IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Horan et al.
U.S. Patent No.: 8,523,921 Attorney Docket No.: 126518.00002
Issue Date: September 3, 2013
Appl. Ser. No.: 11/361,245
Filing Date: February 24, 2006
Title: TIBIAL PLATEAU LEVELING OSTEOTOMY PLATE

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF
CLAIMS 1-11 OF UNITED STATES PATENT NO. 8,523,921
PURSUANT TO 35 U.S.C. §§ 311-319, 37 C.F.R. § 42

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VOI 1003 – Prosecution History of U.S. Patent Application Serial No. 13/538,407

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VOI 1005 – Declaration of Jeffrey N. Peck, DVM, DACVS Regarding U.S. Patent No. 8,523,921

VOI 1006 – U.S. Patent Application Publication No. 2006/0173458 to Forstein

VOI 1007 – Prosecution History of U.S. Provisional Patent Application Serial No. 60/616,680 (Provisional to Forstein)

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VOI 1013 – U.S. Patent Application Publication No. 2006/0009771 to Orbay et al.

VOI 1014 – Palmer, *Understanding Tibial Plateau Leveling Osteotomies in Dogs*, VETERINARY MEDICINE, (June 2005)

VOI 1015 – Slocum et al., *Tibial Plateau Leveling Osteotomy for Repair of Cranial Cruciate Ligament Rupture in the Canine,* VET. CLIN. N. AM. SMALL ANIM. PRACT., 23: 777-95 (1993)

VOI 1016 – U.S. Patent No. 5,304,180 to Slocum

VOI 1017 – U.S. Patent Application Publication No. 2006/0149275 to Cadmus

VOI 1018 – Slone et al., *Orthopedic Fixation Devices*, RADIOGRAPHICS, 11:823-847 (September 1991)

VOI 1019 – Smith & Nephew, *TC-100 Screw & Plating System Catalog*, May 1999

VOI 1020 – Stryker, *Small Fragment Set Trauma Product Catalog*, 2004

VOI 1021 – Pacchiana et al., *Surgical and postoperative complications associated with tibial plateau leveling osteotomy in dogs with cranial cruciate ligament rupture: 397 cases (1998-2001)*, 222(2) J. AM. VET. MED. ASSOC. 184-93 (2003)

VOI 1022 – Priddy et al., *Complications with and owner assessment of the outcome of tibial plateau leveling osteotomy for treatment of cranial cruciate ligament rupture in dogs: 193 cases (1997–2001)*, 222(12) J. AM. VET. MED. ASSOC. 1726-1732 (2003)

VOI 1023 – U.S. Patent No. 4,677,973 to Slocum

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VOI 1034 – Prosecution History of U.S. Provisional Patent Application Serial No. 60/564,853 (Provisional to Huebner)

VOI 1035 – 2004 *Synthes Catalog*

VOI 1036 – U.S. Patent No. 7,267,678 to Medoff

VOI 1037 – Dejardin, L. M., *Tibial Plateau Leveling Osteotomy*, TEXTBOOK OF SMALL ANIMAL SURGERY, 3d Ed., Sauders (2003)

VOI 1038 – International Patent Application Publication No. WO2005/048888 to Burn

VOI 1039 – German Patent Application Publication DE 100 15 734 to MED-Medical Engineering Ltd.

VOI 1040 – Auer, J. A. et al., HISTORY OF AOVET: THE FIRST 40 YEARS, AO Foundation (2013)

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VOI 1042 – *New Products from AO Development*, AO Publishing (2004)

VOI 1043 – Ganesh, V. K. et al., *Biomechanics of Bone-Fracture Fixation By Stiffness-Graded Plates In Comparison With Stainless-Steel Plates*, BIOMEDICAL ENGINEERING ONLINE, 4:46 (July 25, 2005)

VOI 1044 – Tornkvist, H. et al., *The Strength of Plate Fixation in Relation to the Number and Spacing of Bone Screws*; 10 J. ORTHOPEDIC TRAUMA 3:204 (April 1996)

VOI 1045 – Newton, C. D. et al., TEXTBOOK OF SMALL ANIMAL ORTHOPAEDICS, J.B Lippincott Co. (1985)

VOI 1046 – *DePuy Synthes Products, Inc. v. Veterinary Orthopedic Implants, Inc.*, No. 3:18-cv-01342-HES-PDB (M.D. Fla.) – Redacted Excerpts from Plaintiff's Infringement Contentions

VOI 1047 – Image Processing of Canine Tibia Medial Radius – June 28, 2019

Veterinary Orthopedic Implants, Inc. ("Petitioner") petitions for Inter Partes Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-11 ("Challenged Claims") of U.S. Patent No. 8,523,921 ("the '921 Patent"). There exists a reasonable likelihood that Petitioner will prevail with respect to at least one of the Challenged Claims. Petitioner submits that an IPR should be instituted, and the Challenged Claims canceled as unpatentable.

I. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(A)

Petitioner certifies that the '921 Patent is available for IPR. Patent Owner Depuy Synthes Products, Inc. ("PO") and its exclusive licensee Depuy Synthes Sales, Inc. served on Petitioner a complaint of infringement of the '921 Patent on November 16, 2018, and Petitioner is not barred or estopped from requesting this review of the Challenged Claims under 35 U.S.C. § 315(b).

II. CHALLENGE UNDER 37 C.F.R. § 42.104(B) AND RELIEF REQUESTED

Petitioner requests IPR of the Challenged Claims on the grounds set forth below and requests that the claims be found unpatentable. A detailed explanation of the statutory grounds for unpatentability is provided in claim charts. Additional evidence is provided in the Declarations of Jeffrey N. Peck, DVM, DACVS, Ex. 1005, and Troy D. Drewry, MSBE, MEM, Ex. 1027, and appendices.

Ground	Claims	Basis
Ground 1	1-11	Obvious under 35 U.S.C. § 103 over US 2005/0015089 ("Young") in view of US 2006/0173458 ("Forstein") and WO 2004/024009 ("O'Driscoll")
Ground 2	1-11	Obvious under 35 U.S.C. § 103 over WO 2001/019267 ("Weaver") in view of Forstein, O'Driscoll, and Young

The application that issued as the '921 Patent was filed on February 24, 2006 as Serial No. 11/361,245[1]. Ex. 1001 at 1. Forstein's effective filing date is October 7, 2004, before the filing date of the '921 patent and is prior art under §102(e)[2]. Young was published on January 20, 2005. Weaver was published on March 22, 2001. O'Driscoll was published on March 25, 2004. Because each was published

[1] The '245 application was filed prior to the effective date of the AIA; therefore the '921 patent is, subject to pre-AIA rules.

[2] At least one claim of Forstein is supported by provisional Serial No. 60/616,680 (Ex. 1007), filed on October 7, 2004 and for this reason, along with overlapping disclosures, Forstein is entitled to the provisional filing date. *See* Ex. 1027 at ¶51. For example, it discloses the elements of claim 9 including bone plates (Ex. 1007, Figures 1-11), the first guide (*Id.* at 5, 8-9, 196-97), and jig (*Id.* at 5, 8-9, 196-97; Figures 12-25). Similarly claim 13 of Forstein is supported by Forstein's Provisional. *See* Ex. 1007 at 5, 8-9, 196-97, Figures 1-11 (plate), Figures 12-25, (jig and related geometries). *See* Ex. 1027 at ¶51.

prior to the critical date[3] of the ’921 patent, Young, Weaver, and O’Driscoll are prior art under §102(b). Neither Forstein nor O’Driscoll were cited during the prosecution of the ’921 patent. Young was merely cited in an IDS but never cited in any rejection. The Weaver was cited during prosecution. The Office never considered how a person of ordinary skill in the art (“POSA”) would understand the disclosures of Forstein and O’Driscoll in combination with Young and/or Weaver.

III. SUMMARY OF THE ’921 PATENT

A. Level of Ordinary Skill in the Art

A POSA is presumed to be aware of all pertinent art and is a person of ordinary creativity. The level of ordinary skill in the art is evidenced by the prior art. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (approving approach that the level of skill in the art was best determined by references of record). As of February 24, 2006 a POSA of the subject matter of the ’921 Patent would have had at least a Bachelors of Science in Mechanical, Biomechanical or Biomedical engineering, or a related field of science, and at least three to seven years of experience in the field of orthopedic implants or would be a practicing veterinary surgeon with at least three years of experience and at least some experience in the design and/or use of

[3] The critical date for pre-AIA 102(b) art with respect to the ’921 patent is February 24, 2005, one year prior to its filing date.

orthopedic implants. *See* Ex. 1005 at ¶28; Ex. 1027 at ¶32. A POSA would have at least had knowledge of orthopedic bone plates, bone screws, and the application of bone plates in osteotomy procedures and/or bone fracture amelioration. *Id.*

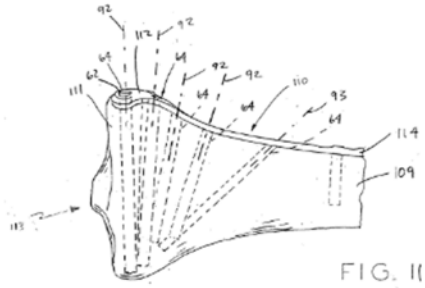
B. State of the Prior Art

At the time of the invention, the use of plates and screws for attachment to bones, including tibial bones, was well known. *See* Ex. 1005 at ¶13; Ex. 1027 at ¶16, App'x B; *see also* Ex. 1018 at 830-36, Figures 27a-b, 30a-b; Ex. 1019 at 14-29, Ex. 1020 at 9-14; *see also* Ex. 1040 at 2, 9-10, 12, 17, 20, 26, 30-31, 34, 36, 42, 46, 48, 50, 52, 57, 61, 71, 74, 83. It was also well known to pre-contour bone plates to fit/conform to a particular bone anatomy. *See* Ex. 1005 at ¶¶13-14; Ex. 1027 at ¶¶16-17, App'x B; *see also* Exs. 1006 at Abstract, ¶¶9, 67, 69, 71, 75-80, 84-86, 92, Figures 1-34 (Figure 11 reproduced below); 1009 at ¶¶8, 13-15, 49, 75, 80, Figures 6, 6A, 9; 1010 at 3, 9-11, Figures 7-26 (Figure 22 reproduced below); 1011 at Figures 1-34; 1012 at 2, 6-10, 13-14, 19, 21, 24, 26-27, Figures 1-48 (Figure 2 reproduced below); 1013 at Figures 1-6; 1016 at Figure 2; 1017 at Figures 3B, 4B, 5B; 1019 at 19, 22-23; 1024 at Figures 1-9; 1025 at Figures 1-19; 1026 at Figures 1-8; 1028 at 62, 65, 68-69, 71-79, 86, 89-92, 103, 109; 1030 at 1:40-57, Figures 1-23; 1031 at Figures 1-4, 10, 13-27 (Figure 1 reproduced below); 1032 at Figures 1-12; Ex. 1038

at 11:9-13; Figure 7; Ex. 1039 at Figures 1A, 1C; *see also* Ex. 1033[4] at ¶26 ("the inner surface of a plate may be generally complementary in contour to the bone surface"); Ex. 1045 at 21 ("the plate should be contoured to the bone very accurately"). Plates used in tibial plateau leveling osteotomy ("TPLO") procedures specifically were well known for treating canine cranial cruciate ligament rupture, including with contoured TPLO plates. *See* Ex. 1005 at ¶¶15-19; Ex. 1027 at ¶¶18-22; *see also* Exs. 1008 at Abstract, ¶¶19, 30, 35; Figures 1a-4b; Ex. 1015 at 8-11; Ex. 1016 at Abstract, 1:9-38, 1:60-2:7, 2:34-44; Figures 1-2, 5; Ex. 1017 at Abstract, ¶¶10, 24-25, 33, 36, 39, 44, 47, 76, Figures 3A, 5A, 8; Ex. 1023.

[4] At least one claim of Huebner is supported by provisional Serial No. 60/564,853 (Ex. 1034), filed on April 22, 2004 and for this reason as well Huebner is entitled to the provisional filing date. *See* Ex. 1027 at ¶16n1.

Forstein, Ex. 1006 at Figure 11.



Weaver, Ex. 1010 at Figure 22.

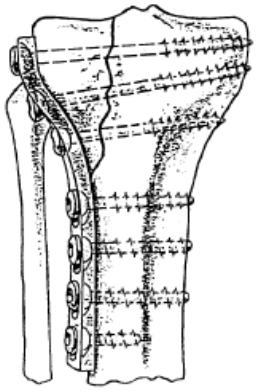


Fig. 22

O'Driscoll, Ex. 1012 at Figure 2.

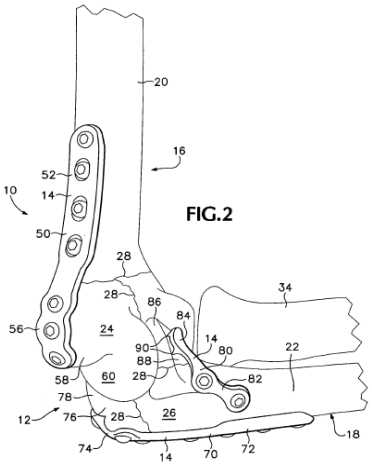


FIG.2

Grady, Ex. 1031 at Figure 1.

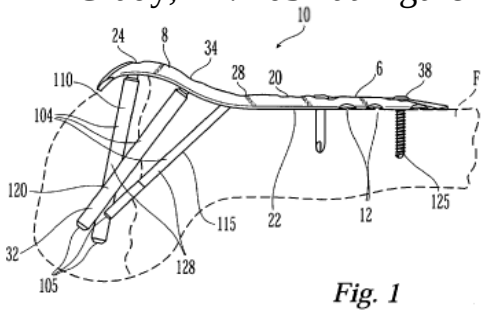


Fig. 1

It was well known to provide several screw holes in the head or proximal portion of a bone plate arranged in a triangular superior (distally)/cranial/caudal relationship, including holes configured to accept threaded locking screws. *See* Ex. 1005 at ¶15; Ex. 1027 at ¶18, App'x B; *see also* Exs. 1006 at ¶¶71-73, 86, 88, 93, 100, 111, 113, 115; Figures 1, 9, 12, 23, 26; 1008 at ¶34, Figures 1a, 1b; 1009 at ¶82, Figures 7-8; 1010 at Abstract, 1-2, 4, 6-11, Figure 2; 1011 at Figures 1, 2, 6-7, 11, 14, 27; 1018 at Figure 30a; 1019 at 19; 1033 at ¶41; 1035 at 357, 362, 392, 419, 430, 449-450, 459-460. It was also well-known that screws attaching plates to the

tibia should be angled to avoid articular surface penetration and be provided with convergent screw paths. *See* Ex. 1005 at ¶¶15, 18; Ex. 1027 at ¶¶18, 21, App'x B; *see also* Exs. 1006 at ¶¶75-78, Figures 8, 11, 13, 15, 17; 1008 at ¶39 Figure 4b; 1010 at 10-11, Figure 22; 1011 at Figure 32; 1014 at 434, Figure 12B; 1018 at Figure 27a, 27b, 30a, 30b; 1021 at 187, 189, Figure 1, 4; 1028 at 62, 71, 86, 100, 103, 109; 1030 at Figures 7-8; 1031 at ¶¶6, 71, Figures 1, 3, 10, 13, 17, 21-22, 25-27; 1033 at ¶74, Figures 7-8; Ex. 1036 at Figures 2-3, 9. Various mechanisms for screw angulation were known, including screw holes allowing a surgeon to determine a screw angle at the time of implantation and fixed-axis screw holes having a predetermined screw angle. *See Id.*; *see also* Wack at Figure 9.

Ex. 1006 at Figure 11.

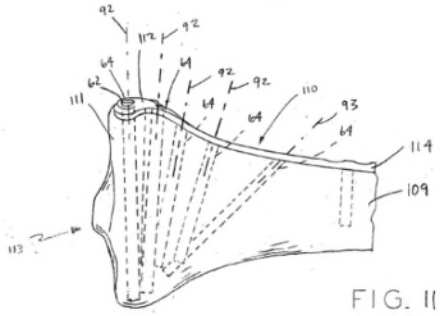


FIG. 11

Ex. 1008 at Figure 4a.

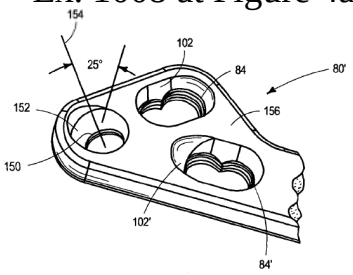


FIG. 4b

Ex. 1010 at Figure 26.

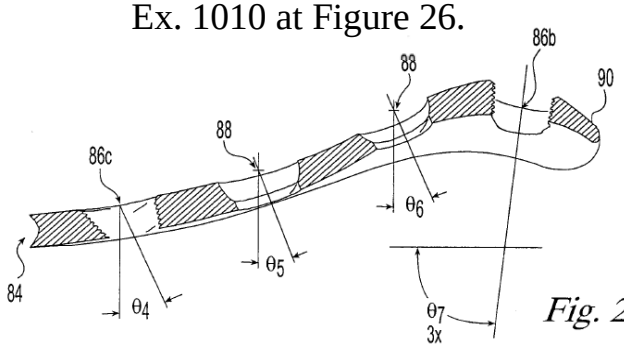


Fig. 26

Ex. 1014 at Figure 12B.

Ex. 1045 at Figure 43-4.

