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Paper 44
Date: October 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2019-00898
Patent 9,259,253 B2

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, 3–9, 12–15, 17–19, 46–48, and 50–53 of U.S. Patent No. 9,259,253 B2 ("the '253 Patent," Ex. 1004). 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, 3–9, 12–15, 17–19, 46–48, and 50–53 are unpatentable.

A. Procedural History

Paragon 28, Inc. ("Petitioner" or "Paragon") filed a Petition for an *inter partes* review challenging claims 1, 3–9, 12–15, 17–19, 46–48, and 50–53 of the '253 Patent as unpatentable as obvious under 35 U.S.C § 103.[1] 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 14, respectively. We instituted a trial to determine whether Petitioner had shown that claims 1, 3–9, 12–15, 17–19, 46–48, and 50–53 of the '253 Patent were unpatentable. Paper 15 ("Institution Decision" or "Inst. Dec."), 35.

After institution, Patent Owner filed a Patent Owner Response to the Petition. Paper 20 ("PO Resp."). Petitioner then filed a Reply (Paper 28, "Reply") to the Patent Owner Response, and Patent Owner filed a Sur-reply

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. § 103. Because the challenged claims of the '253 Patent appear to have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103 throughout this Decision.

(Paper 32, "Sur-reply") to Petitioner's Reply. Upon our authorization (Paper 34), Petitioner further filed a Sur-sur-reply (Paper 39, "Sur-sur-reply").

Patent Owner also filed a Motion to Exclude Evidence directed to Exhibits 1057–1060, 1070, 1073–1075, 1081, 1086, and 1088. Paper 38. Petitioner filed an Opposition (Paper 40) to the Motion and Patent Owner filed a Reply (Paper 41).

On June 25, 2020, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 42 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). 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, 3–9, 12–15, 17–19, 46–48, and 50–53 of the '253 Patent.

Considering the record before us, Petitioner has shown by a preponderance of the evidence that claims 1, 3–9, 12–15, 17–19, 46–48, and 50–53 of the '253 Patent are unpatentable.

B. Real Parties-in-Interest

Petitioner identifies only itself as the real party-in-interest. Pet. 81. 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. 81; Paper 6, 2.

The '253 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 9,545,278 B2 ("the '278 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. 81; 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 '253 Patent are entitled to the benefit of the 2006 Application.

D. The '253 Patent (Exhibit 1004)

The '253 Patent discloses "a series of orthopedic plates for use in repair of a bone" such as a clavicle. Ex. 1004, Abstract, 1:20–23, 2:19–21. Figure 1 of the '253 Patent is reproduced below:

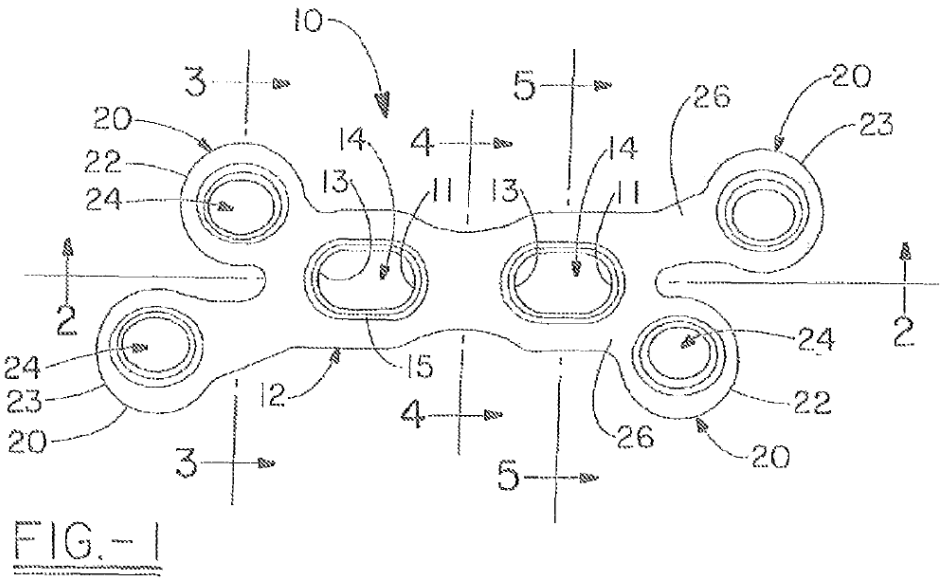


FIG. - 1

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, 5:28–29, 6:40–44, 7:9–11. Central trunk portion 12 includes two screw holes or slots 14. *Id.* at 6:43–45. 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.[2] *Id.* at 7:9–26. The differing angles of divergence ensure that 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.* at 1:57–61, 3:55–66, 7:66–8:4.

