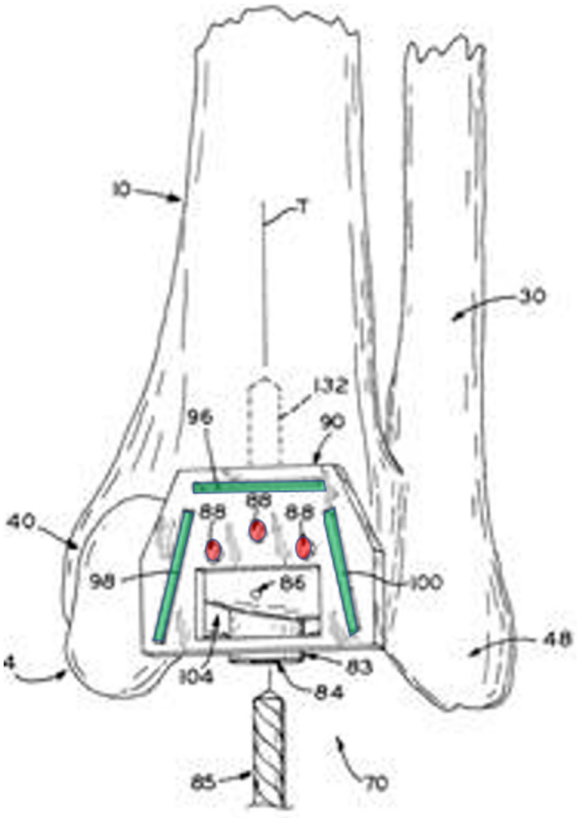


FIG. 9

Id., Fig. 9.[4]

B. Lutz

Lutz is titled "Bone Plating Implants, Instruments and Methods" and generally describes issues associated with proper positioning and placement of bone plates to repair fractured bones. Ex. 1008, 1:47-2:35. To address these problems, Lutz discloses an instrument that includes "radiopaque markers" that can be "superimposed over a fractured bone, and [once] an image of the fracture, such as through the use of fluoroscopy, is acquired, the radiopaque [] markers are visible over the fractured bone in the image." *Id.*, 2:58-63. These radiopaque markers are placed along the length of the instrument, and also surround screw holes to "indicate positions of screw holes" or surround slots that "facilitate[] insertion of a scalpel." *Id.*, 3:7-17. These radiopaque markers "are intended to assist in preoperative planning of the fracture fixation surgery by being visible in a fluoroscopic image, and providing a surgeon with an approximation of where the corresponding bone plate holes would be oriented on the distal femur." *Id.*, 11:48-12:10.

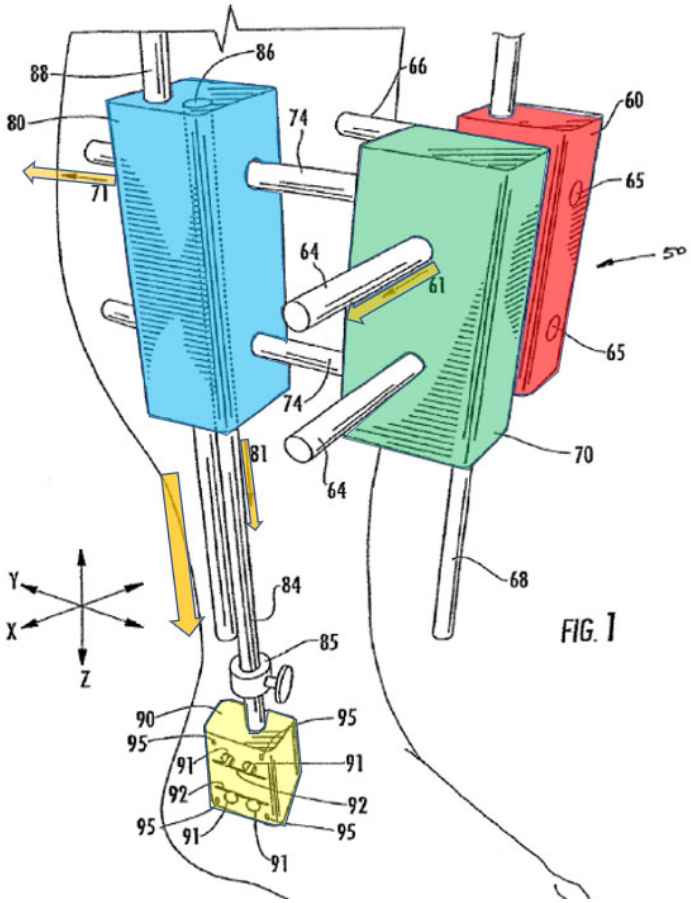
C. Landes

Landes relates to "[a]n implant for use in ankle arthroplasty." Ex. 1009, Title, Abstract. Landes discloses using dovetail joints when coupling components relating to ankle replacement surgery together. *Id.*, [0173]; *id.*, [0079]-[0081].

[4] All colorized figures were annotated by Petitioner.

D. Hasselman

Hasselman describes"a method of preparing an ankle joint for replacement" and "an alignment apparatus that enables such replacement to be performed from a medial position on the ankle." Ex. 1006, 1:18-23. Hasselman discloses an alignment apparatus with an attached cut guide that surgeons position by adjusting different frames of the alignment apparatus. *Id.*, 7:19-24, 54-65; *see also id.*, 7:66-9:7; 10:4-17; Figs. 1-4, 7-9. Figure 1 shows an overview of the alignment apparatus in which the green and blue frames are movable in different directions to align the yellow cut guide:



Id., Fig. 1.

E. Irving

Irving is titled "Extramedullary Fluoroscopic Alignment Guide" and describes a "fluoroscopic alignment guide for use in joint replacement surgery." Ex. 1007, Title, 1:19-20. Irving discloses an alignment guide that includes "radiopaque longitudinal instrument references … that are visible fluoroscopically." *Id.*, 8:4-7. "The radiopaque material provides a radiopaque instrument reference that is sized, shaped and positioned so that the surgeon can simultaneously fluoroscopically view the patient's bone and the radiopaque instrument reference." *Id.*, Abstract.

F. Federspiel

Federspiel discloses an " instrument that attaches to the bone plate and provides at least one radiopaque region to facilitate positioning the bone plate on bone visualized by radiographic imaging." Ex. 1010, Title, Abstract. Federspiel discloses using a targeting guide with radiographic markers "to check, monitor, and improve the position of a bone plate on a bone," where the marker "may be described as a pin and/or a post." *Id.*, 12:28-33, 13:31-51.

VII. THE CHALLENGED CLAIMS OF THE '336 PATENT ARE UNPATENTABLE.

A. Ground 1: Li In View Of Lutz

POSITAs would have found it obvious to combine Li and Lutz, and combined they render obvious Claims 1-4, 6, and 8-9. Ex. 1003 ¶¶98-165.

1. Motivation to Modify Li in View of Lutz

Li discloses a tibial guide for use in ankle replacement surgery. Ex. 1003 ¶99. The tibial guide includes drill holes and cut slots that are used by the surgeon to determine where to drill into or cut the tibia during an ankle replacement surgery. *Id.*, 7:49-57, 8:24-55, 11:21-32, 12:54-13:8, Figs. 6, 8-11. After the guide is created, Li discloses that it is desirable to ensure the tibial guide is "properly aligned with and seated on tibia 10." *Id.*, 10:62-63.

Lutz discloses methods to fluoroscopically visualize features of instruments used to preoperatively align and orient implants used to repair bones, including the tibia. Ex. 1003 ¶101. For example, Lutz discloses a tool for surgeons to locate and align the screw holes of a bone plate using radiopaque markers. Ex. 1008, 11:48-12:10. Lutz discloses that use of radiopaque markers "assist in preoperative planning of the fracture fixation surgery by being visible in a fluoroscopic imagine and providing a surgeon with an approximation of where the corresponding bone plate holes would be oriented." *Id.*, 11:57-62; *see also id.*, 12:7-9 (radiopaque markers permit surgeon to "visualize the position of [the] bone plate and its screw holes as juxtaposed over the fractured bone."). Lutz also discloses that these "radiopaque markings may be formed by the addition of barium" or other methods, "[a]s is known in the art." *Id.*, 11:52-54. Use of fluoroscopic devices for such purposes has been known for a long time; as a 1999 article describes, fluoroscopic devices are "an integral part of the standard equipment used in orthopedic surgery

to provide real-time feedback of bone and surgical tool positions." Ex. 1027, 65. Fluoroscopy provides surgeons with an intraoperative assessment of component position and "it may increase ideal safe zone placement of components." Ex. 1028, Abstract.

POSITAs would have been motivated to add radiopaque markings to the tibial guide of Li in view of the teachings of Lutz and the known advantages of radiopaque markings. Ex. 1003 ¶103; *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006). Though Li states the proper alignment of the tibial guide is desirable, Li does not explicitly disclose mechanisms to ensure the tibial guide is properly aligned beyond "tactile feedback" and visual inspection. Ex. 1005, 8:61-66; Ex. 1003 ¶103. POSITAs would have been motivated to add features to ensure Li's tibial guide is properly aligned with the tibial bone because precisely locating the cut slots and drill guides of Li's tibial guide improves patient outcomes. Ex. 1003 ¶104. Ensuring the cuts and holes are appropriately located in the bone is necessary during ankle replacement surgery because poorly located cuts or holes can lead to increased mobility issues, durability issues, and potential complications. *Id.*

POSITAs seeking to improve the alignment of Li's tibial guide would have found it obvious to look to Lutz because both are directed to repairing deformation of bones, and even more specifically to repairing deformation of tibia bones. *Id.* ¶105. Moreover, as of the '336 patent's priority date, it was well-known to POSITAs that radiopaque markers were useful for aligning surgical instruments, like Li's tibial

guide. *E.g.* Ex. 1035, 9:38-48 ("to ensure that the guide instrument 20 is positioned properly, the main body 22 may include one or more fluoroscopic visualization markers 26 that may be used to orient the guide instrument 20 relative to the bone to be treated"); Ex. 1007, 8:35-38 ("the surgeon can adjust the position of the alignment guide [] until the radiopaque instrument references [] are in the desired position relative to the anatomic landmarks."); *Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.,* 424 F.3d 1293, 1321 (Fed. Cir. 2005). In addition, adding multiple fluoroscopic cues would have been a common-sense and obvious design choice because it permits surgeons to orient and locate Li's tibial guide using multiple markers for precision, aiding in proper position and placement. Ex. 1003 ¶106. Further, given the long history of radiopaque markers used for this purpose (*see* Section I.A), adding such markers were within the technical grasp of POSITAs, and POSITAs would have anticipated success in using these markers for their known purpose. Ex. 1003 ¶107. Thus, POSITAs would have been motivated and found it obvious to add radiopaque markers to Li's tibial guide based on Lutz. *Id.* ¶108.

2. <u>Claim 1</u>

a) [Preamble] A surgical guide, comprising:

To the extent the preamble is limiting, Li discloses a surgical guide (tibial guide 70) for use in ankle replacement surgery. Ex. 1005, 7:49-9:3, Figs. 6, 8-11.

Tibial guide 70 includes two primary components: patient-specific referencing portion 74 and resection guide portion 90. *Id.*, 7:49-52, 8:23-26. These

two components "may be integral with or modular and separately attached to" each other. *Id.*, 8:24-27. Depicted below is tibial guide 70, including the patient-specific referencing portion (blue), the resection guide portion (orange), and the slots forming the cutting guide (purple), attached to the tibia (yellow):

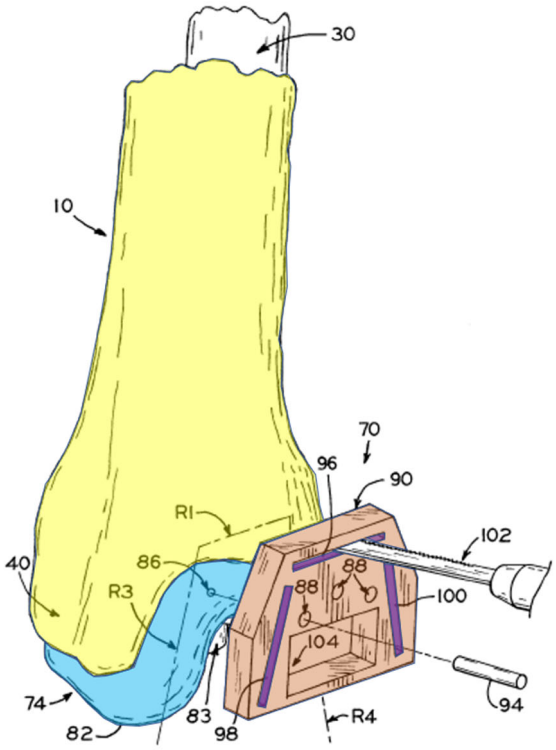


FIG_10

Id., Fig. 10, *see also id.*, 1:36-57, Figs 6, 8-9, 11; Ex. 1003 ¶110.

b) [1.1]: a body configured to be inserted into a block that is configured to be coupled to a bone,

Li discloses the tibial guide includes a body (resection guide portion 90) that is configured to be inserted into a block (patient-specific referencing portion 74) that is configured to be coupled to a bone (tibia 10). Ex. 1003 ¶111. Li discloses that patient-specific referencing portion 74 is manufactured to "substantially conform[]

to and is a negative of surfaces and/or landmarks of the distal tibia" such that it anatomically contours to and fits on the tibial bone. Ex. 1005, 7:49-8:7, 8:19-23, 8:61-66. Depicted below is the patient-specific referencing portion (blue) coupled to the bone (yellow):

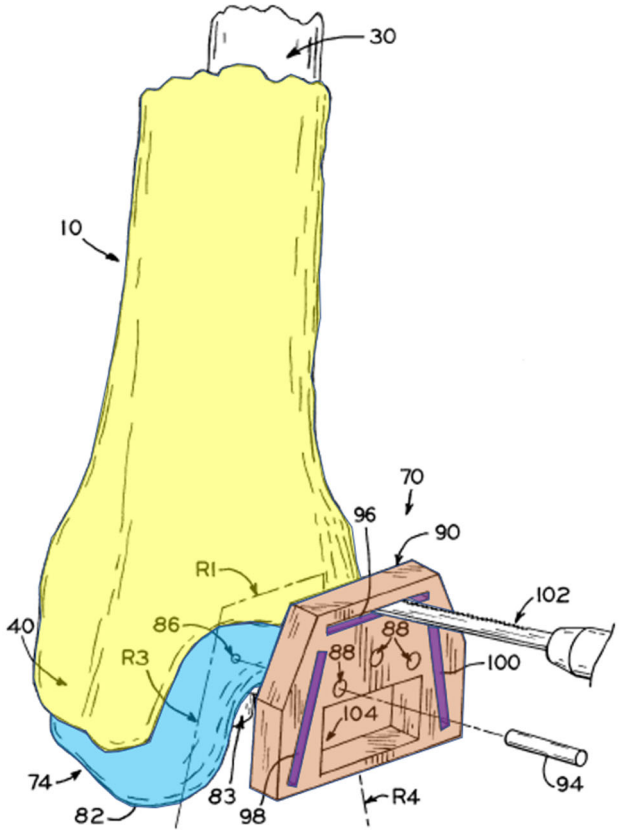


FIG_10

Id., Fig. 10; Ex. 1003 ¶112.