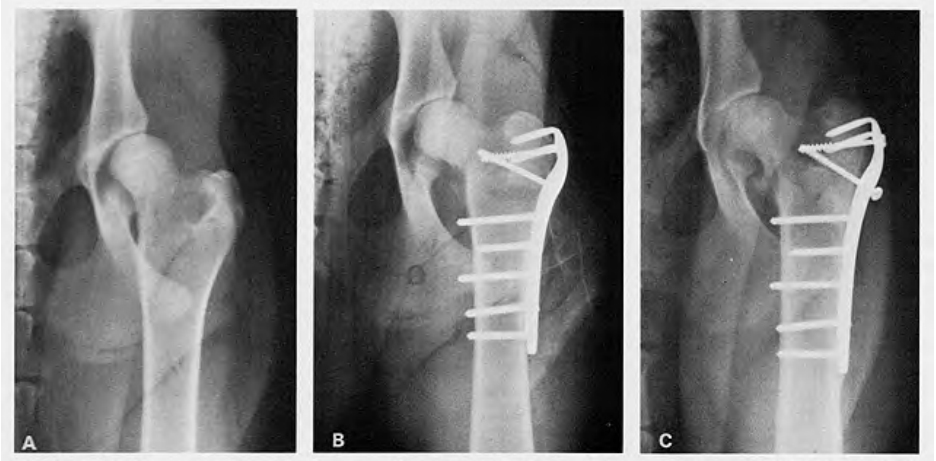
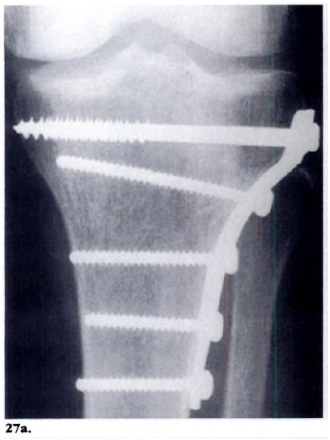
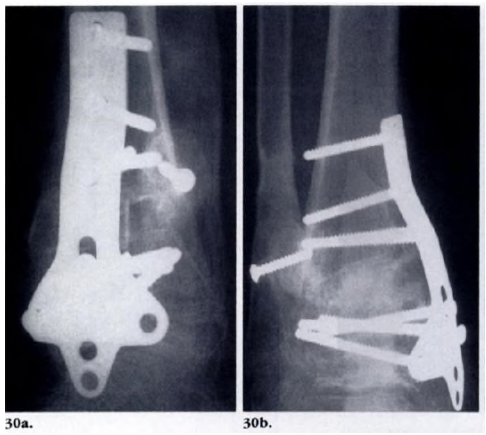


FIG. 43-4 (*A*) This preoperative film shows subluxation of the hip in a 10-month-old mastiff. (*B*) A double-hook plate was used for osteotomy. Note the normal round femoral head and deep acetabulum that is normally associated with the syndrome of increased anteversion. (*C*) This 152-week follow-up radiograph shows complete healing of the osteotomy site. The position of the hip remains unchanged. Screw loosening of the proximal fragment must have occurred during the healing process. (Courtesy of Marvin L. Olmstead, Ohio State University)

Ex. 1018 at Figure 27a.

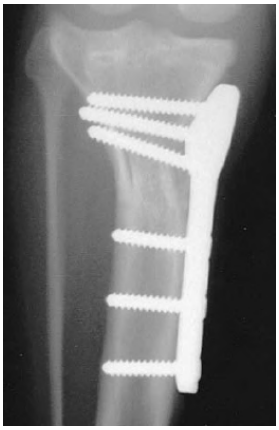


Ex. 1018 at Figures 30a, 30b.

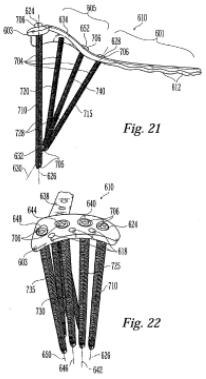


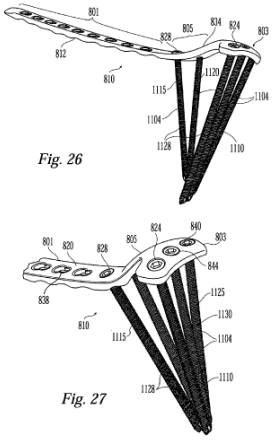
Ex. 1021 at Figure 1.

Ex. 1021 at Figure 4.

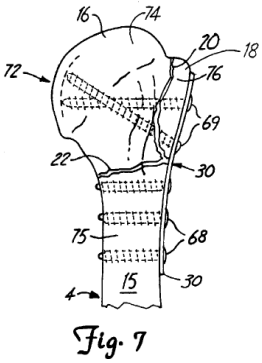


Ex. 1031, Figures 21, 22, 26, 27

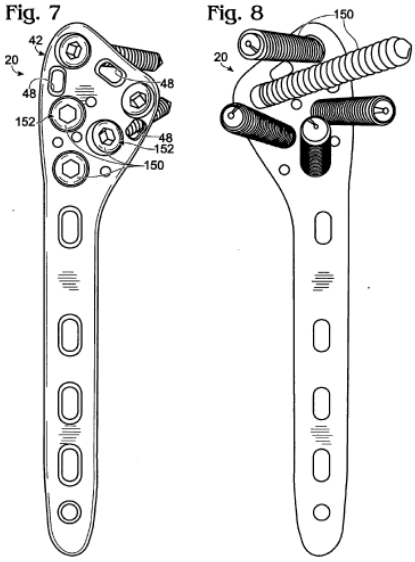




Ex. 1030 at Figure 7.



Ex. 1033 at Figures 7, 8.



C. Overview of the ’921 Patent

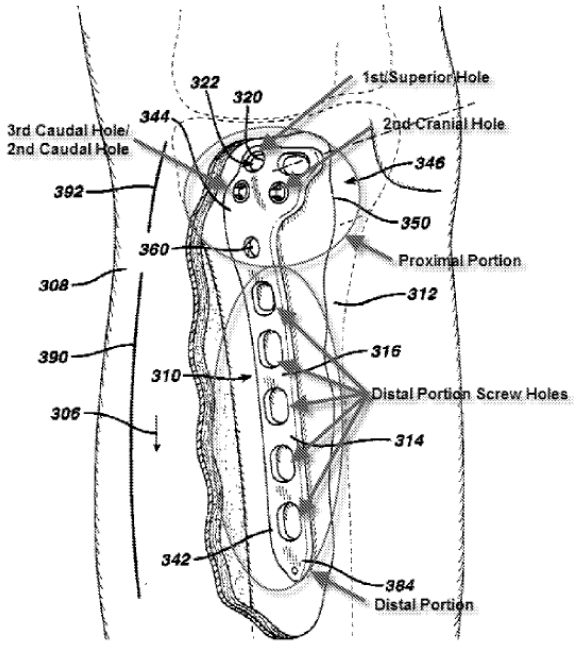
The prosecution history of the ’921 Patent is submitted as Exhibit 1002. The prosecution history of related application Serial No. 13/538,407 is submitted as Exhibit 1003; and related application Serial No. 16/031,792 is submitted as Exhibit 1004.

The ’921 Patent discusses orthopedic plates generally and for use in tibial plateau osteotomies. *See, e.g.*, Ex. 1001 at 1:62-67. The Challenged Claims generally recite a bone plate having an elongated shaft and a head each of which include several screw holes. *See Id.* at 9:61-65, 10:13-19 (claim 1). The head (“proximal portion”) includes a bone-contacting surface that is preconfigured and dimensioned to conform to a tibial bone segment. *Id.* at 9:66-10:3. The contour of the bone-contacting surface is described as an “arc of a cylinder” having a “contour axis” and using a set of geometric features that are merely geometric constructs to orient the bone contacting surface in a head on view. *Id.* at 10:3-12. A plurality of screw holes are disposed in the head of the bone plate which are designed to accept a locking screw and have targeted screw paths through the bone segment. *Id.* at 10:13-19. The remainder of the Challenged Claims recite the location and angulation of holes for accepting a locking screw (claims 2-7) and well-known sizing limitations of the contour of the bone-contacting surface dictated by the patient’s anatomy and bone size (claims 8-11). *See Id.* at 10:20-64.

D. Summary of the Prosecution of the ‘921 Patent

The ‘245 application was filed on February 24, 2006. *See* Ex. 1002 at 89. During prosecution, the Challenged Claims were rejected numerous times by the United States Patent and Trademark Office (“USPTO”) and only allowed after the Board reversed the USPTO’s anticipatitory references because they lacked “a mid-plane bisecting the base plane.” Ex. 1002 at 439. In a February 22, 2008 office action, the USPTO initially rejected claims 1 and 12-20 as being obvious over the combination of US 2006/00009771 to Orbay (Ex. 1013) and US 6,623,486 to Weaver (U.S. counterpart to Ex. 1010). Combined with Orbay, the USPTO found Weaver taught a pre-contoured surface configured and dimensioned to conform to a tibial bone segment and defined, in part, by an arc of a cylinder as recited by claims 1, 19, and 20. *See* Ex. 1002 at 152; 1010 at Figures 22-23. The USPTO also found that US 7,267,678 to Medoff (Ex. 1036) combined with Orbay/Weaver taught the limitations of claims 2, 4-6. Specifically, the USPTO found that Medoff taught a targeted screw path angled away in a distal direction. *See* Ex. 1002 at 155; Ex. 1036 at Figure 2. In rejecting claim 4, the USPTO found US 2005/0240187 to Huebner (Ex. 1033) taught “a second locking screw that has a targeted screw path that angles caudally away from the bone-contacting surface.” Ex. 1002 at 158; Ex. 1033 at Figure 8.

In a March 31, 2009 office action, the USPTO withdrew its prior office action and rejected all claims. *See Id.* at 189. Claims 1-8 and 12 were rejected as anticipated by 2002/0156474 to Wack (Ex. 1009). *See Id.* at 189-92. Citing to Figures 7, 8, and 11, the USPTO found that Wack disclosed every limitation of claims 1 and 12, including the contour of the proximal portion bone-contacting surface and the superior/caudal/cranial screw hole locational limitations (and that Weaver taught similar limitations in claims 19-20). *See Id.* at 192 (figure reproduced below). The USPTO also rejected claims 9-11 as obvious over Wack stating "where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." Ex. 1002 at 195-97 (citing *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955)). In its June 25, 2009 reply, PO made no separate arguments for the patentability of claims 2-11. *Id.* at 216.



In a final office action dated October 27, 2009, the USPTO maintained its rejection of claims 1-18 as anticipated by or obvious over Wack. Ex. 1002 at 223-26, 229-30. The USPTO explained that "a single segment or section of the bone-contacting surface [needs to be] defined by a cylinder" and that Wack (and Weaver) discloses this limitation. *See Id.* at 231; *see also* Wack at Figure 6. In an after-final reply dated December 18, 2009, PO amended claims 1, 19, and 20 to include additional geometric limitations to the contour of the bone-contacting surface of the proximal portion. Ex. 1002 at 239

Following a January 20, 2010 USPTO advisory action maintaining all rejections, PO filed and RCE on January 26, 2010. *Id.* at 255. In a March 17, 2010 office action, the USPTO rejected claims 1-11 as indefinite and found the claim language "being partially defined by a cylinder" and "the mid-plane bisecting in the distal portion of the bone plate a base plane defined by a surface of the distal portion" unclear. The USPTO also maintained its prior anticipation rejections of amended claims 1-8 stating, "it appears the [arc of a cylinder] limitation is strictly functional and is only required 'to be configured and dimensioned to conform to a tibial bone segment and being partially defined by a cylinder', the device is capable of being dimensioned via bending and in its current state to conform to a tibial segment and to the shape of a cylinder." *Id.* at 275. The USPTO found Wack disclosed this

feature. *Id.* at 266-67. In reply, PO further amended the claims into the issued form. *See Id.* at 295, 299-300.

In an August 4, 2010 office action, the USPTO maintained the prior art rejections. Ex. 1002 at 318-27. Regarding the anticipation rejection of claims 1-8 and 12 based on Wack, the USPTO found that the added geometric limitations do not "recite any structure tied to the bone plate." *Id.* at 327. In response to PO's argument that these limitations "permit viewing of the plane of the contour axis of the cylinder forming the contour of the bone plate," the USPTO stated that PO "has not stated in the claims that the bone plate is required to exhibit this feature through a head on viewing of the bone plate." *Id.* at 305, 327. In an October 4, 2010 after-final response, PO argued against the rejections and the USPTO again rejected PO's arguments in a November 9, 2010 advisory action stating explicitly that Wack (and Weaver) "disclose[s] the bone plate being shaped/pre-configured to the shape of a tibia." *Id.* at 348, 336-43. PO Appealed. *See Id.* at 351. The USPTO argued that PO "failed to define the starting orientation of the bone plate prior to rotation of the plate about the first and second rotation axes [or] how many degrees the plate is to be rotated." *Id.* at 400.

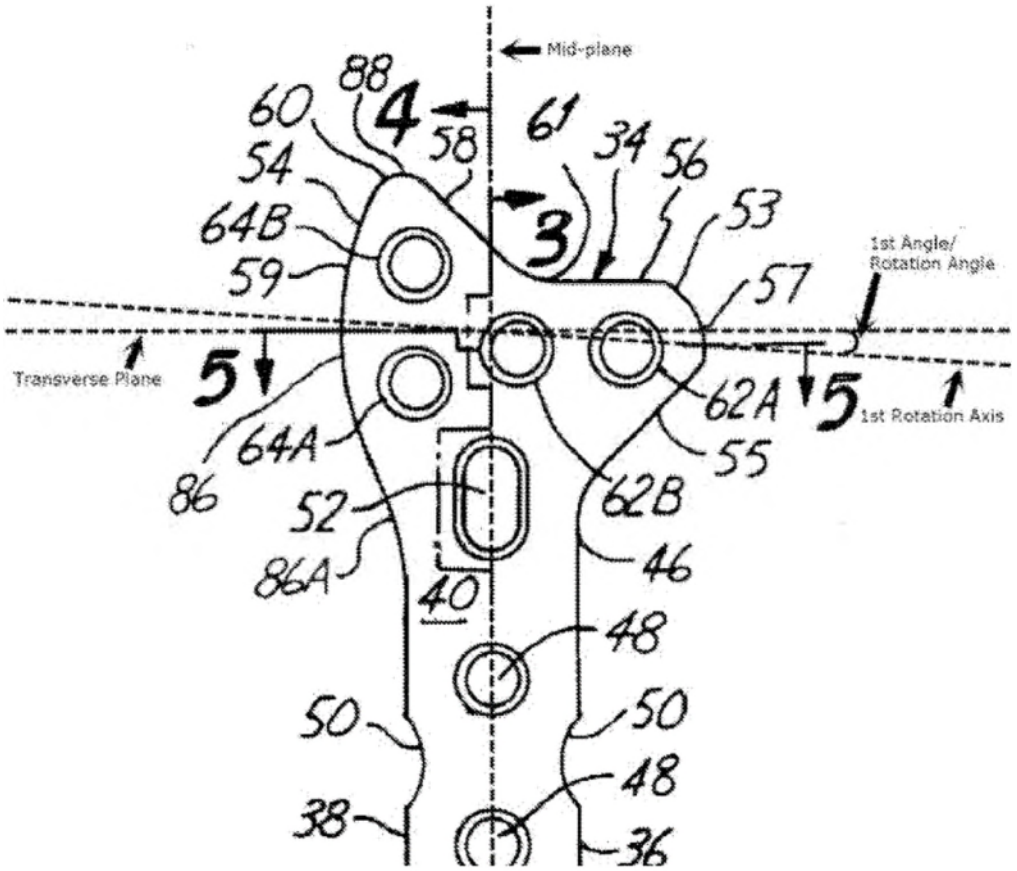
The Board found Wack disclosed a tibial bone plate and holes for receiving locking screws. *See* Ex. 1002 at 436-37 (Findings of Fact 1, 2). In reversing the USPTO's anticipation rejections on claim 1, the Board construed the phrase "a mid-

plane bisecting the base plane" to require that "the mid-plane of the proximal portion must also bisect the base plane of the distal portion." *Id.* at 439. Thus, since the mid-plane of the proximal portion of Wack does not "bisect the base plane defined by the distal portion of the bone plate," it cannot alone meet this limitation. *Id.* The Board did not base its decision on any other limitation and made no findings regarding claims 2-11. *See Id.* at 441. The USPTO then allowed the claims and PO did not submit any comments in response to the Board's conclusions or the Examiner's allowance based on those conclusions. *Id.* 444-49. At no point did PO argue, nor did the Board find, that claims 2-11 were separately patentable from claim 1.

E. Prosecution of Related Applications

PO filed Serial No. 13/538,407 on June 29, 2012, claiming priority to the '921 Patent. See Ex. 1003 at 1-3. The '407 application claims a bone plate similar to that of the '921 patent, but with some additional structural limitations not relevant to the Challenged Claims. *See, e.g., Id.* at 45-47. The claims of the '407 application have been rejected by the USPTO five times over the same prior art: US 6,096,040 to Esser (Ex. 1030) and US 2005/0020226 to Grady (Ex. 1031), including one Board affirmance. *See Id.* at 90-98, 128-39, 185-95, 349-64, 384-401, 325-31. Notably, PO added limitations reciting a "contour of the bone-facing surface formed as an arc of a cylinder" in its February 20, 2018 reply. *See Id.* at 372. The USPTO rejected the amended claims because the "newly amended feature[s] are taught by Esser." *Id.* at

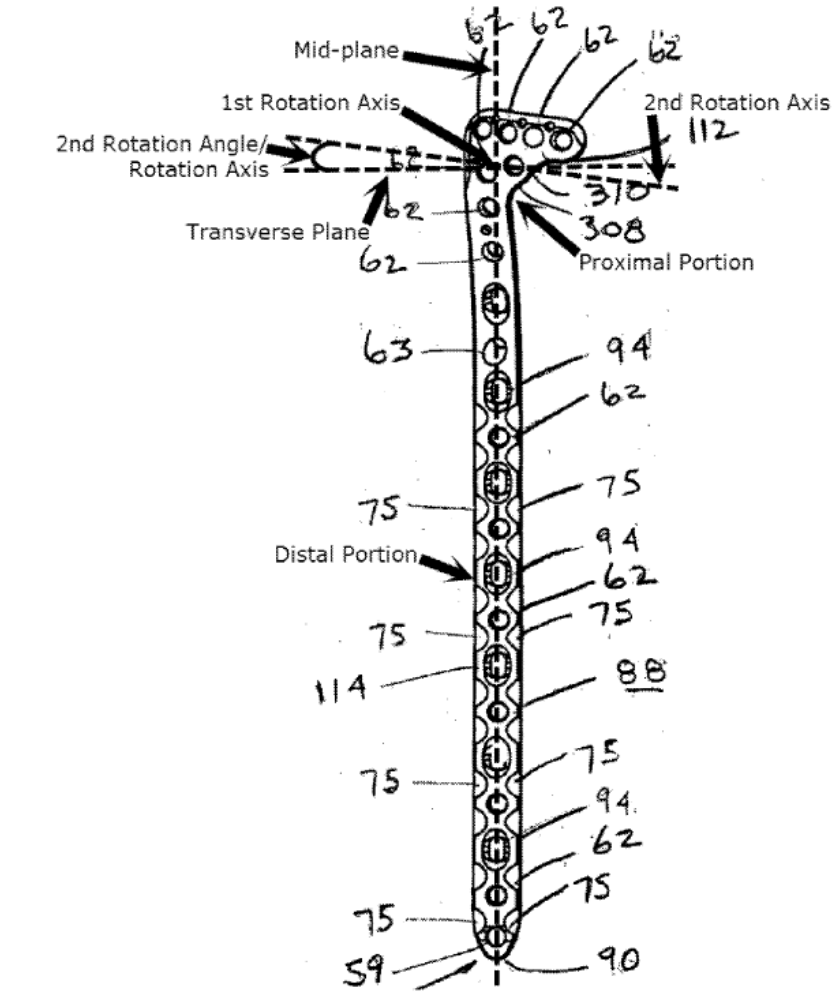
384, 386, 401 (figure reproduced below). The USPTO also found that Grady taught conically threaded locking holes. *Id.* at 391. In response to PO arguments, the USPTO again stated that the claims rely on imaginary axes "to achieve a curved shape to which the bone plate is to cover." *Id.* at 416. The USPTO made similar arguments on appeal. *Id.* at 455-57. The '407 application is pending another appeal. *Id.* at 653.

