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. 9,907,561

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

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 (Excerpted) of U.S. Patent No. 9,907,561 to Luna et al.
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 6 and 13-15 ("Challenged Claims") of U.S. Patent No. 9,907,561 ("the '561 Patent") (Ex. 1002).

The Challenged Claims relate to methods for performing joint replacement surgery. But for decades before the priority date of the '561 Patent, surgeons had been replacing patients' deteriorated or deformed joints (such as knees or ankles) by cutting away bone near the joint area and replacing it with implants that replicate the "hinging" function of the joint. To do this, surgeons used guides to ensure the holes and cuts made to the bone were located at the correct position, and used "trial" or "test" components prior to affixing implants to ensure they were optimally placed to replicate the hinging function. The Challenged Claims cover obvious variations of known methods of using guides and trial components. There is nothing inventive about the method in the Challenged Claims, and this Board should institute IPR and find the Challenged Claims unpatentable.

I. BACKGROUND OF THE '561 PATENT

A. Technology Overview

The '561 Patent generally relates to systems and methods for joint replacements, and in particular, guide systems and trialing systems for ankle replacement surgeries. Ex. 1002, Title, Abstract, claims 6, 13-15; Ex. 1003 ¶¶26, 54. 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, are a "joint that acts much like a hinge." Ex. 1002, 1:26. Typically, in joint replacement surgery (one form of arthroplasty, a surgical procedure to restore joint function), a physician replaces the joint by removing or resecting portions of the bones that form the hinge (in ankle replacement, the tibia and talus bones), implanting protheses in the portion of the bone that was removed, and inserting a spacer that sits between the 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 bone in an advantageous manner during joint replacement surgery. Ex. 1003 ¶30; Ex. 1015, 1:35-45, 2:18-41. Physician chose the implant type and size based on the patient's bone size, bone shape, age, activity level, joint problems, general health, and other factors. Ex. 1003 ¶30; Ex. 1021, 119; Ex. 1022, 710-719.

To optimize the replaced joint's function and movement, the positioning and size of the implants must be accurate so that the implant components articulate properly with each other and the bones of the joint. Ex. 1003 ¶¶31, 42; Ex. 1015, 1:35-43. Thus, during joint replacement surgery, trial components resembling the physical features and characteristics of the final implanted components are used to assess the sizing and positioning of the implants before permanently affixing the final prosthesis to the patient's bone. Ex. 1003 ¶42. This procedure is referred to as

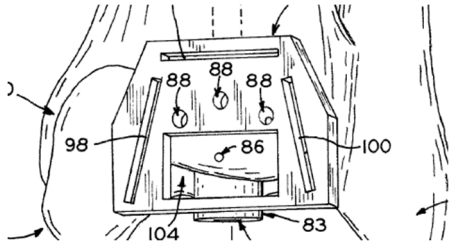
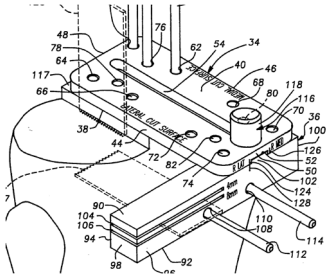
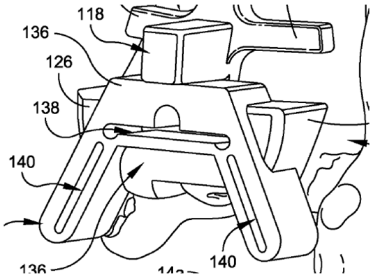
"trialing." *Id.* Trialing prior to implantation was a known technique used in joint replacement surgeries since at least the mid-1990s, if not earlier. *Id.*; *see also, e.g.*, Ex. 1012, 3:5-19, Fig. 10A (1997); Ex. 1013, 2:40-63, Fig. 7 (2007), Ex. 1014, 6:56-7:62, Fig. 48 (2009), Ex. 1009, ¶27, Fig. 21 (2009); Ex. 1036, 17:30-51 (2012).

Trial components are particularly useful for adjusting and fine-tuning the implant placement to, for example, optimize soft tissue tension with different joint movements. Ex. 1003 ¶43; Ex. 1017, 71:4-10. To optimize implant placement, physicians placed the trial components and conducted range of motion tests by moving and rotating the joint with the trial components in place to measure flexion and extension gaps. Ex. 1003 ¶44; Ex. 1012, 3:28-56. Surgeons often repeated such procedures with different sized trial components, and with the components in different positions, until the desired results are achieved. *Id*. Once the position and size of the prosthetic components are confirmed, the final components can be implanted. Ex. 1003 ¶44; Ex. 1012, 3:48-4:15.

Prior to insertion of an implant in the bone, surgeons would remove, or resect, portions of the bone to make room for the implant. Ex. 1003 ¶31; Ex. 1015, 1:35-43. To optimize the replaced joint's function, cuts made to the bone must be accurate so the implants are properly aligned *Id*. 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. Ex. 1003 ¶32; Ex. 1005, 4:22-35. Physicians rely on these systems to aid in resecting the appropriate portion of patient bone and preparing the remaining bone for receiving an implant. *Id*. 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 cuts and holes made to the bone are properly located and placed relative to one another so that an implant can be attached in the desired position and orientation. Ex. 1003 ¶¶33-38. Often, the hole is a pilot hole, which is formed when the physician removes the drill from the bone, leaving behind a path to guide the bone screw or implant stem and ease its insertion into the bone. Ex. 1003 ¶36; Ex. 1025, 208. Different guides have different placements of holes and cut slots based on the implant design and size, as shown in the prior art examples below. Ex. 1003 ¶38.

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

B. Alleged Invention Of The '561 Patent

The Challenged Claims of the '561 Patent are directed to methods used in joint replacement surgery. Ex. 1002, 1:20-25, 31:1-3, Claims 6, 13-15; Ex. 1003 ¶54. The method steps of independent Claim 6 include:

- inserting "a floating trial" and "a poly trial insert" into a "resected joint space,"
- "moving the floating trial…"
- "inserting a plurality of fixation pins…."
- "removing the floating trial and the poly trial insert from the resectioned joint space," and
- "forming … resection cuts."

The method steps of independent Claim 13 include:

- using a "drill guide" to form a "plurality of pilot holes,"
- using a "cutting guide" to guide "one or more resectioning cuts,"
- "inserting a first trial…," and
- "performing a trial reduction …"

Ex. 1002, Claims 6, 13.

The '561 Patent discloses a drill guide having "at least two guide holes 281 to be used to drill pilot holes in the tibia 260. The drill guide also has pin holes 282 that can be used to pin the drill guide to the bone[.]" *Id.*, 17:5-11. Figure 35 shows

drill guide 280 with guide holes (red)[1] and a sizing pattern (green):

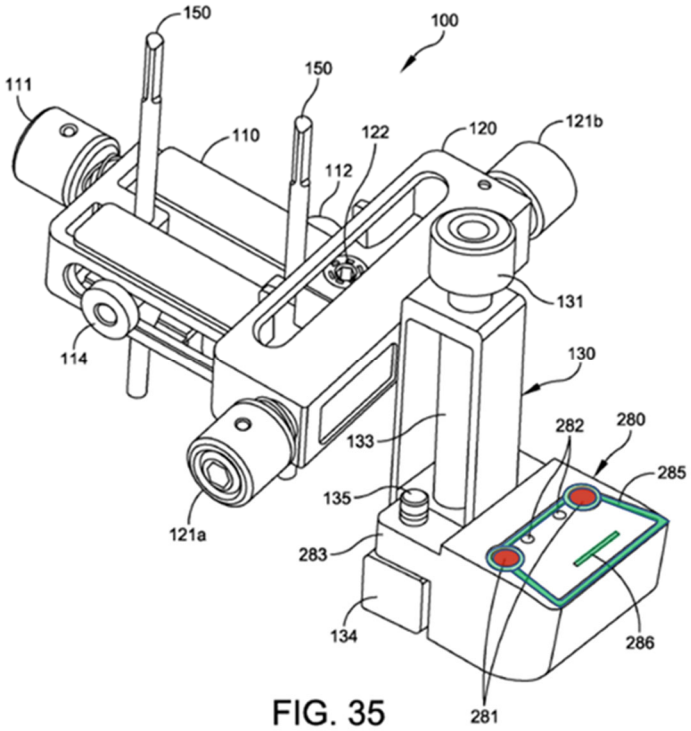


FIG. 35

The drill guide holes are "drilled in the bone 260 [and] define proximal corners of a resectioning cut to be performed in the tibia." Ex. 1002, 33:56-58. The '561 patent discloses that once the guide and pin holes are drilled, and the anchor pins securing the drill guide are embedded into the bone, the drill guide is removed and replaced with a cutting guide having "a plurality of slots 295, sized and located to connect the corner holes drilled with the drill guide 280." *Id.*, 18:9-11, 33:58-63. Figure 37 depicts cutting guide 290 with a plurality of slots 295 (red) used for resection cuts:

[1] All colorized figures were annotated by Petitioner.

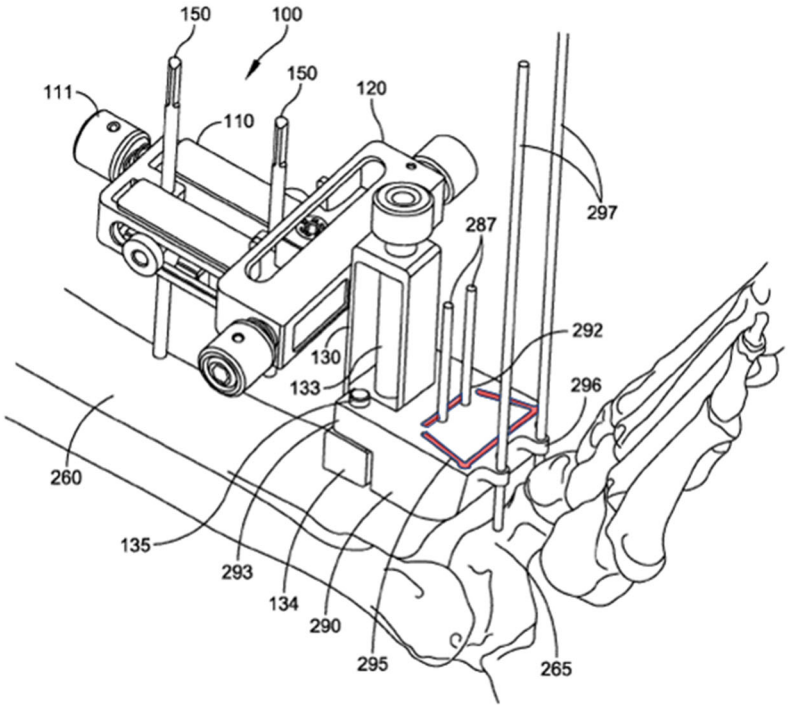


FIG. 37

The cutting guide is secured to the tibia with the same fixation pins 287 used by the drill guide. Ex. 1002, 33:67-3. Once the cutting guide is secured, the operator may "perform[] the resectioning cuts through the guide slots 295, cutting the bone to connect the previously drilled holes." *Id.*, 34:4-6. Once the cuts are made and "cut guide 290 is [] removed from the surgery site," then "[t]he sections of the tibia 260 and talus 265 that have been cut are removed, along with the fixation pins 287." *Id.*, 34:9-12.

The '561 Patent also discloses using trial components after the cuts are made to determine the size and position of the implant, specifically (1) a "poly trial insert" having a "top surface 231 adapted to be detachably mounted to the bottom surface

216 of the plate 211 of the tibia trial" and a "concave bottom surface" and (2) a "floating trial" that is "configured to be inserted beneath the poly trial insert 230 to contact the concave bottom surface 232 of [the] insert." *Id.*, 16:3-33. Figure 30 shows poly trial insert 230 (blue) and floating trial 250 (red):

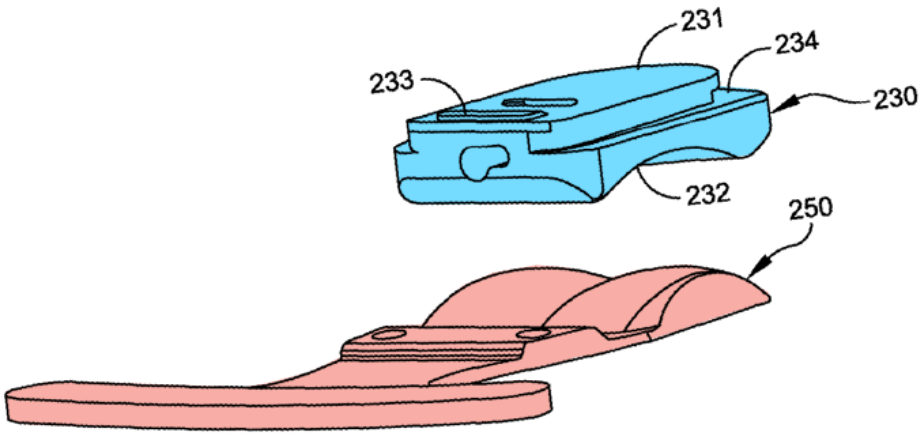


FIG. 30

Once tibia trial 210 is in place, it is secured using drills and fixation pins. *Id.*, 34:24-32. Figure 38 depicts tibia trial 210 (yellow) inserted into the resected joint space:

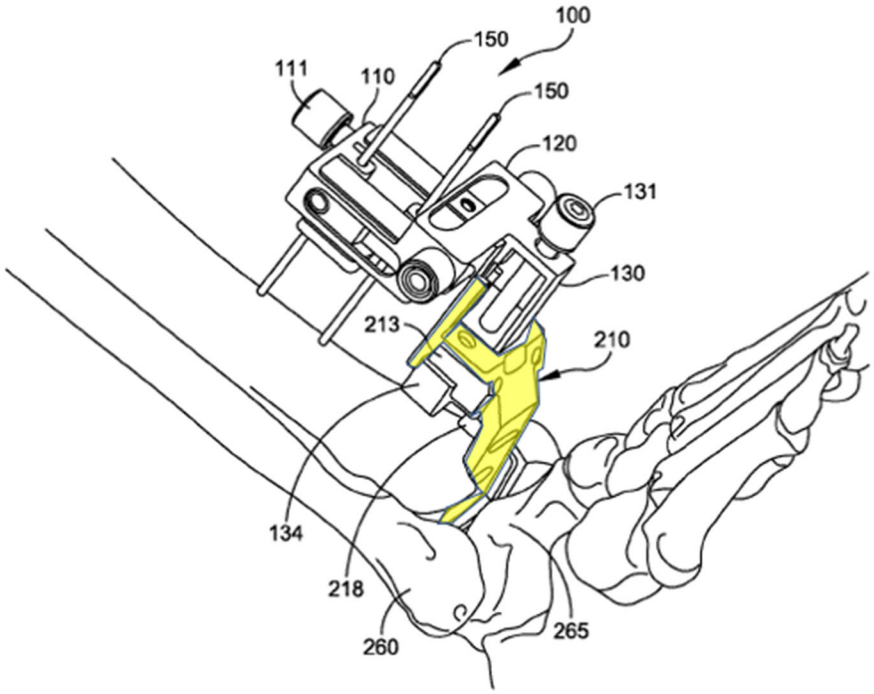


FIG. 38

Once tibia trial 210 is secured, the operator "performs a trial reduction to ensure the correct height of the poly trial insert 230 and the correct position of the talus dome." *Id.*, 34:38-40.

