

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PARAGON 28, INC.,  
Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,  
Patent Owner.

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IPR2019-00896  
Patent 9,545,278 B2

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

POLLOCK, *Administrative Patent Judge*.

JUDGMENT  
Final Written Decision

Determining All Challenged Claims Unpatentable  
*35 U.S.C. § 318(a)*

Dismissing Patent Owner's Motion to Exclude Evidence  
*37 C.F.R. § 42.64*

## I. INTRODUCTION AND BACKGROUND

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 1–9 of U.S. Patent No. 9,545,278 B2 (“the challenged claims”). We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a).

Considering the record before us, Petitioner has shown by a preponderance of the evidence that claims 1–9 are unpatentable.

### A. Procedural History

Paragon 28, Inc. (“Petitioner” or “Paragon”) filed a Petition for an *inter partes* review challenging claims 1–9 of U.S. Patent No. 9,545,278 B2 (“the ’278 Patent”, Ex. 1005) as unpatentable as obvious under 35 U.S.C. § 103. Paper 2 (“Pet.”). Wright Medical Technology, Inc. (“Patent Owner” or “Wright”) timely filed a Preliminary Response. Paper 10 (“Prelim. Resp.”). The parties further submitted an authorized Reply and Sur-Reply to the Preliminary Response. Papers 13 and 15, respectively. We instituted a trial to determine whether Petitioner had shown that claims 1–9 of the ’278 Patent were unpatentable. Paper 16 (“Institution Decision” or “Inst. Dec.”), 45.

After institution, Patent Owner filed a Patent Owner Response to the Petition. Paper 21 (“PO Resp.”). Petitioner then filed a Reply (Paper 29, “Reply”) to the Patent Owner Response, and Patent Owner filed a Sur-reply (Paper 33, “Sur-reply”) to Petitioner’s Reply, and Petitioner filed a Sur-sur-reply (Paper 40).

Patent Owner also filed a Motion to Exclude Evidence directed to Exhibits 1057–1060, 1070, 1073–1075, 1081, 1086, and 1088. Paper 39.

Petitioner filed an Opposition (Paper 41) to the Motion and Patent Owner filed a Reply (Paper 42).

On June 25, 2020, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 43 (“Tr.”).

B. Real Parties-in-Interest

Petitioner identifies only itself as the real party-in-interest. Pet. 75. Patent Owner, likewise, identifies only itself as the real party-in-interest. Paper 6, 2.

C. Related Proceedings

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. 75; Paper 6, 2.

The ’278 Patent shares essentially the same Specification with, among others, U.S. Patent Nos. 9,144,443 B2 (“the ’443 Patent”), 9,259,252 B2 (“the ’252 patent”), and 9,259,253 B2 (“the ’253 Patent”). Paragon filed Petitions for *Inter Partes* Review of the ’443, ’252, ’278, and ’253 Patents in IPR2019-00894, IPR2019-00895, IPR2019-00896, and IPR2019-00898, respectively. See Pet. 75; Paper 6, 2. The ’443, ’252, ’278, and ’253 Patents claim benefit of priority to application No. 12/380,177, filed on February 24, 2009 (“the 2009 application”), which is a continuation-in-part of application No. 11/340,028, filed January 26, 2006 (“the 2006 Application”). As discussed in section III(C), below, the parties dispute whether the claims of the ’278 Patent are entitled to the benefit of the 2006 Application.

D. The '278 Patent (Exhibit 1005)

The '278 Patent discloses “a series of orthopedic plates for use in repair of a bone” such as a clavicle. Ex. 1005, Abstract, 1:22–24, 2:19–21.

Figure 1 of the '278 Patent is reproduced below:

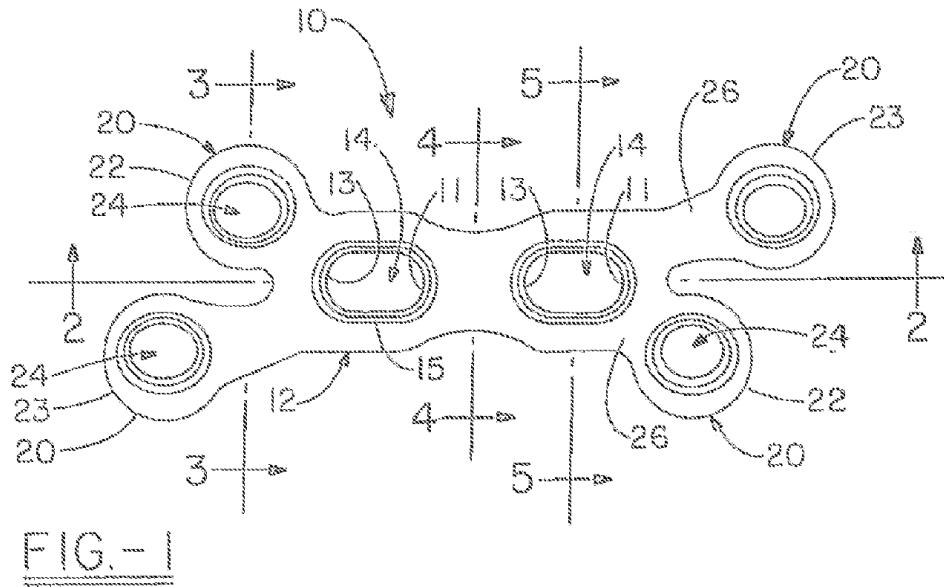


Figure 1 illustrates orthopedic plate 10 having an X-shaped profile, formed by central trunk portion 12 and two pairs of arms 20 extending diagonally from opposed terminal ends of central trunk portion 12. *Id.* at Abstract, 5:31–32, 6:48–51, 7:19–27. Central trunk portion 12 includes two screw holes or slots 14. *Id.* at 6:51–53. The opposing pairs of arms 20 each include short arm 22 and long arm 23, which extend from central trunk portion 12 at different angles of divergence relative to the longitudinal axis of trunk portion 12.<sup>1</sup> *Id.* at 7:24–34. The differing angles of divergence ensure that screws inserted into respective screw holes 24 of short arm 22 and long

<sup>1</sup> The '278 Patent suggests these angles are identified as  $\alpha$  and  $\beta$  in Figure 1 of the '278 Patent (Ex. 1005, 7:27–36), but that figure does not identify  $\alpha$  and  $\beta$ . The angles are, however, identified in Figure 1 of the 2006 Application. *See* Ex. 2001, Fig. 1.

arm 23 (at the right side of Figure 1, for example) will not impinge on each other inside a bone underneath plate 10. *Id.* at 1:56–2:1, 3:54–4:2, 8:11–16.

Screw holes 24 may be either “locking” or “non-locking” screw holes. *Id.* at 3:44–47. Figures 6 and 7 of the ’278 Patent are reproduced below:

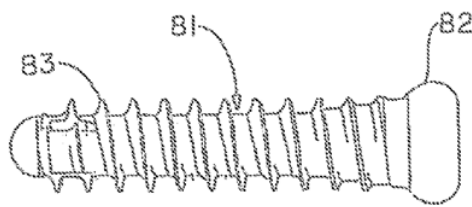


FIG. -6

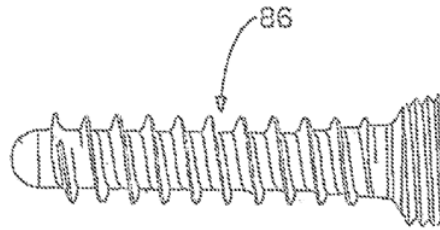


FIG. -7

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 8:55–9:3. Screw holes 24 in plate 10 “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 4:32–36.

#### E. Challenged Claims

The ’278 Patent recites 9 claims, of which claims 1 and 5 are independent. Claim 1 recites:

1. An orthopedic plate system comprising at least one screw and a contoured plate having an inferior surface which is capable of engaging a bone surface in use and having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end and further including at the first end a pair of arms, each arm including an arm screw hole which defines a central screw hole axis and having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal axis of the trunk area, and wherein the longitudinal arm axis of the first of the pair of arms is

different than the longitudinal arm axis of the second pair of arms; and

wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis.

Ex. 1005, 12:7–25.

Depending from claim 1, claim 2 requires that the orthopedic plate system comprise at least two screws, which “do not impinge on each other”; claim 3 relates to the orientation angle of the screw axis in the arm screw hole; and claim 4 requires that “the arm screw hole includes internal threads.”

Independent claim 5 is directed to an orthopedic plate system comprising in part,

an orthopedic plate having an inferior surface which is capable of facing a bone surface in use and which is pre-contoured to accommodate the shape of the bone surface . . . wherein the plate has a medial line which describes a curve in a lateral plane or in a longitudinal plane wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface such that said at least one screw can engage said arm screw hole so as to allow a plurality of angular orientations of said at least one screw axis relative to said screw hole axis.

Ex. 1005, 12:38–62.

Depending from claim 5, claim 6 requires that the orthopedic plate system comprise at least two screws, which “do not impinge on each other”; claim 7 relates to the orientation of the plate arms; claim 8 relates to the orientation angle of the screw axis in the arm screw hole; and claim 9 requires that “the curve in the lateral plane or in the longitudinal plane is an S-curve.”

F. Asserted Grounds of Unpatentability

We address the following grounds for unpatentability (Pet. 21; Inst. Dec. 7, 45):

Ground	Claim(s)	Basis	Asserted Reference(s)
1	1–8	103	Kay <sup>2</sup> , Chan <sup>3</sup>
2	9	103	Kay, Chan, Heintl <sup>4</sup>
3	1–8	103	Grusin <sup>5</sup> , Fernandez <sup>6</sup>

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<sup>2</sup> Kay et al., US 2006/0173459 A1, published Aug. 3, 2006 (Ex. 1006), originally filed as US Application No. 11/340,028 on January 26, 2006 (Ex. 2001).

<sup>3</sup> Chan et al., US 2008/0140130 A1, published June 12, 2008 (Ex. 1007).

<sup>4</sup> Heintl, US 4,903,691, issued Feb. 27, 1990 (Ex. 1009).

<sup>5</sup> Grusin et al., US 6,283,969 B1, issued Sept. 4, 2001 (Ex. 1010).

<sup>6</sup> Fernandez, US 2005/0165400 A1, published July 28, 2005 (Ex. 1011).

In support of its patentability challenges, Petitioner further relies on, *inter alia*, the Declaration of Javier E. Castañeda (Ex. 1001) and the Reply Declaration of Javier E. Castañeda (Ex. 1087); see also Ex. 2019 (Castañeda deposition transcript). In opposing these challenges, Patent Owner relies on, *inter alia*, the Declaration of Steven Neufeld, M.D. (Ex. 2017) and the Declaration of Timothy P. Harrigan Sc.D. (Ex. 2018); see also Ex. 1072 and 1066 (Neufeld and Harrigan deposition transcripts, respectively).

G. Principles of Law

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish by a preponderance of the evidence that the challenged claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2018).

A patent claim is unpatentable under 35 U.S.C. § 103(a) 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 skill in the art; and (4) any objective evidence of non-obviousness, if present.<sup>7</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

## II. 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

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<sup>7</sup> The Patent Owner Response discusses the needs met by the ’278 Patent, and the “benefits of the inventions disclosed and claimed” in the ’278 Patent and related patents. PO Resp. 4–6. However, during the hearing, Patent Owner’s counsel confirmed Patent Owner is not relying on objective indicia of nonobviousness. Tr. 56:12–20.

reasons grounded in the Federal Rules of Evidence. *See* Paper 39. We do not rely on any of these Exhibits in this Decision. Although the parties 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. *See* Reply 5; Sur-Reply 13–15. Petitioner offers Exhibit 1088 solely for the unremarkable proposition that the radius bone has a cortical bone portion, but that proposition is also established by Exhibit 1084, which is not challenged. *See* Ex. 1087 ¶ 38 (citing Ex. 1088 for the “well-known physiological fact that the radius is categorized as a long bone, and long bones are made of cortical bone or cortical bone on the outside and cancellous bone on the inside”); 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.

### III. ANALYSIS

#### A. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, we consider the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (internal quotation marks and citation omitted).

Petitioner contends a person having ordinary skill in the art pertaining to the ’278 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. 23; Ex. 1001 ¶¶ 28–29. Patent Owner does not dispute Petitioner’s proposed definition in the context of this proceeding. Prelim. Resp. 12; PO Resp. 7 & n.2. Finding that Petitioner’s unopposed definition is consistent with the ’278 Patent and the prior art of record, we adopt that definition here. *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 ’278 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).” 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).

