UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,

Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,

Patent Owner

Case: IPR2019-00895

U.S. Patent No. 9,259,252

PATENT OWNER'S NOTICE OF APPEAL

To: Office of the General Counsel
U.S. Patent and Trademark Office
Madison East 10B20
600 Dulany Street
Alexandria, Virginia 22314

Pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. §§90.2 and 90.3, Patent Owner, Wright Medical Technology, Inc., hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board ("Board") entered September 23, 2020 (Paper 44) and from all underlying orders, decisions, rulings, and opinions adverse to Patent Owner regarding U.S. Patent 9,259,252 ("the '252 Patent") at issue in *inter partes* review IPR2019-00895.

Pursuant to 37 C.F.R. § 90.2(a)(3)(ii) Patent Owner indicates that the expected issues on appeal may include, but are not limited to:

1. Whether the Board erred in finding Patent Publication No. 2006/0173459 ("Kay") is prior art to Claims 17-27 of the '252 Patent and any finding or determination supporting or related to this issue.

2. Whether the Board erred in finding the Petitioner met its burden to show unpatentability by a preponderance of the evidence that Claims 17-21 and 23-27 of the '252 Patent would have been obvious under 35 U.S. C. §103 over Patent No. 6,283,969 ("Grusin") and further in view of Patent Publication No. 2005/0165400 ("Fernandez") and any finding or determination supporting or related to this issue;

3. Any issues decided adversely to Patent Owner in any orders, decisions, rulings and opinions.

Patent Owner has electronically filed this notice with the Patent Trial and Appeal Board, pursuant to 37 C.F.R. § 90.2(a)(1), 37 C.F.R. § 42.6(b)(1) and Federal Circuit Rule 15(a)(1).

Simultaneously herewith, Patent Owner is providing the Federal Circuit with a copy of the present Notice of Appeal (pursuant to 37 C.F.R. § 90.2(a)(2)(i) and Federal Circuit Rule 15(a)(1)) together with a $500 fee (pursuant to 37 C.F.R. § 90.2(a)(2)(ii) and Federal Circuit Rule 52(a)(3).

Respectfully submitted,

Dated: November 23, 2020

By: /D. Joseph English/
D. Joseph English
USPTO Reg. No. 42,514
Duane Morris LLP
505 9th Street NW, Suite 1000
Washington, D.C. 20004

ATTORNEY FOR PATENT OWNER

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on the 23rd day of November 2020, a complete and entire copy of this Patent Owner's Notice of Appeal was provided via the Patent Trial and Appeal Board End to End (PTAB E2E) System as well as filed with the Director of the United States Patent and Trademark Office by hand delivery, at the following address:

Office of the General Counsel
U.S. Patent and Trademark Office
Madison East 10B20
600 Dulany Street
Alexandria, Virginia 22313-1450

The undersigned also certifies that a true and correct copy of this Notice of Appeal and the required fee were electronically filed on November 23, 2020, with the Clerk of Court for the United States Court of Appeals for the Federal Circuit.

The undersigned also certifies that a true and correct copy of this Notice of Appeal was served on November 23, 2020 on counsel of record for Petitioner by electronic mail (by agreement of the parties) at the following addresses:

George Foster: billy.foster@kirkland.com
Gregory Polins: greg.polins@kirkland.com
Joel Merkin: jmerkin@kirkland.com

Respectfully submitted,

Dated: November 23, 2020

By: /D. Joseph English/
D. Joseph English
USPTO Reg. No. 42,514

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505 9th Street NW, Suite 1000
Washington, D.C. 20004

ATTORNEY FOR PATENT OWNER

Attachment A

Trials@uspto.gov
571-272-7822

Paper 44
Date: September 23, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2019-00895
Patent 9,259,252 B2

Before GEORGE R. HOSKINS, ROBERT A. POLLOCK, and RICHARD H. MARSCHALL, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Dismissing Patent Owner's Motion to Exclude
35 U.S.C. § 318(a); 37 C.F.R. § 42.64

I. INTRODUCTION

Paragon 28, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 17–27 of U.S. Patent No. 9,259,252 B2 (Ex. 1003, "the '252 patent").

Wright Medical Technology, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp.").

We instituted a trial to determine whether claims 17–27 are unpatentable, on all challenges presented in the Petition. Paper 15 ("Institution Decision" or "Inst. Dec."), 2, 6, 28.

Patent Owner filed a Patent Owner Response (Paper 21, "PO Resp.") to the Petition. Petitioner filed a Reply (Paper 29, "Reply" or "Pet. Reply") to the Patent Owner Response. Patent Owner filed a Sur-reply (Paper 33, "Sur-reply") to the Reply. Petitioner, with prior approval from the Board (*see* Paper 35), filed a Sur-sur-reply (Paper 40, "Sur-sur-reply") to the Sur-reply.

Patent Owner filed a Motion to Exclude Evidence (Paper 39). Petitioner filed an Opposition (Paper 41) to the Motion. Patent Owner filed a Reply (Paper 42). As discussed below, we dismiss the Motion as moot.

An oral hearing was held, for which the transcript was entered into the record (Paper 43, "Tr.").

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2018). This

Decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of claims 17–27 of the '252 patent.

We determine Petitioner has shown by a preponderance of the evidence that claims 17–27 are unpatentable.

II. BACKGROUND

A. Real Parties-in-Interest and Related Proceedings

Petitioner identifies itself as the sole real party-in-interest. Pet. 73. Patent Owner identifies itself as the sole real party-in-interest. Paper 7, 2.

The parties identify one U.S. District Court litigation as related to this proceeding: *Wright Medical Technology, Inc. v. Paragon 28, Inc.*, Case No. 18-cv-00691-PAB-STV (D. Colo.) ("the District Court Litigation"). Pet. 74; Paper 7, 2.

There are three related IPR proceedings. Pet. 74; Paper 7, 2; Paper 24, 1. The first is IPR2019-00894, challenging U.S. Patent No. 9,144,443 B2 ("the '443 patent"), to which the '252 patent asserts priority as a continuation. Ex. 1003, code (60); Ex. 1002, code (21). The second is IPR2019-00896, challenging U.S. Patent No. 9,545,278 B2 ("the '278 patent"), another continuation of the '443 patent. Ex. 1005, code (60). The third is IPR2019-00898, challenging U.S. Patent No. 9,259,253 B2, another continuation of the '443 patent. Ex. 1004, code (60).

B. The '252 Patent Disclosure

The '252 patent discloses "a series of orthopedic plates for use in repair of a bone" such as a clavicle. Ex. 1003, Abstract, 1:21–23, 2:17–19. Figure 8 of the '252 patent is reproduced here:

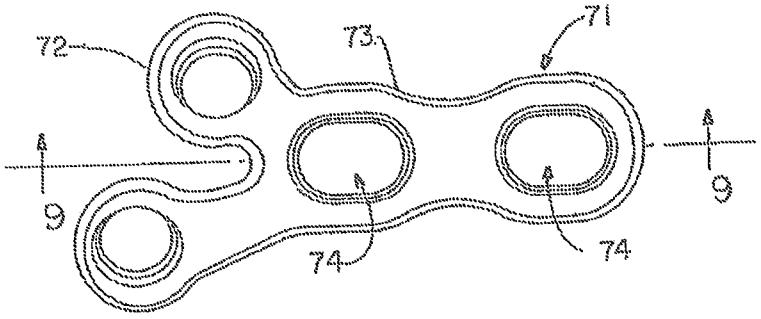

FIG.-8

'252 Patent Figure 8 (Ex. 1003).

Figure 8 illustrates orthopedic plate 71 having a Y-shaped profile, formed by central trunk portion 73 and a pair of arms 72 diverging asymmetrically from one end of central trunk portion 73. *Id.* at Abstract, 7:9–14, 8:56–63. Central trunk portion 73 includes two screw holes 74 to receive screws secured in bone underneath plate 71. *Id.* at 1:61–65, 6:43–45, 8:41–55, 8:62–63.

The pair of arms 72 includes a short arm and a long arm. *Id.* at 7:9–17, Fig. 8. The arms are configured so screws inserted into respective screw holes of the arms (not numbered in Figure 8) will not impinge on each other inside a bone underneath plate 71. *Id.* at 1:54–57, 3:55–66, 7:66–8:6.

The arm screw holes may be "locking" or "non-locking" screw holes. *Id.* at 3:41–44. Figures 6 and 7 of the '252 patent are reproduced here:

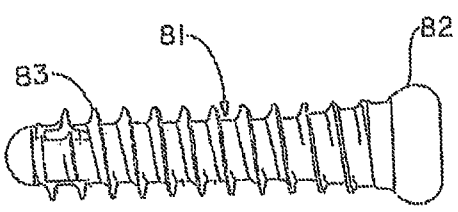

FIG.-6

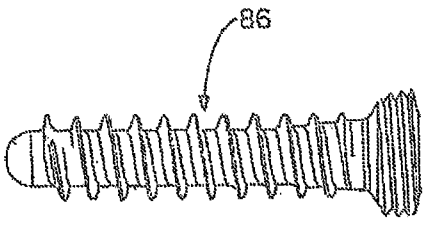

FIG.-7

'252 Patent Figures 6 and 7 (Ex. 1003).

Figure 6 illustrates screw 81 with head 82 that is devoid of threads, and Figure 7 illustrates "locking" screw 86 with a head that has threads. *Id.* at 8:41–55. The screw holes in arms 72 of plate 71 "preferably . . . can include internal threads which mate with external threads on the head of the screws to cause locking of the screws relative to the plate." *Id.* at 4:29–33.

Further according to the '252 patent: "Some surgeons prefer bicortical fixation in which a screw is sized so that the [distal] end is secured in cortical bone giving the screw better purchase, however, other surgeons may prefer to avoid placing a screw so that it projects beyond the outer surface of the anchoring bone." *Id.* at 1:61–65.

C. The '252 Patent Claims at Issue During Trial

The '252 patent lists twenty-seven claims. Ex. 1003, 11:45–14:40. Claim 17 is the sole independent claim challenged in the Petition, and it recites:

> 17. A method of conducting a surgery on a bone in a patient comprising the steps of:
>
> using a plate system on the bone, the plate system comprising a pre-contoured plate having an elongate trunk which extends along a longitudinal medial axis and at one end of the longitudinal medial axis only a first arm and a second arm which diverge from the end of the trunk asymmetrically relative to the other arm, and *the first arm and second arm each including at least one threaded screw hole*, and;
>
> *inserting a first locking screw* having a proximal end and a distal end *into the threaded screw hole of the first arm, and a second locking screw* having a proximal end and a distal end *into the threaded locking screw hole of the second arm* so that the proximal end of the first locking screw is locked in the threaded screw hole of the first arm and the proximal

> end of the second locking screw is locked in the threaded hole of the second arm and so that the distal ends of the first and the second locking screws converge toward each other but do not impinge and also *so that the distal end of the screw is secured in cortical bone.*

Id. at 13:18–39 (emphases added).

D. Tried Grounds of Unpatentability

Petitioner challenges claims 17–27 of the '252 patent on two grounds, as shown in this table. *See* Pet. 15–16.

Claims Challenged	35 U.S.C. §	References
17–27	103	Kay[1], Chan[2]
17–21, 23–27	103	Grusin[3], Fernandez[4]

E. Testimonial Evidence

The following table identifies the witnesses, their roles in this proceeding, and the exhibits in which their testimony is presented:

[1] Ex. 1006, U.S. Patent App. Pub. No. 2006/0173459 A1, pub. Aug. 3, 2006.

[2] Ex. 1007, U.S. Patent App. Pub. No. 2008/0140130 A1, pub. June 12, 2008.

[3] Ex. 1010, U.S. Patent No. 6,283,969 B1, iss. Sept. 4, 2001.

[4] Ex. 1011, U.S. Patent App. Pub. No. 2005/0165400 A1, pub. July 28, 2005.

Witness	Role	Exhibits
Javier E. Castañeda	Petitioner's engineering expert[5]	Ex. 1001 (declaration of Mar. 28, 2019). Ex. 2019 (transcript of deposition of Dec. 5, 2019). Ex. 1087 (declaration of Mar. 16, 2020). Ex. 2023 (transcript of deposition of Apr. 29, 2020).
Steven K. Neufeld, M.D.	Patent Owner's medical expert[6]	Ex. 2017 (declaration of Dec. 21, 2019). Ex. 1072 (transcript of deposition of Mar. 10, 2020).
Timothy P. Harrigan, Sc.D.	Patent Owner's engineering expert[7]	Ex. 2018 (declaration of Dec. 23, 2019). Ex. 1066 (transcript of deposition of Mar. 5, 2020).

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner has moved to exclude Petitioner's Exhibits 1057–1060, 1070, 1073–1075, 1081, 1086, and 1088 from evidence, citing several reasons grounded in the Federal Rules of Evidence. *See* Paper 39. We do not rely on any of these Exhibits in this Decision. Although we briefly refer to the substance of Exhibit 1086 in connection with the priority dispute, we ultimately do not reach the pin versus screw issue for which Petitioner cites Exhibit 1086. Petitioner offers Exhibit 1088 solely for the unremarkable proposition that the radius bone has a cortical bone portion, but that

[5] *See* Ex. 1001 ¶¶ 1, 3, 8.

[6] *See* Ex. 2017 ¶¶ 2, 6, 10, 12, 14, 16; Tr. 38:23–39:5.

[7] *See* Ex. 2018 ¶¶ 2, 7, 11, 17; Tr. 38:23–39:5.

proposition is also established by Exhibit 1084, which is not challenged. *See* Ex. 1087 ¶ 38 (discussing Ex. 1088); Ex. 1084 ¶¶ 34–35, 51 (Figs. 11–12 illustrate radius bone 400); *id.* ¶¶ 7–8, 21, 52 (Figs. 11–12 illustrate drill bit 260 extending through the cortical bone portion of radius bone 400). Therefore, we dismiss the motion as moot.

IV. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends a person having ordinary skill in the art pertaining to the '252 patent "would have had 2–3 years of experience in the design of orthopedic plates or 2–3 years of experience using orthopedic plates in surgery." Pet. 18; Ex. 1001 ¶¶ 28–29. Patent Owner "does not dispute Petitioner's definition of a person of ordinary skill in the art" in this proceeding. PO Resp. 11–12. We determine the level of ordinary skill proposed by Petitioner is consistent with the '252 patent and the prior art of record. We, therefore, adopt that level in this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579–80 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

B. Claim Construction

We interpret the claims of the '252 patent "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)." *See* 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) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at

37 C.F.R. § 42.100(b) (2019)). This "includ[es] construing 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.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

In the District Court Litigation, the court held a *Markman* hearing on April 26, 2019, and took the issues presented under advisement. *See* District Court Litigation, Docket No. 149. The parties have not informed us of any claim construction order in the District Court Litigation. *See* Tr. 4:22–6:2.

Petitioner "does not believe construction of any terms are necessary for this proceeding." Pet. 17–18. Patent Owner contends we should construe just one term, "threaded screw hole" in claim 17, to resolve Petitioner's obviousness challenge relying on Grusin and Fernandez. PO Resp. 12–14. We consider this issue below in Section IV.E.3.

Apart from that one issue, we determine no explicit claim construction of any claim term is needed to resolve the patentability issues presented in this proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. Priority of Claims 17–27 of the '252 Patent

1. Legal Standards

Pursuant to 35 U.S.C. § 120, a patent application is entitled to assert priority to the filing date of a prior application only for an invention disclosed in the prior application in the manner provided by 35 U.S.C.

