

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VETERINARY ORTHOPEDIC IMPLANTS, INC.,
Petitioner,

v.

DEPUY SYNTHES PRODUCTS, INC.,
Patent Owner.

IPR2019-01332
Patent 8,523,921 B2

Before HYUN J. JUNG, CHRISTOPHER G. PAULRAJ, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Veterinary Orthopedic Implants, Inc. (“Petitioner”),¹ on July 15, 2019, filed a Petition to institute *inter partes* review of claims 12–18 of U.S. Patent No. 8,523,921 (Ex. 1001, “the ’921 patent”). Paper 1 (“Pet.”). DePuy Synthes Products, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). We granted (Paper 11) Petitioner’s request to file a pre-institution Reply to Patent Owner’s Preliminary Response. Paper 12. We also permitted Patent Owner to file a Sur-Reply to Petitioner’s authorized Reply. Paper 14.

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon considering the arguments and evidence, we conclude that Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 12–14 are unpatentable. (Claims 15–18 are disclaimed as noted below). Thus, for reasons detailed below, we do not institute *inter partes* review of claims 12–18 of the ’921 patent.

Patent Owner statutorily disclaimed claims 10, 11, and 15–18 of the ’921 patent. See Ex. 2023, 1; Prelim. Resp. 10 n.2; 37 C.F.R. § 42.107(e) (2019); 35 U.S.C. § 253; see *Vectra Fitness, Inc. v. TWNK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) (“This court has interpreted the term ‘considered as part of the original patent’ in section 253 to mean that the patent is treated as though the disclaimed claims never existed.”). Among

¹ Petitioner identifies itself as the real party-in-interest. Pet. 62.

the claims challenged in this Petition, claims 15–18 are disclaimed and, thus, *inter partes* review cannot be instituted on those claims. See 37 C.F.R. § 42.107(e) (“No *inter partes* review will be instituted on disclaimed claims.”); see, e.g., *Paragon 28, Inc. v. Wright Med. Tech., Inc.*, IPR2019-00894, Paper 17 at 29 (PTAB Sept. 25, 2019) (instituting review on some claims but not those that were disclaimed because “we conclude we cannot institute a trial on claims that have been disclaimed, and, thus, no longer exist.”); *Gen. Elec. Co. v. United Techs. Corp.*, IPR2017-00491, Paper 9 at 2–3 (PTAB July 6, 2017) (precedential) (determining that review cannot be instituted where Patent Owner disclaimed all challenged claims). Accordingly, we do not further address Petitioner’s challenge to claims 15–18 in this Decision.

A. Related Proceedings

The ’921 patent issued September 3, 2013, from U.S. Patent Application No. 11/361,245 (“the ’245 Application”), filed February 24, 2006. Ex. 1001, at [21], [22], [45]. Petitioner identifies the following related applications that directly or indirectly claim priority to the ’921 patent:

US Patent Application No. 13/538,407, filed June 29, 2012 (hereafter “the ’407 Application”), which is a child application to the ’921 patent; and

US Patent Application No. 16/031,792, filed July 10, 2018 (hereafter “the ’792 Application”), which is a grand-child application to the ’921 patent.

Pet. 16–22, 62. Both of the above related applications remain pending

before the U.S. Patent and Trademark Office. *Id.* In addition, Petitioner identifies U.S. Design Patent Application No. 29/656,918, which issued July 2, 2019. *Id.* at 62–63; *see also* Prelim. Resp. 13 (identifying U.S. Patent No. D852957).

Petitioner further states that it is a defendant in a pending litigation concerning the '921 patent: *Depuy Synthes Products, Inc. v. Veterinary Orthopedic Implants, Inc.*, 3:18-cv-01342-HES-PDB, filed in the United States District Court for the Middle District of Florida, Jacksonville Division. Pet. 62.

Patent Owner, for its part, also identifies a separate lawsuit between Petitioner and Patent Owner on the related and above-noted design patent. Prelim. Resp. 13; Ex. 2020 (Complaint for Design Patent Infringement, Case No. 3:19-cv-00801-MMH-JRK (M.D. Fla., filed July 3, 2019)). According to Patent Owner, Petitioner has since agreed to have judgment taken against it for infringement of the design patent, including an injunction barring Petitioner's further manufacture and sale of the infringing designs. Prelim. Resp. 15; Ex. 2021 (notice of the executed offer of judgment).

Beyond the instant Petition, Petitioner concurrently filed two additional petitions for *inter partes* review of the '921 patent (IPR2019-01331 (challenging claims 1–12)) and (IPR2019-01333 (challenging claims 19 and 20)). *See* Prelim. Resp. 1.

B. Asserted Grounds of Unpatentability

Petitioner asserts four grounds of unpatentability in this Petition (Pet. 1–3), which are provided in the table below:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
12	102(e) ²	Forstein ³
12–18	103(a)	Forstein
12–18	103(a)	Young, ⁴ Forstein
12–18	103(a)	Wack, ⁵ Forstein

Petitioner also relies on the declarations of Dr. Jeffrey N. Peck and Troy D. Drewry, among other evidence. Ex. 1005 (“Peck Decl.”); Ex. 1027 (“Drewry Decl.”). Patent Owner, in its Preliminary Response, cites the declarations of Dr. Michael P. Kowaleski and Timothy Horan, among other evidence. Ex. 2022 (“Kowaleski Decl.”); Ex. 2112 (“Horan Decl.”).

² The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the ’921 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 throughout this Decision.

³ Forstein, US 2006/0173458 A1, published Aug. 3, 2006 (Ex. 1006, “Forstein”). The application that published as Forstein was filed Oct. 6, 2005 and claims the benefit of U.S. Provisional Application No. 60/616,680, filed Oct. 7, 2004 (Ex. 1007, “Forstein Provisional” or “Forstein Prov.”).

⁴ Young, US 2005/0015089 A1, published Jan. 20, 2005 (Ex. 1008, “Young”).

⁵ Wack, US 2002/0156474 A1, published Oct. 24, 2002 (Ex. 1009, “Wack”).

C. The '921 Patent

The '921 patent is titled “Tibial Plateau Leveling Osteotomy Plate.”

Ex. 1001, at [54]. The '921 patent's abstract reads as follows:

An improved tibial plateau leveling osteotomy plate is disclosed. The plate is contoured in its proximal head portion to more closely resemble the structure of the tibial bone segment that is cut and rotated during the procedure. The plate also preferably has screw holes in the proximal head portion that are machined through the pre-contoured proximal head portion and are designed to angle the screw in a targeted screw path with respect to the osteotomy.

Id. at [57]; *see also id.* at 2:18–21 (“By machining these [proximal] screw holes through the pre-contoured bone-contacting surface, the screw holes define a pre-determined and targeted screw path through the tibial bone segment.”).

As background, the '921 patent describes a tibial plateau leveling osteotomy (or “TPLO”) as a surgical procedure that is “well known in the veterinary art.” Ex. 1001, 1:14–15. TPLO procedures, the '921 patent discloses, “are used to correct ruptured cranial cruciate ligaments for various animals, primarily for canines.” *Id.* at 1:15–17; *see also id.* at 1:22–25 (disclosing that “the cranial cruciate ligament stabilizes a canine's stifle joint (called the knee for humans),” and explaining that “[o]ne of the important functions for the ligament is to control sliding of the upper femur bone on the lower tibia bone”). According to the '921 patent, TPLO has “become the standard of care for medium and large canines.” *Id.* at 1:19–21; *see also id.* at 1:27–28 (TPLO “provides a way to correct this problem [(rupture of the

canine's cranial cruciate ligament)]").⁶

The '921 patent describes an actual TPLO procedure as follows:

Basically, a curvilinear cut is made to the upper and lower portion of the tibia. This cut portion is then rotated on the order of about 20–30 degrees thereby creating a more level plane or surface on the top of the tibia upon which the femur can rest. The cut and repositioned portion of the tibia is then secured to the lower portion of the tibia.

Ex. 1001, 1:29–39; *see also* Ex. 1005 ¶¶ 16 (describing TPLO procedure to control “cranial tibial thrust . . . by leveling the [tibial] plateau to enhance the effectiveness of the active forces of the stifle flexors of the thigh”), 17 (describing TPLO as involving a “medial incision extending from the medial aspect of the stifle (knee) joint through the proximal one-third of the tibia,” making a “cylindrical cut” to the tibia, rotation of the cut proximal segment, and stabilization of the bones in a rotated position with a TPLO plate).⁷

The '921 patent acknowledges that various means have been used to fix or secure the cut bone portion to the remaining portion of the tibia as part of a TPLO procedure, including the use of metal plates secured with bone

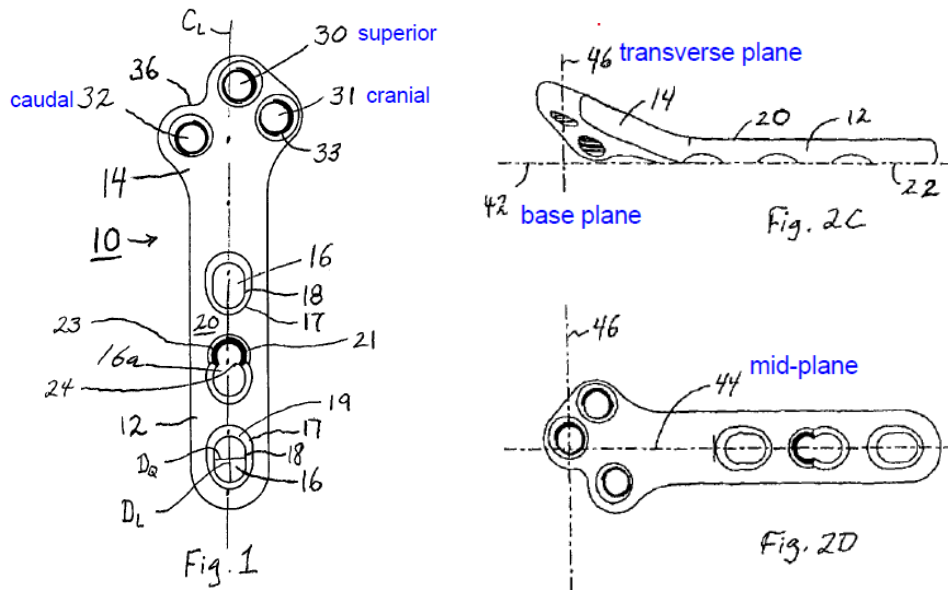
⁶ Dr. Kowaleski provides an anatomical overview on canines and other quadrupeds. Ex. 2022 ¶¶ 11–16 (showing, for example, relevant bones in the hind limb of a dog).