Prior to institution, neither party asserted that any claim term requires express construction and Petitioner asserted that “all claim terms relevant to the Petition should be given their plain and ordinary meaning.” Pet. 21–22; Prelim. Resp. 13. Patent Owner, however, asserts in its Patent Owner Response that Petitioner ignores the plain and ordinary meaning of “pre-contoured,” the limitation relating to an “S-curve,” and the meaning of “threaded” with respect to e.g., internally threaded screw hole of challenged

claim 4 (the “threaded screw-hole limitation”). PO Resp. 8–17; Ex. 1005, claim 4 (“wherein the arm screw hole includes internal threads”). We address “pre-contoured” and the S-curve limitation directly below. Because the threaded screw hole language pertains to Petitioner’s obviousness challenge relying on Grusin and Fernandez (Ground 3), we address its meaning in Section III(F)(4), below.

As of the date of oral hearing, the parties were unaware of any claim construction order in the related District Court Litigation. *See* Tr. 4:22–6:2. On September 30, 2020, the District Court issued a *Markman* Order addressing disputed claim terms for nine related patents, including the ’278 Patent. Paper 44. The terms construed by the District Court, however, do not overlap with those contested in this *inter partes* review and the District Court’s constructions do not affect our Decision.

1. Construction of Pre-Contoured

Independent claim 5 recites “an orthopedic plate . . . pre-contoured to accommodate the shape of the bone surface.” Ex. 1005, 12:37–62. Patent Owner, in its Patent Owner Response, asserted “Petitioner failed to address the distinction between the plain and ordinary meaning of the term ‘pre-contoured’ as recited in Claim 5, and the individualized contouring enabled by the bendability of the plates disclosed in Kay and Grusin.” PO Resp. 8. According to Patent Owner, a “pre-contoured” plate refers to the plate as made by a manufacturer and presented to a surgeon, prior to any individualized contouring made by the surgeon bending or otherwise modifying the plate for use within a particular patient. PO Resp. 10–11, 41–42. Petitioner, however, agrees with this definition. Reply 20–21; Tr. 35:3–17. As this unopposed definition is consistent with the disclosure of the ’278

Patent and the art of record, we adopt it for the purpose of this Decision. *See* PO Resp. 8–9 (Ex. 1005, 1:46–48, 3:24–57, 5:16–18); Reply 20 (citing Ex. 1066, 115:1–117:5; Ex. 1072, 111:10–112:2).

## 2. Construction of the S-curve Limitation

Independent claim 5 states that the “orthopedic plate . . . has a medial line which describes a curve in a lateral plane or in a longitudinal plane.” Ex. 1005, 12:37–62. The parties agree the shape described by a plate’s medial line *in a lateral plane* is determined from a *top view* of the plate, such as shown in Figures 1, 8, 10, 13, 19, 25, 31, 35, 37, and 43 of the ’278 Patent. *See* Pet. 6 (citing Ex. 1001 ¶ 41); PO Resp. 1 n.1; Ex. 2017 ¶ 33; Ex. 2018 ¶ 31. The parties also agree the shape described by a plate’s medial line *in a longitudinal plane* is determined from a *side view* of the plate, such as shown to varying extents in Figures 2, 9, 11, 15, 17, 21, 23, 27–29, 33, 39, and 45 of the ’278 Patent. *See* Pet. 6 (citing Ex. 1001 ¶ 41); PO Resp. 1 n.1. We do not find any disclosure in the ’278 Patent which contradicts the parties’ mutual understanding, so we apply this understanding here.

Depending from claim 5, claim 9 further requires that “the curve in the lateral plane or in the longitudinal plane is an S-curve.” Ex. 1005, 13:9–11. Patent Owner emphasizes claim 9 requires the medial line of the plate, and not the plate itself, to be S-shaped and contends that both Petitioner and Mr. Castañeda interpret the claim incorrectly to require the plate itself to be S-shaped. PO Resp. 12–16 (citing Ex. 2019, 25:1–25, 33:18–23; Ex. 1001 ¶¶ 41, 77, 114–116). Although the Petition and Mr. Castañeda’s Declaration often refer loosely to “a plate with an S-curve” or employ similar phrases, Petitioner does not dispute that the claims require

specifically that the plate's medial line describes an S-curve. *See* Pet. 17, 47–49, 73; Ex. 1001 ¶¶ 41, 77–79. Based on the plain claim language, we agree.

The parties disagree, however, as to how an S-curve of a “medial line” of a plate is to be determined. Reply 9–11 (citing e.g., PO Resp. 36, 39); Sur-reply 20–21. We do not resolve this dispute, because claim terms need to be construed “only to the extent necessary to resolve the controversy.” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

As discussed below, we determine the 2006 Application does not demonstrate possession of the “threaded head” limitation of claims 1–9 nor, with respect to claim 9, of a plate having a medial line describing an S-curve in the longitudinal plane. *See infra* Section III(C)(5). Accordingly, we need not reach the lateral plane issue to resolve the parties' priority dispute.

### C. Priority of Challenged Claims

Petitioner contends that claims 1–9 are not entitled to the priority date of the 2006 application, with the result that Kay and Chan qualify as prior art to these claims. Pet. 2–3, 10–21. Because this is a threshold issue to the merits of Grounds 1 and 2 we begin our analysis here.

#### 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).<sup>8</sup> 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 ’278 Patent was filed as a continuation of U.S. Patent Application No. 13/348,888, which is 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. 1005, [60], 1:6–18. For consistency, we adopt the parties’ convention of referring to the latter parent

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<sup>8</sup> 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 ’278 Patent was filed on June 24, 2014, so we cite the AIA version. *See* Ex. 1004, code (22). However, we would reach the same conclusion as to written description support in the 2006 Application regardless of which version applies.

applications as “the 2006 Application” and “the 2009 Application,” reflecting their respective filing dates. *See* Pet. 2; PO Resp. 14.

In response to Petitioner’s assertion that the challenged claims are entitled to a priority date of no earlier than the filing date of the 2009 Application, Patent Owner asserts the ’278 Patent claims have written description support in the 2006 Application and, thus, a priority date of no later than the filing date of the 2006 Application. PO Resp. 2–3, 17–40.

We must resolve this dispute because it determines whether Kay and Chan are prior art to the challenged claims of the ’278 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. 21 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 ’278 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 2006 Application (Ex. 2001)

The 2006 Application discloses “an orthopedic plate and screw system and instruments for surgical fixation of a small bone or bones. The plate facilitates three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape.” Ex. 2001, Abstract. “The plate is designed specifically for the small bone market, i.e. for use in bones [distal] to the elbow and knee, including, for example, the ulna, radius, tibia, fibula, as well as the metacarpals, carpals, metatarsals, tarsals, and phalanges.” *Id.* ¶ 6. The plate is also “configured to

bend laterally, longitudinally, and to wrap or spiral about its longitudinal axis so that it can be molded to an optimal shape for small bone procedures.”

*Id.*

Figure 1 of the 2006 Application is reproduced below:

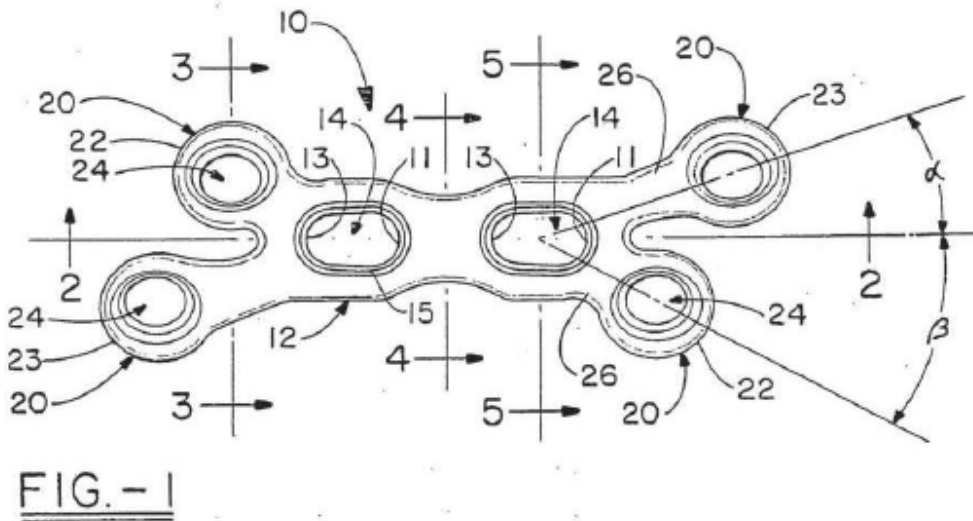


Figure 1 illustrates orthopedic plate 10 having a modified X-shaped profile, formed by central trunk portion 12 and two pairs of arms 20 extending diagonally from opposed terminal ends of central trunk portion 12. *Id.* at

Abstract, ¶¶ 45, 47. In certain embodiments, plate 10

includes at least one set, and preferably two opposing sets of arms 20. As viewed in Figure 1, these sets of arms can be viewed as a set of diagonally opposed short 22 and long arms 23, or as a pair [of] upper and lower arms which are mirror images.

*Id.* ¶ 47.

The opposing pairs of arms 20 illustrated in Figure 1 each include short arm 22 and long arm 23, which extend from central trunk portion 12 at different angles of divergence (identified as  $\alpha$  and  $\beta$ ) relative to the longitudinal axis of trunk portion 12. *Id.* ¶ 47. In this way, screws inserted into respective screw holes 24 of short arm 22 and long arm 23 (at the right

side of Figure 1, for example) will not impinge on each other inside a bone underneath plate 10. *Id.* ¶¶ 10, 49.

Central trunk portion 12 includes two screw holes or slots 14 along the longitudinal axis. *Id.* ¶45. “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.* ¶ 3. “The [screw hole] bores are typically about 3.75 mm for a 3.5 mm diameter screw for small bones . . . . In a further embodiment, the bore could be threaded.” *Id.* ¶ 51.

4. The Parties’ Arguments, and Scope of Replies Regarding the Threaded-Head Limitation Common to All Challenged Claims

a) The Petition and the Institution Decision

In the Petition, Petitioner contends that the claims challenged in Grounds 1 and 2 do 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, 12–16. In this respect, Petitioner notes that independent claim 1 (from which claims 2–4 depend) recites “wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface” and independent claim 5 (from which claims 6–9 depend) similarly recites “wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface.” *Id.* at 12.

According to Petitioner, 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, i.e., “the ‘threaded head limitation.’” *Id.* at 12–16; Ex. 1001 ¶¶ 80–82; Reply 2–8. According to the Petition, the 2006 Application discloses only non-locking screws, that is, screws with non-threaded heads. Pet. 2, 12–16 (citing, e.g., Ex. 2001,<sup>9</sup> Figs. 6 & 8, ¶¶ 8–9, 11, 19–21, 52; Ex. 1001 ¶¶ 80–82). For example, Petitioner points out that whereas claims 15 and 27 in the published version of the 2006 application recite “screws having [] threaded shafts and a head,” similar language in claim 5 of the ’278 Patent reads “a threaded shaft and a threaded head.” Pet. 14–15 (emphasis removed); Ex. 1001 ¶¶ 81–82. Petitioner further notes that both the 2006 Application and the ’278 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 ¶ 10; Ex. 1005, 4:23–26); Ex. 1001 ¶¶ 81–82. However, the ’278 Patent, unlike the 2006 Application, additionally discloses: “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.” Ex. 1005, 4:32–36.

Patent Owner disputed these assertions in the Preliminary Response. *See, e.g.*, Prelim. Resp. 20–28. In the Institution Decision, we addressed whether the “[c]laims 1–9 are not entitled to the priority date of the 2006 [A]pplication because they recite a ‘threaded head’ limitation that is not

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<sup>9</sup> 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. 21 n.4.

supported by the 2006 [A]pplication.” Inst. Dec. 4–19. 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 “how ‘[t]he screw holes of the trunk portion’ may have a ‘threaded’ bore. Ex. 2001 ¶ 51. That is, the holes have a mating interface that can engage a threaded-head (i.e., locking) screw.” Inst. Dec. 18. Although Petitioner agreed that such a threaded-head screw is a locking screw (*see* Pet. 7–10, 122–13), at that stage of the proceeding we determined that “Petitioner has not identified any reason for a screw hole to be threaded, other than to engage a correspondingly threaded head of a screw,” and that “the evidence of record suggests that a person of ordinary skill in the art would have understood that disclosure of a threaded screw hole demonstrates possession of a threaded-head screw to be received in the threaded screw hole.” Inst. Dec. 18–19.

