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 12-18 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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EXHIBITS

VOI 1001 – U.S. Patent No. 8,523,921 to Horan et al.

VOI 1002 – Prosecution History of U.S. Patent No. 8,523,921

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)

VOI 1008 – U.S. Patent Application Publication No. 2005/0015089 to Young et al.

VOI 1009 – U.S. Patent Application Publication No. 2002/0156474 to Wack et al.

VOI 1010 – International Patent Application Publication No. WO2001/019267 to Weaver et al.

VOI 1011 – French Patent Application Publication No. 2 405 062 to Dayan

VOI 1012 – International Patent Application Publication No. WO2004/024009 to O'Driscoll et al.

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

VOI 1024 – U.S. Patent No. 4,762,122 to Slocum

VOI 1025 – U.S. Patent No. 4,800,874 to David et al.

VOI 1026 – U.S. Patent No. 5,904,684 to Rooks

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VOI 1028 – Zimmer Periarticular Distal Radial Locking Plates Surgical Technique, Zimmer Periarticular Proximal Humeral Locking Plate Surgical Technique, Zimmer Periarticular Distal Femoral Locking Plate Surgical Technique, Zimmer Periarticular Proximal Tibial Locking Plate Surgical Technique, Zimmer Periarticular Distal Tibial Locking Plates Surgical Technique, and Zimmer Periarticular Radial Styloid Locking Plate Surgical Technique, distributed by Zimmer, Inc., Warsaw, Ind. – Incorporated by Reference into U.S. Patent Application Publication No. 2006/0173458 (VOI 1006)

VOI 1029 – U.S. Patent No. 4,867,144 to Karaś et al.

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VOI 1031 – U.S. Patent Application Publication No. 2005/0010226 to Grady et al.

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VOI 1033 – U.S. Patent Application Publication No. 2005/0240187 to Huebner et al.

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)

VOI 1041 – *Synthes Veterinary Brochure* (February 2004)

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 12-18 (the "Challenged Claims") of U.S. Patent No. 8,523,921 ("the '921 Patent"). As explained in this petition, there exists a reasonable likelihood that Petitioner will prevail with respect to at least one of the Challenged Claims. Petitioner respectfully 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. (hereinafter "Patent Owner") 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 in the table below and requests that the claims be found unpatentable. A detailed explanation of the statutory grounds for unpatentability is provided in claim charts. Additional supporting evidence is provided in the Declarations of Jeffrey N. Peck, DVM, DACVS, Ex. 1005, and Troy D. Drewry, MSBE, MEM, Ex. 1027, and the appendices.

Ground	Claims	Basis
Ground 1	12	Anticipated under 35 U.S.C. § 102 by U.S. Patent Application Publication No. 2006/0173458 ("Forstein")
Ground 2	12-18	Obvious under 35 U.S.C. § 103 over Forstein
Ground 3	12-18	Obvious under 35 U.S.C. § 103 over U.S. Patent Application Publication No. 2005/0015089 ("Young") in view of Forstein
Ground 4	12-18	Obvious under 35 U.S.C. § 103 over 2002/0156474 ("Wack") in view of Forstein

The application that issued as the '921 Patent was filed on February 24, 2006[1] as U.S. Patent Appl. Serial No. 11/361,245. *See* Ex. 1001 at 1. Forstein has an effective filing date of October 7, 2004, which is prior to the filing date of the '921 patent.[2] Forstein is therefore prior art under §102(e). Young was published on

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

[2] At least one claim of Forstein is supported by provisional application Serial No. 60/616,680 (Ex. 1007), filed on October 7, 2004 and for this reason, along with its overlapping disclosures, Forstein is entitled to the provisional filing date for purposes of §102(e). *See* Ex. 1027 at 43. For example, Forstein's Provisional discloses the elements of claim 9 including bone plates (Ex. 1007 at Figures 1-11), the first guide (*Id.* at 5, 8-9, 196-97), and claimed jig (*Id.* at 5, 8-9, 196-97; Figures 12-25). Similarly claim 13 of Forstein is supported by Forstein's Provisional. *See*

January 20, 2005, which is prior to the critical date[3] of the ’921 patent. Young is therefore prior art under §102(b). Wack was published on October 24, 2002, which is prior to the critical date of the ’921 patent. Wack is therefore prior art under §102(b). Forstein was not cited in the prosecution of the ’921 patent. Young was merely cited in an Information Disclosure Statement during prosecution of the ’921 patent but was never cited in any rejection during prosecution. Wack was cited against the claims of the ’921 patent during prosecution. The Office never considered how a person of ordinary skill in the art (“POSA”) would understand the disclosures of Forstein alone or in combination with Young and/or Wack.

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. As such, 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 the approach that the level of skill in the art was best determined by references of record). Thus,

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Ex. 1007 at 5, 8-9, 196-97, Figures 1-11 (plate), Figures 12-25, (jig and related geometries). *See* Ex. 1027 at ¶43.

[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.

as of February 24, 2006, a POSA with respect to the subject matter of the '921 Patent would typically have had at least a Bachelors of Science in Mechanical, Biomechanical or Biomedical engineering, or a related field of science, as well as at least three to seven years of experience in the field of orthopedic implants or would be a practicing veterinary surgeon with at least 3 years of experience and at least some experience in the design and/or use of orthopedic implants. *See* Ex. 1005 at ¶19; Ex. 1027 at ¶22. Such 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

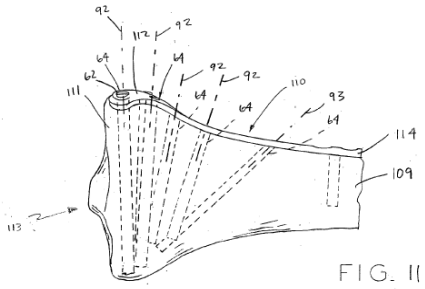
At the time of the invention of the '921 Patent, the use of plates and screws for attachment to bones, including tibial bones, was well known. *See* Ex. 1005 at ¶13; Ex. 1027 at ¶16, App'x B; *see also* Ex. 1018 at 830-36, Figures 27a-b, 30a-b; Ex. 1019 at 14-29, Ex. 1020 at 9-14. It was also well known at the time 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"). And plates used in tibial plateau leveling osteotomy ("TPLO") procedures specifically were well known, including contoured TPLO[5] 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.

[4] At least one claim of Huebner is supported by provisional application Serial No. 60/564,853 (Ex. 1034), filed on April 22, 2004 and for this reason, in addition to their overlapping disclosures, Huebner is entitled to the provisional filing date for purposes of §102(e). *See* Ex. 1027 at ¶16n1.

[5] TPLO is a well known procedure for treating crainal cruciate ligament rupture in canines. *See generally* Ex. 1015, Ex. 1023.

Forstein, Ex. 1006 at Figure 11.



Weaver, Ex. 1010 at Figure 22.

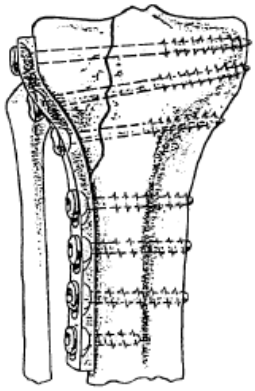
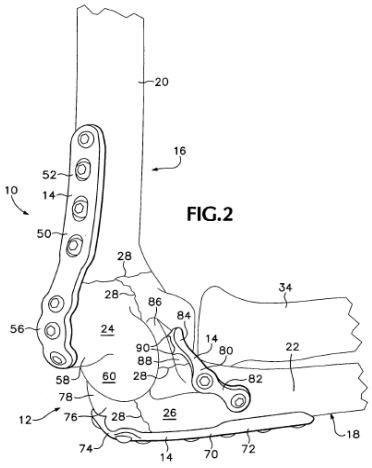


Fig. 22

O'Driscoll, Ex. 1012 at Figure 2.



Grady, Ex. 1031 at Figure 1.

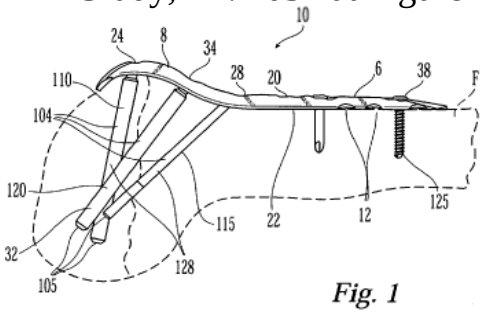


Fig. 1

It was well known in the art to provide a plurality of 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, 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; Ex. 1045 at 40, Figure 43-4. 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* Ex. 1009 at Figure 9.

Forstein, Ex. 1006 at Figure 11.

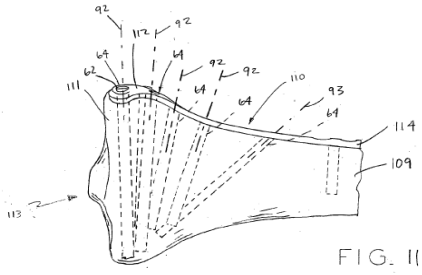


FIG. 11

Young, Ex. 1008 at Figure 4a.

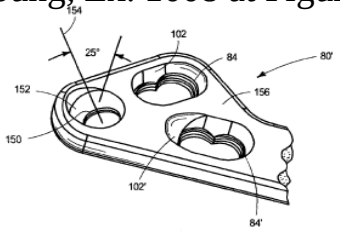


FIG. 4b

Weaver, Ex. 1010 at Figure 26.

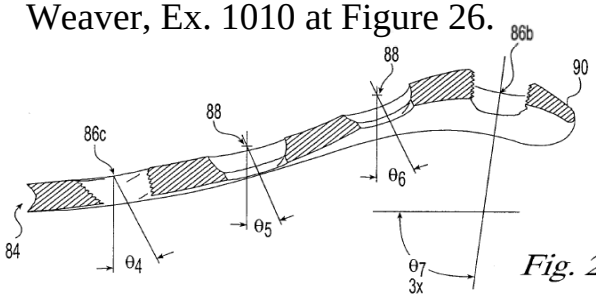
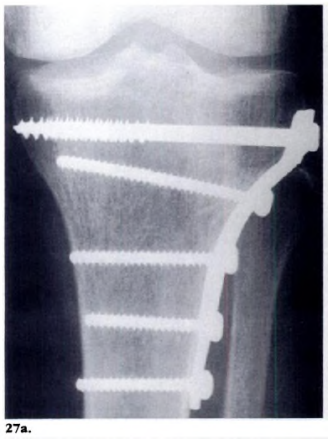


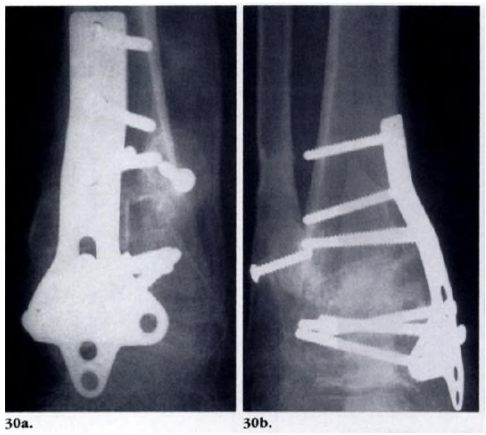
Fig. 26

Ex. 1014 at Figure 12B.

Ex. 1018 at Figure 27a.

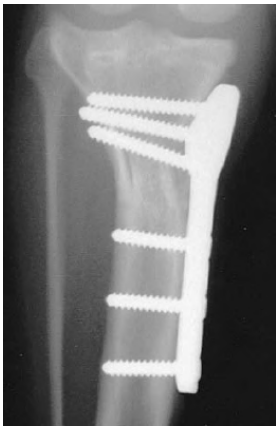


Ex. 1018 at Figures 30a, 30b.

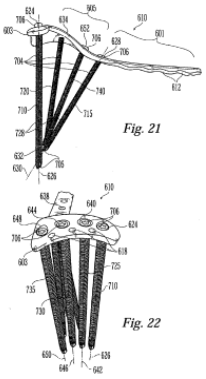


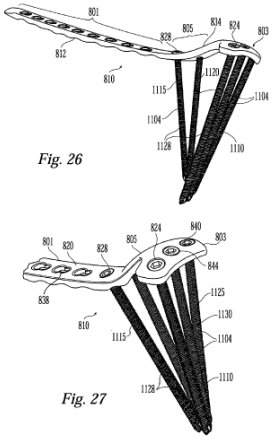
Ex. 1021 at Figure 1.