C. Prosecution History Of The '561 Patent

U.S. Patent Appl. No. 14/446,921 ("the '921 application"), which led to the '561 Patent, was filed on July 30, 2014. Ex. 1002, Cover. Through a series of applications, the '561 Patent claims priority to a provisional application filed December 27, 2012. *Id.* [2]

[2] For purposes of this IPR, Petitioner assumes the priority date is December 27, 2012, the earliest priority date on the face of the '561 patent. Petitioner reserves

Prior to action by the PTO, the applicant filed a preliminary amendment cancelling the originally submitted claims and adding claims 61-83. Ex. 1004, 3-7. The examiner rejected claims 67 (issued claim 6) and 68 as anticipated or rendered obvious by U.S. Publication No. 2007/0173947 ("Ratron").[3] *Id.*, 12-13. The examiner also rejected claims 61-65 (issued claims 1-5) as anticipated, but found claims 76-83 (issued claims 13-20) allowable and claims 66 and 69-75 allowable if rewritten in independent form. *Id.*, 11-13.

The applicant amended independent claim 67 (issued claim 6) to recite "inserting a plurality of fixation pins through a plurality of pin holes defined by the floating trial" (a limitation that the Examiner had previously found rendered obvious by Ratron) as well as "removing the floating trial and the poly trial insert from the resected joint space; and forming at least two resectioning cuts on the second bone." *Id.*, 17-18. The applicant explained that the claim 67 amendment added "all of the allowable subject matter from [] claims 68 and 69." *Id.*, 22. The applicant also canceled claims 66 and 68-69, amended independent claim 61 to include the allowable subject matter from claim 66, added claim 84 combining the limitations

---

the right to challenge any claim of priority in *Wright Med. Tech., Inc. v. Paragon 28, Inc.*, Case No. 1:21-cv-01809-MN (D. Del.) ("the District Court case").

[3] The correlation between the application claim numbers and issued claim numbers can be found in the file history. Ex. 1004, 32.

of claim 67 and 75, and corrected inadvertent spelling and grammatical errors in claims 75-78. *Id*.

The examiner allowed the pending claims following applicant's amendment. *Id.*, 29. The examiner did not include a statement regarding the reasons for allowance; specifically, the examiner did not explain why the applicant's amendment adding limitations "removing the floating trial and the poly trial insert from the resected joint space; and forming at least two resectioning cuts on the second bone" to claim 67 overcame the rejections based on Ratron.

II. IDENTIFICATION AND BASIS OF CHALLENGE

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

- **Johnson** - U.S. Patent No. 5,683,470 (Ex. 1012), issued November 4, 1997. Johnson is prior art under 35 U.S.C. §§102(a) and (b).[4]
- **Ratron** - U.S. Patent No. 8,114,091 (Ex. 1013), issued February 14, 2012. Ratron is prior art under 35 U.S.C. §102(a).
- **Rosa** - U.S. Patent No. 7,744,601 (Ex. 1014), issued June 29, 2010. Rosa is prior art under 35 U.S.C. §§102(a) and (b).
- **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).

[4] Cites to 35 U.S.C. §§102 and 103 are to the pre-AIA version applicable here.

- **Mumme** - U.S. Patent No. 5,364,402 (Ex. 1011), issued November 15, 1994. Mumme is prior art under 35 U.S.C. §§102(a) and (b).

Ground	Claims	Statutory Basis	Prior Art
1	6	§103	Johnson in view of POSITA knowledge
2	6	§103	Ratron in view of Rosa
3	13-15	§103	Li in view of Ratron
4	13-15	§103	Mumme in view of Johnson

An Index of Exhibits is attached. Section VII details the statutory grounds of unpatentability for each Challenged Claim, 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 Mumme, Li, Rosa, and Johnson are not cited on the face of the '561 Patent. While Patent Owner ("PO") did list the published application that led to Li in an Information Disclosure Statement, the Examiner neither applied the reference against the claims nor discussed it. And although the Examiner rejected originally-presented claim 67 based on the published application that led to Ratron, the Examiner did not discuss or explain how the applicant's amendment to claim 67 (issued claim 6) overcame the rejection, or why the '561 Patent was nevertheless issued over Ratron. *See* Section I.C. Moreover, the Examiner did not address the combination of Ratron and Rosa presented in this Petition.

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"). None of these references weigh in favor of exercising discretion under §325(d).

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 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 '561 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. Johnson

Johnson is titled "Tibial Trial Prosthesis and Bone Preparation System," and discloses a method and apparatus for implanting prosthesis components in the knee

joint. Ex. 1012, Abstract. Johnson further discloses using trial components, including a tibial trial prosthesis with a "plastic, polymeric insert," that is designed to "fit and articulate with" a femoral trial prosthesis. *Id.*, 1:41-45, 6:25-30.

B. Ratron

Ratron is titled "Surgical Instrumentation Kit for Inserting an Ankle Prosthesis," and relates to a surgical instrument and method for implanting a tibial and talus prosthesis on the ankle joint. Ex. 1013, 2:36-39. Ratron also discloses trialing prior to implantation of the prosthesis through use of tibial, talus, and skid "phantoms" that correspond to the features of the implant. *Id.*, Abstract, 3:67-4:5, 13:36-39. Ratron further discloses that the phantom skid has a top and bottom surface that corresponds to the tibial and talus phantoms respectively. *Id.*, 3:5-1; 8:29-36, Fig. 7.

C. Rosa

Rosa is titled "Instrumentation for Minimally Invasive Unicompartmental Knee Replacement," and describes instrumentation used to prepare the femur "to receive a prosthetic femoral component" during knee replacement surgery. Ex. 1014, Title, Abstract. Rosa discloses using trial components, including a trial femoral and tibial component, to assess final component sizing and fit. *Id.*, 6:56-7:62. Rosa also discloses that the trial components may be temporarily secured with "fixation pins or other fixation elements." *Id.*, 13:45-46.

D. Li

Li is titled "Patient-Specific Instruments for Total Ankle Arthroplasty." Ex. 1005, Title. Li discloses a surgical guide with a plurality of guide holes used for drilling. *Id.*, 8:24-34; *see also id.*, 7:49-57, 8:35-55, 11:27-32; 12:54-13:8, Figs. 6, 8-11. Li also discloses a cutting guide with multiple cutting slots for making resectioning cuts on the tibia. *Id.*, 11:21-24, Figs. 6, 8-11.

E. Mumme

Mumme is titled "Tibial Spacer Saw Guide," and describes "surgical instruments used during implantation of orthopedic joint replacement prostheses." Ex. 1011, Title, 1:6-12. Mumme discloses a saw guide for the resection of the tibia. *Id.*, 1:6-12. Mumme further discloses using a trial spacer, trial tibial base plate, and trial femoral component for testing before implanting a prosthesis consisting of a tibial base plate, polyethylene tibia insert and a femoral component. *Id.*, 5:63-6:7.

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Claim 6 Is Rendered Obvious By Johnson In View Of The Knowledge of A POSITA

Johnson in view of a POSITA's knowledge renders obvious Claim 6. Ex. 1003 ¶¶286-309.

1. <u>Claim 6</u>

a) [Preamble]: A method, comprising:

To the extent the preamble is limiting, Johnson discloses a "method of implanting a femoral and a tibial knee prosthesis" that comprises fitting trial

prosthesis components on a patient's knee and trying different rotational positions of the trial prosthesis to ensure proper orientation and an accurate fit. Ex. 1012, Abstract; Ex. 1003 ¶286.

b) [6.1]: inserting a floating trial into a resected joint space between a first bone and a second bone;

Johnson discloses inserting a floating trial (femoral trial prosthesis 45) into a resected joint space between first (tibia) and second (femur) bones. Ex. 1003 ¶¶287-91. Johnson discloses resecting a patient's femoral bone to create a resected joint space between the femoral and tibia bone, and then inserting a femoral trial prosthesis into the resected bone portion. Ex. 1012, 3:7-11, 3:15-16, 4:47-50, 6:62-7:13.

Johnson discloses that the femoral trial prosthesis is floating in that the surgeon can fit the prosthesis to the surgically prepared distal femur and determine its correct orientation prior to pinning it to the bone. *Id.*, 3:56-60, 12:40-44; *see also* Ex. 1003 ¶290. Figure 9 below depicts femoral trial prosthesis 45 (floating trial, red) inserted into a resected joint space between tibia 8 (first bone) and femur 6 (second bone):

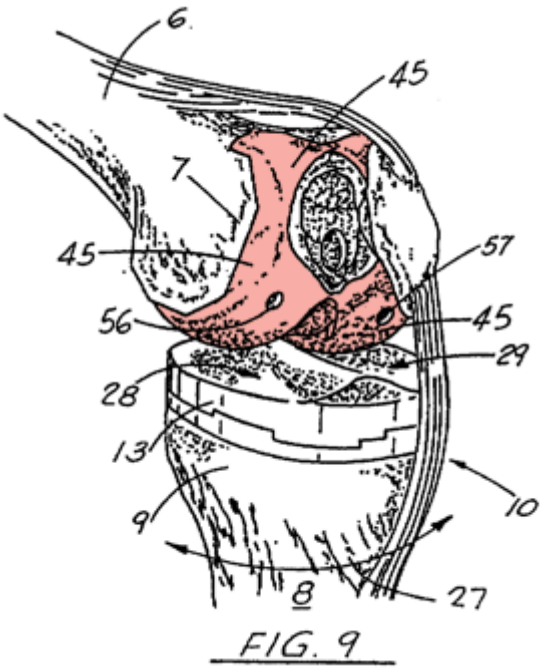


FIG. 9

Id., Fig. 9; Ex. 1003 ¶291.

c) *[6.2]: inserting a poly trial insert into the resected joint space, the poly trial insert comprising a concave surface,*

Johnson discloses inserting a poly trial insert (plastic trial insert 13, also referred to as an "articular insert trial") into the resected joint space, and that the insert comprises a concave surface. Ex. 1003 ¶¶292-96. Johnson discloses plastic trial insert 13 with a "pair of concavities 28, 29 that define articulating surfaces that fit and articulate with condylar[5] portions" of the femoral trial prosthesis. Ex. 1012, 6:25-30; *see also id.*, 1:41-45, 3:18-19, 4:1-5, Figs. 3-4. As Johnson calls the component a "plastic trial insert," The plastic trial insert is made of a plastic material, such as polyethylene, and therefore is a "poly trial insert." Ex. 1003 ¶294. Figure 9

[5] A condyle is the round prominence at the end of a bone. Ex. 1003 ¶293.

below depicts plastic trial insert 13 (poly trial insert, blue) that comprises a concave surface 28, 29 inserted into the resected joint space:

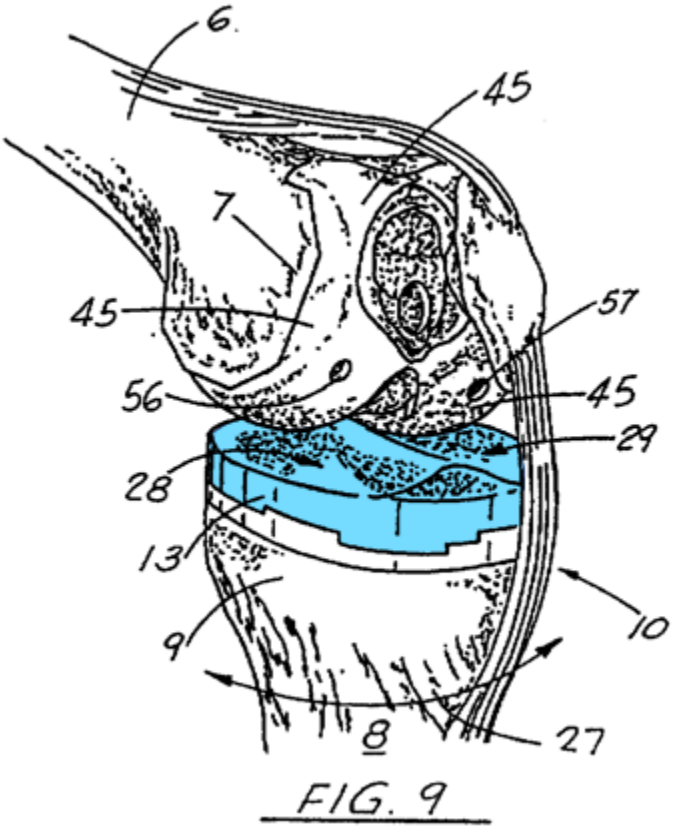


FIG. 9

Ex. 1012, Fig. 9; Ex. 1003 ¶296.

d) [6.3]: wherein the floating trial is sized and configured to articulate with the concave surface of the poly insert;

Johnson discloses the floating trial (femoral trial prosthesis) is sized and configured to articulate with the concave surface of the poly insert (plastic trial insert). Ex. 1003 ¶¶297-300. Johnson discloses the plastic trial insert has a "pair of concavities 28, 29 that define articulating surfaces that fit and articulate with condylar portions" of the floating trial. Ex. 1012, 6:25-30; *see also id.*, 1:41-45, 3:18-19, 4:1-5, Figs. 3-4. Johnson further discloses that the surfaces of the trial

components "articulate with each other" when the patient's knee joint is moved through a full range of motion during surgery. *Id.*, 3:28-38.

e) [6.4]: moving the floating trial to a location corresponding to a desired articulation of the floating trial with the poly trial insert;

Johnson discloses moving the floating trial (femoral trial prosthesis) to a location corresponding to a desired articulation of the floating trial with the poly trial insert (plastic trial insert). Ex. 1003 ¶¶301-03. Johnson discloses placing the "femoral articulating surface" of the floating trial against the poly trial insert so the "fit can be viewed before the actual prosthesis components [] are implanted." Ex. 1012, 3:28-33. Johnson further discloses moving the patient's knee through a full range of motion so that the trial components are positioned to articulate with each other, and "adjust[ing] the relative rotational positions of these trial components before the final positions are fixed" in their desired position. *Id.*, 3:32-38. Johnson discloses surgeons may use a lever to place the trial prosthesis in a desired position. *Id.*, 7:27-45. Placing the trial prosthesis in a desired position involves moving the femoral trial prosthesis to the location where it achieves a desired articulation with the plastic trial insert. Ex. 1003 ¶302.

Figures 10A and 10B of Johnson depict moving the trial prosthesis to a location corresponding to a desired articulation between the floating trial and the poly trial insert.