⁷ Dr. Kowaleski also provides a step-by-step overview of TPLO, illustrating the curvilinear cut made to the tibia's proximal portion, rotation of that cut portion relative to the distal tibia, and finally securing of a plate. *See, e.g.*, Ex. 2022 ¶¶ 17–22; Ex. 2016, 37; *see also* Ex. 1014 *passim* (detailing TPLO surgical procedure). As Dr. Kowaleski explains, TPLO is performed on the medial aspect of the tibia, and cannot be performed on the lateral side due to the presence of the fibula. Ex. 2022 ¶ 18.

screws. Ex. 1001, 1:40–45. According to the '921 patent, however, the “problem” with many of the existing plates is “that they require the surgeon to manipulate the plate to conform to the tibia during the surgical procedure,” which is difficult and “can result in the screw holes becoming deformed.” *Id.* at 1:45–51. Further, the '921 patent discloses, “[a]nother drawback with the TPLO plates currently available” is that the screw holes are “not designed for optimum fixation.” *Id.* at 1:52–58 (explaining that improved designs that “avoid the screws from being located near a cut portion of the tibia or near the articular surface of the tibia and femur” are needed).

The '921 patent's drawings are helpful to understanding the invention. Figures 1, 2C, and 2D are reproduced below (with annotation⁸) and show an exemplary bone plate of the '921 patent in several views, including top (Figs. 1 and 2D) and side (Fig. 2C) views.

⁸ Unless otherwise stated, annotations to the drawings provided in this Decision were made by the Board.



Ex. 1001, Figs. 1, 2C, 2D. Figure 1 is a top view of the bone plate (10), and shows, among other features, the plate's distal (12) and proximal (14) portions, as well as the superior (30), cranial (31), and caudal (32) screw holes. *See, e.g., id.* at 4:42–49.⁹ Figure 2C is a side view of the bone plate and shows a bone-contacting surface (22) of a flat distal portion (12) along a base plane (42), and a transverse plane (46) of the plate, which transverse plane is orthogonal to the base plane. *Id.* at 5:31–40. As seen in Fig. 2C, the proximal portion (14) of the plate is not flat along the base plane as with the plate's distal portion (12); rather it is, as discussed earlier, “designed or configured in its dimensions to advantageously contour to the tibial bone segment that has been cut and rotated during the TPLO procedure.” *See id.*

⁹ As Drs. Peck and Kowaleski explain, the terms “cranial” and “caudal” are common terms in veterinary medicine and, in the context here, indicate the direction of the plate holes in relation to the head (cranial, meaning toward the head) and the tail (caudal, meaning toward the tail) of the four-legged animal to which the plate is attached. Ex. 1005 ¶¶ 31, 33; Ex. 2022 ¶ 14.

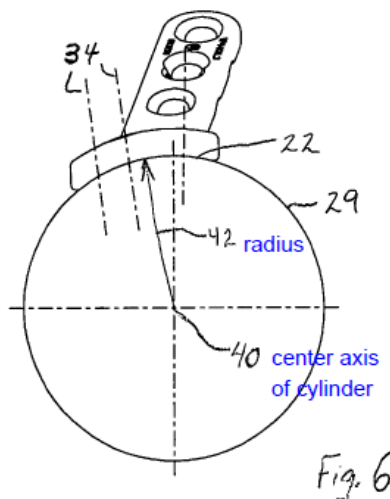
at 5:31–34. The more particular contours of the plate’s proximal portion, the ’921 patent states, are better explained upon defining three orthogonal planes of the plate—the base and transverse planes, discussed above, and the mid-plane (44), which is depicted in the side view of the plate in Fig. 2D above. *Id.* at 5:34–36.

According to the ’921 patent:

A base plane **42** is defined by the flat distal portion **12** at the bone-contacting surface **22**. A mid-plane **44** is defined as bisecting the base plane in the distal portion of the plate. A transverse plane **46** is defined as being orthogonal to the base plane **42** and the mid-plane **44**.

Ex. 1001, 5:38–43. The ’921 patent then states that the contoured shape of the proximal portion can be more readily seen by rotating the plate. *Id.* at 5:54–56. The patent describes the contour as the “arc of a cylinder” and states that a “centerline of the cylinder can be viewed perpendicularly by rotating the plate twice” about two “rotation axes” defined by various intersections of the planes discussed above (or offsets and rotated versions thereof). *Id.* at 5:58–6:13 (describing a second rotation of the plate “downward about a second rotation axis . . . defined by the intersection of the off-set, rotated, transverse plane and base plane **42**”).

A result of the multiple rotations of the plate is depicted in Fig. 6 of the ’921 patent, which is reproduced below (with annotation).



Ex. 1001, Fig. 6. Figure 6 is a rotated proximal end view of the plate, showing an arc of a bone-contacting surface (22) of the proximal portion, and showing “cylinder” (29) having a center axis (40) and radius (42). *Id.* at 5:58–6:13; *see also id.* at Fig. 3 (proximal end view of plate, down the plate’s length without rotation), Fig. 4 (proximal end view upon a first angular rotation of the plate (as depicted in Fig. 3) about a first rotation axis), and Fig. 5 (proximal end view following a second angular rotation of the plate (as depicted in Fig. 4) about a second rotation axis).

As for the proximal portion’s screw holes and screw paths, the ’921 patent describes its “optimized” TPLO design. *See, e.g.*, Ex. 1001, 5:10–12, 6:18–39. According to the ’921 patent, the plate is preferably designed to have the screws in the proximal portion “angle into the tibia so that the screws are directed away from the articular surface between the tibia and the femur, away from the osteotomy surface of the tibia, and away from the edges of the tibia and into the central mass of the tibia.” *Id.* at 6:18–31. The ’921 patent explains that these screw hole paths can be obtained by pre-contouring the proximal portion, and then machining the screw holes

through the pre-contoured portion. *Id.* at 6:31–35. With screw holes designed for use with locking screws, such a design provides for a fixed and targeted screw path through the desired section of the cut and rotated tibial bone segment. *Id.* at 6:35–39; *see also id.* at Figs. 7–9 (showing angled screw paths of the superior, cranial, and caudal screw holes and screws); *see also id.* at 9:32–35 (“The plate is also designed such that after the proximal portion is pre-contoured, the screw holes for the proximal portion are machined through the plate.”).

The '921 patent illustrates implantation of the bone plate in a TPLO procedure. Figure 13 (with annotation) is reproduced below.

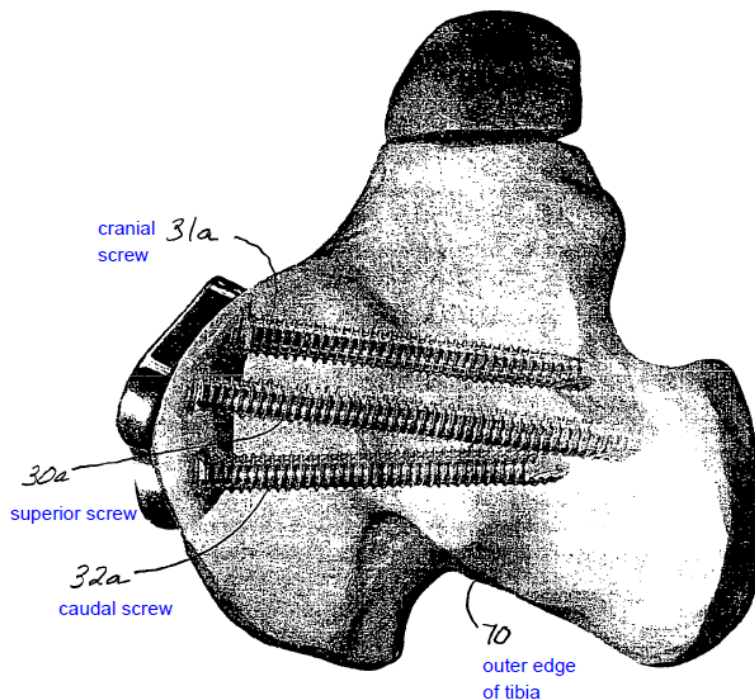


Fig. 13

Ex. 1001, Fig. 13. Figure 13 is a top perspective view of the articular surface between the tibia and femur (i.e., looking down at the tibial plateau) with an exemplary bone plate affixed to the proximal medial portion of the

animal's tibia, with screws having a targeted path. *Id.* at 3:14–16, 9:42–54. Figure 13 shows, for example, caudal screw (32a) that is angled slightly cranially (in a direction of the animal's head) toward the center of the cut portion of the tibia and away from the outer edge (70) of the tibia; *see also id.* at Fig. 14 (side perspective view of an exemplary bone plate affixed to the animal's distal and cut proximal tibial segments (on inner portion of right hind leg) as part of TPLO), 9:42–56.