Li further discloses that resection guide portion 90 is configured to be inserted into patient-specific referencing portion 74 via shafts 92. Ex. 1005, 8:27-29. Depicted below is the patient-specific referencing portion (blue) and the resection guide portion (orange) and the shafts (green):

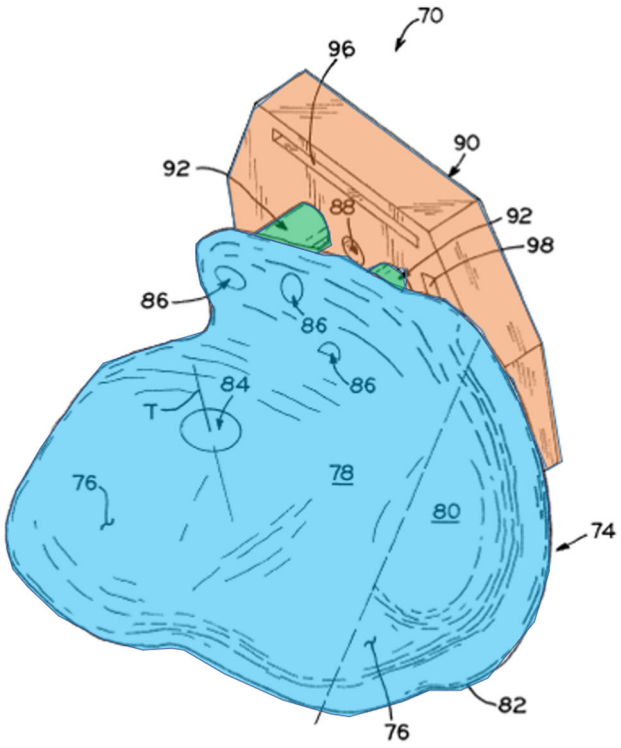


FIG. 8

Id., Fig. 8; Ex. 1003 ¶113.

c) *[1.2]: the body defining at least a first guide hole and a second guide hole,*

Li discloses that the body (resection guide portion) includes at least two guide holes (apertures 86 and 88). Ex. 1003 ¶¶114-115. Li discloses that "each [] guide[] … may be temporarily secured into position with fasteners such as pins, screws" (Ex. 1005, 7:14-16) and that resection guide portion 90 includes apertures 88 that "are sized to receive a pin such as pin 94 (FIG. 10) to attach guide 70 to bone when guide 70 is seated against distal tibia 10" (*id.*, 8:29-31). Because the apertures guide a pin used to attach guide 70 to the bone, the apertures are guide holes. Ex. 1003 ¶115. Figures 9 and 10 below depict a pin 94 going through aperture 88 (red):

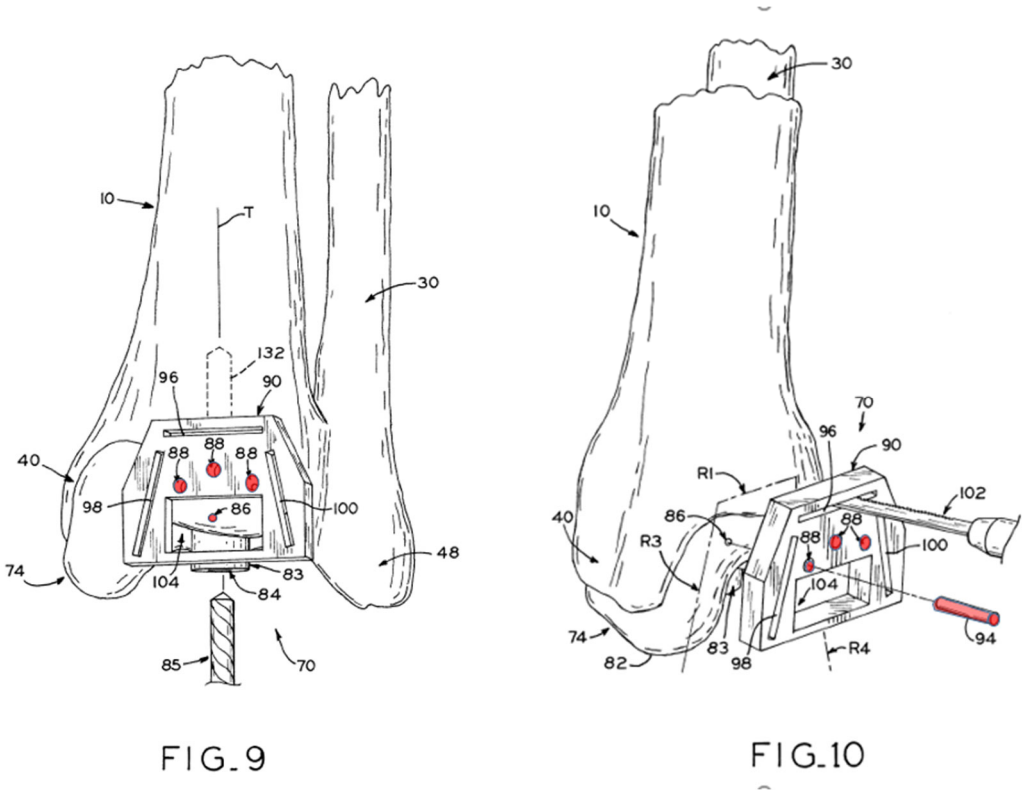


FIG. 9 FIG. 10

Ex. 1005, Figs. 9-10; *see also id.*, 1:48-53, 8:28-32, 8:53-55, Figs 6, 8, 11; Ex. 1003 ¶115.

d) [1.3]: wherein the first and second guide holes are sized and configured to receive a first surgical tool for forming pilot holes in the bone and;

Li discloses that the first and second guide holes (apertures) are sized and configured to receive pins 94 to "temporarily secure guide 70 to tibia 10." Ex. 1005, 8:48-55; *see also id.*, 8:28-32. Li discloses that "holes may be drilled [through the pin guide holes] for use in locating and placing pins onto the respective bone." Ex. 1005, 7:35-38; *see also id.*, 1:49-53, 8:53-55. Thus, Li discloses using a drill (a first surgical tool) to drill a pilot hole in the tibia through the apertures prior to inserting the pins. Ex. 1003 ¶118. Drilling pilot holes such that the pin naturally sits in the

drilled hole was well-known and one of the most commonly used methods for coupling guides to bones. *Id.* ¶¶118-119; Ex. 1005, 7:35-38; Ex. 1024, 11:60-12:11.

e) [1.4]: wherein the body comprises radiopaque surfaces defining the first and second guide holes; and

Li in view of Lutz renders obvious a body (resection guide portion) having radiopaque surfaces defining the first and second guide holes (apertures). Ex. 1003 ¶¶120-125. As described above, POSITAs understood that radiopaque materials were useful in combination with fluoroscopy when precise alignment was desirable. *See* Section VII.A.1. Li's guide holes are an example of a situation where precise alignment was desirable, as they are designed to be located at a specific location for resecting the tibia. Ex. 1005, 7:36-46. Lutz discloses using radiopaque markers on the surface of a surgical instrument to fluoroscopically identify screw holes. Ex. 1008, 11:49-12:2. Li's guide holes serve a similar purpose as Lutz's screw holes (attaching an instrument to a bone), and defining Li's guide holes using radiopaque material in the same manner as described by Lutz would further the purpose of ensuring proper alignment. Ex. 1003 ¶122. Lutz also discloses that it was "known and recognized in the art" to use "fluoroscopy, or any other imaging process … at any time during [the] procedure, as deemed appropriate, to provide feedback imaging as to the orientation" of components with radiopaque materials. Ex. 1008, 19:42-45. Thus, POSITAs would have been motivated to add radiopaque material, as taught by Lutz, to surround the apertures of Li so that surgeons would be able to

locate these apertures in relation to the bone using fluoroscopy to aid in precise placement. Ex. 1003 ¶124. Because using radiopaque materials to achieve the goal of precise alignment was well-known, POSITAs further would have expected to succeed in modifying Li's resection guide portion to surround the apertures with radiopaque material such that the radiopaque surface defines the apertures. *Id.* ¶125.

f) [1.5]: a sizing pattern coupled to the body,

Li discloses a sizing pattern (cut slots 96, 98, and 100) coupled to the body (resection guide portion). Ex. 1003 ¶¶126-129. The '336 Patent states that "sizing patterns" at least "show[] the size and location of one or more resectioning cuts corresponding to the holes to be drilled using the drill guide." Ex. 1001, 17:16-19. Li discloses that "resection guide portion 90" contains a sizing pattern that shows the size and location of resectioning cuts because it "has a plurality of cut referencing surfaces, including a proximal cut slot 96, a medial cut slot 98, and a lateral cut slot 100, which together with a bottom surface of resection guide portion 90 define a trapezoidal peripheral shape." Ex. 1005, 8:35-39; *see also id.*, 8:35-47, 11:27-32, Figs. 6, 8, 9, 11. Li discloses that "[t]he trapezoidal peripheral shape formed by cut slots 96, 98, and 100 in turn defines the periphery of a tibial portion that is resected from tibia 10." *Id.*, 8:39-41. As the cut slots are located on resection guide portion 90, the sizing pattern is coupled to the body. Ex. 1003 ¶129.

g) [1.6]: the sizing pattern having a size and being coupled to the body at a location for estimating resectioning cuts to be made to the bone,

Li discloses that the sizing pattern (cut slots) has a size and are at a location for estimating resectioning cuts to be made to the bone (tibia). Ex. 1003 ¶¶130-132. Li's cut slots are intended to "guide an instrument such as reciprocating saw 102 (FIG. 10) to resect the tibial portion from tibia 10 along respective resection planes R1, R3, and R4." Ex. 1005, 8:43-45. Thus, Li discloses that cut slots 96, 98, and 100 are placed at locations for estimating resectioning cuts to be made to the tibia bone, as the surgeon uses these cut slots when adjusting the location of the guide to estimate where the cuts will be made. *Id.*, 8:35-45, 8:53-58, 10:48-52; Ex. 1003 ¶131. Additionally, all three cut slots have a length and a width to ensure the reciprocating saw can fit through the slots and are located on the body, and thus the cut slots have a size and are coupled to the body. Ex. 1003 ¶132. Figure 10 below depicts the cut slots (purple):

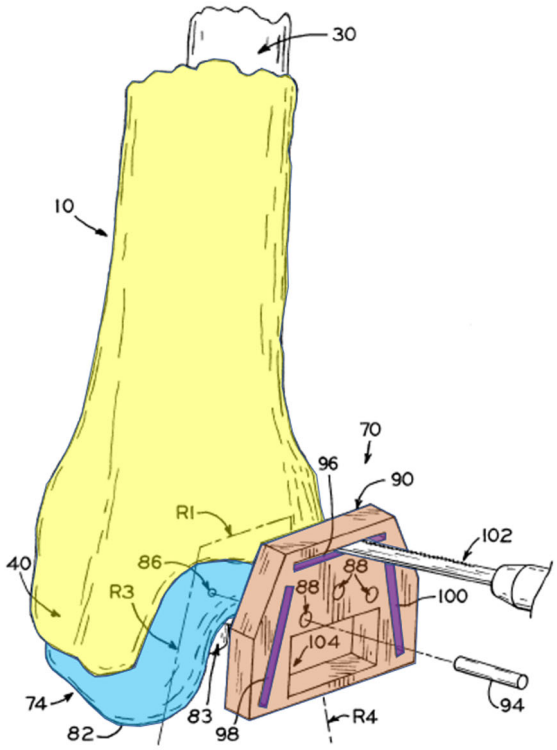


FIG_10

Ex. 1005, Fig. 10; *see also id.*, Figs. 6, 8-9, 11; Ex. 1003 ¶132.

h) [1.7]: wherein the sizing pattern comprises at least two radiopaque lines each comprising a length dimension configured to provide a fluoroscopic cue for positioning the body.