Ex. 1021 at Figure 4.

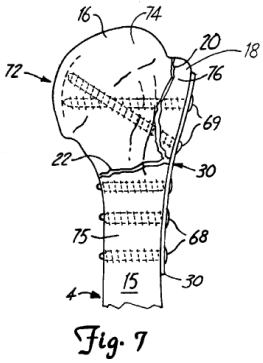


Grady, Ex. 1031, Figures 21, 22, 26, 27

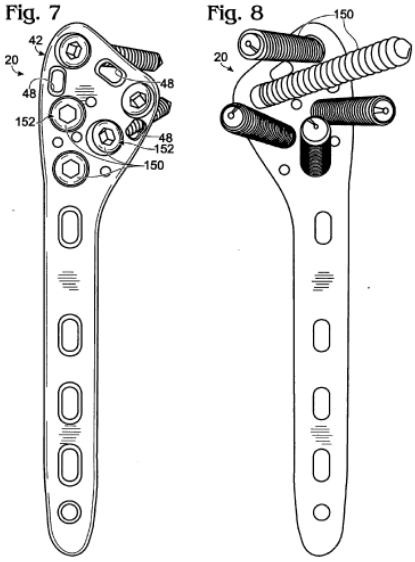




Ex. 1030 at Figure 7.



Ex. 1033 at Figures 7, 8.



C. Overview of the ’921 Patent

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

The application that issued as the ’921 Patent was filed on February 24, 2006 as U.S. Patent Appl. Serial No. 11/361,245. *See, generally*, Ex. 1002. The ’921 Patent is directed generally to an orthopedic plate and further discusses the use of orthopedic plates for a tibial plateau osteotomy. *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 a number of screw holes. *See Id.* at 11:1-5 (claim 12). At least three screw holes are disposed in the head of the bone plate: a first hole in a superior position and a second and third holes distally located on the caudal and cranial directions respective to the first. *Id.* at 11:5-15. The axes of the at least three holes in the head of the bone plate are predetermined and angled so that the screws are directed into the central mass of the tibia and away from the edges and articular surfaces of the bone. *Id.* The remainder of the Challenged Claims are directed to the well-known use of holes for accepting a locking screw (claims 14, 16, 18) and sizing limitations relating to the bone plate screw hole spacing that are largely dictated by the patient’s anatomy and plate size (claims 13, 15, 17) . *See Id.* at 11:16-39.

D. Summary of the Prosecution History of the '921 Patent

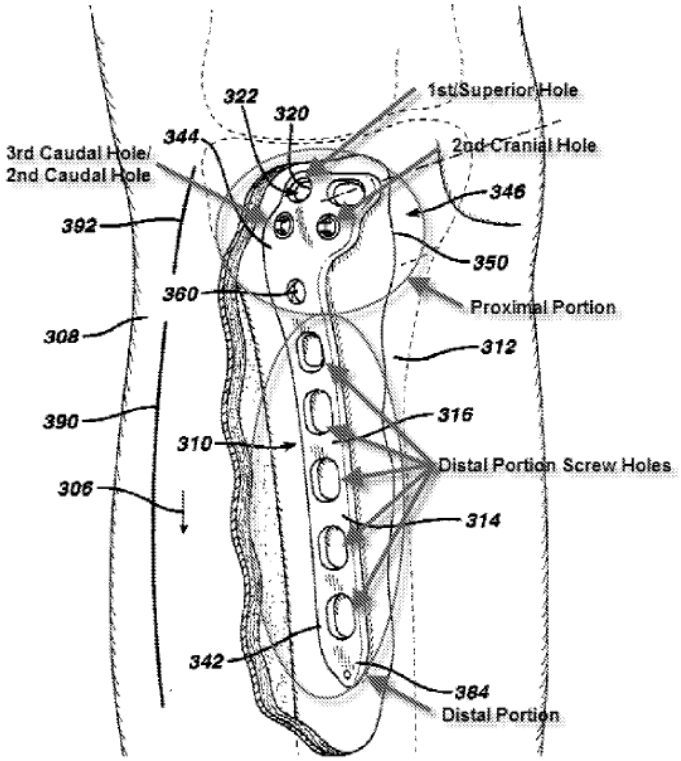
The '245 application was filed on February 24, 2006. During prosecution, the claims were rejected numerous times by the United States Patent and Trademark Office ("USPTO"), and were only allowed after the Board reversed the USPTO's anticipation rejection because it found that Wack lacked "predetermined and angled" screw paths. Ex. 1002 at 440. In an office action dated February 22, 2008, 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 (the U.S. counterpart to Ex. 1010). Specifically, the UPSTO found that Orbay disclosed the claimed distal portion and plurality of distal portion screw holes and the claimed pre-contoured proximal portion with the at least three proximal portion screw holes. *See* Ex. 1002 at 153; Ex. 1013 at Figures 1-4. The USPTO found that Orbay disclosed the superior/caudal/cranial screw hole location limitations recited in claim 12. *See* Ex. 1002 at 153. The USPTO also rejected claims 13-18 because "the specified lengths are seen to be a desired design choice for the purpose of more easily manufacturing to a set range of tibial sizes and maximize the effectiveness of the lock screw locations." Ex. 1002 at 154. 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 that angles 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 reply, on May 22, 2008, Patent Owner attempted to distinguish Weaver by arguing that "a cylinder, even a partial one, by definition does not involve any tapering or twisting, it follows that the tapered, twisted curvature of bone contacting surface 84 of head portion 90 should not be regarded as 'being partially defined by a cylinder.'" *See Id.* at 173. Patent Owner did not argue any feature of the prior art relevant to claims 12-18.

In the next office action, dated March 31, 2009, 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 US 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. *See Id.* (annotated Figure 7, reproduced below). The USPTO also rejected 9-11 and 13-17[6]

[6] Although the office action only lists claims 13-17 as rejected, and only specifically describes rejections for claims 13, 15, and 17, claim 18 was also apparently intended to be rejected. *See* Ex. 1002 at 195-97.

as obvious over Wack because "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).



The USPTO also rejected claims 19 and 20 as anticipated over Weaver, thus flatly rejecting Patent Owner's May 22, 2008 argument that Weaver did not disclose the contouring limitations of the proximal portion bone-contacting surface. *See* Ex. 1002 at 193-94. Shown on page 7 of the Office Action, the USPTO annotated Figure 22 of Weaver that illustrates the location of the relevant limitations. *See Id.* at 194 (annotated figure reproduced below).

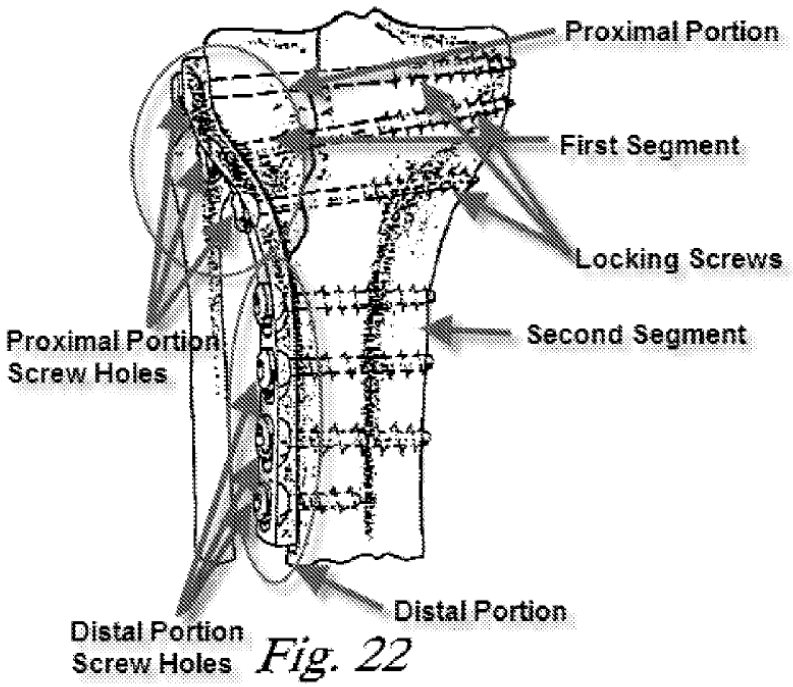


Fig. 22

In reply dated June 25, 2009, Patent Owner again argued that the cited prior art did not disclose the contouring of the proximal portion bone-contacting surface, referencing Wack for claim 1 and Weaver for claims 19 and 20. *See Id.* at 215, 216. The Patent Owner, for the first time, argued against the rejection of claim 12 claiming that the USPTO did not support its anticipation rejection because "there is no basis for considering these screw holes as caudal or cranial." *Id.* at 215-16. Patent Owner made no separate arguments for the patentability of claims 2-11 and 13-18. *Id.*

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. *See Id.* at 223-31. The USPTO explained that "a single segment or section of the bone-contacting

surface [needs to be] defined by a cylinder" and that Wack discloses this limitation. *See Id.* at 231, 232; *see also* Ex. 1009 at Figure 6. Further, the USPTO explained that the terms *cranial* and *caudal* "are directional terms but their locations are arbitrary" and referred to an annotated figure to illustrate "these arbitrary and directional limitations." Ex. 1002 at 226, 231-32 (annotated figure reproduced above).

In an after-final reply dated December 18, 2009, Patent Owner amended claim 12 to recite "wherein screw hole paths for the at least three screw holes are angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia," and argued that Wack does not disclose this limitation. Ex. 1002 at 241, 246.

Following a January 20, 2010 USPTO advisory action maintaining all rejections, Patent Owner filed a request for continued examination on January 26, 2010. In response to this RCE and amendment, the USPTO issued a non-final office action on March 17, 2010 that maintained its anticipation rejection of amended claim 12 stating, "[t]he device of Wack is capable of polyaxial positioning (paragraphs 81-85) via the bushing (324, figure 9) which contains an interior surface (330, figure 9, ¶81) that contains the bone screw(s) (¶82) and allows the screw (370, figure 9) to be positioned at various orientations relative to the bone." Ex. 1002 at 276.

Patent Owner filed a response to the March 17 office action on June 29, 2010 and amended claim 12 to require "predetermined" screw hole paths. *Id.* at 297-98. Patent Owner argued that the polyaxial screw holes and bushings of Wack could not meet this limitation. Ex. 1002 at 306.

In an August 4, 2010 office action, the USPTO again maintained the prior art rejections. *Id.* at 318-27. Regarding claim 12, the USPTO repeated its statement quoted above that "Wack is capable of polyaxial positioning." *Id.* at 328. In an October 4, 2018 after-final response, Patent Owner again argued against the rejections and the USPTO again rejected Patent Owner's arguments in a November 9, 2018 advisory action. *See Id.* at 336-43, 348. Patent owner Appealed. *See Id.* at 351.

In the course of rendering its decision, the Board made a factual finding that Wack disclosed a tibial bone plate and locking screws. *See Id.* at 438 (Findings of Fact 1, 2). The Board focused on two limitations in its decision: 1) "a mid-plane bisecting the base plane" present in claims 1, 19, and 20; and 2) "screw paths for the at least three screw holes are predetermined" present in claim 12 *Id.* at 438-42. With regard to the predetermined screw path limitation of claim 12, the USPTO found that because "the bushing and locking screws of Wack allow placement of the screw in different orientations," Wack lacked predetermined screw hole paths and thus could not anticipate claim 12. *Id.* at 440. The Board did not base its decision on any

other limitation. The Board made no findings whatsoever regarding claims 13-18, and reversed the rejections of those claims because they were predicated on the now reversed anticipation rejections. *See Id.* at 441. The USPTO then allowed the claims and Patent Owner 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 Patent Owner argue, nor did the Board find, that claims 13-18 were separately patentable from claim 12.