§ 112(a).[8] This requires that the prior application provides written description support for the invention claimed by the later application. *See Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306–11 (Fed. Cir. 2008); *Augustine Medical, Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1302–03 (Fed. Cir. 1999). The test for sufficiency of a written description under 35 U.S.C. § 112(a) is whether the prior application's disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description "test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.*

2. Parent Applications at Issue

The application that issued as the '252 patent was filed as a continuation of U.S. Patent Application No. 13/348,888, which was filed as a division of U.S. Patent Application No. 12/380,177 (filed February 24, 2009), which was filed as a continuation-in-part of U.S. Patent Application No. 11/340,028 (filed January 26, 2006). Ex. 1003, code (60), 1:6–17. The parties refer to the two earliest parent applications as the 2006 Application

[8] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, amended 35 U.S.C. § 112 effective September 16, 2012. *See* AIA § 4, 125 Stat. 296–97. The application that issued as the '252 patent was filed on March 31, 2014, so we cite the AIA version. *See* Ex. 1003, code (22). However, we would reach the same conclusion as to written description support in the 2006 Application regardless of which version applies.

and the 2009 Application, reflecting their respective filing dates. *See* Pet. 2; PO Resp. 14. For consistency in the record, we will do likewise.

Petitioner asserts the challenged '252 patent claims lack written description support in the 2006 Application, so the claims have a priority date of no earlier than the filing date of the 2009 Application. Pet. 2–3, 11–15. Patent Owner asserts the challenged '252 patent claims have written description support in the 2006 Application, so the claims have a priority date of no later than the filing date of the 2006 Application. PO Resp. 2–4, 16, 18–29.

We must resolve this dispute because it determines whether Kay and Chan are prior art to the challenged claims of the '252 patent. Kay (Ex. 1006) is the August 3, 2006, publication of the 2006 Application (Ex. 2001), so the respective disclosures of Kay and the 2006 Application "are substantively identical." PO Resp. 20 n.4. Chan is a patent application filed on January 9, 2008, and published on June 12, 2008. Ex. 1007, codes (22), (43). Thus, Kay and Chan are not prior art if the challenged '252 patent claims have priority to the 2006 Application's January 26, 2006, filing date, but are prior art if the claims have priority only to the 2009 Application's February 24, 2009, filing date.

3. The Parties' Arguments, and Scope of Replies

a) The Petition and the Institution Decision

In the Petition, Petitioner contends claim 17 of the '252 patent does not have priority to the 2006 Application, because the application lacks written description support for inserting a locking screw into a threaded

screw hole of a plate. Pet. 2–3, 7–8, 11–15. The Petition challenges the priority of claims 18–27 on the same basis. *Id.* at 11, 15.

The Petition particularly asserts the 2006 Application does not disclose a "locking screw," which Petitioner equates to a screw having a threaded head that matches corresponding threads in the screw hole of a plate receiving the screw. *Id.* at 7–8 (citing Ex. 1001 ¶¶ 42–45; Ex. 1023, 18); *id.* at 11–12 (citing Ex. 1003, Figs. 6–7, 8:41–55); Ex. 1001 ¶ 80. According to the Petition, the 2006 Application discloses only non-locking screws, that is, screws with non-threaded heads. Pet. 7–8, 12–13 (citing Ex. 2001, Figs. 6 & 8, ¶¶ 8–9, 11, 19–21, 52);[9] Ex. 1001 ¶ 81. For example, Petitioner points out that both the 2006 Application and the '252 patent disclose screw heads that "are rounded and have a low profile so that the screws can be seated with their longitudinal axes at a variety of angles." Pet. 14 (quoting Ex. 2001 ¶ 9; Ex. 1003, 4:20–23); Ex. 1001 ¶¶ 81–82. However, the '252 patent, unlike the 2006 Application, goes on to disclose: "Alternatively and in many cases, preferably, the screw holes can include internal threads which mate with ***external threads on the head of the screws to cause locking of the screws*** relative to the plate." Pet. 14 (emphasis by Petitioner) (quoting Ex. 1003, 4:29–32); Ex. 1001 ¶ 82.

The Preliminary Response disputed these assertions. *See* Prelim. Resp. 1–4, 11–13, 17–25. In the Institution Decision, we described the issue presented as whether the 2006 Application provides "written description

[9] Petitioner cites to the disclosure of Kay (Ex. 1006) rather than the 2006 Application (Ex. 2001). We have re-cast Petitioner's citations to refer to corresponding disclosures in the 2006 Application, which is "substantively identical" to Kay. PO Resp. 20 n.4.

support for inserting a *locking screw* into a threaded screw hole" of a bone plate, as recited in claim 17. Inst. Dec. 9–10 (emphasis added). As will be seen below, the parties' post-institution arguments raise the same issue.

Based on the record presented prior to institution of trial, we agreed with Patent Owner's position that the 2006 Application demonstrated possession of a locking screw by disclosing "screw holes" in which "the bore could be threaded." Ex. 2001 ¶ 51; Inst. Dec. 11. The parties agreed a locking screw is "a screw having a threaded head that matches corresponding threads in the screw hole of a plate receiving the screw." Inst. Dec. 9–10, 11. We concluded "[o]n the present record Petitioner has not identified any reason for a screw hole to be threaded, other than to receive a correspondingly threaded head of a screw," and determined "a person of ordinary skill in the art would have understood that disclosure of a threaded screw hole demonstrates possession of a locking screw to be received in the threaded screw hole." *Id.* at 11. In particular, Petitioner and its witness Mr. Castañeda had failed to address, in any fashion, the 2006 Application's disclosure of a threaded screw hole in paragraph 51. *Id.* at 12 (citing Ex. 1001 ¶¶ 42–44, 58, 80–82, 199). Despite our conclusion concerning priority, we instituted trial as to Petitioner's proposed obviousness of claims 17–27 over Kay and Chan, based on Board practice implementing *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). Inst. Dec. 15–16.

b) The Parties' Post-Institution Arguments and Evidence

In the Patent Owner Response, Patent Owner continues to agree with Petitioner that a "locking screw," in at least one example, corresponds to a screw having a threaded head that matches corresponding threads in a screw

hole receiving the screw. PO Resp. 2–4, 16, 21–22; Ex. 2017 ¶¶ 36, 40; Ex. 2018 ¶¶ 37, 41. Patent Owner also continues to assert the 2006 Application demonstrates possession of a locking screw by disclosing threaded screw holes, which a person of ordinary skill in the art would have understood receive the threaded head portion of a locking screw. PO Resp. 2–4, 16, 20–29 (citing Ex. 2001 ¶ 51); Ex. 2017 ¶¶ 36–48; Ex. 2018 ¶¶ 37–49.

Patent Owner asserts, and Dr. Neufeld and Mr. Harrigan testify, that the 2006 Application's disclosure of a threaded screw hole bore "necessarily" demonstrates possession of a threaded-head screw to be received in the hole.[10] PO Resp. 2–4, 16, 22–24 (citing illustration of an exemplary locking screw at Pet. 7–8, taken from Ex. 1023, 18); Ex. 2017 ¶¶ 41–43 (testifying that disclosure of "a plate bored with a threaded screw hole necessarily demonstrates that the inventors were in possession of a plate system that included the type of screw that is received in that type of screw hole—i.e., a threaded-head screw" or "a locking screw"); *id.* ¶ 45 ("A POSA understood that a threaded screw hole [or bore] is a ***locking screw hole***." (emphasis by Dr. Neufeld)); Ex. 2018 ¶¶ 42–44, 46 (same). Patent Owner asserts Petitioner's witness Mr. Castañeda "agree[s] that a locking screw hole or threaded screw hole in a bone plate corresponds to a locking or threaded-head screw." PO Resp. 24–25 (citing Ex. 1001 ¶ 58; Ex. 1003, 4:29–32; Ex. 2017 ¶¶ 44–45; Ex. 2018 ¶¶ 45–46).

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[10] Petitioner reads the Patent Owner Response to assert only the reversed proposition: that a locking screw requires a threaded screw hole bore. *See* Pet. Reply 1, 9–10 (citing PO Resp. 20–29; Ex. 2017 ¶¶ 40–48; Ex. 2018 ¶¶ 41–49). We disagree with Petitioner's limited reading of the Patent Owner Response and supporting witness testimony.

In reply, Petitioner correctly observes that the only 2006 Application disclosure cited by Patent Owner as demonstrating possession of a locking screw is that a bone plate screw hole "bore could be threaded." Ex. 2001 ¶ 51; Pet. Reply 1, 4 (citing PO Resp. 22; Ex. 2017 ¶ 41; Ex. 2018 ¶ 42; Ex. 1066, 195:7–196:3). Petitioner then asserts the evidence of record establishes "that a hole in a plate could be threaded for numerous reasons other than for use with a locking screw, confirming that disclosure of a threaded hole ***does not*** 'necessarily demonstrate' possession of a locking screw" as Patent Owner contends and as Federal Circuit precedent requires. Pet. Reply 2–3, 9–10 (citations omitted). In support, Petitioner cites disclosures in the 2006 Application, and deposition testimony of Patent Owner's witness Mr. Harrigan. *Id.* at 4–7 (discussing Ex. 2001, Figs. 6–8, ¶¶ 6, 8, 10, 12–13, 46, 51–52; Ex. 1066, 57:19–58:23, 141:11–25, 155:20–25, 195:7–196:3; Ex. 1087 ¶¶ 29, 31).

Petitioner's Reply also submits new argument and evidence, seeking to establish a person of ordinary skill in the art in January 2006 would have known a screw hole bore may be threaded for various reasons other than to receive the threaded head of a locking screw. Pet. Reply 4–9. This evidence includes Exhibits 1082–1086, which are documents published prior to January 2006, except Exhibit 1085 which was filed after January 2006. This evidence also includes Exhibit 1087, Mr. Castañeda's declaration testimony concerning the new Exhibits. This evidence is relevant to the priority dispute raised here. *See, e.g.*, *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1363–64 (Fed. Cir. 2018) (holding that "[i]n addition to the intrinsic evidence . . . , prior patents reflecting the state of the art at the time of the invention and expert testimony regarding that evidence" may be

considered when determining whether a parent application's disclosure demonstrates possession of later-claimed subject matter).

Patent Owner replies: "Petitioner distorts the relevant law which requires only that the specification reasonably disclose to a POSA that the inventor was in possession of the invention, to improperly assert the specification must disclose that a threaded screw was ***necessary***." Sur-reply 8–9 (emphasis by Patent Owner) (citing *Hologic*, 884 F.3d at 1361). Applying the possession test, Patent Owner argues "the ***only evidence before the Board*** as to the understanding of a POSA from the disclosure of the threaded-screw-hole embodiment in [the 2006 Application] remains that the plate screw holes are threaded '***so that the plate system could accept locking screws***.'" *Id.* at 5–6 (emphases by Patent Owner) (quoting Ex. 1001 ¶ 199); *id.* at 11–12.

According to Patent Owner, whether a person of ordinary skill in the art understood that the threaded screw hole bore disclosed in the 2006 Application could receive a threaded portion of structures other than a locking screw "is not an issue before the Board, and . . . does not negate the evidence . . . that the threaded screw hole . . . is intended for a threaded-head locking screw." *Id.* at 9. Patent Owner emphasizes that the 2006 Application discloses its plates are attached to bones with *screws* received in *screw holes*, thereby demonstrating possession of a locking screw. *Id.* at 12–14, 16 (citing Ex. 2001, pg. 19 (Abstract), ¶¶ 1–4, 6, 8, 50).

c) Whether Petitioner's Reply or Patent Owner's Sur-reply Improperly Presents New Argument and Evidence

Patent Owner argues Petitioner's Reply "amounts to no more than an attempt to rehabilitate its expert and the Petition by impermissibly adding

new evidence, including new testimony from its expert, and arguments relying on the new evidence." Sur-reply 4, 12. Patent Owner urges us to disregard this argument and evidence as belatedly presented under our rules. *Id.* at 4 (citing Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012)).

We determine Petitioner's Reply does not improperly present new argument and evidence. The Reply "may only respond to arguments raised in" the Patent Owner Response. 37 C.F.R. § 42.23(b) (2019). "Additionally, in response to issues arising from the Supreme Court's decision in *SAS* (138 S. Ct. at 1358), the Board will permit the petitioner, in its reply brief, to address issues discussed in the institution decision." Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) ("Consolidated Guide"), 73.[11] "A party also may submit rebuttal evidence in support of its reply." *Id.* (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015)).

The argument and evidence presented in Petitioner's Reply properly respond to issues discussed in the Institution Decision (*see supra* Section IV.C.3(a)) and arguments raised in the Patent Owner Response (*see supra* Section IV.C.3(b)). The Reply does not, as is proscribed in the Consolidated Guide, present argument or evidence that should have been presented earlier to make out a prima facie case of unpatentability. This is particularly true because, as to priority, Petitioner must argue a *negative* proposition: that the parent application at issue (here, the 2006 Application) *does not* demonstrate possession of a claimed invention (here, including a

[11] This Guide is available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance.

locking screw). We determine the Petition satisfied Petitioner's burden of production on this issue (*see supra* Section IV.C.3(a) (discussing the Petition and Institution Decision)) so that the burden of production shifted to Patent Owner to argue why the parent application *does* demonstrate possession of the claimed invention, thereby opening the door for the Reply to address the parent application disclosure(s) cited in the Patent Owner Response, with opposing argument and evidence. *See, e.g.*, *Dynamic Drinkware*, 800 F.3d at 1378–81 (discussing burdens of production and persuasion in the context of determining the effective date of a prior art patent that asserts priority to a provisional application).

Next, Petitioner asserts we should strike Exhibit 2024, which was first filed with the Sur-reply, along with the portions of Exhibit 2023 (Mr. Castañeda's deposition testimony) concerning Exhibit 2024. *See* Paper 35. We determine Patent Owner's Sur-reply does not improperly present new argument and evidence. We acknowledge the Consolidated Guide provides (at 73–75): "The sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness." Nonetheless, pursuant to 37 C.F.R. § 42.5(a), (b), we accept the evidence newly presented with the Sur-reply, to address the argument and evidence newly presented in the Reply concerning the priority dispute. To ensure procedural fairness, we also consider Petitioner's Sur-sur-reply, which addresses Exhibits 2023 and 2024. *See* Paper 35; Sur-sur-reply 1–3.

4. Analysis

The 2006 Application disclosure at issue provides that the "screw holes" of a bone plate include a "bore" and "[i]n a further embodiment, the

bore could be threaded." Ex. 2001 ¶ 51. The issue presented is whether this disclosure demonstrates, to a person of ordinary skill in the art, possession of a locking screw with its threaded head being engaged within the threaded screw hole bore.

It is undisputed that the 2006 Application's disclosures directed specifically to screws do not describe a locking screw, that is, a screw having a threaded head. *E.g.*, Ex. 2001, Figs. 6–8, ¶¶ 8–9, 11, 19–21, 52; Ex. 1001 ¶¶ 80–81; Pet. 11–14. The 2006 Application discloses that screw holes and corresponding screw heads may both be "rounded . . . so that the screws can be seated with their longitudinal axes at a variety of angles" and to provide a low profile. Ex. 2001, Fig. 8, ¶¶ 9, 11, 52. But the '252 patent disclosures of a locking screw are not found in the 2006 Application. *Compare* Ex. 1003, 4:20–33, *with* Ex. 2001 ¶ 9; *compare* Ex. 1003, 5:39–42, 8:41–55, Figs. 6–7, *with* Ex. 2001 ¶¶ 19–21, 52, Figs. 6–8.

At the same time, the parties agree, and we find the evidence establishes, that a person of ordinary skill in the art would have known in January 2006 that one purpose of a threaded screw hole bore is to receive the threaded head of a locking screw. *See* Ex. 1023, 18; Ex. 1001 ¶¶ 42–45, 80–82; Ex. 1087 ¶ 18; Ex. 2017 ¶¶ 36, 40–45; Ex. 2018 ¶¶ 37, 41–46; Pet. 7–8, 11–12; PO Resp. 2–4, 16, 19–25. Nonetheless, it seems odd for the 2006 Application's inventors to attempt to demonstrate possession of a locking screw by disclosing, not the locking screw itself, but instead the screw bore hole capable of receiving the threaded head of the locking screw. Patent Owner's claim to priority thus depends on whether a person of ordinary skill in the art would have connected the 2006 Application's

disclosure of a threaded screw hole bore to the threaded head of a locking screw to interact with the threads of the bore.