Li in combination with Lutz renders obvious adding radiopaque outlines to cut slots 96, 98, and 100, and thus renders obvious a sizing pattern comprising at least two radiopaque lines having a length dimension configured to provide a fluoroscopic cue for positioning the body (resection guide portion). Ex. 1003 ¶¶133-136. POSITAs would have understood and found it obvious, based on Lutz, to define the cut slots of Li with radiopaque surfaces for the same reasons discussed above regarding defining the guide holes of Li with radiopaque surfaces. *See* Sections VII.A.1, VII.A.2.e. The cut slots are similar to Li's guide holes, in that

both are designed to provide an indication to the surgeon as to where to locate a component outside the body to ensure the component is accurately placed in relation to the tibia inside the body. Ex. 1003 ¶134. Thus, just as with Li's guide holes, precise alignment of Li's cut slots would be desirable to ensure the reciprocating saw is precisely located when cutting into the tibia bone. Ex. 1005, 7:36-46; Ex. 1003 ¶135. Indeed, Lutz explicitly discloses radiopaque markers that surround slots that "facilitate[] insertion of a scalpel" and using radiopaque markers on the surface of a surgical instrument to fluoroscopically identify features that are desirable to orient relative to a bone. Ex. 1008, 3:7-17, 11:49-12:2. POSITAs would have been motivated and found it obvious to define Li's cut slots using radiopaque material to ensure proper alignment for all the same reasons described above, such that the resulting surrounding radiopaque material would have a length dimension. Ex. 1003 ¶136.

3. Claim 2

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [2.1]: further comprising a plurality of pin holes sized and configured to receive a plurality of pins to couple the body to the bone.

Li discloses a plurality of pin holes (apertures) configured to receive a plurality of pins to couple the body (resection guide portion) to the bone (tibia). *See* Section VII.A.2.c. In addition, Li discloses that "each of the tibial [] guides of the present disclosure may include pin guide holes through which holes may be drilled

for use in locating and placing pins onto the respective bone." Ex. 1005, 7:35-38; *see also id.*, 1:49-53, 8:53-55; Ex. 1003 ¶¶138-139.

4. Claim 3

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [3.1]: further comprising a cut guide comprising a plurality of slots configured to position a cutting tool to cut the bone, wherein the size of the slots correspond to the sizing pattern.

Li renders obvious a cut guide comprising a plurality of slots, the size of which correspond to the sizing pattern, that are configured to position a cutting tool to cut the bone. Ex. 1003 ¶¶141-146. Li discloses a sizing pattern (cut slots) configured to position a reciprocating saw to cut the tibia. *See* Sections VII.A.2.f-g. Li further discloses that the tibial guide "may then be removed and a separate cut guide, which may be either a patient specific cut guide or a non-patient specific cut guide, may be fitted over the placed pins." Ex. 1005, 7:38-42, 7:50-55, 10:30-41 (tibial guide "may be modified to include additional structures such as … linked cut guides, and adjustable cut or drill guides"). To attach the separate cut guide, pins are inserted through pin guide holes in the tibial guide, and then the separate cut guide is "fitted over the placed pins." *Id.*, 7:38-41. In view of these disclosures in Li, POSITAs would have understood and found it obvious that the separate cut guide would correspond to the sizing pattern (cut slots) and therefore would also contain multiple slots, of the same size, that are configured to position a reciprocating saw to cut the

tibia. Ex. 1003 ¶143. POSITAs would have found it obvious that Li's separate cut guide would correspond to the sizing pattern because separate guides were known to be useful to address angular deformities in the bone, unusual patient anatomy (e.g. a patient with a larger bone may require a separate guide with longer slots or larger holes that correspond to the shorter slots and holes), or to create additional cuts that can only be performed after the initial cuts or holes indicated by the sizing pattern are made. *Id.* ¶¶144-146.

5. Claim 4

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [4.1]: wherein the body comprises a plastic material and

Li renders obvious that the body (resection guide portion) comprises a plastic material. Li discloses that "referencing portion 74 [] may be made of a resilient material such as plastic" (Ex. 1005, 8:66-9:1), but does not explicitly disclose materials to use to create the resection guide portion. POSITAs, however, would have found it obvious to construct resection guide portion 90 from plastic for the same reason Li discloses that referencing portion 74 is made of plastic. Ex. 1003 ¶148. Plastic materials can be subjected to standard hospital sterilization procedures without substantial degradation. *Id.* ¶149; *see also, e.g.,* Ex. 1007, 15:46-49; Ex. 1020, Chapter 3. Moreover, POSITAs would have understood that medical device manufacturers have the capability to manufacture instruments with plastic, plastic

manufacturing techniques are standard in the industry, orthopedic instruments are commonly constructed with plastic materials, and plastic is a cost-effective method of manufacture. Ex. 1003 ¶150. Thus, POSITAs would have been motivated and found it obvious to manufacture Li's resection guide portion using plastic materials. *Id.* ¶151; *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1340 (Fed. Cir. 2020)

c) *[4.2]: the first guide hole, the second guide hole, and the sizing pattern comprise a metal material.*

Li renders obvious this limitation. Ex. 1003 ¶¶152-154. Li discloses that while referencing portion 74 "may [] be made of a resilient material such as plastic," there may also be "metal inserts [] for guidance of the saw blade." Ex. 1005, 8:66-9:3. Li discloses use of metal inserts for guiding the saw blade because metal is less likely to be deformed by a saw. Ex. 1003 ¶152. POSITAs would have understood that it is advantageous for guide holes and sizing patterns to comprise metal materials for the same reason that Li discloses using metal inserts for guidance of the saw blade: the use of a saw blade or drill subjects these features to additional stresses that may cause unwanted deformation for less durable material like plastics. Ex. 1003 ¶153. Therefore, POSITAs would have found it obvious to construct the guide holes and sizing pattern of Li's resection guide portion 90 with metal in order to make those features more durable, and would have expected to succeed in doing so in light of the long history of manufacturing components like these from metal. *Id.* ¶154.

6. Claim 6

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [6.1]: wherein the body comprises a plurality of pin holes configured to receive a plurality of pins to couple the body to at least the tibia.

Li discloses a body with a plurality of pin guide holes configured to receive a plurality of pins. *See* Section VII.A.2.c. Li further discloses that the pins "temporarily secure guide 70 to tibia 10." Ex. 1005, 8:48-55; *see also id.*, 1:49-53, 7:14-16, 7:35-38; Ex. 1003 ¶156.

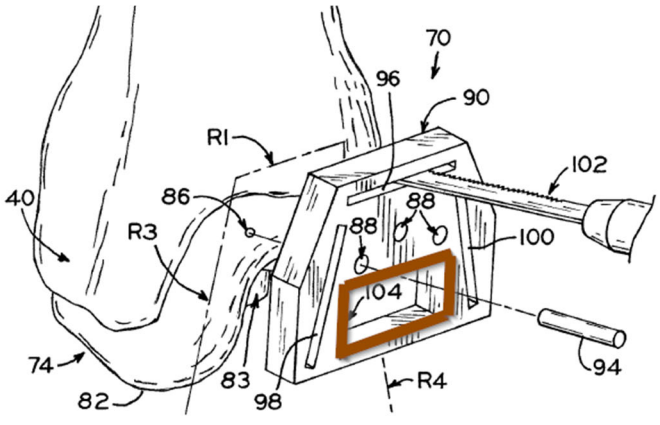
7. Claim 8

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [8.1]: wherein the at least two radiopaque lines comprise at least two parallel radiopaque lines.

Li in view of Lutz renders obvious this limitation. Ex. 1003 ¶¶158-163. Li discloses a rectangular viewing area 104, outlined below in brown:



Ex. 1005, Fig. 9; Ex. 1003 ¶158. POSITAs would have found it obvious to outline viewing area 104 with radiopaque material to provide another fluoroscopic cue to aid in orienting and position Li's guide. *Id.* Viewing area 104 is an obvious location to add radiopaque lines because it is already a defined area on the guide, and POSITAs would have understood that outlining that area with radiopaque material would add two parallel and orthogonal lines that could be used to orient and align the guide, or could be used in conjunction with other radiopaque lines (e.g., the lines outlining the cut slots) to assess the relative orientation of features of the guide for the same purpose. Ex. 1003 ¶159.

Alternatively, POSITAs would have found it obvious to add a radiopaque line at the bottom of the resection guide portion, parallel to cut slot 96. Ex. 1003 ¶160. Li discloses creating a trapezoidal-shaped cut in the tibia bone in which the top and bottom are parallel. Ex. 1005, Fig. 11; Ex. 1003 ¶160. The bottom of the resection guide portion thus indicates where the bottom of the trapezoidal shape will be located once the portion of the tibia bone is cut away. Ex. 1003 ¶160. POSITAs would have found it obvious to provide a fluoroscopic cue to indicate the bottom of the trapezoidal shape for the same reasons discussed above: it would aid the surgeon in orienting and aligning the guide to ensure accurate cuts. *Id.* ¶161. As the bottom of the resection guide portion and the outline of the cut slot 96 are parallel, there would be two parallel radiopaque lines. *Id.* ¶162. In either instance, these radiopaque lines

would be part of a sizing pattern, have a length dimension, and provide a fluoroscopic cue for the positioning the guide. Ex. 1003 ¶163.

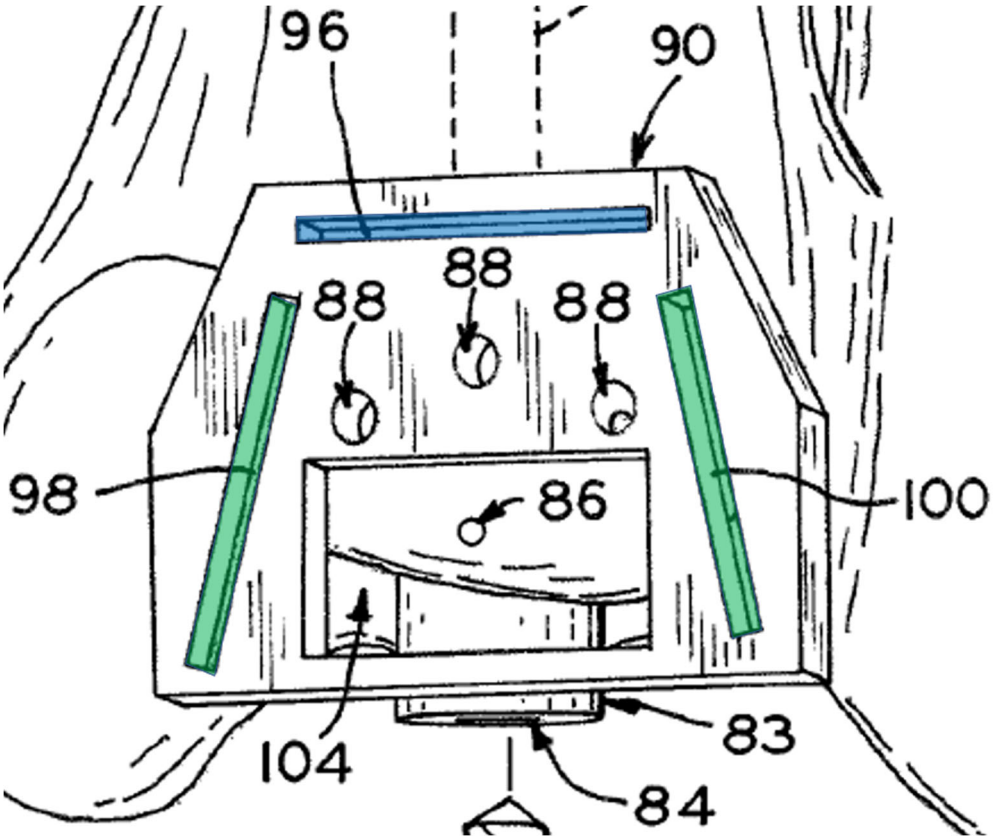
8. Claim 9

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [9.1]: wherein the at least two radiopaque lines comprise a first line extending generally in a medial-lateral direction, a second line extending generally in a proximal-distal direction, and a third line extending generally in a proximal-distal direction.

Li in combination with Lutz renders obvious this limitation. Ex. 1003 ¶165. As discussed above, it would have been obvious to outline the cut slots of Li with radiopaque materials to aid in aligning the cut slots. *See* Section VII.A.2.h. This would result in one radiopaque line extending generally in a medial-lateral direction (blue) and two radiopaque lines extending generally in a proximal-distal direction (green), as depicted below:



Ex. 1005, Fig. 9; Ex. 1003 ¶165.

B. Ground 2: Li In View Of Lutz And Landes

1. Motivation to Modify Li in view of Lutz and Landes

Li in view of Lutz and Landes renders obvious claim 5. As explained above, POSITAs would have been motivated to use the radiopaque teachings of Lutz with the surgical guide taught by Li. *See* Section VII.A.1. POSITAs further would have understood the benefits of using dovetail joints, as taught by Landes, in Li's surgical guide as modified by Lutz, and would have been motivated to do so.