In reaching these preliminary conclusions, we noted that 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. Inst. Dec. 17–18 (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 1-8 over Kay and Chan, and of claim 9 over Kay, Chan, and Heintz, based on our conclusions with respect to Ground 3 and the Board practice implementing *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *See* Inst. Dec. 2–3, 45.

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. 22; Ex. 2017 ¶¶ 36, 40; Ex. 2018 ¶¶ 38, 48. 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. 23–25 (citing Ex. 2001 ¶ 51); Ex. 2017 ¶¶ 59–64; Ex. 2018 ¶¶ 59–63.

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.<sup>10</sup> PO Resp. 21–25 (citing illustration of an exemplary locking screw at Pet. 9, taken from Ex. 1023, 18); Ex. 2017 ¶¶ 59–65; *see e.g., id.* ¶ 60 (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.* ¶ 64 (“A POSA understood that a threaded screw hole [or bore] is a **locking screw hole**.” (emphasis by Dr. Neufeld)); Ex. 2018 ¶¶ 59–63 (same). Patent Owner asserts Petitioner's witness, “Mr. Castañeda, confirms that a threaded

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<sup>10</sup> Petitioner reads the Patent Owner Response to assert only the reversed proposition: that a locking screw requires a threaded screw hole bore. *See* Reply 1, 6 (citing PO Resp. 21–27; Ex. 2017 ¶¶ 59–67; Ex. 2018 ¶¶ 58–66). We disagree with Petitioner's limited reading of the Patent Owner Response and supporting witness testimony.

screw hole in a bone plate corresponds to a threaded-head screw.” PO Resp. 25 (citing Ex. 1001 ¶ 58; Ex. 1002, 4:27–30; Ex. 2017 ¶¶ 63–64; Ex. 2018 ¶ 62).

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; Reply 1, 3 (citing PO Resp. 22–23; Ex. 2017 ¶ 60; Ex. 2018 ¶ 59; Ex. 1066, 195:7–196:3). Petitioner then asserts the evidence of record establishes “that a hole could be threaded for numerous reasons other than for use with a threaded-head screw, confirming that disclosure of a threaded hole *does not* ‘necessarily demonstrate[]’ possession of a threaded-head screw” as Patent Owner contends and as Federal Circuit precedent requires. Reply 2–7 (citations omitted). In support, Petitioner cites disclosures in the 2006 Application and testimony of Patent Owner’s witness Mr. Harrigan. *Id.* at 3–5 (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, 191:3–192:16; Ex. 1087 ¶¶ 27, 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. Reply 3–5. 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 Reply Declaration, which contains testimony regarding Exhibits 1082–1086. 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 and incorrectly asserts the specification must disclose that a threaded screw was *necessary*.” Sur-reply 9 (emphasis by Patent Owner) (citing *Hologic*, 884 F.3d, 1361 (Fed. Cir. 2018)). 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 ¶ 282); *id.* at 6, 11.

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 embodiment of the orthopedic plate having a ‘threaded bore’ that is expressly disclosed in the 2006 Application . . . also discloses the threaded-head screw corresponding to that bore . . . for affixing the plate to a bone. Hence, the inventors were clearly ‘in possession’ of an orthopedic plate system having threaded-head screws.” PO Resp., 24 (citing Ex. 2017 ¶ 62; Ex. 2018 ¶ 61); *see also id.* at 15 (“Since the plates disclosed by Kay include only *screw*

*holes* and Kay discloses only *screw fixation* of the plate to bone, a POSA understood that a threaded screw hole receives a threaded-head locking screw.”).

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

Patent Owner argues Petitioner’s Reply “amounts to no more than a belated 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, 6, 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)).

Petitioner’s 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.<sup>11</sup> “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)).

We determine Petitioner’s Reply does not improperly present new argument and evidence. Rather, the argument and evidence presented in Petitioner’s Reply properly respond to issues discussed in the Institution

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<sup>11</sup> This Guide is available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL>.

Decision and arguments raised in the Patent Owner Response. *See* Sections III(D)(4)(a)-(b), *supra*. 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 locking screw). We determine the Petition satisfied Petitioner's burden of production on this issue (*see supra* Section III(B)(5)(a) (discussing 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).

Petitioner also asserts we should strike, *inter alia*, 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 (authorizing Petitioner to file a Sur-sur-reply). 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* Sur-sur-reply 1–4.

5. Analysis of Priority Relating to the Threaded-Head Limitation

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. Whether the 2006 Application supports a finding of priority for the claims challenged under Grounds 1 and 2 turns on 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.

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. 12–15. 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 '278 Patent disclosures of a locking screw are not found in the 2006 Application. *Compare* Ex. 1005, 4:23–36, *with* Ex. 2001 ¶ 9; *compare* Ex. 1005, 5:41–44, 8:55–9:3, 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 ¶ 19; Ex. 2017 ¶¶ 55, 59–64; Ex. 2018 ¶¶ 53, 57–63; Pet. 7–9, 12–13; PO Resp. 21–27. 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 a 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, 21–24; PO Resp. 22–25; Ex. 2017 ¶¶ 60–61; Ex. 2018 ¶¶ 59–60. Petitioner agreed that necessity is the applicable legal standard. Reply 2–3 (citing *PowerOasis*, 522 F.3d at 1305–06; *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998)); *id.* at 10–11; *see* Tr. 13:8–24. In its Sur-reply, however, Patent Owner changed tack, asserting that 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); *see* 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. Priority here, therefore, 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 next in Section III(C)(5)(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 III(C)(5)(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. *See Ariad*, 598 F.3d at 1352 (“A description that merely renders the invention obvious does not satisfy the requirement.”).

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

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 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); Reply 4.

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); Reply 4; *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 ¶¶ 55, 59–64; Ex. 2018 ¶¶ 53, 58–64. 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 Would Have Known a Screw Hole Bore May Be Threaded to Receive Structures other than a Locking Screw

In addition to the bending device disclosed in the 2006 Application, Petitioner argues a person of ordinary skill in the art in January 2006 would have known a screw hole bore may be threaded for additional reasons other than to receive the threaded head of a locking screw. *See Reply 4–6* (discussing Exs. 1082–1087). Patent Owner raises various objections and responses to the evidence cited by Petitioner. *See Sur-reply 12–19*.

Upon review of the foregoing, we find some, though not all, of Petitioner's argument and evidence persuasive. 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 Petitioner's expert, Mr. Castañeda, as the sole inventor ("the Castañeda Application"). Ex. 1084, codes (43), (75); Ex. 1087 ¶ 25. Figure 1 of the Castañeda Application is reproduced below:

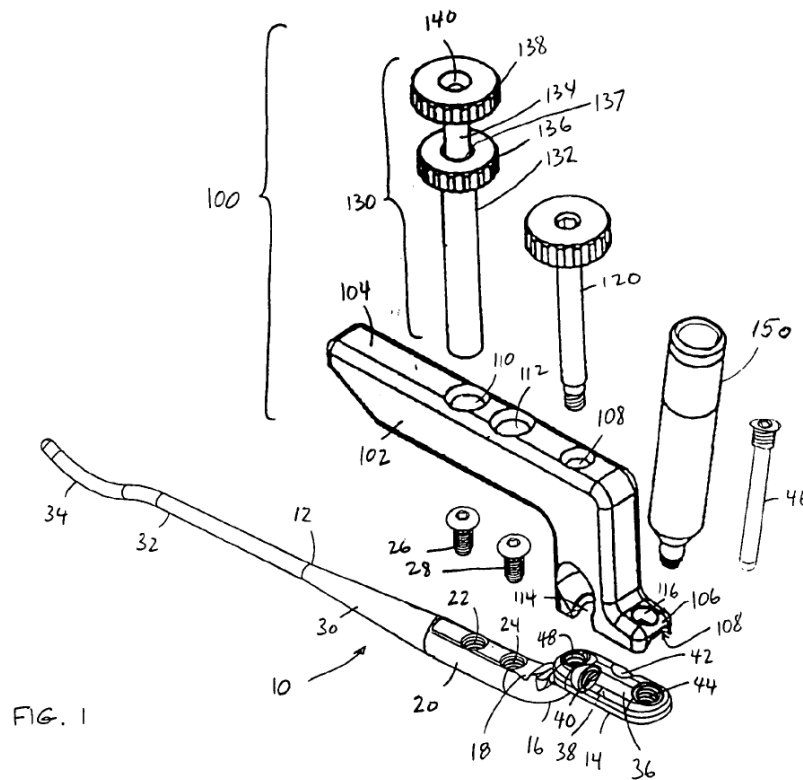


Figure 1 illustrates bone fracture fixation device 10 including threaded screw holes 22, 24 that receive the threaded shafts of cortical screws 26, 28. Ex. 1084, Fig. 1, ¶¶ 8, 42, 45; Ex. 1087 ¶ 27; Reply 4. The heads of screws 26, 28 are not threaded, so they are not locking screws. Ex. 1084, Fig. 1; 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 15–16 (citing Ex. 2001 ¶¶ 11, 51); *see* 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 16–17 (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* Reply 1, 4.

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); Reply 7. 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.

We understand from Mr. Castañeda’s testimony, 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. Ex. 2023, 29:12–30:13; *see* Sur-reply 18. Nevertheless, we find that, viewing the state of the art as a whole in January 2006, a person of ordinary skill in the art would have understood that 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 ¶ 27 (citing Ex. 1082, Fig. 1, ¶¶ 7, 19); Reply 4, 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, 31.

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; Reply 4. 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.

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 18–19. 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, 30:2–13, 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, 7, 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* Reply 4 (citing Ex. 1084 ¶¶ 9, 43–44; Ex. 1087 ¶¶ 25–26, 29–30).

We find persuasive, however, 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. *Sur-reply* 16–17 (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 (misabeled 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). On the record before us, 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. Reply 5; Ex. 1087 ¶¶ 20–24, 26 (citing Ex. 1083 ¶¶ 13–15, 41, Figs. 1–2; Ex. 1085 ¶¶ 60, 73; Ex. 1086, 3–4, 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 13–15 (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 ’278 Patent must have a threaded shaft, as well as Mr. Castañeda’s deposition testimony distinguishing between pegs and screws. Sur-sur-reply 2–3.

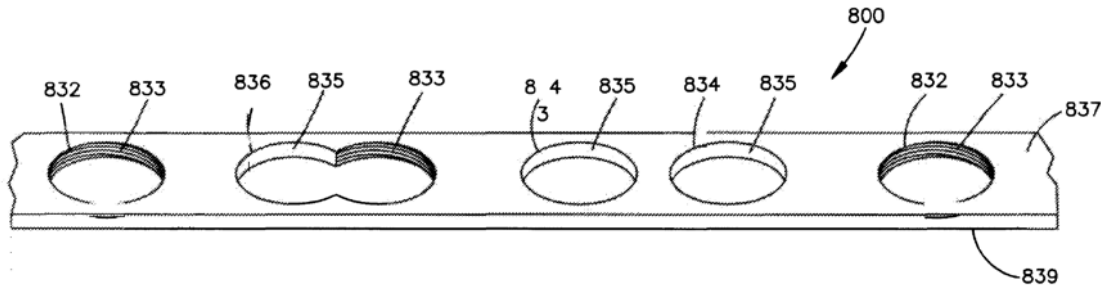
We conclude we need not resolve the foregoing dispute, because we have already concluded (*see supra* Sections III(C)(4)(a) and III(C)(4)(b)(1)-(2)) that a person of ordinary skill in the art in January 2006 would have known the 2006 Application's screw hole bore may have been threaded to receive several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

(5) 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.

c) Arguments Regarding Chan (Ex. 1007)

Patent Owner points to 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. 25–26; Ex. 2017 ¶¶ 65–67; Ex. 2018 ¶¶ 64–66. Figure 8 of Chan is reproduced below:



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. 65–66; Ex. 2017 ¶¶ 50–51; Ex. 2018 ¶¶ 64–65.

Petitioner points out that “Chan describes its threaded holes as ‘locking bone plate holes’ ‘for engaging the threads around the head of a locking bone screw.’” Reply 6 (citing Ex. 1007 ¶ 64). Petitioner contends that Chan’s use of this definition merely establishes that a locking screw requires a threaded screw bore, and “does not inform the discussion of whether a threaded bore discloses a threaded-head screw, but rather only illustrates POSITAs understood that *additional* disclosure was required to understand the use of a ‘threaded bore.’” *Id.* at 6–7 (citing Ex. 1007 ¶ 64).