This factual context leads to a disagreement between the parties regarding the legal standard to be applied here. Patent Owner initially argued, and Dr. Neufeld and Mr. Harrigan have testified, that the 2006 Application's disclosure of a threaded screw hole bore "necessarily" discloses a locking screw. *See* Prelim. Resp. 2, 18–19; PO Resp. 2–4, 16, 22–24; Ex. 2017 ¶¶ 41–45; Ex. 2018 ¶¶ 42–46. In reply, Petitioner agreed that necessity is the applicable legal standard. Pet. Reply 3 (citing *PowerOasis*, 522 F.3d at 1305–06; *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998)); *id.* at 9–10. Patent Owner then changed tack, and asserted written description support does not require the 2006 Application to disclose that a locking screw "was ***necessary***," but rather requires demonstration of possession of a locking screw. Sur-reply 8–9 (emphasis by Patent Owner) (citing *Hologic*, 884 F.3d at 1361); Tr. 57:9–58:8.

We agree with Patent Owner's original position, and Petitioner's reply, that in the circumstances of this case, in order for priority to be found to the 2006 Application, a locking screw must be a necessary counterpart and not merely one of many obvious uses for the disclosed threaded screw hole bore. Demonstration of possession "requires that the written description actually or inherently discloses the claim element"; obviousness is not sufficient. *PowerOasis*, 522 F.3d at 1306–07 (citation omitted); *Tronzo*, 156 F.3d at 1158. It is undisputed that the 2006 Application does not actually disclose a locking screw, because its disclosures specifically directed to screws are limited to non-locking screws, as discussed above.

Therefore priority here requires an inherent disclosure of a locking screw. *PowerOasis*, 522 F.3d at 1310 (determining expert testimony was insufficient to raise genuine issue of material fact as to priority where it did not "claim that use of a customer laptop as the customer interface is necessarily disclosed by the Original Application," and instead indicated at best "that it would be obvious to substitute a customer laptop for the user interface disclosed on the vending machine"). An inherent disclosure may be established only if it "is necessarily present" in the reference, and may not be established by probabilities or possibilities. *In re Montgomery*, 677 F.3d 1375, 1379–80 (Fed. Cir. 2012) (citations omitted); *see also Tronzo*, 156 F.3d at 1159–60 (applying inherency when addressing priority).

The *Hologic* decision cited by Patent Owner is not to the contrary. There, the Federal Circuit considered whether a parent application demonstrated possession of a light guide being "permanently affixed" in an endoscope channel. *Hologic*, 884 F.3d at 1360. The parent application *expressly disclosed* a light guide, and the Court had to determine whether a person of ordinary skill in the art would have understood the disclosed light guide to be permanently affixed. *Id.* at 1363–64. In the present case, by contrast, it is undisputed that the only screws expressly disclosed in the 2006 Application are non-locking screws. Thus, *Hologic* was an actual or express disclosure case, whereas this is an inherent disclosure case. And, inherency requires necessity.

The 2006 Application and related witness testimony establish that a locking screw is not a necessary counterpart to, and instead is only one obvious reason for having, the threaded screw hole bore disclosed in the 2006 Application. Specifically, as discussed in the next Section IV.C.4(a),

the 2006 Application itself discloses a screw bore may have been threaded to receive a bending tool, rather than a locking screw. As discussed in the following Section IV.C.4(b), a person of ordinary skill in the art would have additionally known a screw bore may have been threaded to receive the threaded shaft of a non-locking screw, or the threaded portion of several different instruments such as a drill guide, a screw guide, and a plate positioner, rather than a locking screw. Therefore, we conclude the 2006 Application does not demonstrate possession of a locking screw by simply disclosing a threaded screw hole bore, because a locking screw is not a necessary counterpart to such a bore. Further, even if Patent Owner is correct that strict necessity is not required, at best Patent Owner has established merely the obviousness of using a locking screw in a threaded screw hole bore, which is insufficient to show possession of the claimed invention.

a) The 2006 Application: A Screw Hole Bore May Be Threaded to Receive a Bending Tool, rather than a Locking Screw

The 2006 Application indicates the plate structure may have an "increased annular area around the [screw] bores," to "resist[] deformation *when a bending device is used to apply a force to the plate through the screw holes*" to bend the plate. Ex. 2001 ¶ 46 (emphasis added); *see also id.* at pg. 19 (Abstract), ¶¶ 6, 10 (describing a surgeon's ability to bend a plate into an individualized contour for use with a particular patient, without deforming the screw holes of the plate); Pet. Reply 5–6.

We credit Mr. Castañeda's testimony that a person of ordinary skill in the art in January 2006 would have known that "[w]hile the 2006 Application does not expressly state that the bore of the screw holes would

be threaded in order to engage a bending device," the bore may have been threaded "to engage a bending tool" by providing "a solid engagement between the holes and the bending tool." Ex. 1087 ¶¶ 29, 31 (citing Ex. 2001 ¶ 46); Pet. Reply 6; *see also PowerOasis*, 522 F.3d at 1306 (witness testimony is relevant to priority issue); *Hologic*, 884 F.3d at 1363–64 (same). This bending device disclosure in the 2006 Application is sufficient, on its own, to establish that a locking screw is not a necessary counterpart for the threaded screw hole bore disclosed in the 2006 Application. It is possible for the bore to be threaded only to receive a bending device, and then receive a non-locking screw to attach the bent plate to a bone.

Dr. Neufeld and Mr. Harrigan testify that a locking screw necessarily corresponds to a threaded screw bore hole in a bone plate. *See* Ex. 2017 ¶¶ 36, 39–45; Ex. 2018 ¶¶ 37, 40–46. However, as in the *PowerOasis* and *Tronzo* decisions, we determine this testimony establishes at best that it would have been obvious to use a locking screw in the 2006 Application's threaded screw bore hole, not that a threaded screw bore hole necessarily connotes a locking screw. *See PowerOasis*, 522 F.3d at 1310; *Tronzo*, 156 F.3d at 1159–60. The 2006 Application discloses at least one other use for the threaded bore: to engage a threaded portion of a bending tool for a secure connection. Therefore, a locking screw is at best a possible or probable counterpart to the threaded screw hole bore, which is not sufficient to establish an inherent disclosure and therefore possession of a locking screw. *Montgomery*, 677 F.3d at 1379–80 ("The inherent result must inevitably result from the disclosed steps; '[i]nherency . . . may not be established by probabilities or possibilities.'") (quoting *Bettcher Indus., Inc.*

v. Bunzl USA, Inc., 661 F.3d 629, 639 (Fed. Cir. 2011) and *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)).

For the foregoing reasons, we conclude the 2006 Application discloses a screw hole bore may have been threaded to receive a bending tool, rather than a locking screw.

b) A Person of Ordinary Skill in the Art Would Have Known a Screw Hole Bore May Be Threaded to Receive Structures other than a Locking Screw

Petitioner argues a person of ordinary skill in the art in January 2006 would have known a screw hole bore may be threaded for various reasons other than to receive the threaded head of a locking screw. *See* Pet. Reply 4–12 (discussing Exs. 1082–1087). Patent Owner raises various objections to the evidence cited by Petitioner. *See* Sur-reply 12–22.

Upon review of the foregoing, we conclude Petitioner's argument and evidence is persuasive in some regards, and not persuasive in other regards. In summary, we find a person of ordinary skill in the art in January 2006 would have known a screw hole bore may have been threaded to receive the threaded shaft of a non-locking screw, or the threaded portion of several different instruments such as a drill guide, a screw guide, and a plate positioner, rather than a locking screw. However, we are not persuaded by Petitioner's reliance on a jig assembly, and we determine we need not reach Petitioner's reliance on a locking peg, in this regard.

(1) Threaded Shaft of Non-Locking Screw

The evidence establishes a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore

may have been threaded to receive the threaded shaft of a non-locking screw.

Exhibit 1084 is a patent application published in 2005 and naming Mr. Castañeda as the sole inventor ("the Castañeda Application"). Ex. 1084, codes (43), (75). Figure 1 of the Castañeda Application is reproduced below:

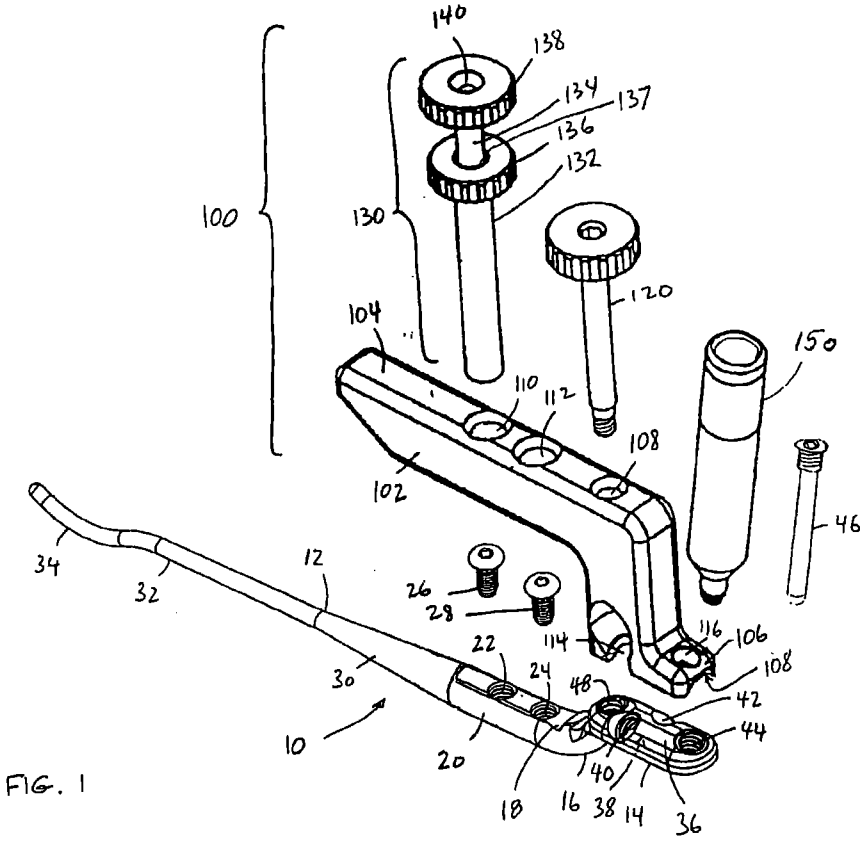


FIG. 1

Castañeda Application Figure 1 (Ex. 1084).

Figure 1 illustrates bone fracture fixation device 10 including threaded screw holes 22, 24 that receive the threaded shafts of cortical screws 26, 28. *Id.* at Fig. 1, ¶¶ 8, 42, 45; Ex. 1087 ¶ 27; Pet. Reply 5. The heads of screws 26, 28 are not threaded, so they are not locking screws. Ex. 1084, Fig. 1; Ex. 1087 ¶ 27. Thus, a person of ordinary skill in the art in January 2006 would have known that a screw hole bore may be threaded to receive the

threaded shaft of a non-locking screw, rather than the threaded head of a locking screw.

Patent Owner asserts the Castañeda Application does not aid Petitioner, because the 2006 Application discloses that its screw hole diameters are larger than its screw shaft diameters, and that its screw shafts are tapered, both of which are inconsistent with the threaded shaft of the screw interfacing with the threads of the screw hole bore. Sur-reply 16–17 (citing Ex. 2001 ¶¶ 11, 51; Ex. 2023, 28:20–24). We disagree.

The 2006 Application discloses only that "[t]he bores are *typically* about 3.75 mm for a 3.5 mm diameter screw for small bones," whereas more generally "the screws and *corresponding* screw holes could be sized to range from a 1.5 mm diameter screw up to a 7.5 mm screw." Ex. 2001 ¶ 51 (emphases added). The former disclosure is only one exemplary embodiment for one particular usage, while the latter more general disclosure suggests that in other embodiments the respective diameters of the screws and the screw holes may correspond, or be equal. The latter disclosure is consistent with the threaded shaft of the screw interfacing with the threads of the screw hole bore.

As to tapered screw shafts, the 2006 Application discloses that the screw may have "a partial taper of *the inner [minor] diameter*" and "a constant *major diameter*." Ex. 2001 ¶¶ 11, 52 (emphases added). A person of ordinary skill in the art would know that the minor diameter of a screw is the diameter of the shaft at the troughs of the threads, and the major diameter of a screw is the outer diameter at the peaks of the threads. *See, e.g.*, Ex. 1007 ¶ 18. Thus, the 2006 Application discloses that the outer diameter of the screw shaft threads is "constant," as is shown in Figures 6 and 8. This

is consistent with the threads of the screw shaft interfacing with the threads of the screw hole bore.

Patent Owner also contends the Castañeda Application's fixation device 10 "is an alternative means for fracture fixation" to the means of the 2006 Application, because device 10 is placed *inside* a bone to receive screws 26, 28 whose heads remain outside of the bone, whereas the plates of the 2006 Application are affixed on the *exterior* surface of a bone by screws whose heads are received in the plate. Sur-reply 18–19 (citing Ex. 1084, Fig. 12; Ex. 2023, 25:3–20, 27:15–28:19). Even acknowledging this difference in operation, however, the Castañeda Application still establishes that the threads of a screw hole bore in a bone fixation device may interact with the threads of a screw shaft (on a non-locking screw) rather than the threads of a screw head (on a locking screw). This is consistent with the 2006 Application, which reflects that the head of a non-locking screw is "rounded" but not threaded. Ex. 2001, Fig. 8, ¶¶ 9, 11, 52.

(2) Drill Guide, Screw Guide, and Plate Positioner

The evidence establishes a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive many instruments, such as a drill guide, a screw guide, and a plate positioner. The 2006 Application indicates its plate system may be used with "instruments" (Ex. 2001 ¶ 12), and allows a surgeon "to perfect a variety of techniques using a set of instruments" (*id.* ¶ 13). *See* Pet. Reply 6.

We credit Mr. Castañeda's testimony that a person of ordinary skill in the art would have known one such instrument is a drill guide. *See* Ex. 1087

¶ 26 (citing Ex. 1084, Fig. 1, ¶ 46); Pet. Reply 6. For example, Figures 1 and 3 of the Castañeda Application illustrate drill guide 150 having threaded end 152 which is "threadably engageable within peg holes 40, 42, 44" of fixation device 10. Ex. 1084 ¶ 46. Drill guide 150 then "accommodates a drill bit appropriately sized for drilling a hole into bone for a peg 46." *Id.* ¶ 46, Fig. 1. Thus, a person of ordinary skill in the art would have known that a screw hole bore may be threaded to receive a drill guide to drill a hole in the bone to receive a screw, rather than the threaded head of a locking screw.

Patent Owner points out that, after drill guide 150 is used to drill a hole into bone, guide 150 is removed and then peg 46 is inserted until the threaded head of peg 46 is received within threaded hole 44 of device 10. *See* Sur-reply 21; Ex. 2023, 29:12–30:13. However, we find that, viewing the state of the art as a whole in January 2006, a person of ordinary skill in the art would understand drill guides may be used in connection with non-locking fasteners as well as locking fasteners. For example, the Castañeda Application indicates its drill guides may include a depth gauge scale to measure the depth of a drilled hole, and thereby determine the location and depth of the drilled hole relative to anatomical structures, which would be useful for non-locking fasteners like the non-locking screws of the 2006 Application. *See, e.g.*, Ex. 1084 ¶¶ 46, 54–59.