Connecting two components via a dovetail joint is a well-known technique. Ex. 1003 ¶168. Dovetail joints are easy to create and provide a strong connection

between two components; indeed "[t]he dovetail joint technique probably pre-dates written history." Ex. 1031; Ex. 1003 ¶¶168-169. Landes discloses using dovetail connections to couple and connect components used in ankle replacement surgery. Ex. 1009, [0079]-[0083], [0173], Figs. 31, 34. Because dovetail joint connections are known to be easy to create and provide strong connections, POSITAs would have been motivated to use these connections and would have expected to succeed in doing so given the long history of dovetail joints. Ex. 1003 ¶¶170-171.

2. Claim 5

a) The surgical guide of claim 1,

Li in view of Lutz renders claim 1 obvious. *See* Section VII.A.2.

b) [5.1]: wherein the body comprises a dovetail extension configured to be coupled to a dovetail joint of the block.

Li in combination with Lutz and Landes discloses this limitation. Ex. 1003 ¶¶173-176. Landes discloses that dovetail connections may be used to couple and connect components used in ankle replacement surgery. Ex. 1009, Title, [0079]-[0083], [0173], Fig. 31 (prosthesis including dovetail lock), Fig. 34 (dovetail joint in talar implant embodiments). Li's body and block are connected, and POSITAs would have known that one obvious design choice for connecting two components such as a body or block is a dovetail joint, which includes a dovetail extension at one end. Ex. 1003, ¶175. Adding a dovetail extension to connect the body and block such that surgeons would be able to easily connect and couple them to other

component, and would have expected succeed in doing so because dovetail joints were known to achieve these goals. Ex. 1003 ¶¶175-176; Section VII.B.1.

C. Ground 3: Hasselman In View Of Irving

POSITAs would have found it obvious to combine Hasselman and Irving, and the combination of these two references disclose all elements of Claims 10-11, 20-21, 23-24, and 26-27. Ex. 1003 ¶¶177-271.

1. Motivation to Modify Hasselman in View of Irving

POSITAs would have found it obvious to combine Hasselman and Irving to arrive at the claimed invention for a variety of reasons. Ex. 1003 ¶177. Both Hasselman and Irving are directed to alignment guides for ankle joint replacements. Ex. 1003 ¶178. Hasselman discloses techniques and instruments for "preparing an ankle joint for replacement," including "an alignment apparatus that enables such replacement to be performed from a medial position on the ankle." Ex. 1006, 1:18-22. Irving is similarly directed to an "alignment guide for use in joint replacement surgery" that can be used "[f]or ankle joint replacement." Ex. 1007, 1:19-20, 6:37-40. POSITAs would have naturally looked to improve an alignment guide for ankle joint replacement as disclosed by Hasselman using techniques and teachings from other alignment guides for ankle joint replacements, such as Irving. Ex. 1003 ¶179.

Hasselman also discloses that it was desirable in ankle joint replacement surgeries to limit the amount of bone that is removed and to avoid "loosening of the components, instability, loss of bone support, subsidence, inadequate motion and

noticeable scarring." Ex. 1006, 2:7-12. To address these known problems, Hasselman discloses an alignment guide to position cutting slots "to ensure the proper cut once the cutting guide [] is aligned." *Id.*, 10:1-3. Similarly, Irving discloses that "[p]roper alignment is also significant in the case of … ankle protheses" surgery. Ex. 1007, 2:27-31. Irving states accurate alignment of cutting guides and implants are "paramount" and its goal is to "address[] the need for optimizing alignment of the surgical instruments prior to making a cut to the bone." *Id.*, 2:35-38; *see also id*., 2:26-35. Thus, POSITAs would have found it obvious to look toward Hasselman and Irving to achieve the "paramount" goal of ensuring proper alignment in ankle replacement surgery. Ex. 1003 ¶¶180-182.

To achieve proper alignment of cutting guides, Irving discloses using "radiopaque instrument references that can be viewed fluoroscopically and compared to the bone, which can be viewed through radiolucent portions of the alignment guide." Ex. 1007, 6:21-24. Irving discloses that "the surgeon can adjust the position of the alignment guide [] until the radiopaque instrument references [] are in the desired position relative to the anatomic landmarks." *Id.*, 8:35-38; *see also id.*, 9:24-33, 13:21-29, 15:33-41, 16:15-62.

POSITAs would have been motivated and found it to be an obvious design choice to add radiopaque references to the alignment guide disclosed by Hasselman to achieve the same purpose that Irving discloses for radiopaque references: to permit the surgeon to adjust the position of the alignment guide to the desired

position. Ex. 1003 ¶184; *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1375 (Fed. Cir. 2020). POSITAs would have found radiopaque references to be desirable because they permit surgeons to make more accurate cuts, which addresses the known problems identified by Hasselman. Ex. 1006, 2:7-12; Ex. 1003 ¶185. Further, surgeons have historically used radiopaque markers with fluoroscopy to aid in positioning or aligning surgical components. *Id.*, ¶¶185-186 For example, a 1999 article described fluoroscopic devices as "an integral part of the standard equipment used in orthopedic surgery to provide real-time feedback of bone and surgical tool positions." Ex. 1027, 65. Fluoroscopy provides surgeons with an intraoperative assessment of component position and "it may increase ideal safe zone placement of components." Ex. 1028, Abstract.

POSITAs understood a variety of materials were known to be useful as radiopaque markers, including stainless steel or other metals. Ex. 1003 ¶187; *see also* Ex. 1007, 16:15-16. The properties of these radiopaque materials, and their use in surgical instruments, were well-known as of the priority date, and POSITAs would have expected to succeed in adding such radiopaque materials to the alignment guide disclosed by Hasselman. Ex. 1003 ¶187. In light of the known advantages of using radiopaque materials to position surgical devices, POSITAs would have been motivated to to add radiopaque markers to Hasselman's alignment guide based on Irving, and would have expected to succeed in doing so. *Id.*

2. Claim 10

a) [Preamble] An adjustable guide assembly comprising:

To the extent the preamble is limiting, Hasselman discloses an adjustable guide assembly (cutting alignment apparatus 50) that adjusts the position of a cutting guide. Ex. 1003 ¶188; Ex. 1006, 2:24-43; *see also id.*, 2:44-54, Abstract, 2:65-3:28, 5:62-6:9, 7:19-9:7, 13:13-25, Figs 1-4, 7-11, 18, 20. The frames of the cutting alignment apparatus (red) and cutting guide (yellow) are depicted below:

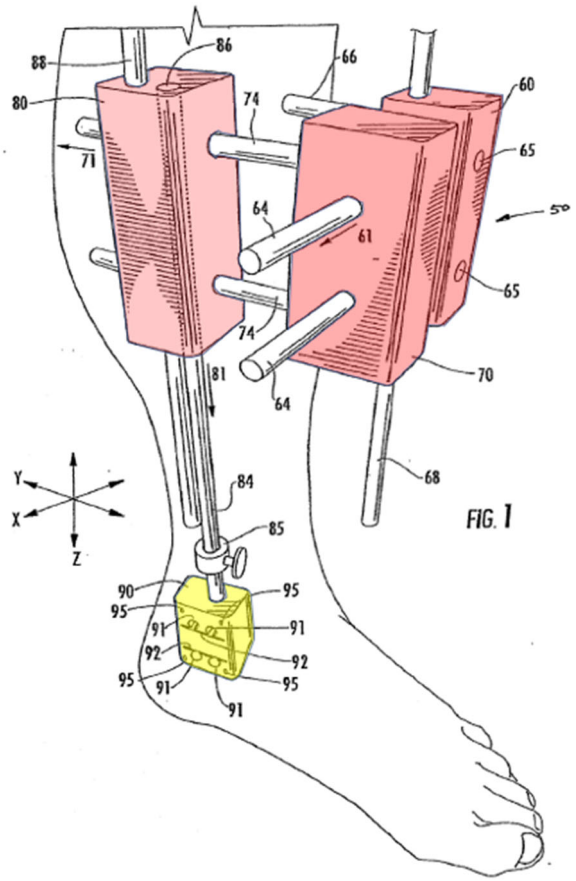
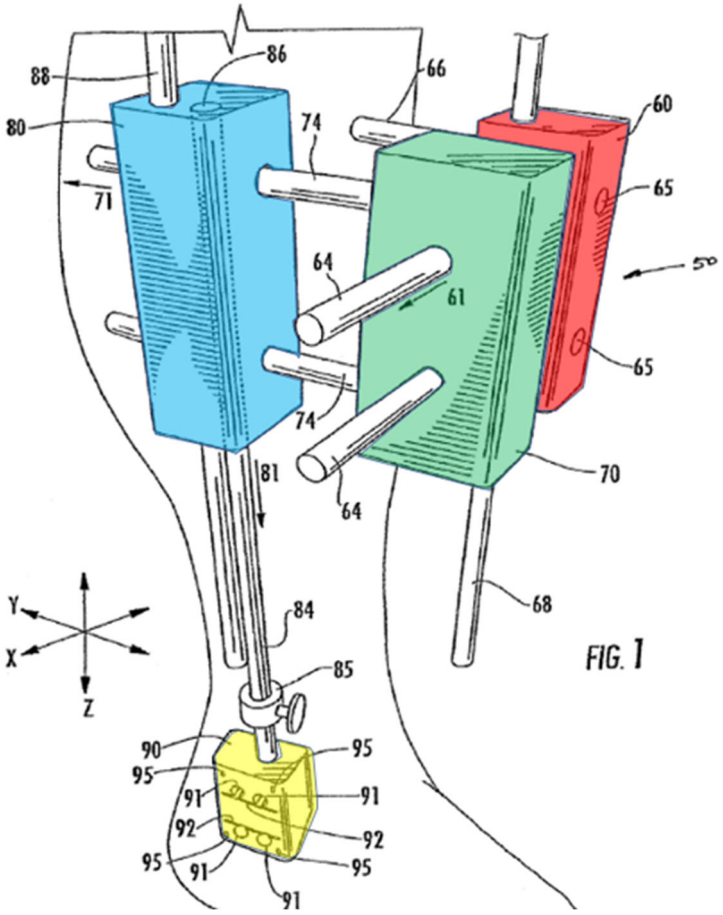


FIG. 1

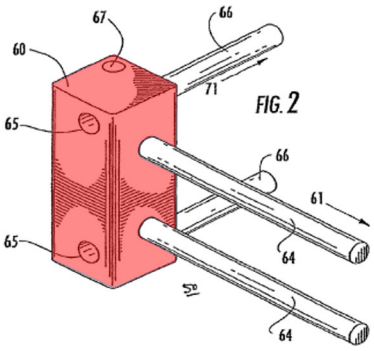
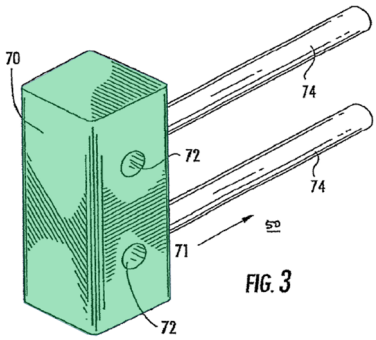
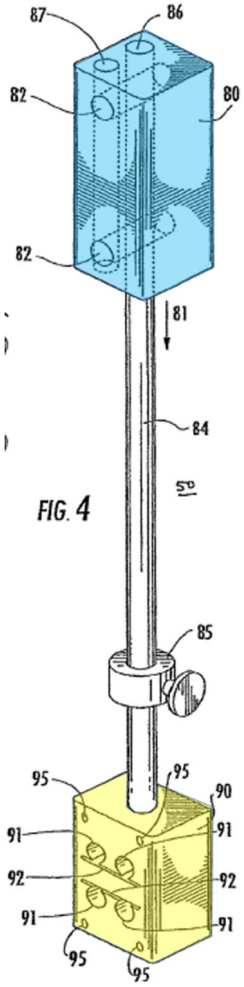
Ex. 1006, Fig. 1, 3:46-48; Ex. 1003 ¶188.

b) [10.1]: one or more positionable frames configured to provide at least proximal-distal and medial-lateral adjustments; and

Hasselman discloses one or more positionable frames (second positioner 70 and third positioner 80 including third rod 84). Ex. 1003 ¶¶189-198. Depicted below in Figure 1 is a first positioner (red), second positioner (green), and third positioner (blue):



Ex. 1006, Fig. 1; Ex. 1003 ¶189. The positioners may be unitary or separable (as depicted in Figures 2-4). Ex. 1006, 7:28-35.