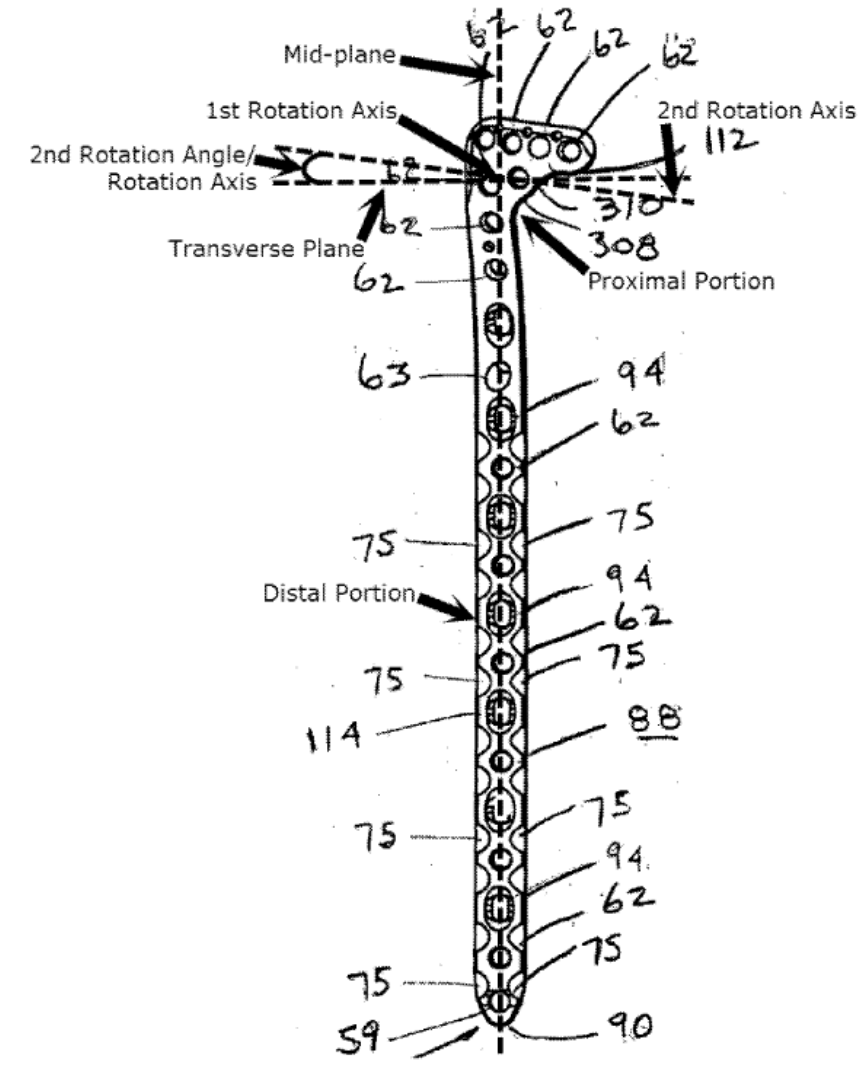
E. Prosecution History of Related Applications

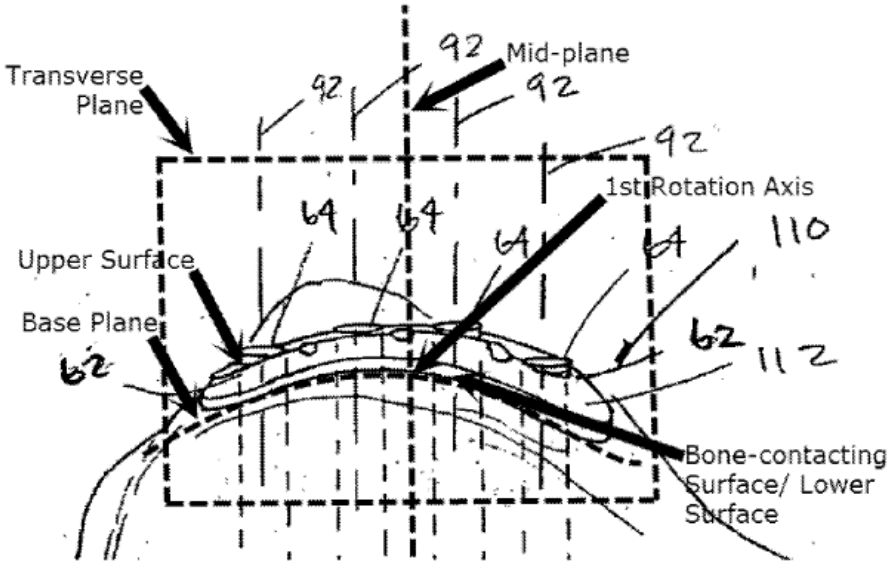
Patent Owner filed U.S. Patent Appl. Serial No. 13/538,407 (the "'407 Appl.") on June 29, 2012, claiming priority to the '921 Patent. *See* Ex. 1003 at 1-3. The '407 Appl. is currently pending. The '407 Appl. claims a bone plate similar to that of the '921 patent, but with some additional structural limitations that are not relevant to the subject matter of 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: U.S. Patent No. 6,096,040 to Esser and U.S. Patent Appl. Pub. No. 2005/0020226 to Grady, including one Board affirmance. *See Id.* at 90-98, 128-39, 185-95, 349-64, 384-401; *see also Id.* at 325-31. The '407 Appl. is currently pending a second appeal. *Id.* at 653.

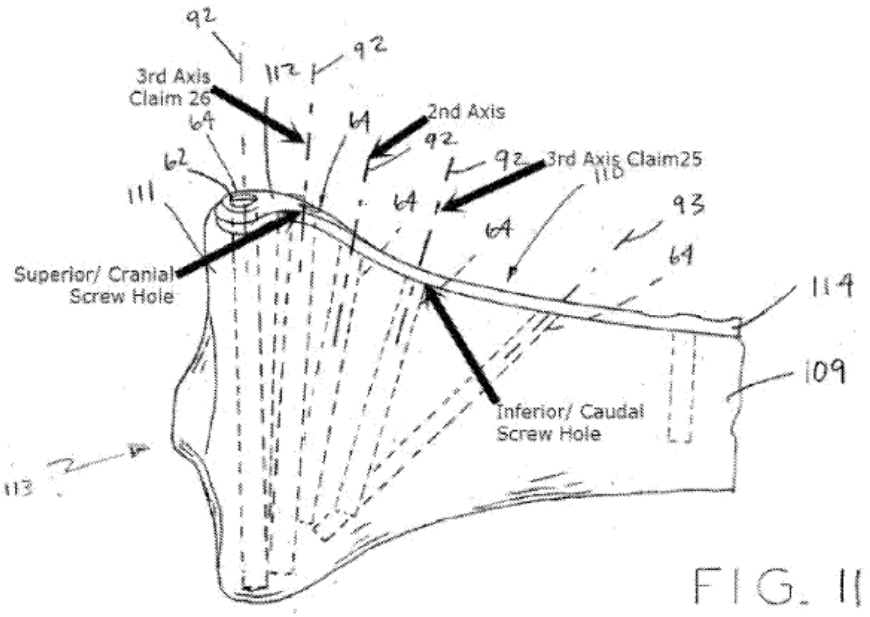
Patent Owner filed U.S. Patent Appl. Serial No. 16/031,792 (the "'792 Appl.") on July 10, 2018, claiming priority to the '407 Appl. and the '921 Patent. *See* Ex.

1004 at 1-2. The ’792 Appl. is currently pending. The ’792 Appl. claims a bone plate similar to that of the ’921 Patent including many similar features. For example, Claim 21 of the ’792 Appl. recites “a plurality of proximal portion locking screw holes located in the proximal portion” nearly identical to the feature recited in claims 1, 19, and 20 and similar to the “at least three screw holes” recited in challenged claim 12 of the ’921 Patent. *Id.* at 194. Claim 21 also recites “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,” which is similar to the recitation of the contour of the proximal portion in claims 1, 19, and 20. Even more specifically, claim 21 recites “the proximal portion being partially defined by a concave bone contacting surface, a curvature of at least a portion of the bone contacting surface extending about a radius of curvature extending in a rotation axis plane including a first rotation axis defined by an intersection of the base plane and a transverse plane transverse to the midplane and the base plane, the rotation axis plane being rotated relative to the base plane about the first rotation axis by a first angle,” which is similar to the geometric limitations of claims 1, 19, and 20. *Id.* Independent claims 31 and 36 include similar limitations. *Id.* Dependent claims 22-30 and 32-35 of the ’792 Appl. claim similar features to the recited features in the challenged claims of the ’921 Patent. *Id.* at 195-97.

In a non-final office action issued on October 18, 2018, 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 all the features of claims 21 and 31, including the geometric limitations quoted above as shown in Examiner annotated figures. *Id.* at 102-04; *see also Id.* at 110-12 (annotated figures 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. to be disclosed by Forstein. *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 the distally and cranially located second screw hole (i.e. claim 24) and the distally and caudally located third screw hole (claim 25) to be anticipated by Forstein. *Id.*


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


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



In reply, on January 10, 2019, Patent Owner argued that the plate in Forstein "is in no way configured to secure two tibial bone segments of an animal as part of a tibial leveling osteotomy procedure." *Id.* at 200. Patent Owner also argued that "there is absolutely no teaching or suggestion in … Forstein that the contour of the head 112 is curved with respect to the first and second axes" and that "the rotation axes appear to be arbitrarily assigned based on a base, medial and transverse planes of the plate 110 defined by the Examiner and have no relation to the actual curvature of bone contacting surface of the head 112." *Id.* at 201. Patent Owner did not argue the limitations of any of the dependent claims.

In a final office action issued February 1, 2019, the USPTO maintained its rejection, noting that, in reference to the Patent Owner's argument regarding the bone plate being "configured to secure two tibial bone segments of an animal,"

Patent Owner "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. The plates disclosed in Forstein, according to the USPTO, "could be used to secure two tibial bone segments of an animal if one so choose[s]." *Id.* The USPTO also explicitly 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 that Patent Owner "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 that "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 over Patent Owner's arguments, finding Forstein to be "capable of" use in TPLO. *Id.* at 209. The USPTO also found the distally and cranially located second screw hole and the distally and caudally located third screw hole to be anticipated by Forstein. *Id.* at 211

Patent Owner replied on March 13, 2019 essentially reiterating the same arguments. *Id.* at 372-75. Following an advisory action issued on April 4, 2019 again rejecting Patent owner's arguments, Patent Owner appealed to the Board on April

29, 2019. *See Id.* at 377-79, 386. On June 17, 2019, Patent Owner filed its appeal brief. *See Id.* at 393-404. The ’792 application is currently 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 to be construed, and only to the extent necessary to resolve the controversy). Petitioner reserves the right to respond to any constructions offered by Patent Owner 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); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

A. Claim 12 – for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal

As noted above, Patent Owner never argued that the preamble is a limitation of claim 12 during prosecution of the ’921 patent, even when presented with rejections based on plates designed for general orthopedic use such as 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 the prosecution of the ’792 application, a continuation of the ’921 patent, the USPTO firmly rejected Patent Owner arguments that the preamble carried patentable weight. *See* Ex. 1004 at 207 (examining an identical preamble of a claim having similar features to claim 12). This preamble is merely a statement of intended purpose. *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 12 should not be considered limiting. *See* Ex. 1005 at 30; Ex. 1027 at ¶37.

B. Claim 12 – located distally, located … caudally, and located … cranially

As noted by the USPTO during the prosecution of the ’921 Patent, the terms *distally, cranially,* and *caudally* are arbitrary directional terms. *See* Ex. 1002 at 231-32. This finding was not challenged by Patent Owner during subsequent prosecution. All that is required to meet these limitations is for the holes to exhibit the arbitrary directional relationship claimed. *See* Ex. 1005 at 31; Ex. 1027 at ¶38. The plain meaning of “distal,” in the context of claim 12, is the opposite of the proximal (or “superior”) direction. *Id.* The terms “cranial” and “caudal” are common veterinary anatomical terms that simply mean towards the tail (“caudal”) and towards the head (“cranial”). *Id.* Thus “located distally” means located away from the proximal end,

"located … caudally" means located toward the tail, and "located … cranially" means located toward the head.

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 45-46; Ex. 1027 at 53-54, and discussions above and below. As detailed in the claim charts below, prior art references anticipate and/or render obvious the Challenged Claims of the '921 Patent.