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* Reply 7.

d) Prosecution History

Patent Owner asserts, absent citation or further explanation, that “during prosecution the examiner expressly determined that Claims 1-8 were entitled to the priority of the 2006 Application.” PO Resp. 18, 22, 27; *cf.* Prelim. Resp. 14–15 (asserting that “while examining the application leading to the related 252 Patent, the same examiner determined that claims including a ‘**locking screw**’ (a screw with a threaded head) were entitled to the priority of the 2006 Application – ‘[a]ccordingly, the effective filing date for the claimed subject matter in the current application is January 26, 2006 and will be treated as such for examination purposes.’”) (citing Ex. 1037, 3) (emphasis in Ex. 1037).

In response, Petitioner notes that “the examiner was silent with respect to the threaded head limitation, . . . did not have the benefit of the record we have in this adversarial proceeding, and her unsupported legal conclusion about the effective filing date of these claims is not entitled to

deference.” Reply 7–8 (internal quotations, citation, and alterations omitted.) We agree with Petitioner that the prosecution history has little applicability here.

During prosecution of the related ’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.

e) 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, 18, 21–22, 27. Specifically, according to Patent Owner: “If screw holes are threaded ***so that they can accept locking screws*** as confirmed by Petitioner’s expert, then Kay’s disclosure of an embodiment of a plating system that includes a plate with threaded screw holes also discloses [for priority] the

corresponding locking screws for insertion into those screw holes to affix the plate to bone.” Sur-Reply 6; Ex. 1001 ¶ 408.

Petitioner replies that its arguments concerning priority and obviousness are not inconsistent. *See* Reply 5–8 (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*.” Sur-reply 6; Ex. 1001 ¶ 408. Petitioner’s position instead is that it would have been “obvious to use screws with a threaded head and threaded screw holes, as disclosed by Chan, with Kay’s plate system” and, thus, to “use the known combination of non-locking screws and locking screws with a threaded head as disclosed by Chan, and 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 with threaded heads.” Pet. 32–33 (citing Ex. 1001 ¶¶ 408–409).

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.

f) Summary and Conclusion Regarding Priority with Respect to the Threaded-Head Limitation

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 in the relevant art. 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 that claims 1–9 of the '278 Patent do not have priority to the filing date of the 2006 Application. They instead have a priority date of no earlier than the filing date of the 2009 Application, which is February 24, 2009.

6. Priority of Claim 9 with Respect to the S-Curve Limitation

Claim 9 of '278 Patent recites an orthopedic plate system “wherein the curve in the lateral plane or in the longitudinal plane is an S-curve” (the “S-curve limitation”). The parties agree that “*in the lateral plane* means “as viewed from the top” and *in the longitudinal plane* means “as viewed from the side.” Petition, 6; PO Resp. 1, n.1.

Petitioner asserts that claim 9 is not entitled to priority of the 2006 Application because, while the 2006 Application indicates a plate may

“bend laterally (or ‘curve’) relative to the longitudinal axis . . . to form a curved area” and “bend longitudinally to form a curved area,” there is no disclosure that such bending may result in an S-curve medial line in either the lateral or longitudinal plane. Pet. 2, 16–19 (citing Ex. 2001 ¶¶ 6, 46). Petitioner asserts that the ’278 Patent’s explicit disclosure concerning S-curves (Ex. 1005, 5:12–23) and figures depicting a plate with an S-curve medial line (*id.* at Figs. 21–23) are not in the 2006 Application. Pet. 17–18; Ex. 1001 ¶¶ 77–79; *see also id.* ¶ 41 (discussing S-curved plates generally).

Patent Owner responds that “the 2006 Application provides sufficient support for the ‘S-curve’ limitation,” such that claim 9 is entitled to a priority date of no later than the filing date of the 2006 Application. PO Resp. 27–41. But the arguments presented in support of this contention in the Patent Owner Response discuss only the lateral plane; they do not address the longitudinal plane. Patent Owner states, for example:

The embodiments of the orthopedic plates [disclosed in the 2006 Application] having an X-shape in the lateral plane (i.e. as viewed from the top) each have *bilateral asymmetry* and *transverse mirror symmetry* (as those terms are defined in the 2006 Application) such that each plate possesses a medial line describing an S-curve in the lateral plane as recited in Claim 9. These embodiments alone provide the requisite support to afford the priority of Kay to Claim 9.

*Id.* at 28 (citing Ex. 2017 ¶ 69; Ex. 2018 ¶ 68). Patent Owner’s experts similarly point to Figures 1, 9, 10, 12, 14, 16, 18, 20, 22, 24, and 26 of the 2006 Application, which are all top views of various plates, as demonstrating possession of “a medial line describing an S-curve in the lateral plane as recited in Claim 9.” Ex. 2017 ¶ 69; Ex. 2018 ¶ 68. Patent Owner’s analysis then focuses, most particularly, on Figure 1 as representative of the contention that the 2006 Application discloses an

S-curve medial line in the lateral plane. PO Resp. 29–40; Ex. 2017 ¶¶ 69–87; Ex. 2018 ¶¶ 70–88.

Petitioner’s Reply correctly points out that the Patent Owner Response does not cite any evidence which might indicate the 2006 Application demonstrates possession of an S-curve medial line in the longitudinal plane. Reply 8. Petitioner asserts that, for priority to be found, the 2006 Application must demonstrate possession of both alternatives recited in claim 9: an S-curve medial line in the lateral plane, and an S-curve medial line in the longitudinal plane. *Id.* (citing *D Three Enterprises, LLC v. SunModo Corp.*, 890 F.3d 1042, 1051–52 (Fed. Cir. 2018); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158–60 (Fed. Cir. 1998)).

Patent Owner presents no new argument or evidence on this issue in its Sur-reply other than attempting to show that Petitioner has admitted that Kay discloses the S-curve limitation. Sur-Reply. Patent Owner first asserts that in the course of mapping the teachings of Kay to claim language challenged as obvious under Ground 1, “Petitioner admits that Kay discloses a plate with a medial line that describes a curve in a lateral plane or in a longitudinal plane.” *Id.* at 20 (citing Pet. 47; Ex. 1001 ¶ 429). On its face, the cited statement says nothing about a S-curve, and merely indicates the disclosure of a curve in a lateral plane *or* a longitudinal plane, not both. Patent Owner further points to Petitioner’s assertion that “Pre-contouring a plate with Kay’s features to also include a medial line describing an S-curve in the lateral or longitudinal plane is both contemplated by Kay and rendered obvious by Heintz.” *Id.* (citing Reply 17–18). Again, Patent Owner attempts to redraft Petitioner’s statement to an admission that Kay discloses a medial line describing an S-curve in the lateral *and* in the longitudinal plane. We

decline to apply Patent Owner's interpretation and, taken in context, do not find Patent Owner's arguments persuasive.

Upon review of the foregoing, we first note it is undisputed that the 2006 Application must demonstrate possession of both claimed S-curve medial line alternatives (lateral and longitudinal planes) for priority to be found. *See* Reply 8; Tr. 44:22–45:6 (Patent Owner's counsel agrees); *see also D Three*, 890 F.3d at 1051–52 (where earlier application disclosed only a washer above the flashing, it did not provide written description support for later-filed application claiming washers that could be either above or below the flashing); *Tronzo*, 156 F.3d at 1158–60 (application disclosing only conical cup did not provide written description support for later-filed claims which were generic as to cup shape).

Next, we find the 2006 Application fails to demonstrate possession of a plate having an S-curve medial line in a longitudinal plane—that is, in a side view of the plate. Figures 2, 11, 17, 19, 21, 23, 25, 27, 29, and 31 of the 2006 Application show cross-sectional side views of various plates. Ex. 2001 ¶¶ 14–15, 23–24, 29–44. Patent Owner does not cite any of those Figures as demonstrating possession of the claimed invention (*see* Tr. 43:6–16), and to our eye, none of them illustrates an S-curve medial line in the longitudinal plane. The top views provided by Figures 1, 9, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, and 30, illustrating the plates in the lateral plane, do not help elucidate the shape of the medial line curve in the longitudinal plane. Further, Patent Owner does not cite, and we do not find, any disclosure in the written description of the 2006 Application that would demonstrate possession of a plate having an S-curve medial line in a longitudinal plane.

Moreover, as Petitioner points out (Pet. 15): “Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed,” such that “[i]t extends only to that which is disclosed.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997); *see also PowerOasis*, 522 F.3d at 1306–07 (same). “While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification,” and “a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.” *Lockwood*, 107 F.3d at 1572 (citations omitted).

Here, the 2006 Application pertinently demonstrates possession of designing plates “specifically for the small bone market, i.e. for use in bones distal to the elbow and knee, including, for example, the ulna, radius, tibia, fibula, as well as the metacarpals, carpals, metatarsals, tarsals, and phalanges.” Ex. 2001 ¶ 6. This disclosure is much too general, and the list of particular bones much too varied in structure, to demonstrate possession of a plate having an S-curve medial line in the longitudinal plane. The 2006 Application does not, itself, suggest that either small bones in general, or any of the specifically identified small bones, might beneficially be repaired with a plate having an S-curve medial line. *Id.*

Patent Owner also cites the testimony of Dr. Neufeld and Mr. Harrigan that “[a] POSA understood that a plate that was customized by bending longitudinally to form a curved area in and out of the plane of the plate,” as described in the ’278 Patent, “*would have a medial line that*

*described an S-curve in the longitudinal plane.”* PO Resp. 10; Ex. 2017 ¶ 46 (emphasis added) (citing Ex. 1005, 7:9–18); Ex. 2018 ¶ 45 (same). While this testimony relates to disclosures in the challenged ’278 Patent, there is somewhat overlapping disclosure in the 2006 Application. *See* Ex. 2001 ¶ 46. Importantly, however, the overlap does not include the ’278 Patent’s disclosure at column 5, lines 11–27, directed to how a clavicle might benefit from applying “a lateral plate [having] an S-curve of the medial line . . . .” *Compare* Ex. 1005, 5:11–27, *with* Ex. 2001 ¶¶ 12–13. As we concluded in the Institution Decision, and which has not been materially disputed by Patent Owner during trial, the 2006 Application does not demonstrate possession of using its plates on the clavicle. *See* Inst. Dec. 24–25 & n.15; Ex. 2001 ¶ 6.

Patent Owner made one more argument during the hearing. *See* Tr. 37:18–40:13, 41:5–8. Patent Owner’s counsel provided the following picture as a demonstrative exhibit 2:



According to counsel, demonstrative exhibit 2 shows the size of one plate embodying the claimed invention in relation to a penny, to illustrate how small the plates can be. *Id.* at 37:18–38:2. Counsel argued “Petitioner fails to appreciate the relative dimensions of the bone plate in the longitudinal direction.” *Id.* at 39:13–17. In counsel’s view, “[b]ecause the plate is so thin in relation to the lateral direction, the medial line takes the same shape as the plate in the longitudinal direction,” so “[i]t’s clear that [the 2006 Application] discloses an S-shaped medial line in a longitudinal direction.” *Id.* at 39:17–40:13

We are not persuaded by Patent Owner’s new argument. First, the argument presented for the first time at the hearing addressing an S-curve medial line in the longitudinal plane was untimely presented, thereby impairing Petitioner’s ability to respond given the expeditious nature of IPR proceedings.

Second, on the record before us, the argument presented for the first time at the hearing—that the thinness of a plate in its lateral direction means the medial line will take the same shape in the lateral and longitudinal planes—is not persuasive on its merits. The ’278 Patent figures demonstrate that the shape of a plate’s medial line in the lateral plane (shown in a top view) provides very little information as to the shape of the medial line in the longitudinal plane (shown in a side view). For example, the top view of Figure 1 does not convey the curvature of plate 10 as seen in the lateral side view of Figure 2 and the end side views of Figures 3–5. *See* Ex. 1005, 5:33–39, 7:61–8:3. Also, the top view of Figure 13 does not convey “the slight longitudinal curve” of plate 210 seen in the lateral side view of Figure 15, reflecting the medial line of plate 210 in the longitudinal plane. *See id.* at

5:52–57, 9:12–27. And the top view of Figure 19 does not convey the curvature of plate 310 seen in the lateral side views of Figures 21 and 22, reflecting the medial line of plate 310 in the longitudinal plane. *See id.* at 5:49–6:2, 9:62–65, 10:42–51. The same is true in the other evidence of record. *See, e.g.*, Ex. 1070, 4 (Figure 4.1-7(a), illustrating a top view and a side view of a 9-hole reconstruction plate used to fix a midshaft fracture of the clavicle).