We credit Mr. Castañeda's testimony that a person of ordinary skill in the art would have known another such instrument is a screw guide. *See* Ex. 1087 ¶ 28 (citing Ex. 1082, Fig. 1, ¶ 7); Pet. Reply 6. For example, Exhibit 1082 is a patent application published in 2005 and naming James Rains as the sole inventor ("Rains"). Ex. 1082, codes (43), (76). In

Figure 1, Rains discloses screw guide 11 comprising threaded end 13 to engage a threaded hole in a bone plate, to receive and guide a locking screw or a non-locking screw into bone underneath the plate. *Id.* at Abstract, ¶¶ 2, 7, 10, 19–20, 23. Thus, a person of ordinary skill in the art would have known that a screw hole bore may be threaded to receive a screw guide for guiding a non-locking screw, rather than the threaded head of a locking screw. Further, as Mr. Castañeda points out, Rains' description of "a threaded screw hole, *such as a locking screw hole or other threaded hole* on a bone plate" (*id.* ¶ 19 (emphasis added)) is yet another indicator that a bone plate hole may be threaded for various reasons, not necessarily to receive the threaded head of a locking screw. Ex. 1087 ¶ 28.

We also credit Mr. Harrigan's testimony that a person of ordinary skill in the art would have known an additional such instrument is a plate positioner, used to place the plate in a hard-to-reach location within a patient's body. *See* Ex. 1066, 191:3–192:16; Pet. Reply 6–7. We acknowledge Mr. Harrigan's further testimony that, in his view, the "primary" purpose, use, or reason for having a threaded screw hole bore in a plate is to receive the threaded head of a locking screw. Ex. 1066, 191:22–23, 192:7–9. However, inherency requires that a locking screw is a necessary counterpart, and not just a probable counterpart or an obvious use, of a threaded screw hole bore. *See supra* Section IV.C.4 (discussing pertinent case law).

Patent Owner asserts the foregoing disclosures of a threaded screw hole bore receiving threaded portions of instruments other than screws do not aid Petitioner. Sur-reply 19–22. In Patent Owner's view, this evidence establishes merely that the instruments are threaded "to avoid damaging the

threads of the screw hole," so the screw hole may still receive the threaded head of a locking screw after the instrument is used. *Id.* (citing Ex. 1085 ¶ 11; Ex. 2023, 29:12–30:13, 31:3–32:4, 34:12–20). We disagree.

As noted above, a drill guide may be useful with non-locking fasteners as well as locking fasteners. *See* Ex. 1084 ¶¶ 46, 54–59. Screw guides also may be useful with non-locking screws as well as locking screws. *See* Ex. 1082, Abstract, ¶¶ 2, 19. The same is true of a plate positioner, in which the threaded plate hole may receive a threaded portion of the plate positioner for positioning the plate within the patient's body, and then receive a non-locking fastener.

(3) Jig Assembly

Petitioner argues a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive a jig assembly. *See* Pet. Reply 7 (citing Ex. 1084 ¶¶ 9, 43–44; Ex. 1087 ¶¶ 15–31).

We, however, agree with Patent Owner's argument that the Castañeda Application's internal bone fixation device 10 "is an alternative means for fracture fixation" to the exterior bone plate of the 2006 Application, such that the Castañeda Application's disclosure of a jig assembly does not apply to the 2006 Application. *See* Sur-reply 18–19 (citing Ex. 1084, Fig. 12; Ex. 2023, 25:3–20, 27:15–28:19).

The Castañeda Application's jig assembly 100 is used to align fixation device 10 inside a bone, which involves the threaded end of locking screw 120 being inserted through hole 118 (mislabeled as "108" in Figure 1) of jig 102 and threaded into locking hole 48 of fixation device 10. Ex. 1084,

Abstract, Fig. 1, ¶¶ 8–12, 41, 43–44; *id.* at Fig. 12 (illustrating the locking screw (unnumbered) received in device 10, which is inserted inside bone 400); Ex. 1087 ¶ 25; Ex. 2023, 25:3–20, 27:15–28:19. The various bone plates of the 2006 Application, by contrast, are mounted on the exterior surface of the bone. *See, e.g.*, Ex. 2001 ¶ 8.

The evidence cited by Petitioner does not support Petitioner's contention that the Castañeda Application's jig assembly 100 could be used with the 2006 Application's exteriorly mounted plate system. *See* Ex. 1084 ¶ 9; Ex. 1087 ¶¶ 25–27, 29–31 (all of Mr. Castañeda's testimony directed to the Castañeda Application). We perceive no rational relationship suggesting to a person of ordinary skill in the art that the Castañeda Application's jig assembly 100 would be useful in connection with the 2006 Application's bone plates. Therefore, we do not rely on a jig assembly as being an instrument that might be usefully threaded into the threaded screw bore hole of the 2006 Application, rather than the threaded head of a locking screw.

(4) Locking Peg

Petitioner additionally argues a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive the threaded head of a locking peg, rather than the threaded head of a locking screw. Pet. Reply 7–9; Ex. 1087 ¶¶ 20–24 (citing Ex. 1083 ¶¶ 13–15, 41, Figs. 1–2; Ex. 1085 ¶¶ 60, 73; Ex. 1086, 4–5, Fig. 6). Mr. Castañeda testifies in support that a locking peg differs from a locking screw because the peg has a smooth shaft, while the screw has a threaded shaft, even though both have a threaded head. Ex. 1087 ¶¶ 20, 23. Patent Owner argues in opposition that Petitioner and

Mr. Castañeda draw a false dichotomy between locking pegs and locking screws, because the evidence reflects the same structure has been labeled as a locking peg and as a locking screw. Sur-reply 14–16 (citing Ex. 1086, Fig. 6; Ex. 2024, 2:8–14, Figs. 2, 8a, 8c). Petitioner replies that Patent Owner's rebuttal overlooks that a "locking screw" in the context of the '252 patent must have a threaded shaft, as well as Mr. Castañeda's deposition testimony distinguishing between pegs and screws. Sur-sur-reply 2–3.

We conclude we need not resolve the foregoing dispute, because we have already concluded (*see supra* Sections IV.C.4(a) and IV.C.4(b)(1)–(2)) that a person of ordinary skill in the art in January 2006 would have known the 2006 Application's screw hole bore may have been threaded to receive several other structures, rather than the threaded head of a locking screw.

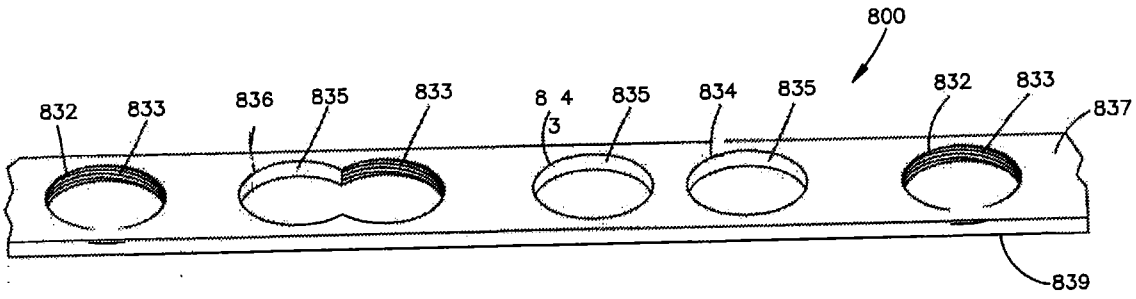
c) Conclusion

For the foregoing reasons, we find a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive a bending tool, the threaded shaft of a non-locking screw, or a threaded portion of a drill guide, a screw guide, or a plate positioner, rather than the threaded head of a locking screw. The evidence, therefore, demonstrates that the 2006 Application does not demonstrate possession of a locking screw by simply disclosing a threaded screw hole bore, because a locking screw is not a necessary counterpart to such a bore. Moreover, even if Patent Owner is correct that strict necessity is not required, at best Patent Owner has established merely the obviousness

of using a locking screw in a threaded screw hole bore, which is insufficient to show possession of the claimed invention.

5. Chan

Patent Owner cites Chan as establishing disclosure of "a plate hole that is threaded" demonstrates possession of "a ***locking screw***" to be received in the hole. PO Resp. 25–27 (emphasis by Patent Owner); Ex. 2017 ¶¶ 46–47; Ex. 2018 ¶¶ 47–48. Figure 8 of Chan is reproduced here:



F. 8 PRIOR ART
ig

Chan Figure 8 (Ex. 1007).

As described in Chan, Figure 8 illustrates bone plate 800 having "locking" holes 832 with threads 833 for engaging threads around the head of a locking bone screw, "non-locking" holes 834 with non-threaded or smooth inner surfaces 835, and "combination locking / non-locking" hole 836. Ex. 1007 ¶ 64; PO Resp. 25–27; Ex. 2017 ¶¶ 46–47; Ex. 2018 ¶¶ 47–48.

Petitioner contends Chan merely establishes that a locking screw requires a threaded screw bore, and "does nothing to inform the discussion of whether a threaded bore, with nothing more [as in the 2006 Application], discloses a 'locking screw.'" Pet. Reply 11 (citing Ex. 1007 ¶ 64). Further: "the fact that Chan felt the need to call its holes 'locking bone plate holes'

(as opposed to just 'threaded holes') . . . shows that POSITAs understood ***additional*** disclosure was required to understand the use of a 'threaded bore.'" *Id.* (emphasis by Petitioner).

We agree with Petitioner that Chan merely establishes a locking screw requires a threaded screw bore to receive the threaded head of a locking screw; Chan does not establish that disclosure of a threaded screw hole bore demonstrates possession of a locking screw to be received in the bore. *See* Ex. 1007 ¶ 64, Fig. 8. For example, Chan specifically describes its threaded holes as "*locking* bone plate holes 832," and the hole's threads 833 as "for engaging the threads around *the head of a locking bone screw*." *Id.* ¶ 64 (emphases added). Chan's decision to describe a threaded screw hole bore functioning to receive the threaded head of a "locking" screw stands in stark contrast to the silence of the 2006 Application on this point. *See* Ex. 2001 ¶ 51. Chan thus supports Petitioner's position that a person of ordinary skill in the art would have known a threaded screw hole bore may receive various structures other than a locking screw, which led Chan to identify the locking screw from among the various structures in this regard, which the 2006 Application does not do. *See* Pet. Reply 11.

6. Prosecution History of the '252 and '278 Patents

Patent Owner next argues that, during prosecution of the '252 patent, the Examiner expressly found claims "which included the locking screw limitation . . . were entitled to the priority of the 2006 Application." PO Resp. 15, 29 (citing Ex. 1037, 3–4).[12] Patent Owner asserts the same

[12] Our page citations to prosecution history documents refer to the page numbering added by Petitioner or Patent Owner when preparing the Exhibit.

Examiner consistently maintained this position during prosecution of the related '278 patent. *Id.* (citing Ex. 1049, 3–4; Ex. 1048, 2). Patent Owner thus concludes the prosecution history supports a finding that claim 17 of the '252 patent is entitled to priority to the 2006 Application's filing date. *Id.* at 15–16.

Petitioner asserts "[t]he [E]xaminer never expressly examined whether the 2006 Application discloses 'locking screws'" or made "any kind of factual finding to that effect." Pet. Reply 12 (citing Ex. 1037, 3–4). On that basis, Petitioner contends the Examiner's grant of priority to the filing date of the 2006 Application is not entitled to deference and is not persuasive here, where the parties have presented a fully developed record on that specific issue. *Id.* at 12–13 (citations omitted).

We conclude the prosecution history has little applicability here. During prosecution of the '252 patent, the Examiner found U.S. Provisional Patent Application No. 60/648,364 (filed January 28, 2005) failed to demonstrate possession of a claim limitation reciting "a pre-contoured plate having only two diverging arms." Ex. 1037, 3–4. It was *solely* on that basis that the Examiner determined "the effective filing date for the claimed subject matter" was the filing date of the 2006 Application, the next-filed application in the priority chain leading to the '252 patent. *Id.* (bolded emphasis omitted). The prosecution history of the '278 patent is substantially the same. *See* Ex. 1049, 3–4. By contrast, the issue presented here is whether the 2006 Application demonstrates possession of a locking screw. The record does not indicate whether the Examiner considered this issue, much less whether the Examiner decided the issue in Patent Owner's (or Petitioner's) favor.

7. Alleged Inconsistency in Petitioner's Arguments

Patent Owner lastly argues Petitioner takes inconsistent positions, on one hand contending the 2006 Application does not demonstrate possession of a locking screw by disclosing a threaded screw hole bore, and on the other hand contending a locking screw would have been obvious to implement in Kay because Kay discloses a threaded screw hole bore. PO Resp. 2–3, 16, 27–28 (citing Pet. 7–8, 11–12, 29–30, 36–38; Ex. 1001 ¶ 199). Specifically, according to Patent Owner: "If screw holes are threaded ***so that*** they can accept locking screws as confirmed by Petitioner's expert [for obviousness], then the 2006 Application's disclosure of an embodiment of an orthopedic plate system that includes a plate with threaded screw holes necessarily also discloses [for priority] the corresponding locking screws for insertion into those screw holes." *Id.* at 2–3, 16, 27–28 (emphasis by Patent Owner) (citing Ex. 1001 ¶ 199).

Petitioner replies that its arguments concerning priority and obviousness are not inconsistent. Pet. Reply 10, 12 (citations omitted).

We disagree with Patent Owner's assertion that Petitioner takes inconsistent positions here. First, Patent Owner mischaracterizes Petitioner's position and Mr. Castañeda's testimony to be that the 2006 Application discloses its "screw holes are threaded ***so that*** they can accept locking screws." PO Resp. 2–3, 27–28 (emphasis by Patent Owner). Petitioner's position instead is that "once Kay [the publication of the 2006 Application] *has been modified to accept the locking or variable locking screws as taught by Chan*," then the "locking screws could successfully be inserted at selected angles within the screw holes as described by Kay." Pet. 29–30, 37–38 (emphasis added) (citing Ex. 1001

¶¶ 199–201, 204). Mr. Castañeda similarly testifies in support that: "*It would have been obvious* to a POSITA *to thread the screw holes of the plate disclosed by Kay using either the thread segments or conventional threading disclosed by Chan*, so that the plate system could accept locking screws." Ex. 1001 ¶ 199 (emphases added); *id.* ¶¶ 200–201, 204.

Obviousness is a different legal issue than priority, requiring a different analysis. "Entitlement to a filing date [for priority] does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed." *PowerOasis*, 522 F.3d at 1306 (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997)); *see also id.* at 1310 ("Obviousness simply is not enough; the subject matter must be disclosed to establish possession."). For example, in *Hologic*, the Court affirmed the Board's finding that a parent "application has sufficient written description to make it a priority document instead of an invalidating obviousness reference." *Hologic*, 884 F.3d at 1358, 1360. Thus, there is nothing inconsistent in Petitioner arguing that the 2006 Application does not disclose locking screws, but nonetheless it would have been obvious to use locking screws in the 2006 Application, in part because the 2006 Application already has threaded screw holes.

8. *Summary and Conclusion Regarding Priority of Claims 17–27 of the '252 Patent*

In summary, we conclude a preponderance of the evidence establishes a person of ordinary skill in the art in January 2006 would have known a threaded screw hole bore, such as is disclosed in the 2006 Application, had many different obvious uses. These obvious uses included receipt of the threaded head portion of a locking screw; a threaded portion of a bending

device; a threaded shaft of a non-locking screw; and a threaded portion of another instrument such as a drill guide, a screw guide, or a plate positioner. Therefore, we determine the 2006 Application's disclosure fails to demonstrate possession of a locking screw. We correspondingly conclude claims 17–27 of the '252 patent do not have priority to the filing date of the 2006 Application. Those claims instead have a priority date of no earlier than the filing date of the 2009 Application, which is February 24, 2009.