First Positioner	Second Positioner	Third Positioner
 FIG. 2	 FIG. 3	 FIG. 4

Hasselman discloses that the second and third positioners are adjustable positionable frames. Ex. 1003 ¶191. Hasselman discloses that first positioner is positioned over the tibia in a "desired aligned orientation" and secured in place using "securing members 63," which may include "pins, nails or screws." Ex. 1006, 8:15-28. The second positioner is then connected to the first positioner. *Id.*, 8:29-34, 45-49. Once the first and second positioners are connected, the second positioner is "adjustably engaged with the first positioner 60 such that the second positioner 70

may be translated along first rods 64 to be positioned appropriately for the overall alignment of the cutting alignment apparatus 50." *Id.*, 8:47-54; *see also id.*, 7:36-48, 8:41-47. As depicted below, the second positioner is adjustable along direction 61, which is a medial-lateral direction, i.e., closer to or further away from the center line of the body:

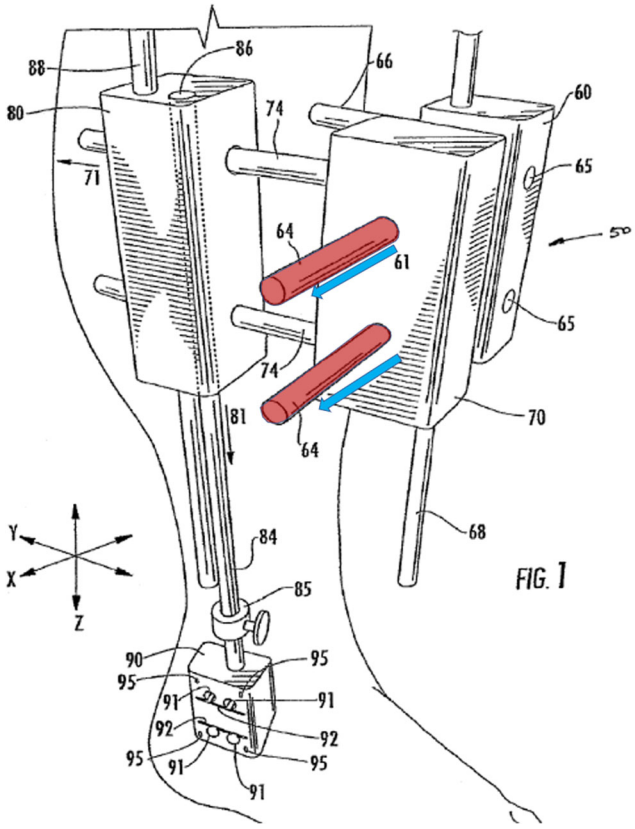
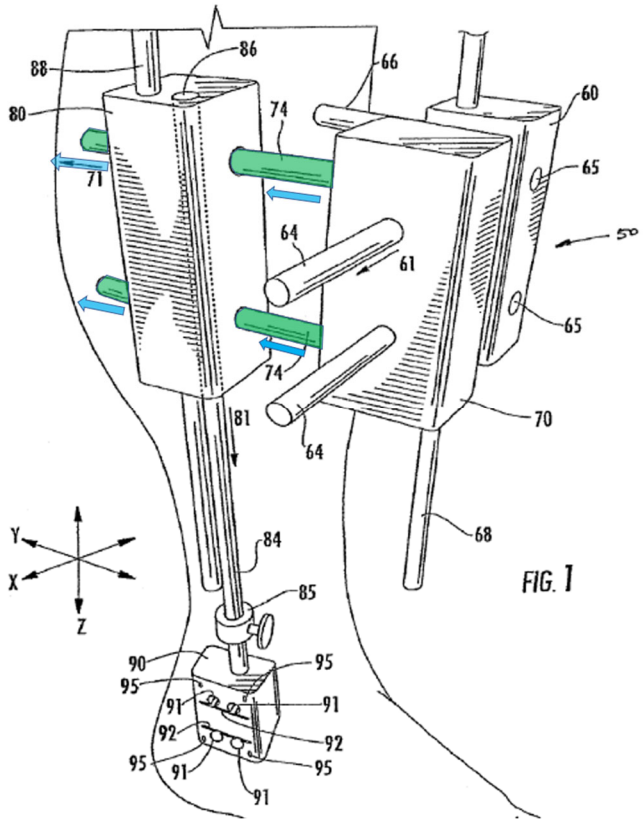


FIG. 1

Id., Fig. 1; Ex. 1003 ¶192.

Hasselman discloses that the third positioner is then "also [] adjustably engaged with the second positioner 70 in a similar manner as the connection between the first and second positioners 60, 70 providing translation of the third positioner 80 in order to properly position the third positioner 80 for the overall alignment of the cutting alignment apparatus 50." Ex. 1006, 8:59-9:7 ("third positioner 80 has

third apertures 82 extending through the third positioner 80 in the second direction 71"); *see also id.*, 7:36-48 ("second direction 71 is also indicated with an arrow"). As depicted below, the third positioner is adjustable along direction 71, which is a posterior-anterior direction, i.e., closer to or further away from the front of the body:



Id., Fig. 1; Ex. 1003 ¶194.

Finally, Hasselman discloses that "third positioner 80 may have a cutter alignment rod 88 positioned within a cutter alignment rod aperture 87 … positioned through the third positioner 80 generally vertically or in a direction with reference to the Z axis." *Id.*, 9:29-35. As shown in Figure 1, adjusting the third positioner 80 along the cutter alignment rod 88 or adjusting rod 84 is done in a proximal-distal direction, i.e., closer or further away from the heart:

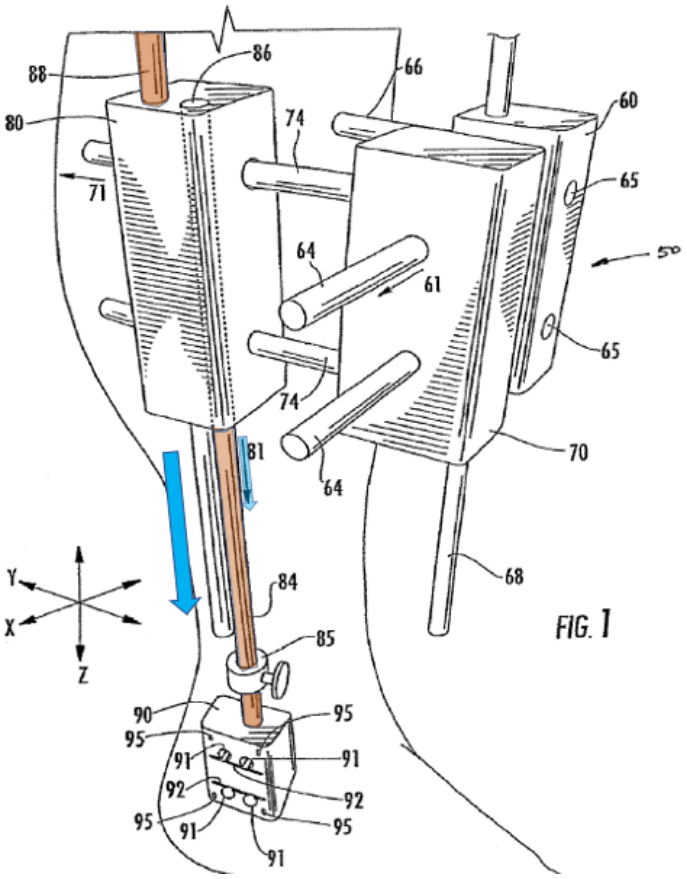
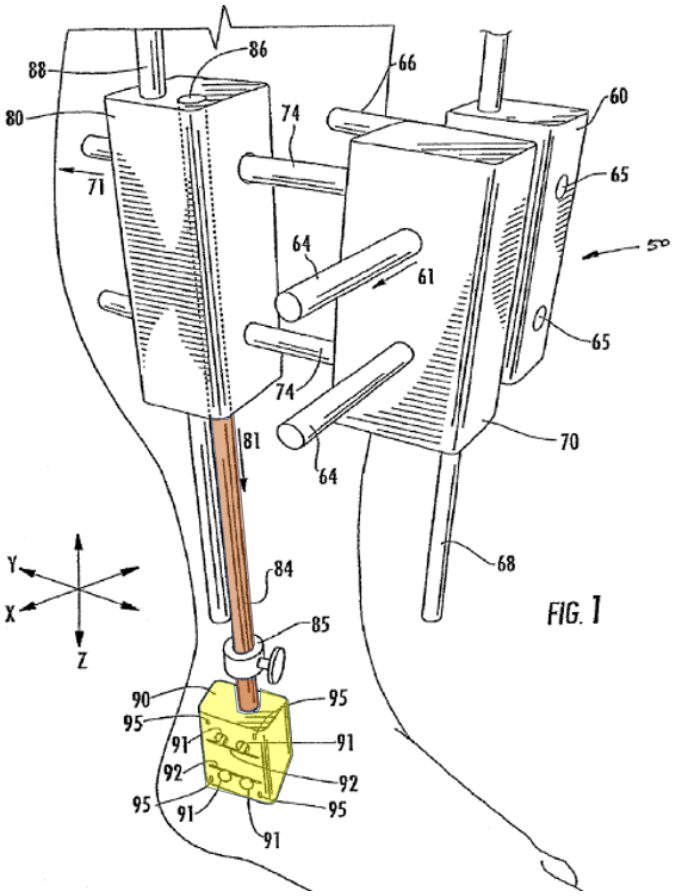


FIG. 1

Ex. 1006, Fig. 1; Ex. 1003 ¶195. Hasselman also discloses third rod 84 connected to the third positioner, at the end of which is cutting guide 90. Ex. 1006, 9:9-13. This is shown below, with the rod in orange and the cutting guide in yellow:



Id., Fig. 1; Ex. 1003 ¶196. This rod permits the cutting guide to "be in communication with the third positioner 80 such that the cutting guide 90 may be adjusted, or translated, along at least the Z axis." Ex. 1006, 9:14-18; *see also id.*, 7:36-48. Thus, both the rod and third positioner are adjustable along the Z axis. Ex. 1003 ¶197. As a result, Hasselman discloses one or more positionable frames configured to provide adjustments in at least three directions, including the proximal-distal and medial-lateral directions. Ex. 1003 ¶198.

c) [10.2]: a guide coupled to the one or more positionable frames such that adjustment of at least one of the one or more positionable frames changes the position of the guide,

Hasselman discloses a guide (cutting guide 90) coupled to the one or more positionable frames (third positioner 80 including third rod 84) such that adjusting at least one positionable frame changes the position of the guide. Ex. 1003 ¶¶199-201. Hasselman discloses that cutting guide 90 is positioned "[a]t the end of the third rod 84" and it is "in communication with the third positioner 80 such that the cutting guide 90 may be adjusted, or translated, along at least the Z axis with reference to the third direction 81." Ex. 1006, 9:8-25; *id.*, 7:19-53, 9:26-10:17, 10:28-42, 10:57-65, 12:38-51, 13:13-25, Figs. 1-4, 9-11, 18, 20. Because cutting guide 90 is attached to third positioner via third rod 84, adjusting the position of the third positioner along cutter alignment rod 88 or adjusting the position of third rod 84 will change the position of cutting guide 90. Ex. 1003 ¶201. This is shown below, with highlighted directional arrows 61, 71, and 81 demonstrating the directions in which the positioners and third rod can be moved to adjust the position of the cutting guide (yellow):

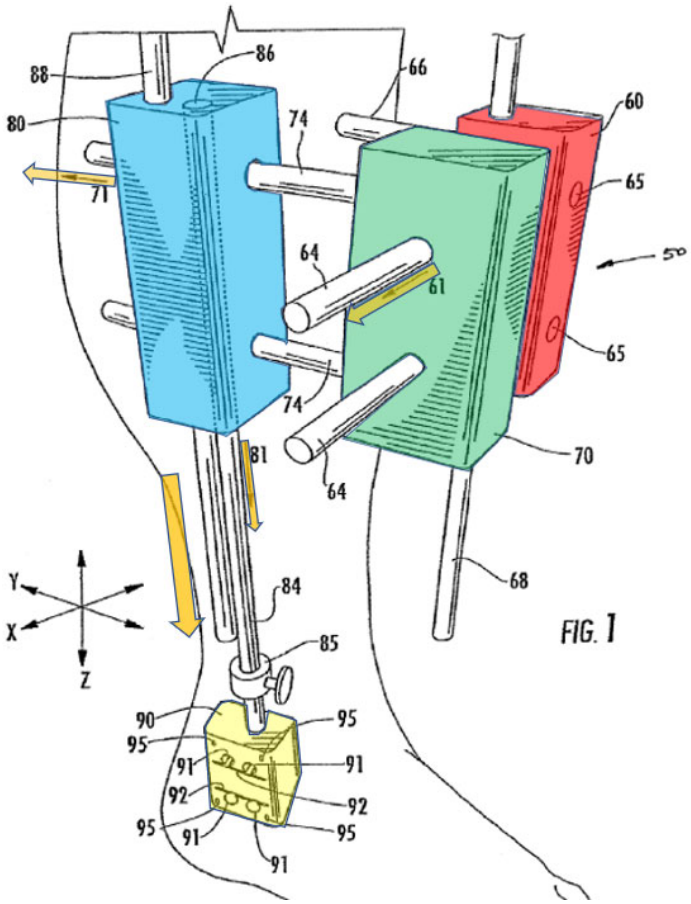


FIG. 1

Ex. 1006, Fig. 1; Ex. 1003 ¶201. Thus, adjusting either second positioner 70, third positioner 80, or third rod 84 will change the position of the guide. Ex. 1003 ¶201.

d) [10.3]: wherein the guide comprises a plurality of radiopaque surfaces defining a plurality of drill holes in a surface of the guide and

Hasselman in view of Irving renders obvious this limitation. Ex. 1003 ¶¶202-206. Hasselman discloses that cutting guide 90 (guide) includes a plurality of mount cut apertures 91 (drill holes). Ex. 1006, 9:48-60; *see also id.*, 10:28-42, 12:38-51, Figs. 1, 4, 9, 10, 18, 20. This is shown below, with mount cut apertures 91 in cutting guide 90 depicted in yellow:

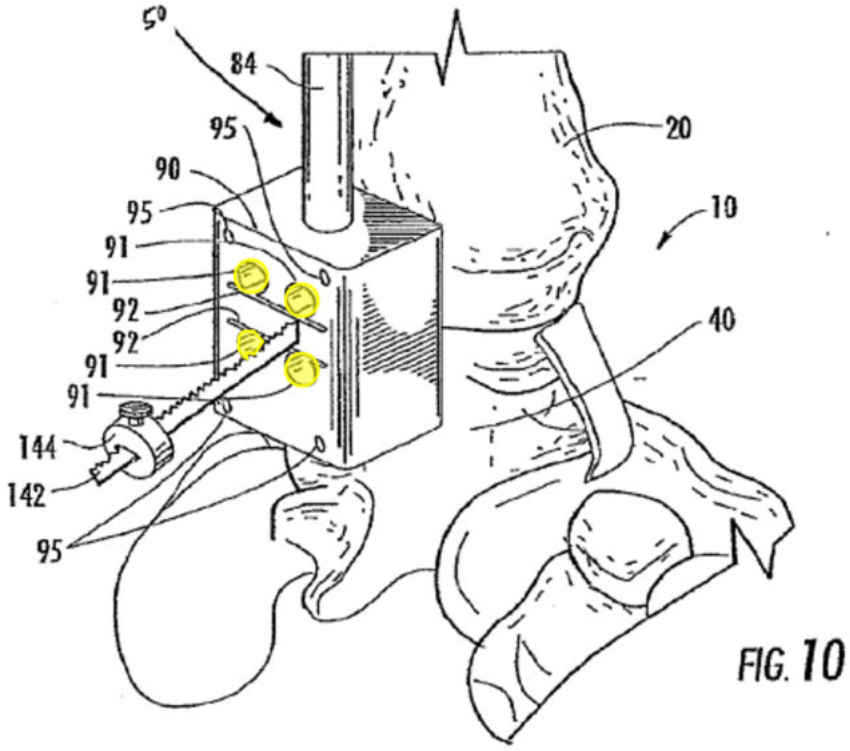


FIG. 10

Id., Fig. 10; Ex. 1003 ¶203. Hasselman discloses that "[t]he drill 97 is positioned within the mount cut aperture 91 and inserted into the tibia 20 a desired depth" and then a hole is drilled. Ex. 1006, 10:32-35. Thus, Hasselman discloses that mount cut apertures 91 in cutting guide 90 are a plurality of drill holes in a surface of the guide. Ex. 1003 ¶204.