In conclusion, we find the 2006 Application fails to demonstrate possession of a plate having an S-curve medial line in a longitudinal plane. Accordingly, for this additional reason, claim 9 is not entitled to the priority date of the 2006 Application. As with our conclusion in Section III(C)(5)(c), above, Kay and Chan qualify as prior art to all challenged claims.

D. Ground 1: Obviousness over Kay and Chan

Petitioner asserts claims 1–8 of the '278 Patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Kay as modified by Chan. Pet. 21, 31–49. Patent Owner opposes first on the basis that Kay is not prior art to the '278 Patent, because the challenged claims are entitled to claim priority to the filing date of the 2006 Application. *See* PO Resp. 2, 41; Sur-reply 7–19; Tr. 56:21–24. For the reasons provided above in Section III(C), we do not find Patent Owner's assertions persuasive. Kay was published on August 3, 2006, and Chan was published on June 12, 2008, both before the '278 Patent's priority filing date of February 24, 2009. Ex. 1006, code (43); Ex. 1007, code (43); *supra* Section IV.C. Therefore, we determine Kay and Chan are both prior art to the '278 Patent. In view of the arguments and evidence set forth in the Petition and additionally adduced at

trial, we further determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–8 of the '278 Patent would have been obvious over Kay and Chan.

1. Kay (Ex. 1006)

Kay (Exhibit 1006) is the USPTO's publication of the 2006 Application filed on January 26, 2006, and submitted by Patent Owner as Exhibit 2001. Accordingly, and as noted by Patent Owner in a parallel proceeding, the two disclosures "are substantially identical" but for pagination. *Paragon 28, Inc. v. Wright Medical Technology, Inc.*, IPR2019-00895, Paper 10 at 16 n.3 (PTAB July 1, 2019) (Prelim. Resp.).<sup>12</sup> In the interest of efficiency, we refer to section III(C)(3), above, for an overview of the shared disclosure and further adopt Mr. Castañeda's overview of Kay as set forth in paragraphs 84–89 of Exhibit 1001.

2. Chan (Ex. 1007)

Chan discloses "[a] bone plate system for internal fixation of fractures includ[ing] a bone plate having a plurality of bone plate holes . . . constructed to receive either a non-locking, locking, or variable-angle locking bone screw." Ex. 1007, Abstract; *see generally*, Ex. 1001 ¶¶ 90–92. According to Chan, non-locking screws are "not secured to the bone plate" which, in use, "can cause the screws to loosen or back out with respect to the plate." Ex. 1007 ¶ 3. In contrast, locking screws are in a fixed relationship to the plate and "provide high resistance to shear, torsional, and bending

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<sup>12</sup> *But see* Ex. 2005 (text added to the 2006 Application by amendment dated Nov. 10, 2008).

forces.” *Id.* ¶ 4. In summarizing the properties of locking and non-locking screws, Chan states that:

an interface formed by a locking screw and bone plate has high resistance to shear forces so as to maintain stability at the screw/plate interface, but has limited ability to compress bone fragments, while an interface formed by a non-locking bone screw and bone plate effectively compresses bone fragments, but has low resistance to shear forces that can lead to screws loosening or backing out. Accordingly, a bone plate system that combines non-locking screws with locking screws is desirable in many clinical situations.

*Id.* ¶ 5.

Further with respect to locking screws, Chan discloses an embodiment that can be secured to the bone plate via “a screw thread on an outer surface of the screwhead,” which “mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate.” *Id.* ¶ 4. Chan further discloses an embodiment of a bone plate hole for locking bone screws wherein, “[i]nstead of screw threads as is known in conventional bone plate holes, the inner surface of the plate holes has discrete columns of teeth or thread segments for engaging compatibly dimensioned and configured threaded heads of locking and variable-angle locking bone screws.” *Id.* ¶ 14.

### 3. Analysis

Petitioner contends that one of ordinary skill in the art would have found it obvious to modify Kay’s plate system by using Chan’s variable angle locking screws. Pet. 32 (citing Ex. 1001 ¶¶408–410). As articulated by Mr. Castañeda, “[i]t would have been obvious to a POSITA to use screws with a threaded head as disclosed by Chan, and 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 with threaded heads.” Ex. 1001 ¶ 408.

Mr. Castañeda notes that [b]oth Kay and Chan recognize the problems of screws becoming loose or pulling out.” *Id.* According to Petitioner, Chan addresses the use of locking screws to increase pullout strength, i.e., the problem of screws loosening or backing out with respect to the plate. *See* Pet. 32 (citing Ex. 1006 ¶ 4). Accordingly one of ordinary skill in the art

would have been motivated by the disclosure in Kay to seek out ways to improve pullout strength. Ex. 1001, ¶408. POSITAs would have understood that a way to achieve increased pullout strength would be to use the known combination of non-locking screws and locking screws with a threaded head as disclosed by Chan, and 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 with threaded heads. *Id.*, ¶409.

*Id.* at 33. Petitioner further asserts that the skilled artisan would have expected this modification to be successful. *Id.* (citing Ex. 1001 ¶ 410 (“Given the long history and known advantages of screws with threaded heads that engage threaded screw holes, POSITAs would have expected that those teachings of Chan could be successfully incorporated into Kay, and would have seen no reason why such screws with threaded heads, and threaded screw holes, could not be used with the plate system of Kay.”)).

Patent Owner contends that Ground 1 fails with respect to claims 5–8 because Petitioner ignores the plain and ordinary meaning of “pre-contoured” as recited in independent claim 5 from which claims 6–8 depend. PO Resp. 41–42. As explained in Section II(B)(1), above, the parties agree that a “pre-contoured” plate refers to the plate as made by a manufacturer and presented to a surgeon, prior to any individualized contouring made by

the surgeon bending or otherwise modifying the plate for use within a particular patient. Despite agreement as to the ordinary meaning of “pre-contoured,” Patent Owner states that “Petitioner ignores the requirement that Claim 5 recites a plate that is “*pre-contoured* ... wherein the plate has a medial line which describes a curve ....” and “fails to establish how [the plate of Kay’s Figure 1] is ‘*pre-contoured*’ wherein the medial line describes a curve.” PO Resp. 41–42.

Petitioner responds that Patent Owner “misrepresents the claim language” by “rely[ing] on conveniently placed ellipses to hide the fact that the claim *never* correlates a pre-contouring requirement with a medial line requirement.” Sur-reply 14. We agree with Petitioner.

Claim 5 recites “[a]n orthopedic plate system comprising at least one screw and an orthopedic plate having an inferior surface which is capable of facing a bone surface in use and which is pre-contoured to accommodate the shape of the bone surface.” The claim elsewhere specifies “the plate has a medial line which describes a curve in a lateral plane or in a longitudinal plane.” Petitioner has adequately demonstrated that Kay discloses each of these features. *See* Reply 15; Pet. 44–45, 47–48; Ex. 1006, Figs 3–5, ¶¶ 7, 9, 47, 49; Ex. 1001 ¶¶ 423, 429. And although Patent Owner points to Petitioner’s statement that “Kay’s plate also is ‘designed to facilitate three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape,’” it is not clear that such “three dimensional contouring” refers to the “individual contouring” by a surgeon as Patent Owner suggests. PO Resp. 41 (quoting Pet. 44); *see also* Reply 21 (noting that “PO’s experts admitted any individual contouring could be accomplished by pre-contouring. Ex. 1072, 127:24–129:21;

Ex. 1066, 177:9–183:15.”). Nor, to the extent the quoted passage *does* refer to a surgeon’s post-manufacturing adjustments, does any such additional functionality detract from Petitioner’s evidence that “Kay discloses a [pre-]contoured plate with an inferior surface capable of engaging a bone surface in use.” *See* Pet. 44 (citation omitted).

Patent Owner does not otherwise oppose Ground 1 on the merits. *See* PO Resp. 41–42; *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. Petitioner and Petitioner’s expert sufficiently address each limitation of claims 1–8 in view of Kay and Chan. Pet. 32–49; Ex. 1001 ¶¶ 396–440. We find Petitioner’s arguments with respect to each limitation of claims 1–8 persuasive and supported by the evidence of record. In light of the evidence adduced, we conclude a preponderance of the evidence establishes it would have been obvious to combine Kay and Chan in the manner recited in claims 1–8, such that the claims are unpatentable under 35 U.S.C. § 103.

E. Ground 2: Obviousness over Kay, Chan, and Heinl

Petitioner asserts claim 9 of the ’278 Patent is unpatentable under 35 U.S.C. § 103 as having been obvious over Kay as modified by Chan as discussed in Section III(D), above, and further in view of Heinl. Pet. 21, 50. Patent Owner opposes first on the ground that Kay is not prior art to the ’278 Patent because the challenged claim is entitled to priority to the filing date of the 2006 Application. *See* PO Resp. 2, 41. For the reasons set forth in Section III(C), above, we do not find this argument persuasive.

Referencing its earlier argument with respect to Ground 1 without further exposition, Patent Owner further asserts in a heading that “Petitioner Ignores the Plain and Ordinary meaning of ‘*Pre-Contoured*.’” PO Resp. 48. We do not find this argument persuasive for the reasons set forth in Section III(D)(3), above. Patent Owner also presents additional arguments directed to the merits of Ground 2, which we consider below. We begin with an overview of Heintl.

1. Heintl (Ex. 1009)

Heintl discloses plates for “joining bone fragments . . . by screw fastening, especially in the case of cranial, facial, vertebral or hand fractures.” Ex. 1009, Abstract, 1:5–9. The plates are “an assortment of differently shaped and curved plates,” with each plate being suitable for use in particular anatomical conditions, to permit a faster surgical operation. *Id.* at 1:62–2:17.

Figure 3 of Heintl is reproduced below:

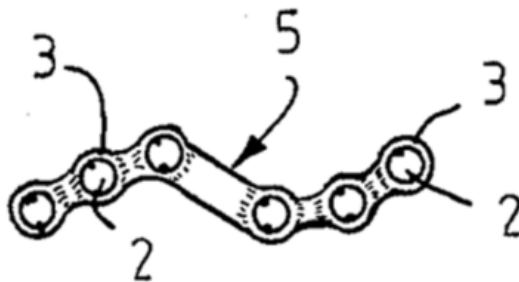


Figure 3 illustrates bone plate 5 having an S-shape, with screw holes 2 within screw rings 3. *Id.* at 2:18–22, 8:41–58. Screw holes 2 are “disposed at the ends of” plate 5, and “introduction of screws into the central area is generally not possible because the bone fracture is located there and the screws would be useless.” *Id.* at 2:51–56, 8:55–58.

2. Analysis of Ground 2 on the Merits

According to Petitioner, one of ordinary skill in the art would have found it obvious to modify the orthopedic plates disclosed in Kay to include locking screws for orthopedic plates as taught by Chan because Kay provides motivation to “seek out ways to improve pullout strength” which one of ordinary skill in the art would have recognized as a benefit of the “combination of non-locking screws and locking screws with a threaded head as disclosed by Chan.” Pet. 32–33, 50; Ex. 1001 ¶¶ 408–410, 421–429, 435–437.

Petitioner argues that it would further have been obvious to incorporate the S-curve shape taught by Heinl into Kay’s orthopedic plates because “Kay states that its plate ‘facilitates three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape,’” and, thus, would have provided motivation “to seek out a number of different shapes of orthopedic plates to accommodate the variety of bone shapes of the human body.” *Id.* at 50 (quoting Ex. 1006, Abstract). In this respect, Petitioner argues that the varying shapes of orthopedic plate disclosed in Heinl, “allow a surgeon to ‘tak[e] into account the particular anatomical conditions [and] to select the plate best suited for its shape and form and use it immediately.’” *Id.* (quoting Ex. 1009, 1:62–2:3). Accordingly, one of ordinary skill in the art “would have understood that the S-form plate disclosed in Heinl would be one way the plate of Kay could ‘accommodate individual variation in bone shape.’” *Id.* (citing Ex. 1001 ¶ 440).

a) Motivation to Combine

Patent Owner contends that Petitioner has not established motivation for one of ordinary skill in the art to modify Kay to incorporate the S-shape taught by Heinl. PO Resp. 43.<sup>13</sup> As we understand Patent Owner's argument, the requisite motivation is lacking because "a POSA understood that the pre-contoured X-shaped plate of Kay includes the same S-shaped footprint of Heinl." *Id.* at 43–44. According to Patent Owner, "for a particular anatomical condition in which the shape of the plate in Figure 3 of Heinl would accommodate, so too would the plate of Kay. Thus, a POSA would not be motivated to bend the plate of Kay in order to accommodate a bone shape as alleged by Petitioner." *Id.* at 45; Ex. 2017 ¶¶ 95, 98; Ex. 2018 ¶¶ 94, 97. Patent Owner further contends that Ground 2 fails because Heinl expressly teaches away from individualized contouring of bone plates whereas, "Petitioner fails to provide any explanation or supporting evidence to a POSA as to how the plate of Kay could be bent laterally at the waist area or how such bending would transform the plate from having an X-shape in the lateral plane to having an S-shape in the lateral plane as disclosed by Heinl." *Id.* at 45, 57; Ex. 1009, 1:27–33, 38–41, 2:3–6, 15–17; Ex. 2017 ¶¶ 97–98; Ex. 2018 ¶¶ 96–97; Tr. 51:13–15.