A. Legal Standards

1. Anticipation

A claim is invalid as anticipated when "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verde-gaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

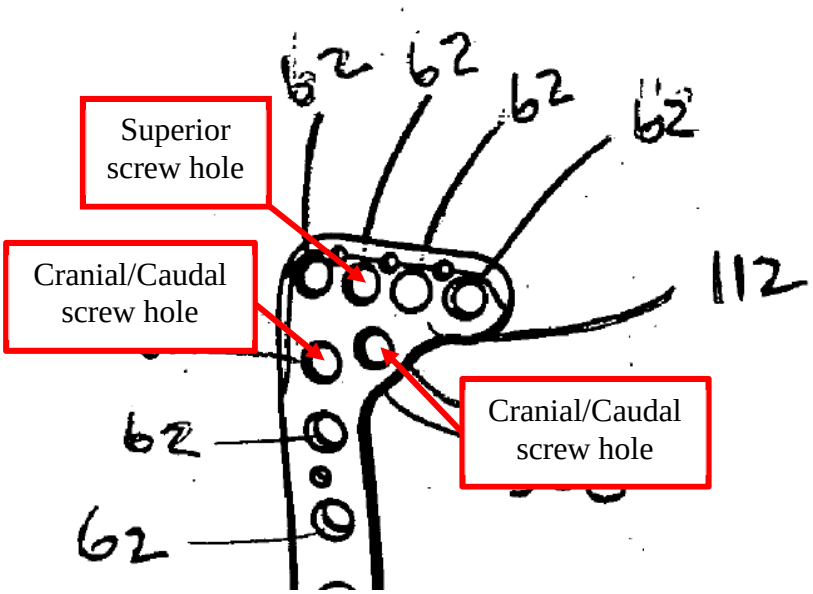
2. Obviousness

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 one of ordinary skill in the art." *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). There is no requirement to find precise teachings directed to specific subject matter of a claim; common sense, inferences, and creative steps that 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 – Claim 12 is Anticipated under 35 U.S.C. § 102 by Forstein

Claim 12 is anticipated by Forstein. Forstein discloses various periarticular bone plates, including a plates for use on a tibia. Forstein at ¶¶66, 75. All bone plates disclosed in Forstein share a basic structure: a head (i.e. a "proximal portion") and a shaft (i.e. a "distal portion"), each of which contain a plurality of screw holes.



See Forstein at ¶¶71-72; *see also* Ex. 1003 at 121-23. Forstein discloses a number of bone plate embodiments, many of which include superior, caudal, and cranial holes. 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. In particular, this embodiment includes, at minimum, six screw holes 62 (though not all are so labeled), as can be seen from the portion of Figure 9 reproduced above. As exemplified and identified in the above figure, one of the screw holes, identified at left, can be identified as a "superior screw hole" relative to other screw holes disposed within head 112. At least two other screw holes are present and are either cranial or caudal (in opposite directions away) from the superior screw hole, and below the superior screw hole, depending on how the bone plate is physically placed and oriented when implanted on the patient. As explained above, as long as the selected holes for the cranial and caudal holes in Figure 9 correspond with the arbitrary directional limitations relative to the superior hole, these locational limitations are met. As noted by the USPTO during the prosecution of the '921 Patent, the terms *superior*, *cranially*, *distally*, and *caudally* are arbitrary directional terms. *See* Ex. 1002 at 231-32. As explained above in §IV.B., the term "superior" simply means most proximal. *See* Ex. 1005 at ¶32. The terms "caudal" and "cranial" simply mean towards the tail and towards the head, respectively. *Id.* at ¶32-33. As

long as the holes selected correspond to holes that are in the appropriate relative position, these claim elements are met. *Id.* at ¶34.

As was well-known and desired in the prior art, each of the screw holes shown in Figure 9 of Forstein is axially angled to produce a particular angulation relative to the surface of the bone the plate is designed to attach to. *See* Ex. 1005 at ¶37, 57. All of the screw holes shown in Figure 9 converge toward the center of the bone mass of the tibia, as shown in Figure 11. *Id.* at ¶38, 57; *see also* Forstein ¶75, Figure 11. Forstein further explains that the "trajectory of screws 64 [is] selected such that the screws do not penetrate into the articular surfaces of the joint." Forstein at ¶81. A POSA at the time of the invention of the '921 patent would have known that angling the screws away from the articular surface, the osteotomy surface, and the edge of the tibia was desirable, at least, to prevent well known complications related to screw penetrations of the articular surface. *See* Ex. 1005 at ¶18, 38, 41, 55-58.

Furthermore, USPTO has finally rejected claims containing similar features to claim 12 in the pending '792 Appl. as anticipated by Forstein. *See* Ex. 1004 at 209-14. The USPTO currently finds that the preamble of claim 21 of the '792 Appl., which is nearly identical to the preamble of claim 12 of the '921 Patent, was "merely an intended use statement" and does not limit the claim, and in addition finds that Forstein is capable of that intended use. *Id.* at 207. In the rejection, the USPTO found 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. *See Id.* at 209-10. The USPTO 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," again referring to Figure 9. *See Id.* 210-11. The USPTO also provided an annotated

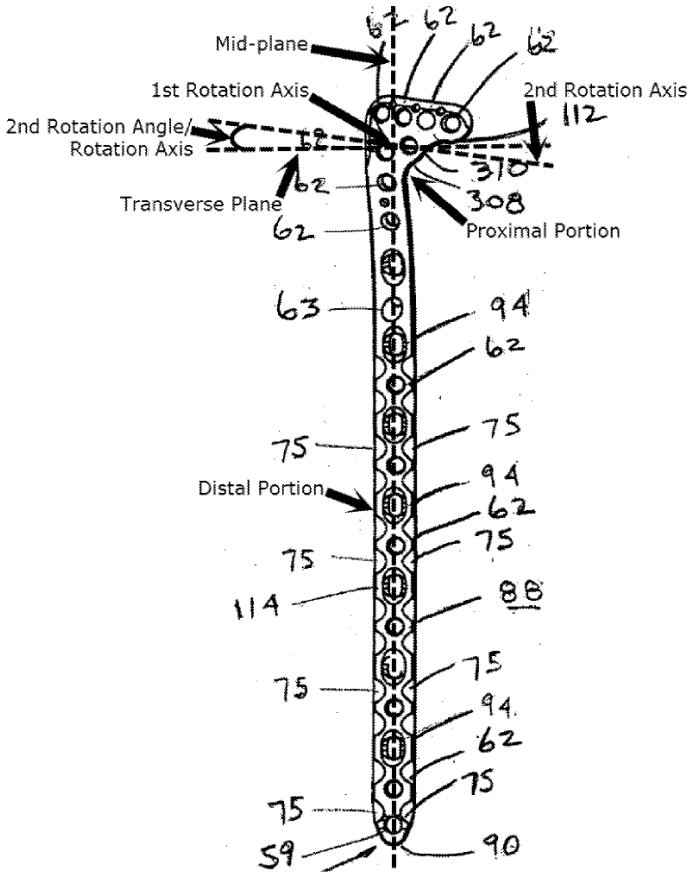


Figure 9 of Forstein to establish the mappings of the claim features, which is reproduced above. *See* Ex. 1004 at 219.

The USPTO also rejected dependent claims reciting screw hole location limitations similar to those in claim 12. Specifically, the USPTO found that Forstein discloses a first superior screw hole, a second screw hole located distally and cranially from the first superior screw hole, and a third screw whole located distally and caudally from the first superior screw hole. *See* Ex. 1004 at 211-12.

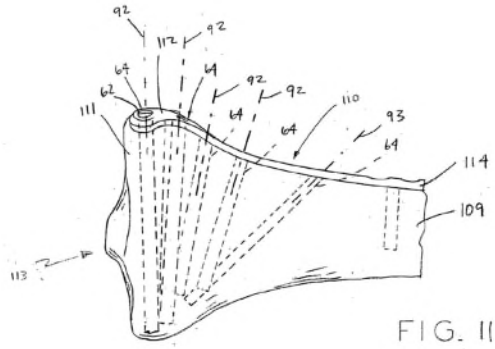
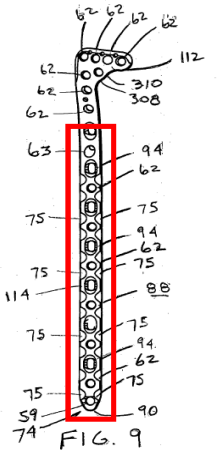
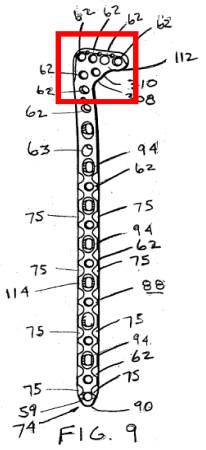
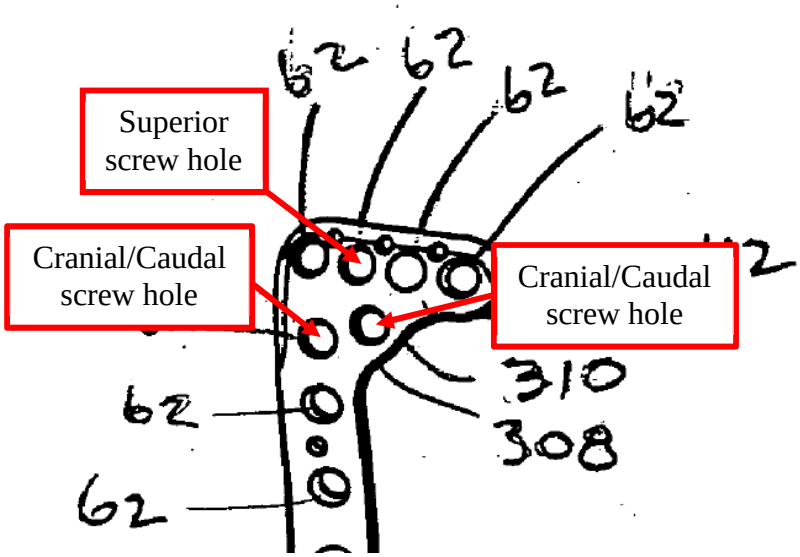


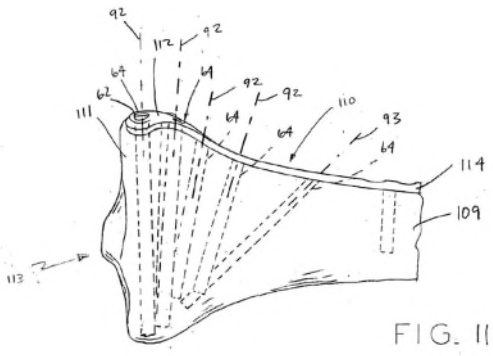
FIG. 11

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. Nothing in claim 12 defines a particular shape or configuration for the "proximal portion." *See* Ex. 1005 at ¶51; Ex. 1027 at ¶59. The claim requires the proximal portion of the plate to have three screw holes that are angled in a way that causes the screws, when the plate is implanted on a bone of a patient, to avoid the articular surfaces of the tibia at the tibiofemoral joint, the edges of the tibia, and the interface of the fracture. *See* Ex. 1005 at ¶27; Ex. 1027 at ¶31. As noted above, the "predetermined and angled" limitations merely require the screw axes to be fixed and to converge into proximal tibial fragment created by the osteotomy. Forstein explicitly discloses a tibial

fixation plate having fixed angle, proximately located screw holes directing screw paths away from the articular surface of the tibia, away from the edges of the tibia, and into the central mass of the tibia. *See* Ex. 1006 at Figure 11 (reproduced above); ¶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."). As shown in the claim chart below, each and every feature recited in claim 12 is disclosed in and anticipated by Forstein.