D. Challenged Claims

The '921 patent includes four independent claims, and several dependent claims. Claim 12 is the only independent claim challenged in this Petition, and reads as follows:

12. A bone plate for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal, the bone plate comprising:

a distal portion comprising an elongated shaft having disposed therein a plurality of screw holes each designed to accept a screw; and

a proximal portion comprising at least three screw holes each designed to accept a screw 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, 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 femur, away from an osteotomy surface of the tibia, and away from edges of the tibia and into a central mass of the tibia.

Ex. 1001, 10:65–11:15. Claims 13 and 14 are also challenged here, and those claims depend, directly or indirectly, from claim 12. *Id.* at 11:16–23.

E. Prosecution History

The prosecution history of the '921 patent (and related applications) is somewhat extensive, and we do not summarize all of it here. *See* Pet. 10–22 (Petitioner’s summary of the prosecution for the '921 patent, the '407 Application, and the '792 Application). As to the three references asserted as part of Petitioner’s four grounds, Petitioner contends that: (i) Forstein was not cited during the prosecution of the '921 patent; (ii) Young was identified in an information disclosure statement, but not cited in a rejection; and (iii) Wack was cited against then-pending claims of the '921 patent in a rejection, which was appealed to the Board. Pet. 3, 10–16.

In the lead-up to the appeal to the Board during the '921 patent’s prosecution, the examiner had rejected claim 12 as anticipated by Wack, and the claims depending from claim 12 for obviousness over Wack. Ex. 1002, 432–443 (Board decision dated May 31, 2013). Relevant to claim 12, the Board determined that “[b]ecause the bushing and locking screws of Wack allow placement of the screw in different orientations, the screw does not follow a predetermined path as required by the claims.” *Id.* at 440 (“Wack does not disclose screw holes that are predetermined and angled.”). The Board, thus, reversed the rejection of claim 12 for anticipation, as well as the obviousness rejection for the dependent claims. *Id.* at 438–441 (concluding “the same issues are dispositive for both the anticipation rejection and obviousness rejection based on Wack”).¹⁰ After the Board’s reversal of the

¹⁰ The other pending claims (i.e., independent claim 1 and its dependent

rejections, the examiner entered a notice of allowance without further comment on any particular reasons for allowing the claims. *Id.* at 444–449 (Notice of Allowance dated June 26, 2013).

As Petitioner points out, Forstein was cited by an examiner in the rejection of pending claims in the related '792 Application. Pet. 18–22. The prosecution of the '792 Application is ongoing, and a rejection citing Forstein has been appealed and is awaiting a decision from the Board. *Id.* at 21–22; Ex. 1004, 205–221 (Final Rejection dated Feb. 1, 2019), 392–413 (Appeal Br. in '792 Application).

II. ANALYSIS

A. *Principles of Law*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)).

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir.

claims, and independent claims 19 and 20) stood rejected for anticipation and obviousness based on Wack and another reference known as “Weaver” (Ex. 1010, which is a counterpart to Weaver applied during prosecution), which is not asserted in the grounds here. The Board, for different reasons, reversed those rejections as well. Ex. 1002, 432–443.

2008); *In re Chudik*, 851 F.3d 1365, 1372 (Fed. Cir. 2017) (“[A] prior art reference anticipates a claim only if it discloses all the elements in the same form and order as in the claim.”) (internal quotation marks and citation omitted). Indeed, “[i]t is not sufficient to constitute an anticipation that the device relied upon might, *by modification*, be made to accomplish the function performed by the patent in question, if it were not designed by its maker, nor adapted, nor actually used, for the performance of such functions.” *Chudik*, 851 F.3d at 1372 (quoting *Topliff v. Topliff*, 145 U.S. 156, 161 (1892)) (emphasis in original).

Turning to obviousness, a claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness when presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing obviousness based on a proposed combination of prior art elements, we also consider, *inter alia*, whether the evidence shows a sufficient reason that would have prompted one of ordinary skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. And, a party who petitions the Board for a

determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted).

B. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the problems encountered in the art, the art’s solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner contends a person of ordinary skill in the art (or “POSA”) as of February 24, 2006, would 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.

Pet. 3–4; Ex. 1005 ¶ 28; Ex. 1027 ¶ 32. Patent Owner does not oppose this definition at this time. Ex. 2022 ¶ 7 (Dr. Kowaleski accepting Petitioner’s definition for purposes of his declaration).

Because Petitioner’s proposed definition is unopposed and is not inconsistent with the cited prior art, we adopt it for the purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001)

(explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019).¹¹ Under this standard, we construe the claim “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 pertaining to the patent.” *Id.* “[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” See *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

¹¹ The Office has changed the claim construction standard in AIA proceedings to replace the broadest reasonable interpretation standard with the same claim construction standard used in a civil action in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). The change applies to petitions filed on or after November 13, 2018. *Id.* Because the present Petition was filed after that date, we construe the claims in accordance with the federal district court standard, now codified at 37 C.F.R. § 42.100(b).

1. Preamble

The preamble of claim 12 recites “[a] bone plate for securing two tibial bone segments as part of a tibial leveling osteotomy for an animal.” Ex. 1001, 10:65–67.

Petitioner argues “[t]his preamble is merely a statement of intended purpose” and “should not be considered limiting.” Pet. 22–23 (citing *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810 (Fed. Cir. 2002)). In support, Petitioner contends Patent Owner never argued the preamble was limiting during prosecution of the ’921 patent when faced with plates designed for general orthopedic use and, during prosecution of a claim with an “identical” preamble in the related ’792 Application, “the USPTO firmly rejected Patent Owner arguments that the preamble carried patentable weight.” *Id.* at 23; Ex. 1004, 207.¹²

We disagree with Petitioner and conclude that the preamble is limiting. On this issue, the Federal Circuit’s decision in *Rowe v. Dror*, 112 F.3d 473 (Fed. Cir. 1997) is instructive. In that case, the court noted that when a patentee “uses the preamble only to state the purpose or intended use for the invention, the preamble is not a claim limitation.” *Rowe*, 112 F.3d at 478. The court noted, however, the corollary principle that the claim preamble has the import that the claim as a whole suggests for it, and that

¹² The preamble of the claims (claims 21 and 31) in the ’792 Application recited “[a] bone plate dimensioned for securing two tibial bone segments of an animal as part of a tibial leveling osteotomy procedure.” Ex. 1004, 91, 93–94. The preamble is not “identical” to claim 12’s preamble as Petitioner asserts, but we consider the language to be substantially the same for purposes of this analysis.

answering questions about the significance of the preamble “involves examination of the entire patent record to determine what the patentee intended to define and protect.” *Id.*; *see also id.* at 479–480 (examining the entirety of the claims, the specification, and drawings, in route to holding the term “angioplasty” in preamble reciting a “balloon *angioplasty* catheter” did further limit the claimed apparatus);¹³ *Poly-Am., LP v. GSI Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) (holding that where the specification is “replete with references” to preamble language, this can show the inventor regarded the language as “an important characteristic of the claimed invention” and thus limit the claims).

As pointed out by Patent Owner, Petitioner does not provide this threshold analysis of the entire ’921 patent to explain why the patent does (or does not) support Petitioner’s interpretation. Prelim. Resp. 45–50. We agree with Patent Owner that the ’921 patent is about TPLO and plates designed and dimensioned for that procedure, and does not describe other types of procedures or applications for the bone plate disclosed therein. *Id.*

¹³ After considering the entire patent record, the Federal Circuit ultimately interpreted the claims as requiring “a balloon angioplasty catheter capable of expanding radially and exerting pressure on the plaque encrusted walls of a surrounding blood vessel.” *Rowe*, 112 F.3d at 480. One of the court’s considerations, which is not specifically present in the claims here, is that the claims in *Rowe* were drafted in Jepson format to an “improvement” of prior balloon catheters for angioplasty procedures. *Id.* at 476, 479. That being said, upon a review of the *whole* ’921 patent, it is clear that improved TPLO plates (not generic or general purpose bone plates) are exactly what the patent describes and is intended to protect. *See, e.g.*, Ex. 1001 [57]. (“An improved tibial plateau leveling osteotomy plate is disclosed”).

at 46–47 (“The use of bone plates to secure tibial segments as part of a tibial leveling osteotomy appears throughout the specification of the ’921 patent, to the exclusion of any other uses.”); *see also supra* Section I(C); *see, e.g.*, Ex. 1001, [57] (“The plate is contoured in its proximal head portion to more closely resemble the structure of the tibial bone segment that is cut and rotated during the procedure”).

Moreover, a claim’s preamble is limiting when it is “necessary to give life, meaning, and vitality to the claim.” *MBO Labs., Inc. v. Becton Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007). Here, and unlike the facts of *Catalina Mktg.* cited by Petitioner, the preamble gives life and provides meaning to the remainder of claim 12. Pet. 22–23. As Patent Owner notes (and Petitioner elsewhere agrees) the terms “cranially” (or “cranial”) and “caudally” (or “caudal”) are veterinary terms and distinguish the plates claimed from human or general purpose bone plates. Prelim. Resp. 47–48. These terms signal a design of the claimed plate for a four-legged (quadruped) patient, not a human use or design. And, to provide antecedent basis and/or meaning for these latter terms (e.g., “caudal”) appearing in the body of the claim, we note the preamble’s recitation of the bone plate “securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an *animal*.” Ex. 1001, 10:65–66 (emphasis added).

Even Petitioner’s declarants testify that terms in the body of claim 12 (e.g., caudal) “only make sense as terms descriptively locating the screw holes *after* implantation of the plate.” Ex. 1005 ¶ 34; Ex. 1027 ¶ 41. If that is so, this begs the question as to what kind of “patient” is required for the bone plate and what type of implantation it is utilized for. The answer to

this question is, however, informed by the preamble—indicating that the subject is a four-legged “animal” and the implantation is part of a “tibial leveling osteotomy.” *See, e.g.*, Prelim. Resp. 48 (“In other words, it is the orientation of the plate in the tibial leveling procedure that gives meaning to the anatomical locations described in the body of the claim”).