Patent Owner and its experts misconstrue the basis of Ground 2. As set forth in the arguments and evidence at pages 16–18 of Petitioner's

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<sup>13</sup> By way of context, we note that the District Court applied the plain and ordinary meaning to "Y-shaped plate," as the term is used in the related '251, '252, '253, '457, '846, '848, and '954 Patents. Paper 44, 19 (noting that "defendant concedes that 'the plain meaning of Y-shaped is just that: shaped like the letter Y'. . . and there is no genuine dispute between the parties' interpretations." *Id.*

Reply—which we adopt—“Petitioner actually argued Heintl would have suggested to POSITAs that Kay’s plate could be modified to include an S-curve along the medial line in either the lateral or longitudinal plane, *not* that Kay’s Figure 1 plate would be bent to match the exact physical structure of the Figure 3 plate of Heintl.” Reply 16; *see* Pet. 50 (“POSITAs would have understood that the S-form plate disclosed in Heintl would be one way the plate of Kay could ‘accommodate individual variation in bone shape.’ Ex. 1001 ¶ 440.”).

In sum, we agree with Mr. Castañeda’s testimony that Kay’s stated goal, to provide a set of plates which are pre-contoured differently to suit the different shapes of small bones, would have motivated a person of ordinary skill in the art to seek out other pre-contoured plate shapes to supplement Kay’s collection. Ex. 1001 ¶ 440. Heintl provides several such pre-contoured plates, one of which is shown in Heintl’s Figure 3 to have a medial line that describes an S-curve in the lateral plane, to match the individual contours of particular bones. Ex. 1001 ¶¶ 95–97, 439. Considering the overlapping disclosures of Kay and Heintl, we credit Mr. Castañeda’s testimony that “Kay discloses a plate having a medial line which describes a curve in a lateral plane or in a longitudinal plane,” and “[i]t would have been obvious to a POSITA to pre-contour Kay’s orthopedic plate such that the medial line describes an S-curve.” Ex. 1001 ¶¶ 429, 440.

Further, because we do not understand Petitioner’s argument to require one of ordinary skill in the art to “bend the trunk of Kay to include the shape of the entire plate (trunk and arms) of Heintl,” as Patent Owner posits, we find it irrelevant for the purpose of Ground 2 that one of ordinary skill in the art might understand that the “X-shaped plate of Kay includes the

same S-shaped footprint of Heintl.” *See* PO Resp. 43–44. Accordingly, we do not find Patent Owner’s argument persuasive.

Patent Owner also contends that Ground 2 is deficient because it “ignores the fact that the X-shaped plate of Kay is already pre-contoured such that the medial line describes an S-curve in the lateral plane.” PO Resp. 46–47. Claim 9, however, recites, in the alternative, an S-curve “in the lateral plane *or* in the longitudinal plane.” Insofar as Patent Owner’s argument admits that Kay discloses one of the claimed alternatives (a medial line having an S-curve in the lateral plane) we need not rely on Heintl for this element. *See In re May*, 574 F.2d 1082, 1090 (CCPA 1978); *In re Kronig*, 539 F.2d 1300, 1304 (CCPA 1976) (in finding obviousness, the Board may rely upon less than all the references cited). Nevertheless, we credit Petitioner’s reliance on Heintl as disclosing a variety of orthopedic bone plates which are pre-contoured to accommodate a variety of bone shapes, including the plate shown in its Figure 3 having a medial line that describes an S-curve in the lateral plane. Ex. 1001 ¶¶ 95–97, 440, 439. In light of Heintl, we credit Mr. Castañeda’s testimony that “[i]t would have been obvious to a POSITA to pre-contour Kay’s orthopedic plate such that the medial line describes an S-curve.” *Id.* ¶ 440.

According to Patent Owner, claim 5 (from which claim 9 depends) “recites a central trunk portion ‘defining a longitudinal trunk axis extending between a first end and a second end.’” Patent Owner asserts that Ground 2 is further deficient because “Petitioner provides no explanation or supporting evidence that the combined plate of Kay and Heintl having been bent to have an S-shape also includes a central trunk portion ‘defining a longitudinal trunk axis extending between a first end and a second end.’” PO Resp. 47–

48 (citing Ex. 2017 ¶ 100; Ex. 2018 ¶ 99). We do not find Patent Owner’s argument persuasive. As noted above, Petitioner’s Ground 2 argument does not require the bending of Heini’s plate into an S-shape. We also find persuasive Petitioner’s explanation that Kay discloses this element because “the ‘longitudinal trunk axis’ of an orthopedic plate is the axis that runs the length of the plate from one end to the other,” which one of ordinary skill in the art reading Kay would understand as an imaginary line defining “a straight line from one end of the trunk to the other, regardless of whether the trunk includes a S-curve along the medial line.” Reply 19–20 (citing Ex. 1001 ¶ 115; Ex. 1006 ¶¶ 7, 10, 47; Ex. 1005, 3:27–31, 7:9–13. We, therefore, agree with Petitioner that, “[r]egardless of the trunk’s shape, it includes an imaginary line that runs the length of the trunk in the longitudinal plane.”

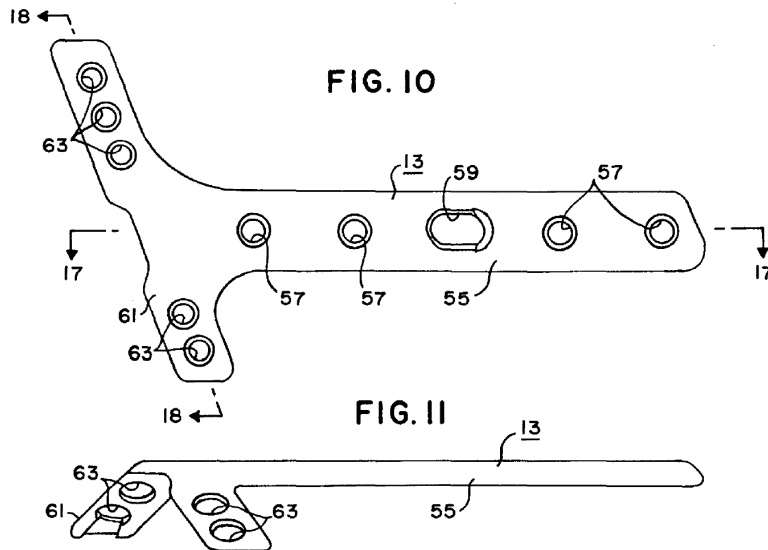
F. Ground 3: Obviousness of Claims 1–8 in view of Grusin and Fernandez

In Ground 3, Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, in support of its contentions that claims 1–8 would have been obvious in view of Grusin and Fernandez. Pet. 51–74; Reply 21–27; Sur-sur-reply 3–5; Ex. 1001 ¶¶ 441–492; Ex. 1087 ¶¶ 32–38. Patent Owner provides arguments and evidence in opposition, including testimony from Dr. Neufeld and Mr. Harrigan. PO Resp. 3, 48–74; Sur-reply 7, 22–30; Ex. 2017 ¶¶ 101–116; Ex. 2018 ¶¶ 89–127.

Considering all the evidence, 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.

1. Grusin (Ex. 1010)

Grusin discloses a bone plating system particularly suitable for fractures of the distal radius. Ex. 1010, Title, 1:18–20. Figures 10 and 11 of Grusin are reproduced below:



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 either bone screws 37 as shown in Figure 76, or buttress pin shank 23 and head 25 combinations as shown in Figures 43–53. *Id.* at 5:66–6:1, 6:12–17, 6:60–7:6.

Figures 45 and 50 of Grusin are reproduced below:

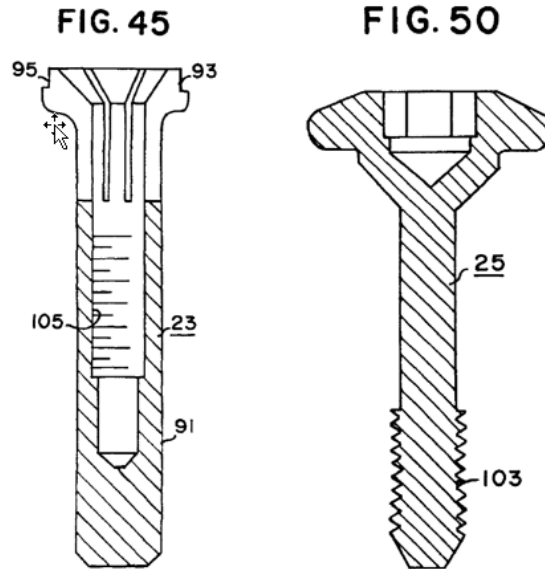


Figure 45 is a sectional view of buttress pin shank 23, and Figure 50 is a sectional view of pin head 25. *Id.* at 4:5–23, 8:63–67. In use, pin shank 23 is inserted into hole 57 or 63 of plate 13, until the flange of collar 93 is caught underneath plate 13, “to lock” pin shank 23 to plate 13. *Id.* at 8:29–53, 9:6–10. Then, screw portion 103 of pin head 25 is received by threaded aperture 105 of pin shank 23, and pin head 25 is threaded into pin shank 23 to cause collar 93 to expand to lock pin shank 23 to plate 13 “in a very solid connection.” *Id.* at 8:63–9:14.

2. Fernandez (Ex. 1011)

Fernandez discloses a “variable angle locked bone fixation system.”  
Ex. 1011, Title.

Figure 10 of Fernandez is reproduced below:

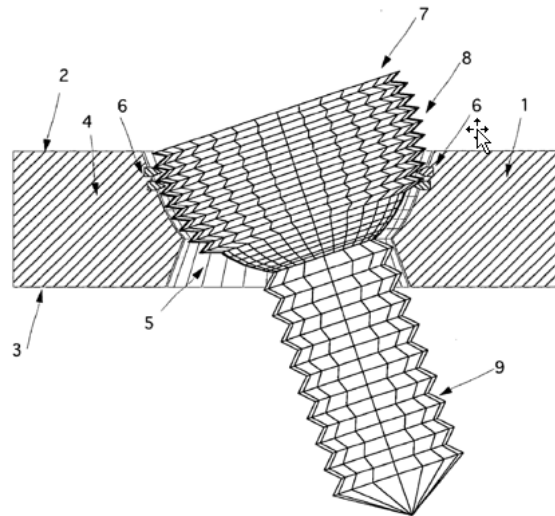


Figure 10 is a sectional view of screw 7 driven through hole 5 of bone plate 1, into bone underneath plate 1 (not shown), and locked at a tilt. *Id.* ¶¶ 27, 29, 30. Screw 7 has head 8, which “is threaded with a constant pitch.” *Id.* ¶ 30. Further, the wall of plate hole 5 “has a small number of isolated 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. “[O]nce the screw 7 has been driven in, it locks tightly against the protrusions 6 . . . in either perpendicular or tilted position,” with “up to 20 degrees of angulation in any direction” being allowed. *Id.* ¶ 33.

### 3. Overview of the Parties’ Contentions

Petitioner relies on Grusin as disclosing every element of claim 1–8, except for certain limitations relating to engagement of a threaded-head screw in the plate arm screw hole. Pet. 51–74. With respect to these limitations, Petitioner relies in-part on Fernandez as disclosing element 1[g]<sup>14</sup> (“wherein said at least one screw has a threaded shaft, a screw axis,

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<sup>14</sup> For convenience, we apply Petitioner’s convention of referring to certain claim phrases by claim number and bracketed letter. *See, e.g.*, Pet. 39.

and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis) (*id.* at 60–62); element 2[a], relating to “screws . . . locked in their respective screw holes” (*id.* at 62); element 4[a] reciting an “arm screw hole includ[ing] internal threads” (*id.* at 64–65).