12[PRE]: A bone plate for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal, the bone plate comprising:	Forstein discloses a bone place capable of securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal. *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 as a femur, **a tibia**, a fibula, a humerus, an ulna and/or a radius, to stabilize the bone during the healing process."); ¶75; Ex. 1004 at 209; *see also* §V.B.12[A], *infra.*
12[A]: a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw; and	 FIG. 9 Forstein discloses a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw. *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 ("Referring to FIGS. 9-11, proximal lateral tibial plate 110 includes head 112 contoured to match the contour of a proximal

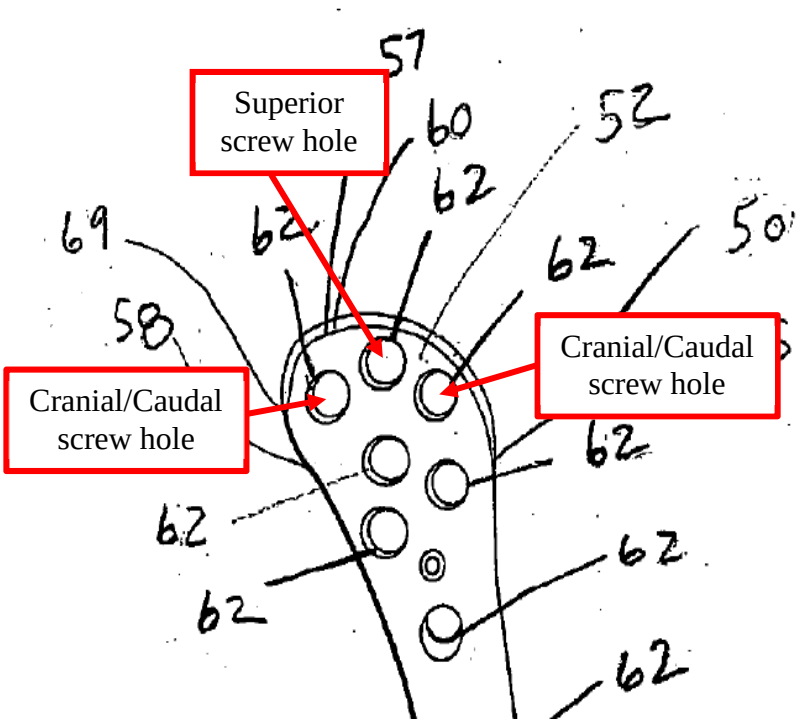
	lateral tibial metaphysis, i.e., metaphysis 111 of tibia 113, and **plate shaft 114** sized and configured to match the contour of diaphysis 109 of the tibia 113."); FIG. 9.
12[B]: a proximal portion comprising at least three screw holes each designed to accept a screw	Forstein discloses a proximal portion comprising at least three screw holes each designed to accept a screw. *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.");  FIG. 9
12[C]: wherein a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole,	Forstein discloses a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole. *See* Forstein  at FIG. 1; ¶75 ("Referring to FIGS. 9-11, proximal lateral tibial plate 110 includes **head 112** contoured to match the contour of a proximal lateral tibial metaphysis, i.e., metaphysis 111 of tibia 113, and plate shaft 114 sized and configured to match the contour of diaphysis 109 of the tibia 113."); Figure 9 (reproduced above).

12[D]: wherein screw hole paths for the at least three screw holes are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia.	Forstein discloses screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Forstein at ¶73 ("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. Referring to FIGS. 9-11,  FIG. 11 proximal lateral tibial plate 110 includes head 112 contoured to match the contour of a proximal lateral tibial metaphysis, i.e., metaphysis 111 of tibia 113, and plate shaft 114 sized and configured to match the contour of diaphysis 109 of the tibia 113. As illustrated in FIG. 11, **axes 92 of screw holes 62 converge in tibia 113**); ¶81 ("Regardless of whether axes 92 of screw holes converge in the bone or diverge, **the length and/or trajectory of screws 64 are selected such that the screws do not penetrate into the articular surfaces of the joint**."). Because axes 92 are positioned in a way that avoids the articular surface, osteotomy surface, and the edges of the tibia, the screws are fixed along the axes, they are angled as claimed.

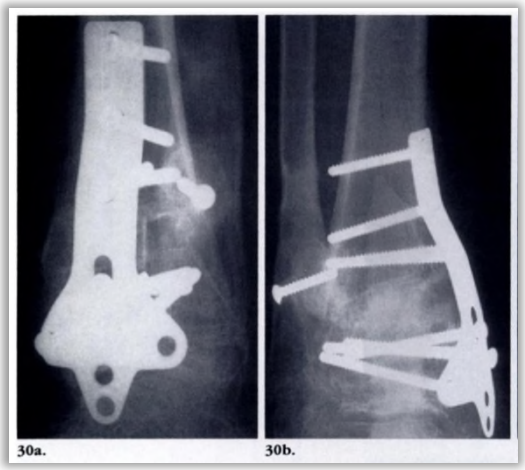
C. Ground 2 – Claims 12-18 are Obvious under 35 U.S.C. § 103 over Forstein

1. Claim 12

Because "anticipation is the epitome of obviousness," Forstein also renders claim 12 obvious. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019). To the extent any feature of claim 12 is not found in the tibial plate embodiment of Forstein described above, it would have been obvious to a POSA to add the features from any of the other embodiments disclosed in Forstein. For example, the embodiment shown in Figure 1 of Forstein, although disclosing a bone femoral bone plate, clearly exhibits the claimed locational relationship between at least three screw holes. A portion of Figure 1 of Forstein is reproduced below, annotated to illustrate the locations of the superior, cranial, and caudal screw holes. As explained above, these limitations are simply arbitrary directional limitations relative to the superior hole. When implanted in a



patient, one hole would be closer to the head of the patient relative to the superior hole (i.e., be "cranially" located) and another hole would be closer to the tail of the patient (i.e., be "caudally" located). This analysis applies equally to the distal radial dorsal delta bone plate shown in Figure 12. Additionally, a POSA at the time of the invention of the '921 patent would be well aware of the many examples of superior,

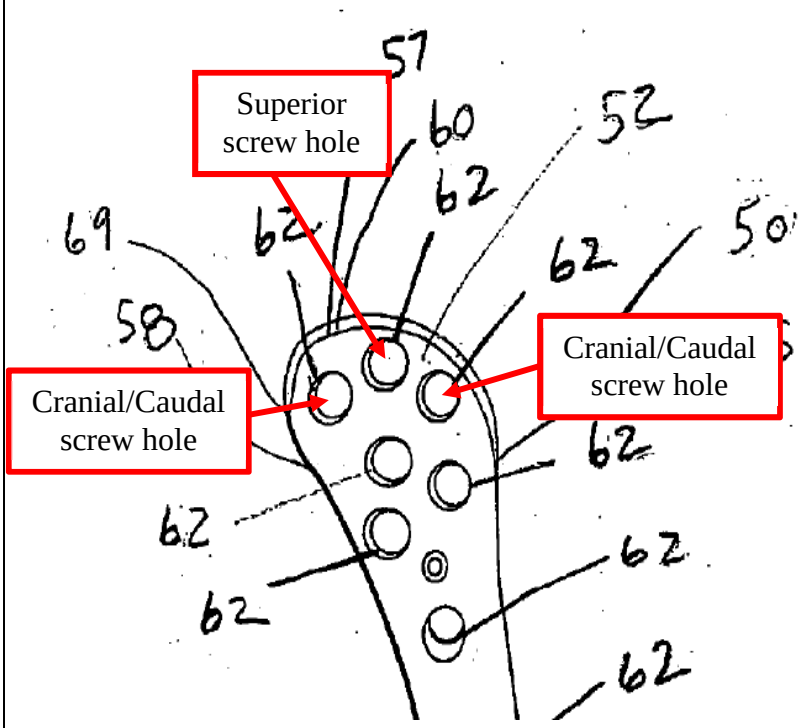


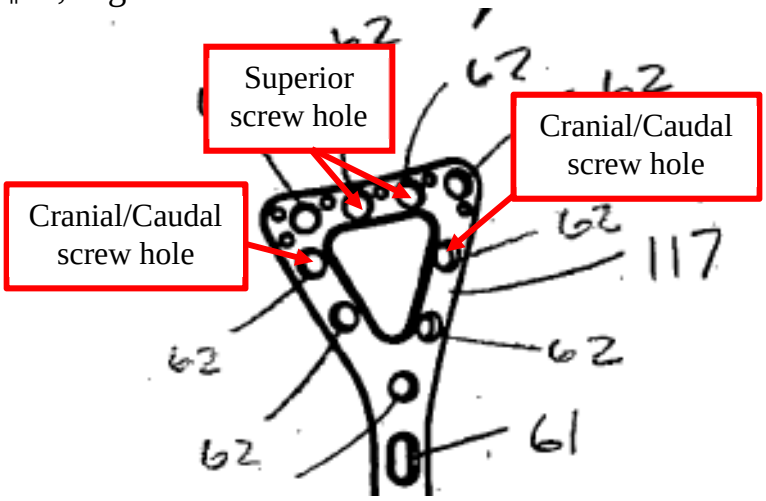
cranial, and caudal configurations in bone plates. *See* Ex. 1005 at ¶¶13-15; Ex. 1027 at ¶¶16-18; *see also* §III.B., *supra*. (incorporated here); §V.D.1., *infra.*, (figures incorporated here). It would therefore be obvious in view of Forstein's disclosure, particularly in view of the well-known positioning of such screws, to position screw holes in the head portion of the plate using the locational configuration claimed.

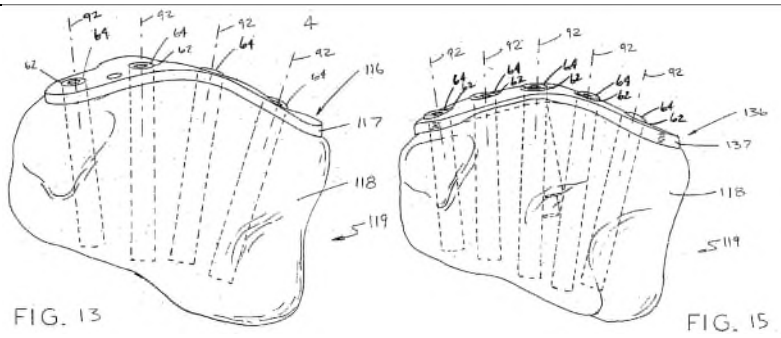
Similarly, both the radial bone plates shown in Figures 12-15 of Forstein also exhibit a converging screw hole axis pattern, most clearly shown in Figures 13 and 15. This convergence of screw hole paths is well known in the art and a person of skill would have been motivated to achieve it. *See* Ex. 1005 at ¶18; *see also* §III.B., *supra*. (incorporated here). As explained above, a POSA at the time of the invention of the '921 patent would have known that angling the screws away from the articular surface, the osteotomy surface, and the edge of the tibia was desirable, at least, to

prevent well known complications related to screw penetrations of the articular surface. *See* Ex. 1005 at ¶55; *see also* Ex. 1021 at 186; 189 ("complications … unique to TPLO … include intra-articular screw impingement"); Ex. 1022 at 1730 ("[i]mplant-related complications [include] intra-articular placement of screws…"); Ex. 1037 at 2141 ("Other complications, such as intra-articular placement of the most proximal plate screw, are inherent to the [TPLO] procedure and have been reported."). For similar reasons, a POSA would also understand that the edge of the tibia and the edge of the osteotomy surface should not be impinged by the screws. *See* Ex. 1005 at ¶55. For example, was also well known in the art to angle screw paths caudally, as well as distally, because there is more bone in the caudal direction from the superior screw hole due to the rotation of the proximal bone segment in TPLO. *Id.* 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. In view of this disclosure and the established knowledge in the art of the intra-articular screw impingement complications "unique to TPLO", a POSA would have been motivated to angle screws in the proximal portion of the bone plate of claim 12, at least, to avoid the well-known complications that result from intra-articular placement of screws. Ex. 1021 at 189; *see also* Ex. 1005 at ¶¶55-58; Ex. 1027 at ¶¶63-66. Thus it would be obvious to fix the angle the screw holes as claimed.

12[PRE]: A bone plate for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal, the bone plate comprising:	Forstein discloses a bone place for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal. *See* §V.B.12[PRE], *supra.* (incorporated here); Forstein at Abstract; ¶66; ¶75 (*see* §V.C.12[A], *infra.*); *see also* Ex. 1004 at 209 (USPTO finding Forstein is "capable of" such use). 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 subject. *See, e.g.*, Ex. 1008, at Abstract; Ex. 1016 at Abstract.
12[A]: a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw; and	Forstein discloses a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw. *See* §V.B.12[A], *supra.* (incorporated here); Forstein at ¶71 (referencing FIG. 1); ¶73; ¶75; FIG. 9.
12[B]: a proximal portion comprising at least three screw holes each designed to accept a screw	Forstein discloses a proximal portion comprising at least three screw holes each designed to accept a screw. *See* §V.B.12[B], *supra.* (incorporated here); Forstein ¶72; ¶73.