As for a lack of argument that the preamble was limiting during the prosecution of the ’921 patent, that is a factor we consider. Pet. 22. It does not, however, override all other considerations, such as a review of the totality of the ’921 patent as discussed. And, it is not decisive here because, for reasons explained above, we conclude the preamble provides necessary context and meaning for the claim as a whole.

Furthermore, on review of the ’921 patent’s prosecution, whether the preamble language was argued as an important or limiting aspect of the claims is not completely clear. In the appeal to the Board during that prosecution, Patent Owner asserted, *inter alia*:

In contrast [to Wack], the device of the present invention is directed to a tibial leveling osteotomy . . . [and] as recited in claim 12 is particularly suited ‘as part of a tibial leveling osteotomy procedure for an animal,’ . . . and finds no utility in a system and method for fixation of fractured bones, wherein the positioning of a bone screw varies from procedure to procedure.

Ex. 1002, 366. Although the Board did not comment on those assertions specifically, or decide expressly whether the preamble was limiting, Patent Owner’s position on the significance of the preamble language during prosecution is arguably more nuanced than Petitioner’s contentions here might suggest. Pet. 22.

Finally, the examiner's determination that preamble language was not limiting during the prosecution of the grand-child '792 Application is also a factor that we have considered. *See, e.g.*, Ex. 1004, 207. Notably, however, Patent Owner is challenging the examiner's rejection on that point (among others) in a pending appeal to the Board. *See, e.g., id.* at 398–399 (arguing that preamble language relating to the plate being dimensioned for securing tibial bone segments as part of TPLO is *not* simply intended use language). The contested conclusion of the examiner in an ongoing prosecution of different claims of a different, yet related, application does not outweigh our consideration of the other factors noted above that point to the preamble being limiting to claim 12 of the '921 patent.

Altogether, we conclude claim 12's preamble is limiting and requires a bone plate designed for and capable of securing two tibial bone segments of an animal (i.e., quadruped) in a tibial plateau leveling osteotomy procedure.¹⁴

¹⁴ Even if considered partly functional language, there is no rule against reciting limitations of an apparatus claim in functional terms. *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (“A patent applicant is free to recite features of an apparatus claim either structurally or functionally.”). Reciting elements functionally can, however, broaden the claim language and may encompass prior art capable of performing the recited function. *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971).

2. “cranial screw hole located distally and cranially from the superior screw hole . . . , a caudal screw hole located distally and caudally from the superior screw hole”

According to Petitioner, “the terms distally, cranially, and caudally are arbitrary directional terms,” and “[a]ll that is required to meet these limitations is for the holes to exhibit the arbitrary directional relationship claimed.” Pet. 23.

We are unpersuaded that each of these terms is “arbitrary” as alleged. The terms define the relative direction and relationship of the features of the claimed bone plate—particularly the three “screw holes” in the proximal portion—in relation to each other and the plate itself, along with adding meaning to the claim as to the orientation of the holes and plate upon implantation as discussed above. As Petitioner seemingly acknowledges, “distal” in the context of claim 12 has a more particular meaning. Pet. 23. It means the opposite of proximal and, in relation to, for example, the superior screw hole of claim 12 means that the other two proximal screw holes (cranial and caudal) must be located away from the superior screw hole in a distal direction—toward the distal portion of the bone plate by some longitudinal distance just as described and shown in the ’921 patent. *See, e.g.*, Ex. 1001, Fig. 10 (showing a distance 30–32L parallel to the longitudinal axis of the plate between a center of the superior screw hole and a center of the caudal screw hole).

As for “cranial” and “caudal,” we agree that those are “common veterinary anatomical terms” that “mean towards the tail (‘caudal’) and towards the head (‘cranial’).” Pet. 23. Insofar as Petitioner apparently interprets those terms as just arbitrary and interchangeable for any bone

plate, however, Petitioner does not identify support in the '921 patent for that interpretation. *See, e.g., id.* at 25, 33 (characterizing screw holes in asserted prior art bone plates as “Cranial/Caudal”). The '921 patent never discloses that a “caudal” screw hole can somehow transform into a “cranial” screw hole if, for example, the bone plate were rotated 180° on its longitudinal axis and implanted on the tibia of the other leg, or the other side of the tibia on the same leg—even if such implantation were theoretically possible with the claimed plates. In any event, we need not conclusively decide the exact bounds of what it means to be a “caudal” or “cranial” screw hole, or to be located “caudally” or “cranially” as claimed in order to resolve the dispute here.¹⁵ To the contrary, it is sufficient for present purposes to recognize that those terms, at minimum, refer to the respective direction of the plate’s screw holes in relation to the animal’s head and tail upon implantation of the plate as already discussed.

D. Anticipation by Forstein

Petitioner asserts that claim 12 is unpatentable as anticipated by Forstein. Pet. 25–32.

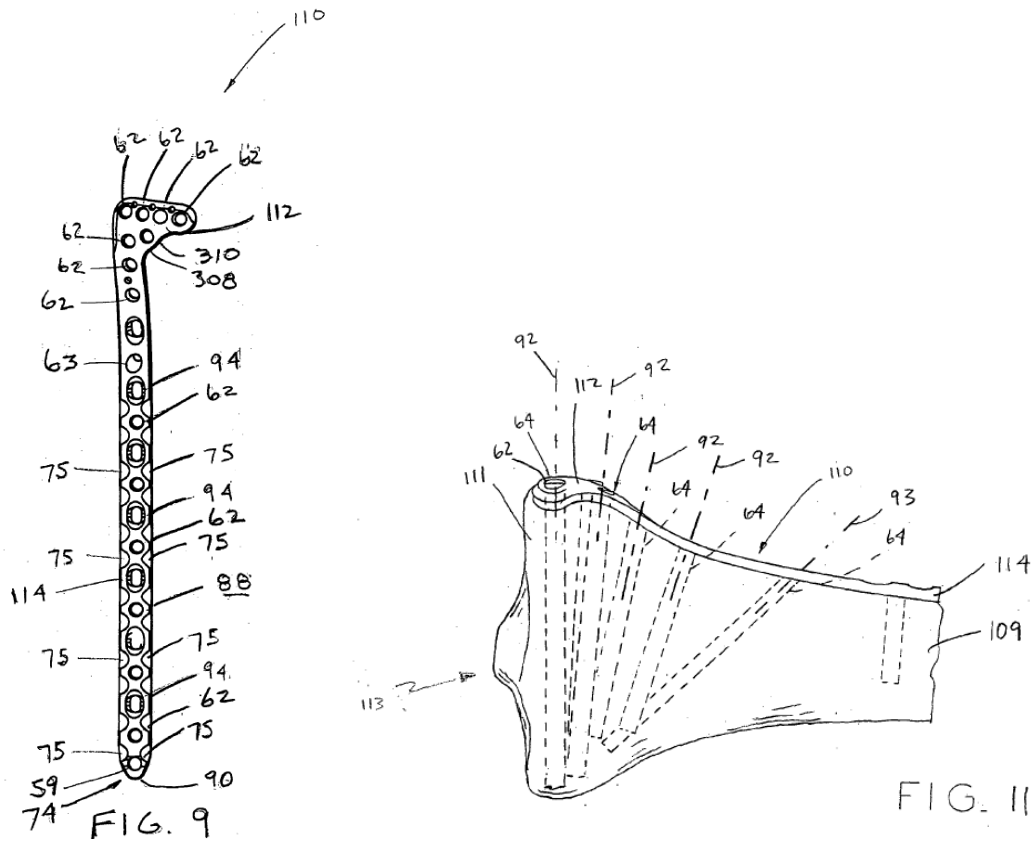
We provide an overview of Forstein below, we then discuss the asserted prior-art status of Forstein, and then turn to analysis of the alleged anticipation of claim 12.

¹⁵ *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board (Final rule) referenced at Federal Register 83 Fed. Reg. 51,340 (Oct. 11, 2018), at 51,353 (“it also may not be necessary to determine the exact outer boundary of claim scope”).

1. Overview of Forstein (Exhibit 1006)

Forstein relates to periarticular bone plates designed for attachment to the metaphysis and diaphysis of a broken bone, such as a femur, tibia, fibula, or radius to stabilize the bone during healing, and to fixation systems that include a jig to guide bone plates into position. Ex. 1006 ¶ 66, Abstr.

Forstein describes, for example, a tibial bone plate, which is shown in some of Forstein's drawings. Ex. 1006, Figs. 9–11, ¶ 75.¹⁶ Figures 9 and 11 of Forstein are reproduced below.



Id. Fig. 9. Figure 9 is an elevational view of a proximal lateral tibial bone

¹⁶ Dr. Kowaleski testifies that Forstein's plate "is intended for the lateral proximal tibia of a human patient." Ex. 2022 ¶ 24; Ex. 1007, 159–177.

plate (110), and Figure 11 is a partial perspective view of Figure 9's plate positioned on the proximal lateral tibia. Ex. 1006 ¶¶ 31, 33. As shown in Figures 9 and 11, the bone plate includes a head (112) and shaft (114), which Forstein describes as, respectively, "contoured to match" the "proximal lateral tibial metaphysis, i.e., metaphysis **111** of tibia **113**" and the "diaphysis **109** of the tibia **113**." *Id.* ¶ 75.

The head of Forstein's tibial bone plate includes screw holes (62), having screw holes axes (92). Ex. 1006 Fig. 11, ¶ 75. According to Forstein, "[a]s illustrated in **FIG. 11**, axes **92** of screw holes converge in tibia **113**." *Id.* ¶ 75 ("In at least one embodiment, axes **92** of screw holes **62** in the head of a bone plate are non-parallel."); *see also id.* ¶ 77 and Figs. 14–15 (describing a "distal radial dorsal T-plate" having a "converging screw pattern"), ¶ 80 and Fig. 19 (describing a "distal radial volar medial column" bone plate in which the axes of the screw paths "substantially diverge with respect to each other" in the bone (i.e., radius)).