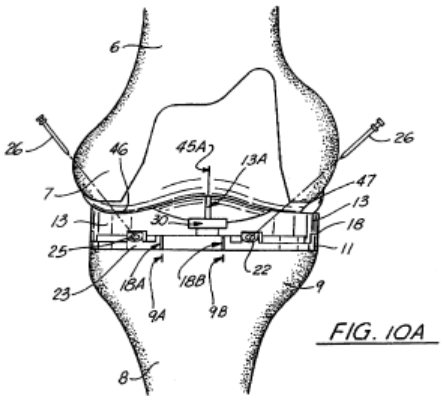


FIG. 10A

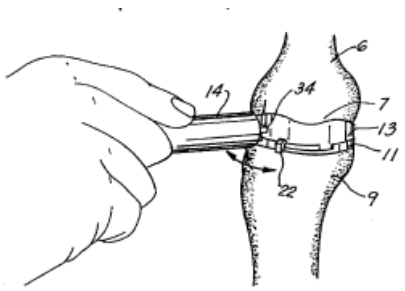


FIG. 10B

Ex. 1012, 4:55-59, 7:26-8:3, Figs. 10A-B; Ex. 1003 ¶303.

f) [6.5]: inserting a plurality of fixation pins through a plurality of pin holes defined by the floating trial;

Johnson discloses inserting a plurality of fixation pins (pegs) through a plurality of pin holes (openings 55, 56) defined by the floating trial (femoral trial prosthesis). Ex. 1003 ¶¶304-06. Johnson discloses that "[t]rial femoral prosthesis 45 (FIG. 8) can be drilled at openings 55, 56 and affixed to the distal femur 7 using bone screws or pegs." Ex. 1012, 7:21-23. "Pegs" include fixation pins, and openings receiving fixation pins are pin holes. Ex. 1003 ¶305. Figure 8 below shows the rear surface 48 of femoral trial prosthesis 45 (floating trial, red) with a plurality of pin holes 55 and 56 (purple):

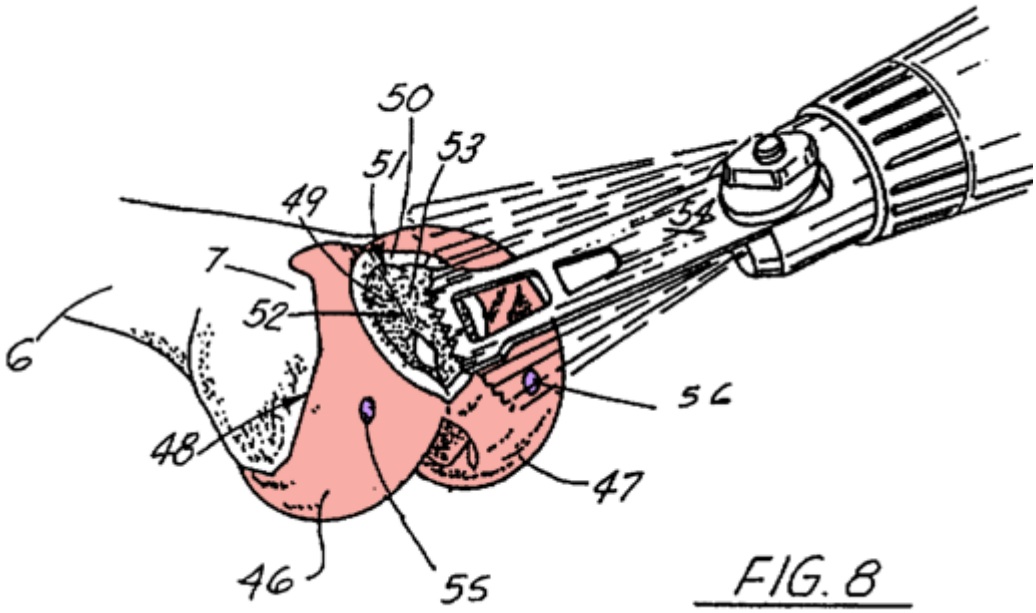


FIG. 8

Ex. 1012, Fig. 8; *see also id.*, 7:4-25; Ex. 1003 ¶306.

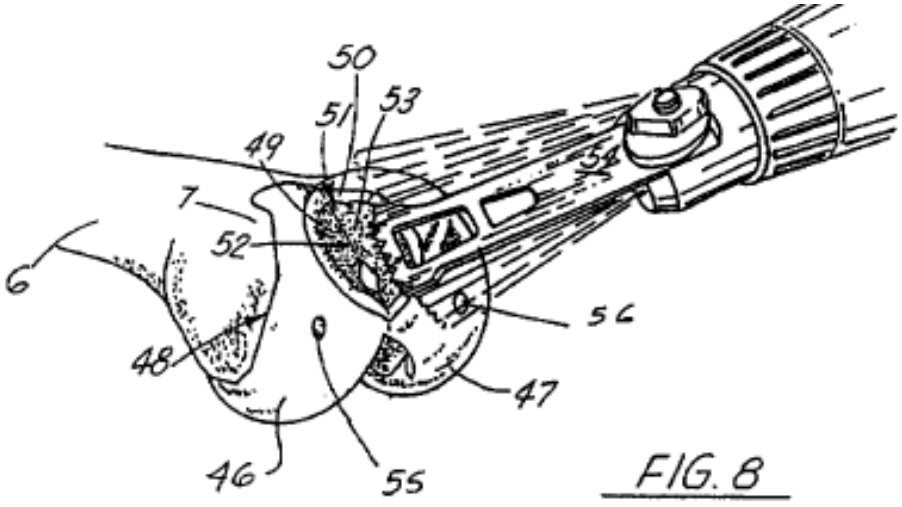
g) *[6.6]: removing the floating trial and the poly trial insert from the resected joint space; and*

Johnson discloses removing the floating trial (femoral trial prosthesis) and the poly trial insert (plastic trial insert) from the resected joint space. Ex. 1003 ¶307. Johnson discloses removing both the femoral trial prosthesis and the plastic trial insert (aka articular insert trial) from the resected joint space. Ex. 1012, 3:61-4:7.

h) *[6.7]: forming at least two resectioning cuts on the second bone.*

Johnson discloses forming at least two resectioning cuts on the second bone (femur). Ex. 1003 ¶¶308-09. Johnson discloses "form[ing] surgical cuts 52, 53" in the patient's distal femur so as to "resect[] the distal femur." Ex. 1012, 7:7-12; *see also id.*, 3:7-9 ("form[ing] a plurality of cuts on the patient's distal femur."). Figure

8 below shows the resection of the femoral bone by cutting along the "medial and lateral sides of the femoral trial." *Id.*, 4:47-50.



Id., Fig. 8; Ex. 1003 ¶308.

POSITAs additionally would have found it obvious that additional resectioning cuts may need to be made to the femur after assessing the fit and position of the trial components on the bone to ensure the proper alignment of the final implants. Ex. 1003 ¶309. To ensure an optimal fit of the trial components, POSITAs would have found it obvious and been motivated to make two or more resectioning cuts to the femur after removing the floating trial and poly trial insert because it achieves the stated goal of the trialing process. *Id.*

B. Ground 2: Claim 6 Is Rendered Obvious By Ratron In View Of Rosa

During prosecution, the Examiner found that Ratron disclosed or rendered obvious all limitations of claim 6 but the "removing the floating trial and the poly trial insert from the resected joint space" and "forming at least two resectioning cuts

on the second bone" limitations. Ex. 1004, 12-13. During prosecution, PO did not contest the Examiner's findings in this regard. Ratron in combination with Rosa discloses all limitation of claim 6, and POSITAs would have found it obvious to combine Ratron and Rosa. Ex. 1003 ¶¶310-42.

1. Motivation to Modify Ratron in view of Rosa

Ratron discloses a method for implanting trial components (which it calls "phantoms") on a bone during joint replacement surgery by securing a phantom to the bone with a "hollow [bone anchor] stud" or another suitable "bone anchor mechanism." Ex. 1013, 1:38-54, 2:36-39, 6:10-19, 6:26-30, 9:12-15, 11:7-22. Similarly, Rosa discloses trial components for use during joint replacement surgery. Ex. 1014, Abstract. Rosa discloses the trial components are temporarily fixed to the bone with multiple "fixation pins or other fixation elements." *Id.*, 13:43-51.

The only method step of claim 6 not explicitly disclosed by Ratron is inserting a plurality of fixation pins, as Ratron discloses the use of a "hollow stud." Ex. 1013, 6:10-19, 6:26-30. However, Ratron discloses that the "hollow stud" can be replaced with "any other suitable mechanism." *Id.* Rosa discloses one other such suitable mechanism, namely inserting a plurality of fixation pins. Ex. 1014, 13:43-51.

POSITAs would have been motivated to add holes for fixation pins to Ratron's tibial and talus phantoms in view of the teachings of Rosa to use "any other suitable mechanism" and the known advantages of using fixation pins to secure implants to the bone. Ex. 1003 ¶¶311-12; *Cross Med. Prod., Inc. v. Medtronic*

Sofamor Danek, Inc., 424 F.3d 1293, 1321 (Fed. Cir. 2005). Though Ratron discloses securing the tibial and talus phantoms to the bone with a single stud, it invites using "other suitable mechanism[s]," and POSITAs seeking to improve the ability to maintain the proper positioning and alignment of Ratron's phantoms would have found it obvious to look to Rosa for another "suitable mechanism" because both are directed to surgical methods and instruments related to joint replacement surgery. Ex. 1003 ¶¶314-15. Moreover, as of the '561 Patent's priority date, it was well-known to POSITAs that using multiple fixation pins (like in Rosa) is one of many known ways to secure components to a bone during surgery. *Id.* POSITAs would have expected to be successful in modifying Ratron to use multiple fixation pins as taught by Rosa, because POSITAs would have known that in some instances fixation pins would better secure an implant to the bone as compared to a hollow stud. *Id.* Thus, POSITAs would have been motivated and found it obvious to add holes for the use of multiple fixation pins to replace the anchor stud in Ratron's trial components based on Rosa. *Id.* ¶¶310-16.

2. Claim 6

a) [Preamble]: A method, comprising:

To the extent the preamble is limiting, Ratron discloses "a surgical instrumentation kit and associated method for implanting an ankle prosthesis" that includes the use of trial components. Ex. 1013, 1:20-21; Ex. 1003 ¶317.

b) [6.1]: inserting a floating trial into a resected joint space between a first bone and a second bone;

Ratron discloses inserting a floating trial (both tibial phantom 110 and talus phantom 120 are floating trials) into a resected joint space between first (talus) and second (tibia) bones. Ex. 1003 ¶¶318-22.

Ratron discloses using a cutting block to cut the tibia "so as to resect the bottom end of the tibia" prior to inserting the tibial and talus phantoms. Ex. 1013, 7:4-13. Ratron then discloses inserting the tibial phantom and talus phantom into the resected joint space between the tibia and talus. *Id.*, Abstract, 1:46-54, 3:48-4:5, 13:32-39.

Ratron discloses that the tibial phantom is floating because it is "adapted to move freely" on the tibia such that it is "displaced to the optimum location" during extension and flexion of the ankle joint. Ex. 1013, Abstract, 3:67-4:5, 9:12-36 (tibial phantom "is driven freely to move relative to the talus phantom"); Ex. 1003 ¶320.

Ratron also discloses that the talus phantom is floating, as the surgeon can freely position the talus phantom in the desired location for the final talus implant before securing the talus phantom to the bone. Ex. 1013, 9:11-17 ("surgeon begins by putting the talus phantom 120 in place … Relative to talus A of the tibia T, the talus phantom then occupies the same position that will subsequently be occupied by the talus implant 20"); *see also id.*, 4:60-66; Ex. 1003 ¶321.

Figure 9 below depicts the tibia phantom (orange) and the talus phantom (red) floating trials inserted in the resected joint space between the tibia and talus:

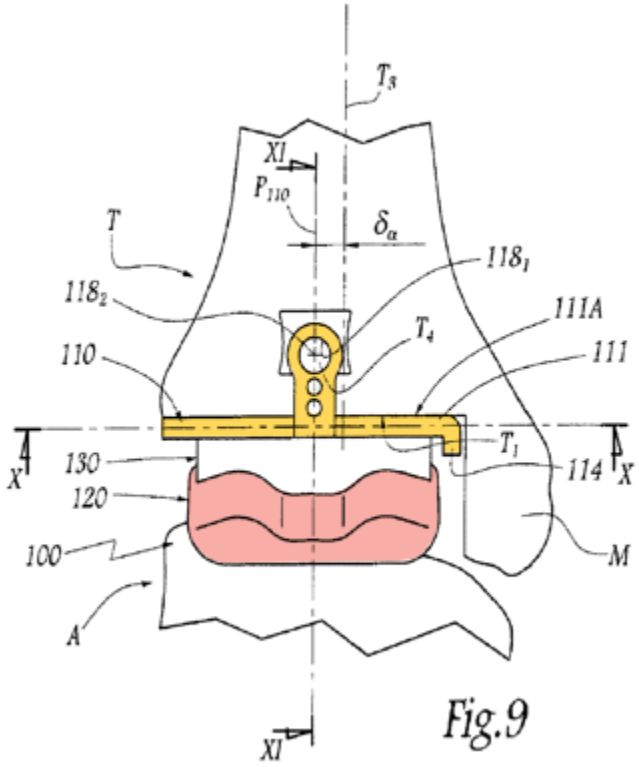


Fig.9

Ex. 1013, Fig. 9; *see also id.* 7:4-13, 8:54-65, 9:12-17; Ex. 1003 ¶322.

c) [6.2]: inserting a poly trial insert into the resected joint space, the poly trial insert comprising a concave surface,

Ratron discloses inserting a poly trial insert (phantom skid) comprising a concave surface into the resected joint space. Ex. 1003 ¶¶324-27. Ratron discloses that the phantom skid "correspond[s] to the prosthetic skid" and is "interposed between the talus and tibial implant phantoms." Ex. 1013, 1:46-54, 2:47-52, 9:18-25; *see* Section VII.B.2.b (talus and tibial phantoms are in resected joint space).

Ratron further discloses that the phantom skid may be made of "plastics material," which would include polyethylene. *Id.*, 6:61-67; Ex. 1003 ¶325.

Ratron discloses that the upper surface of phantom skid 130 has a "cylindrical cavity 131 being formed downwards in [the] central zone." Ex. 1013, 8:29-36. A "cavity formed downwards" on the phantom skid forms a concave surface on the poly trial insert. Ex. 1003 ¶326. Figure 7 below shows cylindrical cavity 131 (concave surface, green) on phantom skid 130 (poly trial insert, blue).

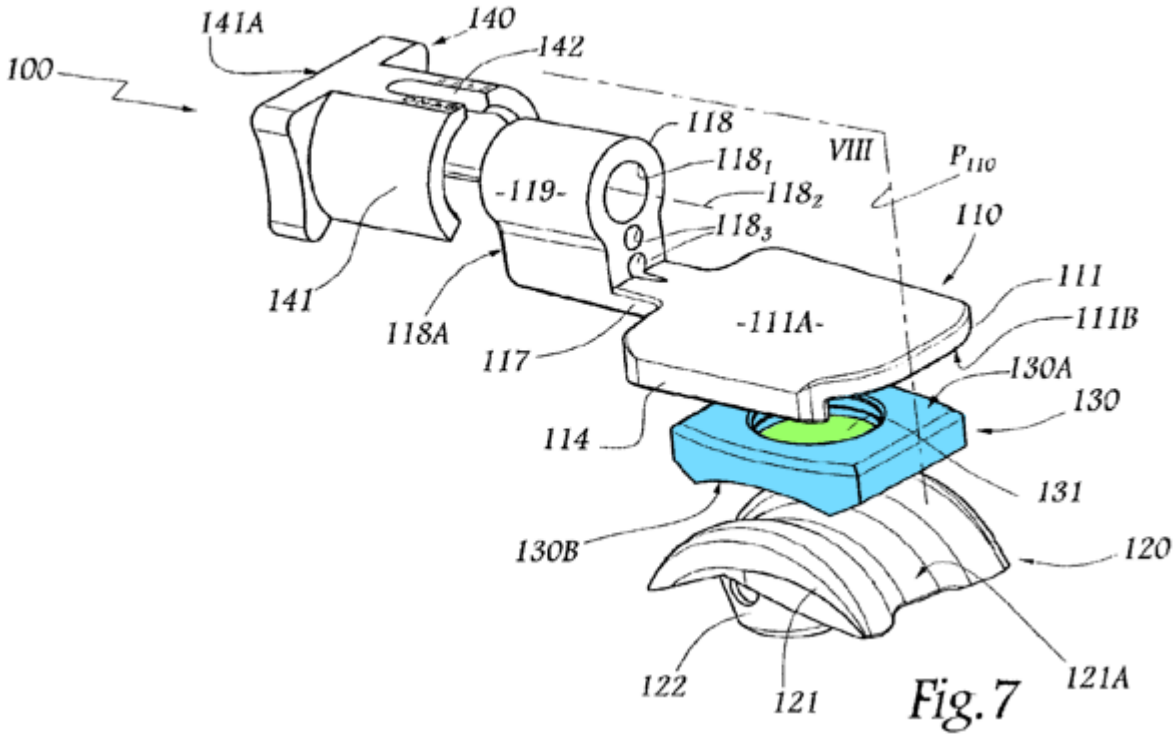


Fig. 7

Ex. 1013, Fig. 7, 8:32-35; Ex. 1003 ¶326.