12[C]: wherein a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole,	Forstein discloses a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole. *See* §V.B.12[C], *supra*. (incorporated here); Forstein at FIG. 1; ¶73 ("Referring to FIG. 4,  each threaded hole 62 is defined by a conical wall (63) having threads 66 extending therefrom. Threaded holes 62 can receive, referring to FIG. 6, screws 64 having threaded head 67 and threaded shaft 68. The threads on head 67 are configured to threadingly engage threads 66 of holes 62, while the threads on shaft 68 are configured to engage the bone underlying the bone plate."); ¶75; Figure 9;

	¶76; Figure 12.  Additionally, it was well known to a POSA to arrange proximal portion screw holes with a first screw hole as a superior screw hole, a second screw hole as a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole as a caudal screw hole located distally and caudally from the superior screw hole. *See* Ex. 1018 at 835-36, Figures 30a, 30b; Ex. 1008 at Figures 1a, 1b; Ex. 1009 at Figures 1, 7, 8; Ex. 1011 at Figures 1, 2, 6, 7, 11, 14, 27; Ex. 1012 at Figures 31-42; Ex. 1016 at Figures 1, 5; Ex. 1019 at 19, 23; Ex. 1020 at 1, 11, 14; Ex. 1033 at Figures 1, 7, 8, Ex. 1035 at 357, 362, 419, 430, 449, 450, 459, 460.
12[D]: wherein screw hole paths for the at least three screw holes are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia.	Forstein discloses screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* §V.B., *supra.* (incorporated here); *see also* Forstein at ¶76 ("Another bone plate, i.e., distal radial dorsal delta bone plate 116, illustrated in FIGS. 12 and 13, also **has a converging screw pattern**."); ¶77 ("Another bone plate, i.e., distal radial dorsal T-plate 136, illustrated in FIGS. 14 and 15, also **has a converging screw pattern**."); ¶81.

	 Additionally, it was well known to a POSA to include screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Ex. 1021 at 187, 189, Figures 1, 4; Ex. 1014 at 434, Figure 12b; Ex. 1018 at 835-36, Figures 27a, 27b, 30a, 30b; Ex. 1031 at ¶¶6, 71, Figures 26-27; Ex. 1033 at ¶74, Figures 7-8.

2. Claims 13-18

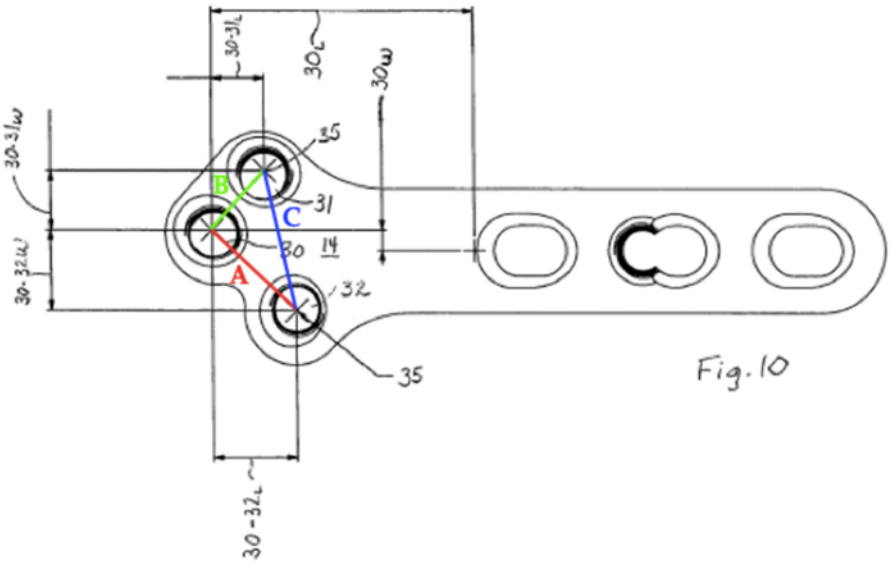
The additional features recited in claims 13-18 are either expressly disclosed in Forstein or are obvious in view of the state of the art at the time of invention. Claims 13, 15, and 17 are each dependent on claim 12 and are directed to different bone plate size ranges, recited as limitations on the relative distances between the at least three screw holes on the proximal portion. For example, claim 13 recites:

> 13. The bone plate of claim 12 wherein the cranial screw hole is located between about 3.5 mm and about 6 mm distally from the superior screw hole and the caudal screw hole is located about 6 mm to about 9 mm distally from the superior screw hole.

Claim 15 replaces the hole location ranges of claim 13 with ranges of 2mm to 4mm and 4mm to 7mm, respectively. Claim 17 replaces the hole location ranges of claim 13 with ranges of 5.5mm to 9.5mm and 7.5mm to 11.5mm, respectively. Claims 14, 16, and 18 each depend on claims 13, 15, and 17 respectively and require that the superior, cranial, and caudal screw holes "are each designed to accept a locking screw." During prosecution, USPTO found these claims to be obvious over Wack. The USPTO based its decision on a finding that the size ranges were result effective variables, the optimization of which is well within the scope of ordinary skill. *See* Ex. 1002 at 325-27 (*citing In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955) ("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"); *see also 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."). The USPTO also found that a POSA would find nearly identical limitations as obvious over the disclosure of Forstein (claims 32, 34, 35 of the '792 application) based on the same doctrine. *See* Ex. 1004 at 216-18.

Here, the whole spacing limitations of claims 13, 15, and 17 are claimed as distances along the longitudinal axis (i.e. "distally"). *See* Ex. 1027 at ¶¶67-68. As illustrated below using an annotated version of Figure 10 of the '921 patent, these distances inform where the centers of the screw holes are in a coordinate plane, i.e.

distances 30-31_L and 30-32_L shown in the Figure below, but does not give the distances ***between*** screw holes. *See Id.* at ¶¶70-76.



Distances A, B and C on the Figure below were calculated to show the following ranges of distances between screw holes corresponding to the claim elements:

For Claim 13:

A = 7.8 mm to 12.7 mm

B = 5.3 mm to 8.8 mm

C = 9.3 mm to 15.8 mm

For Claim 15:

A = 5.0 mm to 9.2 mm

B = 4.0 mm to 6.0 mm

C = 5.9 mm to 11.9 mm

For Claim 17:

A = 11.0 mm to 16.6 mm

B = 6.8 mm to 12.4 mm

C = 12.2 mm to 20.1 mm

See Ex. 1027 at ¶74. Comparing these distances to those available in the prior art, i.e., Ex. 1035 (labeled as "Synthes") and Ex. 1019 (labeled as "Smith & Nephew"), and found that the ranges corresponding to the claimed distances were found in the prior art as shown in the chart reproduced below:

Plate	Bone Plate Screw Hole Spacing (mm)											
	Prior Art		US Patent 8,523,921									
	Synthes	Smith & Nephew	Claim 13			Claim 15			Claim 17			
			A	B	C	A	B	C	A	B	C	
Large Plates												
Titanium Semi-Tubular Plate	26											
												20.1
Titanium LC-DCP® Lateral Tibial Head Buttress Plates	18											
Titanium Lateral Tibial Head Buttress Plates-DCP®	16											
Stainless Steel Lateral Tibial Head Buttress Plates	16	16							16.6			
4.5mm Stainless Steel Medial Distal Tibia Plates	16	16										
4.5mm Stainless Steel Reconstruction Plates	15				15.8							
Small Plates												
3.5mm Stainless Steel LCP Reconstruction Plates	14											
3.5mm Stainless Steel LCP Plates	13	12										
3.5mm Titanium Reconstruction Plates	12		12.7					11.9		12.4	12.2	
									11.0			
Mini Plates					9.3	9.2						
2.7mm Titanium DCP® Plates	8			8.8								
2.7mm Stainless Steel Reconstruction Plates	8	8										
			7.8									
2.4mm Titanium Straight Plates	6						6.0			6.8		
2.0mm Titanium Straight Plates	5			5.3		5.0		5.9				
2.0mm Stainless Steel Straight Plates	5	5										
1.3mm Titanium Straight Plates	4						4.0					

Because "the general conditions of [claims 13, 15, 17] are disclosed in the prior art," they are obvious. *See* Ex. 1027 at ¶¶75-76; *see also* Ex. 1005 at ¶¶59-64.

Additionally, Forstein expressly discloses a tibial plate with a head that is "sized for attachment" to a tibia. *See* Ex. 1005 at ¶61; Ex. 1027 at ¶69; Forstein at ¶21 ("a tibial bone plate comprises … a flared head portion **sized for attachment** to the metaphysis of the tibia") (emphasis added). For example, Forstein repeatedly teaches that the "head" of the bone plate is "sized and configured" for each embodiment's particular purpose. *See, e.g.*, *Id.* at ¶67 ("head 52 is **sized and configured** to rest on the distal metaphysis of a femur"); ¶76 ("head 117 [is] **sized and configured** to match the contour of distal dorsal metaphysis 118 of radius 119"); ¶77 ("head 137 [is] **sized and configured** to match the contour of distal metaphysis 118 of radius 119"); ¶78 ("head 140 [is] **sized and configured** to match the contour of distal anterolateral metaphysis 141 of tibia 142"); ¶80 ("head 83 [is] **sized and configured** to match the contour of metaphysis 147 of radius 148…."); ¶86 ("head 106 [is] **sized and configured** to match the contour of the proximal metaphysis of the humerus") (emphasis added). The suggestion of Forstein that each plate is "sized and configured" and therefore may be constructed with various dimensions as appropriate is made explicit in paragraph 89:

> It is contemplated that different embodiments of the bone plates of the present invention **will have different lengths and quantities of screw holes**.

To the extent any motivation is required to justify the plain obviousness of sizing the bone plates and related location of the screw holes, 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*, 912 F.3d at 1374. 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 person of ordinary skill." *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1371 (Fed. Cir. 2018) (quoting *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013)). The above quoted passages in Forstein would have suggested to a POSA to alter the dimensions between the screw holes in the head of the bone plate as a common sense modification to produce and accommodate variously sized bone plates in accordance with the varying shapes and sizes of canine tibias. *See* Ex. 1005 at ¶61; *see also In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1332 (Fed. Cir. 2016) (affirming a Board finding that a "plug ... generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column" teaches dimensional limitations recited in the claim even without a disclosure of the exact dimensions because obviousness "does not require the prior art to reach expressly each limitation exactly") (quoting *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 727 (Fed. Cir. 2002)).

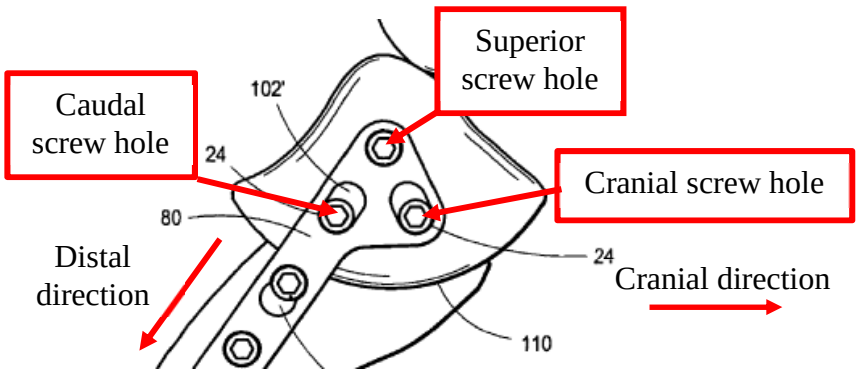
With respect to claims 14, 16, and 18, Forstein expressly discloses threaded locking screws and screw holes. *See, e.g.*, Ex. 1006 at ¶¶71-73, 86, 88, 93, 100, 111, 113, 115. Forstein's Provisional also expressly discloses screw holes that "are each designed to accept a locking screw." *See* Ex. 1007 at 161 ("The Periarticular Locking Plates will accommodate standard screws, as well as locking screws with threaded heads that allow the screw to be locked into position to facilitate proper plate/screw placement."). Forstein also incorporates by reference a number of Zimmer product brochures ("Zimmer Brochures") describing products embodying Forstein's disclosed embodiments and which were submitted with the application as filed. *See* Forstein at ¶66, Ex. 1028. One of the Zimmer Brochures describes 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 ("The Periarticular Locking Plates will accommodate standard screws, as well as locking screws with threaded heads."). Thus, both Forstein's Provisional and the Zimmer Brochures discuss locking screws extensively. Locking screws and screw holes were also well known to POSA at the time of the invention of the '921 patent, as recognized by the USPTO during the 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 13; Ex. 1008 at ¶34; *See* §III.B., *supra*. (incorporated here).

The features recited in claims 13-18 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. Thus, all the Challenged Claims are obvious.