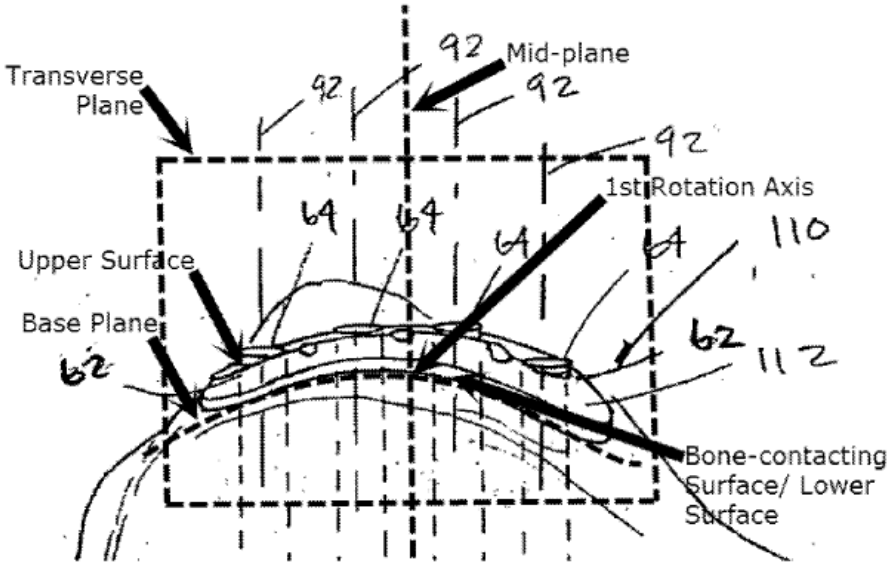


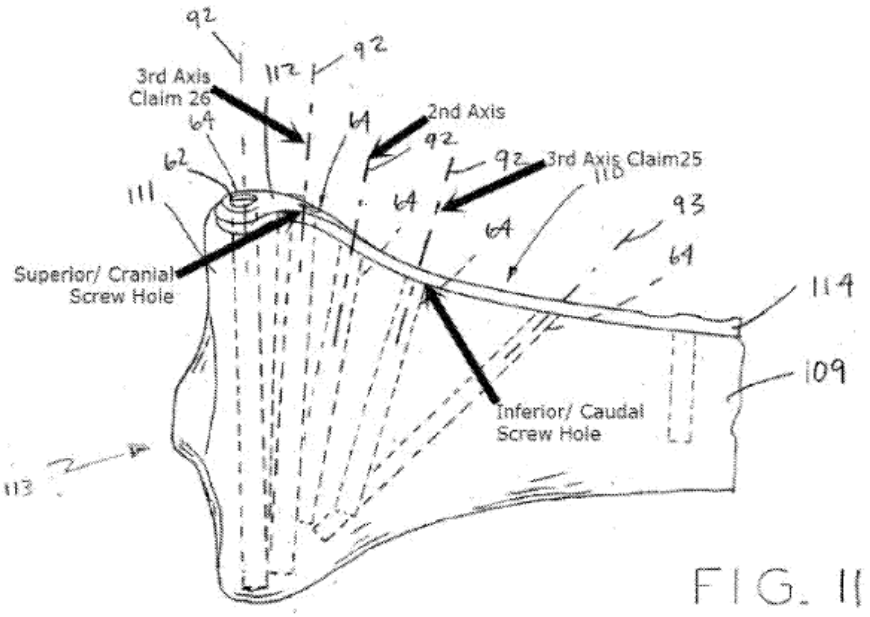
PO filed Serial No. 16/031,792 on July 10, 2018, claiming priority to the '407 application and the '921 Patent. *See* Ex. 1004 at 1-2. The '792 application claims a bone plate similar to that of the '921 Patent. *See* Ex. 1004 at 194-98 (pending

claims). For example, Claim 21 recites "a plurality of proximal portion locking screw holes located in the proximal portion" nearly identical to the feature recited in claim 1. *Id.* at 194. Claim 21 also recites a "bone-contacting surface" having similar to the geometric limitations to those recited in the Challenged Claims, as do dependent claims 22-30 and 32-35. *Id.* at 194-97.

In the October 18, 2018 non-final office action, the USPTO rejected all claims of the '792 Appl. as anticipated by or obvious over Forstein. *See Id.* at 102-12. Citing Figure 9-11 and ¶¶71 and 75, the USPTO found that Forstein disclosed the geometric limitations cited above as shown in Examiner annotated figures. *Id.* at 102-04, 110-12 (reproduced below). Citing to Figures 9-11 and ¶75 of Forstein, the USPTO found the features described above in claims 22-26 of the '792 Appl. *Id.* at 104-05. Specifically, The USPTO found that Forstein discloses "a first one of the proximal portion locking screw holes (see figure below) defines a first screw axis (see figure below) angled so that the axis extends further distally as it passes away from the bone contacting surface into the resected portion of bone (figures 9-11)." *Id.* at 104. The USPTO also found that Forstein anticipates the distally/cranially located second screw hole (claim 24) and the distally/caudally located third screw hole (claim 25). *Id.*


Mid-plane
1st Rotation Axis
2nd Rotation Axis
112
2nd Rotation Angle/
Rotation Axis
370
Transverse Plane
308
Proximal Portion
Distal Portion
62
63
94
75
88
114
90
59


Transverse
Plane
92
Mid-plane
1st Rotation Axis
64
110
Upper Surface
Base Plane
62
112
Bone-contacting
Surface/ Lower
Surface



In its January 10, 2019 reply, PO unsuccessfully argued against the rejections. *See Id.* at 200-01. PO did not argue the limitations of any dependent claims. Through amendment, PO added new claim 36 which recites nearly identical limitations to those of the Challenged Claims. *Id.* at 197-198.

In its February 1, 2019 final office action, the USPTO maintained its rejection noting, in reference to the PO's argument regarding the bone plate being "configured to secure two tibial bone segments of an animal," that PO "is arguing the preamble of [its] invention" which "does not distinguish the claimed invention from the prior art such that the preamble transforms into a claim limitation." *Id.* at 207. Further, the plates disclosed in Forstein "could be used to secure two tibial bone segments of an animal if one so choose[s]." *Id.* The USPTO also found that Figure 10 of Forstein "clearly depicts a contoured lower bone-contacting surface of the bone plate which

has a contour that is formed as an arc of a cylinder." *Id.* at 208. Further, the USPTO noted PO "is referencing their invention based upon imaginary axes and planes of their plate to achieve a curved shape in the arc of a cylinder to which the bone plate is to cover" and found "the same arced cylindrical curvature and the claimed axes … can be found and [are] provided in the Final Office Action [reproduced above] to expressly show how the prior art achieve[s] the same curvature" required by the claims of the '792 application. *Id.* The USPTO thus maintained its rejection, finding Forstein "capable of" use in TPLO. *Id.* at 209. The USPTO also found that Forstein anticipates the distally/cranially located second screw hole (claim 24) and the distally/caudally located third screw hole (claim 25). *Id.* at 211.

PO replied on March 13, 2019. *Id.* at 372-75. Following an advisory action issued on April 4, 2019 again rejecting PO's arguments, PO appealed to the Board on April 29, 2019. *See Id.* at 377-79, 386. On June 17, 2019, PO filed its appeal brief. *See Id.* at 393-404. The '792 application is pending appeal.

IV. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(B)(3)

Petitioner proposes construction of the terms below solely for purposes of this proceeding. *Vivid Techs. v. Am. Sci. & Eng'g*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only claim terms in controversy need be construed, only to the extent necessary to resolve the controversy). Petitioner reserves the right to respond to any constructions offered by PO or adopted by the Board. Petitioner is not waiving any arguments

concerning indefiniteness, alternative claim scope or other claim constructions that may be raised in litigation. Claim terms are to be construed in an IPR "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history." 37 C.F.R. §100(b).

A. Claim 1 – *for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal*

PO never argued that the preamble is a limitation of claim 1 during prosecution of the '921 patent, even when presented with rejections based on plates designed for general orthopedic use like Wack and Weaver. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810 (Fed. Cir. 2002) (holding preamble not limiting and "insignificant for patentability" when not relied on when responding to rejection). In any case, during prosecution of the '792 application, a continuation of the '921 patent, the USPTO rejected PO's arguments that the preamble carried patentable weight. *See* Ex. 1004 at 207 (examining an identical preamble of a claim having similar features to claim 1). This preamble is merely a statement of intended use. *See Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). Thus, the preamble of claim 1 it not limiting. *See* Ex. 1005 at 30; Ex. 1027 at 37.

B. Claim 1 – *pre-configured and dimensioned to conform to a tibial bone segment*

The claim language "pre-configured and dimensioned to conform to a tibial bone segment" means that the bone plate is pre-contoured or pre-shaped to fit a tibial bone segment prior to some unspecified event. *See* Ex. 1005 at ¶31; Ex. 1027 at ¶38. The claims do not specify when this configuration should occur and what it is supposed to precede. One interpretation is that pre-configuration can occur anytime before the plate is secured to the patient. *Id.* Another interpretation, offered by the PO during prosecution, was that the plate is "pre-configured" if it is shaped and contoured at the manufacturing stage, before it is sold. *Id.* The USPTO never indicated this construction or the PO argument regarding it were persuasive and did not allow the claims based on them. *Id.* Solely for purposes of this proceeding, although this term is ambiguous and unsupported beyond the PO's self-serving arguments, Petitioner assumes the first interpretation is correct and advances the construction stated above. Regardless of which interpretation is applied, the claims are obvious as demonstrated below.

C. Claim 1 – *a contour axis … rotated relative to the mid-plane about the first rotation axis by a first angle, … and wherein the axis is rotated relative to a second rotation axis defined by an intersection of the transverse plane and the base plane by a second angle*

The claim language is unclear as to what is "rotated" and is entirely ambiguous, but Petitioner's position, solely for purposes of this petition, is that the

contour axis is what is rotated. *See* Ex. 1005 at ¶¶ 33-34; Ex. 1027 at ¶46-47. It is also unclear what "rotated relative to the mid-plane" means. Solely for purposes of this petition, Petitioner construes this phrase as *rotated starting at a point on the mid-plane about the first rotation axis for a radial distance defined by a first angle*. *See* Ex. 1005 at ¶35; Ex. 1027 at ¶48. The rotation relative to the second rotation axis is similarly construed, though the claim does not include any limitation regarding the starting point of the rotation. The specification provides that the first angle is between 5-15° and the second angle is between 15-30°. Additionally, although the term "the axis" lacks antecedent basis, and fails to inform a POSA about the scope of the invention with reasonable certainty, Petitioner submits, for purposes of this petition only, that "the axis … rotated relative to a second rotation axis" is the contour axis, although it could be any other axis previously set forth in the claim, some other axis not defined, hence the ambiguity. *See* Ex. 1005 at ¶36; Ex. 1027 at ¶49.

D. Claim 1 – *the mid-plane bisecting the base plane*

The Board's decision to reverse the issued rejections on claim 1 turned solely on the interpretation of this phrase. *See* Ex. 1002 at 439, 442. The Board found that the claimed "mid-plane bisecting the base plane" is "a single plane where the mid-plane of the proximal portion must also bisect the base plane of the distal portion." *Id.* at 439. PO, prior to the issuance of the Board's decision for the '921 patent,

argued against a written description rejection of a claim requiring a "distal body portion being symmetrical about the mid-plane" during the prosecution of the '407 application, admitting that "[t]he term 'bisect' is defined as 'to divide into two usu. equal parts.'" Ex. 1003 at 151. PO argued the specification "clearly supports an embodiment where the distal portion 12 is divided into two equal parts, ***which are inherently symmetrical to one another***." *Id.* (emphasis added). Thus, PO argued the bisected body must be symmetrical. The Board, in an initial *Ex Parte* appeal of the child application, agreed with PO. *Id.* at 328. In contrast to the child application claims, where the mid-plane is expressly recited only as part of the distal portion, the '921 patent – according to the Board as the basis for patentability (and left unaddressed by the PO) – recites the mid-plane as part of the proximal portion yet also requires that the proximal portion mid-plane bisect the distal portion base plane. *See* Ex. 1002 at 442. Thus, a POSA would understand the phrase "the mid-plane bisecting the base plane" to mean, by the Board's decision and PO's acts and admissions, that the proximal portion must be symmetrical and share the same mid-plane as the distal portion. *See* Ex. 1005 at ¶37; Ex. 1027 at ¶50.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The Challenged Claims recite a bone plate having features that were well known prior to the filing date of the '921 Patent. *See*, *e.g.*, Ex. 1005 at ¶¶50-51; Ex.

1027 at ¶¶64-65. As detailed below, various prior art references render obvious the Challenged Claims.

A. Legal Standards

Under 35 U.S.C. § 103(a), a claim is invalid for obviousness if, at the time the invention was made, "the combined teachings of the prior art, taken as a whole, would have rendered the claimed invention obvious to [a POSA]." *In re Napier*, 55 F. 3d 610, 613 (Fed. Cir. 1995). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416, (2007). No requirement exists to find precise teachings directed to specific subject matter of a claim; common sense, inferences, and creative steps that a POSA would employ should be considered. *Id.* at 1741. The Board should apply common sense, recognizing that "familiar items may have obvious uses beyond their primary purposes, and in many cases a [POSA] will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 1742. If "a patent 'simply arranges old elements with each performing the function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 1740.

B. Ground 1 – Claims 1-11 are Obvious under 35 U.S.C. § 103 over Young in view of Forstein and O'Driscoll

1. Claim 1

Claim 1 is directed to a bone plate as an article of manufacture. The Challenged Claims are obvious over the combination of Young, Forstein, and O'Driscoll. *See* Ex. 1005 at ¶¶50-51, 53, 55-57; Ex. 1027 at ¶64-65, 70-71. As discussed further below, Young discloses elements 1[PRE], 1[A], 1[B], and 1[D]. Forstein discloses elements 1[A]-1[D]. O'Driscoll discloses elements 1[A], 1[B], and portions of elements 1[C] and 1[D]. And the preamble (1[PRE]) is not limiting. *See* §IV.A. Indeed, the USPTO found the preamble of claim 21 of the '792 Appl., which is nearly identical to the preamble of claim 1, was "merely an intended use statement" and "does not distinguish the claimed invention from the prior art." Ex. 1004 at 207; *see also* Ex. 1005 at ¶¶58-59; Ex. 1027 at ¶¶72-73.