Ratron further discloses that phantom skid 130 has a second concave surface 130B (green) as shown in Figure 8.

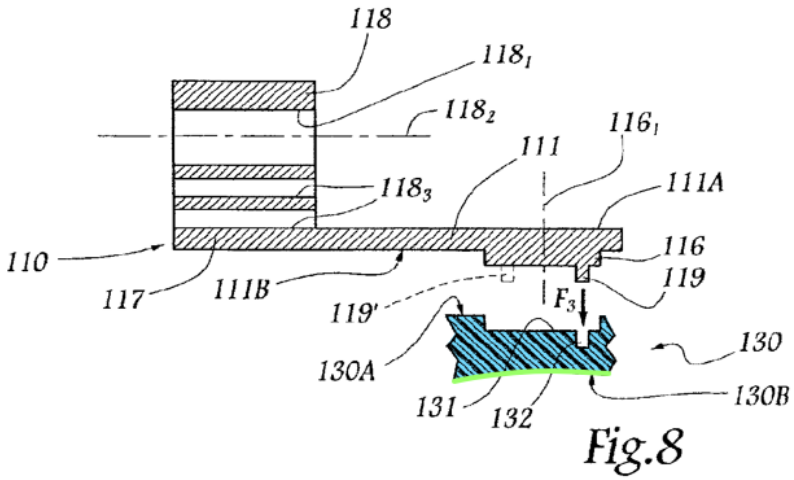


Fig.8

Id., Fig. 8, 3:5-1; Ex. 1003 ¶327.

d) [6.3]: wherein the floating trial is sized and configured to articulate with the concave surface of the poly insert;

Ratron discloses that the floating trial (tibial phantom/talus phantom) is sized and configured to articulate with the concave surface of the poly trial insert (phantom skid). Ex. 1003 ¶¶328-32. Ratron discloses that the top surface of the phantom skid has a "cylindrical cavity 131 being formed downwards in [the] central zone" that is "complementary to the disk-shaped protrusion" of the tibial phantom. Ex. 1013, 8:29-36; Ex. 1003 ¶329. Ratron also discloses that "when the phantom skid and tibial phantom are assembled to each other … the protrusion 116 is received into the cavity 131." *Id.* As Ratron's tibial phantom and phantom skid are "complementary" and "assembled to each other," they are sized and configured to articulate or interrelate together. Ex. 1003 ¶329.

Figure 8 below shows protrusion 116 of the tibial phantom (floating trial, orange) being sized and configured to articulate with cylindrical cavity 131 (concave surface, green) of phantom skid 130 (poly trial insert, blue).

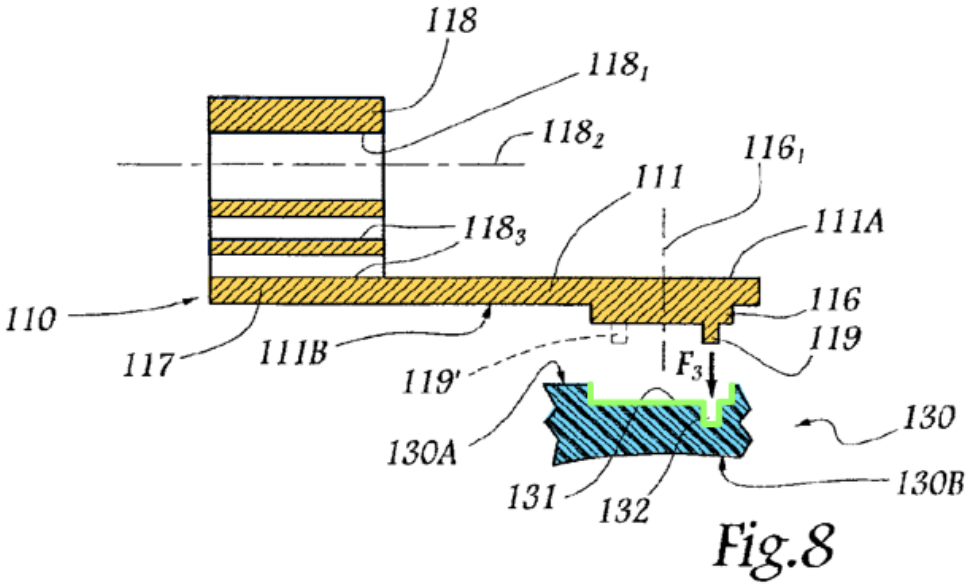


Fig.8

Ex. 1013, 8:32-35, Fig. 8; Ex. 1003 ¶330.

Ratron also discloses that the phantom skid and talus phantom "preferably include complementary surfaces that simulate movement of the talus implant and a prosthetic skid in the ankle joint" and are thus configured to articulate with each other. Ex. 1013, 3:5-11; Ex. 1003 ¶325. Figure 7 below shows talus phantom 120 (floating trial, red) being sized and configured to articulate with concave surface 130B (green) of the phantom skid (poly trial insert, blue).

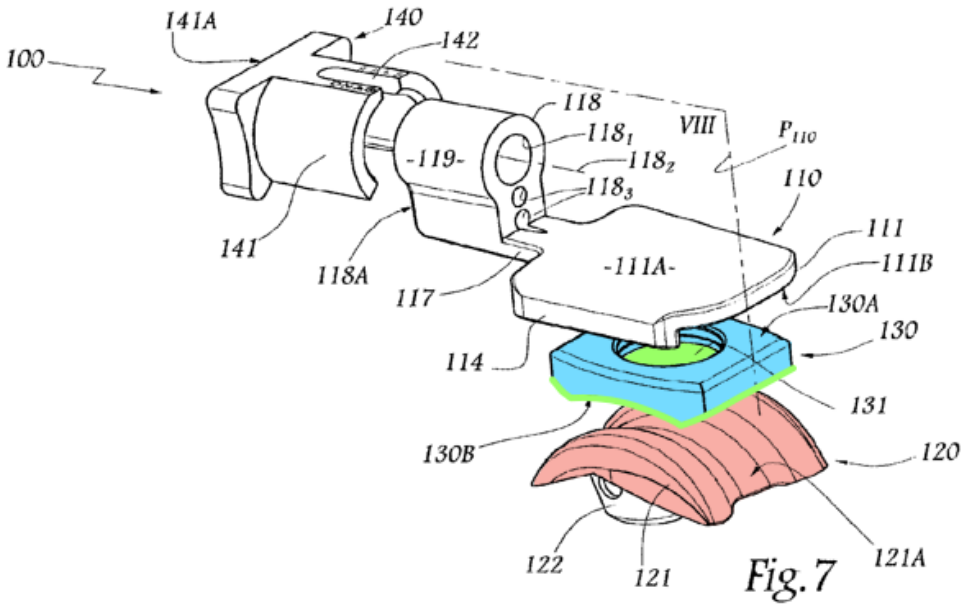


Fig. 7

Ex. 1013, Fig. 7; Ex. 1003 ¶¶331-332.

e) [6.4]: moving the floating trial to a location corresponding to a desired articulation of the floating trial with the poly trial insert;

Ratron discloses moving the floating trial (tibial phantom/talus phantom) to a location corresponding to a desired articulation of the floating trial with the poly trial insert (phantom skid). Ex. 1003 ¶¶333-35. Ratron discloses "slid[ing] [the tibial phantom] on the prepared bottom end of the tibia during extension and flexion of the ankle joint" such that it is "displaced to the optimum location" that "most closely approximates natural movement of the ankle joint." Ex. 1013, 3:67-4:6. The location where the trial components most closely approximate the natural movement of the joint is "optimum" because it corresponds to the desired articulation between the floating trial and poly trial. Ex. 1003 ¶334.

Ratron also discloses moving the talus phantom to a location where the phantom skid "hinges against the talus phantom … with the same movement as will occur between the talus implant and the prosthetic skid once they have been implanted." Ex. 1013, 4:60-66; 2:44-52. The position at which the talus phantom hinges against the phantom skid with the same movement that will occur between the final implants is the location where the desired articulation or interrelation between the components is achieved. Ex. 1003 ¶335.

f) [6.5]: inserting a plurality of fixation pins through a plurality of pin holes defined by the floating trial;

Ratron in view of Rosa renders obvious this limitation. *Id.* ¶¶336-39. Ratron discloses that the tibial and talus phantoms are secured to the bone via a "hollow stud" or "any other suitable mechanism." Ex. 1013, 2:36-39, 6:27-29, 9:12-15, 11:7-22. Rosa discloses trial components with holes for "fixation pins or other fixation elements for temporarily fixating the trial femoral component." Ex. 1014, 13:43-51. POSITAs would have found it obvious to use multiple fixation pins, as in Rosa, to replace the hollow stud of Ratron because fixation pins are a known "other suitable mechanism" for securing surgical components to bone. *See* Section VII.B.1; Ex. 1003 ¶¶310-316, 336-339. POSITAs would have been motivated and found it obvious to do so because POSITAs would have understood that multiple fixation pins are another obvious design choice to secure trial components to the bone, and that using such pins would better secure trial components to the bone and hold them

in a selected position, as compared with using a single stud or anchor. *Id.* POSITAs thus would have been motivated to add a plurality of pin holes for fixation pins to Ratron's floating trials to better secure the trials in the desired position. *Id.*

g) [6.6]: removing the floating trial and the poly trial insert from the resected joint space; and

Ratron discloses removing the floating trial (tibial phantom/ talus phantom) and the poly trial insert (phantom skid) from the resected joint space because the trial components are "separated from the ankle" prior to implantation of the implant components. Ex. 1013, 11:22-27; Ex. 1003 ¶340.

h) [6.7]: forming at least two resectioning cuts on the second bone.

Ratron discloses or renders obvious forming at least two resectioning cuts on the second bone (tibia). Ex. 1003 ¶¶341-42. Ratron discloses using a cutting block "to resect the bottom end of the tibia" prior to inserting the floating trials. Ex. 1013, 7:4-13, 7:26-34. POSITAs would have understood or found it obvious that resecting the bottom end of the tibia would take multiple cuts, and therefore Ratron discloses forming at least two resectioning cuts on the tibia. Ex. 1003 ¶341.

Additionally, Ratron discloses that its phantoms make it possible to ensure that bone preparation operations performed on the joint "are satisfactory for the purpose of implanting the ankle prosthesis" and that "[o]ther secondary bone preparation operations are typically subsequently performed" after trialing. Ex. 1013, 7:35-37, 12:30-35. If trialing demonstrated that the bone preparation was not

satisfactory for implanting the prosthesis, POSITAs would have been motivated and found it obvious to make two or more additional resectioning cuts to the tibia to ensure the prosthesis is properly aligned and positioned on the bone. Ex. 1003 ¶342.

C. Ground 3: Claims 13-15 Are Rendered Obvious By Li In View Of Ratron

POSITAs would have found it obvious to combine Li and Ratron to arrive at the method claimed in Claims 13-15. Ex. 1003 ¶¶343-91.

1. Motivation to Modify Li in View of Ratron

Li discloses a cutting guide for resectioning bone, surgical techniques for preparing bones for the receipt of orthopedic prostheses, and a prosthesis to restore mobility to the ankle joint. Ex. 1005, Abstract, 3:25-42. Similarly, Ratron discloses a surgical instrument and method for implanting tibial and talus prostheses on an ankle joint. Ex. 1013, 2:36-39. Additionally, Ratron discloses inserting trial components into a resectioned joint space and "mov[ing] the ankle joint of the patient" to ensure the size and positioning of the implants is suitable. *Id.*, 4:20-31.

Although Li discloses a prosthesis for restoring mobility in the joint, it does not explicitly disclose a specific method for using trial components to ensure that the prosthesis is properly positioned and aligned. Ex. 1005, 3:25-42. POSITAs would have been motivated by the disclosures in Li to seek out methods of ensuring that the prosthesis is properly sized and positioned on the bone because properly sized and positioned implants were known to improve patient mobility and decrease

surgical complications. Ex. 1003 ¶¶344-46; *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006). POSITAs seeking to improve the methods disclosed in Li would have found it obvious to look to Ratron because both are directed to instruments and techniques for joint replacement surgery, and specifically ankle replacement surgery. Ex. 1003 ¶347; Ex. 1005, Abstract; Ex. 1013, 1:20-21. Moreover, as of the '561 Patent's priority date, it was well-known to POSITAs that trial components were useful for assessing the size and positioning of an implant to ensure optimum fit, and they therefore would have expected that using trialing, as disclosed in Ratron, in Li's ankle replacement method would be successful. Ex. 1003 ¶348; Section I.A. Thus, POSITAs would have been motivated and found it obvious to use Ratron's trial components with the surgical methods disclosed in Li to arrive at the claimed invention. Ex. 1003 ¶348.

2. <u>Claim 13</u>

a) [Preamble] A method comprising:

To the extent the preamble is limiting, Li discloses "an exemplary method," illustrated in the flow chart of Figure 5, that uses "the present disclosure." Ex. 1005, 2:42-43; Ex. 1003 ¶349.

b) [13.1]: coupling a drill guide to a first bone,

Li discloses a drill guide (tibial drill guide) coupled to a first bone (tibia). Ex. 1003 ¶¶350-52. Li discloses that its tibial guide "may be modified to include additional structures such as … drill guides, linked cut guides, and adjustable cut or

drill guides." Ex. 1005, 10:30-33; *see also id.*, 7:35-38 (tibial guide "may include pin guide holes through which holes may be drilled"). Figure 10 illustrates the "tibial guide," which may constitute separate drill guides and cut guides, although only one figure is shown. *Id.*, 2:66-3:2, 10:30-33; Ex. 1003 ¶350.