[2] The '253 Patent suggests these angles are identified as α and β in Figure 1 of the '253 Patent (Ex. 1004, 7:17–26), but that figure does not identify α and β. The angles are, however, identified in Figure 1 of the 2006 Application. *See* Ex. 2001, Fig. 1.

Screw holes 24 may be either "locking" or "non-locking" screw holes. *Id.* at 3:41–44. Figures 6 and 7 of the '253 Patent are reproduced below:

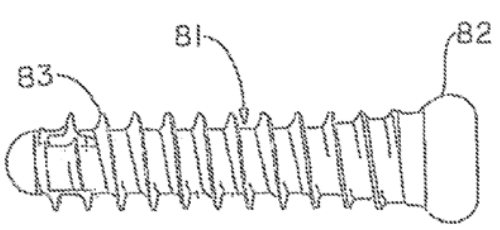


FIG.-6

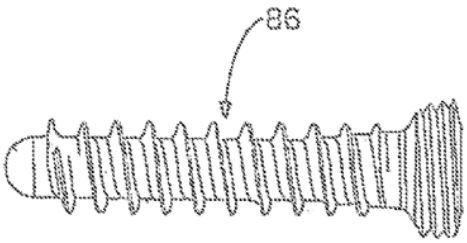


FIG.-7

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 8:41–55. 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 4:29–32. According to the '253 Patent: "Some surgeons prefer bicortical fixation in which a screw is sized so that the [distal] end is secured in cortical bone giving the screw better purchase, however, other surgeons may prefer to avoid placing a screw so that it projects beyond the outer surface of the anchoring bone." *Id.* at 1:61–65.

E. Challenged Claims

Petitioner challenges '253 Patent claims 1, 3–9, 12–15, 17–19, 46–48, and 50–53 of which claims 1, 13, and 46 are independent. Illustrative claim 1 recites (italics and paragraphing added):

> 1. An orthopedic plate comprising:
>
> an elongate central trunk portion having a medial longitudinal plane and at least one pair of divergent arms,

> each arm including *a threaded screw hole*, and each arm of the pair of divergent arms diverging asymmetrically away from the medial longitudinal plane relative to the other arm of the pair of divergent arms and
>
> wherein the central trunk portion has an inferior surface defining a curve transverse to the medial longitudinal plane and has a compression slot having an internal edge which includes a shoulder that slopes toward the inferior side of the orthopedic plate as it extends away from the first end of the central trunk portion.

Ex. 1004, 11:46–58.

Pertinent to our analysis, independent claims 13 and 46 are similarly directed to orthopedic plate systems with a plate having threaded screw holes, but further reciting corresponding locking screws in communication with the threaded screw holes. In particular, claim 13 recites

> a first locking screw and a second locking screw, and a . . . plate having . . . at least one set of arms disposed at a terminal end of the plate . . . each arm . . . including a threaded locking screw hole, and each of the threaded locking screw holes . . . having one of the first locking screw and the second locking screw locked to the plate.

Independent claim 46 recites

> a first locking screw, and a second locking screw, and a plate having . . . at least one pair of terminal arms . . . each of the terminal arms having a threaded locking hole which is in locked communication respectively with one of the first and the second locking screw.

Id. at 12:56–66, 16:8–15.