1[PRE]: A bone plate dimensioned for securing two tibial bone segments of an animal as part of a tibial leveling osteotomy procedure for an animal, the bone plate comprising:	Young discloses a bone plate dimensioned for securing two tibial bone segments of an animal as part of a tibial leveling osteotomy procedure for an animal. See Young at Abstract ("A bone plate(s) of complex form is provided, particularly suited to tibial plateau-leveling osteotomy…"); ¶2 ("This invention relates to ... bone plates used to reinforce fractured bones and thus promote healing."); ¶35 ("Referring now to FIG. 1b, application of the bone plate 80 is shown for tibial plateau-leveling osteotomy in a canine subject."). Forstein discloses this element. See Forstein at Abstract ("A bone fracture fixation system including a bone plate having a contour that substantially matches the contour of an underlying bone."); ¶66 ("Periarticular bone plates,

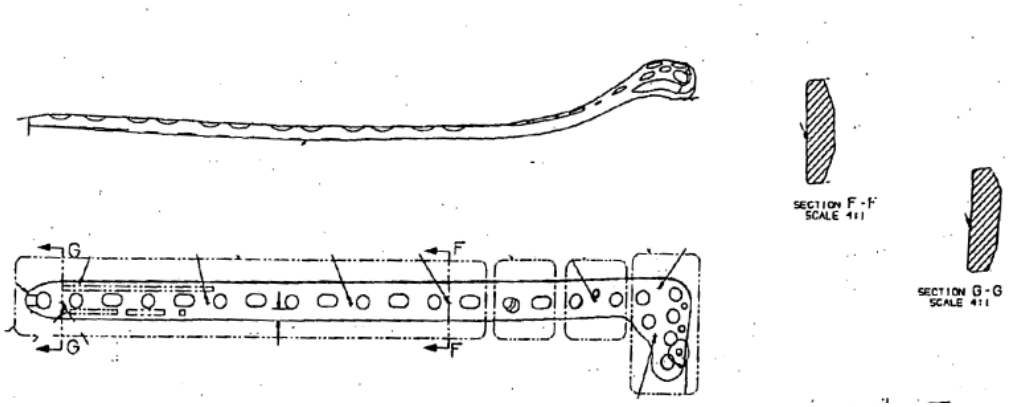
	such as the bone plates illustrated in FIGS. 1-34, are affixed to the metaphysis and diaphysis of a broken bone, such … a tibia … to stabilize the bone during the healing ..."). Forstein is "capable of" use in TPLO. Ex. 1004 at 209. Additionally, it was well known to a POSA to use a bone plate for securing two tibial bone segments as part of a TPLO procedure in a canine. *See, e.g.*, Young, at Abstract; Ex. 1016 at Abstract.

a. Element 1[A]

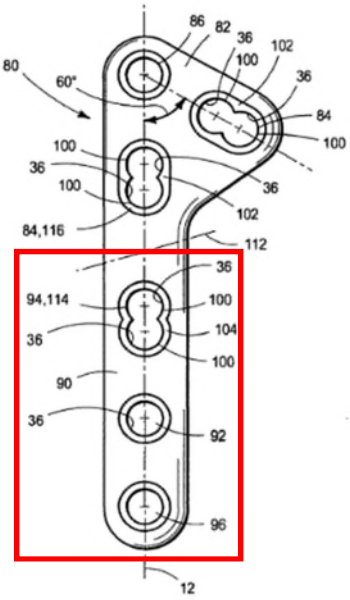
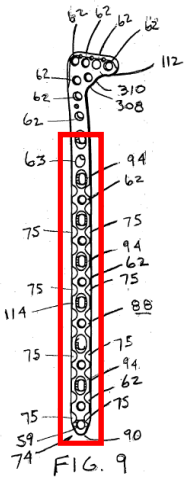
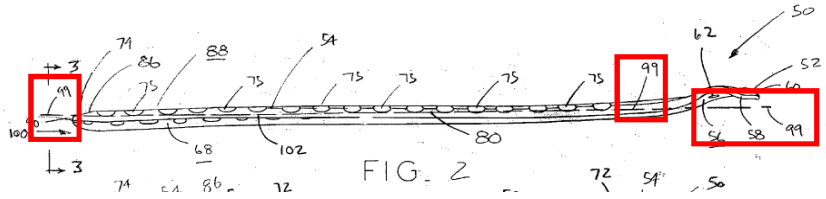
Element 1[A] recites "a distal portion comprising an elongated shaft having disposed therein a plurality of distal portion screw holes each designed to accept a screw and defining a longitudinal axis and a base plane along a bone-contacting surface thereof." Ex. 1005 at ¶53; Ex. 1027 ¶67. The bone plate disclosed in Young "has a main longitudinal axis 12, a bone-contacting bottom side (not shown) and a top side 16." Young at ¶30. Geometrically, the Young's longitudinal axis is the intersection of an imaginary base plane running along the bone-contacting bottom side of the plate and a mid-plane that is perpendicular to the base plane. *See* Ex. 1027 at ¶¶55-57. Further, the elongated lower portion 90 defines the longitudinal axis 12 which, as shown in Figure 1a, bisects the lower portion. *See Id.* at Figure 1a. *Id.*

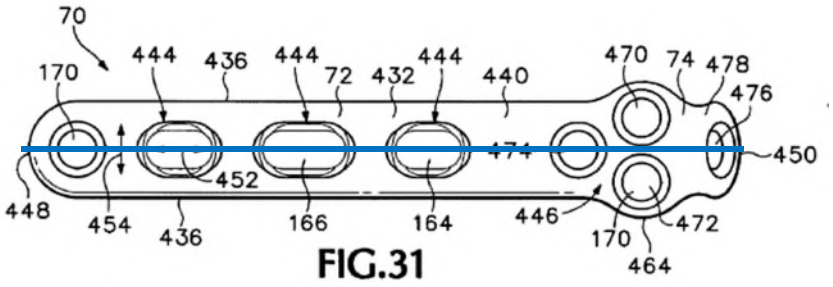
Forstein also discloses various periarticular bone plates, including plates for use on a tibia. Forstein at ¶¶66, 75. All bone plates disclosed in Forstein share a basic structure: a head (a "proximal portion") and a shaft (a "distal portion"), each of which contain a plurality of screw holes. *See* Forstein at ¶¶71-72; *see also* Ex. 1003

at 121-23; Ex. 1005 at ¶39; Ex. 1027 at ¶¶52-53. The distal portion includes embodiments having at least partially planar surface as shown in the Forstein Provisional. *See* Ex. 1007 at 156 (sections F-F and G-G, reproduced below); *see also* Ex. 1005 at ¶63; Ex. 1027 at ¶77.



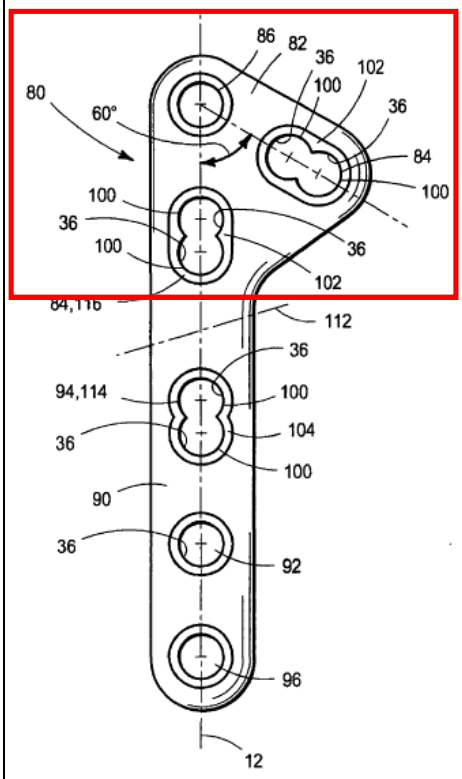
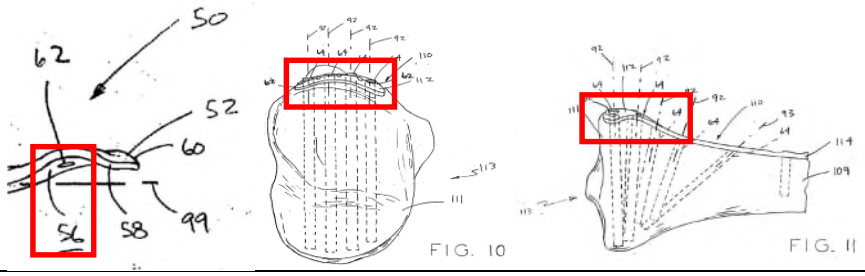
Furthermore, the USPTO has finally rejected claims containing similar features to claim 1 in the pending '792 Appl. as anticipated by Forstein, finding that Forstein discloses "a bone plate [that] includes a distal portion," referring to shaft 114 of Figure 9, and "a plurality of distal portion screw holes," referring to holes 62, 94 of Figure 9. Ex. 1004 at 209-20. O'Driscoll also discloses an elongated distal portion having a longitudinal axis. See 1012 at Figure 31. Thus, Young, Forstein, and O'Driscoll disclose element 19[B]. See Ex. 1005 at ¶63; Ex. 1027 at ¶77.

1[A]: a distal portion comprising an elongated shaft having disposed therein a plurality of distal portion screw holes each designed to accept a screw and defining a longitudinal axis and a base plane along a bone-contacting surface thereof;	 FIG. 1a Young discloses a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw and defining a longitudinal axis and a base plane along a bone-contacting surface thereof. *See* Young at ¶30 ("The bone plate 80 has a **main longitudinal axis 12**, **a bone-contacting bottom side** (not shown) and a top side 16 with at least two sets of overlapping holes 100 which communicate through the plate from the top to the bottom side."); ¶32 ("The plate 80 has … **an elongated lower portion 90** in which are located **a plurality of apertures 92, 94 and 96**, substantially co-axially with two of the apertures 84 and 86 in the head 82."); ¶38.  FIG. 9 Forstein discloses this element. *See* Forstein at ¶71 ("**Shaft 54** includes portions 72 intermediate adjacent **threaded screw holes 62 and elongate screw holes 94**.") (referencing FIG. 1); ¶73 ("**Threaded holes 62 can receive**, referring to FIG. 6, **screws 64** having threaded head 67 and threaded shaft 68."); ¶75 ("…tibial plate 110 includes … **plate shaft 114** …."); FIG. 9; ¶84 ("…femoral bone plate 50 includes **longitudinal axis 99** ….").  FIG. 2

	O'Driscoll discloses this element. *See* O'Driscoll at Figure 31.  FIG.31

b. Element 1[B]

Element 1[B] recites "a proximal portion having an upper surface and a bone-contacting surface opposite the upper surface." The bone plate of Young has a "triangular head 82" with a flat "bone-contacting bottom side." Young at ¶¶30, 32. Forstein also discloses a proximal portion having an upper surface and a bone-contacting surface. *See* Forstein at ¶67, 83. O'Driscoll similarly discloses this element. *See* O'Driscoll at Figure 31. Thus, Young, Forstein, O'Driscoll also discloses element 1[B]. *See* Ex. 1005 at ¶64; Ex. 1027 at ¶78.

1[B]: a proximal portion having an upper surface and a bone-contacting surface opposite the upper surface,	Young discloses a proximal portion comprising at least three screw holes each designed to accept a screw. *See* Young ¶30 ("The bone plate 80 has a **main longitudinal axis 12**, **a bone-contacting bottom side** (not shown) …."); ¶32 ("The plate 80 has **a flat triangular head 82** ….").  FIG. 1a  FIG. 10 FIG. 11 Forstein this element. *See* Forstein ¶67 ("In particular, head 52 is sized and configured to rest on the distal metaphysis of a femur, i.e., head 52 includes **bone-contacting surface 56** (FIG. 2) which is contoured to substantially match the contour of distal femoral metaphysis 53.") ¶83.

c. Element 1[C]

Element 1[C] recites "the bone-contacting surface of the proximal portion being pre-configured and dimensioned to conform to a tibial bone segment and having a contour formed as an arc of a cylinder having a contour axis extending in a

plane including a first rotation axis defined by an intersection of a mid-plane and a transverse plane and rotated relative to the mid-plane about the first rotation axis by a first angle, the mid-plane bisecting the base plane, and the transverse plane being orthogonal to the mid-plane and the base plane, and wherein the axis is rotated relative to a second rotation axis defined by an intersection of the transverse plane and the base plane by a second angle." Ex. 1005 at ¶53, 65; Ex. 1027 ¶67, 79. To the extent the scope and meaning of this element is at all discernable, it is obvious over the prior art. *See* Ex. 1005 at ¶66, Ex. 1027 at ¶80. Notably, PO in Infringement Contentions acknowledged that a "concave contour of the bone-contacting surface of one or more arcs of a cylinder [of the accused devices] is insubstantially different from a clinical and mechanical standpoint" from this claimed contour. Ex. 1046 at 5. This aspect of the accused devices is similar to the disclosure in the cited prior art. *Compare* Ex. 1046 *with* discussion below.

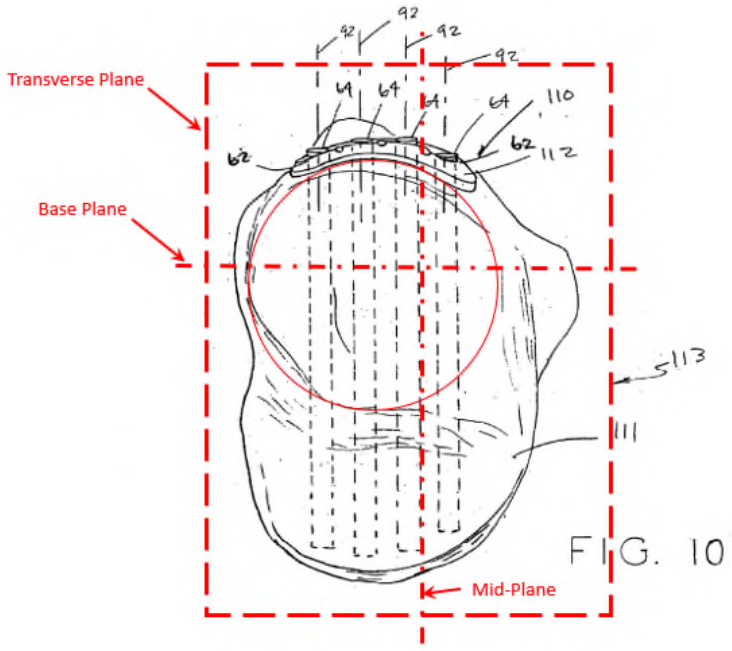
Contoured plates were also well known at the time, as surgeons have long contoured plates prior to surgery to fit a particular bone region. *See* Ex. 1005 at ¶¶68-72; Ex. 1027 at ¶¶82-85. TPLO plates, like those developed by Slocum, are "formed preferably substantially to conform in three dimensions to the to-be-fixed proximal tibia and metaphysis sections." Ex. 1016 at Abstract; 1:47-49; 6:2-4; claims 11, 16. Slocum discloses a contoured bone-contacting surface having "an arc of … radius rD" and provides the well-known motivation to contour TPLO plates, i.e., to match

the contour of the underlying bone. *Id.* at 5:56-62; Figure 2, Ex. 1005 at ¶¶68-69; Ex. 1027 at ¶¶82-83. Young teaches a TPLO plate that is intended to be contoured. Young at ¶39. Young also discusses multiple prior art patents that "conform to the anatomy of the bone," further emphasizing that contouring a plate to match the shape of a bone was well known. *Id.* at ¶6, 13. O'Driscoll also teaches "the plates may include … tubular inner surfaces that are adapted to face bone." O'Driscoll at 9:7-8. O'Driscoll further teaches that a bone-contacting surface "may be generally tubular, for example, having a substantially constant radius of curvature." Thus, O'Driscoll expressly teaches a bone-contacting surface having an arc of a cylinder. *See* Ex. 1005 at ¶68; Ex. 1027 at ¶82. Hence, a POSA would have been motivated to pre-contour bone plates, among other reasons, "so that the surgeon needs to adjust the shape only slightly before application." O'Driscoll at 6:29-30; *see also* §III.B, *supra.*; Ex. 1005 at ¶¶74-75; Ex. 1027 at ¶¶87-88

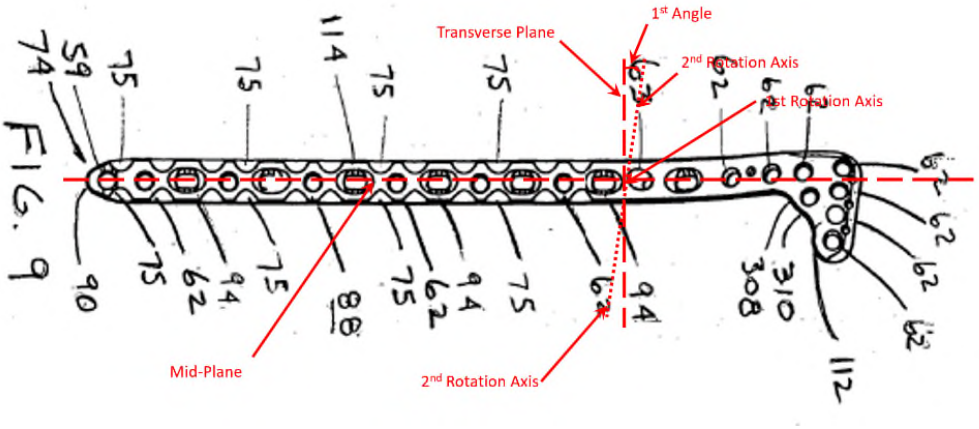
Young also discloses that the angle of the contour roughly matches the preferred angle of the axis of the superior screw hole, or 25 degrees from the perpendicular. *Id.* at ¶39. Element 1[C] requires that "the axis is rotated relative to a second rotation axis defined by an intersection of the transverse plane and the base plane by a second angle." This second rotation angle is disclosed in the '921 patent as between 15 and 30 degrees, preferably 20-25 degrees. *See* Ex. 1001 at 6:4-8. Since the second rotation is relative the second rotation axis, a line which is by definition

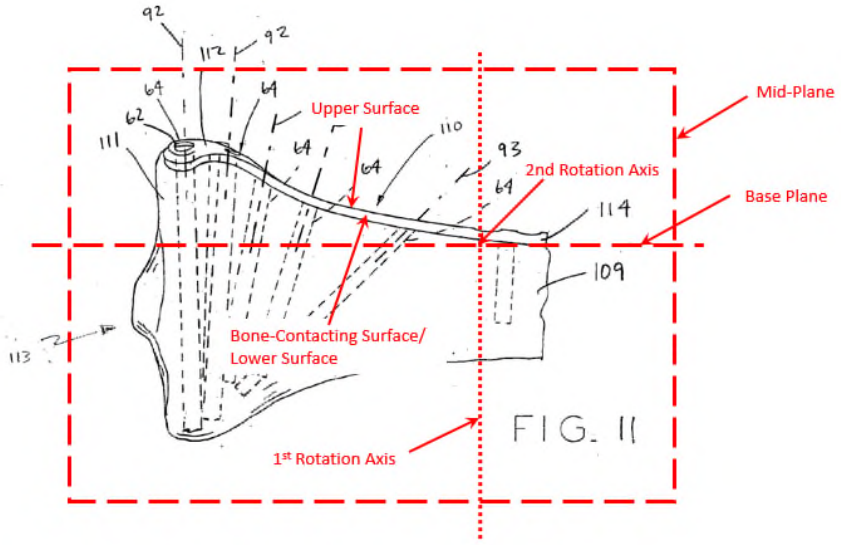
within the base plane, the second rotation occurs relative to the perpendicular of the base plane. Because the 25 degree angle from the perpendicular disclosed in Young is within the preferred range of the '921 patent's disclosure, a POSA would have had full possession of the preferred angle required for the contour, based on Young's disclosure. Ex. 1027 at ¶83.