Forstein discloses that, in embodiments of the bone plates, threaded screw holes and screws may be used. *See, e.g.*, Ex. 1006 ¶ 73. According to Forstein, "[o]wing to the threaded engagement of screws **64** and threaded holes, the orientations of screws relative to the bone plate . . . are fixed along axes **92**." *Id.* In other words, "the orientation of threaded head **67** is controlled by the orientation of conical wall **63** and threads **66**," such that "the surgeon cannot change the orientation of screws **64**." *Id.*; *see also id.* Fig. 6 (perspective view of a distal lateral femoral plate attached to the femur, and depicting structures 63, 66, and 67).

Separately, Forstein discloses that, "[r]egardless of whether axes . . .

of screw holes converge in the bone or diverge, the length and/or trajectory of screws . . . are selected such that the screws do not penetrate into the articular surfaces of the joint.” Ex. 1006 ¶ 81. In some embodiments, Forstein teaches, the axes of the screws are substantially parallel to each other and/or to the articular surfaces of the joint, and “the screws can extend through the bone plate all the way across the bone, sometimes to the far bone cortex.” *Id.* Moreover, Forstein teaches, “[a]dvantageously substantially parallel screws extending through the bone plate head can support the metaphysis of a bone such as, for example, the tibial plateau.” *Id.*

2. Prior Art Status of Forstein

Petitioner contends that Forstein has “an effective filing date of October 7, 2004, which is prior to the filing date of the ’921 patent.” Pet. 2; *see also id.* at 2 n.2 (asserting that “[a]t least one claim of Forstein is supported by” the Forstein Provisional, and for that reason “along with its overlapping disclosures,” Forstein is entitled to the filing date of the Forstein Provisional).

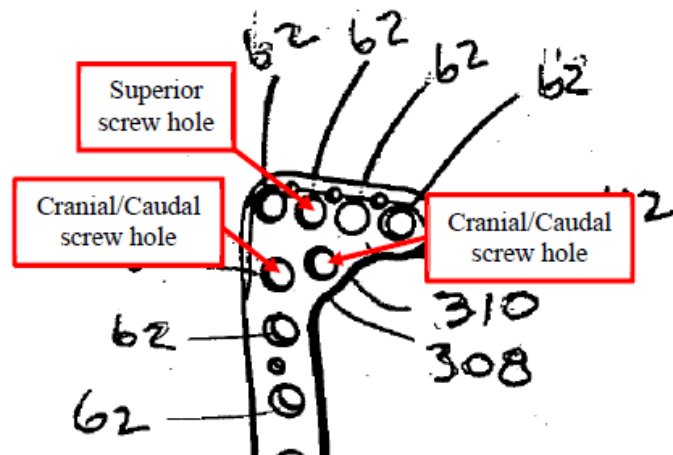
Patent Owner disagrees, arguing that Petitioner has not met its burden of showing that Forstein is prior art as of the Forstein Provisional’s filing date. *See, e.g.,* Prelim. Resp. 19–35. Patent Owner also asserts that it has produced evidence (in the related district court proceedings and here) showing that the claimed invention was reduced to practice before Forstein was filed (Oct. 6, 2005). *Id.* at 35–42. So, Patent Owner argues, the Board should deny institution based on a failure of Petitioner to establish that Forstein’s effective date is the provisional application filing date, and in view of the unrebutted evidence related to the alleged earlier reduction to

practice of the claimed subject matter. *Id.*; *see also* Paper 14, 2–4.

For the reasons discussed below, we conclude that Petitioner has not met its burden to show a reasonable likelihood of prevailing on the grounds raised in this Petition, even if Forstein is assumed to be prior art as of October 7, 2004—the filing date of the Forstein Provisional. We need not, accordingly, decide the issue of whether institution should be denied based on the alleged failure of the Petition to: (i) establish sufficiently Forstein’s entitlement to the provisional application filing date; or (ii) address evidence allegedly showing a reduction to practice date for the claimed subject matter that is “no later than August 11, 2005.” Prelim. Resp. 41.

3. Analysis of Alleged Anticipation

Petitioner argues that claim 12 is anticipated by Forstein and, in particular, cites the proximal lateral tibial bone plate described and shown in Forstein’s Figures 9–11. Pet. 25–32. Petitioner provides, for example, the following partial view of Forstein’s Figure 9, with Petitioner’s annotations:



Id. at 25, 31; *see also* Ex. 1006, Fig. 9. The above annotated image shows an upper or “proximal” head portion of Forstein’s lateral proximal tibial

plate. See Pet. 25, 31. Forstein does not describe its screw holes as being “superior,” “cranial,” or “caudal” but Petitioner, considering those terms “arbitrary” has annotated the screw holes in the head of Forstein’s plate accordingly as shown above. *Id.*

As for claim 12’s preamble, Petitioner reiterates its position that the preamble language is not limiting. Pet. 28; *see supra* Section II(C)(1). Also, Petitioner asserts that “Forstein discloses a bone place [sic] capable” of satisfying the preamble. Pet. 30; *see also id.* at 28 (citing the examiner’s assertion in prosecution of the ’792 Application); Ex. 1004, 207.

Turning to claim 12’s limitations related to the “distal portion” of the bone plate and the “proximal portion” with the particular screw holes (which limitations Petitioner labels 12[A], [B], and [C]), Petitioner contends those limitations are described in Forstein—again referencing Forstein’s Figure 9 with annotations as shown above. Pet. 25–26, 30–31; *see also id.* at 30–31 (annotations to a shaft of Forstein’s plate as allegedly showing a “distal portion” with the claimed features in that part of the plate).

And, for claim 12’s limitations related to the “screw hole paths” being “predetermined and angled” to direct the screws “away from” the articular surface, the osteotomy surface, and the edges of the tibia “and into a central mass of the tibia,” (labeled limitation 12[D] by Petitioner), Petitioner argues this limitation is met by the angled hole paths of Forstein’s lateral tibial plate embodiment. Pet. 27, 32 (citing, for example, Ex. 1006, Fig. 11).

According to Petitioner, “[a]ll 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 27. Petitioner argues, it was “well-known” with prior art plates

“to produce a particular angulation relative to the surface of the bone the plate is designed to attach to” (like shown in Forstein’s Fig. 9). *Id.* Indeed, Petitioner contends, Forstein discloses that the trajectory of the screws should be selected such that the screws do not penetrate into the joint’s articular surfaces. *Id.* (citing Ex. 1006 ¶ 81). Petitioner contends, moreover, that the ordinarily skilled person “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.” Pet. 27 (citing Ex. 1005 ¶¶ 18, 38, 41, 55–58).

On this record, we are unpersuaded Petitioner has established a reasonable likelihood of prevailing on its assertion that claim 12 is anticipated by Forstein.

First, Petitioner has not made a sufficient evidentiary showing that Forstein’s bone plate meets the preamble language of claim 12, which we consider to be limiting as discussed above. From Petitioner’s flawed claim construction position comes Petitioner’s flawed anticipation analysis. Petitioner simply declares that Forstein’s bone plate is “capable” of use in TPLO.¹⁷ But we find no evidence on this record that adequately supports

¹⁷ An examiner’s statement on the “capability” of Forstein’s plates in a related prosecution is not the Office’s final position on the issue. Indeed, as explained above, the examiner’s rejection has been appealed to the Board. Ex. 1004, 392. In any event, the examiner’s belief about the capability of Forstein’s plates may be appropriate in the context of examination as a burden-shifting mechanism given the limitations in the Office’s ability to

Petitioner's assertion. Forstein does not describe TPLO plates or suggest any use of its plates in such a procedure. To the contrary, Forstein's plates appear to be designed for the human anatomy and correcting fractures of human bones. *See supra* Section II(D)(1); *see, e.g.*, Ex. 2022 ¶ 24. Even assuming human bone plates might somehow be modifiable for use with, for example, a dog's anatomy, that does not demonstrate that Forstein's cited human proximal lateral tibial bone plate anticipates claim 12. Using a canine as the exemplary patient, TPLO involves a surgical procedure and implantation of the plate on the canine's cut and rotated *medial* proximal tibia. Ex. 1001, Figs. 13–14; Ex. 1005 ¶ 17; Ex. 2022 ¶ 18; Ex. 1014, 430–433. Petitioner does not persuade us that a bone plate designed and contoured for placement at the proximal lateral tibia of a human, as with Forstein's Figure 9 plate, is designed for or capable of implantation on the opposite, medial side of the canine's tibia after that bone has been cut and shifted by about 20–30° incident to TPLO. Ex. 1006, Fig. 11, ¶ 75; Ex. 1001, 1:35–39. Neither of Petitioner's declarants address here, at least

itself test for capabilities or functionalities. *See, e.g., Schreiber*, 128 F.3d at 1478 (holding that the Office “possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on”) (quoting *Swinehart*, 439 F.2d at 213); *see also In re Best*, 562 F.2d 1252, 1254–55 (CCPA 1977) (same and noting “the PTO's inability to manufacture products or to obtain and compare prior art products”). Such burden shifting is not justified here in contested *inter partes* review proceedings. *Harmonic*, 815 F.3d at 1363 (explaining Petitioner's “burden from the onset” to make its case with particularity). Patent Owner does not have to disprove Petitioner's conclusory assertions about the “capability” of the asserted prior art.

not clearly and directly, whether Forstein’s cited plates necessarily have this capability. And, for such reasons, Petitioner’s anticipation challenge fails on this record.