Patent Owner refers to claims 13 and 46, and their dependent claims, as "Plate+Screw" claims. *See, e.g.,* Prelim. Resp. 18; PO Resp. 1–2. Because the type of locking screw indicated in claims 13 and 46 employs "a threaded head that 'locks into' the screw hole and firmly holds the screw in place," (Pet. 7); Petitioner refers to the first and second locking screws of claims 13 and 46 as either the "locking screw" or "threaded head" limitations. *See, e.g.*, Pet. 7–9, 11, 15–16; Ex. 1001 ¶ 42–47; *see also* Prelim. Resp. 2–4, 8 (indicating that a threaded-head screw is a locking screw). We adopt the parties' conventions as convenient.

F. Asserted Grounds of Unpatentability

We address the following grounds for unpatentability (Pet. 17; Inst. Dec. 35):

Ground	Claim(s)	Basis	Asserted Reference(s)
1	13–15, 17–19, 46–48, and 50–53	103	Kay[3] and Chan[4]
2	1, 3–9, and 12	103	Grusin[5] and Fernandez[6]

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. 2023 (Castañeda deposition transcript). In opposing these challenges, Patent Owner relies on,

[3] 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 ("the 2006 Application," Ex. 2001).
[4] Chan et al., US 2008/0140130 A1, published June 12, 2008 (Ex. 1007).
[5] Grusin et al., US 6,283,969 B1, issued Sept. 4, 2001 (Ex. 1010).
[6] Fernandez, US 2005/0165400 A1, published July 28, 2005 (Ex. 1011).

inter alia, the Declaration of Steven Neufeld, M.D. (Ex. 2017) and the Declaration of Timothy P. Harrigan Sc.D. (Ex. 2018); see also Exs. 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).

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

nonobviousness, if made available in the record.[7] *See 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 reasons grounded in the Federal Rules of Evidence. *See* Paper 38. We do not

[7] Although the Patent Owner Response discusses the needs met by the '253 Patent, and the "great commercial success" of products embodying the patent's claims, Patent Owner's counsel confirmed at oral hearing that Patent Owner is not relying on objective indicia of nonobviousness. Tr. 56:12–20, PO Resp. 5–9. Accordingly, we do not address such elements here.

rely on any of these Exhibits in this Decision. Although we briefly refer to the substance of Exhibit 1086 in connection with the priority dispute, we ultimately do not reach the pin versus screw issue for which Petitioner cites Exhibit 1086. *See* Reply 8–9; Sur-Reply 14. 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).

In our Institution Decision, we noted that although Petitioner does not expressly address the standard of one of ordinary skill in the art here, its Petitions in copending proceedings involving related patents, as well as its expert in the instant proceeding, define a person having ordinary skill in the art as having "2–3 years of experience in the design of orthopedic plates or

2–3 years of experience using orthopedic plates in surgery." Inst. Dec. 10 (citing, IPR2019-000896, Paper 2 at Pet. 23; Ex. 1001 ¶¶ 28–29). Patent Owner does not dispute that definition in the context of this proceeding. Prelim. Resp. 12; PO Resp. 13 & n.2. Finding that Petitioner's unopposed definition is consistent with the '253 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); *GPAC*, 57 F.3d at 1579–80; *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

B. Claim Construction

We interpret the claims of the '253 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, 51,358 (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).

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 '253 Patent. Paper 43. 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.[8]

With respect to the instant proceeding, Petitioner "does not believe construction of any terms are necessary." Pet. 18. Patent Owner contends we should construe only the term "threaded screw hole," recited in claim 1, to resolve Petitioner's obviousness challenge relying on Grusin and Fernandez (Ground 2). PO Resp. 13–15. We consider this issue below in Section (III)(E)(3).

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

C. Priority of Claims Challenged under Ground 1

Petitioner contends that claims 13–15, 17–19, 46–48, and 50–53 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, 11–16. Because

[8] We note, for example, that claims 17 and 50 recite an orthopedic plate having "an outline that forms a Y-shape." Ex. 1004, 13:19–23, 16:35–39. Relevant to this term, the District Court applied the plain and ordinary meaning to "Y-shaped plate." Paper 43, 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"). Although the meaning of "an outline that forms a Y-shape" is not at issue in this *inter partes* review, for the sake of clarity and comity, we apply the plain and ordinary meaning as construed by the District Court.

this is a threshold issue to the merits of Ground 1, 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).[9] 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.*

[9] The AIA amended 35 U.S.C. § 112 effective September 16, 2012. *See* AIA § 4, 125 Stat. 296–97. The application that issued as the '253 Patent was filed on March 31, 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.