As the USPTO explained during prosecution of the '792 Appl., the axes and planes described in the claim are "imaginary" in that they are not physical attributes of the plate itself, but are geometric constructs the PO used to define certain physical features of the plate, for example, the shape of the contoured bone-contacting surface of the proximal portion. *See* Ex. 1004 at 207-08; *see also* Ex. 1005 at ¶70; Ex. 1027 at ¶84. As shown below, the same axes and planes can be applied to the prior art plates described in Forstein. *See* Ex. 1005 at 71-73; Ex. 1027 at ¶85-86. The rotations enable the contour axis of the cylinder that defines the contour of the bone-contacting surface of the proximal portion to be viewed head-on, similar to what Figure 6 of the '921 patent portrays. *Id.* This is most easily viewed in an annotated Figure 10



of Forstein reproduced above. Thus, the planes described in claim 1 are present to the same extent they are in the plate disclosed in the '921 patent. *Id.*; Figures 9, 11 (annotated and reproduced above and below).





The detailed geometric recitations in claim 1 amount to little more than manufacturing instructions for a plate to approximate the shape of the tibia of a canine. *See* Ex. 1005 at ¶73; Ex. 1027 at ¶85. As the USPTO has already found multiple times, nothing in this claim element is beyond ordinary skill. *See* Ex. 1005 at ¶¶73-75 Ex. 1027 at ¶¶86-88; *see also* §III.D-E, *supra.* (incorporated here). As

explained in O'Driscoll, "bone plates may be sized and/or precontoured (i.e., prebent, cast, machined, etc.) to a shape that at least nearly matches a particular region of bone." O'Driscoll at 6:27-29. O'Driscoll also teaches that "plates may be precontoured in two or three dimensions to wrap around the intended region of bone." *Id.* at 7:1-2, 8:30-9:14 ("plates may be preshaped, that is, precontoured (preformed), generally to fit an average target anatomy, for example, a population-averaged shape of a particular anatomical region," i.e. "a human (***or other animal***) anatomy averaged over any suitable set, for example, [animals] that fall within a particular size range") (emphasis added). Further, Forstein teaches bone plates that have "a contour that substantially matches the contour of an underlying bone." Forstein at ¶9. In fact, the Forstein Provisional, incorporated into Forstein, expressly teaches bone plates "may have a three-dimensional contour where any portion of the bone plate may curve, twist or bow about ***several axes***." Ex. 1007 at 6 (emphasis added). Indeed, during prosecution of the '792 application, the USPTO also found that Forstein discloses "the bone-contacting surface being pre-contoured to conform to a target portion of a surface of the resected portion of the tibia to which the proximal portion is to be attached, the proximal portion being partially defined by a concave bone contacting surface." Ex. 1004 at 210. The USPTO also provided an annotated Figure 9 of Forstein to establish the mappings of the claim features, reproduced above in §III.E. *See Id.* at 219.

Further, at the location where the proximal portion of a TPLO plate is attached to the medial proximal tibia, of either a dog or a human, the bone shape is generally cylindrical. *See* Ex. 1005 at ¶74 (figure reproduced below); *see also* §V.B.2.b., *infra.* (incorporated here). Because the surface of the bone is roughly cylindrical and the bone plates are contoured to match the shape of the bone, the contours must necessarily be roughly cylindrical. *Id.*; *see also* Ex. 1027 at ¶87. Thus, a POSA would understand, from the disclosures of O'Driscoll and Forstein, that pre-contouring of bone plates, for example those of Young, can be achieved through bending and machining "about several axes" to match a roughly cylindrical contour of the bone, for example, the canine medial proximal tibia, and one way this is accomplished is using a machining cylinder resulting in a contour formed as an arc of a cylinder. *See* Ex. 1005 at ¶¶72-75; Ex. 1027 at ¶85-88.

The Board previously found that element 1[C] requires a symmetrical plate (i.e. that the mid-plane of the proximal portion bisects the mid-plane of the distal portion.). *See* §III.D., *supra.* (incorporated here); §IV.D., *supra.* (incorporated here); Ex. 1005 at ¶37; Ex. 1027 at ¶50. In addition to the embodiment of Figure 9, Forstein discloses a plurality of additional embodiments that demonstrate various features of the Challenged Claims as shown in the following claim chart. *See*, *e.g.*, Forstein at ¶¶74-78 and Figures 7, 12, 14, 16. Forstein discloses head 52 having a bone-contacting surface 56 that is contoured to match the contour of the proximal lateral tibial metaphysis. *See* Forstein at ¶67, 83, Figures 2, 9. Both Forstein and O'Driscoll disclosed symmetrical bone plates as well which have a mid-plane of the proximal portion that bisects the base plane of the distal portion. This is the sole feature the Board found lacking in the prior art during prosecution. *See* Ex. 1002 at 439; Ex. 1005 at ¶37; Ex. 1027 at ¶50. For example, Forstein discloses a symmetrical bone plate for use on the distal medial tibia. *See* Forstein at Figure 7 (reproduced at left). O'Driscoll also discloses a number of symmetrical bone plates, including for use on the proximal-posterior ulna. *See* O'Driscoll at Figure 31. A POSA would have been motivated to use a symmetrical bone plate to eliminate issues involving handedness, meaning they may prefer to use a plate that is not limited by which

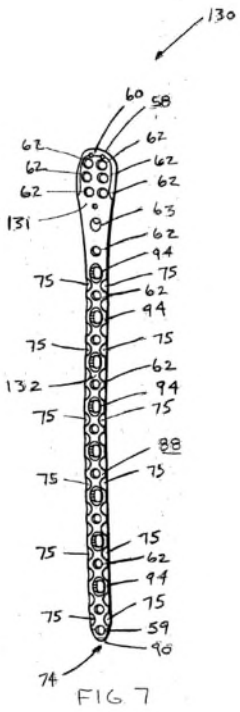


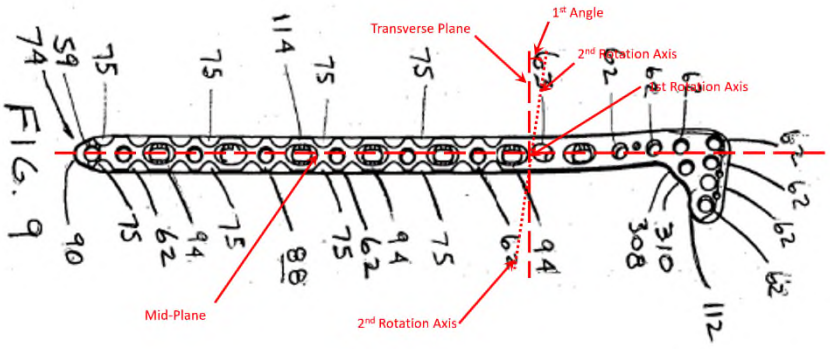
FIG 7

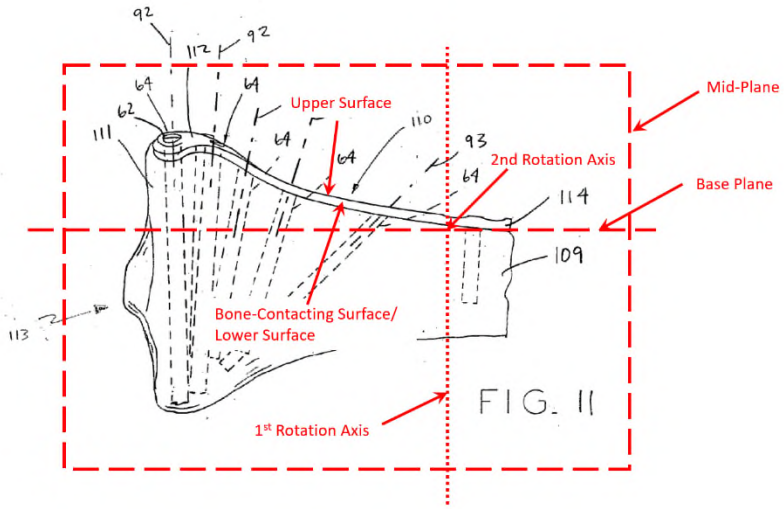
side of the patient the plate applies to, as disclosed by O'Driscoll. *See* O'Driscoll at 19:13-15; *see also* Ex. 1005 at ¶67; Ex. 1027 at 81.

Combining these interchangeable features with the TPLO plate of Young and/or the tibial plates of Forstein would yield predictable results and would be well within ordinary skill because various configurations of plates for similar uses and/or for a particular anatomical area was well known at the time of invention. *See* Ex. 1005 at ¶75; Ex. 1027 at ¶88.

1[C]: the bone-contacting surface of the proximal portion being pre-configured and dimensioned to conform to a tibial bone segment and having a contour formed as an arc of a cylinder having a contour axis extending in a plane including a first rotation axis defined by an intersection of a mid-plane and a transverse plane and rotated relative to the mid-plane about the first rotation axis by a first angle, the mid-plane bisecting the base plane, and the transverse plane being orthogonal to the mid-plane and the	Forstein discloses a bone-contacting surface of the proximal portion being pre-configured and dimensioned to conform to a tibial bone segment and having a contour formed as an arc of a cylinder having a contour axis. *See* Forstein at ¶1 (fully incorporating by reference U.S. Provisional Ser. No. 60/616,680 (Ex. 1007)); Ex. 1007 at 6 ("The present concept includes bone plates that are configured to conform to the anatomical contours of a bone. The bone plate may have **a three-dimensional contour where any portion of the bone plate may curve, twist or bow about several axes**."); Forstein at ¶9 ("… the **bone plate has a contour that substantially matches the contour of an underlying bone**."); ¶85 ("Bone plate 50, referring to FIG. 2, is also **contoured to match** the anatomical bow of the femur along its length. More particularly, bone plate 50 includes curvature 102 along the length of the bone plate which matches the anatomical bow of the diaphysis of the femur. Other bone plates … **have twists and curves such that the bone plates substantially abut a particular bone at a particular location**. For example, proximal lateral humeral plate 105 (FIGS. 23 and 24) is configured to abut against the anatomic contours of a proximal lateral humerus. In some embodiments, each humeral plate 105, e.g., is **contoured to match** the contours of either a left humerus or a right humerus, but not both. In other

base plane, and wherein the axis is rotated relative to a second rotation axis defined by an intersection of the transverse plane and the base plane by a second angle;	embodiments, plates 110, 130, 139 and 312 (FIGS. 7-11, 16-17 and 26-27) are **configured to abut against the anatomic contours of a tibia**, and plates 81, 116, 136, 145 and 150 (FIGS. 12-15, 18-22 and 28-34) are configured to abut against the anatomic contours of a distal radius. In some embodiments, the contour of a bone plate matches the contour of one of a medial or lateral side of a bone. In some embodiments, a lateral bone plate, for example, may match the lateral sides of both a left and a right bone such as, e.g., a left and right tibia.”).





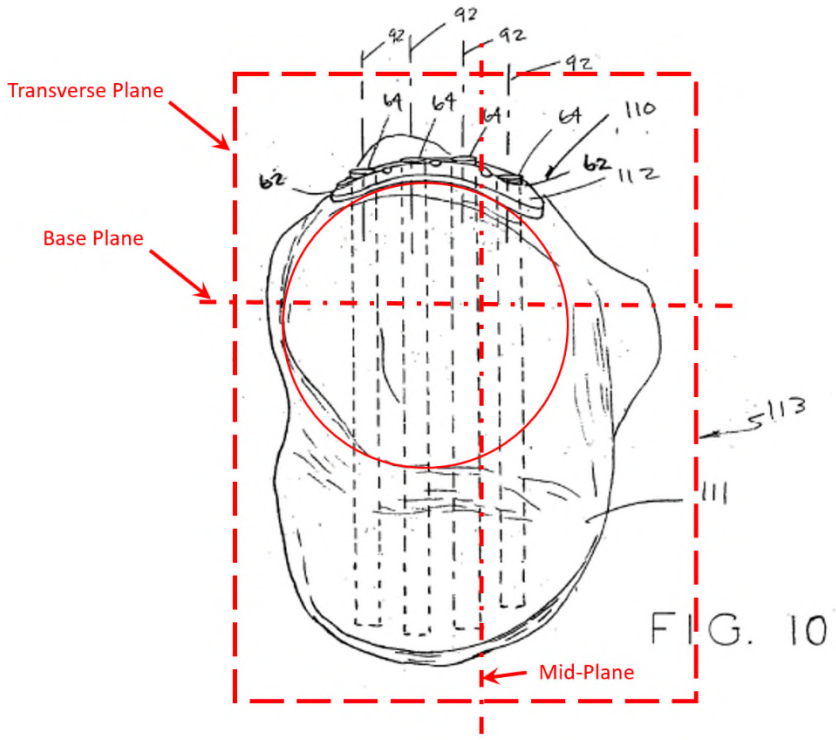
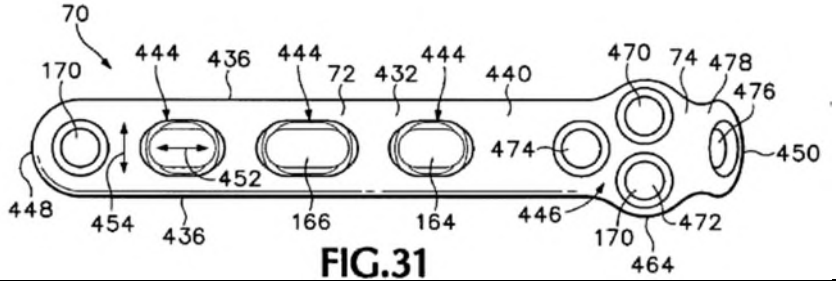


FIG. 10

O'Driscoll discloses a mid-plane bisecting the base plane. *See* O'Driscoll at Figures 31-36; 6:25-32; 7:1-9 ("The plates may be precontoured in two or three dimensions to wrap around the intended region of bone. Moreover, these plates may be configured so that each successive plate includes an additional precontoured portion configured to wrap around an additional portion of the intended target region of bone, for example a shaft region and/or periarticular region, among others. In some cases, bone plates may be somewhat undercontoured so that some additional bending is required to match the bone plate to the contour of bone. Alternatively, or in addition, the bone plates may possess a handedness necessary to fit a left or a right bone."); 8:30-9:14 ("In particular, the plates may be preshaped, that is, precontoured (preformed), **generally to fit an average target anatomy**, for example, **a population-averaged shape of a particular anatomical region**. … The preshaping allows the inner or bone-facing surface of the plate to follow and **substantially match the three-dimensional contour of a bone**, along the length of the

	plate and/or across the width of the plate. For example, the plates may include curved, bent, twisted, and/or tubular inner surfaces that are adapted to face bone and to guide the plates to set onto the bones, initially to enhance fixation and/or to template reduction of bone, and subsequently to increase stability, by grabbing and holding bone fragments."); 25:15-18 ("Inner surface 434 may be generally tubular, for example, having a substantially constant radius of curvature (measured transversely) throughout distal portion 72 and bridge portion 440.").  FIG.31

d. Element 1[D]

Element 1[D] recites: "a plurality of proximal portion screw holes located in the proximal portion that were machined through the pre-contoured bone-contacting surface, the proximal portion screw holes being designed to accept a locking screw, whereby locking screws anchored through the proximal portion screw holes will have a targeted screw path through the first tibial bone segment." Ex. 1005 at ¶53; Ex. 1027 ¶67.

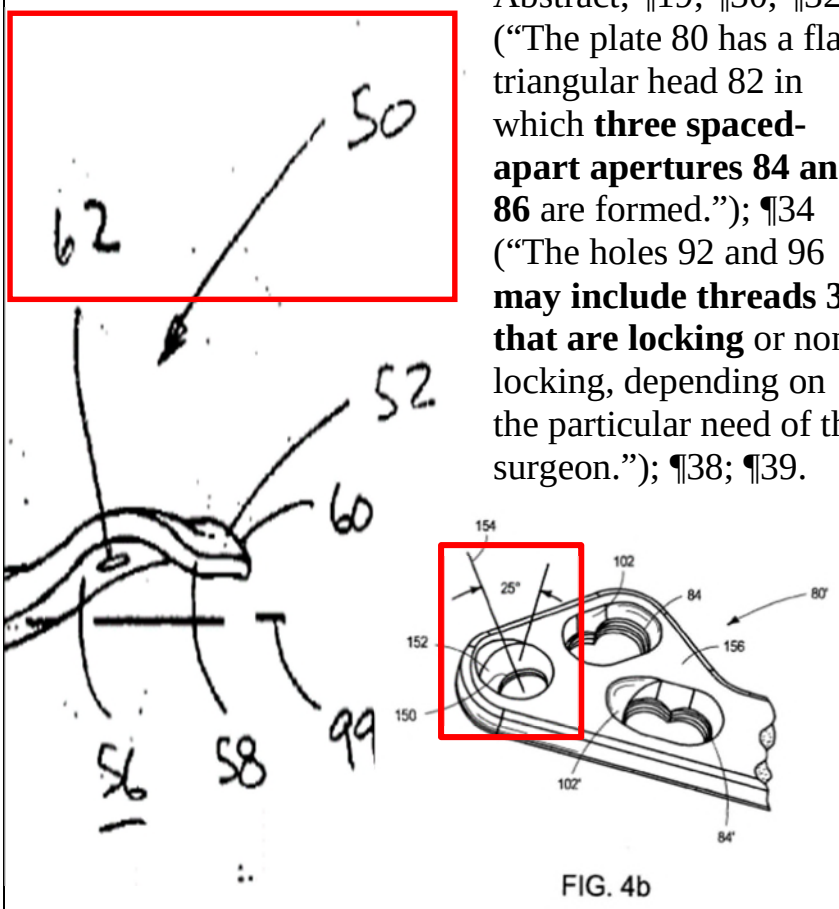
Forstein expressly discloses threaded locking screws and screw holes. *See, e.g.*, Forstein at ¶¶71-73, 86, 88, 93, 100, 111, 113, 115. For example, the tibial plate embodiment of Figure 9 includes a number of screw holes in the head 112 and shaft