Second, the Petition does not make a sufficient evidentiary showing that other claim limitations are expressly or inherently described in Forstein. As Patent Owner highlights, for certain features of what Petitioner has described as element 12[D], Petitioner invokes what the ordinarily skilled person allegedly “would have known” or would have been “desirable” about the prior art. Prelim. Resp. 51–52 (emphasis omitted). Petitioner cites an express teaching in Forstein about directing the screw hole paths and screws away from a joint’s articular surface. *See, e.g.*, Pet. 27. But, as Patent Owner notes, “this is only one part of element 12[D].” Prelim. Resp. 52. Petitioner does not persuade us on this record that Forstein expressly or inherently teaches other parameters required with the screw hole paths recited in claim 12—that the screw holes are angled and directed away from an osteotomy surface and the edges of the tibia and into a central mass of the tibia. In part, this too turns on the fact that the Petition does not show with any specificity how Forstein’s cited plate would be implanted as part of a TPLO on a four-legged patient, such as a dog. We cannot assume that whatever screw hole angulation is described for Forstein’s proximal lateral tibial plate would be equally suitable for, and meet all of the relevant claim limitations here as specific to, a plate designed for TPLO.

For the reasons discussed above, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that claim 12 is unpatentable as anticipated by Forstein.

E. *Obviousness over Forstein*

Petitioner asserts that claims 12–14 would have been obvious over Forstein. Pet. 33–46.

Forstein is summarized above. *See supra* Section II(D)(1).

1. Analysis of Alleged Obviousness

Petitioner argues that “[t]o the extent any feature of claim 12 is not found in the tibial plate embodiment of Forstein . . . , it would have been obvious to a POSA to add the features from any of the other embodiments disclosed in Forstein.” Pet. 33. In support, Petitioner cites a distal lateral femoral bone plate (*see, e.g.*, Forstein’s Fig. 1), a distal radial dorsal delta bone plate (*see* Forstein’s Figs. 12–13), and a distal radial dorsal T-plate (Forstein Figs. 14–15). *Id.* at 33–34, 37–38; Ex. 1006, Figs. 1, 12–15.

This challenge suffers from many of the same problems noted above. Petitioner asserts, with respect to claim 12’s preamble, that “Forstein discloses a bone place [sic] for securing two tibial bone segments as part of a tibial leveling osteotomy procedure for an animal.” Pet. 36. But that is incorrect as discussed above. Forstein does not describe any suitability or use of its plates in four-legged animals, much less for TPLO. Here too, Petitioner fails to make a requisite evidentiary showing that Forstein’s cited plates meet the claim language and are capable of implantation in a TPLO procedure.

Petitioner’s argument about simply adding features from “any of the other” embodiments in Forstein fares no better in demonstrating that claim 12 is likely unpatentable. For one, this argument lacks the level detail required by our statute. *See* 35 U.S.C. 312(a)(3) (requiring that the petition

identify unpatentability grounds “with particularity”). Insofar as Petitioner identifies two or three other plates in Forstein, we are unpersuaded the skilled artisan would have turned to, and added features from, a plate designed for implantation on a human thigh bone or a plate designed for the bone in a human forearm and used those plates or features from them to create a modified tibial plate designed for TPLO on, for example, a dog. At best, this is hindsight. Also, we agree with Patent Owner that the Petition “does not even attempt to address the differences between the human tibia, the human femur, and the human radius, let alone explain how a POSA would modify a tibial bone plate in view of plates designed for those very different bones and joints.” Prelim. Resp. 53–54. Although an obviousness inquiry is a flexible one, it requires a more reasoned and evidence-backed analysis than set forth here. *Cf. In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (“[W]here a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.”). Prior art should not be treated as a grab bag into which the ordinarily skilled person plunges their hand until something is plucked out that might work. In any event, adding features from Forstein’s other cited embodiments still fails to deal with a key problem with the present challenge—the Petition does not provide evidence to *show* that a plate, so modified, is capable of TPLO implantation.

The vague and under-developed assertion about it being “well known to a POSA to use a bone plate . . . as part of a TPLO procedure in a canine subject” does not explain with particularity what further modifications (if any) are proposed for the plates of Forstein, why those modifications would

be made, and why the ordinarily skilled artisan would have a reasonable expectation of success in arriving at the claimed subject matter as a result. Pet. 36. “[T]o have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365 (Fed. Cir. 2007) (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006)). Indeed, Petitioner’s analysis does not even make passing mention to any reasonable expectation of success in achieving the invention of claim 12 with Forstein’s plates (through adding features or otherwise), thus sidestepping an important legal hurdle that its challenge must, but has not, overcome. *In re Stepan Company*, 868 F.3d 1342, 1347 (Fed. Cir. 2017) (reversing a determination of obviousness that did not “articulate why a person of ordinary skill would have had a reasonable expectation of success to formulate” the system claimed).

Petitioner contends it was known to angle screws away from the articular surface of a joint. The evidence supports Petitioner on that point. *See, e.g.*, Pet. 34–35. As to “predetermined and angled” screw hole paths with *all* the features recited in claim 12 being obvious over the asserted prior art, however, Petitioner’s evidence is too thin. Dr. Peck opines that it was “well known” and “best practice” to avoid screw impingement of the osteotomy surface and the edges of the tibia. Ex. 1005 ¶ 55.¹⁸ But despite

¹⁸ Dr. Peck opines “it was also well known that screw impingement of the edge of the osteotomy surface because it is a well-known best practice”

such angulation allegedly being “best practice,” the Petition and Dr. Peck do not specifically cite prior art or other documentary support actually describing screw placement or angulation as such. To the extent Petitioner contends it would have been obvious to modify Forstein’s cited plates with the exact screw hole pattern and angulation for TPLO that is claimed, we conclude that Petitioner’s contentions are, on balance, rooted in hindsight, and we find them unpersuasive on this record.

For the reasons explained above, we determine the Petition has not established a reasonable likelihood that Petitioner would prevail in showing that claim 12 is unpatentable as obvious over Forstein.

Because the challenge to dependent claims 13 and 14 depends on Petitioner first establishing that independent claim 12 would have been obvious over Forstein, and Petitioner’s arguments for the dependent claims do not compensate for the deficiencies noted above as to claim 12, there is also not a reasonable likelihood that Petitioner would prevail in establishing the challenged dependent claims are unpatentable under 35 U.S.C. § 103. Pet. 39–46.

F. *Obviousness over Young in view of Forstein*

Petitioner asserts that claims 12–14 would have been obvious over the combination of Young and Forstein. Pet. 46–55.

Ex. 1005 ¶ 55. The referenced sentence seems to be missing some language, and we assume Dr. Peck intended to say screw impingement at that location was “to be avoided” or similar wording.

Forstein is summarized above. *See supra* Section II(D)(1)–(2). An overview of Young is below, followed by our analysis of the alleged obviousness of the challenged claims.

1. Overview of Young (Exhibit 1008)

Young describes a bone plate of “complex form” that is “particularly suited to tibial plateau-leveling osteotomy.” *See, e.g.*, Ex. 1008 ¶ 19; *see also id.* Figs. 1a and 1b. Young’s Figure 1a is reproduced below.

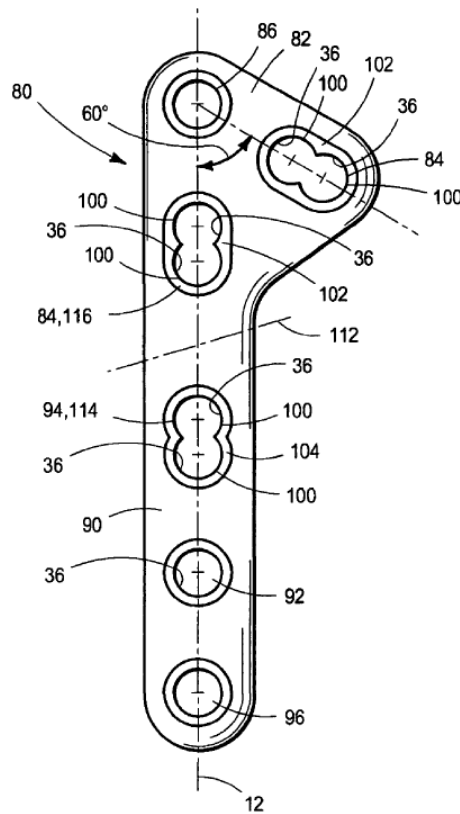


FIG. 1a

Id. Fig. 1a. Young’s Figure 1a is a top view of a TPLO bone plate. *Id.* ¶ 30. Young teaches that “plate **80** has a flat triangular head **82** in which three spaced-apart apertures **84** and **86** are formed,” and an “elongated lower

portion **90** in which are located a plurality of apertures **92, 94** and **96.**” *Id.*

¶ 32. According to Young, the plate’s “top side” (16) includes at least two sets of overlapping holes (100) that “define threaded apertures having multi-faceted surfaces **36.**” *Id.* ¶ 30.

In an embodiment, Young teaches that the bone plate includes a single screw hole having an axis angled at 25° from perpendicular. Ex. 1008 ¶ 39, Fig. 4b. This embodiment is shown in the bottom perspective view below.