D. Ground 3 – Claims 12-18 are Obvious under 35 U.S.C. § 103 over Young in view of Forstein under 35 U.S.C. § 103

1. Claim 12

The Challenged Claims are obvious over the combination of Young and Forstein. *See* Ex. 1005 at ¶48; Ex. 1027 at ¶56. Young discloses a bone plate “particularly suited to tibial plateau-leveling osteotomy.” Young at ¶19. The bone plate disclosed in Young includes “a flat triangular head 82 in which three spaced-apart apertures 84 and 86 are formed” and which “is integrally formed with an elongated lower portion 90 in which are located a plurality of apertures 92, 94 and 96.” *Id.* at ¶32. The three screw holes formed in the triangular head of Young, when the bone plate is implanted onto a patient, form a triangular pattern with a superior screw hole in a superior position, a cranial screw whole distally cranial from the superior hole, and a caudal screw hole distally caudal from the superior hole. *See* Ex. 1008 at Figure 1b (annotated below); Ex. 1005 at ¶39-41, 51; Ex. 1027 at ¶47-49, 59.



Young also discloses a "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.* Young does not teach that all three of the screw holes in the head of the bone plate are angled, but it would be obvious for a POSA to modify Young to include predetermined, angled axes to the three screw holes. Screw hole angulation was well known in the art and a POSA would have been motivated 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. 1014 at 434, Figure 12b (reproduced at right) (showing "proper angling of screws such that intra-articular penetration is avoided"); 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); Ex. 1037 at 2141 ("Other complications, such as intra-articular placement of the most proximal plate screw, are inherent to the [TPLO] procedure and have been reported."); *see also* Ex. 1005 at ¶¶55-58; Ex. 1027 at ¶¶63-66. It is beyond dispute that 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. 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 immediately corrected. *See Id.*; Ex. 1021 at 187, 189; Ex. 1022 at 1730; Ex. 1037 at 2141 (recommending use of a "proximal screw aimed parallel to the tibial plateau rather than perpendicularly to the plate"). Therefore, a POSA would have ample motivation to modify the plate of Young to create a fixed angle in all proximal screw holes, as provided in Forstein, to avoid these complications. *See* Ex. 1005 at ¶55.

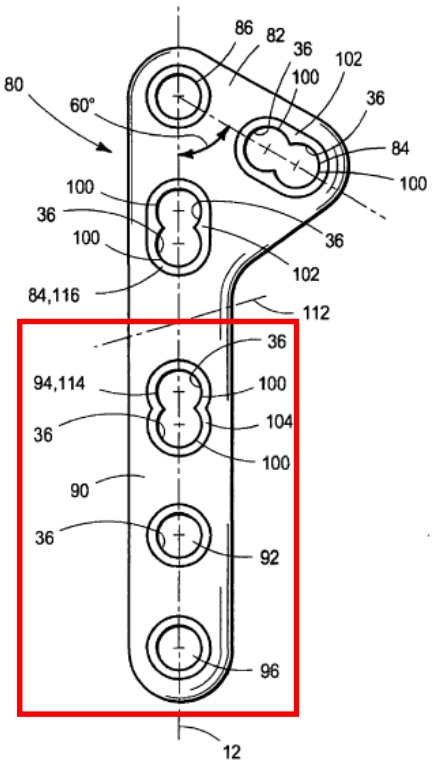
In addition, there were many bone plates known to a POSA that included multiple-screw hole angulation exhibiting a converging screw pattern. As noted

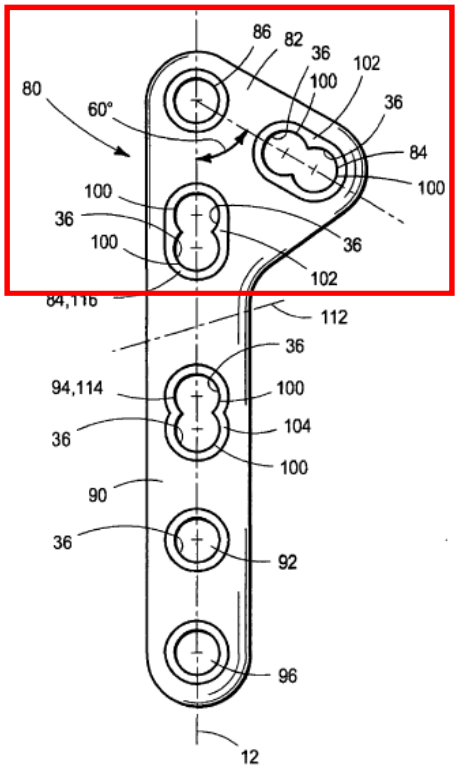
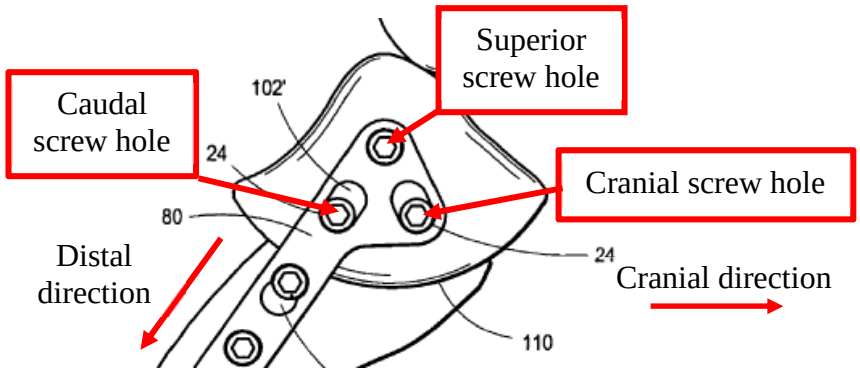
above, the "predetermined and angled" limitations merely require the screw axes to be fixed and to converge into proximal tibial fragment created by the osteotomy. *See* Ex. 1005 at ¶56. For example, Forstein explicitly discloses a tibial fixation plate having fixed angle, proximately located screw holes directing screw paths away from the articular surface of the tibia, away from the edges of the tibia, and into the central mass of the tibia. *See* §V.B., V.C.1., *supra*. (incorporated here); Ex. 1006 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.").

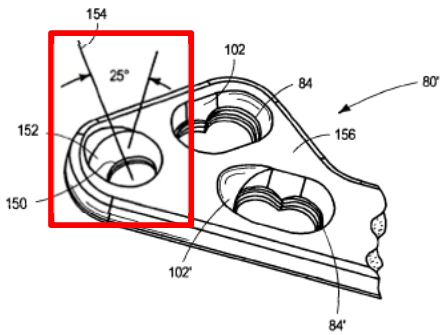
A POSA would have been motivated to combine Young and Forstein to utilize the well-known advantages of fixed screw angulation known in the art. First, both are in the same field and are all directed to bone plate fixation devices and procedures. Second, screw impingement of the articular surface was a well-known complication of tibial plateau leveling osteotomy ("TPLO") procedures and the combination of Young and Forstein. Forstein specifically discloses the use of fixed angle threaded screw holes and teaches the selection of screws that "do not penetrate into the articular surfaces of the joint." Ex. 1006 at ¶81; *see also* Ex. 1005 at ¶38. Further, Young also teaches use of an angled screw hole in a TPLO plate to enable "screw placement that is parallel to the adjacent bone surface." Ex. 1008 at ¶39; *see also* Ex. 1005 at ¶41. Finally, has also long been a well-known best practice to avoid screw placement through the fracture boundary by implanting screws into a single

bone segment, when possible. *See* Ex. 1005 at ¶55. Thus, combining these references would therefore yield predictable benefits and results. In view of the common knowledge in the art that articular surface screw impingement was undesirable and to be avoided and the explicit disclosures of angled screw holes in Young and Forstein, a POSA would have had ample motivation to angle the proximal screw holes so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Ex. 1005 at ¶55-58.

12[PRE]: A bone plate for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal, the bone plate comprising:	Young discloses a bone place for securing two tibial bone segments 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 devices, implants and prostheses used in orthopaedic surgery, and, more particularly, 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.”). 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 subject. *See*, *e.g.*, Ex. 1008, at Abstract; Ex. 1016 at Abstract.

12[A]: a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw; and	Young discloses a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw. *See* Young at ¶32 ("The plate 80 has … **an elongated lower portion 90** in which are located **a plurality of apertures 92, 94 and 96**…."); ¶38  FIG. 1a Additionally, it was well known to a POSA to have a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw. *See* §III.B., *supra.* (incorporated here); *see also* §V.B.12[A], *supra.* (incorporated here); §V.C.1.12[A], *supra.* (incorporated here).

12[B]: a proximal portion comprising at least three screw holes each designed to accept a screw	Young discloses a proximal portion comprising at least three screw holes each designed to accept a screw. *See* Young ¶32 ("The plate 80 has **a flat triangular head 82** in which **three spaced-apart apertures 84 and 86** are formed."); ¶38  FIG. 1a Additionally, it was well known to a POSA to have a proximal portion comprising at least three screw holes each designed to accept a screw. *See* §III.B., *supra.* (incorporated here); *see also* §V.B.12[B], *supra.* (incorporated here); §V.C.1.12[B], *supra.* (incorporated here).
12[C]: wherein a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole,	Young discloses a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole. *See* Young at ¶32 ("The plate 80 has **a flat triangular head 82** in which **three spaced-apart apertures 84 and 86** are formed."); ¶33; ¶35 ("Referring now to FIG. 1b, 

	application of the bone plate 80 is shown for tibial plateau-leveling osteotomy in a canine subject."); *see also* Fig. 1a, 1b. Additionally, it was well known to a POSA to arrange proximal portion screw holes with a first screw hole as a superior screw hole, a second screw hole as a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole as a caudal screw hole located distally and caudally from the superior screw hole. *See* §III.B., *supra*. (incorporated here); *see also* §V.B.12[C], *supra*. (incorporated here); §V.C.1.12[C], *supra*. (incorporated here); Ex. 1018 at 835-36, Figures 30a, 30b; Ex. 1008 at Figures 1a, 1b; Ex. 1009 at Figures 1, 7, 8; Ex. 1011 at Figures 1, 2, 6, 7, 11, 14, 27; Ex. 1012 at Figures 31-42; Ex. 1016 at Figures 1, 5; Ex. 1019 at 19, 23; Ex. 1020 at 1, 11, 14; Ex. 1033 at Figures 1, 7, 8, Ex. 1035 at 357, 362, 419, 430, 449, 450, 459, 460.
12[D]: wherein screw hole paths for the at least three screw holes are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia.	Young discloses a screw hole path that is predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Young at ¶39 ("Referring now to FIGS. 4a and 4b, in another embodiment, the bone plate 80′ has **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** and whose form corresponds to the shape of the head of a representative bone screw. The angle from perpendicular is preferably 25 degrees as this angulation generally matches the amount which the plate 80′ is contoured in situ. This angle allows **screw placement that is parallel to the adjacent bone surface**.").  FIG. 4b

	Forstein discloses screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* §V.B.12[D], *supra*. (incorporated here); §V.C.1.12[D], *supra*. (incorporated here). Additionally, it was well known to a POSA to include screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Ex. 1021 at 187, 189, Figures 1, 4; Ex. 1014 at 434, Figure 12b; Ex. 1018 at 835-36, Figures 27a, 27b, 30a, 30b; Ex. 1031 at ¶¶6, 71, Figures 26-27; Ex. 1033 at ¶74, Figures 7-8.

2. Claims 13-18

As noted above, the additional features recited in claims 13-18 are either expressly disclosed in Forstein or are obvious in view of the state of the art at the time of invention. *See* §V.C.2., *supra.* (incorporated here). Claims 13, 15, and 17 are each dependent on claim 12 and are directed to different bone plate screw hole locations based on different sizes of ranges, recited as limitations on the relative distances between the at least three screw holes on the proximal portion. For example, claim 13 recites an intermediate bone plate with relative locations ranging from 3.5 mm to 6 mm and 6 mm to 9 mm, respectively. Claim 15 recites a bone plate with smaller relative location ranges of 2mm to 4mm and 4mm to 7mm, respectively.

Claim 17 recites a bone plate with larger relative location ranges of 5.5mm to 9.5mm and 7.5mm to 11.5mm, respectively. Claims 14, 16, and 18 each depend on claims 13, 15, and 17 respectively and require that the superior, cranial, and caudal screw holes "are each designed to accept a locking screw."