2. Parent Applications at Issue

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 '253 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. 2–5, 15–36.

We must resolve this dispute because it determines whether Kay and Chan are prior art to the challenged claims of the '253 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. 26 n.5. 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 '253 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. Overview of 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:

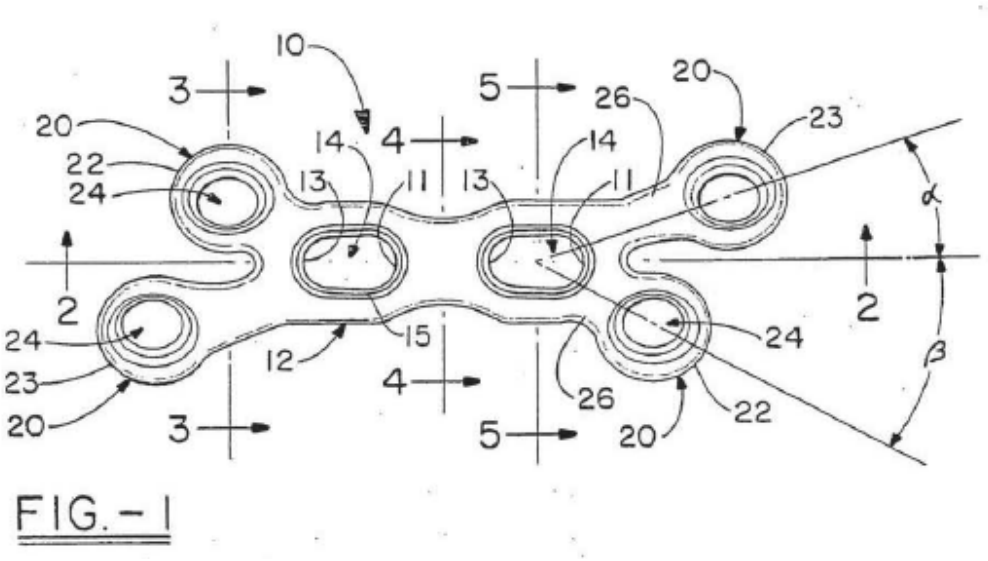


FIG.-1

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 or 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 α and β) 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

a) The Petition and the Institution Decision

In the Petition, Petitioner contends that the claims challenged in Ground 1 are not entitled to the priority benefit of the 2006 Application, because the 2006 Application lacks written description support for inserting a locking screw into a threaded screw hole of a plate. Pet. 2, 11–16. With respect to those challenged claims, Petitioner notes that both independent claim 13 (from which claims 14, 15, and 17–19 depend) and independent claim 46 (from which claims 47, 48, and 50–53 depend) are directed to orthopedic plate systems having "a first locking screw and a second locking screw." *Id.* at 11.

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 7–9 (citing Ex. 1001 ¶¶ 42–47; Ex. 1023, 18; Ex. 1024, Fig. 7; Ex. 1011, Fig 10, Ex. 1025 Fig.

6B); *id.* at 11–12 (citing Ex. 1004, Figs. 6–7, 8:41–55); Ex. 1001 ¶ 80; Reply 1. According to the Petition, the 2006 Application discloses only non-locking screws, that is, screws with non-threaded heads. Pet. 2, 12–15 (citing, e.g., Ex. 2001,[10] Figs. 6 & 8, ¶¶ 8–9, 11, 19–21, 52; Ex. 1001 ¶¶ 80–82). For example, Petitioner points out that both the 2006 Application and the '253 Patent disclose screw heads that "are rounded and have a low profile so that the screws can be seated with their longitudinal axes at a variety of angles." Pet. 14 (quoting Ex. 2001 ¶ 9; Ex. 1004, 4:20–23); Ex. 1001 ¶¶ 81–82. However, the '253 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." Pet. 14 (quoting Ex. 1004, 4:29–32) (emphasis by Petitioner); Ex. 1001 ¶¶ 81–82.