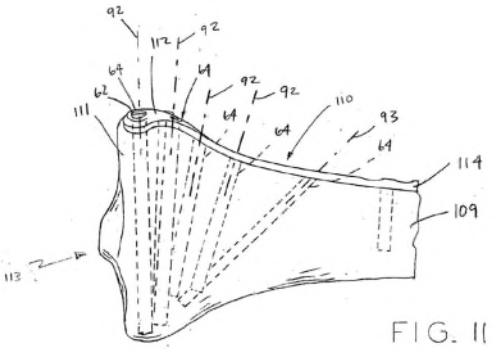
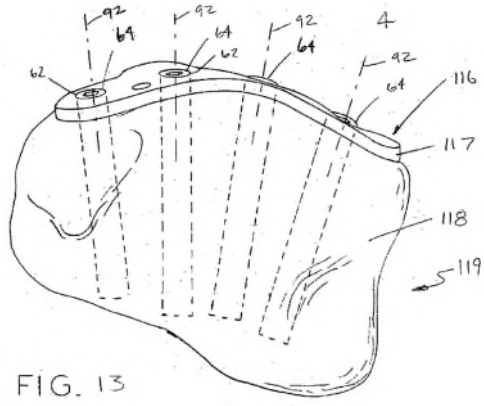
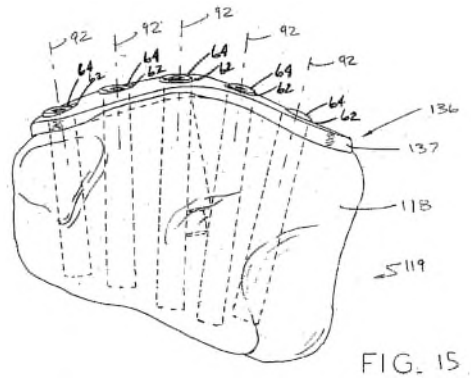
114 of the bone plate 110. *See Id.* at ¶75. Additionally, the Forstein Provisional also expressly discloses screw holes that "are each designed to accept a locking screw." *See* Ex. 1007 at 161 (plates "will accommodate standard screws, as well as locking screws with threaded heads …."). Forstein also incorporates by reference a number of Zimmer product brochures ("Zimmer Brochures") describing a proximal tibial locking plate and expressly discloses the use of locking screws in a periarticular plate adapted for the proximal tibia. *See* Ex. 1028 at 64 (plates "will accommodate standard screws, as well as locking screws with threaded heads"). The USPTO, during the prosecution of the '792 application, also found that Forstein discloses "a proximal portion" having "a plurality of proximal portion locking screw holes [having] screw axes selected to pass into the resected portion of the bone without intersecting the articular surface." Ex. 1004 at 210-11. Locking screws and screw holes were also well known at the time of the invention, as recognized by the USPTO during prosecution of the '921 patent. *See* Ex. 1002 at 155 (citing Orbay, Ex. 1013, Figure 1, numeral 108); 158 (citing Huebner, Figure 8); *see also* Ex. 1005 at ¶¶55, 79-80; Ex. 1027 at ¶¶69, 92-93; Young at ¶34; Wack at ¶82; Weaver at Abstract, 1-2 ("One method of securing the screw to the plate involves the use of so-called 'locking screws'."), 4, 6-11, Figure 2; Ex. 1033 at ¶41; Ex. 1035 at 392.

Young also discloses a plurality of screw holes machined through the proximal portion of a bone plate. Young further discloses "a round hole 150 having

a countersink 152 whose axis 154 is angled off of perpendicular from the top surface 156 of the bone plate." *Id.* at ¶39. Young discloses that "This angle allows screw placement that is parallel to the adjacent bone surface." *Id.* It would have been obvious to modify Young to include targeted screw paths for the proximal portion screw holes. *See* Ex. 1005 at ¶¶76-80; Ex. 1027 at ¶¶89-93. Screw hole angulation was well known in the art and a POSA would have been motivated to angle each of the holes in the head of the bone plate because of the well-established need to avoid penetrating the articular surface of the tibiofemoral joint. *See*, *e.g.*, Ex. 1021 at 187, 189 (describing "intra-articular screw impingement" as a surgical complication "unique to TPLO"); Ex. 1022 at 1730 (identifying "intra-articular placement of screws" as an "implant-related complication" that is "potentially the most serious" and requires an immediate return to surgery where "the screws were removed and replaced with ***appropriately directed screws***.") (emphasis added). It would have been well understood by a POSA as common knowledge in the art at the time of the invention of the '921 patent that screws should be inserted into the proximal tibia so as to avoid the articular surface of the tibiofemoral joint. Ex. 1005 at ¶¶76-77; Ex. 1027 at ¶¶89-90. It was specifically understood that articular surface screw impingement as a complication of a canine TPLO procedure was to be avoided and, if it were to occur, should be corrected. *Id.*; Ex. 1022 at 1730

Bone plates that included targeted screw paths exhibiting a converging screw pattern were well known at the time of the invention. *See* Ex. 1005 at ¶¶76-78; Ex. 1027 at 89-91. For example, Forstein explicitly discloses a tibial fixation plate having fixed angle, proximately located screw holes with targeted screw paths. *See* Forstein at Figure 11; ¶81 ("the length and/or trajectory of screws 64 are selected such that the screws do not penetrate into the articular surfaces of the joint."); Ex. 1005 at ¶78; Ex. 1027 at ¶91. Similarly, both the radial bone plates shown in Figures 12-15 of Forstein also exhibit a converging screw hole axis pattern, most clearly shown in Figures 13 and 15. *See* Forstein at ¶¶76-77. Forstein also expressly discloses that the screw axes are fixed and cannot be changed by the surgeon. Forstein at ¶73. Additionally, screws are "selected such that the screws do not penetrate into the articular surfaces of the joint." *Id.* at ¶81. Thus it would be obvious to fix the angle the screw holes as claimed and doing so would yield predictable benefits and results. *See* Ex. 1005 at ¶¶76-79; Ex. 1027 at ¶89-92.

1[D]: a plurality of proximal portion screw holes located in the proximal portion that were machined through the pre-contoured bone-contacting surface, the proximal portion screw holes being designed to accept a locking screw, whereby locking screws anchored through the proximal portion screw holes will have a targeted screw path through the tibial bone segment.	Young discloses a plurality of proximal portion screw holes located in the proximal portion that were machined through the bone-contacting surface, the proximal portion screw holes being designed to accept a locking screw, whereby locking screws anchored through the proximal portion screw holes will have a targeted screw path through the tibial bone segment. *See* Young at Abstract; ¶19; ¶30; ¶32 ("The plate 80 has a flat triangular head 82 in which **three spaced-apart apertures 84 and 86** are formed."); ¶34 ("The holes 92 and 96 **may include threads 30 that are locking** or non-locking, depending on the particular need of the surgeon."); ¶38; ¶39.  FIG. 4b Forstein discloses this element. *See* Forstein ¶72 ("Similar to plate shaft 54, **head 52** includes **threaded holes 62** for receiving screws that fasten bone plate 50 to femur 51."); ¶73 ("**Threaded holes 62** can receive, referring to FIG. 6, screws 64 having threaded head 67 and threaded shaft 68…. Owing to the threaded engagement of screws 64 and threaded holes 62, **the orientations of screws 64 relative to bone plate 50 are fixed along axes 92** (FIG. 6). More particularly, the orientation of threaded head 67 is controlled by the

	orientation of conical wall 63 and threads 66. Accordingly, as **the surgeon cannot change the orientation of screws 64**, the quantity and orientations of threaded holes 62 are selected such that a fracture, and the fragments thereof, may be fully engaged by screws 64."); ¶75 ("In at least one embodiment, axes 92 of screw holes 62 in the head of a bone plate are non-parallel. … As illustrated in FIG. 11, **axes 92 of screw holes 62 converge in tibia 113**."); ¶76 ("Another bone plate, … illustrated in FIGS. 12 and 13, also **has a converging screw pattern**."); ¶77 ("Another bone plate, … illustrated in FIGS. 14 and 15, also **has a converging screw pattern**."). Ex. 1007 at 161 ("Locking Screw Technology The heads of the locking screws contain male threads while the holes in the plates contain female threads. This allows the screw head to be threaded into the plate hole, locking the screw into the plate. This technical innovation provides the ability to create a fixed-angle construct while using familiar plating techniques.") (incorporated by reference into Forstein).  FIG. 11  FIG. 13  FIG. 15

It would have been obvious for a POSA to combine the features of Forstein and O'Driscoll and modify Young based on the clear motivation in the prior art to pre-contour the plate. *See* Ex. 1005 at ¶82; Ex. 1027 at ¶95. For example, For example, O'Driscoll expressly discloses that plates are sized and pre-contoured (i.e., "pre-configured and dimensioned") "so that the surgeon needs to adjust the shape only slightly before application in some cases, and not at all in other cases." O'Driscoll at 6:27-30. A POSA would be further motivated to pre-contour a bone plate to "reduce or eliminate the degree to which a fracture must be fixed before applying the plate, since matching the bone and plate will help to fix the fracture." *Id.* at 6:30-32; Ex. 1005 at ¶75; Ex. 1027 at ¶88. Further, a POSA would be motivated to machine screw holes into a pre-contoured plate with targeted screw paths to avoid the well-known risks of intra-articular screw penetration associated with manual contouring as identified in Cadmus. *See* Ex. 1017 at ¶14; Ex. 1005 76-80; Ex. 1027 at ¶89-93. It was also well known that bone plates would be contoured to conform with the shape of the underlying bone at the location the plate was intended to be used. *See* Ex. 1005 at ¶74; Ex. 1027 at ¶87. Further, the disclosures of Forstein and O'Driscoll explicitly suggest the bowing and contouring about "several axes" to arrive at a bone plate that conforms to the shape of an underlying bone, for example, a tibia. *See* Ex. 1005 at ¶71; Ex. 1027 at ¶85. It was also well known to use locking screws in tibial bone plates. *See* Ex. 1005 at ¶80; Ex. 1027 at

¶93. Finally, a POSA would be motivated to use a symmetrical plate to eliminate issues involving handedness and to use a plate that is not limited by which side of the patient the plate applies to, as disclosed by O'Driscoll, for example to aid in inventory control, reduce the need to have sufficient left or right sided plates, and to avoid waste or potential mistakes. *See* Ex. 1005 at ¶67; Ex. 1027 at ¶81; O'Driscoll at 19:13-15.

In view of the common knowledge in the art that articular surface screw impingement is undesirable and the explicit disclosures of angled screw holes in Young and Forstein, a POSA would have had ample motivation to machine the screw holes to have a targeted screw path through the tibial bone segment. *See* Ex. 1005 at ¶80; Ex. 1027 at ¶93. Combining these interchangeable features with the TPLO plate of Young and/or the tibial plates of Forstein would yield predictable results and would be well within ordinary skill because various configurations of plates for similar uses and/or for a particular anatomical area was well known at the time of the invention of the '921 patent and there would have been a reasonable expectation of their success in orthopedic treatment. *See* Ex. 1027 at ¶81; Ex. 1005 at ¶67.

2. Dependent Claims

Claims 2-11 recite features related to angulation of the screw holes (claims 2-7) and the size of the arc of the contoured bone-contacting surface (claims 8-11).

These features are within the knowledge and skill of a POSA. *See* Ex. 1005 at ¶83; Ex. 1027 at ¶96; *see also* §V.B.1.c., *supra.* (incorporated here); §V.B.1.d., *supra.* (incorporated here). During prosecution of the '921 patent, the USPTO found that these claims were anticipated or obvious over Wack. *See* Ex. 1002 at 318-20, 325. PO never argued against these rejections.

a. Claims 2-7

Claim 2 depends from claim 1 and recites "the proximal portion has a first screw hole that is designed to accept a first locking screw that has a targeted screw path that angles away from the bone-contacting surface of the proximal portion in a distal direction." Both Young and Forstein disclose threaded locking screw holes and the screw paths angling in a distal direction. *See* Ex. 1005 at 84; 1027 at ¶97; Young at Figure 4a (annotated figure reproduced below); §V.B.1.d., *supra.* The USPTO also found that Forstein discloses similar features during prosecution of the related '792 application. *See* Ex. 1004 at 211. 220 (figure reproduced below). It was

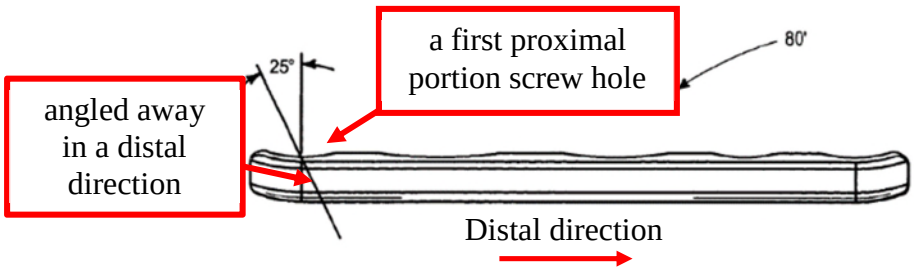
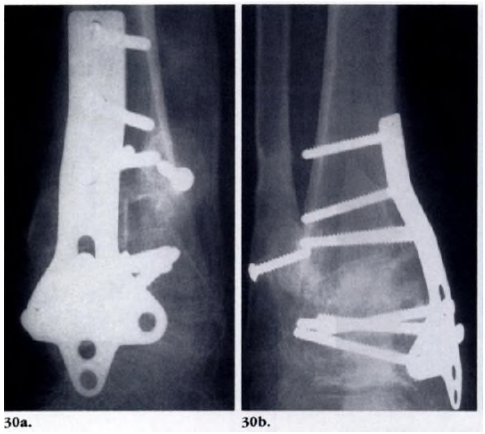
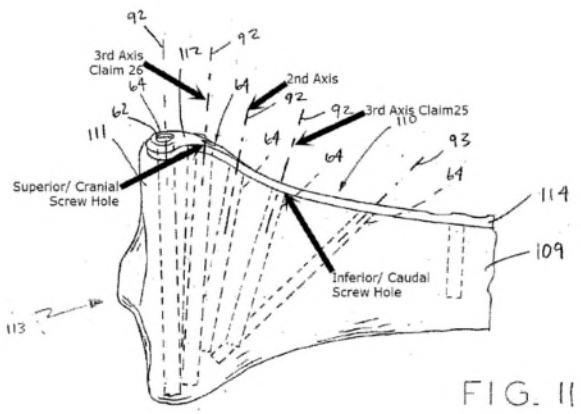


FIG. 4a

well known to a POSA at the time of the invention that screw hole paths could angle distally from the bone-contacting surface. *See* Ex. 1005 at 84; Ex. 1027 at 97; *see*

also Ex. 1018 at Figures 30a, 30b (reproduced below). A POSA would have been motivated to angle the screw paths to avoid articular surfaces, osteotomy surfaces, or the edge of the bones to avoid post-operative complications, especially those involving articular surface screw impingement. *See* Ex. 1005 at 84; Ex. 1027 at ¶97; Ex. 1021 at 187, 189.





Claim 3 depends from claim 2 and recites "the screw path for the first locking screw also angles caudally away from the bone-contacting surface." Both Young and Forstein disclose threaded locking screw holes. *See* §V.B.1.d., *supra*. As the USPTO indicated, Forstein expressly discloses a screw path that angles caudally. *See* Ex. 1004 at 211-12; Forstein at Figures 13, 15 (reproduced below); *see also* Ex. 1005 at 85; Ex. 1027 at ¶98. As shown in Figures 13 and 15, the screw paths of superior (i.e., most proximal) screw holes can be angled either caudally or cranially. It was also well known to angle screw paths to avoid screw impingement of the articular and other surfaces of the bone. In practice, this meant that the superior

screw was angled caudally. *See* §V.B.1.d., *supra.*; Ex. 1005 at 85; Ex. 1027 at ¶98; Ex. 1021 at 187, 189; Ex. 1022 at 1730.

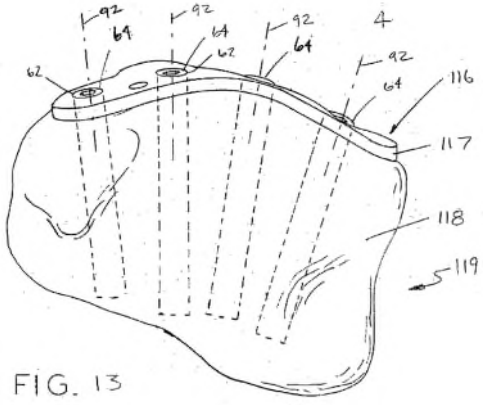


FIG. 13

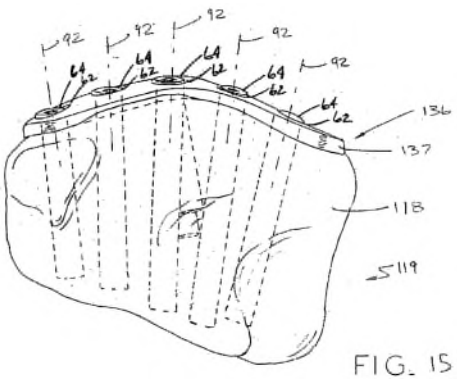
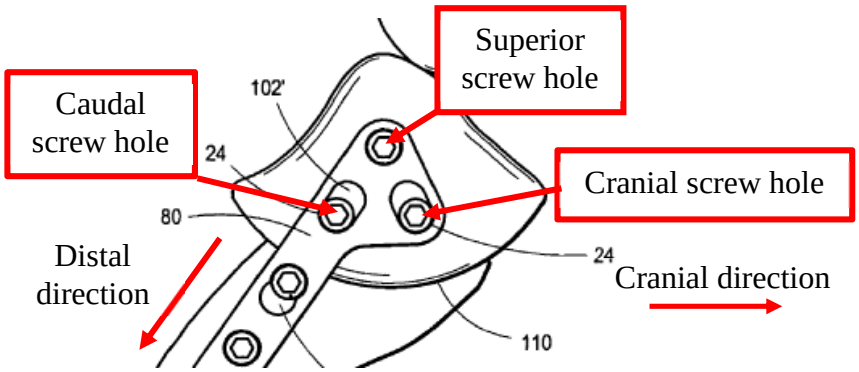


FIG. 15

Claim 4 depends from claim 2 and recites that the "proximal portion has a second screw hole that is located distally and cranially from the first screw hole and is designed to accept a second locking screw that has a targeted screw path that angles caudally away from the bone-contacting surface." Claim 5 depends from claim 2 and recites "proximal portion has a second screw hole that is located distally and caudally from the first screw hole and is designed to accept a second locking screw that has a targeted screw path that angles cranially away from the bone-contacting surface." Both Young and Forstein disclose threaded locking screw holes and locating proximal portion screw holes using the relative relationships recited in the claims. *See* §V.B.1.d., *supra.* For example, Young discloses a triangular screw pattern that, when implanted, exhibits the superior, caudal, cranial relationship required by claims 4 and 5. *See* Ex. 1005 at 86; Ex. 1027 at ¶99, Young at Figure 4a (reproduced below). In addition, during prosecution of the '792 application, the

USPTO found that Forstein discloses elements similar to those in claims 4 and 5. *See* Ex. 1004 at 211-12 (citing Forstein at ¶75, Figures 9-11). Further, as shown above in reference to Forstein Figures 13 and 15 and in Huebner, angling screw paths caudally and/or cranially was well known in the art and was well within ordinary skill. *See* Ex. 1005 at 86; Ex. 1027 at ¶99; *see also* Ex. 1033 at Figure 8 (showing distally located screw holes angling caudally and cranially).