Li discloses that "[o]nce the tibial guide is properly aligned with and seated on tibia 10, respectively, the surgeon may temporarily secure the respective guide to tibia 10. For example, the surgeon may temporarily secure tibial guide 70 to tibia 10 by inserting screws, pins, or other suitable anchors, such as pin 94 of FIG. 10, through apertures 86 and 88 in guide 70 and into the bone of tibia 10." Ex. 1005, 10:62-11:1. Figure 10 below illustrates the tibial guide drill guide coupled to tibia 10 (first bone, blue) using pin 94 (purple) inserted through the left most aperture 88 (yellow):

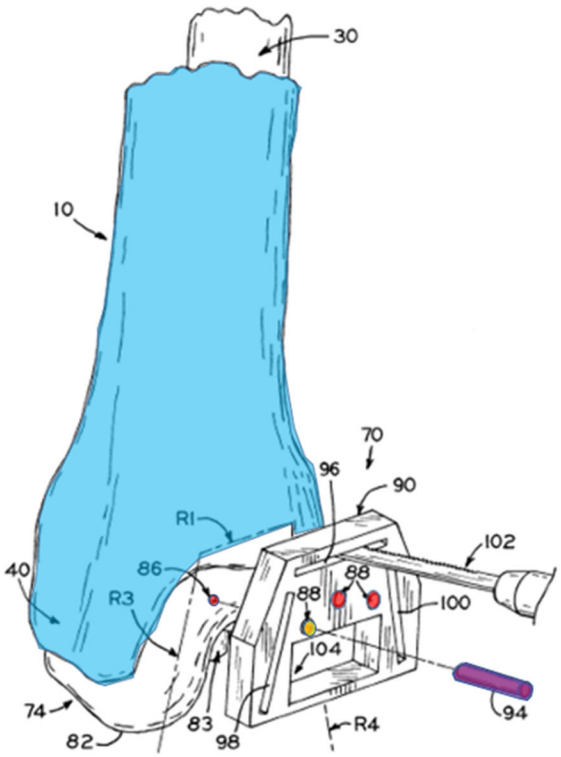


FIG_10

Id., Fig. 10; Ex. 1003 ¶352.

c) [13.2]: wherein the drill guide comprises a plurality of guide holes;

Li discloses that the drill guide (tibial drill guide) comprises a plurality of guide holes (pin guide holes). Ex. 1003 ¶¶353-54. Li states that "each of the tibial and/or talus 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 bones." Ex. 1005, 7:35-38; *see also id.*, 10:30-33 (tibial guide "may be modified to include … drill guides").

d) [13.3.]: forming a plurality of pilot holes in the first bone through the plurality of guide holes of the drill guide,

Li discloses drilling holes in the first bone (tibia) through the plurality of guide holes of the drill guide (tibial drill guide's pin guide holes). Ex. 1003 ¶¶355-56; Ex. 1005, 7:35-38 (tibial guide "may include pin guide holes through which holes may be drilled"); *see also id.*, 10:30-33; Section VII.C.2.c. These drilled holes guide the insertion of other fixation components, and therefore are pilot holes. Ex. 1003 ¶356.

e) [13.4]: wherein the pilot holes define proximal corners of a resection cut to be made in the first bone;

Li renders obvious that the pilot holes define the proximal corners of a resection cut made to the tibia. Ex. 1003 ¶¶357, 364-70. Petitioner explains the basis that this limitation is rendered obvious in Section VII.C.2.i, in connection with the "cutting the one or more resecting cuts" limitation, so that the explanation of Li's disclosure of both resection cuts and the proximal corners of those cuts are discussed together.

f) [13.5]: removing the drill guide from the first bone;

Li discloses removing the drill guide (tibial drill guide) from the first bone (tibia). Ex. 1003 ¶358. Li states that after holes are drilled "for use in locating and placing pins onto the respective bone," the tibial guide "may then be removed and a separate cut guide … may be fitted over the placed pins." Ex. 1005, 7:35-38; *see also id.*, 10:30-33 (tibial guide illustrated may include separate drill and cut guides).

g) [13.6]: coupling a cutting guide to the first bone,

Li discloses coupling a cutting guide (resection guide portion 90) to the first bone (tibia). Ex. 1003 ¶¶359-61. Li discloses that "resection guide portion 90 has a plurality of cut referencing surfaces" that "may guide an instrument such as reciprocating saw 102 (FIG. 10) to resect the tibial portion from tibia 10." Ex. 1005, 8:35-47. As disclosed in Section VII.C.2.f, Li discloses fitting a cut guide over the pins placed into the tibia bone after drilling holes in the bone using the drill guide. Ex. 1005, 7:35-38, 10:30-33. Li also discloses that "the surgeon may temporarily secure tibial guide 70 [including resection guide portion 90] to tibia 10 by inserting screws, pins, or other suitable anchors, such as pin 94 of FIG. 10, through apertures 86 and 88 in guide 70 and into the bone of tibia 10." *Id.*, 10:62-11:1; 11:50-56. Figure 10 below illustrates the resection guide portion 90 (cutting guide, yellow) coupled to tibia 10 (blue) using pin 94 (purple) inserted through apertures 86 and 88 (red):

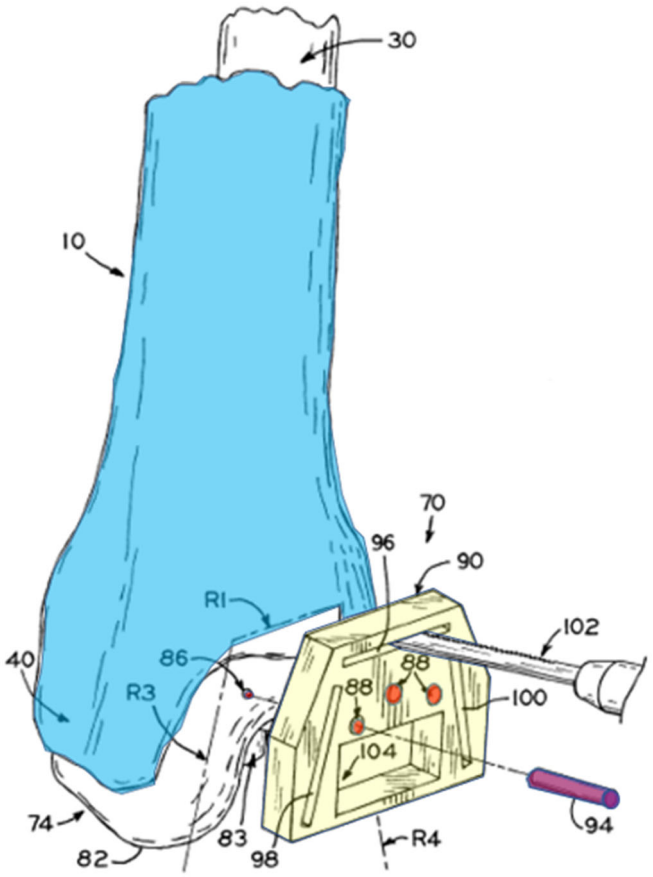


FIG_10

Id., Fig. 10; Ex. 1003 ¶361.

h) [13.7]: wherein the cutting guide defines at least two slots for guiding a surgical tool to form one or more resectioning cuts;

Li discloses a cutting guide (resection guide portion 90) that defines at least two slots for guiding a surgical tool to form one or more resectioning cuts (cut slots 96, 98, 100). Ex. 1003 ¶¶362-63. Li discloses that "resection guide portion 90 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., Figs. 6, 8-11. Li further discloses that "cut slots 96, 98, and 100 may guide an instrument such as reciprocating saw 102 (FIG. 10) to resect the tibial portion from tibia 10." *Id.*, 8:39-47. Figure 10 below illustrates cut slots 96, 98, and 100 (green) of resection guide portion 90 with reciprocating saw 102 (red) being guided through slot 96:

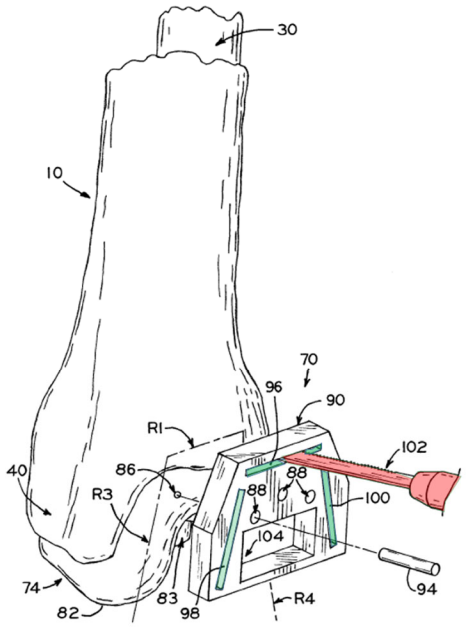


FIG_10

Id., Fig. 9-10; Ex. 1003 ¶363.

i) [13.8]: cutting the one or more resectioning cuts to form a resectioned joint space between the first bone and a second bone;

Li discloses cutting one or more resectioning cuts to form a resectioned joint space between the first bone (tibia) and a second bone (talus). Ex. 1003 ¶¶364-70. Li discloses that a "surgeon may use a saw blade of reciprocating saw 102 (FIG. 10)

to resect a tibial portion from distal tibia 10 along proximal cut slot 96 …, along medial cut slot 98 …, and along lateral cut slot 100." Ex. 1005, 11:21-32. Figure 10 below illustrates reciprocating saw 102 (red) being guided through slot 96, with cut slots 96, 98, and 100 shown in green, and Figure 11 below illustrates the resected portion of the tibia (purple) being removed to create a resected joint space (yellow) between the tibia and talus bones:

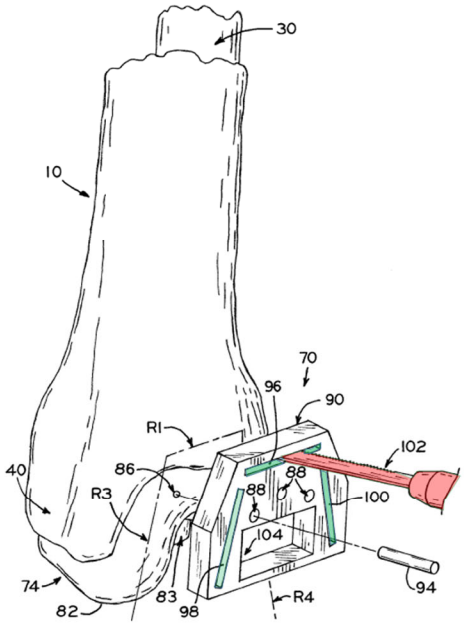


FIG.10

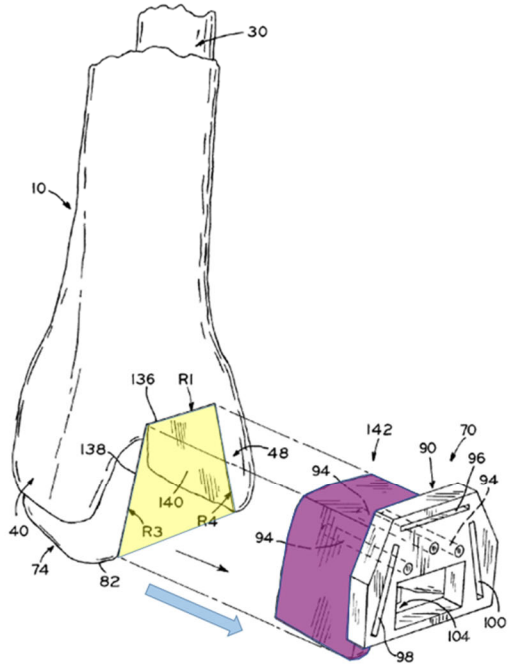


FIG.11

Id., Figs. 10-11; Ex. 1003 ¶365.

Though Li does not explicitly disclose that the three pilot holes (apertures 88) define the proximal corner of the resecting cuts made through slots 96, 98, and 100, POSITAs would have found it obvious to do so in two different ways.

First, POSITAs would have found it obvious to drill pilot holes at each end of slots 96, 98, and 100 to aid in making the resecting cuts through these slots using the reciprocating saw. *Id.* ¶369. There is a gap between slots 96 and slots 98/100 and at the bottom end of slots 98 and 100, making it an obvious location to place a hole. *Id.* Adding a hole there would be obvious because, depending on bone anatomy and condition, it can be difficult to start a cut using a reciprocating saw. *Id*. In such instances, POSITAs knew that one technique to aid in starting a cut using a reciprocating saw was to drill a pilot hole at the desired starting point of the cut. *Id*. Drilling a pilot hole created a surface that the teeth of the saw could grab to firmly hold onto the surface of the bone, thereby permitting the saw to cut into the bone. *Id*. This surgical technique to aid in creating cuts using saws has been used in surgeries for decades, and was well-known by the priority date of the '561 Patent. *Id*. As the slots are straight lines, drilling pilot holes at the end of the slots would place the holes at the proximal corners of the resecting cut. *Id.* ¶370. Thus, POSITAs would have been motivated to drill pilot holes that define the proximal corners of the resecting cut made through slots 96, 98, or 100 and would have found it obvious to do so. *Id*.

Second, POSITAs would have found it obvious to replace the three apertures 88 with two apertures at each end of slots 96, 98, or 100. Ex. 1003 ¶367. Li discloses that the apertures may be "positioned within a periphery defined by the cut referencing surfaces such that, when the resections are made and the resected tibial

bone portion [] removed, the guide and its associated pins are removed along with the resected bone portion." Ex. 1005, 1:48-53; *see also id.*, 7:14-21, 8:53-55, claims 1, 6. Li already discloses making resecting cuts along these three slots, and placing the pins at each end of the slot would achieve Li's stated goal of removing the pins along with the resected bone portion. Ex. 1003 ¶368. Further, POSITAs would have understood the advantages of placing the apertures at the end of each cut slot. *Id.* Placing the apertures in this location is beneficial because it minimizes the space between the cuts made through the cut slots and creates a rounded corner at the edge of the resectioning cut, instead of a sharp corner. *Id*. POSITAs understood that creating rounded corners at the edge of the resection cut reduces the risk of the bone cracking or fracturing during resectioning. *Id.* Li contemplates that such modifications are within the skill of POSITAs, stating that "[a]ny suitable number and arrangement of apertures may be provided in tibial guide 70." Ex. 1005, 11:1-2; *see also id.*, 12:44-52. As the slots are straight, placing apertures 88 at the end of the slots would place the holes at the proximal corners of the resecting cut. Ex. 1003 ¶367. Thus, POSITAs would have been motivated to move the location of apertures 88 such that the pilot holes define the proximal corners of the resecting cut made through slots 96, 98, or 100 and would have found it obvious to do so. *Id.* ¶368.

j) [13.9]: inserting a first trial into the resectioned joint space,

Li in view of Ratron renders this obvious. Ex. 1003 ¶¶371-72. Li discloses creating a resectioned joint space for ankle replacement surgery and implanting a

prosthesis to restore mobility to the ankle joint. *See* Section VII.C.2.i; *see also* Ex. 1005, 3:25-42. Ratron discloses inserting a first trial (tibial phantom) into a resected joint space for ankle replacement surgery. *See* Section VII.B.2.b; *see also* Ex. 1013, Abstract, 3:67-4:5, 13:36-39.