Patent Owner disputed these assertions in the Preliminary Response. *See, e.g.,* Prelim. Resp. 18–33. In the Institution Decision, we addressed whether the "claims challenged in Ground 1 (claims 13–15, 17–19, 46–48, and 50–53) . . . lack written description support in the 2006 Application for the 'locking screw' (i.e., 'threaded head') limitation recited in independent claims 13 and 46." Inst. Dec. 11. 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

[10] 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. 26 n.5.

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. 19. Although Petitioner agreed that such a threaded-head screw is a locking screw (*see* Pet. 7–8, 11–12), 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 "[t]he 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 locking screw to be received in the threaded screw hole." *Id.* at 19, 21.

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. 18–19 (citing Ex. 1001 ¶¶ 42–44, 58, 80–82, 282). Despite our conclusion concerning priority, we instituted trial as to Petitioner's proposed obviousness of claims 13–15, 17–19, 46–48, and 50–53 over Kay and Chan, based on our conclusions with respect to Ground 2 and the Board's practice implementing *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *See* Inst. Dec. 2–3, 34–35.

b) The Parties' Post-Institution Arguments and Evidence

In the Patent Owner Response, Patent Owner continues to agree with Petitioner that a "locking screw," in at least one example, corresponds to a screw having a threaded head that matches corresponding threads in a screw hole receiving the screw. PO Resp. 2–4, 15–23; 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. 2–4, 15–16, 20–36 (citing Ex. 2001 ¶ 51); Ex. 2017 ¶¶ 39–53; Ex. 2018 ¶¶ 37–51.

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.[11] PO Resp. 2–5, 15–16, 22–23 (citing illustration of an exemplary locking screw at Pet. 7–8, taken from Ex. 1023, 18); Ex. 2017 ¶¶ 45–47 (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.* ¶ 49 ("A POSA understood that a threaded screw hole [or bore] is a ***locking screw hole***." (emphasis by Dr. Neufeld)); Ex. 2018 ¶¶ 43–45, 47 (same). Patent Owner asserts Petitioner's witness Mr. Castañeda "agree[s] that a locking screw hole or threaded screw hole in a bone plate corresponds to a locking or threaded-head screw." PO Resp. 31 (citing Ex. 1001 ¶ 58; Ex. 1002, 4:27–30; Ex. 2017 ¶¶ 48–49; Ex. 2018 ¶¶ 46–47).

In reply, Petitioner correctly observes that the only 2006 Application disclosure cited by Patent Owner as demonstrating possession of a locking

[11] 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, 10–11 (citing PO Resp. 27–36; Ex. 2017 ¶¶ 44–53; Ex. 2018 ¶¶ 42–51). We disagree with Petitioner's limited reading of the Patent Owner Response and supporting witness testimony.

screw is that a bone plate screw hole "bore could be threaded." Ex. 2001 ¶ 51; Reply 1, 4 (citing PO Resp. 28; Ex. 2017 ¶ 43; Ex. 2018 ¶ 41; Ex. 1066, 195:7–196:3). Petitioner then asserts the evidence of record establishes "that a hole in a plate could be threaded for numerous different reasons other than for use with a locking screw, confirming that disclosure of a threaded hole ***does not*** 'necessarily demonstrate[]' possession of a locking screw" as Patent Owner contends and as Federal Circuit precedent requires. Reply 2, 10–11 (citations omitted). In support, Petitioner cites disclosures in the 2006 Application and testimony of Patent Owner's witness Mr. Harrigan. *Id.* at 5–8 (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).

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 4–10. 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 which requires only that the specification reasonably disclose to a POSA that the inventor was in possession of the invention, to improperly assert the specification must disclose that a threaded screw was ***necessary***." Sur-reply 8–9 (emphasis by Patent Owner) (citing *Hologic*, 884 F.3d at 1361). Applying the possession test, Patent Owner argues "the ***only evidence before the Board*** as to the understanding of a POSA from the disclosure of the threaded-screw-hole embodiment in [the 2006 Application] remains that the plate screw holes are threaded '***so that the plate system could accept locking screws***.'" *Id.* at 5–6 (emphases by Patent Owner) (quoting Ex. 1001 ¶ 282); *id.* at 7, 11–12.