Claim 6 depends on claim 1 and requires that "the first screw hole is a superior screw hole and the proximal portion has a cranial screw hole that is located distally and cranially from the first screw hole and is designed to accept a cranial locking screw that has a targeted screw path that angles caudally away from the bone-contacting surface, and the proximal portion has a caudal screw hole that is located distally and caudally from the first screw hole and is designed to accept a caudal locking screw that has a targeted screw path that angles cranially away from the bone-contacting surface." Claim 7 depends on claim 6 and recites that "the screw path for the superior screw hole also angles caudally away from the bone-contacting

surface." The recitation in claim 6 of "the first screw hole" and "the bone-contacting surface" lacks adequate antecedent basis and, because there is no way for a POSA to understand which of claim 1's "screw holes" claim 6 is directed to, fails to inform a POSA of its scope with reasonable certainty. *See* Ex. 1005 at ¶87; Ex. 1027 at ¶100. Similarly, there is no indication in claim 6 whether the recited "bone-contacting surface" refers to the bone-contacting surface of the distal portion or the proximal portion. A POSA therefore cannot ascertain the scope of claims 6 and 7 with reasonable certainty. *Id.*; *see also* Ex. 1005 at 87; Ex. 1027 at 100. For purposes of this petition only, and to the extent the Board attempts to discern the scope of claim 6, these elements are obvious over the prior art for at least the same reasons as claims 2-5 above (incorporated here). *See* Ex. 1005 at 88; Ex. 1027 at ¶101. In addition, during prosecution of the '792 application, the USPTO found Forstein also discloses similar elements to those in claim 6. *See* Ex. 1004 at 211-12 (citing Forstein at ¶75, Figures 9-11).

Forstein suggested to a POSA to alter the trajectory of screws "such that the screws do not penetrate into the articular surfaces of the joint." Forstein at ¶81. Such articular surface impingement by bone screws was, at the time of the invention of the '921 patent, a well-known complication "unique to TPLO." Ex. 1021 at 187, 189; *see also* Ex. 1022 at 1730. Thus, a POSA would have ample motivation to angle

proximal portion screws as required in claims 2-7. *See* Ex. 1005 at 94; Ex. 1027 at ¶107.

b. Claims 8-11

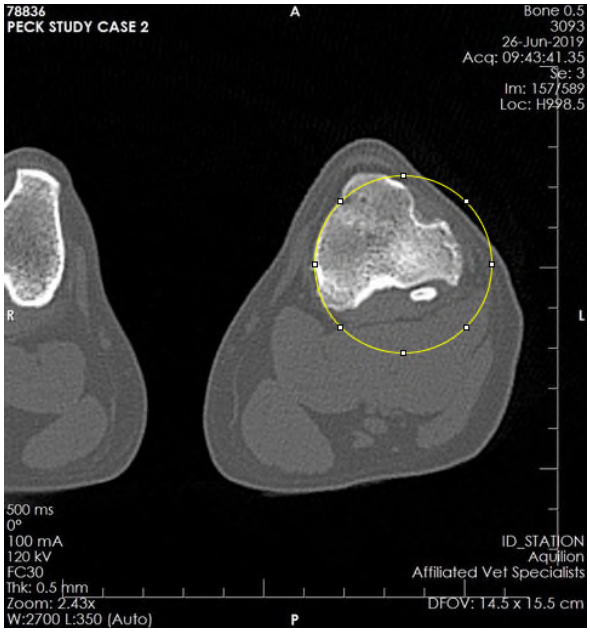
With regard to claims 8-11, the USPTO also found a POSA would find nearly identical limitations as obvious over the disclosure of Forstein (claims 27-20 of the '792 application). Ex. 1004 at 214-20. Claim 8 depends on claim 7 and recites that "the bone-contacting surface is contoured in the shape of a cylinder," which is found in the prior art discussed above and below. Claims 9-11 depend on claim 8. Claim 9 recites "the radius of the cylinder that defines at least part of the bone-contacting surface of the proximal portion of the plate is between about 18 mm and about 24 mm." Claim 10 recites a range of "22 mm and about 30 mm" and claim 11 recites a range of "12 mm and about 20 mm." By virtue of their dependence on claims 6 and 7, and for at least the same reasons provided above regarding the lack of adequate antecedent basis for "the bone-contacting surface," claims 8-11 also fail to inform a POSA of their scope with reasonable certainty. *See* Ex. 1005 at ¶89; Ex. 1027 at ¶102.

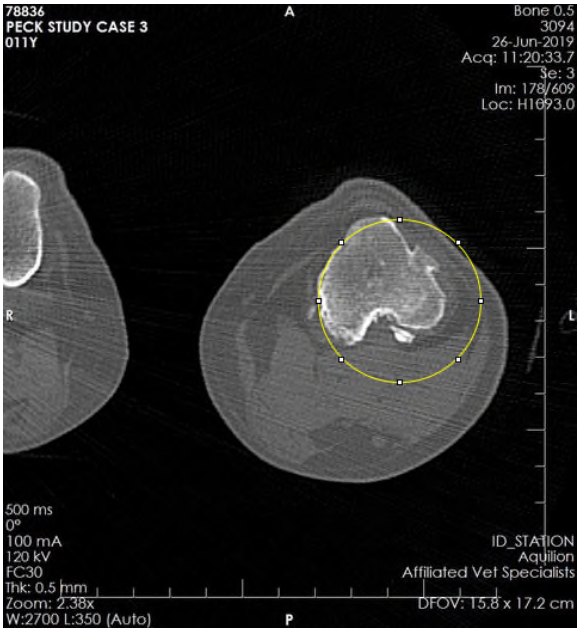
For purposes of this petition only, and to the extent the Board attempts to discern the scope of claims 8-11, they are obvious over the prior art. O'Driscoll discloses that the bone-contacting surface is "generally tubular, for example, having a substantially constant radius of curvature," in other words, cylindrical. O'Driscoll

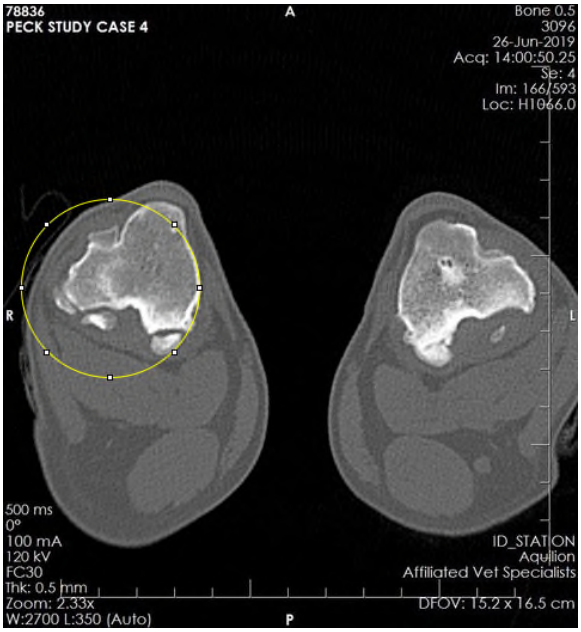
at 25:15-18; *see also* Ex. 1027 at ¶¶82, 102; §V.B.1.c., *supra*. Further, the USPTO found nearly identical claims to be obvious over Forstein. Ex. 1004 at 214-16; *see also* §III.E., *supra*. (incorporated here). The USPTO found these size ranges were result effective variables, the optimization of which is well within the scope of ordinary skill. *Id.*; *see also* Ex. 1002 at 325-27 (citing *Aller*, 220 F.2d at 456 ("where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation"); *In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012) ("A recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective."). Here, the range of the cylinder's radius that defines the contour of the bone-contacting surface is entirely predicated on the shape and size of the underlying bone. *See Id.* at 1005 at ¶89; Ex. 1027 at ¶102. Further, it was well known at the time that a bone-contacting surface could be pre-contoured to conform to the shape of an underlying bone and that the contour could take the shape of a cylinder. *See* Ex. 1005 at ¶¶65-75; Ex. 1027 at ¶¶79-88, 102; *see also* §V.B.1.c., *supra*..

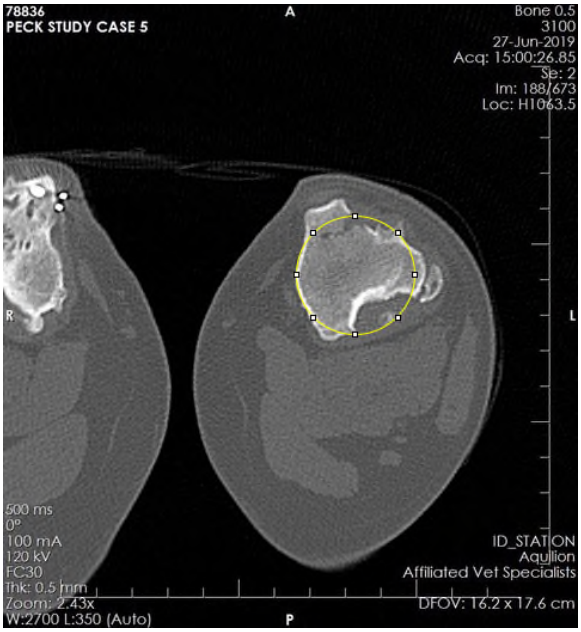
It was well known that the shape of the medial proximal tibia, the location where the proximal portion of a TPLO plate is attached, is roughly cylindrical in shape and that this is generally true for both humans and canines. *See* Ex. 1005 at 92. CT scans show a roughly cylindrical profile of the bone surface to which a bone plate would be contoured to conform. *See* Ex. 1005 at 92, Ex. 1027 at ¶105 (CT scan

images reproduced below). An analysis of the CT scan images establishes that each of the radii of each cylinder arc fall within one or more of the overlapping ranges recited in claims 9-11. *See* Ex. 1027 at ¶106, e.g., Case #2, #4; Ex. 1047.









The limitations of claims 8-11 regarding the size of the cylinder radius are essentially directed toward plates designed for differently sized patients. Ex. 1027 at

¶103. In veterinary orthopedics, especially in canines, there is a wide variety in the sizes and shapes of bones. A properly sized and configured plate for use on a Pomeranian will be different than a plate sized and configured for a Mastiff. *See* Ex. 1005 at ¶91; Ex. 1027 at ¶104; *see also* Ex. 1045 at 440, Figure 31-1 (reproduced below). Forstein expressly discloses a tibial plate with a head that is "sized for

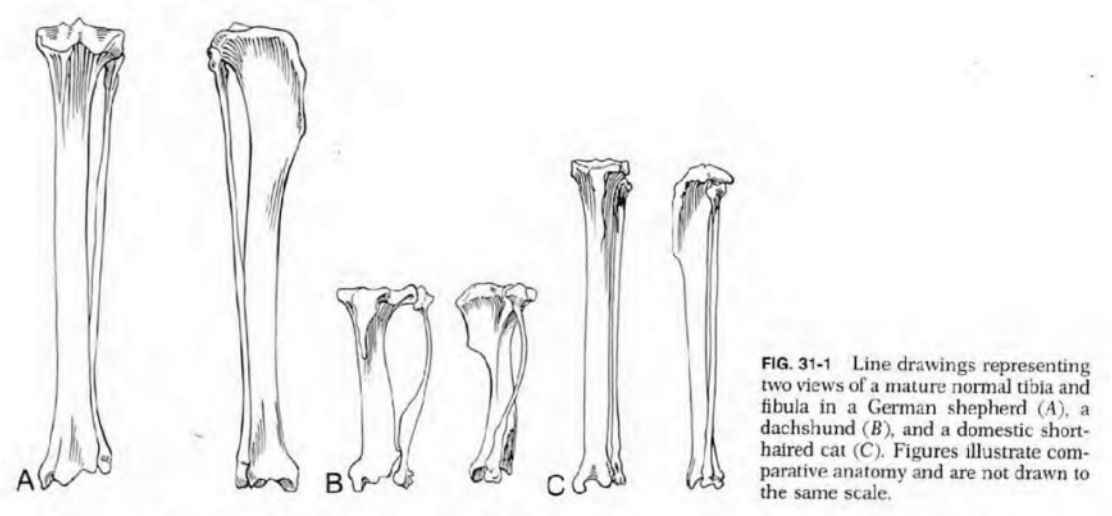


FIG. 31-1 Line drawings representing two views of a mature normal tibia and fibula in a German shepherd (*A*), a dachshund (*B*), and a domestic short-haired cat (*C*). Figures illustrate comparative anatomy and are not drawn to the same scale.

attachment" to a tibia and/or "sized and configured" to conform to a particular bone region. Forstein at ¶21 ("a tibial bone plate comprises … a flared head portion sized for attachment to the metaphysis of the tibia"), ¶¶67, 76, 77, 78, 80, 86. Forstein would have suggested to a POSA that various dimensions of the plate may be adjusted to properly dimension and configure the bone plate to a particular average anatomy, as explicitly disclosed in O'Driscoll. Ex. 1027 at ¶103; O'Driscoll at 8:30-9:5. Therefore, a POSA would have found substantial teachings in the prior art that bone plates could be sized and configured to conform to average anatomies for classes of patients, for example, large, medium, and small dog breeds by adapting

the plates to fit the varying sizes of different breeds and by approximating a range of bone sizes using varyingly sized cylinders. *See* Ex. 1005 at ¶90-91; Ex. 1027 at ¶103-104. This would not have yielded unexpected results. *Id.*

To the extent any motivation is required, it is well established that a POSA would be motivated to seek out and apply teachings that are "well known" in the art. *Realtime Data, LLC v. Iancu*, 912 F.3d 1386, 1374 (Fed. Cir. 2019). A motivation to combine may be found "explicitly or implicitly in market forces; design incentives; the 'interrelated teachings of multiple patents'; 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent'; and the background knowledge, creativity, and common sense of the [POSA]." *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1371 (Fed. Cir. 2018). Sizing the bone plates to varyingly sized bones, which are approximated by varyingly sized cylinders, is a common sense modification to produce variously sized bone plates in accordance with the varying shapes and sizes of canine tibias because obviousness "does not require the prior art to reach expressly each limitation exactly" *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1332 (Fed. Cir. 2016) (affirming that a "plug ... generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column" teaches specific dimensional limitations); *see also* Ex. 1005 at 92-93; Ex. 1027 at ¶¶105-06.

The features recited in claims 2-11 do not have patentable weight in light of Forstein's disclosures and the well-established state of the art at the time of the invention of the '921 Patent. Thus, all the Challenged Claims are obvious.

C. Ground 2 – Claims 1-11 are Obvious under 35 U.S.C. § 103 over Weaver in view of Forstein, O'Driscoll and Young

1. Claim 1

The Challenged Claims are obvious over the combination of Weaver and Forstein. The Office has previously found that Weaver discloses claim elements 19[A]-[E] and 20[A]-[E], which are similar to elements 1[A]-[D]. *See* Ex. 1002 at 321-24; §III.D., *supra.* (incorporated here). Additionally, Forstein discloses 1[A]-1[D] and O'Driscoll discloses elements 1[A], 1[B], and portions of 1[C] and 1[D]. *See* §V.B.1., *supra.* (incorporated here). As noted above, the preamble was never argued as a claim limitation by the PO during prosecution, including in response to the rejections under Weaver. *See, e.g.*, Ex. 1002 at 340-42. Further, claim element 1[PRE] is obvious in view of the well-known TPLO procedures and prior art bone plates, such as those disclosed in Slocum and Young. *See, generally* Ex. 1015 (disclosing TPLO procedure); Ex. 1016 (disclosing TPLO Plate); Young (same); and *see generally* Ex. 1017. Further, both Slocum and Young discuss general orthopedic bone plates as background knowledge in the art, and PO promoted such plates for veterinary uses (Ex. 1041). Thus, a POSA would be motivated to apply the teachings of general orthopedic plates, such as Weaver and Forstein, to veterinary plates, such

as Young, used during TPLO procedures. *See* Ex. 1027 at ¶73-74; Ex. 1040 at 2 ("small animal veterinary surgeons … profited from … experience gained in the treatment of human patients").

Forstein discloses many claim features as discussed above. *See* §V.B.1a-d., *supra*. (incorporated here). Weaver also teaches tibial segment fixation using a bone plate. *See* Weaver at 10-11, Figure 22 (reproduced at right). During the prosecution of the '921 patent, the USPTO found that Weaver discloses elements 1[PRE]-1[B] and 1[D] and PO never argued otherwise to the USPTO. *See, e.g.*, Ex. 1002 at 322-34; *see also* Weaver at 10, Figures 20, 21, 23, 26.