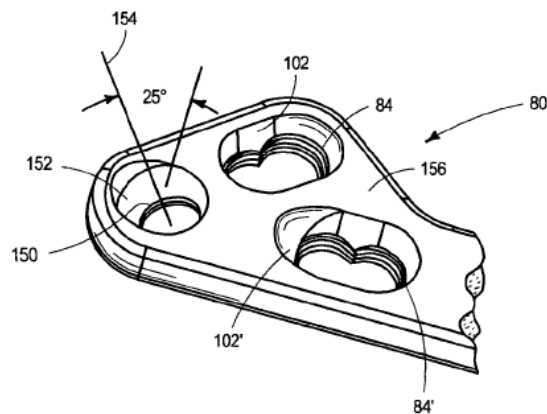


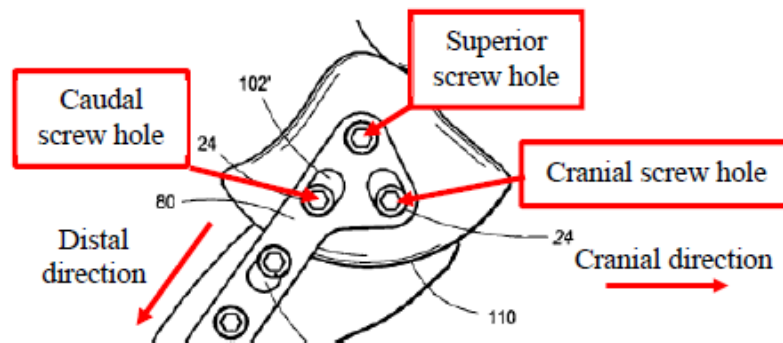
FIG. 4b

Id. Fig. 4b. Young’s Fig. 4b depicts a partial view of the bone plate (80') that includes “round hole **150** having a countersink **152** whose axis **154** is angled off of perpendicular from the top surface **156.**” *Id.* ¶ 39. According to Young, “[t]he angle from perpendicular is preferably 25 degrees as this angulation generally matches the amount which the plate . . . is contoured in situ,” and “allows screw placement that is parallel to the adjacent bone surface.” *Id.*

2. Analysis of Alleged Obviousness

Petitioner argues that claim 12 (and dependent claims 13 and 14) would have been obvious over Young in view of Forstein. Pet. 46–55.

More specifically, Petitioner cites Young's teaching of a bone plate suited for TPLO with "three screw holes formed in the triangular head of Young, [that] when the bone plate is implanted, form a triangular pattern with" superior, cranial, and caudal screw holes. *Id.* at 46–47. To illustrate its contentions, Petitioner provides the annotated drawing below.



Id. at 47, 52 (Petitioner's annotated, partial version of Ex. 1008, Fig. 1b). As shown in the figure above, Petitioner has labeled the uppermost aperture as the superior screw hole, and the two lower apertures on the head portion as the caudal and cranial screw holes. *Id.* at 47; *see also* Ex. 1008 ¶ 32 (Young describes various of the apertures (e.g., which Petitioner has labeled here as caudal and cranial screw holes) as comprising overlapping holes having elongated or overlapping chamfers); *see id.* at Fig. 1a and Fig. 4b (for greater clarity of these structures, e.g., 84, 94, 100, 102, 104).

As Petitioner notes, Young discloses an embodiment in which the uppermost aperture or screw hole in the flat triangular head includes a countersink to angle the axis of the screw off perpendicular and, thus, "allows screw placement [at that position] that is parallel to the adjacent bone surface." Pet. 47; Ex. 1008 ¶ 39 ("this angulation generally matches the amount which the plate . . . is contoured in situ . . . and allows screw

placement that is parallel to the adjacent bone surface”), Fig. 4b. Because “Young does not teach that all three of the screw holes in the head are angled,” Petitioner turns to Forstein, arguing it would have been obvious to modify Young to “include predetermined, angled axes to the three screw holes.” Pet. 47–49. According to Petitioner, “[a] POSA would have been motivated to combine Young and Forstein to utilize well-known advantages of fixed screw angulation known in the art.” *Id.* at 49–50, 53–54.

For three reasons, we are unpersuaded that Petitioner has shown a reasonable likelihood of prevailing on its assertion that claim 12 would have been obvious over Young and Forstein.

First, as Patent Owner points out, it appears that the proposed change Petitioner is urging would be inconsistent with Young’s plates and stated objectives. Prelim. Resp. 55–56. Young discloses flat plates designed to be bent in situ (i.e., during the procedure) to interface with the underlying bone. Pet. 53; Prelim. Resp. 55; Ex. 1008 ¶¶ 32, 39. Young teaches that its plate design and screw holes should “provide[] greater flexibility and choice to the surgeon,” and that its plates were designed to provide “a bone plate that has multiple orientations for the locking screws and, thus, plate placement.” Ex. 1008 ¶¶ 14–15, 31 (allowing the configuration of the bone plate to “vary, depending on the physiology of the patient.”).

To the extent Petitioner has invoked Forstein’s teachings of pre-contoured plates that do not require bending during the procedure, and further Forstein’s screw hole paths that are fixed so that “the surgeon cannot change the orientation of the screws” (*see, e.g.*, Ex. 1006 ¶ 73), the Petition fails to reconcile the inconsistent structural features and objectives of the

Young and Forstein plates. Indeed, Petitioner does not persuasively explain why the ordinary artisan would, absent hindsight, have made the proposed changes to Young's plates in spite of the inconsistencies.¹⁹ Pet. 46–54; Prelim. Resp. 56 (citing *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 759 (Fed. Cir. 2015) (“[A] change in a reference's ‘principle of operation’ is unlikely to motivate a person of ordinary skill to pursue a combination with that reference.”)); see also *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984); *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959).

Second, if Petitioner is proposing the ordinarily skilled person would not modify Young's plates with Forstein's contour features but would, instead, add only the fixed screw paths described in Forstein, that raises another problem with the challenge. Pet. 53–54. We are unpersuaded on this record that adding fixed, angular screw paths to a flat plate designed and intended to be bent in situ for proper TPLO implantation on the underlying bone (as Young's plates are) would satisfy the requirement for the three screw hole paths that “are predetermined and angled” in the manner claimed. In that sense, the path and angle of the screw holes would be determined by the surgeon's bending and manipulation of the plate during the TPLO, not “**predetermined**” as recited in claim 12.²⁰ The patent describes such “pre-

¹⁹ We further find that the fact that Young induces an angle to only *one*, and not multiple, of the proximal apertures in a TPLO plate cuts against the obviousness argued by Petitioner. See *supra* Section II(F)(1); Ex. 1008, Fig. 4b, ¶ 39.

²⁰ Insofar as this is a claim construction issue, Petitioner does not address it in detail in the Petition. Petitioner simply declares that “predetermined and

determined” paths as being created by machining the screw holes through an already contoured plate, thereby providing the targeted path (and angles) desired. *See, e.g.*, Ex. 1001, 2:18–21. It does not describe providing desired or predetermined screw hole paths by virtue of the surgeon’s bending of an otherwise flat plate during TPLO. In fact, bending of the plates is something the ’921 patent cites as a problem to avoid. *See, e.g., id.* at 1:50–51 (“bending of the plate during the procedure can result in the screw holes becoming deformed”).

Third, here too, the Petition does not provide a sufficient showing of a reasonable expectation of success in arriving at the claimed subject matter. The Petition’s assertion, on this record, that “combining these references [i.e., Young and Forstein] would therefore yield predictable benefits and results” does not constitute a robust or persuasive analysis on the issue. Pet. 49–50; *Stepan*, 868 F.3d at 1347.

For the reasons above, we determine the Petition has not established a reasonable likelihood that Petitioner would prevail in showing that claim 12 is unpatentable as obvious over Young in view of Forstein.

Because the challenge to dependent claims 13 and 14 depends on Petitioner first establishing that independent claim 12 would have been obvious over Young and Forstein, and Petitioner’s arguments for the dependent claims do not compensate for the deficiencies noted above as to

angled” “merely require[s] the screw axes to be fixed and converge into proximal tibial fragment created by the osteotomy.” Pet. 49 (citing Ex. 1005 ¶ 56). The cited paragraph does not, however, even address this claim language, let alone provide a persuasive claim construction analysis.

claim 12, there is also not a reasonable likelihood that Petitioner would prevail in establishing the challenged dependent claims are unpatentable under 35 U.S.C. § 103. Pet. 54–55.

G. Obviousness over Wack in view of Forstein

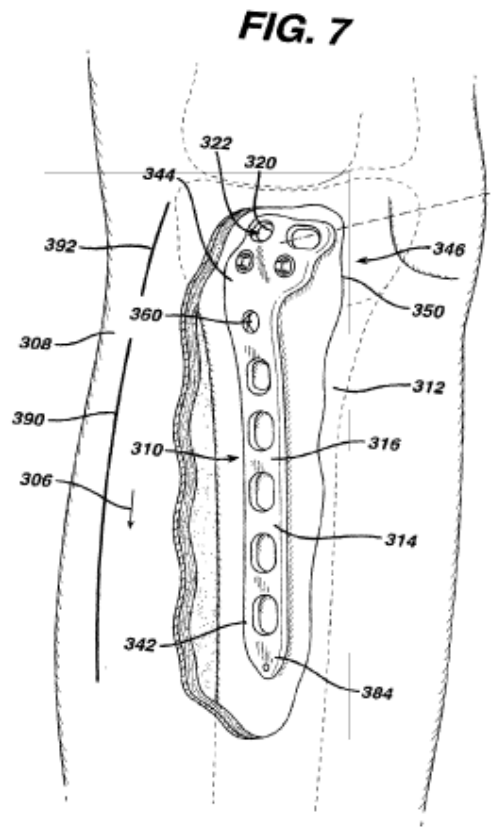
Petitioner asserts that claims 12–14 would have been obvious over the combination of Wack and Forstein. Pet. 55–61.

Forstein is summarized above. *See supra* Section II(D)(1)–(2). An overview of Wack is below, followed by our analysis of the alleged obviousness of the challenged claims.