In view of the teachings of Ratron and the known advantages of using trial components, POSITAs would have found it obvious to insert a first trial as disclosed in Ratron into the resectioned joint space formed using the methods of Li to enable surgeons to assess the proper size and position of the prosthesis. *See* Section VII.C.1; Ex. 1003 ¶¶343-48, 371-72.

k) [13.10]: wherein the first trial is seated flush against the first bone, and wherein the first trial is removably coupled to the first bone; and

POSITAs would have found it obvious to seat the first trial flush against the first bone and to removably couple the trial to the bone in view of the teachings of Ratron. Ex. 1003 ¶¶373-76; *see also* Section VII.C.1 (POSITAs would have been motivated to use Ratron's trialing procedures in Li's method). Ratron discloses a first trial (tibial phantom) positioned "against the resected end T1 of the tibia" that "includes a top surface adapted to move freely against the prepared bottom end of the tibia." Ex. 1013, 2:42-63. Ratron further discloses that the "tibial phantom preferably slides on the prepared bottom end of the tibia during extension and flexion of the ankle joint" such that it is "displaced to the optimum location on the prepared surface of the tibia that most closely approximates natural movement of the ankle

joint." *Id.*, 2:65-66, 4:3-5. The first trial (tibial phantom) thus would be seated flush against the tibia to slide along the prepared bottom end of the tibia to its optimum location. Ex. 1003 ¶375. Depicted below is tibial phantom 110 (first trial, orange) seated flush against the tibia T (first bone):

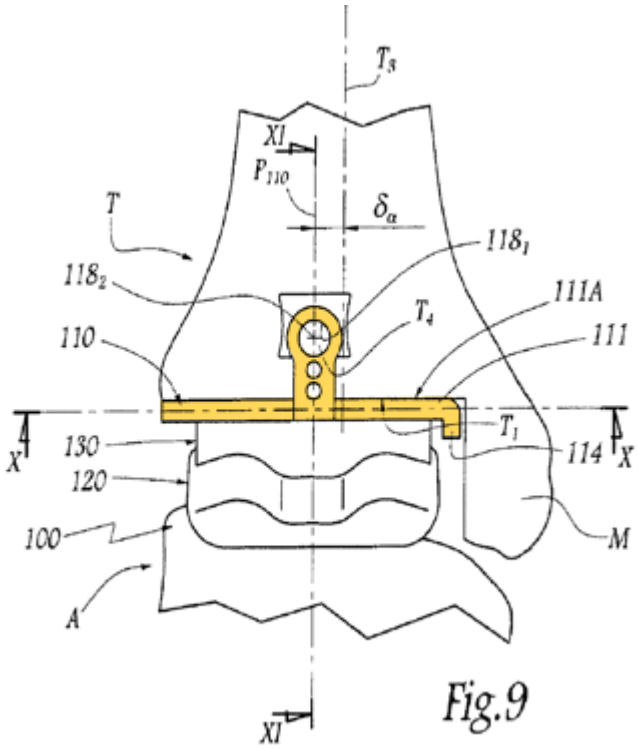


Fig.9

Id.; Ex. 1013, Fig. 9.

Ratron further discloses that the first trial is removably coupled to the first bone. Ex. 1003 ¶376. Specifically, Ratron discloses that the tibial phantom has bores 118 that can be used to drill holes to accommodate an "anchor stud." Ex. 1013, 11:7-22. Ratron further discloses that the tibial phantom is removable. *Id.*, 11:22-27. To the extent PO argues that Ratron does not explicitly disclose coupling the trial to the bone, POSITAs would have found it obvious to do so by inserting studs

or pins through the bores to hold the trial in its optimum position prior to implanting the final prosthesis. Ex. 1003 ¶376; *see also* Section VII.B.1.

l) [13.11]: performing a trial reduction to determine a height and a position of one or more implants.

POSITAs would have found it obvious to perform a trial reduction to determine the height and position of one or more implants in view of the teachings of Ratron. Ex. 1003 ¶¶377-79; *see also* Section VII.C.1. Ratron discloses "mov[ing] the ankle joint of the patient, in particular with flexion-extension movements" to "verify the quality with which the bones have been prepared, and also the dynamic behavior of the ankle provided with the phantom components, which is representative of the dynamic behavior the ankle will subsequently have, once fitted with the prosthetic components that are to be implanted." Ex. 1013, 2:4-12. Ratron further discloses that this provides "reliable information concerning the precise position of the tibial phantom" and "[t]he dynamic engagement between the phantom skid and talus phantom preferably self-positions the tibial phantom on the prepared bottom end of the tibia in a precise anatomical location corresponding to optimum operation of the ankle joint." *Id.*, 2:59-63. As claim 14 explains, a trial reduction at least consists of inserting trial components (phantoms) into a resected joint space and moving the trial components until they achieve a desired articulation. Ex. 1003 ¶378; *see also* Ex. 1002, claim 14. By determining the desired position of the trial components, a trial reduction determines the height and position of the trial

components. Ex. 1003 ¶378. POSITAs would have found it obvious to perform the trial reduction disclosed in Ratron as part of the surgical method disclosed in Li to assess the proper size and position of the implants and to achieve the desired articulation between the implant components and bone. Ex. 1003 ¶¶343-48, 377-79; Section VII.C.1.

3. Claim 14

a) The method of claim 13, wherein performing a trial reduction comprises:

Li in view of Ratron renders claim 13 obvious. *See* Section VII.C.2.

b) [14.1]: inserting a poly trial insert in to the resected joint space;

Ratron discloses inserting a poly trial insert (phantom skid) into the resected joint space. *See* Section VII.B.2.c; Ex. 1003 ¶¶381-82. POSITAs would have been motivated and found it obvious to use trial components, including the poly trial insert, disclosed in Ratron as part of the surgical method disclosed in Li to ensure the proper size, fit, and orientation of the prosthesis ultimately implanted. Ex. 1003 ¶¶343-48, 381-82; *see also* Section VII.C.1.

c) [14.2]: inserting a floating trial into the resected joint space, wherein the floating trial is sized and configured to articulate with the concave surface[6] of the poly trial insert; and

Ratron discloses inserting a floating trial (both tibial phantom 110 and talus phantom 120 are floating trials) into the resected joint space that is sized and configured to articulate with a concave surface(s) of the poly trial insert. *See* Section VII.B.2.b-d; Ex. 1003 ¶¶318-32, 383-84. POSITAs would have been motivated and found it obvious to use the trial inserts disclosed in Ratron as part of the surgical method disclosed in Li to ensure the proper size, fit, and orientation of the prosthesis ultimately implanted. Ex. 1003 ¶¶343-48; *see also* Section VII.C.1.

d) [14.3]: determining an implant coordinate, wherein the implant coordinate is determined by moving the floating trial to a location corresponding to a desired articulation with the concave surface.

Ratron discloses moving a floating trial to a location corresponding to a desired articulation with a concave surface of the poly trial, which would result in determining an implant coordinate corresponding to a desired articulation with the concave surface. *See* Section VII.B.2.e; Ex. 1003 ¶¶333-35, 385-86. POSITAs

---

[6] Claim 14 lacks an antecedent basis in that it refers to "*the* concave surface of the poly trial insert," when the claim on which it depends does not include any such limitation. For purposes of this petition, Petitioner interprets "*the* concave surface" as meaning "*a* concave surface." Petitioner reserves the right to challenge this claim as lacking an antecedent basis in other forums.

would have been motivated and found it obvious to use the trial inserts disclosed in Ratron as part of the surgical method disclosed in Li to ensure the proper size, fit, and orientation of the prosthesis ultimately implanted. Ex. 1003 ¶¶343-48; *see also* Section VII.C.1.

4. Claim 15

a) The method of claim 13, further comprising:

Li in view of Ratron renders claim 14[7] obvious. *See* Sections VII.C.2-3.

b) [15.1]: removing the floating trial and the poly trial insert from the resectioned joint section and

Ratron discloses or renders obvious removing the floating trial and poly trial insert from the resectioned joint space. Ex. 1003 ¶¶340, 388-89; *see* Section VII.B.2.g; *see also* Section VII.C.1

[7] As written, claim 15 depends from claim 13. Claim 15 lacks an antecedent basis in that it refers to "*the* floating trial and *the* poly trial insert" and "the resectioned joint *section*" when claim 13 does not include any such limitations. In the District Court case, PO asserted that claim 15 was intended to depend from claim 14 and that "the resectioned joint *section*" refers to "the resectioned joint *space*" of claim 13. Ex. 1037. Petitioner applies that understanding in this Petition, but reserves the right to challenge PO's position in the District Court case.

c) [15.2]: forming at least two additional resection cuts in the second bone.

Li in view of Ratron renders this limitation obvious. Ex. 1003 ¶¶390-91. Li discloses making one or more resecting cuts to the tibia. Section VII.C.2.i. Li also discloses performing a resection of the second bone (talus) by forming one or more cuts in the second bone. Ex. 1005, 6:40-48 ("[T]he system may determine … that a resection must be made of a proximal end of talus 18"); *see also id.*, 10:10-14, 12:1-14 ("Talar guide … provides one or more cut guide slots to guide a saw that resects a portion of the talus.").

In addition, POSITAs would have found it obvious that additional resectioning cuts may need to be made to the second bone (talus) to ensure the proper alignment of the final implants, particularly after assessing the size and positioning of the implant using trial components, such as those disclosed in Ratron. Ex. 1003 ¶391; *see also* Sections VII.C.1, VII.C.2.j-l, VII.C.3. Ratron discloses that the tibial and talus phantoms (floating trial) and phantom skid (poly trial insert) make it possible to ensure that bone preparation operations performed on the joint "are satisfactory for the purpose of implanting the ankle prosthesis." Ex. 1013, 12:30-35. If the trial components demonstrate that the bone preparation was not satisfactory for implanting the prosthesis, POSITAs would have found it obvious to make additional resectioning cuts to ensure the prosthesis is properly aligned and positioned on the second bone. Ex. 1003 ¶391.

D. Ground 4: Claims 13-15 Are Rendered Obvious By Mumme In View Of Johnson

POSITAs would have found it obvious to combine Mumme and Johnson to arrive at the method claimed in Claims 13-15. Ex. 1003 ¶¶392-446.

1. Motivation to Modify Mumme in view of Johnson

Mumme discloses using a tibial spacer saw guide to guide the resection of the proximal tibia during knee replacement surgery. Ex. 1011, Abstract, 1:5-16, 3:14-15. Mumme explains that it is desirable to provide "good prosthesis-to-bone contact" to ensure the prosthesis fits well and discloses testing with trial components before implanting a final prosthesis. *Id.*, 1:59-2:12, 5:63-6:7.

Johnson discloses a method of knee replacement surgery that involves fitting a trial prosthesis on a surgically prepared bone, moving the patient's knee through a full range of motion, and using a lever to rotate the prosthesis into different rotational positions to ensure proper orientation and an accurate fit. Ex. 1012, Abstract, 1:41-45, 3:5-4:15, 6:25-30, 7:27-45.

Although Mumme discloses testing with trial components after performing a resection of the joint, Mumme does not explicitly disclose the details of the trial components or testing. Ex. 1011, 5:63-6:3. POSITAs therefore would have been motivated by the disclosures in Mumme to seek out trial components and methods of testing trial components to ensure good prosthesis to bone contact. Ex. 1003 ¶¶393-95; *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1375

(Fed. Cir. 2020). POSITAs would have found it obvious to look to Johnson because both Johnson and Mumme relate to surgical methods for joint replacement, specifically knee joint replacement. Ex. 1003 ¶396. Given that both Mumme and Johnson disclose similar methods of knee replacement surgery, and Mumme specifically discloses testing with trials, POSITAs would have expected that combining Johnson's trialing methods with Mumme's surgical methods would be successful. *Id.* Moreover, as of the '561 Patent's priority date, it was well-known to POSITAs that trial components were useful for ensuring the proper positioning, fit and size of a final implant. *See* Section I.A; Ex. 1003 ¶397. Thus, POSITAs would have found it obvious to use the trial components and methods disclosed in Johnson as part of the surgical method disclosed in Mumme. Ex. 1003 ¶397.

2. Claim 13

a) [Preamble]: A method, comprising:

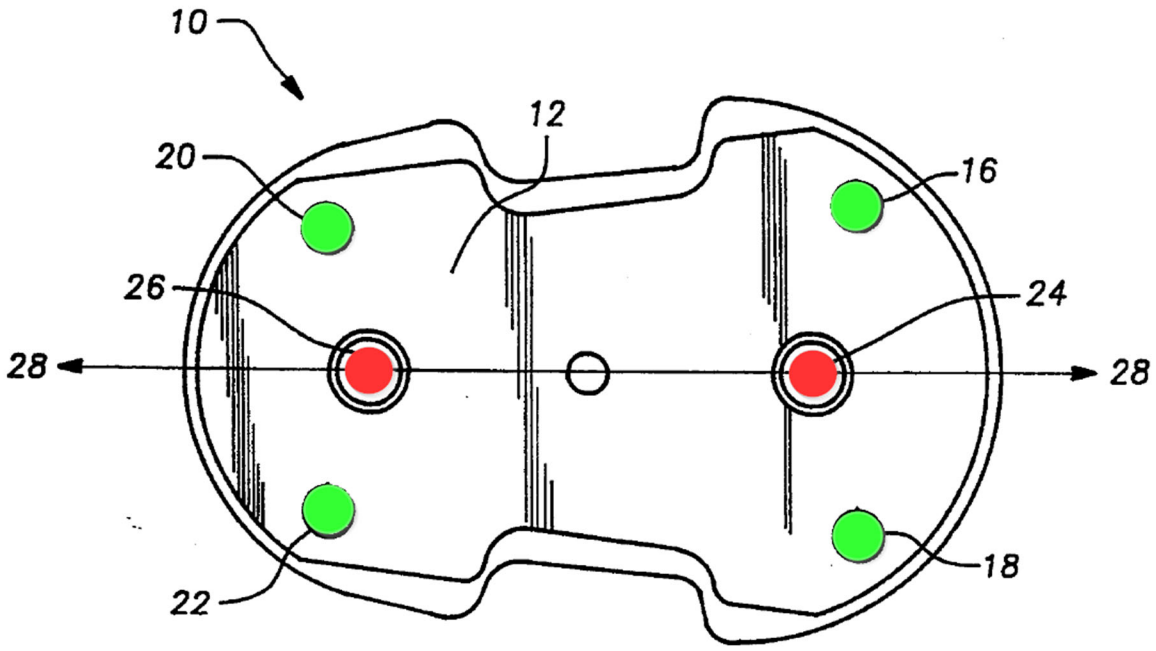
To the extent the preamble is limiting, Mumme discloses a method for knee replacement surgery. Ex. 1011, Abstract, 4:58-59; Ex. 1003 ¶398.

b) [13.1]: coupling a drill guide to a first bone,

Mumme discloses coupling a drill guide (proximal tibial drill guide) to a first bone (tibia). Ex. 1003 ¶399. Mumme discloses that the "proximal tibial drill guide … is positioned onto the initially cut surface of the proximal tibia" and therefore it is coupled to the proximal tibia. Ex. 1011, 5:2-6; Ex. 1003 ¶399.

c) [13.2]: wherein the drill guide comprises a plurality of guide holes;

Mumme discloses that the drill guide comprises a plurality of guide holes. Ex. 1003 ¶¶400-02. Though Mumme does not visually depict the drill guide, Mumme discloses that "[t]he drill guide has six holes corresponding in location to pegs 16, 18, 20 and 22, and screw holes 24 and 26, of a correspondingly sized tibial baseplate 10 of FIG. 1." Ex. 1011, 5:6-9. Tibial baseplate 10 is shown below with four peg holes (green) and two screw holes (red):



Ex. 1011, Fig. 1; Ex. 1003 ¶401. Thus, Mumme discloses a drill guide having a plurality of guide holes, located in the same or similar arrangement as holes 16, 18, 20, 22, 24, and 26 of Fig. 1. Ex. 1003 ¶¶401-02.

d) [13.3.]: forming a plurality of pilot holes in the first bone through the plurality of guide holes of the drill guide,

Mumme discloses forming a plurality of pilot holes in the first bone (tibia) through the plurality of guide holes of the drill guide. Ex. 1003 ¶¶403-05. Mumme discloses that "[h]oles are drilled in the tibial plateau at the site of each of the drill guide holes," and that after the drill guide is removed, these holes are "filled with smooth guide pins" or a "stabilizing pin." Ex. 1011, 5:9-11, 5:19-25. As Mumme discloses that holes are drilled for the purpose of insertion of guide pins or stabilizing pins, Mumme discloses forming pilot holes. Ex. 1003 ¶405.

e) [13.4]: wherein the pilot holes define proximal corners of a resection cut to be made in the first bone;

Mumme discloses or renders obvious that the holes define the proximal corners of a resection cut made in the tibia. Ex. 1003 ¶¶406, 418-23. Petitioner explains the basis on which this limitation is disclosed or rendered obvious in Section VII.D.2.i, in connection with the "cutting the one or more resecting cuts" limitation, so that the explanation of Mumme's disclosure of both resection cuts and the proximal corners of those cuts are discussed together.

f) [13.5]: removing the drill guide from the first bone;

Mumme discloses that "[t]he drill guide is removed" from the tibia. Ex. 1011, 5:19-23; Ex. 1003 ¶407.

g) [13.6]: coupling a cutting guide to the first bone,

Mumme discloses that after the drill guide is removed, a cutting guide (tibial spacer saw guide 30) is coupled to the tibia. Ex. 1003 ¶¶408-10. Mumme discloses that "the pair of medial holes corresponding in location to pegs 16 and 18 of tibial baseplate 10 … are filled with smooth guide pins 56 and 56. The associated hole on the medial side of the resected tibial surface corresponding to screw hole 24 of tibial baseplate 10 is filled with a stabilizing pin 119." Ex. 1011, 5:19-25. Mumme also discloses a cutting guide, tibial spacer saw guide 30, that includes "two principal components, plate 34 and block 36." *Id.*, 3:51-52; *see also id.*, Fig. 3, 4:58-63, 5:17-25, 5:35-40, 6:11-23; Ex. 1003 ¶408.