Hasselman does not explicitly disclose radiopaque surfaces defining a plurality of drill holes in the surface of the guide. However, POSITAs would have found it obvious to use radiopaque surfaces to define mount cut apertures 91 of cutting guide 90 in Hasselman's adjustable guide assembly in view of the teachings of Irving. Ex. 1003 ¶205; *see* Section VII.C.1. Irving discloses that radiopaque markings permit "the surgeon [to] adjust the position of the alignment guide [] until

the radiopaque instrument references [] are in the desired position relative to the anatomic landmarks." Ex. 1007, 8:35-38; *see also id.*, 9:24-33, 13:21-29, 15:33-41, 16:15-62. Irving further discloses that radiopaque material may be used within bores of through holes. *Id.*, 10:46-48. The drill holes of Hasselman's guide are an obvious location to define using radiopaque material surrounding the hole because Hasselman discloses drilling into the tibia via these drill holes. Ex. 1006, 10:28-42. Both the tibia and radiopaque surfaces would be visible using fluoroscopy, and surgeons would have found it desirable to use fluoroscopy to ensure that the drill holes are located at a proper position for drilling into the tibia. Ex. 1003 ¶206. Thus, Hasselman in view of Irving renders obvious this limitation. *Id.*

e) *[10.4]: at least one radiopaque line on the surface of the guide comprising a length dimension configured to provide a fluoroscopic cue for positioning the guide by the one or more positionable frames.*

Hasselman in view of Irving renders obvious this limitation. Ex. 1003 ¶¶207-212. Hasselman discloses a guide (*see* Section VII.D.2.c), but does not explicitly disclose the claimed radiopaque line on the surface of the guide. Irving, however, discloses placing multiple radiopaque lines on the surface of an alignment guide to "provide[] a fluoroscopically visible reference for the surgeon" so that "the surgeon can ensure that the alignment guide is properly positioned with respect to the underlying bony landmark." Ex. 1007, 13:21-24. As Irving discloses, "if the surgeon sees more than a single radiopaque line when viewing the guide from the anterior side, then the alignment guide may be improperly positioned, and the

surgeon can adjust its position until a single radiopaque line is visible at the first portion when viewed from an anterior perspective." *Id.*, 13:23-29. POSITAs would have found it obvious to add radiopaque lines to Hasselman's cutting guide 90 for the same purpose disclosed by Irving, e.g. permitting the surgeon to orient and position the guide to ensure accurate placement prior to drilling or cutting into the tibia. Ex. 1003 ¶210; Section VII.C.1.

Hasselman discloses that cutting guide 90 is used not only to drill into the tibia, but also to make cuts using a saw through cutting slots. Ex. 1006, 10:58-11:5. Also, cutting guide 90 is both adjustable in the proximal-distal direction and "permitted to rotate about the Z axis." *Id.*, 9:23-25. Thus, it would have been obvious to POSITAs to ensure Hasselman's cutting guide is placed at a precise position and correctly oriented to permit accurate and optimal cuts to the bone. Ex. 1003 ¶211. The disclosure in Irving would have motivated POSITAs to add radiopaque lines to cutting guide 90 to aid in precisely placing it. Ex. 1003 ¶212; *see also* Section VII.C.1.

3. Claim 11

a) [Preamble] An adjustable guide assembly comprising:

To the extent the preamble is limiting, Hasselman discloses it. *See* Section VII.C.2.a.

b) [11.1]: two independently positionable frames suitable for locating a tool relative to a joint of a patient, the frames comprising:

Hasselman discloses two frames (second positioner 70 and third positioner 80 including third rod 84). *See* Section VII.C.2.b; Ex. 1003 ¶¶214-216. Hasselman's frames are independently positionable because adjusting second positioner 70 in a medial-lateral direction is accomplished independently of adjusting third positioner 80 in a proximal-distal direction. *Id*. Hasselman further discloses that these frames are used to locate cutting guide 90, which locates tools used with or attached to the cutting guide, e.g., saws or drills, relative to the ankle joint of a patient. Ex. 1006, 7:19-35, 9:8-25, 9:48-10:3, 10:28-42, 10:57-65, 13:12-25, Figs. 1-4, 9-11, 18, 20; Section VII.C.2.c; Ex. 1003 ¶216.

c) [11.2]: a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint,

Hasselman discloses a first frame (third positioner 80 including third rod 84). Ex. 1003 ¶217. Hasselman discloses that third positioner 80 is connected to second positioner 70, which, in turn, is connected to first positioner 60. *See* Section VII.C.2.b; Ex. 1003 ¶218. Hasselman further discloses that first positioner 60 is secured "in the desired aligned orientation" to tibia 20 through securing members 63. Ex. 1006, 8:15-28. Securing members "may generally comprise pins, nails or screws," and thus fixation pins are one option for securing first positioner 60 to tibia 20, which also secures third position 80 to the tibia. *Id.*, 8:19-21; Ex. 1003 ¶218.

The fixation pins secure the positioner by projecting outwardly from the anterior surface of the tibia, a bone located adjacent to ankle joint 10. *Id*. Figure 7 illustrates securing members 63 in red projecting outwardly from the anterior surface of the tibia:

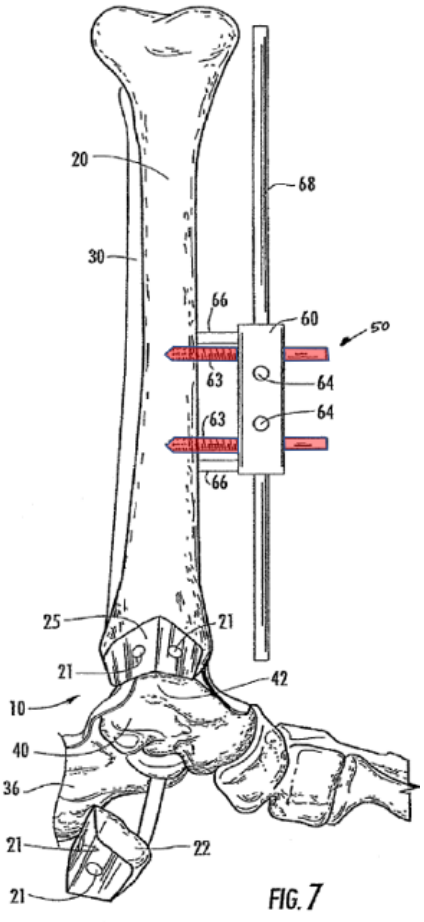


FIG. 7

Ex. 1006, Fig. 7; Ex. 1003 ¶219. This fixation releasably secures the first frame, because removing securing members 63 would release third positioner 80 from its position. Ex. 1003 ¶220.

To the extent PO (incorrectly) argues that securing members 63 do not releasably secure the first frame, it would have been obvious to releasably secure the

first frame directly with a fixation pin configured to project outwardly from the anterior surface of the tibia. Ex. 1003 ¶221. Hasselman discloses that prior to drilling or cutting, certain components of its alignment guide may be secured to the tibia "to ensure proper cutting orientation." Ex. 1006, 10:11-14; *see also id.*, 8:15-21. In particular, Hasselman discloses securing first positioner 60 and cutting guide 90 using "nails, screws, pins, etc." *Id*. Once the second positioner and third positioner are properly aligned, and there is no need for further adjustment, it would have been obvious to also secure these two positioners with fixation pins because securing these components would lock into place the position and orientation of the entire guide assembly, which would further the goal of securing the precise position of the cutting guide. Ex. 1003 ¶221. Given Hasselman's explicit disclosure of using fixation pins to accomplish this goal with respect to the first positioner and cutting guide, POSITAs would have found it obvious and expected to succeed in doing the same for other components such as third positioner 80. Ex. 1003 ¶222.

d) [11.3]: the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

Hasselman discloses that the first frame (third positioner 80 including third rod 84) is movable to effect a proximal-distal position adjustment of a tool used with cutting guide 90. *See* Sections VII.C.2.b, VII.C.3.b. Hasselman discloses that cutting guide 90 is "in communication with" third positioner 80 and "may be adjusted, or translated, along at least the Z axis" through third rod 84. Ex. 1006, 9:8-

25. Third rod 84 may be adjusted with adjuster 85, "a fine screw" that permits "fine adjustments along the Z axis or may otherwise be a course position holder used to secure third rod 84 in a desired position." Ex. 1006, 9:20-23. As screws have threaded shafts, POSITAs would have understood that the first frame (third positioner including third rod) is coupled to a first threaded shaft (the "fine screw" of adjuster 85) such that by turning adjuster 85, third rod 84 is advanced or retracted in a proximal-distal direction, and tools (e.g., saws or drills) used with or attached to cutting guide 90 are likewise moved in that same direction. Ex. 1003 ¶225.

Hasselman also discloses that third positioner 80 is coupled to a shaft (cutter alignment rod 88). Ex. 1006, 9:29-32. Cutter alignment rod 88 is "retained within the cutter alignment rod aperture 87 to assess the alignment of the ankle," and once the alignment "is diagnosed through use of the cutter alignment rod 88, the cutting guide 90 may be positioned more accurately to the desired orientation." *Id.*, 9:34-42. Hasselman does not directly disclose the means by which third positioner 80 is coupled to cutter alignment rod 88, however it would have been obvious to thread cutter alignment rod 88 such that turning it effected a proximal-distal adjustment of third positioner 80, which in turn effected a proximal-distal adjustment of cutting guide 90. Ex. 1003 ¶227. Threading the shaft of a rod is a very old and well-known technique. *Id.*; *see also* Ex. 1029, 12. POSITAs understood that threading the shaft of a rod was useful to couple two components where it is desirable to lengthen or shorten an exposed portion of the rod, because such a goal is achieved easily via

turning the threaded rod clockwise or counter-clockwise. Ex. 1003 ¶228. POSITAs also understood that using threaded shafts to create screw-like adjustment mechanisms for surgical instruments are desirable because surgeons are able to quickly and easily use these mechanisms without significant interruption to the surgical process or learning new techniques. *Id.* Thus, POSITAs would have found it obvious to thread cutter alignment rod 88 because it would achieve a stated goal of Hasselman—adjusting the proximal-distal position of third positioner 80—in an obvious and desirable manner. Ex. 1003 ¶229.

e) [11.4]: a second frame secured to the first frame,

Hasselman discloses a second frame (second positioner 70) that is secured to the first frame (third positioner 80 including third rod 84). *See* Section VII.C.2.b.