1. Overview of Wack (Exhibit 1009)

Wack relates to a polyaxial locking plate for repairing fractured bones. Ex. 1009, Abstr., ¶ 2. Wack teaches “a bone locking plate that includes an adjustable attachment component.” *Id.* ¶ 2. More specifically, the bone locking plate “includes an attachment component whose angle relative to the locking plate may be manipulated during surgery so that an accompanying screw extends into the bone in a desirable orientation.” *Id.*

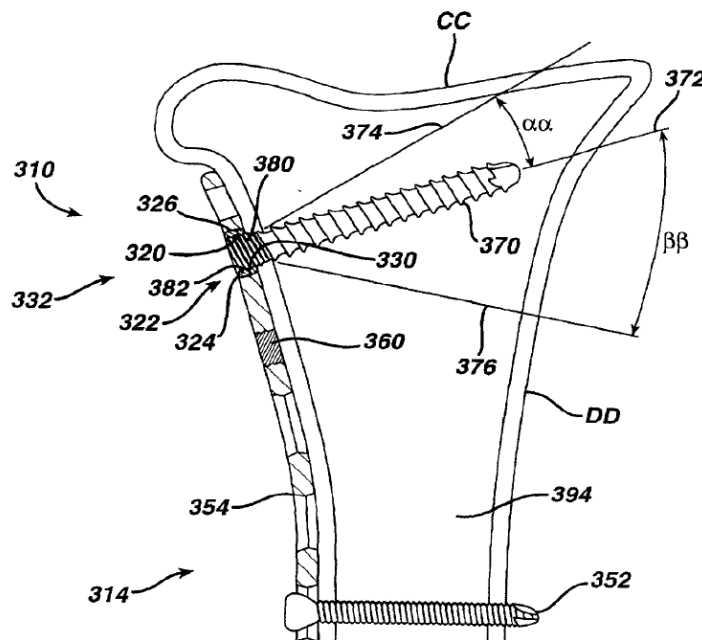
Wack describes, for example, human tibial and femoral bone plates. *See, e.g.*, Ex. 1009 ¶¶ 56–57, 75–76. Wack’s proximal lateral tibia plate is shown in Figure 7, reproduced below.



Id. Fig. 7; *see also id.* at Figs. 8–9 (other views of the plate). Figure 7 depicts lateral tibia plate (314) superimposed over the tibia (312) in a human leg (308). *Id.* ¶ 77. The plate includes, among other features, body portion (316), and a proximal portion (344) with multiple plate holes (322). *Id.* ¶ 80. Wack teaches that “proximal portion 344 of the tibia plate 314 is designed to follow the general contours of the lateral proximal tibia.” *Id.* ¶ 75.

Figure 9 of Wack is reproduced (partial) below, and depicts a cross-sectional view of the lateral tibia plate from Figure 7. Ex. 1009 ¶¶ 25, 27. Figure 9 better illustrates the polyaxial, multi-orientation, attachment features of Wack discussed above.

FIG. 9



Ex. 1009, Fig. 9 (partial). Figure 9 shows a screw (370) inserted through plate hole (322) and passageway (332) into a proximal tibial bone segment. *Id.* ¶¶ 81–82. Wack teaches that the plate includes one or more bushings (324) having an exterior surface (326) that cooperates with the interior wall (320) of the plate “to permit polyaxial rotation of the bushing 324 within the plate hole 322.” *Id.* ¶ 81. These features allow screw (370) to be set as desired at various orientations as depicted in Figure 9 by, for example, path (372) and angles “ββ” or “αα.” *Id.* ¶ 82. Wack describes several advantages of including these polyaxial features in the bone plate. *See, e.g., id.* ¶ 88 (noting “the ability to position divergently to the secure the fracture of the bone most efficiently” and “bone fragments may be reached by orienting the attachment component relative to the plate in such a direction to reach various bone fragments”).

2. Analysis of Alleged Obviousness

Petitioner argues that Wack discloses all of the elements of claim 12, except for a part of element 12[D]. Pet. 56. According to Petitioner, the limitation 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.” *Id.* (citing Ex. 1002, 440).

Petitioner argues that this missing element, however, is taught in Forstein. Pet. 56–57, 60. Petitioner contends, the same motivations (e.g., “to create bone plates that angle away from the articular surface of the tibiofemoral joint”) advanced for its other challenges would have prompted the ordinarily skilled artisan to modify Wack with Forstein’s alleged predetermined and angled screw paths. *Id.*

Petitioner’s challenge to claim 12 over Wack and Forstein fails for similar reasons to those discussed for the other grounds. We explain below.

At the outset, we note that the Board’s conclusion during prosecution that a particular limitation was missing in Wack is not the same thing as the Board finding that *all the other claim limitations are disclosed* in Wack—contrary to what Petitioner’s argument implies. To the extent involved during prosecution, the Board generally plays an appellate role. And, if the Board agrees that even one limitation is missing in the art, as was the case here based on the arguments made, that can be a sufficient reason to reverse the appealed rejection. Ex. 1002, 440. In such circumstances, the Board routinely does not identify *each and every* claim element that, were it sitting as fact-finder, the Board might determine is absent in the prior art.

As with Petitioner's challenge based on Forstein, the Petition fails to demonstrate that the bone plate of Wack, modified by Forstein, would meet claim 12's preamble language and be capable of TPLO implantation. Petitioner tells us this capability exists, but does not show it with sufficient evidence. *See, e.g.*, Pet. 57. Petitioner does not demonstrate that Wack's human lateral tibia plate, contoured for the human anatomy, would be capable of use on a canine's proximal medial tibia, after the proximal portion of that tibia is cut and rotated 20–30° in TPLO. And, as before, Petitioner's vague invocation of it being “well known . . . to use a bone plate for securing two tibial bone segments as part of a TPLO procedure in a canine subject” cannot save the challenge. *Id.* at 57. Of course, TPLO plates were known. *See, e.g.*, Ex. 1008 *passim*. But what has not been shown by Petitioner is how and why the modified Wack plate is designed for TPLO (nor what specific further modifications would make it so). *Shopkick, Inc. v. Novitaz, Inc.*, IPR2015-00279, Paper 7 at 26–30 (PTAB May 29, 2015) (noting, in denying institution, that “conclusory labels do not substitute for a fact-based analysis . . . establishing what is being modified and why”); Prelim. Resp. 57 (Petitioner “fails to address why a POSA would have combined features of two human bone plates to address concerns that were only relevant to a surgical procedure for an animal's stifle joint.”).

In addition, as with other of Petitioner's grounds, Petitioner does not persuasively address the apparent incompatibilities between Wack and Forstein. The purpose of Wack's bone plate and invention is aimed at having *adjustable* attachment components—the bushing and screw hole arrangement that permits *polyaxial rotation* and setting of the screw in the

bone at any desirable orientation. See *supra* Section II(G)(1); see, e.g., Ex. 1009, Fig. 9, ¶ 2 (“[T]he present invention relates to a bone locking plate that includes an attachment component whose angle relative to the locking plate may be manipulated during surgery so that an accompanying screw extends into the bone in a desirable orientation.”). Yet Petitioner’s proposed modification jettisons the features and principle of operation of Wack’s plates in favor of Forstein’s *fixed*-angle screw holes. See, e.g., Ex. 1006 ¶ 73 (“the surgeon cannot change the orientation of the screws”). Petitioner does not provide a sufficient, persuasive rationale to support the conclusion that the ordinarily skilled person, without hindsight, would have modified Wack in this way. *Gordon*, 733 F.2d at 902 (reversing obviousness determination where the proposed modification would render the modified prior art unsuitable for its intended purpose).

And finally, here again, Petitioner provides neither adequate evidence nor analysis to demonstrate that the ordinarily skilled person would have modified Wack in view of Forstein in the manner proposed with a reasonable expectation of success in arriving at claim 12’s subject matter. Generic assertions about applying the teachings of human or general orthopedic plates to veterinary applications do not suffice. Pet. 55–56.

For the reasons above, we determine the Petition has not established a reasonable likelihood that Petitioner would prevail in showing that claim 12 is unpatentable as obvious over Wack in view of Forstein.

Because the challenge to dependent claims 13 and 14 depends on Petitioner first establishing that independent claim 12 would have been obvious over Wack and Forstein, and Petitioner’s arguments for the

dependent claims do not compensate for the deficiencies noted above as to claim 12, there is also not a reasonable likelihood that Petitioner would prevail in establishing the challenged dependent claims are unpatentable under 35 U.S.C. § 103. Pet. 61.

H. *Other*

Patent Owner contends that there are other bases on which the Board should deny institution, even without needing to reach the merits of Petitioner's grounds. Prelim. Resp. 15–45. Patent Owner urges denial of institution because it contends Petitioner fails to comply with 37 C.F.R. § 42.104(b)(3)–(4). *Id.* at 15–19; Paper 14, 1–2. Patent Owner further argues the Petition neither establishes that Forstein is prior art nor addresses Patent Owner's evidence on an earlier reduction to practice as discussed above. *See supra* Section II(D)(2); Prelim. Resp. 19–42; Paper 14, 2–4. And, Patent Owner cites a host of reasons that it contends justify the Board denying the Petition on a “discretionary” basis. Those reasons include, *inter alia*, (i) an alleged failure of the Petitioner to reveal and address objective indicia of nonobviousness, and (ii) overlap with issues pending before the district court leading to a waste of Board resources. Prelim. Resp. 42–45 (although Patent Owner cites to overlap of issues, Patent Owner also contends the Board cannot provide a full resolution like the district court (e.g., on the alleged invalidity of the claims for indefiniteness)); Paper 14, 5.

Because we have considered the merits of Petitioner's challenge, yet nonetheless found Petitioner has not met its burden to proceed with institution of trial as explained above, we need not decide whether these

“other” reasons offered by Patent Owner warrant declining institution.

III. CONCLUSION

On this record, for the reasons provided above, Petitioner has not established a reasonable likelihood of prevailing on its assertion that at least one of the challenged claims is unpatentable based on the grounds advanced.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and we do not institute *inter partes* review of any claim of the '921 patent based on the grounds asserted in this Petition.

IPR2019-01332
Patent 8,523,921 B2

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