According to Petitioner, “[l]ocking screws’ were a known method of coupling a plate to a bone” and a person of ordinary skill in the art “would have found it obvious to modify the plate system of Grusin to use screws with a threaded head and threaded screw holes, as disclosed by Fernandez, so that Grusin’s plates accept locking screws with threaded heads at variable angles.” *Id.* at 51–53 (citing Ex. 1001, ¶¶ 454, 456–458; Ex. 1011 ¶¶ 5, 6, 12; Ex. 1024 ¶ 2). Relying on the testimony of Mr. Castañeda, Petitioner further asserts that the skilled artisan would have seen no reason why screws with threaded heads and threaded screw holes as taught in Fernandez could not be used with the plate system of Grusin. Pet. 53 (citing Ex. 1001 ¶ 458). Moreover, Petitioner contends, one of ordinary skill in the art would have been motivated by the disclosure in Grusin to seek out screws that would increase the strength with which the plate is locked, and would have understood the benefits of using at least one screw that has a threaded head and forms a mating interface with a threaded screw hole that allows variable angles as disclosed by Fernandez. Ex. 1001, ¶¶ 456–57. Such a combination is a way to achieve a very solid connection between the plate and the bone, as desired by Grusin, and gives the advantage of allowing a surgeon to choose the most desirable angular orientation for a screw while still locking. Pet. 52. Petitioner similarly argues that persons of ordinary skill in the art

“would have been motivated to use screws with a threaded head and threaded screw holes, as disclosed by Fernandez, with Grusin’s plate system so that the plate could accept locking screws with threaded heads at a plurality of angular orientations and increase pullout strength.” *Id.* at 61 (citing Ex. 1001 ¶¶ 456–458).

Patent Owner argues that Ground 3 fails because (1), Petitioner has failed to demonstrate that a POSA understood Fernandez to disclose threaded screw holes in the bone plate to accept its spherical threaded head screws; (2), one of ordinary skill in the art would not have been motivated to combine Fernandez’s polyaxial locking screws with Grusin’s bone plating system; and (3) Petitioner ignores the meaning of “pre-contoured” as used in claim 5. PO Resp. 3, 48–74. With respect to Patent Owner’s first argument, Petitioner correctly points out that “the two independent claims at this issue in this IPR do not require a ‘threaded screw hole.’” Rather, independent claims 1 and 5 do refer to a “mating interface” between the screw hole and the threaded head of a corresponding screw. And while we agree with Petitioner that the “mating interface” limitation is undisputably disclosed in Fernandez, that does not render Patent Owner’s argument “irrelevant” as Petitioner contends. Reply 21.

Petitioner also relies on Fernandez with respect to claim 4, which recites that “the arm screw hole includes internal threads,” and thus requires a threaded screw hole. We also note that in the context of claims other than claim 4, Petitioner relies on Fernandez as disclosing “threaded screw holes,” a usage that we find helpful to explore here. *See e.g.*, Pet. 61; Ex. 1001 ¶ 354. For these reasons, we begin our analysis with the

construction of a “screw hole include[ing] internal threads,” *i.e.*, “the threaded screw hole limitation.”

4. Construction of “screw hole include[ing] internal threads”

Focusing on the word “threaded,” 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. 16, 61 (citing Ex. 2017 ¶ 54; Ex. 2018 ¶ 52); Sur-reply 24–25 (further 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. 14 (emphases by Patent Owner).

Petitioner responds that “Fernandez’s protrusions mate with the threaded-head screw, and thus are threads.” Reply 22. Petitioner 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.* & n.4. 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 ¶ 54; Ex. 2018 ¶ 52; 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 ¶ 54.

Our construction also is supported by the ’278 Patent’s illustration of “cancellous thread 83” and “external threads 88” as helical structures of a screw. Ex. 1005, Figs. 6–7, 4:33–36, 8:53–54. It is further supported by the ’278 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 9:33–35; *see also id.* at 10:14–20 (describing plate 312 illustrated in Figs. 18 and 19 as including an elongate central trunk with screw holes having “internal threads”).

We further determine that the helical structure formed by the threaded screw hole (“screw hole includ[ing] internal threads”) in claim 4 may be either continuous or interrupted. The ’278 Patent itself indicates a threaded screw hole may be formed by a series of interrupted structures. Figures 12 and 13 of the ’278 Patent are reproduced below:

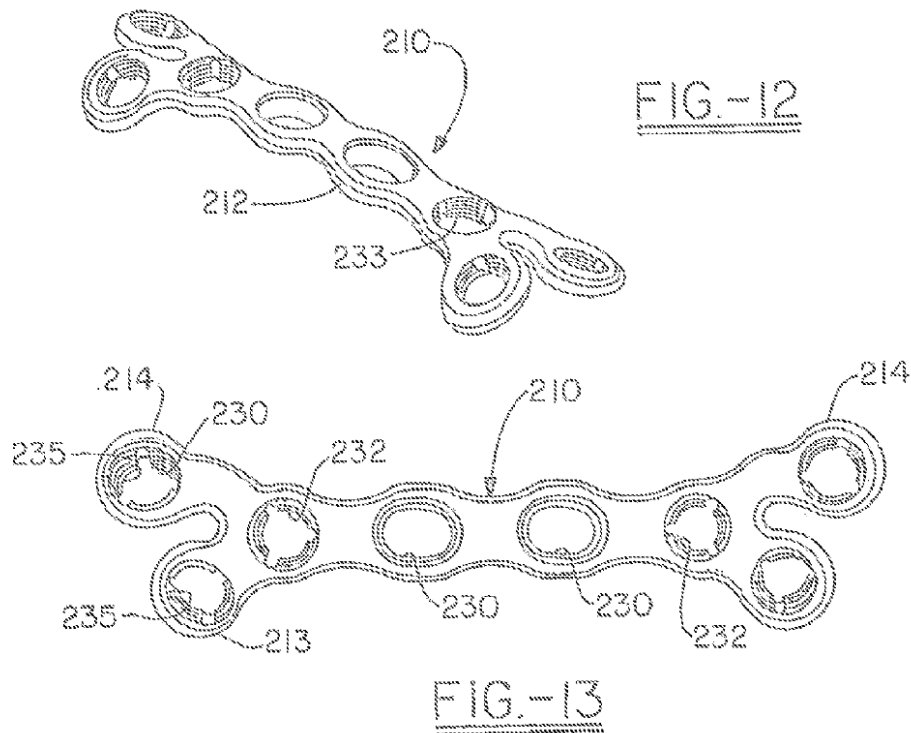


Figure 12 is a perspective view, and Figure 13 is a top view, of plate 210. Ex. 1005, 5:53–55, 9:12–15. Plate 210 exhibits “locking holes [232] having internal threads” and “keyways 233 for the mating portion of a drill guide.” *Id.* at 9:32–27; *see also id.* at Figs. 18 and 19, 10:12–14 (plate 312 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 4 may be either continuous or interrupted. Mr. Castañeda testified via declaration that Fernandez’s protrusions 6 form “internal threads” (Ex. 1001 ¶¶ 468–470) 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; 88:1–11 (stating that Fernandez has “threads that are interrupted basically”); 89:20–90:8. 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 recognize Mr. Castañeda’s struggle with the ’278 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. 16–17; Sur-reply 22–25. We do not discern such a minimum amount from our independent review of the ’278 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 4 simply requires the individual structures, taken together, form an a helical structure, which may be an interrupted helical structure.

Patent Owner additionally contends that the threaded screw hole limitation of claim 4, 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. 61–65, 69 (citing Ex. 2018 ¶¶ 113–119, 127; Ex. 1011, Figs. 4, 5, 10, ¶ 32, 33, 35; Ex. 2019, 88:8–10); Sur-reply 25–27 (further citing Ex. 1011, Fig. 6, ¶¶ 6, 30; Ex. 2023, 44–45, 63–64). We have reviewed Mr. Harrigan's testimony in support. Ex. 2018 ¶¶ 110–120, 126. However, Patent Owner and Mr. Harrigan do not cite any intrinsic evidence to support this narrow view of the “threaded screw hole” limitation of claim 4. 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 4 or in the '278 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 “screw hole includ[ing] internal threads” of dependent claim 4 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 form a mating interface with a screw, and function to receive that screw at several different angles or at one fixed angle.

5. Whether Grusin Discloses the Claimed Subject Matter

As noted above, Petitioner relies on Grusin as disclosing every element of claim 1–8, except for certain limitations relating to engagement of a screw in the plate arm screw hole. Pet. 51–74; Ex. 1001 ¶¶ 441–492.

Claim 5 recites “[a]n orthopedic plate system comprising at least one screw and an orthopedic plate having an inferior surface which is capable of facing a bone surface in use and which is pre-contoured to accommodate the shape of the bone surface.” Echoing the arguments discussed in section III(D)(3), above, Patent Owner contends that “Petitioner does not contend that the plate of Grusin as disclosed includes a curved medial line, but relies on the disclosure that the plate may be bent by a plate bender and that this additional contouring would result in a curved medial line.” PO Resp. 74 (citing Pet. 73). As such, Patent Owner contends that “Petitioner fails to address the distinction between ‘pre-contoured’ and the ‘individual contouring’ enabled by the bendability of the plate.” *Id.*

We do not find Patent Owner’s argument persuasive for the reasons set forth at page 27 of Petitioner’s Reply. As Petitioner notes, Grusin teaches that its bone plates “are ‘preferably pre-bent’ so that they ‘conform[] as closely as possible to the surface of the distal radius R.’” Reply 27 (citing Ex. 1010, 6:36–40; Ex. 1001 ¶ 484). Whether Grusin’s plates may be further

bent by individual contouring does not detract from this express disclosure. Considering all the evidence, we agree with Petitioner that Grusin discloses and renders obvious the “pre-contoured” limitation of claim 5. We further credit Petitioner’s statement that Patent Owner’s experts admit that the shape achieved by any individual contouring could also be accomplished by pre-contouring. *See id.* (citing Ex. 1072, 127:24–129:21; Ex. 1066, 177:9–183:15). Accordingly, even if Grusin did not disclose pre-contouring, the testimony of Patent Owner’s experts shows that one of ordinary skill in the art would consider pre-contouring obvious.

Patent Owner does not dispute Petitioner’s remaining contentions with respect to the subject matter disclosed in Grusin in comparison to the ’278 Patent claims. PO Resp. 48–74; *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.

#### 6. Whether Fernandez Discloses Claimed Subject Matter

Fernandez discloses that “[a] locking screw has 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” and that corresponding “[b]one plates having threaded holes for accommodating locking screws are known.” Ex. 1011 ¶5. 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. 51–54, 60–66 (citing Ex. 1011, Abstract, Figs. 1–3, 7–10, ¶¶ 5, 6, 11, 12, 15, 32, claim 1); Ex. 1001 ¶¶ 442, 443, 452, 454–471, 485–488, 491–492. Relying on the testimony of Mr. Castañeda, Petitioner contends one of ordinary skill in the art “would have understood

the benefits of using at least one screw that has a threaded head and forms a mating interface with a threaded screw hole that allows for a plurality of angular orientations, as disclosed by Fernandez.” Pet. 51–52 (citing Ex. 1001 ¶¶ 456–457).

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”); *see also* PO Resp. 51–56 (illustrating same) (citations omitted). As such, Fernandez satisfies the “mating interface” limitation of independent claims 1 and 5.

Patent Owner, however, disputes Petitioner’s contention that Fernandez’s protrusions 6 form “a threaded screw hole,” which we map in the present IPR to the “screw hole includ[ing] internal threads,” recited in claim 4. *See* PO Resp. 51–69; Ex. 1001 ¶¶ 469–470. 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. 16, 61; Ex. 2017 ¶ 54; Ex. 2018 ¶ 52. 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. 56–64 (citing Ex. 1011 ¶¶ 32, 35, Figs. 4–5); Ex. 2018 ¶¶ 111–119. 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. 17, 58–59, 65 (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 ¶¶ 115–119; PO Resp. 62–64. 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 ¶¶ 116–119; PO Resp. 62–64. 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 ¶¶ 119–120, 127 (citing Ex. 1011 ¶ 33; Ex. 2019, 88:8–10); PO Resp. 64–65, 69.