For at least the same reasons discussed above, the features recited in claims 13-18 do not have patentable weight in light of the disclosures of Young, Forstein, 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.

E. Ground 4 – Claims 12-18 are Obvious under 35 U.S.C. § 103 over Wack in view of Forstein

1. Claim 12

The Challenged Claims are obvious over the combination of Wack and Forstein. The Office has previously found that Wack discloses claim elements 12[A]-[C]. *See* Ex. 1002 at 320-21, 392-93; §III.D., *supra*. (incorporated here). As noted above, the preamble was never argued as a claim limitation by the Patent Owner during prosecution of the '921 patent, including in response to the Office's rejections under Wack. *See*, *e.g.*, *id.* at 338-40. To the extent the preamble is limiting, claim element 12[PRE] is obvious in view of the well-known history of TPLO procedures and prior art TPLO bone plates, such as those disclosed in Slocum and Young. *See generally* Ex. 1015 (disclosing TPLO procedure); Ex. 1016 (disclosing TPLO Plate); Ex. 1008 (same). Further, both Slocum and Young discuss general

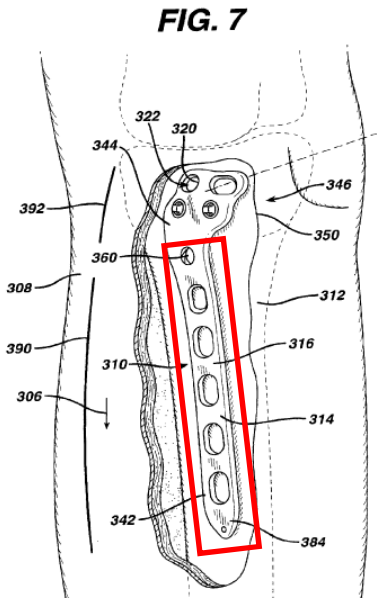
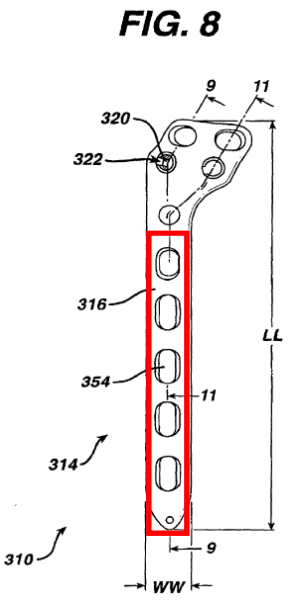
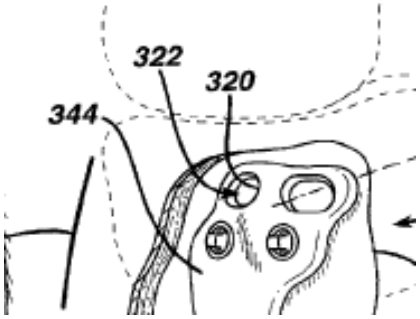
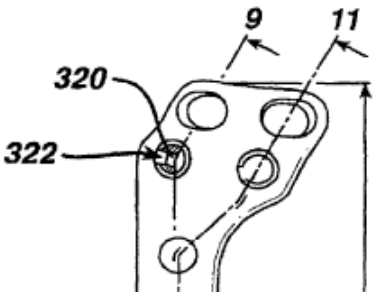
orthopedic bone plates as background knowledge in the art. And Huebner, which teaches a plate with predetermined converging locking screw holes, explicitly notes that its disclosed bone plates "may be configured for use on any suitable bone, in any suitable animal species, including … canine…." *See* Ex. 1033 at ¶21. Thus, a person of ordinary skill would be motivated to apply the teachings of general orthopedic plates, such as Wack and Forstein, to veterinary plates, such as those used during TPLO procedures. *See* Ex. 1005 at ¶¶48-54; Ex. 1027 at ¶¶56-62; *see also In re Warsaw Orthopedic*, 832 F.3d at 1334 (affirming a Board finding that a POSA would be motivated to combine what was known); §III.B., *supra*. (incorporated here).

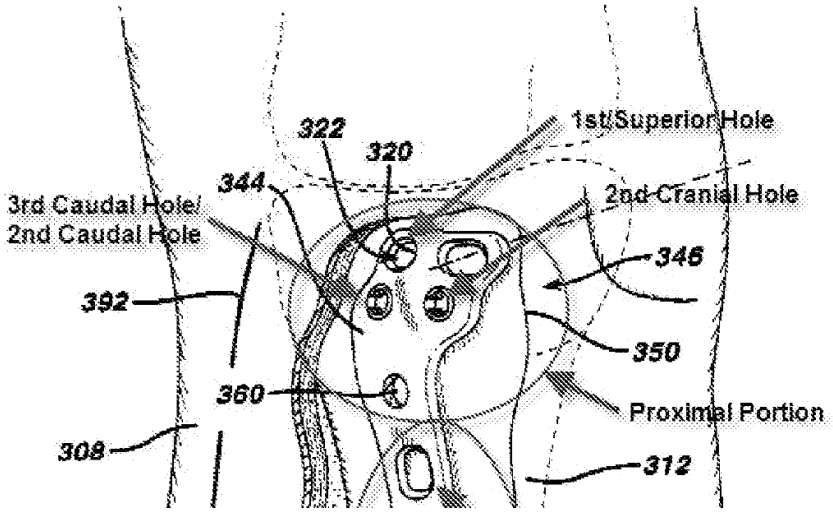
Claim element 12[D], and more specifically the recitation of screw paths that "are predetermined and angled so as to direct screws away from an articular surface between the tibia and a femur," is the only claim element the Board previously found Wack did not disclose. *See* Ex. 1002 at 440. In particular, the Board found that "the targeted screw paths [of the '921 patent] are determined by the threads contained in the walls of the holes 30, 31, and 32 that are engaged by the mating threads 38 on the underside of the head of the locking screws." *Id.* at 438 (quoting Ex. 1001 at 5, 49-53). Forstein discloses this feature. *See* Forstein at ¶73 ("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 [and] the surgeon cannot change the

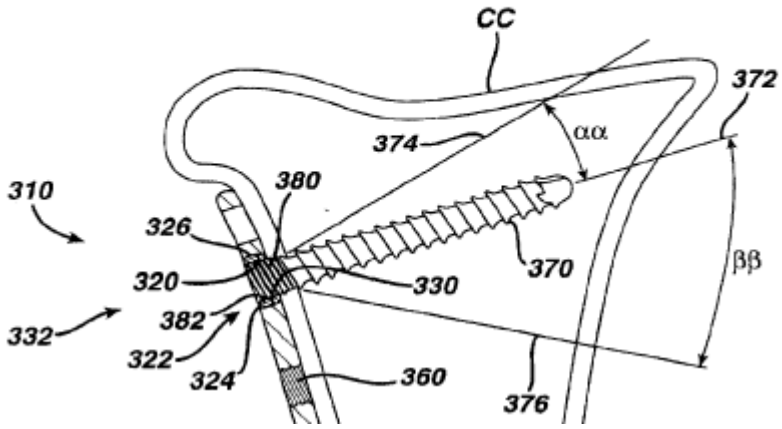
orientation of screws 64."). As explained above, there is ample motivation in the background art to create bone plates that angle screw paths away from the articular surface of the tibiofemoral joint. *See* §V.D.1, *supra.* (incorporated here); *see also* Ex. 1005 at ¶¶55-58; Ex. 1027 at ¶¶63-66.

In view of the common knowledge in the art that articular surface screw impingement was undesirable and to be avoided and the explicit disclosures of angled screw holes in Wack and Forstein, a POSA would have had ample motivation to angle the proximal screw holes so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Ex. 1005 at ¶57-58; Ex. 1027 at ¶65-66.

12[PRE]: A bone plate for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal, the bone plate comprising:	Wack discloses a bone place capable of securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal. *See* Wack at Abstract ("a fracture repair system for engagement with a bone [that] includes a plate."); ¶74 ("While heretofore the fracture repair system has been described in more detail as a femur plate, it should be appreciated that the plate may be utilized for supporting any long bone for example a **tibia**, humerus, ulna, radius or fibula."); Ex. 1002 at 318. 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 subject. *See, e.g.*, Ex. 1008, at Abstract; Ex. 1016 at Abstract.

12[A]: a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw; and	Wack discloses a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw. *See* Wack at FIGs. 7-9; ¶75 ("The fracture repair system 310 for use on the tibia 312 includes a tibia plate 314 having a **body portion**   **316**."); ¶79 ("To provide for a range of standard tibial plates, the tibial plates may be provided in varying lengths of, for example, a length with **a number of elongated openings 354** of, for example, 4, 7, 11, or 14 elongated openings.").
12[B]: a proximal portion comprising at least three screw holes each designed to accept a screw	Wack discloses a proximal portion comprising at least three screw holes each designed to accept a screw. *See* Wack ¶75 ("The body portion 316 includes a distal   portion 342 and a **proximal portion 344**."); ¶73 ("**Threaded holes 62 can receive**, referring to FIG. 6, **screws 64** having threaded head 67 and threaded shaft 68."); FIGs. 7, 8.

12[C]: wherein a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole,	Wack discloses a first screw hole is a superior screw hole, a second screw hole is a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole is a caudal screw hole located distally and caudally from the superior screw hole. *See* Wack at FIGs. 7, 8; ¶80 ("The tibia plate 314 also includes an interior wall 320 which defines a tibia plate hole 322 through the body portion 316.")*see also* Ex. 100X at 84 (reproduced below).  Additionally, it was well known to a POSA to arrange proximal portion screw holes with a first screw hole as a superior screw hole, a second screw hole as a cranial screw hole located distally and cranially from the superior screw hole, and a third screw hole as a caudal screw hole located distally and caudally from the superior screw hole. *See* §III.B., *supra.* (incorporated here)

12[D]: wherein screw hole paths for the at least three screw holes are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia.	Wack discloses screw hole paths for at least three screw holes that direct screws away from an articular sufrace between a tibia and a femur, away from an osteotomy surface of the tibia, and away from the edges of the tibia and into a central mass of the tibia. *See* Wack at FIG. 9. **FIG. 9**  Forstein discloses screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* §V.B.12[D], *supra.* (incorporated here); §V.C.1.12[D], *supra.* (incorporated here); §V.D.1.12[D], *supra.* (incorporated here). Additionally, it was well known to a POSA to include screw hole paths for the at least three screw holes that are predetermined and angled so as to direct screws away from an articular surface between a tibia and a femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia. *See* Ex. 1021 at 187, 189, Figures 1, 4; Ex. 1014 at 434, Figure 12b; Ex. 1018 at 835-36, Figures 27a, 27b, 30a, 30b; Ex. 1031 at ¶¶6, 71, Figures 26-27; Ex. 1033 at ¶74, Figures 7-8.

2. Claims 13-18

As noted above, the additional features recited in claims 13-18 are either expressly disclosed in Forstein or are obvious in view of the state of the art at the time of invention. *See* §V.C.2., *supra.* (incorporated here). Claims 13, 15, and 17 are each dependent on claim 12 and are directed to different bone plate hole locations, recited as limitations on the relative distances between the at least three screw holes on the proximal portion. For example, claim 13 recites an intermediate bone plate with distance ranges of 3.5 mm to 6 mm and 6 mm to 9 mm between the holes, respectively. Claim 15 recites a bone plate with smaller distance ranges of 2mm to 4mm and 4mm to 7mm, respectively. Claim 17 recites a bone plate with larger distance ranges of 5.5mm to 9.5mm and 7.5mm to 11.5mm, respectively. Claims 14, 16, and 18 each depend on claims 13, 15, and 17 respectively and require that the superior, cranial, and caudal screw holes "are each designed to accept a locking screw."

For at least the same reasons discussed above, the features recited in claims 13-18 do not have patentable weight in light of the disclosures of Wack, Forstein, 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.

VI. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for claims 12-18 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.

Patent Owner has filed two utility continuations and one design application claiming priority to the ’921 Patent. U.S. Patent Application Serial No. 13/538,407 was filed on June 29, 2012 and is currently pending. Patent Owner has appealed a final rejection of all claims. U.S. Patent Application Serial No. 16/031,792 was filed on July 10, 2018 and is currently pending. All claims are currently under a final rejection and Patent Owner has filed a Notice of Appeal. 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
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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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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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Dated: July 12, 2019

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Petition for Inter Partes Review contains 13,808 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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