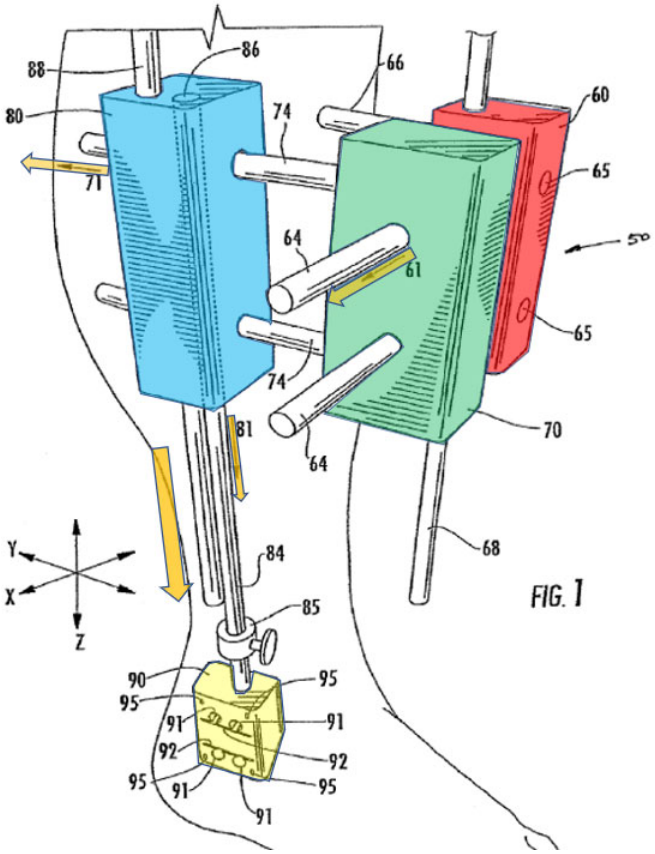
f) [11.5]: the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool; and

Hasselman discloses that second positioner 70 is movable to effect a medial-lateral adjustment of tools used with or attached to cutting guide 90. *See* Section VII.C.2.b. Hasselman discloses that this medial-lateral adjustment is achieved by moving the position of second positioner 70 along first rod 64. *Id.*; Ex. 1001, 8:48-58 ("the second positioner 70 will be adjustably engaged with the first positioner 60 such that the second positioner 70 may be translated along first rods 64") Hasselman does not directly disclose the means by which second positioner 70 is coupled to first rod 64, however it would have been obvious to thread first rod 64 such that

turning first rod 64 effects a medial-lateral adjustment of second positioner 70, which in turns effects a medial-lateral adjustment of cutting guide 90 and tools coupled to that cutting guide. Ex. 1003 ¶232. POSITAs would have found it obvious to couple second positioner 70 and first rod 64 using a threaded shaft and screw-like mechanism for all the same reasons expressed above with respect to third positioner 80 and cutter alignment rod 88, namely that the mechanism is well-known technique for adjusting the exposed portion of a rod, in this case first rod 64. *See* Section VII.C.3.d; Ex. 1003 ¶233. Further, threading shafts to adjust the position of rods has long been known; indeed, screws are a classic "simple machine" that converts rotational torque to linear movement. *Id.* Use of threaded shafts, as opposed to smooth shafts, would provide additional benefits by ensuring that the shaft does not move once positioned, creating additional motivation for POSITAs to thread the shafts of Hasselman's rods. *Id.*

g) [11.6]: a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a radiopaque line located on the guide.

Hasselman discloses a guide (cutting guide, yellow) coupled to each of the frames (third positioner, blue, and second positioner, green) as shown below in Figure 1:



Ex. 1006, Fig. 1; Ex. 1003 ¶235; *see also* Section VII.C.2.c. Cutting guide 90 is located adjacent to ankle 10 (joint) and positionable relative to tibia 20 (bone). Ex. 1006, 7:19-35, 8:59-9:7-10:17, 13:13-25, Figs. 1-4, 9-11, 18, 20.

Hasselman does not disclose a radiopaque line on cutting guide 90, however, as described above, POSITAs would have found it obvious in view of Irving to add radiopaque lines to Hasselman's cutting guide. *See* Sections VII.C.1, VII.C.2.e; Ex. 1003 ¶237.

4. Claim 20

a) [Preamble]: An adjustable guide assembly comprising:

Hasselman discloses this limitation. *See* Section VII.C.2.a.

b) [20.1]: two independently positionable frames suitable for locating a tool relative to the joint of a patient, the frames comprising:

Hasselman discloses this limitation. *See* Section VII.C.3.b.

c) [20.2]: a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint,

Hasselman discloses or renders obvious this limitation. *See* Section VII.C.3.c.

d) [20.3]: the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

Hasselman discloses or renders obvious this limitation. *See* Section VII.C.3.d.

e) [20.4]: a second frame secured to the first frame,

Hasselman discloses or renders obvious this limitation. *See* Section VII.C.3.e.

f) [20.5]: the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool; and

Hasselman renders obvious this limitation. *See* Section VII.C.3.f.

g) [20.6]: a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a cue located on the guide,

Hasselman in view of Irving renders obvious adding a radiopaque line, and that radiopaque line functions as a "cue" acting as a reference to aid in positioning of the guide (cutting guide) coupled to the frames (second and third positioners). *See* Section VII.C.3.g; Ex. 1003 ¶244.

h) [20.7]: the guide having a tool holder such that adjustment of at least one of the first and second frames changes the position of the tool coupled to the tool holder relative to the joint.

Hasselman discloses a guide (cutting guide) and tools used with or attached to the guide (e.g., drills and saws), such that adjusting one of the first and second frames changes the position of the guide (and thus the tool) relative to the ankle joint. *See* Sections VII.C.2.c, VII.C.3.b, VII.C.3.d, VII.C.3.f-g; Ex. 1003 ¶¶245-247. The '336 Patent discloses that a tool holder is, at minimum, "adapted to hold a drilling tool [or] a cutting tool." Ex. 1001, 15:42-43. Hasselman discloses that "drill 97 is positioned within the mount cut aperture 91." Ex. 1006, 10:32-34. Hasselman also discloses that cutting slots 92 are positioned to accept the blade of a saw, which is a cutting tool. Ex. 1006, 9:61-10:3; Ex. 1003 ¶246. Thus, the cutting guide's mount cut apertures and cutting slots are tool holders because they are adapted to hold a drilling tool and a cutting tool, respectively. *Id.* To the extent PO argues (incorrectly) that the cut apertures and cutting slots are not tool holders, POSITAs would have found it obvious to add a small support base with a clamp to the guide such that the aforementioned drills or saws remain with the guide. Ex. 1003 ¶247. POSITAs would have understood, and found it obvious, that the addition of a small support base to hold drills or saws would be a simple design choice that beneficially reduced surgical time by keeping tools nearby the location where the tool is to be used. *Id.* Tool holders have been used for this purpose for centuries, if not millennia, and have long been used in medical devices for the same purpose. *Id.*

5. Claim 21

a) An adjustable guide assembly according to claim 20,

Hasselman in view of Irving renders claim 20 obvious. *See* Section VII.C.4.

b) [21.1]: wherein the cue comprises radiopaque material.

Hasselman in view of Irving renders obvious adding a cue comprised of radiopaque material. *See* Sections VII.C.2.e, VII.C.3.g, VII.C.4.g.

6. Claim 23

a) An adjustable guide assembly according to claim 20,

Hasselman in view of Irving renders claim 20 obvious. *See* Section VII.C.4.

b) [23.1]: wherein the position of the cue relative to at least one fixation pin, indicates fluoroscopically at least one of an orientation and a position of the guide assembly relative to the bone.

Hasselman in view of Irving renders obvious adding a a radiopaque cue that is fluoroscopically visible to aid in positioning and orienting cutting guide 90 relative to tibia 20. *See* Sections VII.C.2.e, VII.C.3.g, VII.C.4.g; Ex. 1003 ¶¶251-253. POSITAs would have understood and found it obvious to use fixation pins made from metallic material, as that is one of the most common materials for fixation pins due to its durability, strength, and ability to be sterilized for use in an operating room. Ex. 1003 ¶252. Metallic materials are fluoroscopically visible and thus POSITAs would have known to use the relative position of the radiopaque cue and the fixation pins, both of which are fluoroscopically visible, to orient and position the guide relative to the bone, which would also be fluoroscopically visible. *Id.* ¶¶252-253.

7. Claim 24

a) An adjustable guide assembly according to claim 20,

Hasselman in view of Irving renders claim 20 obvious. *See* Section VII.C.4.

b) [24.1]: wherein the first frame is attached to two fixation pins which have been inserted into the anterior surface of the bone.

Hasselman discloses or renders obvious securing the first frame using two fixation pins. *See* Section VII.C.3.c. As shown in Figures 7–9, Hasselman discloses two fixation pins (securing members 63) inserted into the anterior surface of tibia bone. Ex. 1006, Figs. 7–9; *see also id.*, Fig. 1 (adjustable guide assembly 50 shown on anterior surface of bone); Ex. 1003 ¶¶255-256.

8. Claim 26

a) [Preamble]: An adjustable guide assembly comprising:

Hasselman discloses this limitation. *See* Section VII.C.2.a.

b) [26.1]: two independently positionable frames suitable for locating a tool relative to the joint of a patient, the frames comprising:

Hasselman discloses this limitation. *See* VII.C.3.b above,

c) [26.2]: a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint,

Hasselman discloses or renders obvious this limitation. *See* Section VII.D.3.c.

d) [26.3]: the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

Hasselman discloses or renders obvious this limitation. *See* Section VII.C.3.d.

e) [26.4]: a second frame secured to the first frame,

Hasselman discloses this limitation. *See* Section VII.C.3.e.

f) [26.5]: the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool; and

Hasselman renders obvious this limitation. *See* Section VII.C.3.f.

g) [26.6]: a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a cue located on the guide,

Hasselman in view of Irving renders obvious this limitation. *See* Sections VII.C.3.g, VII.C.4.g.

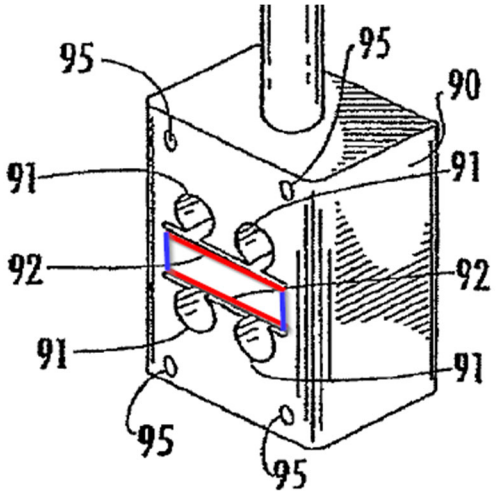
h) [26.7]: the guide having a tool holder such that adjustment of at least one of the first and second frames changes the position of the tool coupled to the tool holder relative to the joint,

Hasselman discloses or renders obvious this limitation. *See* Section VII.C.3.h.

i) [26.8]: wherein the cue comprises a first line extending generally in a medial-lateral direction, a second line extending generally in a proximal-distal direction, and a third line extending generally in a proximal-distal direction.

Hasselman in view of Irving renders obvious adding radiopaque lines (i.e., cues) on the surface of cutting guide 90 to aid in accurate positioning of the cutting guide. *See* Sections VII.C.2.e, VII.C.3.g, VII.C.4.g. When deciding on where to place the radiopaque lines suggested by Irving, POSITAs would have found it obvious to locate the lines to delineate the cutting slots 92. One obvious way to do so would be to place two parallel lines at the bottom and top of the two cutting slots, and then two orthogonal connecting line on each side such that a rectangular area is

formed by the radiopaque lines. Ex. 1003 ¶266. This is depicted below, with the two lines in the medial-lateral direction in red and the two lines in the proximal-distal direction in blue:



Ex. 1006, Fig. 1; Ex. 1003 ¶267. Locating the lines in this manner would have been an obvious design choice because it would permit the surgeon to fluoroscopically locate where the cutting slots, and therefore the cuts, would be made. Ex. 1003 ¶268.

9. Claim 27

a) *The adjustable guide assembly of claim 26,*

Hasselman in view of Irving renders claim 26 obvious. *See* Section VII.C.8.

b) *[27.1]: wherein the second line is adjacent to the first line at a first end of the first line and the third line is adjacent to the first line at a second end of the first line.*

POSITAs would have been motivated and found it obvious to add radiopaque lines outlining the cutting slots of Hasselman's cutting guide 90 based on Hasselman in view of Irving. *See* Section VII.C.8.i; Ex. 1003 ¶271. As depicted in the

annotated figure above, this would result in lines that are adjacent to each other, including the claimed second and third line being adjacent to the first line at the different ends. *Id*.

D. Ground 4: Hasselman In View Of Irving and Federspiel

1. Motivation to Modify Hasselman in View of Irving and Federspiel

POSITAs would have been motivated to use the radiopaque teachings of Irving with the adjustable guide assembly taught by Hasselman. *See* Section VII.C.1. POSITAs further would have understood the benefits of using radiopaque pins, as taught by Federspiel, in Hasselman's adjustable guide assembly as modified by Irving, and would have been motivated to do so.

Federspiel discloses an instrument used in orthopedic surgery that includes radiopaque areas to "to facilitate positioning." Ex. 1010, Abstract. Like Hasselman and Irving, Federspiel emphasizes that "[p]recise positioning … may be critical" for successful orthopedic surgery. *Id.*, 1:38-40. Because Hasselman, Irving, and Federspiel all discuss the importance of alignment in orthopedic surgery, POSITAs would have been motivated to look to Federspiel in addition to Hasselman and Irving for ideas about how to improve the alignment of cutting guides used in ankle joint replacement surgery. Ex. 1003 ¶275.

Additionally, Irving discloses that any number of different shapes of radiopaque cues can be added to aid in proper positioning or alignment of a guide.

Ex. 1003 ¶276; Ex. 1007, 16:20-25 ("a plurality of other shapes can be used in a variety of patterns; for example, a plurality of spaced radiopaque dots can be set in a linear pattern on the connecting portion of the guide, along with a second set of radiopaque dots set in a differently-oriented linear pattern on the cephalad portion of the guide."). Because Irving and Federspiel both disclose using radiopaque cues to improve alignment during orthopedic surgery, POSITAs would have been motivated to look to Federspiel for additional shapes that could be used as radiopaque cues on Hasselman's adjustable guide assembly. Ex. 1003 ¶277; *see also Acoustic Tech.*, 949 F.3d at 1375. POSITAs would have expected to succeed in adding radiopaque cues in a variety of shapes, including a pin as taught by Federspiel, to Hasselman's adjustable guide assembly because using radiopaque materials in surgical instruments was well-known as of the priority date of the '336 patent. Ex. 1003 ¶277.