Mumme discloses that the tibial saw guide is coupled to the tibia by sliding the tibial saw guide over the guide pins and stabilizing pins and "lower[ing] [the tibial saw guide] until inferior surface 38 rests flush against initially resected surface 117 of the proximal tibia." Ex. 1011, 5:26-32; Ex. 1003 ¶409. Figure 3 below illustrates tibial spacer saw guide 30 (cutting guide, purple) coupled to initially resected tibia surface 117 (first bone, blue), using pins 56, 58, and 119 (green):

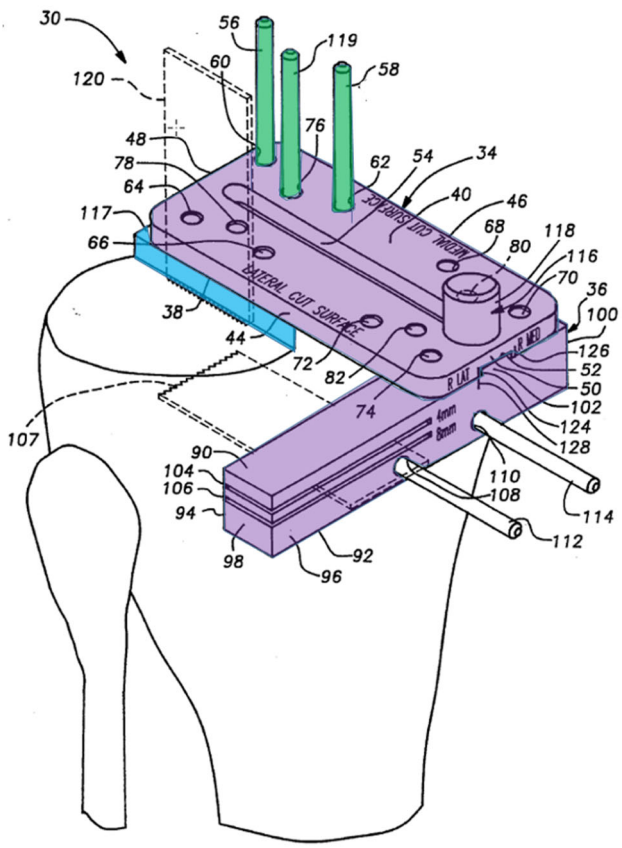


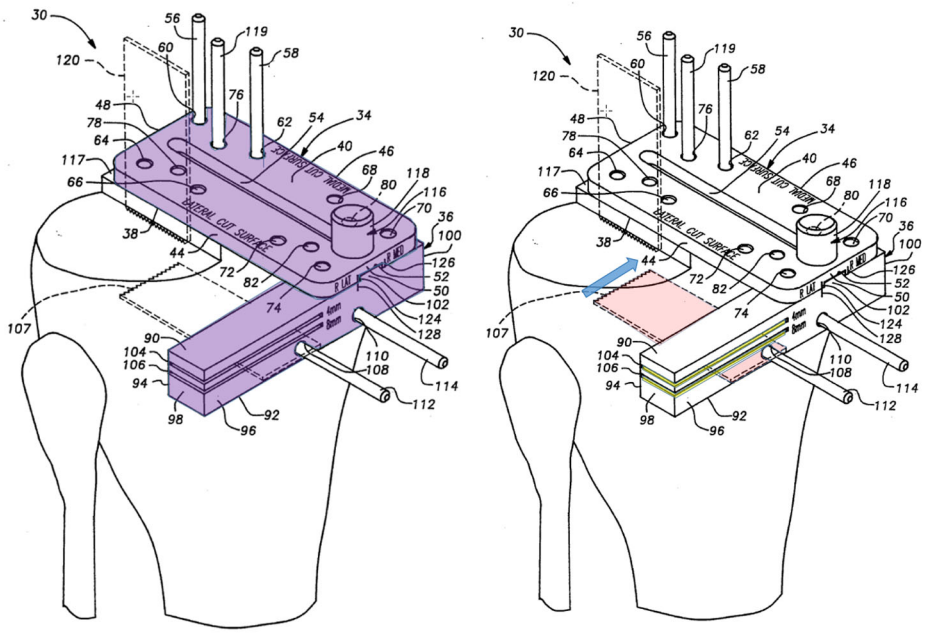
FIG. 3

Ex. 1011, Fig. 3; Ex. 1003 ¶410.

h) [13.7]: wherein the cutting guide defines at least two slots for guiding a surgical tool to form one or more resectioning cuts;

Mumme discloses that the cutting guide (tibial saw spacer guide) defines at least two slots (saw guide slots 104 and 106) for guiding a surgical tool to form one or more resectioning cuts. Ex. 1003 ¶¶411-13. Mumme discloses that "block 36" of "[t]ibial saw spacer guide 30" has "[s]aw guide slots 104 and 106." Ex. 1011, 3:51-52, 4:25-27. "Each of slots 104 and 106 are sized to receive[] therethrough a saw blade 107 such that the saw blade can reciprocate in the lateral-medial direction and can be displaced in the anterior-posterior direction, but is restrained from motion

in the vertical direction." *Id.*, 4:30-34; *see also id.*, Fig. 3, 4:27-30, 4:58-63, 5:17-25, 5:35-40, 5:54-62, 6:11-23, 6:53-56, 7:3-8, 8:5-15, 8:49-50. Figure 3 below illustrates tibial spacer saw guide 30 (cutting guide, in purple on the left) with at least two slots 104 and 106 (in green on the right) for guiding a surgical tool (saw blade 107, in red on the right) to form one or more resectioning cuts:



Id., Fig. 3; Ex. 1003 ¶413.

i) [13.8]: cutting the one or more resectioning cuts to form a resectioned joint space between the first bone and a second bone;

Mumme discloses cutting one or more resection cuts through the slots to form a resectioned joint space between the first bone (tibia) and a second bone (femur). Ex. 1003 ¶¶414-17. Mumme discloses that "[a] horizontal osteotomy is made using … saw blade 107 inserted through either slot 104 or 106, depending on the size of the defect and the size of the spacer that has been selected. The saw blade is moved

in the anterior-posterior direction and in the medial-lateral direction until the affected side has been completely resected, as shown in FIG. 3." Ex. 1011, 5:54-60; *see also id.*, Fig. 3, 4:25-32, 6:53-56, 7:3-8, 8:5-15, 8:49-50. Figure 3 below illustrates cutting the one or more resectioning cuts using saw blade 107 (red) passing through at least one of slots 104 and 106 (green):

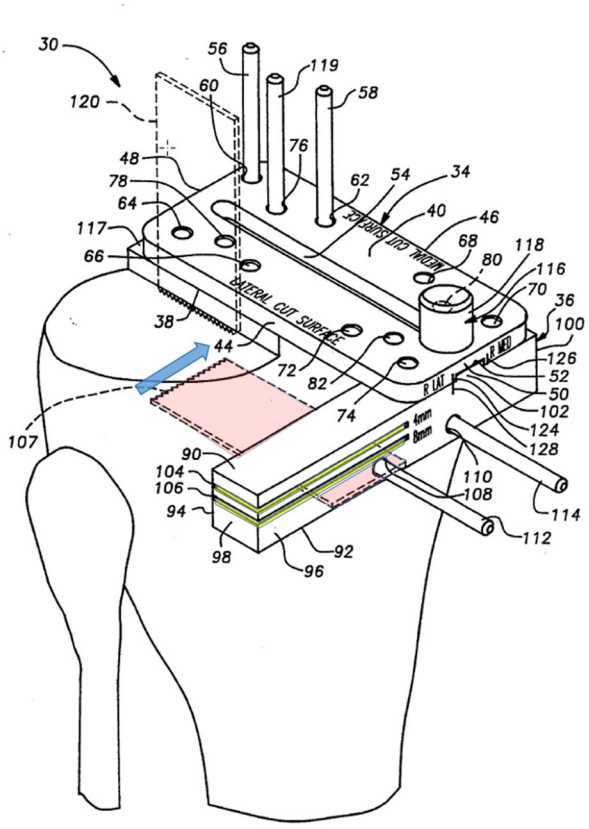


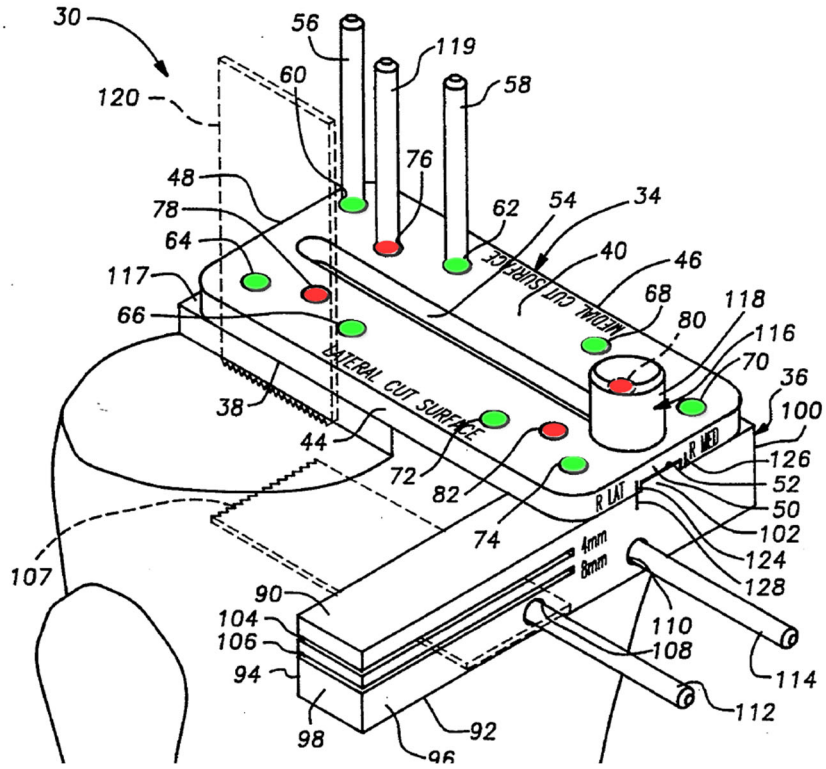
FIG. 3

Id., Fig. 3; Ex. 1003 ¶416.

Mumme also discloses that "[a] vertical sagittal osteotomy is made using, for example, a one inch wide saw blade 120 held flush against lateral guide edge 44" before making the horizontal osteotomy through slots 104 or 106. Ex. 1011, 5:37-39; *see also id.*, 5:39-54. Mumme further discloses that a "composite base plate and

spacer are placed on the prepared surface of the tibia" and a "tibial insert" is placed on the tibial baseplate. *Id.*, 5:63-6:7. By "completely resect[ing]" the affected portion of the tibia as taught by Mumme, there is space to place the composite base plate, spacer, and a tibial insert, and thus a resected joint space is created between the first bone (tibia) and a second bone (femur). Ex. 1003 ¶417.

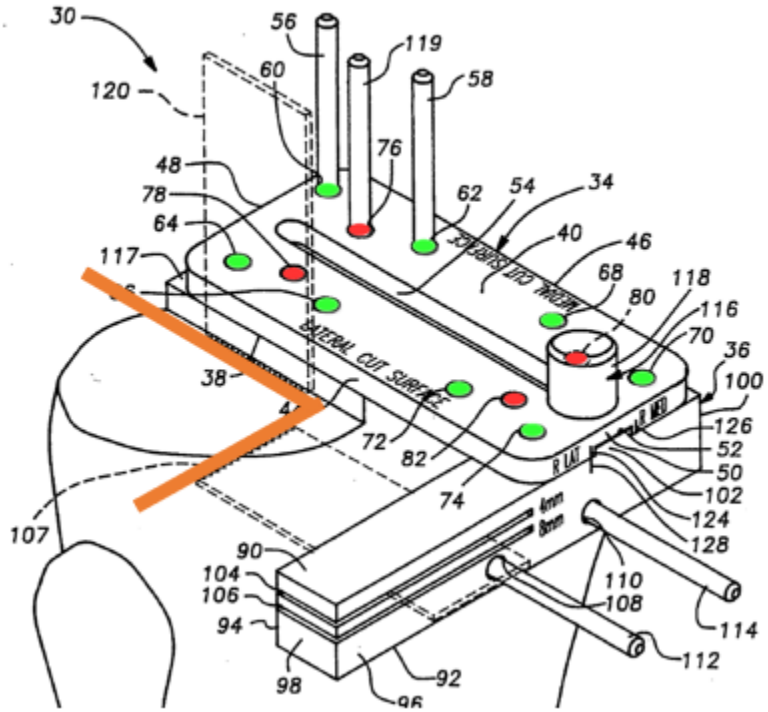
The pilot holes discussed in reference to element 13.3 define the corners of the resection cut made using the saw. Ex. 1003 ¶¶418-23; *see* Sections VII.D.2.d-e. Mumme discloses that "[i]n each corner of plate 34, there is situated a pair of locating holes for receiving therethrough locating pins 56 and 56." Ex. 1011, 3:63-66. Each locating hole also has an associated stabilizing hole. *Id.*, 4:6-13. These locating holes are "[t]he peg holes drilled in the initially resected tibial plateau." *Id.*, 2:57-64. Depicted below are the locating holes (green) and stabilizing holes (red) of the tibial saw spacer guide:



Ex. 1011, Fig. 3; Ex. 1003 ¶419. The sets of holes on either side of the saw guide are arranged in the same manner as the pin holes drilled using the drill guide. Ex. 1003 ¶420. Thus, the pilot holes formed using Mumme's drill guide create the locating holes in each corner of plate 34. *Id*.