D. Obviousness over Kay and Chan

Petitioner asserts claims 17–27 of the '252 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Kay and Chan. Pet. 15–16, 27–49. Patent Owner opposes on the sole basis that Kay and Chan are not prior art to the '252 patent, because the '252 patent is entitled to priority to the filing date of the 2006 Application. *See* PO Resp. 1–4, 30; Sur-reply 7; Tr. 56:21–24. For the reasons provided above in Section IV.C (analyzing the priority issue), we disagree. Kay was published on August 3, 2006, and Chan was published on June 12, 2008, both before the '252 patent's priority filing date of February 24, 2009. Ex. 1006, code (43); Ex. 1007, code (43); *supra* Section IV.C (analyzing the priority issue). Therefore, we determine Kay and Chan are both prior art to the '252 patent. In view of the arguments and evidence set forth in the Petition and additionally adduced at trial, we further determine Petitioner has demonstrated by a preponderance of the evidence that claims 17–27 of the '252 patent would have been obvious over Kay and Chan.

"The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented." *LG Elecs.*,

Inc. v. Conversant Wireless Licensing S.A.R.L., 759 F. App'x 917, 925 (Fed. Cir. 2019) (quoting *In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016)).[13] Nonetheless, to provide a complete record, we summarize our findings and conclusions as to obviousness below. We begin our analysis with a brief summary of the law of obviousness, then we address the claims.

1. Law of Obviousness

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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 said 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, if made available in the record. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

2. Claim 17

We find Kay discloses a method of conducting bone surgery on a patient, using screws to affix a plate to the bone. Ex. 1006, Abstract, ¶¶ 2, 9, 12; Ex. 1001 ¶¶ 190–192; Pet. 30–32. Figure 28 of Kay is reproduced here:

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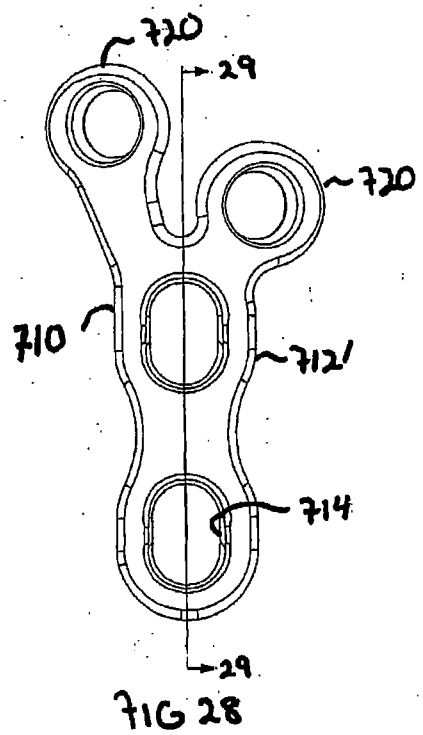
[13] *See also Papst Licensing GmbH & Co. v. Samsung Elecs. Am.*, 924 F.3d 1243, 1250 (Fed. Cir. 2019) (holding that patentee forfeited argument for patentability because it did not present it to the Board); *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1048 (Fed. Cir. 2019) (explaining that arguments not presented to the Board are waived).



Kay Figure 28 (Ex. 1006).

Figure 28 illustrates plate 710, which is pre-contoured to have elongate trunk 712 extending along a longitudinal medial axis (matching the cross-sectional view line 29–29 in Figure 28) and two arms 720 diverging asymmetrically from one end of the trunk. Ex. 1006 ¶¶ 42–43, 48, 51, 56; Ex. 1001 ¶¶ 192–196; Pet. 32–34. Each arm 720 exhibits a screw hole, which are shown but not numbered in Figure 28, to receive respective screws which converge toward each other but which do not impinge. Ex. 1006 ¶¶ 48, 50, 56; Ex. 1001 ¶¶ 196–203; Pet. 34–37. According to Kay, in one embodiment the screw hole bores "could be threaded," but Kay does not disclose using locking screws as are required by claim 17. Ex. 1006 ¶ 52; Ex. 1001 ¶¶ 197–204; Pet. 34–38; *see supra* Section IV.C (analyzing the priority issue). Kay discloses the distal end of each screw may be secured in cortical bone. Ex. 1006 ¶ 4; Ex. 1001 ¶ 205; Pet. 38.

Chan discloses a bone plate system including locking screws 1360 received in threaded screw hole bores 1340 of plates 1300. Ex. 1007, Fig. 13, Abstract, ¶¶ 14, 21, 67, 72; Ex. 1001 ¶¶ 198–201; Pet. 35–38. A person of ordinary skill in the art would have known that locking screws such as disclosed in Chan resist loosening of the screw, better than non-locking screws being received in non-threaded screw hole bores, and so would have been motivated to use Chan's locking screws and threaded plate holes in Kay's plate 28 to increase pullout resistance. Ex. 1001 ¶¶ 199–201; Ex. 1006 ¶ 4; Ex. 1007 ¶¶ 5–11, 14; Pet. 28–30, 35–36.

Thus, we conclude a preponderance of the evidence establishes claim 17 would have been obvious over Kay and Chan.

3. Claims 18–27

Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, that claims 18–27 would have been obvious over Kay and Chan. *See* Pet. 38–49; Ex. 1001 ¶¶ 206–228. Patent Owner does not address these claims separately from arguments addressed above in connection with their common parent claim, independent claim 17. *See* PO Resp. 30; *LG Elecs.*, 759 F. App'x at 925 ("The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented."); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that claims 18–27 would have been obvious over Kay and Chan.

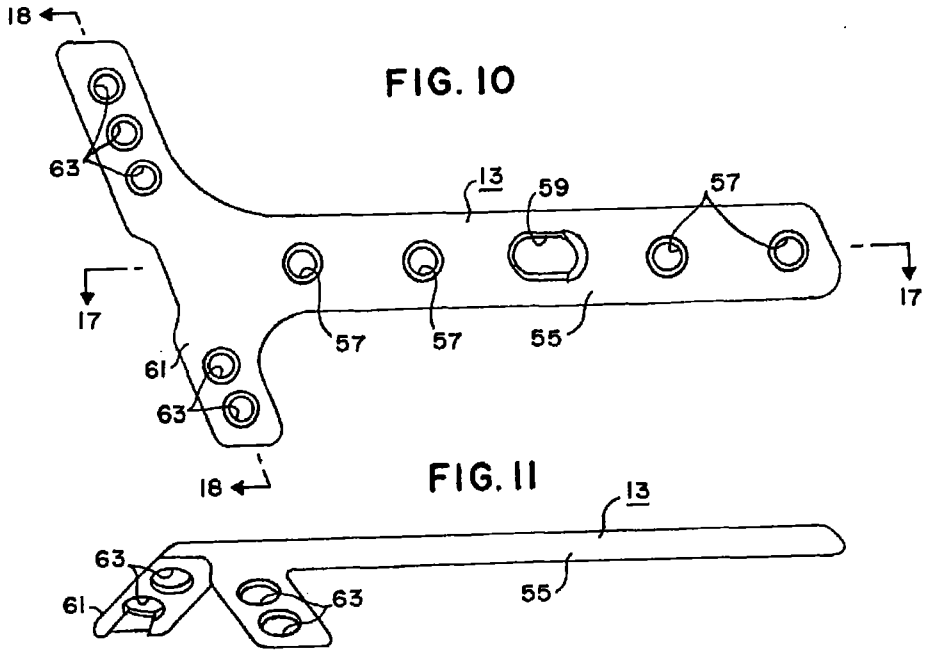
E. Obviousness over Grusin and Fernandez

Petitioner asserts claims 17–21 and 23–27 of the '252 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Grusin and Fernandez. Pet. 15–16, 49–73. Patent Owner opposes. PO Resp. 5, 30–59.

We determine Petitioner has demonstrated, by a preponderance of the evidence, that each of these claims would have been obvious over Grusin and Fernandez. We begin our analysis with a brief summary of the pertinent disclosures of Grusin and Fernandez, then we construe claim 17, and finally we address Petitioner's and Patent Owner's contentions as to obviousness.

1. Grusin Disclosure

Grusin discloses a bone plating system. Ex. 1010, Title. Figures 10 and 11 of Grusin are reproduced here:



Grusin Figures 10 and 11 (Ex. 1010).

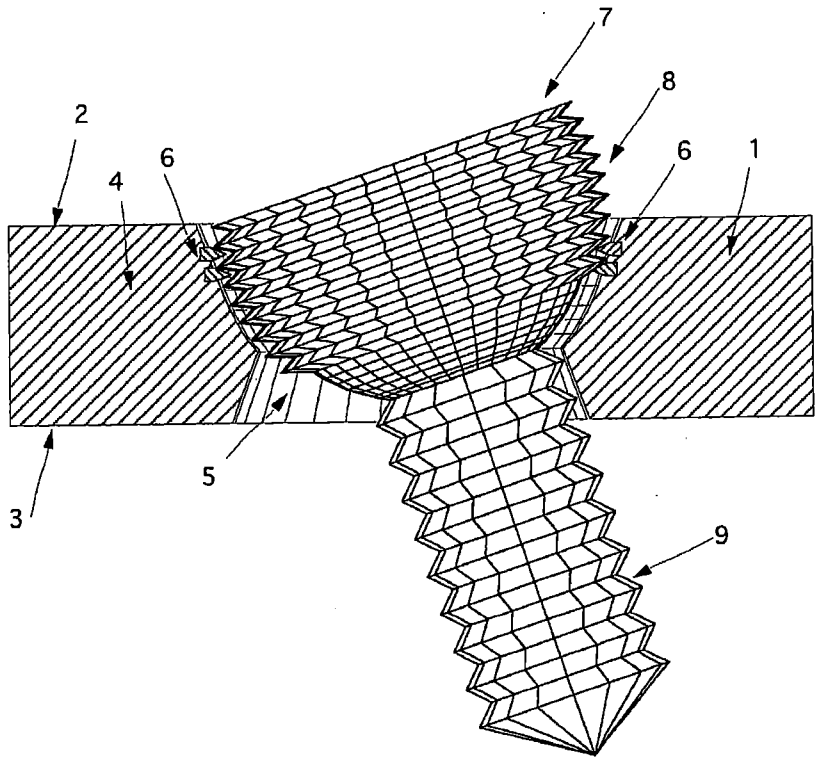
Figures 10 and 11 show, respectively, a top view and a side view of bone plate 13. *Id.* at 2:60–65, 6:60–64. Several spherically recessed holes 57

and 63 may accept fasteners, such as bone screws 37 (shown in Figure 76) or pin shank 23 and head 25 combinations (shown in Figures 43–53). *Id.* at 5:66–6:1, 6:13–17, 6:60–7:6.

2. Fernandez Disclosure

Fernandez discloses a variable angle, locked, bone fixation system. Ex. 1011, Title. Figure 10 of Fernandez is reproduced here:

FIG. 10



Fernandez Figure 10 (Ex. 1011).

Figure 10 is a sectional view of screw 7 driven through hole 5 of bone plate 1, into bone underneath plate 1 (not shown), and locked at a tilt. *Id.*

¶¶ 27–30. Screw 7 has head 8 which "is threaded with a constant pitch."[14] *Id.* ¶ 30. Further, the wall of plate hole 5 "has a small number of isolated protrusions 6 (such as pegs or spikes), which number is within 2 and 30, designed to lock against the threaded spherical head of the screws 8." *Id.* ¶ 32, Fig. 4 (showing protrusions 6 in a perspective view). Thus, "once the screw 7 has been driven in, it locks tightly against the protrusions 6 . . . in either perpendicular or tilted position," allowing "up to 20 degrees of angulation in any direction." *Id.* ¶ 33.

3. Claim Construction: "threaded screw hole"

Claim 17 recites first and second arms "each including at least one threaded screw hole." Ex. 1003, 13:25–27.

Patent Owner asserts a person of ordinary skill in the art "would have understood a ***threaded screw hole*** to be 'a hole having a helical structure such as a rib or ridge for receiving a screw.'" PO Resp. 13 (emphasis by Patent Owner) (citing Ex. 2017 ¶ 35; Ex. 2018 ¶ 35); Sur-reply 25–26 (citing Ex. 1087 ¶ 33; Ex. 2019, 85). In support, Patent Owner proffers dictionary definitions of the term "thread" as meaning "[a] ***continuous helical rib***, as on a screw or pipe" (Ex. 2008, 4), "[a] ***projecting helical rib*** (as in a fitting or on a pipe) by which parts can be screwed together" (Ex. 2009, 4), and "[a] ***helical ridge*** of a screw" (Ex. 2010, 4). PO Resp. 13 (emphases by Patent Owner). Patent Owner explains this claim construction issue arises in

[14] In the Institution Decision, we noted that although the Fernandez figures illustrate the threading of screw 7 as having zero pitch, it seems likely that the threading would have at least some non-zero, helical, pitch. Inst. Dec. 24. Patent Owner "does not dispute the threads of screw 7 have some non-zero pitch." PO Resp. 44. Petitioner also agrees. Pet. Reply 17.

connection with determining whether Fernandez's protrusions 6 correspond to a threaded screw hole. *Id.* at 12–13.

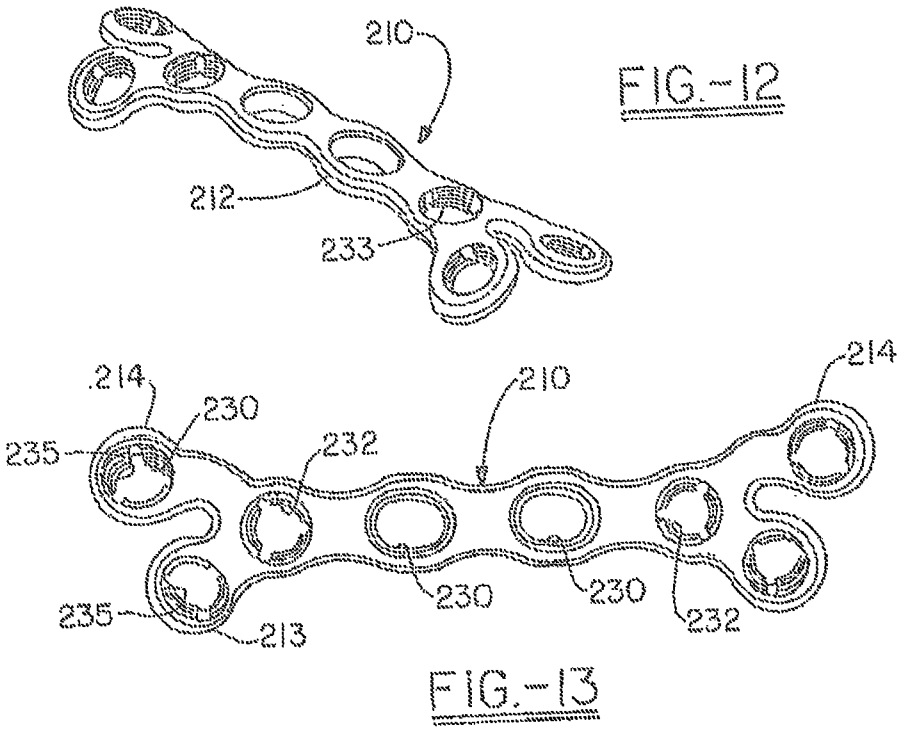
Petitioner responds that "Fernandez's protrusions mate with the threaded head of a screw, and thus are threads *under any reasonable meaning*." Pet. Reply 15–16 (emphasis added). Petitioner nonetheless argues "[t]here is no basis to accept PO's narrow construction," because it is supported only by dictionary definitions rather than intrinsic evidence. *Id.* at 15 & n.6. Petitioner further asserts Patent Owner's expert witness Dr. Neufeld "testified that a thread ***does not*** require a helical structure." *Id.* (emphasis by Petitioner) (citing Ex. 1072, 148:3–5).