2. Claim 22

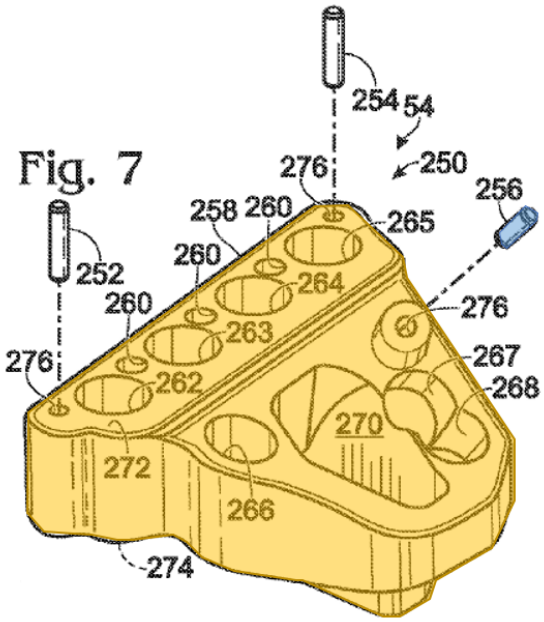
a) An adjustable guide assembly according to claim 21,

Hasselman in view of Irving renders claim 21 obvious. *See* Section VII.C.5.

b) [22.1]: wherein the cue comprises a pin centrally located on the guide.

Hasselman in view of Irving renders obvious adding radiopaque lines or surfaces on a cutting guide to aid in properly positioning the cutting guide to ensure accurate and precise sawing or drilling into the tibia. *See* Sections VII.C.2.d-e. Irving discloses that any number of different shapes of radiopaque cues can be added

to aid in proper positioning or alignment of a guide. Ex. 1003 ¶280; Section VII.D.1. One such shape is a radiopaque pin as taught by Federspiel as shown below, with a radiopaque pin cue (styloid marker 256, blue) located on a guide (guide block 250, yellow):



Ex. 1010, Fig. 7; *see also id.*, 12:28-33, 12:60-13:15, 13:31-51 ("[t]he marker may be described as a pin and/or a post"), 13:52-61; Ex. 1003 ¶281.

Federspiel teaches that this radiopaque pin permits surgeons to "predict a prospective fastener trajectory into bone" via fluoroscopy "without the need for the labor-intensive and time consuming insertion of K-wires to define prospective trajectories." Ex. 1010, 13:22-30. Hasselman also teaches that "[b]efore the cutting step begins, the cutting guide 90 may be secured to the tibia 20 to ensure the cutting guide 90 is properly positioned." Ex. 1006, 10:4-6. Thus, Hasselman teaches that

fasteners may be used with cutting guide 90, and Federspiel teaches using radiopaque cues to predict fastener trajectory into bone. Ex. 1003 ¶282.

POSITAs would have been motivated and found it obvious to add a radiopaque pin, as taught by Federspiel, to Hasselman's cutting guide in a central location to predict the trajectory of a fastener and ensuring any fasteners attaching cutting guide 90 to tibia 20 are properly positioned. *Id.* ¶283. The center location of the cutting is an obvious reference position to add a radiopaque marker because it is a location that surgeons naturally focus on, and can be used to orient and locate other positions (e.g., edges). *Id.* POSITAs would have found the use of a radiopaque pin inserted into a guide to be one of several obvious variations designed to achieve the same result, i.e., providing a marker viewable to a surgeon under fluoroscopy. *Id.*; *see* Section VII.D.1.

VIII. SECONDARY CONSIDERATIONS

Petitioner is unaware of any secondary considerations relevant to the Challenged Claims. PO did not assert secondary considerations during prosecution of the '336 Patent, and, as of the filing of this petition, has not asserted them in the district court litigation.

IX. DISCRETIONARY DENIAL IS NOT APPROPRIATE

The Board should not exercise its discretion under §314(a) to deny institution.

Fintiv factor 1: Petitioner intends to move to stay the District Court case. Simplifying that case by allowing the Board to resolve issues regarding the validity

of the Challenged Claims, and the relatively early stage of the case, will weigh in favor of granting a stay. *See Helios Streaming, LLC v. Vudu, Inc.*, No. 19-1792, 2021 WL 8155604, at *3 (D. Del. Aug. 5, 2021); *PACT XPP Schweiz AG v. Intel Corp.*, No. 19-cv-01006, 2020 WL 13119705, at *1-2 (D. Del. Nov. 5, 2020).

Fintiv factor 2: A FWD is expected in this IPR in March 2024. Trial in the District Court case is currently set for March 11, 2024. Ex. 1032. However, the Director's guidance states that the median time to trial be used to assess the *Fintiv* factors, and as of June 30, 2022, the median time to trial in the District of Delaware is 36 months. Ex. 1033. The District Court case was filed in December 2021, such that the median time to trial means this case is likely to be tried in December 2024. Because the FWD on this petition would occur nine months before trial in that case, this factor is thus neutral or weighs against discretionary denial. Ex. 1034.

Fintiv factor 3: The parties and district court will have invested limited resources in the District Court case, particularly regarding invalidity, prior to the deadline for the Board's institution decision. The *Markman* hearing is scheduled for approximately two months ***after*** the institution decision (Ex. 1032), which weighs against the Board exercising its discretion to deny institution. *MED-EL Elektromedizinische Gerate GmbH v. Advanced Bionics AG*, IPR2020-00190, Paper 15 at 12 (PTAB June 3, 2020). The deadlines for completing expert discovery and filing dispositive motions also occur after the anticipated deadline for the institution decision, and Petitioner's filing is timely (approximately eleven weeks before the

statutory deadline and seven weeks after filing its invalidity contentions). Ex. 1032.

Fintiv factor 4: Petitioner expects that there will be minimal to no overlap between the issues raised in the District Court case and in this IPR. Upon institution, Petitioner plans to move to stay the District Court case. If a stay is granted, there will be no overlap of issues while the stay is pending, because the Board will be the only tribunal considering invalidity. If a stay is not granted, the FWD is scheduled to issue prior to median time to trial in the district. Once the FWD on this Petition is issued, Petitioner will be bound by the estoppel provisions of 35 U.S.C. §315(e)(2), ensuring only this Board considers the invalidity issues raised in this Petition.

Fintiv factor 5: Petitioner is the defendant in the District Court case, but this factor alone is not determinative. *See, e.g., VMWare, Inc. v. Intellectual Ventures I LLC*, IPR2020-00470, Paper 13 at 20-22 (PTAB Aug. 18, 2020).

Fintiv factor 6: As set forth above, the merits of the grounds of this Petition are strong. "[W]here the PTAB determines that the information presented at the institution stage presents a compelling unpatentability challenge, that determination alone demonstrates that the PTAB should not discretionarily deny under *Fintiv*." Ex. 1034, 4-5.

"Considering the *Fintiv* factors as part of a holistic analysis," it would run counter to "the interests of the efficiency and integrity of the system" if this Board were to exercise its discretion to deny institution under §314(a) in this instance. *See*

Sand Revolution II, LLC v. Continental Intermodal Group-Trucking LLC, IPR2019-01393, Paper 24 at 14 (PTAB June 16, 2020).

X. GROUNDS FOR STANDING

Petitioner certifies that the '336 Patent is available for IPR and Petitioner is not barred or estopped from requesting IPR of the Challenged Claims on the grounds identified herein.

XI. MANDATORY NOTICES

A. Real Party-In-Interest

Petitioner identifies the following real parties-in-interest: Paragon 28, Inc.

B. Related Matters

PO has asserted the '336 Patent against Petitioner in the District Court case, *Wright Med. Tech., Inc. v. Paragon 28, Inc.*, Case No. 1:21-cv-01809-MN (D. Del.), filed December 23, 2021. Petitioner is concurrently filing an IPR petition challenging the other patent asserted in the District Court case, U.S. Patent No. 9,907,561. Pending Patent Application No. 17/137,585 filed on December 30, 2020 claims priority to Application No. 16/047,425, now the '336 Patent.

C. Counsel and Service Information

Lead Counsel	Back-Up Counsel
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Petitioner concurrently submits a Power of Attorney with this Petition. 37 C.F.R. § 42.10(b). Petitioner consents to service by email at Paragon28_PTAB@kirkland.com.

XII. PAYMENT OF FEES

Petitioner authorizes the Office to charge the filing fee and any other necessary fee to Deposit Account No. 506092.

XIII. CONCLUSION

For the reasons set forth above, the Challenged Claims of the '336 patent are unpatentable. Paragon therefore requests that an IPR of these claims be instituted.

Date: October 4, 2022

Respectfully submitted,

/s/ Alan Rabinowitz

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 13,925 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a).

DATED: October 4, 2022

/s/ Alan Rabinowitz
Alan Rabinowitz (Reg. No. 66,217)
Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105(a), I certify that I caused to be served a true and correct copy of the foregoing of Petition For Inter Partes Review of U.S. Patent No. 10,888,336 (and accompanying Exhibits) by overnight courier on the Patent Owner at the correspondence address of the Patent Owner as follows:

Duane Morris LLP
IP Department
30 South 17th Street
Philadelphia, PA 19103-4196

A courtesy copy of the foregoing was also served via email on the counsel of record for Patent Owner in the related district court action.

DATED: October 4, 2022

/s/ *Alan Rabinowitz*
Alan Rabinowitz (Reg. No. 66,217)
Attorney for Petitioner

APPENDIX A

Full text of Challenged Claims:

What is claimed is:

1. A surgical guide, comprising:

a body configured to be inserted into a block that is configured to be coupled to a bone, the body defining at least a first guide hole and a second guide hole, wherein the first and second guide holes are sized and configured to receive a first surgical tool for forming pilot holes in the bone and wherein the body comprises radiopaque surfaces defining the first and second guide holes; and

a sizing pattern coupled to the body, the sizing pattern having a size and being coupled to the body at a location for estimating resectioning cuts to be made to the bone, wherein the sizing pattern comprises at least two radiopaque lines each comprising a length dimension configured to provide a fluoroscopic cue for positioning the body.

2. The surgical guide of claim **1**, further comprising a plurality of pin holes sized and configured to receive a plurality of pins to couple the body to the bone.

3. The surgical guide of claim **1**, further comprising a cut guide comprising a plurality of slots configured to position a cutting tool to cut the bone, wherein the size of the slots correspond to the sizing pattern.

4. The surgical guide of claim **1**, wherein the body comprises a plastic material and the first guide hole, the second guide hole, and the sizing pattern comprise a metal material.

5. The surgical guide of claim **1**, wherein the body comprises a dovetail extension configured to be coupled to a dovetail joint of the block.

6. The surgical guide of claim **1**, wherein the body comprises a plurality of pin holes configured to receive a plurality of pins to couple the body to at least the tibia.

8. The surgical guide of claim **1**, wherein the at least two radiopaque lines comprise at least two parallel radiopaque lines.

9. The surgical guide of claim **1**, wherein the at least two radiopaque lines comprise a first line extending generally in a medial-lateral direction, a second line extending generally in a proximal-distal direction, and a third line extending generally in a proximal-distal direction.

10. An adjustable guide assembly comprising:

one or more positionable frames configured to provide at least proximal-distal and medial-lateral adjustments; and

a guide coupled to the one or more positionable frames such that adjustment of at least one of the one or more positionable frames changes the position of the guide,

wherein the guide comprises a plurality of radiopaque surfaces defining a plurality of drill holes in a surface of the guide and at least one radiopaque line on the surface of the guide comprising a length dimension configured to provide a fluoroscopic cue for positioning the guide by the one or more positionable frames.

11. An adjustable guide assembly comprising:

two independently positionable frames suitable for locating a tool relative to a joint of a patient, the frames comprising:

a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint, the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

a second frame secured to the first frame, the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool; and

a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a radiopaque line located on the guide.

20. An adjustable guide assembly comprising:

two independently positionable frames suitable for locating a tool relative to a joint of a patient, the frames comprising:

a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint, the first frame being coupled to a first threaded shaft so

that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

a second frame secured to the first frame, the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool; and

a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a cue located on the guide, the guide having a tool holder such that adjustment of at least one of the first and second frames changes the position of the tool coupled to the tool holder relative to the joint.

21. An adjustable guide assembly according to claim **20** wherein the cue comprises radiopaque material.

22. An adjustable guide assembly according to claim **21** wherein the cue comprises a pin centrally located on the guide.

23. An adjustable guide assembly according to claim **20** wherein the position of the cue relative to at least one fixation pin, indicates fluoroscopically at least one of an orientation and a position of the guide assembly relative to the bone.

24. An adjustable guide assembly according to claim **20** wherein the first frame is attached to two fixation pins which have been inserted in the anterior surface of the bone.

26. An adjustable guide assembly comprising:

two independently positionable frames suitable for locating a tool relative to a joint of a patient, the frames comprising:

a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint, the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

a second frame secured to the first frame, the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft,

the second frame is movable to effect a medial-lateral adjustment of the tool; and

a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a cue located on the guide, the guide having a tool holder such that adjustment of at least one of the first and second frames changes the position of the tool coupled to the tool holder relative to the joint.

wherein the cue comprises a first line extending generally in a medial-lateral direction, a second line extending generally in a proximal-distal direction, and a third line extending generally in a proximal-distal direction.

27. The adjustable guide assembly of claim **26**, wherein the second line is adjacent to the first line at a first end of the first line and the third line is adjacent to the first line at a second end of the first line.