In reply, Petitioner correctly points out that, in contrast to claim 4, “the two independent claims at issue in this IPR **do not** require a “threaded screw hole.”” Reply 21. Instead, the claims merely require an arm screw hole with a mating interface that can engage with a threaded head of a screw.” *Id.* Petitioner, nevertheless, argues that the evidence of record shows that Fernandez does disclose threaded screw holes, even applying Patent Owner’s claim construction. *Id.* 21–22; Ex. 1087 ¶¶ 32–36. In support,

Petitioner argues that because Fernandez “starts with a description of a threaded-head locking screw that ‘matches with corresponding threading on the surface of a plate hole,’” one of ordinary skill in the art would have understood “that Fernandez’s protrusions would obviously be arranged in a helical manner.” Reply 24–25 (quoting Ex. 1011 ¶ 5); Ex. 1086 ¶¶ 33–36. 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. Reply 23–24 (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. Reply 22–23 (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.* at 23 (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 25 (citing PO Resp. 62–63).

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 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 26–27 (citing Ex. 1011 ¶¶ 6, 30, 33, Figs. 9–10; Ex. 1087 ¶ 18; Ex. 2018 ¶¶ 64, 67–71; Ex. 2019 ¶¶ 85–86; Ex. 2023, 44–45, 56–69, 63–64). Patent Owner also asserts Mr. Harrigan’s testimony does not rely on any scale being provided in Fernandez’s figures. *Id.* at 28 (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. Sur-Reply 23–24, 27 (citing Ex. 1011 ¶¶ 30, 32; Ex. 2026, 5:23–25, Fig. 6; Ex. 2027, 12; Ex. 2023, 56–59; Ex. 2028, Abstract, 1:39–45).<sup>15</sup> 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 27 (citing Ex. 2026, 5:23–25, Fig. 6). Patent Owner also argues that “the Fernandez Patent further describes the protrusions as ‘distributed in two substantially parallel planes along the inner surface of the opening’ as illustrated in Figure 6, decidedly not characteristics of a helical pattern, a contradiction Petitioner’s expert was unable to justify.” *Id.* (citing Ex. 1011 ¶ 30; Ex. 2023, 56:21–59:2 (Mr. Castañeda’s testimony concerning Figure 6)).

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<sup>15</sup> We overrule Petitioner’s objection that Exhibits 2026–2028 were belatedly presented with Patent Owner’s Sur-reply. *See* Paper 34; 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* Reply 18–21; 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.

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.” *Id.* at 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; Reply 23–25; 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 III(F)(4) (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. PO Resp. 62–63; Reply 23–24; Ex. 2017 ¶ 116. 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 disclosures in Fernandez, a person of ordinary skill in the art would have understood protrusions 6 correspond to “internal threads.” Ex. 1001 ¶¶ 454–469–470; 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 the threaded screw hole of dependent claim 4. Ex. 1087 ¶¶ 33, 36; *see supra* Section III(F)(4) (claim construction). No doubt, the interrupted structures illustrated in the ’278 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 III(F)(4) (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 ¶¶ 118–119. 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 1 may function to receive a screw at a fixed angle or at several different angles. *See supra* Section III(F)(4) (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* Reply 25. 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 28; Ex. 2018 ¶¶ 68. Therefore, we do not rely on this argument 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<sup>[16]</sup>” 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.

The issue presented here, however, is whether Fernandez’s protrusions 6 form a “threaded screw hole” and, in particular, the “screw hole includ[ing] internal threads” recited in claim 4 of the ’278 Patent. We have adopted Patent Owner’s construction of this limitation as requiring “a helical structure such as a rib or ridge for receiving a screw.” *See supra* Section III(F)(4) (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 4. 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 narrower than the full scope of disclosure of a patent.

For the foregoing reasons, we find Fernandez’s protrusions 6 form a “screw hole include[ing] internal threads,” as recited in claim 4.

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<sup>16</sup> Ex. 2028, U.S. Patent No. 5,709,686, iss. Jan. 20, 1998.

7. 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 “lock[]the unit . . . together in a very solid connection.” *See* Pet. 26, 27, 51–52, 59, 64–66; Ex. 1010, 5:67–6:3, 6:12–21, 6:60–7:6, 8:67–9:6, 9:5–14, 10:11–31; Ex. 1001 ¶¶ 442, 447–448, 467. 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 polyaxial screw 7 at a desirable screw angle. *See* Pet. 51–53, 64–65; Ex. 1011, Abstract, ¶¶ 10–13, 15, 32, Figure 10, and claim 1. Accordingly, Petitioner contends it would have been obvious to modify Grusin in view of Fernandez. Pet. 51–52 (citing Ex. 1001 ¶¶ 456–458).

Petitioner argues that a person of ordinary skill in the art would have been motivated “to seek out screws that would increase the strength with which the plate is locked, and would have understood the benefits of using at least one screw that has a threaded head and forms a mating interface with a threaded screw hole that allows variable angles as disclosed by Fernandez.” Pet. 52 (citing Ex. 1001, ¶¶ 456–57).<sup>17</sup>

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<sup>17</sup> Citing paragraphs 354–355 of Mr. Castañeda first Declaration, Patent Owner and its expert further note that “Petitioner's asserted motivation to replace the pins of Grusin with the screws and screw holes of Fernandez is predicated on the notion that ‘POSITAs understood the screws of a plate are used to create a strong hold, particularly for a fracture at the end of the radius where the patient's use of their hand or arm to grasp or manipulate objects stresses the screws.’” PO Resp. 72; Ex. 2017 ¶ 113.

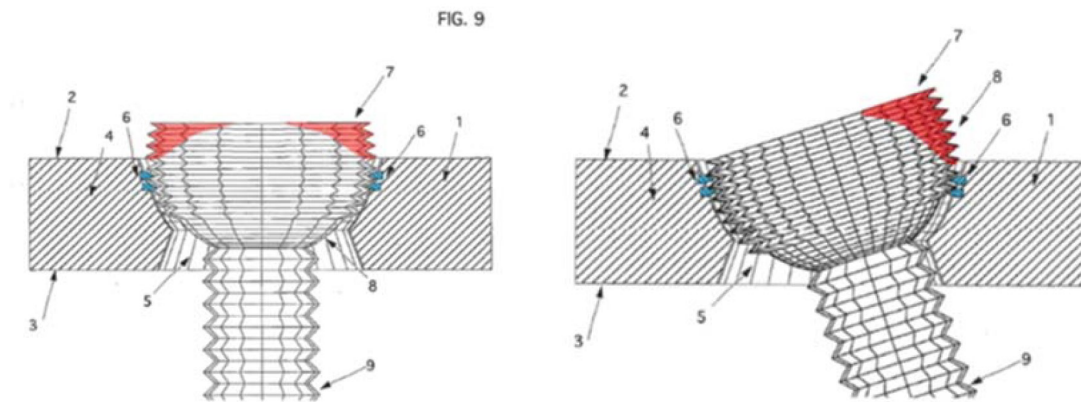
According to Petitioner, Fernandez discloses that the use of locking screws “was a well known method of coupling an orthopedic fixation device to a bone,” and further discloses a variable locking screw system that improves on prior screws and other fasteners. *Id.*; Ex. 1011 ¶ 5, 10–13, 15; Ex. 1001 ¶¶ 456–457. Petitioner contends that it would, therefore, have been obvious “to thread Grusin’s plate screw holes, as taught by Fernandez, so the plate could accept locking screws with threaded heads at a plurality of angular orientations while maintaining a strong hold on the bone.” *Id.* (citing Ex. 1011, ¶ 12); Ex. 1001 ¶¶ 456–458.

Petitioner further argues that:

Given the long history and known advantages of screws with threaded heads that engage threaded screw holes, POSITAs would have expected that those teachings of Fernandez could be successfully incorporated into Grusin. Ex. 1001, ¶458. And POSITAs would have seen no reason why such screws with threaded heads and threaded screw holes could not be used with the plate system of Grusin. *Id.*

*Id.* at 52.

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. PO Resp. 56, 69–73; Ex. 2017 ¶¶ 107–116. Specifically, Dr. Neufeld testifies that Fernandez’s screw 7 would frustrate Grusin’s intended purpose, which is to avoid tendon and soft tissue irritation and wear by maintaining a low profile of the fastener above the plate. Ex. 2017 ¶¶ 107–111 (citing Ex. 1010, 2:10–15, 2:29–33; Ex. 2018 ¶ 127); PO Resp. 69–70 (further citing Ex. 2019, 82:20–83:5); *see* Sur-reply 28–30. To illustrate his conclusion, Dr. Neufeld annotates Figures 9 and 10 of Fernandez, as reproduced below:



Dr. Neufeld's annotations of Figures 9 and 10 of Fernandez identify in red where the peripheral threaded edge of Fernandez's screw head 8 will extend above Grusin's plate. Ex. 2017 ¶¶ 109–111; PO Resp. 70–72. Dr. Neufeld testifies this would traumatize tendons and soft tissue in the region of the patient's wrist. Ex. 2017 ¶¶ 110; PO Resp. 70–72.

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 ¶¶ 103, 114 (citing Ex. 1010, 2:11–14); PO Resp. 49, 73; Sur-reply 28. 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 ¶¶ 114–116 (citing Ex. 1010, 2:11–14); PO Resp. 73; Sur-reply 28.

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.’” Reply 25–26

(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. *Id.* at 26.

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 26 (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.* 26–27 (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 29.

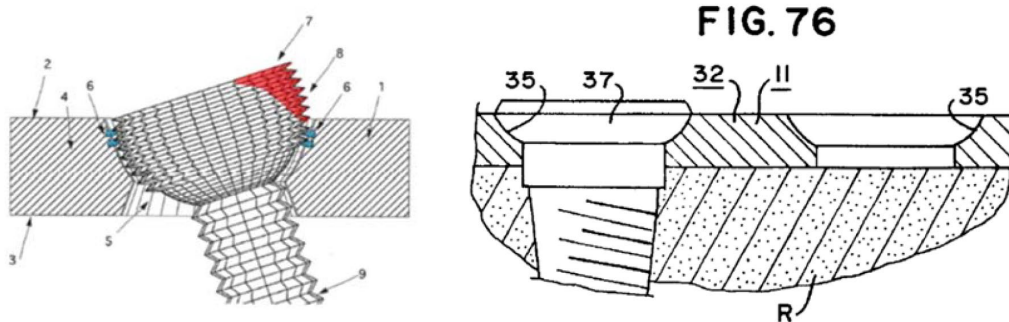


Figure 10 is an annotated front view of Fernandez’s bone fixation assembly where the screw is locked at a tilt (i.e., non-perpendicular relative to the plate). Figure 76 is a front view of Grusin’s bone fixation assembly where the screw is perpendicularly locked relative to the plate. Patent Owner argues 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 30 (quoting Ex. 2017 ¶ 110).

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 ¶ 354; Pet. 56–58; *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. 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. 52 (citing Ex. 1001 ¶¶ 456–457). 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 on this record 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 ¶ 110. However, Dr. Neufeld does not provide any reasons or analysis in support of this conclusion. *Id.* ¶¶ 110–111. 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 ¶¶ 113–116. 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.

#### 8. Conclusion

In addition to the elements discussed in detail above, Petitioner provides further arguments and evidence, including testimony from Mr. Castañeda, in support of its contention that claims 1–8 are unpatentable as having been obvious over Grusin and Fernandez. *See* Pet. 51–74; Ex. 1001 ¶¶ 363–392. Patent Owner does not separately address these additional elements. *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. We, nevertheless, agree with and adopt Petitioner’s arguments and evidence regarding these undisputed elements.

After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that each of claims 1–8 would have been obvious over Grusin and Fernandez and, thus, unpatentable under 35 U.S.C. § 103.

#### IV. SUMMARY OF CONCLUSIONS

In summary, we determine a preponderance of the evidence establishes claims 1–9 of the '278 Patent are unpatentable,<sup>18</sup> as shown in the following table:

<b>Claims</b>	<b>35 U.S.C. §</b>	<b>References</b>	<b>Claims Shown Unpatentable</b>	<b>Claims Not Shown Unpatentable</b>
1–8	103	Kay, Chan	1–8	
9	103	Kay, Chan, Heinl	9	
1–8	103	Grusin, Fernandez	1–8	
<b>Overall Outcome</b>			<b>1–9</b>	

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<sup>18</sup> 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).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–9 of the '278 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.

IPR2019-00896  
Patent 9,545,278 B2

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