We construe the term "threaded screw hole" to require "a helical structure such as a rib or ridge for receiving a screw," as proposed by Patent Owner. This construction is supported by the plain and ordinary meaning of the term "thread," as established by the dictionary definitions and witness testimony cited by Patent Owner. *See* Ex. 1087 ¶ 33; Ex. 2008, 4; Ex. 2009, 4; Ex. 2010, 4; Ex. 2017 ¶ 35; Ex. 2018 ¶ 35; Ex. 2019, 85:10–86:24. Thus, Dr. Neufeld's statement during deposition that "[a] thread could be helical or not" is contrary to his own declaration and the weight of other evidence presented in this proceeding, and is not persuasive. Ex. 1072, 148:3–5; Ex. 2017 ¶ 35.

Our construction also is supported by the '252 patent's illustration of "cancellous thread 83" and "external threads 88" as helical structures of a screw. Ex. 1003, Figs. 6–7, 4:29–32, 8:41–55. It is further supported by the '252 patent's illustration of plate 210 in Figures 12, 13, and 15 having locking holes 232 with "internal threads," wherein the threads are helical structures to match the helically threaded structure of a screw. *Id.* at

9:14–16; *see also id.* at 10:12–14 (describing plate 312 illustrated in Figs. 18 and 19 as having screw holes with "internal threads").

However, we further determine that the helical structure formed by the threaded screw hole in claim 17 may be either continuous, or interrupted. The '252 patent indicates a threaded screw hole may be formed by a series of interrupted structures. Figures 12 and 13 of the '252 patent are reproduced here:



'252 Patent Figures 12 and 13 (Ex. 1003).

Figure 12 is a perspective view, and Figure 13 is a top view, of plate 210. Ex. 1003, 5:50–53, 8:64–67. Plate 210 exhibits "locking holes [232] having internal threads" and "keyways 233 for the mating portion of a drill guide." *Id.* at 9:14–19; *see also id.* at Figs. 18 and 19, 10:12–14 (plate 312 has screw holes with internal threads interrupted by keyway grooves). In light of these disclosures, the extrinsic dictionary definition of "thread" being limited to

"[a] *continuous* helical rib" is not consistent with the intrinsic evidence. *See* Ex. 2008, 4 (emphasis added).

Extrinsic evidence also indicates the helical structure formed by the threaded screw hole in claim 17 may be either continuous, or interrupted. Mr. Castañeda testified via declaration that Fernandez's protrusions 6 form "internal threads" (Ex. 1001 ¶¶ 238–239) and create an "interrupted helical thread" (Ex. 1087 ¶¶ 33, 36). At the same time, Mr. Castañeda also testified during his deposition that "I don't have an opinion as to whether [Fernandez's protrusions 6] could be categorized as threads or not." Ex. 2019, 86:8–10. However, in context, he also stated Fernandez's protrusions are positioned "such that they would interact with the threads of the screw," so they "have to follow the same pattern, the helical path, if you will, as a screw head." *Id.* at 85:10–22. He further testified that the protrusions "behave as threads" and "act as threads" to mate and lock with the threads of the screw. *Id.* at 85:23–86:8; *id.* at 88:1–11, 89:20–90:8 (stating that Fernandez has "threads that are interrupted basically"). Thus, he "didn't say [the protrusions] are not threads," and "Fernandez calls them protrusions, so [he] would use that terminology, but they certainly serve the function of threads" because they "behave[] just like a thread in accepting the threads of a screw." *Id.* at 86:8–24.

Viewing Mr. Castañeda's declaration and deposition testimony together as a whole, we understand and share Mr. Castañeda's struggle with the '252 patent's lack of clarity in disclosing that a threaded screw hole may comprise interrupted threads, without defining a minimum amount by which each interrupted structure must extend to form the helical structure of the thread. Mr. Harrigan provided his views on this issue during his deposition,

but his testimony reflects the same struggle, as he was unable to provide a clear demarcation. *See* Ex. 1066, 146:6–148:8 ("I can't give you the simple understanding, because it depends on whether a screw would fit in that interrupted thread . . . ."). Patent Owner's arguments, similarly, do not identify a minimum amount by which each interrupted structure must extend to form the helical structure of the thread. *See* PO Resp. 12–14; Sur-reply 25–26. We do not discern such a minimum amount from our independent review of the '252 patent disclosure. Thus, given the record developed in this proceeding, we conclude there is no minimum amount by which an individual structure forming the interrupted helical structure of the thread must extend around the periphery of the hole. Instead, claim 17 simply requires the individual structures, taken together, form an interrupted helical structure.

Patent Owner additionally contends that the "threaded screw hole" of claim 17, requiring a helical structure such as a rib or ridge, is inconsistent with Fernandez's receipt of screw 7 within hole 5 of plate 1 at several different angles, rather than one fixed angle. *See* PO Resp. 44–47, 51 (citing Ex. 2018 ¶¶ 68–72; Ex. 1011, Fig. 10, ¶ 33; Ex. 2019, 88:8–10); Sur-reply 26–29 (further citing Ex. 1011, Fig. 9, ¶¶ 6, 15; Ex. 2023, 44–45, 63–64). We have reviewed Mr. Harrigan's testimony in support. Ex. 2018 ¶¶ 64–72, 83. However, Patent Owner and Mr. Harrigan do not cite any intrinsic evidence to support this narrow view of the "threaded screw hole" recited in claim 17. Patent Owner suggests Mr. Castañeda's deposition testimony supports Mr. Harrigan's opinion in this regard. Sur-reply 27 (citing Ex. 2023, 44–45). However, Mr. Castañeda testified only that the "third method" of the prior art described in Fernandez (Ex. 1011 ¶ 5) was a

"fixed-angle type screw." Ex. 2023, 44:2–45:7. He did not testify that a threaded screw hole is inconsistent with Fernandez's polyaxial receipt of screw 7 within hole 5 of plate 1. *Id.* We discern no requirement in claim 17 or in the '252 patent's intrinsic evidence for the threaded screw hole to receive the screw at only one fixed angle within the plate.

For the foregoing reasons, we construe the "threaded screw hole" of claim 17 to require a helical structure such as a rib or ridge for receiving a screw. The helical structure may be continuous, or interrupted, and if it is interrupted then there is no minimum amount by which an individual structure forming the interrupted helical structure of the thread must extend around the periphery of the hole. The helical structure may function to receive a screw at several different angles, or at one fixed angle.

4. Claim 17

Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, that claim 17 would have been obvious over Grusin and Fernandez. Pet. 49–62; Pet. Reply 15–25; Sur-sur-reply 3–5; Ex. 1001 ¶¶ 98–104, 229–247. Patent Owner provides arguments and evidence in opposition, including testimony from Dr. Neufeld and Mr. Harrigan. PO Resp. 5, 30–59; Sur-reply 6, 22–32; Ex. 2017 ¶¶ 50–72; Ex. 2018 ¶¶ 51–83.

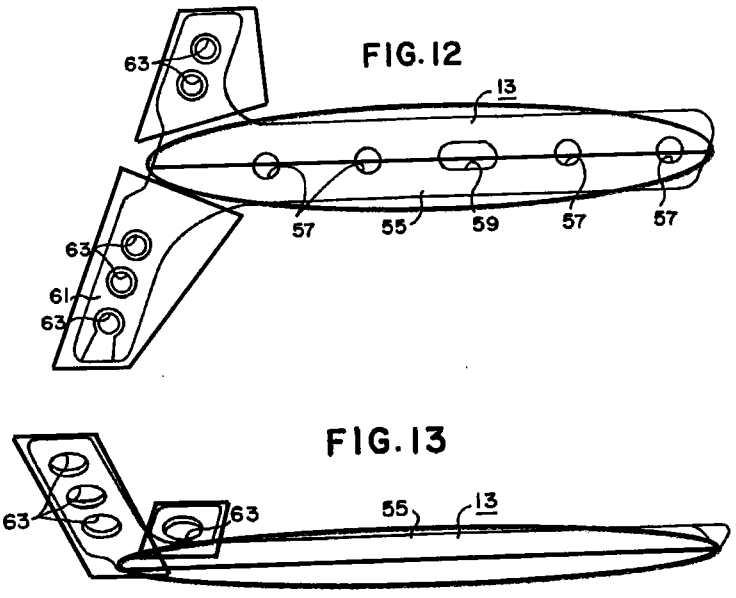
a) Whether Grusin Discloses the Claimed Subject Matter

Petitioner contends Grusin discloses each and every limitation of claim 17, except for (a) threaded screw holes to receive first and second locking screws, and (b) the distal end of the screw being secured in cortical bone. Pet. 52–62; Ex. 1001 ¶¶ 229–247. Prior to institution of trial, there was some question as to whether Petitioner might be relying on Grusin as

disclosing threaded screw holes. *See* Inst. Dec. 23 n.11. It is now clear from the Reply that Petitioner does not rely on Grusin as disclosing threaded screw holes. *See* PO Resp. 41–43 (arguing Petitioner relies solely on Fernandez as disclosing threaded screw holes); Pet. Reply 15–21 (relying solely on Fernandez as disclosing threaded screw holes).

Patent Owner does not dispute Petitioner's foregoing contentions. PO Resp. 30–59; *see LG Elecs.*, 759 F. App'x at 925 ("The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented."); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. Nonetheless, to provide a complete record, we summarize our findings comparing Grusin with the subject matter of claim 17.

Figures 12 and 13 of Grusin are reproduced here, with annotations added by Petitioner. *See* Pet. 56.



Grusin Figures 12 and 13 (Ex. 1010) (as annotated by Petitioner).

Figure 12 is a bottom plan view and Figure 13 is a side elevational view of plate 13 of Grusin's bone plating system (*see* Ex. 1010, 2:60–3:2, 6:61),

with both Figures including blue, red, and orange annotations added by Petitioner. We find Petitioner's annotations reflect how Grusin's plate 13 is pre-contoured to have an elongate trunk (circled in blue), with a longitudinal medial axis (red) and only first and second arms (circled in orange) diverging asymmetrically from one end of the trunk, and with the arms having holes 63 for receiving a screw or a pin fastener. Ex. 1001 ¶¶ 229–236; Pet. 52–56. We further find a person of ordinary skill in the art would have known, based on Grusin's disclosure, to choose screws having a length and diameter such that the screws inserted into one arm will converge toward, but not impinge upon, the screws inserted into the other arm. Ex. 1001 ¶¶ 242–243; Pet. 59–60.

Thus, we find Grusin's plate system embodies the subject matter of claim 17, which Petitioner cites Grusin as disclosing.

b) Whether Fernandez Discloses the Claimed Subject Matter

Petitioner contends Fernandez discloses a threaded screw hole (i.e., hole 5 with protrusions 6) for receiving a locking screw (i.e., screw 7) at a selected angle. *See* Pet. 57–58, 60–61 (citing Ex. 1011, Abstract, Figs. 1 & 4–10, ¶¶ 12, 15, 32–33); Ex. 1001 ¶¶ 238–241, 244–246.

Patent Owner does not dispute, and we find a preponderance of the evidence establishes, that Fernandez's screw 7 is a locking screw, having threaded head 8 that interfaces with protrusions 6 in plate hole 5 to lock screw 7 in place. *See* Ex. 1011, Abstract ("locking bone engaging members such as screws"), ¶¶ 30, 32–33 ("protrusions 6 [are] designed to lock against the threaded spherical head of screws 8," and "screw 7 . . . locks tightly against the protrusions 6 . . . in different positions").

Patent Owner disputes Petitioner's contention that Fernandez's protrusions 6 form "a threaded screw hole," as is required by claim 17. PO Resp. 39–52; Ex. 2017 ¶¶ 54–57; Ex. 2018 ¶¶ 55–72. We first summarize the parties' arguments concerning this issue, then we explain the reasons we find Fernandez's protrusions 6 do form a threaded screw hole.

(1) The Parties' Arguments

Patent Owner relies on its construction of the term "threaded" as requiring "a helical structure such as a rib or ridge." PO Resp. 39; Ex. 2017 ¶¶ 56–57; Ex. 2018 ¶¶ 62–63. Patent Owner asserts Fernandez's protrusions 6 are not threads because they are not helical structures, and because Fernandez describes them not as "threads" but rather as "isolated" "pegs or spikes" that may be flattened, round, or have a circular cross section. PO Resp. 39–44 (citing Ex. 1011 ¶¶ 32, 35, Figs. 4–5); Ex. 2018 ¶¶ 64–66. Patent Owner contends Petitioner's witness Mr. Castañeda "implicitly acknowledges that the 'isolated protrusions' of Fernandez are, in fact, ***not threads***, and expressly states that he does not offer an opinion that the protrusions are threads." PO Resp. 40–41, 47 (emphasis by Patent Owner) (citing Ex. 2019, 85:23–86:13).

Mr. Harrigan testifies on behalf of Patent Owner that, although Fernandez's screw head 8 is threaded at a non-zero helical pitch, this is "irrelevant" to whether the interfacing protrusions 6 are threads. Ex. 2018 ¶¶ 67–72; PO Resp. 44–47. Mr. Harrigan states that, due to the spherical shape of head 8, protrusions 6 will contact the threads of head 8 in different ways and at different locations, depending on the angle of screw 7 within hole 5. Ex. 2018 ¶¶ 68–70; PO Resp. 44–46. Mr. Harrigan also concludes

Fernandez does not disclose "a helical arrangement of the protrusions to match the threads on" screw head 8 because this "would be superfluous as Fernandez's particular polyaxial solution . . . eliminates any need for the protrusions to precisely match the threads on the screw head at several angles." Ex. 2018 ¶¶ 71–72, 83 (citing Ex. 1011 ¶ 33; Ex. 2019, 88:8–10); PO Resp. 46–47, 51.

In reply, Petitioner maintains Fernandez discloses threaded screw holes, even applying Patent Owner's claim construction. Pet. Reply 17–18; Ex. 1087 ¶¶ 32–36. In support, Petitioner notes the parties agree that Fernandez's screw head 8 has a helically pitched thread, so "a POSITA would have considered it obvious that Fernandez's protrusions also have a helical pitch," because Fernandez describes how the interaction between screw head 8 and protrusions 6 "provide[s] a simple effective and strong locking mechanism for locking the bone screw to the fixation device." Pet. Reply 17–18, 20 (quoting Ex. 1011 ¶ 10); Ex. 1087 ¶¶ 33–36. Fernandez also, according to Petitioner, describes prior art "locking screws" having "threaded heads 'that ***match[] with*** corresponding threading on the surface of a plate hole,'" which is how screw 7 of Fernandez's invention also works because it is also a locking screw. Pet. Reply 18, 20 (quoting Ex. 1011 ¶ 5; citing *id.* ¶¶ 6–7, 9, 11, 15); Ex. 1087 ¶¶ 34–36. Petitioner additionally points to testimony from Mr. Castañeda and Mr. Harrigan that "interrupted" threads are still threads, and argues Fernandez's protrusions 6 are interrupted threads. Pet. Reply 19 (citing Ex. 1087 ¶ 36; Ex. 1066, 146:6–148:8, 155:2–7).

Petitioner further asserts Patent Owner mischaracterizes and distorts Mr. Castañeda's testimony as implicitly acknowledging Fernandez's

protrusions are not threads. Pet. Reply 16–17 (citing Ex. 1001 ¶¶ 239–240; Ex. 2019, 85:10–86:24, 88:1–11, 89:20–90:8). According to Petitioner, Mr. Castañeda's full deposition testimony "shows he was simply stating his preference for the *terminology* of Fernandez [i.e., 'protrusion' rather than 'thread'], but his opinion was that Fernandez discloses threaded screw holes, even under PO's narrow construction." *Id.* (emphasis by Petitioner).