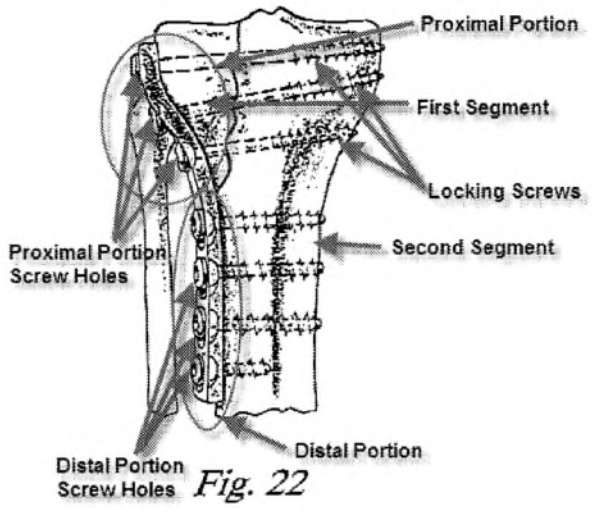


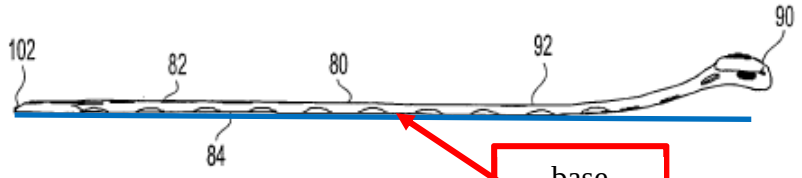
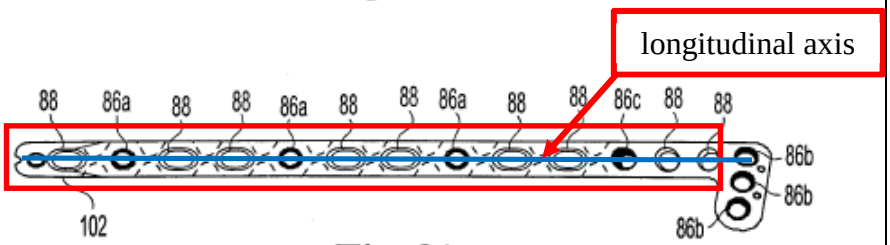
Fig. 22

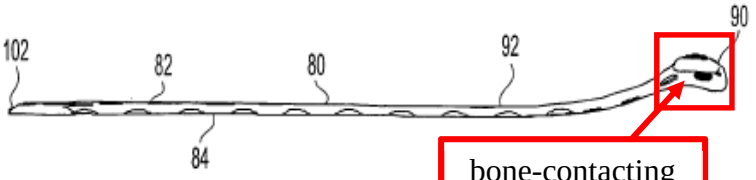
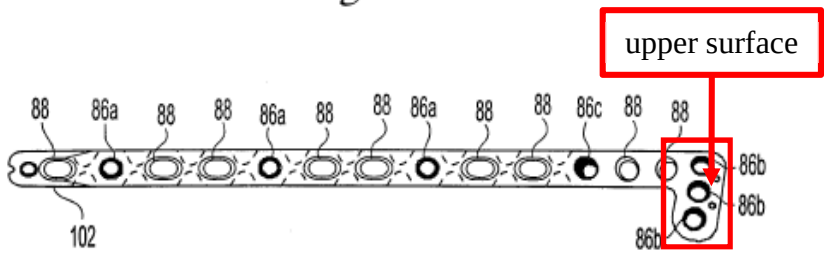
Claim element 1[C], specifically "the mid-plane bisecting the base plane," is the only claim element the Board previously found Weaver did not disclose. *See* Ex. 1002 at 441-42. The Board found that "Weaver contains a proximal portion (with holes 86b) having a mid-plane that does not bisect the base plane defined by the distal portion of the bone plate (with holes 86a, 86c, and 88)." *Id.* at 442. Both Forstein and O'Driscoll disclose symmetrical bone plates. For example, Forstein discloses a symmetrical bone plate for use on the distal medial tibia. *See* Forstein at Figure 7. O'Driscoll also discloses a number of symmetrical bone plates. *See*

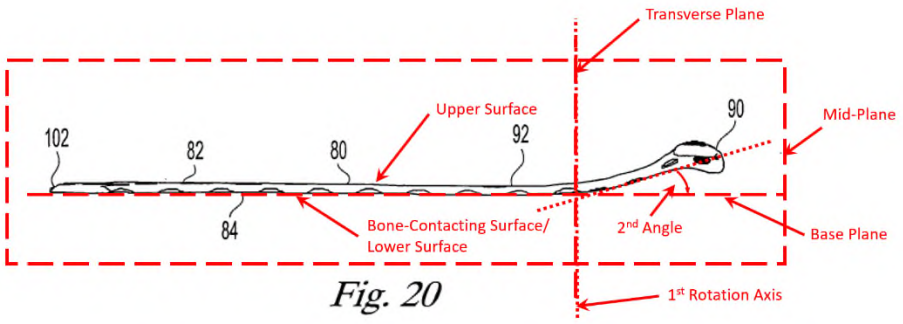
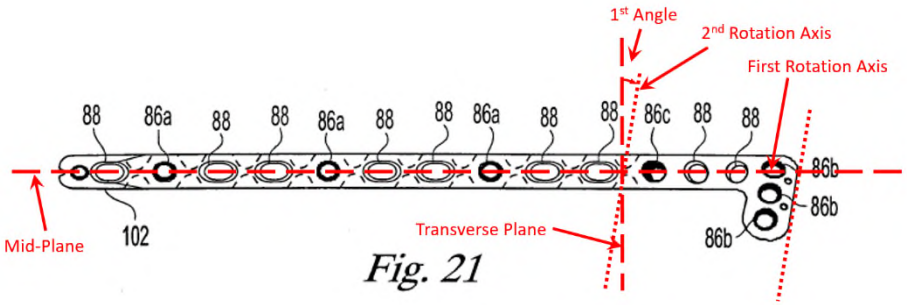
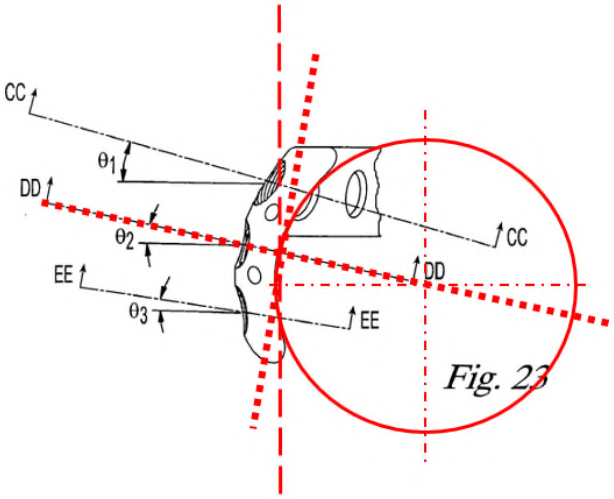
O'Driscoll at Figure 31. The curved shapes of Forstein and Weaver both can be adapted, based on the disclosure of O'Driscoll and the other cited art, to include a "contour formed as an arc of a cylinder." Further, the contours of these prior art references is similar to the concave contour on the accused products. *See* §V.B.1.d, *supra*. (incorporated here); Ex. 1046 at 6; *compare with* discussion of prior art curvatures. Weaver further teaches that the "plate holes 86b are oriented to converge at a predetermined distance from plate surface 84 to optimize the position of locking screws 20 within the tibia plateau." Weaver at 11. For the reasons discussed above, a POSA would be motivated to modify Weaver to be symmetric in view of Forstein and/or O'Driscoll. *See* O'Driscoll at 19:13-15; Ex. 1027 at 81; *see also* §V.B.1.d., *supra*. (incorporated here)

In view of the common knowledge in the art that articular surface screw impingement was undesirable and the explicit disclosures of angled screw holes in Weaver and Forstein, a POSA would have had ample motivation to conform a bone plate to a particular bone shape using "a three-dimensional contour where any portion of the bone plate may curve, twist or bow about several axes." Ex. 1007 at 6; *see also* Ex. 1005 at ¶¶50-51, 56-64, 71-74, 79-82; Ex. 1027 at ¶¶64-65, 70-79, 85-87, 92-95.

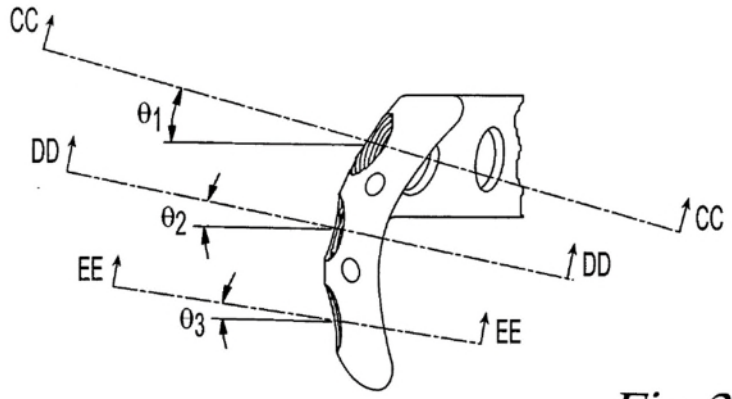
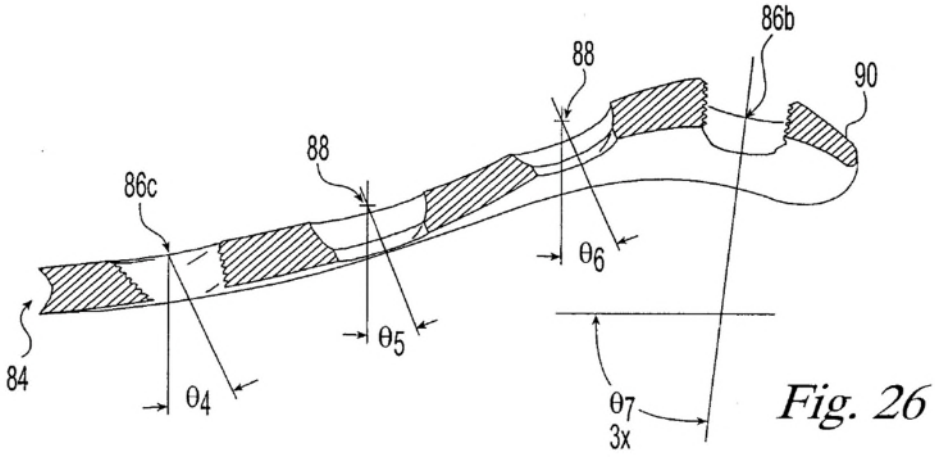
1[PRE]: *See* §V.B.1.1[PRE]	Weaver discloses a bone plate dimensioned for securing two tibial bone segments of an animal as part of a surgical procedure. *See* Weaver at 10 ("FIGS. 20-26 show a bone plate 80 … specifically designed for use in the proximal tibia. Bone

	plate 80 would be primarily used for, but not limited to fractures of the lateral proximal tibial plateau."). Forstein discloses this element. *See* §V.B.1[PRE], *supra.* (incorporated here); Forstein at Abstract; ¶66. Young discloses this element. *See* §V.B.1[PRE], *supra.* (incorporated here); Young at Abstract; ¶2; ¶35.
1[A]: *See* §V.B.1.a.1[A]	Weaver discloses a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw and defining a longitudinal axis and a base plane along a bone-contacting surface thereof. *See* Weaver at Figures 20, 21; 10 ("Bone plate 80 has a plurality of threaded plate holes 86a, 86b and 86c (collectively referred to  *Fig. 20*  *Fig. 21* as threaded plate holes 86) for receiving locking screws 20 and a plurality of non-threaded plate holes 88 for receiving non-locking screws 10. Each of threaded and non-threaded plate holes 86 and 88 pass through upper 82 and bone-contacting surfaces 84."); 10-11 ("Bone plate 80 includes … **a shaft portion 92**"). Forstein discloses this element. *See* §V.B.1.a.1[A], *supra.* (incorporated here); Forstein at ¶71; ¶73; ¶75; FIG. 9; ¶84.
1[B]: *See* §V.B.1.b.1[B]	Weaver discloses a proximal portion having an upper surface and a bone-contacting surface opposite the upper surface. *See*

	Weaver at 10-11 ("Bone plate 80 includes a **head portion 90** …. As seen in FIGS. 20 and 26, **bone contacting surface 84 of head portion 90** is a curved, tapered, and twisted to fit the contours of the lateral proximal tibial plateau.")  *Fig. 20*  *Fig. 21* Forstein discloses this element. *See* §V.B.1.b.1[B], *supra.* (incorporated here); Forstein ¶67; ¶83.
1[C]: *See* §V.B.1.c.1[C]	Weaver discloses the bone-contacting surface of the proximal portion being pre-configured and dimensioned to conform to the outer surface of the first tibial bone segment and having a contour formed as an arc of a cylinder. *See* Weaver at 10-11 ("Bone plate 80 includes a head portion 90 **configured and dimensioned to conform to the metaphysis of the lateral proximal tibia** …. As seen in FIGS. 20 and 26, **bone contacting surface 84 of head portion 90 is a curved, tapered, and twisted to fit the contours of the lateral proximal tibial plateau**.")

	 Fig. 20  Fig. 21  Fig. 23 Forstein discloses this element. *See* §V.B.1.c.1[C], *supra.* (incorporated here); Forstein at ¶1 (incorporating by reference provisional (Ex. 1007)); Ex. 1007 at 6; Forstein at ¶9; ¶85. O'Driscoll discloses the mid-plane bisecting the base plane, i.e. a symmetrical plate. *See* §V.B.1.c.1[C], *supra.* (incorporated here); O'Driscoll at Figures 31-36; 6:25-32; 7:1-9; 8:30-9:14; 25:15-18.
1[D]: *See* §V.B.1.d.1[D]	Weaver discloses a plurality of proximal portion screw holes located in the proximal portion that were machined through

	the pre-contoured bone-contacting surface, the proximal portion screw holes being designed to accept a locking screw, whereby locking screws anchored through the proximal portion screw holes will have a targeted screw path through the tibial bone segment. *See* Weaver at 8-9 ("As management of certain peri-articular fractures typically involves **insertion of screws at various angles** with respect to the bone plate and **it is highly desirable to maintain the initial angular relationships between the individual screws and the bone plate**, the bone plating system … is particularly well- suited for these clinical applications."); 10 ("FIGS. 12-18 show the various angular orientations of the individual threaded holes 56b, 56c. In [general], threaded holes 56b, 56c are arranged so that **the inserted locking screws converge towards each other**."); 11 ("In similar fashion to shaft portion 92, **head portion 90 contains threaded holes 86** and non-threaded holes 88. Head portion 90 features threaded plate holes 86b and 86c. … In general, **threaded holes 86b, 86c are arranged so that the inserted locking screws converge towards each other**. As shown in FIG. 23, **plate holes 86b are oriented to converge at a predetermined distance from plate surface 84 to optimize the position of locking screws 20 within the tibia plateau**. As shown in FIG 26, plate hole 86c is oriented to converge with plate hole 86b at predetermined distance to provide additional stability to **the locked fixed-angle construct**. It should be noted that if a surgeon elects, non-locking screws can be used in any of threaded plate holes 86.").

	 *Fig. 23*  *Fig. 26* Forstein discloses this element. *See* §V.B.d.1[D], *supra.* (incorporated here); Forstein ¶72; ¶73; ¶75; ¶76; ¶77. Ex. 1007 at 161 (incorporated by reference into Forstein).

2. Claims 2-11

For at least the same reasons discussed above, The features recited in claims 2-11 do not have patentable weight in light of the disclosures of Forstein and the well-established state of the art at the time of the invention of the ’921 Patent, including the well-known shapes and sizes of canine tibias. *See* §V.B.2.a-b., *supra.* (incorporated here); §V.C.1, *supra.* (incorporated here). Weaver also discloses the elements of claims 2-11. For example, Weaver includes locking screw holes that

angle distally, caudally, and/or cranially. *See* Ex. 1005 at 83-94; Ex. 1027 at 96-107; Weaver at Figures 23, 26 (reproduced above); *see also* §V.C.1.1[D], *supra.* (incorporated here).

VI. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for claims 1-11 of the ’921 patent.

VII. PAYMENT OF FEES – 37 C.F.R. §42.103

Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 50-1943, referencing Attorney Docket No. 126518.00002, for any fees due as a result of the filing of the present petition.

VIII. MANDATORY NOTICES UNDER § 42.8

A. Real Party-in-Interest Under § 42.8(b)(1)

Petitioner is the real party-in-interest for the instant petition.

B. Related Matters Under § 42.8(b)(2)

Petitioner is the named defendant in litigation concerning the ’921 Patent, *Depuy Synthes Products, Inc. v. Veterinary Orthopedic Implants, Inc.*, 3:18-cv-01342-HES-PDB, filed in the Middle District of Florida, Jacksonville Division.

PO has filed two utility continuations and one design application claiming priority to the ’921 Patent. The ‘407 was filed on June 29, 2012 and is currently pending and appeal of the final rejection of all claims. The ‘792 was filed on July

10, 2018 and is currently pending and appeal of the final rejection of the claims. U.S. Design Patent Application Serial No. 29/656,918 issued on July 2, 2019.

C. Lead and Back-Up Counsel Under § 42.8(b)(3)

LEAD COUNSEL	BACK-UP COUNSEL
Jeff E. Schwartz, Reg. No. 39,019 1030 15th Street, NW Washington, DC 20005	Ryan N. Miller, Reg. No. 68,262 2000 Market Street, 20th Floor Philadelphia, PA 19103

D. Service Information

Please address all correspondence and service to both counsel listed above. Petitioner consents to service by email at jeschwartz@foxrothschild.com, rmiller@foxrothschild.com, and ipdocket@foxrothschild.com (referencing Attorney Docket No. 126518.00002).

Respectfully submitted,

Dated: July 12, 2019

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Attorneys for Petitioner

CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(a)

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), the undersigned certifies that on the 12th day of July 2019 a complete and entire copy of this Petition for Inter Partes Review and all supporting exhibits was provided via Federal Express to Patent Owner at the following address(es):

Joseph F. Shirtz
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New Brunswick, NJ 08933-7003

Dated: July 12, 2019

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Petition for Inter Partes Review contains 13,948 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. § 42.24 (d)

Dated: July 12, 2019

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