The locating holes are used to define the resectioning cut, including the corners of the resectioning cut. *Id*. Mumme discloses that the plate "includes a lateral guide edge for guiding a saw blade for making a sagittal osteotomy when the plate is in the first orientation, the lateral guide edge being spaced and oriented relative to the first pair of locating holes." Ex. 1011, 2:40-45; *see also id.*, 2:45-49 (saw guide's plate "includes a medial guide edge for guiding a saw blade for making a sagittal osteotomy when the plate is in the second orientation, the medial guide

edge being spaced and oriented relative to the second pair of locating holes"); 7:53-68 (the "first and second pairs of drill holes in the proximal tibia serve as references for locating the sagittal osteotomy, and whereby the resected planar proximal end surface of the tibia serves as a reference for locating the generally horizontal osteotomy."). As the lateral guide edge of the saw guide's plate is spaced and oriented relative to the first pair of locating holes, the pilot holes (locating holes) define the location of a resection cut (sagittal osteotomy) made in the first bone (tibia). Ex. 1003 ¶421. The resectioning cuts require a horizontal and vertical osteotomy, ultimately resulting in a box-like area of the bone being removed, as illustrated below in orange:



Ex. 1011, Fig. 3; Ex. 1003 ¶421. As the resectioning cut includes corners, and the locating holes define the location of the resectioning cuts, the locating holes define the proximal corners of the resectioning cut. Ex. 1003 ¶422.

To the extent PO argues Mumme does not disclose that the pilot holes define the proximal corners of a resection cut, POSITAs would have found it obvious to move the locating holes 74 and 76 to the proximal corners of the resection cuts formed by cutting along the lateral guide edge of the guide 44 and slots 104 or 106. Ex. 1011, 5:37-39; *see also id.*, 5:39-54; Ex. 1003 ¶423. POSITAs would have found it obvious to do so because placing the locating holes in this location creates a rounded corner where the resectioning cuts meet, which reduces the risk of the bone cracking or fracturing during resectioning. *Id.* ¶423; *see* Section VII.C.2.i. Thus, POSITAs would have been motivated to move the locating holes such that the pilot holes define the proximal corners of the resecting cut made along the lateral guide edge 44 and slots 104 or 106, and would have found it obvious to do so. Ex. 1003 ¶423.

j) [13.9]: inserting a first trial into the resectioned joint space,

Mumme discloses inserting a first trial into the resectioned joint space. Ex. 1003 ¶¶424-26. Mumme discloses creating a resectioned joint space. Ex. 1011, 5:54-60; *see also id.*, Fig. 3, 4:25-32, 6:53-56, 7:3-8, 8:5-15, 8:49-50; *see* Section VII.D.2.i. Mumme further discloses that, after testing with a trial spacer, trial tibial base plate, and trial femoral component, a spacer and tibial base plate are placed on

the prepared surface of the tibia and a femoral component is placed on the prepared surface of the femur. Ex. 1011, 5:63-6:3. POSITAs would have understood that the prepared surfaces of the tibia and femur are boundaries of the resectioned joint space, and "testing" with the trial components involves inserting the trial components into the resectioned joint space in a location corresponding to where the spacer, tibial base plate, and femoral components are ultimately implanted on the bone. Ex. 1003 ¶426; Ex. 1011, 5:63-6:3.

k) [13.10]: wherein the first trial is seated flush against the first bone, and wherein the first trial is removably coupled to the first bone; and

Mumme in view of Johnson renders obvious this limitation. Ex. 1003 ¶¶427-30. Mumme discloses a first trial. *See* Section VII.C.2.j.

Mumme does not explicitly disclose that the first trial is seated flush against the first bone or removably coupled to the bone. However, POSITAs would have found it obvious to seat the first trial flush against the bone and to removably couple the trial to the bone in view of the teachings of Johnson. Ex. 1003 ¶427; *see also* Section VII.D.1. Johnson discloses placing a first trial (tibial trial prosthesis) on the first bone (tibia), and that the trial is built to "fit the patient's anatomy." Ex. 1012, 3:49-60. Figure 9 of Johnson shows tibial trial prosthesis (first trial, yellow) installed so that it is seated flush against the first bone (tibia):

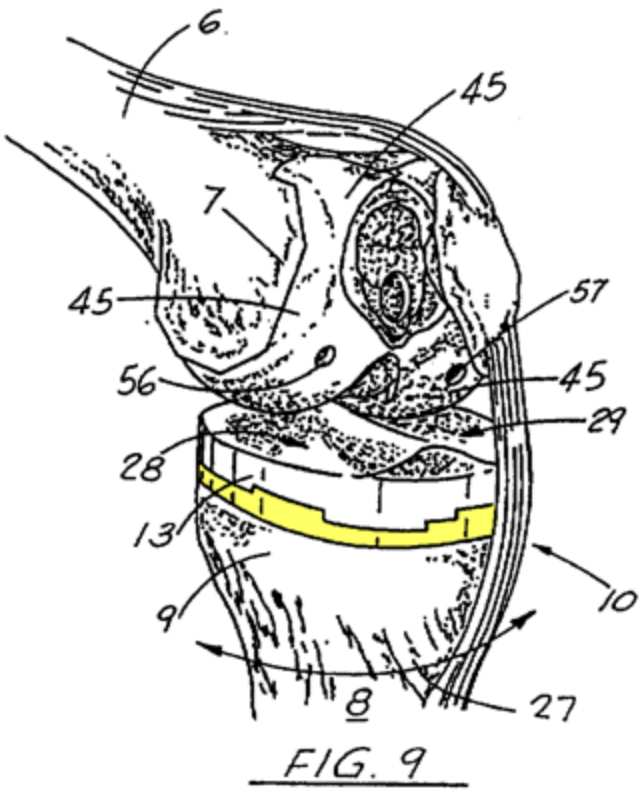


FIG. 9

Ex. 1012, 7:14-17, Fig. 9.

Johnson also discloses that the trial is removably coupled to the first bone with "pins" such that it can be removed before implanting the final prosthesis. Ex. 1012, 3:61-67, 4:8-15. POSITAs would have found it desirable and obvious to seat Mumme's first trial flush against the bone, as taught by Johnson, to ensure proper fit of the final prosthesis because the final prosthesis in Mumme is seated flush against the bone. Ex. 1003 ¶430.

l) [13.11]: performing a trial reduction to determine a height and a position of one or more implants.

Mumme in view of Johnson renders obvious this limitation. Ex. 1003 ¶¶431-33. Mumme discloses "testing" with trial components but does not explicitly

disclose a method for testing. Ex. 1011, 5:63-6:7. Johnson, however, discloses "mov[ing] the patient's knee joint through a full range of motion" such that the "surfaces of the corresponding trial prosthesis components articulate with each other." Ex. 1012, 3:28-39, 3:48-55; *see also* Section VII.D.1 (POSITAs would have been motivated to use Johnson's trialing procedures in Mumme's method); Ex. 1003 ¶432. As claim 14 explains, a trial reduction at least consists of inserting trial components (phantoms) into a resected joint space and moving the trial components until they achieve a desired articulation. Ex. 1003 ¶432; *see also* Ex. 1002, claim 14. By determining the desired position of the trial components, a trial reduction determines the height and position of the trial components. Ex. 1003 ¶432. Thus, POSITAs would have found it obvious to perform the trial reduction disclosed in Johnson as part of Mumme's "testing" for the same purpose disclosed by Mumme: a trial reduction would permit the surgeon to assess the proper size and position of the implants to ensure there is "good prosthesis-to-bone contact" and fit. Ex. 1003 ¶433; *see also* Ex. 1011, 1:59-62, 5:63-66; Section VII.D.1.

3. Claim 14

a) The method of claim 13, wherein performing a trial reduction comprises:

Mumme in view of Johnson renders claim 13 obvious. *See* Section VII.D.2.

b) [14.1]: inserting a poly trial insert in to the resected joint space;

Mumme in view of Johnson renders this limitation obvious. Ex. 1003 ¶¶435-37. Mumme discloses inserting trials, including a trial spacer, into a resected joint

space, but does not disclose specific characteristics of the trials. *See* Section VII.D.2.j. POSITAs would have found it obvious to use a poly trial insert in Mumme's resected joint space in view of the teachings of Johnson. Ex. 1003 ¶437; Section VII.D.1; Section VII.A.1.c.

c) *[14.2]: inserting a floating trial into the resected joint space, wherein the floating trial is sized and configured to articulate with the concave surface[8] of the poly trial insert; and*

Mumme in view of Johnson renders this limitation obvious. Ex. 1003 ¶¶438-39. Mumme discloses inserting a trial into the resected joint space. *See* Section VII.D.2.j. Although Mumme does not disclose specific characteristics of the trial, POSITAs would have found it obvious to use a floating trial sized and configured to articulate with a concave surface of the poly trial insert in Mumme's resected joint space in view of the teachings of Johnson. Ex. 1003 ¶439; Sections VII.D.1, VII.A.1.b, VII.A.1.d.

d) *[14.3]: determining an implant coordinate, wherein the implant coordinate is determined by moving the floating trial to a location corresponding to a desired articulation with the concave surface.*

Mumme in view of Johnson renders this obvious. Ex. 1003 ¶¶440-41. Mumme discloses "testing" with trial components but does not explicitly disclose a method for testing. Ex. 1011, 5:63-6:7. Johnson discloses moving a floating trial to a location corresponding to a desired articulation with the concave surface of the

[8] *See* FN6.

poly trial. *See* Section VII.A.1.e. POSITAs would have understood that determining the location with the desired articulation between the floating trial and poly trial insert would result in determining an implant coordinate. Ex. 1003 ¶441. Thus, POSITAs would have found it obvious to move the floating trial in the manner disclosed in Johnson as part of the "testing" disclosed by Mumme, to determine the implant coordinate corresponding to the desired articulation. *See* Section VII.C.1, Ex. 1003 ¶441.

4. Claim 15

a) The method of claim 13, further comprising:

Mumme in view of Johnson renders claim 14[9] obvious. *See* Sections VII.D.2-3.

b) [15.1]: removing the floating trial and the poly trial insert from the resectioned joint section; and

Mumme in view of Johnson renders this limitation obvious. Ex. 1003 ¶¶443-44. Mumme discloses implanting the final prosthesis "following testing" with trial components. Ex. 1011, 5:63-6:7. POSITAs would have understood from this disclosure in Mumme that the floating trial and poly trial insert are removed from the resectioned joint space. Ex. 1003 ¶¶443-444. POSITAs also would have found it obvious to do so in view of the teachings of Johnson. *See* Sections VII.A.1.g, VII.D.1; Ex. 1003 ¶444.

[9] *See* FN7.

c) [15.2]: forming at least two additional resection cuts in the second bone.

Mumme discloses this limitation. Ex. 1003 ¶¶445-46. Mumme discloses resecting the distal end of the second bone (femur) before implanting prosthetic components. Ex. 1011, 1:29-35; *see also id.*, 6:3-7 (disclosing "implantation of the femoral component on the *appropriately prepared* distal femur") (emphasis added). POSITAs would have understood that resecting the femur would involve forming at least two resection cuts in the bone. Ex. 1003 ¶445.

POSITAs would also have understood and found it obvious that additional resectioning cuts may need to be made to the second bone (femur) to ensure the proper alignment of the final implants after testing the trial components. Ex. 1003 ¶446. Thus, POSITAs would have found it obvious to make at least two resectioning cuts on the second bone after testing the trial components to ensure proper fit and alignment. *Id.*

VIII. SECONDARY CONSIDERATIONS

PO did not assert secondary considerations during prosecution of the '561 Patent, and, as of the filing of this petition, has not asserted them in the District Court case. Petitioner is unaware of any secondary considerations relevant to the Challenged Claims.

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 '561 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 '561 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 PO asserted in the District Court case, U.S. Patent No. 10,888,336.

Two pending patent applications claim priority to Application No. 14/446,921, now the '561 Patent: Application No. 15/881,321, filed on January 26, 2018, and Application No. 17/803,285, which as of the date of this Petition does not show a filing date.

C. Counsel and Service Information

Lead Counsel	Back-Up Counsel

Alan Rabinowitz (Reg. No. 66,217) KIRKLAND & ELLIS LLP 601 Lexington Avenue New York, NY 10022 Telephone: (212) 446-4800 Facsimile: (212) 446-4900 alan.rabinowitz@kirkland.com	Luke L. Dauchot, P.C. (*pro hac* to be requested) KIRKLAND & ELLIS LLP 555 South Flower Street Suite 3700 Los Angeles, CA 90071 Telephone: (213) 680-8400 Facsimile: (213) 680-8500 LDauchot@kirkland.com Greg Polins (*pro hac* to be requested) KIRKLAND & ELLIS LLP 300 North LaSalle Chicago, IL 60654 Telephone: (312) 862-2000 Facsimile: (312) 862-2200 greg.polins@kirkland.com Sharre Lotfollahi (*pro hac* to be requested) KIRKLAND & ELLIS LLP 2049 Century Park East Suite 3700 Los Angeles, CA 90067 Telephone: (310) 552-4200 Facsimile: (310) 552-5900 slotfollahi@kirkland.com

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 '561 Patent are unpatentable. Paragon therefore requests that an IPR of these claims be instituted.

Date: October 4, 2022

Respectfully submitted,

/s/ Alan Rabinowitz

Alan Rabinowitz (Reg. No. 66,217)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900
alan.rabinowitz@kirkland.com

Attorneys For Petitioner

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 13,950 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. 9,907,561 (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 case.

DATED: October 4, 2022

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

APPENDIX A

Full text of Challenged Claims:

6. A method, comprising:

inserting a floating trial into a resected joint space between a first bone and a second bone;

inserting a poly trial insert into the resected joint space, the poly trial insert comprising a concave surface, wherein the floating trial is sized and configured to articulate with the concave surface of the poly insert;

moving the floating trial to a location corresponding to a desired articulation of the floating trial with the poly trial insert;

inserting a plurality of fixation pins through a plurality of pin holes defined by the floating trial;

removing the floating trial and the poly trial insert from the resected joint space; and

forming at least two resectioning cuts on the second bone.

13. A method, comprising:

coupling a drill guide to a first bone, wherein the drill guide comprises a plurality of guide holes;

forming a plurality of pilot holes in the first bone through the plurality of guide holes of the drill guide, wherein the pilot holes define proximal corners of a resection cut to be made in the first bone;

removing the drill guide from the first bone;

coupling a cutting guide to the first bone, wherein the cutting guide defines at least two slots for guiding a surgical tool to form one or more resectioning cuts;

cutting the one or more resectioning cuts to form a resectioned joint space between the first bone and a second bone;

inserting a first trial into the resectioned joint space, wherein the first trial is seated flush against the first bone, and wherein the first trial is removably coupled to the first bone; and

performing a trial reduction to determine a height and a position of one or more implants.

14. The method of Claim **13**, wherein performing a trial reduction comprises:

inserting a poly trial insert into the resected joint space;

inserting a floating trial into the resected joint space,

wherein the floating trial is sized and configured to articulate with the concave surface of the poly trial insert; and

determining an implant coordinate, wherein the implant coordinate is determined by moving the floating trial to a location corresponding to a desired articulation with the concave surface.

15. The method of claim **13** further comprising:

removing the floating trial and the poly trial insert from the resectioned joint section; and

forming at least two additional resection cuts in the second bone.