Petitioner finally contends Mr. Harrigan's testimony improperly relies on "measuring the dimensions of the screw depicted in Figure 3 of Fernandez," assuming the figure is drawn to scale. *Id.* at 20–21 (citing PO Resp. 44).

Patent Owner replies that Petitioner presents "a veiled inherency argument" that the "protrusions were necessarily helically arranged," which is not supported by the evidence. Sur-reply 23, 24–25. Patent Owner asserts Fernandez's variable angle locking feature is inconsistent with, and precludes, a finding that protrusions 6 are helically arranged, because a helical arrangement can provide only one fixed angle of entry for the screw. *Id.* at 26–29 (citing Ex. 1011 ¶¶ 6, 15, 33, Figs. 9–10; Ex. 2018 ¶¶ 67–71; Ex. 2023, 44–45, 63–64). Patent Owner also asserts Mr. Harrigan's testimony does not rely on any scale being provided in Fernandez's figures. *Id.* at 29–30 (citing Ex. 1011 ¶¶ 30–32; Ex. 2018 ¶ 68).

Patent Owner further cites the prosecution history of Fernandez as establishing Fernandez's protrusions 6 are *not* "interrupted or partial threads," as Petitioner would have it. *Id.* at 23–24, 29 (citing Ex. 2026,

5:23–25, Fig. 6; Ex. 2027, 12; Ex. 2028, Abstract, 1:39–45, Fig. 1).[15] For example, Patent Owner cites dependent claim 12 in the patent (Ex. 2026) that issued from Fernandez (Ex. 1011), as reciting a non-helical configuration. Sur-reply 29 (citing Ex. 2026, 5:23–25, Fig. 6). Patent Owner also argues Mr. Castañeda "testified that the protrusions [in Figure 6 of Fernandez] could be in a helical pattern *if* the screw head had a quadruple lead (entry) thread," but "Fernandez explicitly discloses that the screw head engaging the hole of Figure 6 only has a double entry thread." *Id.* (citing Ex. 1011 ¶ 30); *see also* Ex. 2023, 56:21–59:2 (Mr. Castañeda's testimony concerning Figure 6).

In reply, Petitioner asserts statements made by Fernandez's attorney during the prosecution history of Fernandez "do not offer any clarification" to what a person of ordinary skill in the art would have understood Fernandez to disclose. Sur-sur-reply 4–5. Petitioner faults Patent Owner for providing only one Amendment from the prosecution history (Exhibit 2027), and argues "the Examiner did not allow the claims after this amendment, providing evidence that the Examiner did not find applicant's statements persuasive." Sur-sur-reply 5 & n.3. Petitioner asserts the Amendment supports Petitioner's case, because it confirms the Examiner's position was the same as Petitioner's here. *Id.* (citing Ex. 2027, 12; Pet. Reply 16–20;

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[15] We overrule Petitioner's objection that Exhibits 2026–2028 were belatedly presented with Patent Owner's Sur-reply. *See* Paper 35; Sur-sur-reply 3–4. We accept these Exhibits as a rebuttal to arguments made in the Reply about the structure and operation of Fernandez's protrusions 6. *See* Pet. Reply 17–20; 37 C.F.R. § 42.5(a), (b). To ensure procedural fairness, we also consider Petitioner's Sur-sur-reply, which addresses these Exhibits. *See* Paper 35; Sur-sur-reply 4–5.

Ex. 1087 ¶¶ 33–36). Petitioner finally argues the scope of the Fernandez patent's dependent claim 12 "is of no moment" to the Fernandez disclosure, and Patent Owner's critique of Mr. Castañeda's testimony concerning claim 12 is baseless. *Id.* at 4 (citing Ex. 2023, 53:20–54:13, 57:2–59:2).

(2) Analysis

We find Fernandez's protrusions 6 form a threaded screw hole, even applying Patent Owner's claim construction of this term as requiring a helical structure such as a rib or ridge for receiving a screw. *See supra* Section IV.E.3 (claim construction). This finding is based on Fernandez's descriptions of the interaction between protrusions 6 and the helical structure of Fernandez's screw head 8, and the related testimony of Mr. Castañeda.

It is undisputed that Fernandez's screw head 8 has threads, and the threads of screw head 8 have a helical pitch, so the screw head 8 threads are helical structures. *See* Inst. Dec. 24 (citing Ex. 1011, Abstract, ¶¶ 11, 15, 30, 32–33); PO Resp. 44; Pet. Reply 17. Fernandez indicates the interaction between the helically threaded screw head 8 and protrusions 6 is "designed to lock" screw head 8 against protrusions 6, as screw 7 is driven into hole 5. Ex. 1011 ¶ 32. Also, "once the screw 7 has been driven in, it locks tightly against the protrusions 6," providing "a good fit among the thread of the screw head 8 and the protrusions 6 in either perpendicular or tilted position." *Id.* ¶ 33; *see also id.* ¶¶ 10–12 (describing "locking mechanism" as a feature of Fernandez's invention). Thus, screw head 8 has "a thread configured and dimensioned *to match with* the isolated protrusions." *Id.* at Abstract (emphasis added); *see also id.* ¶ 5 (describing prior art devices as similarly including a "locking screw" with "threading on an outer surface of its head

that *matches with* corresponding threading on the surface of a plate hole to lock the screw to the plate" (emphasis added)).

We are persuaded by Mr. Castañeda's testimony that, based on the foregoing disclosures in Fernandez, a person of ordinary skill in the art would have understood protrusions 6 correspond to "internal threads." Ex. 1001 ¶¶ 238–241, 244–246; Ex. 1087 ¶¶ 32–36. In particular, protrusions 6 are helically structured to interact with the helical structure of screw head 8. Protrusions 6 therefore form an interrupted helical thread, as is encompassed by claim 17. Ex. 1087 ¶¶ 33, 36; *see supra* Section IV.E.3 (claim construction). No doubt, the interrupted structures illustrated in the '252 patent are much longer, and the interruptions are much shorter, than the structures and interruptions of Fernandez. However, there is no minimum amount by which an individual structure forming the interrupted helical structure of the thread must extend around the periphery of the hole. *See supra* Section IV.E.3 (claim construction).

Mr. Harrigan's declaration testimony that Fernandez's protrusions 6 do not form a thread is not persuasive because it is undeveloped, confusing, and largely unsupported by citation to evidence. *See* Ex. 2018 ¶¶ 64–72. Mr. Harrigan appears to suggest that the spherical shape of screw head 8, which allows screw 7 to interact with protrusions 6 to lock screw 7 at a range of different angles in plate 1, precludes protrusions 6 from being threads. *Id.* But, regardless of the selected angle, according to Fernandez, screw 7 engages with protrusions 6 by rotating screw 7 within hole 5 so that screw 7 advances by protrusions 6 interacting with the helical threading of screw head 8. Ex. 1011, Abstract, ¶¶ 11, 15, 30, 32–33. As discussed above, the helical structure of the threaded screw hole in claim 17 may

function to receive a screw at several different angles. *See supra* Section IV.E.3 (claim construction).

We have considered Petitioner's argument that Mr. Harrigan's testimony improperly relies on measuring scaled dimensions of screw 7 as depicted in Figure 3 of Fernandez. *See* Pet. Reply 20–21. However, we agree with Patent Owner's rebuttal that Petitioner mischaracterizes the testimony as being premised upon a scale in Figure 3. *See* Sur-reply 29–30; Ex. 2018 ¶¶ 64–72. Therefore, we do not rely on this as a basis for our Decision.

We have also considered Patent Owner's citation to the prosecution history of Fernandez. There, the applicant representatively amended claim 21 to recite a method for fixing bone, using a bone plate opening "provided with non-thread protrusions configured and dimensioned to have the same pitch and mate with the threads on a bone screw head." Ex. 2027, 6 (underlined verbiage added by amendment). The applicant argued this amendment was supported by Fernandez's specification "describ[ing] the protrusions as non-thread elements such as pegs or spikes." *Id.* at 12 (citing Ex. 1011 ¶ 32). The applicant asserted the Examiner's prior finding that the "partial threads 3 of Talos[16]" correspond to the claimed protrusions "no longer holds because a 'non-thread protrusion' cannot be met by a thread." *Id.* Although not reflected in the record of this proceeding, the Office's prosecution history file for Fernandez indicates the succeeding September 18, 2008, Office Action withdrew the claim rejection based on Talos, in favor of a new rejection based on different prior art.

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[16] Ex. 2028, U.S. Patent No. 5,709,686, iss. Jan. 20, 1998.

The issue presented here, however, is whether Fernandez's protrusions 6 form a "threaded screw hole," as recited in claim 17 of the '252 patent. We have adopted Patent Owner's construction of that term as requiring "a helical structure such as a rib or ridge for receiving a screw." *See supra* Section IV.E.3. (claim construction). Further, based on the record of this proceeding, the helical structure may be interrupted, and there is no minimum amount by which an individual structure forming the interrupted helical structure of the thread must extend around the periphery of the hole. *See id.* Applying this construction, we find Fernandez's protrusions 6 form an interrupted helical structure, as encompassed by claim 17. Further, we agree with Petitioner's position that even if the scope of dependent claim 12 in the Fernandez patent (Ex. 2026) excludes threads, this does not necessarily mean that the disclosure of Fernandez (Ex. 1011) is correspondingly limited; it is quite often the case that a dependent claim is more narrow than the full scope of disclosure of a patent.

For the foregoing reasons, we find Fernandez's protrusions 6 form a threaded screw hole, as recited in claim 17.

c) Whether it Would Have Been Obvious to Modify Grusin's Plate to Incorporate Threaded Screw Holes to Receive Locking Screws

For obviousness, Petitioner contends Grusin discloses spherically recessed holes 63 in the arms of plate 13, which receive either bone screws 37, or pin shank 23 and pin head 25 to create a locking feature. *See* Pet. 49, 50, 57, 59 (citing Ex. 1010, 6:13–21, 8:67–9:6, 10:11–31); Ex. 1001 ¶ 240. Petitioner asserts Fernandez similarly discloses rounded hole 5, which receives threaded spherical head 8 of screw 7, such that the head's threads engage protrusions 6 in hole 5 to lock screw 7 at a selected angular

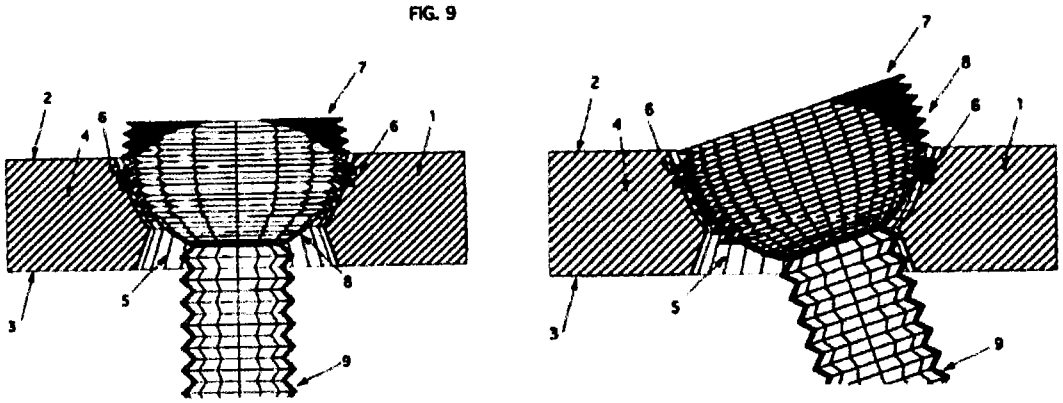
orientation. *See* Pet. 50, 57–58 (citing Ex. 1011, Abstract, ¶¶ 10–13, 15, 32, and claim 1); Ex. 1001 ¶¶ 238–240.

According to Petitioner, a person of ordinary skill in the art would have been motivated "to look for features of bone plate systems which resist screws loosening or pulling out" for use with Grusin's plate 13, "particularly given Grusin's application to the end of the radius where use of a patient's hand could increase stress on the screws." Pet. 49–50, 58–59; Ex. 1001 ¶¶ 240–242. In Petitioner's view, such a system is found in Fernandez, because "POSITAs would have known that threaded screw holes for use with locking screws could be used to increase pullout strength," so "POSITAs would have been motivated to apply the threaded screw holes of Fernandez to the bone plate of Grusin." Pet. 49–51, 58–59 (citing Ex. 1011, Abstract, ¶¶ 10–13, 15, 32, and claim 1); Ex. 1001 ¶¶ 240–242. An additional motivation for the proposed obviousness, according to Petitioner, is that using Fernandez's threaded screw holes 5 and locking screws 7 with Grusin's plate 13 would advantageously permit insertion of screws at variable angular orientations. *See* Pet. 51–52, 61–62 (citing Ex. 1011 ¶¶ 6, 12); Ex. 1001 ¶¶ 240–242, 244–246.

Patent Owner argues Grusin teaches away from using Fernandez's polyaxial screw 7 in Grusin's plate 13, so it would not have been obvious to do so.[17] PO Resp. 55–59; Ex. 2017 ¶¶ 62–72. Specifically, Dr. Neufeld testifies that Fernandez's screw 7 would frustrate Grusin's intended purpose,

[17] The Patent Owner Response also discusses the needs met by the '252 patent, and the "great commercial success" of products embodying the '252 patent claims. PO Resp. 5–9. However, during the hearing, Patent Owner's counsel confirmed Patent Owner is not relying on objective indicia of nonobviousness. Tr. 56:12–20.

which is to avoid tendon and soft tissue irritation and wear by maintaining a low profile of the fastener above the plate. Ex. 2017 ¶¶ 62–64 (citing Ex. 1010, 2:10–15, 2:29–33); PO Resp. 55 (further citing Ex. 2019, 82:20–83:5). To illustrate his conclusion, Dr. Neufeld annotates Figures 9 and 10 of Fernandez, as reproduced here:



Figures 9 and 10 of Fernandez (Ex. 1011).

Figure 9 is a front view of Fernandez's bone fixation assembly where the screw is perpendicularly locked, and Figure 10 is a front view of Fernandez's bone fixation assembly where the screw is locked at a tilt (i.e., non-perpendicular relative to the plate), with both Figures including red shading where the peripheral threaded edge of Fernandez's screw head 8 will extend above Grusin's plate. Ex. 2017 ¶¶ 65–67; PO Resp. 56–57. Dr. Neufeld testifies this would traumatize tendons and soft tissue in the region of the patient's wrist. Ex. 2017 ¶¶ 66–67; PO Resp. 56–57.

Dr. Neufeld further testifies that Grusin discloses inserting only unthreaded pins within holes 63 in the arms of plate 13, because fasteners in that region will engage bone fragments "that otherwise would not hold a screw," and the pins will "beneficially allow for some movement of the bone along the axis of the pin." Ex. 2017 ¶¶ 51, 68, 70 (citing Ex. 1010, 2:5–15, 2:22–33); PO Resp. 31, 57–58; Sur-reply 30. Dr. Neufeld's view is that a

person of ordinary skill in the art would therefore not have been motivated to replace Grusin's pins with Fernandez's screws to increase hold strength, because this would be "anathema to the teaching of Grusin," which already provides a "very solid connection." Ex. 2017 ¶¶ 52–53, 69–71 (citing Ex. 1010, 2:11–15, 8:64–9:6, Figs. 44 and 50; Ex. 1001 ¶¶ 240–241); PO Resp. 31–33, 57–59; Sur-reply 30–31.

Petitioner replies that Dr. Neufeld's testimony ignores that Grusin discloses "the screws and buttress pins for use with Grusin's plate can extend beyond the plate without causing 'great trauma.'" Pet. Reply 23–24 (citing Ex. 1010, Figs. 76–77, 5:25–33, 5:66–6:17). Petitioner asserts there is no evidence to indicate that threads traumatize tendons, and if this were the case then "threaded-headed screws would be of no use to surgeons." *Id.* at 24.

Petitioner also replies that Grusin contradicts Dr. Neufeld's testimony that screws should not be used in Grusin's system, because Grusin discloses holes 63 in the arms of plate 13 can accept "bone screws." *Id.* at 24 (citing Ex. 1010, 6:13–17). Petitioner also asserts there is no teaching away from a more secure connection in Grusin, because Grusin contemplates a "locking feature." *Id.* at 24–25 (citing Ex. 1010, 6:17–21).

In rebuttal, Patent Owner presents an annotated comparison, reproduced below, between Fernandez's Figure 10 (on the left) and Grusin's Figure 76 (on the right). *See* Sur-reply 31.

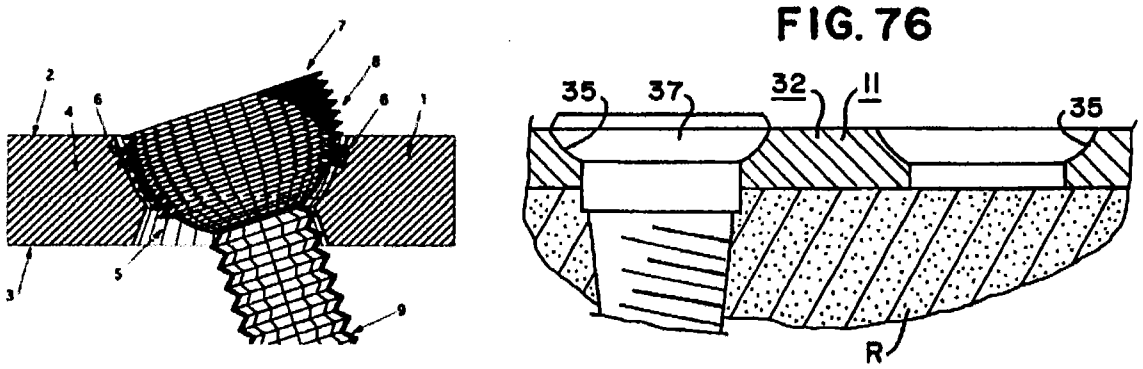


Figure 10 of Fernandez (Ex. 1011) and Figure 76 of Grusin (Ex. 1010).

Figure 10 is a front view of Fernandez's bone fixation assembly where the screw is locked at a tilt, with red shading where the peripheral threaded edge of Fernandez's screw head 8 will extend above Grusin's plate. Figure 76 is a sectional view of a portion of a longitudinal segment of Grusin's plate 11 showing a low profile head bone screw 37 securing the plate to radius R. Patent Owner argues this side-by-side comparison of installed screws "demonstrates that the exposed threads of Fernandez," which are annotated in red, "are unsuitable for Grusin's purpose." *Id.* Patent Owner asserts this comparison supports Dr. Neufeld's testimony that Fernandez's "edges . . . would not only irritate the tendons . . . but would undoubtedly cause great trauma to the tendons or other soft tissue if used in the transverse plate of Grusin." *Id.* at 31–32 (quoting Ex. 2017 ¶ 66).

We determine a preponderance of the evidence supports Petitioner's contentions of obviousness. First, Petitioner provides a rational underpinning for the proposed obviousness of modifying holes 63 in Grusin's plate 13 to include protrusions 6 to receive Fernandez's screw 1—to permit the fastener to be locked at a selected angular orientation in Grusin's plate, *i.e.,* the addition of Fernandez's polyaxial screw system beneficially adds "flexibility to choose a desired screw angle." *See*

Ex. 1011, Abstract, ¶¶ 10–12, 32–33; Ex. 1001 ¶ 240; Pet. 50–52; *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418. However, Petitioner's additional contention that this modification would "increase the hold strength" versus what Grusin already provides is not supported by a preponderance of the evidence, which does not compare the relative holding strengths of the respective fastening mechanisms. *See* Pet. 49–50 (citing Ex. 1011 ¶ 12; Ex. 1001 ¶¶ 240–241). Nonetheless, we find the modification would not materially reduce or sacrifice the holding strength, because Grusin and Fernandez both describe their respective fastening mechanisms as locking the fastener in the plate. *See* Ex. 1010, 6:13–21, 8:63–9:16; Ex. 1011 ¶¶ 10–12, 32. Indeed, Patent Owner does not dispute these findings and determinations.

We further find Grusin does not teach away from modifying holes 63 in plate 13 to include protrusions 6 to receive Fernandez's screw 1. In order to teach away, a reference must criticize, discredit, or otherwise discourage the claimed solution. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Here, by contrast, Grusin discloses that one object of Grusin's invention "is to provide specially designed screws with *low profile* heads to complement the plates and *reduce* tendon irritation and wear," in an effort to avoid "a secondary surgery due to plate [or screw]-derived tendon irritation and wear." Ex. 1010, 2:10–13 (emphases added), 2:18–32. In other words, Grusin does not criticize, discredit, or otherwise discourage using a fastener that extends above a plate. Instead, Grusin seeks to reduce, but not necessarily to eliminate, the extent to which a fastener extends above a plate. *See, e.g., id.* at Figs. 76–77 (illustrating bone screw 37 and buttress pin 19 both extend above plate 11). The problem addressed by Grusin is thus one

of degree, not absolutes. Moreover, while Grusin indicates its invention improves upon "more bulky prior art distal radius systems," Grusin does not otherwise describe the bulky nature of the prior art systems, much less in a fashion that would indicate Fernandez's system is materially similar to such systems. *See id.* at 2:5–18.

We are not persuaded that Fernandez's screw head 8 will extend so far above Grusin's plate 13 that it will cause materially more damage to the tendons and soft tissue surrounding the plate and screw than Grusin's existing low profile fasteners. Dr. Neufeld's testimony in this regard is that Fernandez's screw head 8, which is threaded around its entire periphery, including a portion which extends above the plate, "would not only irritate the tendons associated with the distal radius, but would undoubtedly cause great trauma to the tendons or other soft tissue if used" with Grusin's plate 13. Ex. 2017 ¶ 66. However, Dr. Neufeld does not provide any reasons or analysis in support of this conclusion. *Id.* ¶¶ 66–67. For example, he does not compare an expected range of sizes for Fernandez's screw 7 if used with the radius bone, versus the size and durability of tendons and soft tissue in the wrist region. Thus, his opinion is too conclusory to be persuasive on this record.

Moreover, even if Petitioner's proposed modification might, in some instances, cause the Fernandez screw to extend above Grusin's plate to a greater extent than Grusin's screw, nonetheless this modification comes with the benefit of adding a variable angular orientation feature to Grusin. *See, e.g., In re Urbanski,* 809 F.3d 1237, 1243 (Fed. Cir. 2016) (holding that a combination of references may be obvious even if the combination is at the expense of a benefit of one of the references); *Henny Penny Corp. v.*

Frymaster LLC, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (explaining that, in an obviousness analysis, the "benefits, *both lost and gained*, should be weighed against one another") (quoting *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000)).

We are also not persuaded that using a threaded shaft screw fastener, rather than a smooth shaft pin fastener, would fail to affix Grusin's plate 13 to a patient's radius bone or related bones. The disclosure of Grusin at issue here provides, in full: "Other objects of the bone plating system of the present invention is to provide specially designed *screws with low profile heads* to complement the plates and reduce tendon irritation and wear, [and] *provide buttress pins for comminuted fragments that otherwise would not hold a screw*." Ex. 1010, 2:10–15 (emphases added), 2:31–33; *see also id.* at 6:13–17 (disclosing plate 11 in Fig. 1 has transverse segment 42 with holes 45 that can receive bone screws 37), 6:60–7:15 (disclosing plate 13 in Fig. 10 has transverse segment 61 with holes 63 that are "identical" to holes 45). That is, according to Grusin, in some cases a threaded-shaft screw fastener is useful, while in other cases a smooth-shaft pin fastener is useful.

We therefore disagree with Dr. Neufeld's testimony that Grusin "only" discloses "the use of locking pins" in holes 63 of plate 13, and that the strong hold provided by a screw is "anathema" to or otherwise contrary to the purpose of Grusin. *See* Ex. 2017 ¶¶ 68–72. And we find that in situations where screws are useful as expressly contemplated by Grusin, it would have been obvious to use Fernandez's screw 7, because Fernandez's screw unlike Grusin's screw can be locked at a selected angular orientation.

For the foregoing reasons, we determine a preponderance of the evidence establishes it would have been obvious to modify Grusin's plate system to use Fernandez's screw 7 and protrusions 6 in the arms of Grusin's plate 13.

d) Whether it Would Have Been Obvious to Use Grusin's Plate System such that the Distal End of a Screw is Secured in Cortical Bone

Petitioner asserts "Grusin in view of Fernandez discloses," as recited in claim 17, "the distal end of the screw is secured in cortical bone." Pet. 38 (claim element 17[e]), 62. In support, Petitioner cites Fernandez's disclosure that it is desirable for a surgeon to be able to select a variable screw insertion angle when attaching a plate to a bone, using a "polyaxial" system. *Id.* (citing Ex. 1011 ¶ 6). According to Petitioner, "POSITAs would thus have been motivated to use variable locking screws as disclosed by Fernandez of the proper length and at an angle *so that their distal ends were secured in cortical bone for a secure hold in the radius bone.*" *Id.* (emphasis added); Ex. 1001 ¶ 247. This is particularly so, in Petitioner's view, because Grusin's plate 13 is designed for use with "the radius bone, where movement of a patient's hand or arm would increase the stress on the screws and require a more secure hold," which would be provided by securing the distal end of a screw in cortical bone. Pet. 62; Ex. 1001 ¶ 247.

Patent Owner responds by first explaining that human bone is generally classified as one of two types—cortical bone, and cancellous bone—based on porosity and unit microstructure. PO Resp. 52–53 (citing Ex. 2017 ¶ 59). Specifically, cortical bone is much denser and less porous than cancellous bone, and "[c]ortical bone . . . forms the outer shell around cancellous bone." *Id.*

Patent Owner then argues neither Grusin nor Fernandez discloses securing the distal end of their respective fasteners in cortical bone, as "[t]here is ***no*** discussion regarding cortical bone" in either reference, much less a teaching of securing the distal end of a fastener in cortical bone. *Id.* at 53, 54 (emphasis by Patent Owner) (citing Ex. 2017 ¶ 61). Patent Owner further asserts there is no discussion in the Petition "regarding the basis of this limitation" as part of the Grusin-Fernandez combination, "other than attorney argument" and "bald assertion" testimony from Mr. Castañeda. *Id.* at 54. Thus, Patent Owner concludes Petitioner's case falls short, for failing to establish all claim limitations are taught or suggested by the prior art, and for failing to provide an articulated reasoning why the claimed invention would have been obvious. *Id.*

Petitioner replies that "whether the word 'cortical' appears in Grusin and Fernandez is" irrelevant, because Petitioner relies on the combination of Grusin and Fernandez as establishing the obviousness of claim 17. Pet. Reply 21 (citing Pet. 62). Petitioner also cites Dr. Neufeld's testimony that cortical bone is "much denser" than cancellous bone as further support for Mr. Castañeda's testimony that "securing the distal end of a screw in cortical bone would provide a more secure hold of the plate to the bone," so this would have been obvious to do in the context of Grusin and Fernandez. *Id.* at 22 (citing Ex. 2017 ¶ 59; Ex. 1072, 121:3–122:12; Ex. 1001 ¶ 247). Petitioner asserts this testimony from Mr. Castañeda is not an improperly bald assertion, but rather is "an appropriate application of his knowledge of a POSITA." *Id.* Petitioner finally contends a person of ordinary skill in the art would have known that the distal radius bone, which Grusin's plate 13 is designed to repair, has a cortical bone component, so Grusin "both expressly

discloses to POSITAs that its fasteners terminate in cortical bone and renders it obvious to do so." *Id.* at 22–23 (citing Ex. 1010, 8:24–28; Ex. 1072, 59:13–61:6, 121:3–16; Ex. 1087 ¶ 38); *see also* Ex. 1084 ¶¶ 7–8, 21, 34–35, 51–52 (disclosing that a radius bone has a cortical bone portion).

Patent Owner's Sur-reply and Petitioner's Sur-sur-reply do not address this cortical bone dispute.

We, first, determine it is undisputed that a person of ordinary skill in the art in January 2006 would have known that many human bones are formed by cortical bone forming an outer shell around cancellous bone, with the outer cortical bone being much denser than the inner cancellous bone. *See* Ex. 2017 ¶ 59; Ex. 1087 ¶ 38; Ex. 1072, 59:13–61:6, 121:3–16. Also, the radius bone, which Grusin's plate 13 is designed specifically to fix, is such a bone. *See* Ex. 1084 ¶¶ 34–35, 51 (Figs. 11–12 illustrate radius bone 400); *id.* ¶¶ 7–8, 21, 52 (Figs. 11–12 illustrate drill bit 260 extending through the cortical portion of radius bone 400).

Further, and consistent with the evidence discussed above, the '252 patent itself acknowledges as background that "[s]ome surgeons prefer bicortical fixation in which a screw is sized so that the [distal] end is secured in cortical bone giving the screw better purchase." Ex. 1003, 1:61–65. That is, it was known before the '252 patent that it can be advantageous to secure the distal end of the screw in cortical bone, to provide a more secure attachment, given the denser nature of cortical bone relative to cancellous bone. *See* Ex. 1072, 121:3–122:12.

Given the foregoing undisputed knowledge of a person of ordinary skill in the art in January 2006, and based on the testimony of Mr. Castañeda, it would have been obvious to secure the distal end of

Fernandez's polyaxial screw in a patient's cortical bone, to provide a more secure attachment. *See Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337–38 (Fed. Cir. 2020) (holding the Board did not err in holding claims unpatentable over one prior art reference that did not disclose pipelining, in light of the "general knowledge" concerning pipelining as evidenced by expert testimony and corroborated by another prior art reference). In the circumstances of this case, where the cortical / cancellous structure of many bones and the greater density of cortical bone were known, it is not necessary for Grusin or Fernandez to disclose securing the distal end of a screw in cortical bone, to establish the obviousness of claim 17 in this regard. *See id.* This is particularly the case where Grusin's plate 13 may be used to heal "factures of the distal radius" (Ex. 1010, 1:18–20, 5:37–39), which includes a cortical bone portion, and "the use of the hand or arm to grip or hold something could result in increased stress on the screws and a need for increased strength" (Ex. 1001 ¶ 247).

e) Conclusion as to Claim 17

We conclude a preponderance of the evidence establishes that it would have been obvious to combine Grusin and Fernandez in the manner recited in claim 17, so the claim is unpatentable under 35 U.S.C. § 103.

5. Claims 18–21 and 23–27

Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, that claims 18–21 and 23–27 would have been obvious over Grusin and Fernandez. *See* Pet. 62–73; Ex. 1001 ¶¶ 248–275. Patent Owner does not address these claims separately from arguments addressed above in connection with their common parent independent claim 17. *See*

PO Resp. 22–32; *LG Elecs.*, 759 F. App'x at 925 ("The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented."); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that these claims would have been obvious over Grusin and Fernandez.

V. SUMMARY OF CONCLUSIONS

In summary, we determine a preponderance of the evidence establishes claims 17–27 of the '252 patent are unpatentable,[18] as shown in the following table:

Claims	**35 U.S.C. §**	**References**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
17–27	103	Kay, Chan	17–27	
17–21, 23–27	103	Grusin, Fernandez	17–21, 23–27	
Overall Outcome			17–27	

[18] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 17–27 of the '252 patent have been proven by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2019-00895
Patent 9,259,252 B2

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