According to Patent Owner, whether a person of ordinary skill in the art understood that the threaded screw hole bore disclosed in the 2006 Application could receive a threaded portion of structures other than a locking screw "is not an issue before the Board, and . . . does not negate the evidence . . . that a threaded screw hole is intended for a threaded-head locking screw." *Id.* at 9. Patent Owner emphasizes that the 2006 Application discloses "orthopedic plates designed to be affixed to bone by ***screws***, including plates designed to be affixed by ***locking screws***," thereby demonstrating possession of a locking screw. *Id.* at 12–14 (citing Ex. 2001, Abstract, ¶¶ 1–4, 6, 8, 50); *see also id.* at 16 ("[S]ince the plates disclosed by Kay include only ***screw hole***s 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, 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*, 73 (Nov. 2019) ("Consolidated Guide").[12] "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 Decision and arguments raised in the Patent Owner Response. *See* Sections III(C)(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

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

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(C)(4)(a)) 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, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1378–81 (Fed. Cir. 2015) (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 34 (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 Trial Practice 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. Sur-sur-reply 1–3.

5. Analysis

The 2006 Application disclosure at issue provides that the "screw holes" of a bone plate include a "bore" and "[i]n a further embodiment, the bore could be threaded." Ex. 2001 ¶ 51. Whether the 2006 Application supports a finding of priority for the claims challenged under Ground 1 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. 11–15. 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 '253 Patent disclosures of a locking screw are not found in the 2006 Application. *Compare* Ex. 1004, 4:20–33, *with* Ex. 2001 ¶ 9; *compare* Ex. 1004, 5:39–42, 8:41–55, Figs. 6–7, *with* Ex. 2001 ¶¶ 19–21, 52, Figs. 6–8.

At the same time, the parties agree, and we find the evidence establishes, that a person of ordinary skill in the art would have known in January 2006 that *one* purpose of a threaded screw hole bore is to receive the threaded head of a locking screw. *See* Ex. 1023, 18; Ex. 1001 ¶¶ 42–45, 80–82; Ex. 1087 ¶ 19; Ex. 2017 ¶¶ 40, 44–49; Ex. 2018 ¶¶ 38, 42–47; Pet. 7–8, 10–13; PO Resp. 2–4, 27–31. Nonetheless, we find it odd that the 2006 Application's inventors would 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. 3, 26–27; PO Resp. 2–5, 22–23, 28–31; Ex. 2017 ¶¶ 45–49; Ex. 2018 ¶¶ 43–47. Petitioner agreed that necessity is the applicable legal standard. Reply 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.

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

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

The 2006 Application and related witness testimony establish that a locking screw is not a necessary counterpart to, and instead is only one

obvious reason for having, the threaded screw hole bore disclosed in the 2006 Application. Specifically, as discussed in the next Section IV.C.4(a), the 2006 Application itself discloses a screw bore may have been threaded to receive a bending tool, rather than a locking screw. As discussed in the following Sections III(C)(5)(a)-(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 6–7.

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 6; *see also PowerOasis*, 522 F.3d at 1306 (witness testimony is relevant to priority issue); *Hologic*, 884 F.3d at 1363–64 (same). This bending device disclosure in the 2006 Application is sufficient, on its own, to establish that a locking screw is not a necessary counterpart for the threaded screw hole bore disclosed in the 2006 Application. It is possible for the bore to be threaded only to receive a bending device, and then receive a non-locking screw to attach the bent plate to a bone.

Dr. Neufeld and Mr. Harrigan testify that a locking screw necessarily corresponds to a threaded screw bore hole in a bone plate. *See* Ex. 2017 ¶¶ 40, 44–49; Ex. 2018 ¶¶ 38, 41–47. 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 find that 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 4–13 (discussing Exs. 1082–1087). Patent Owner raises various objections and responses to the evidence cited by Petitioner. *See* Sur-reply 12–22.

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:

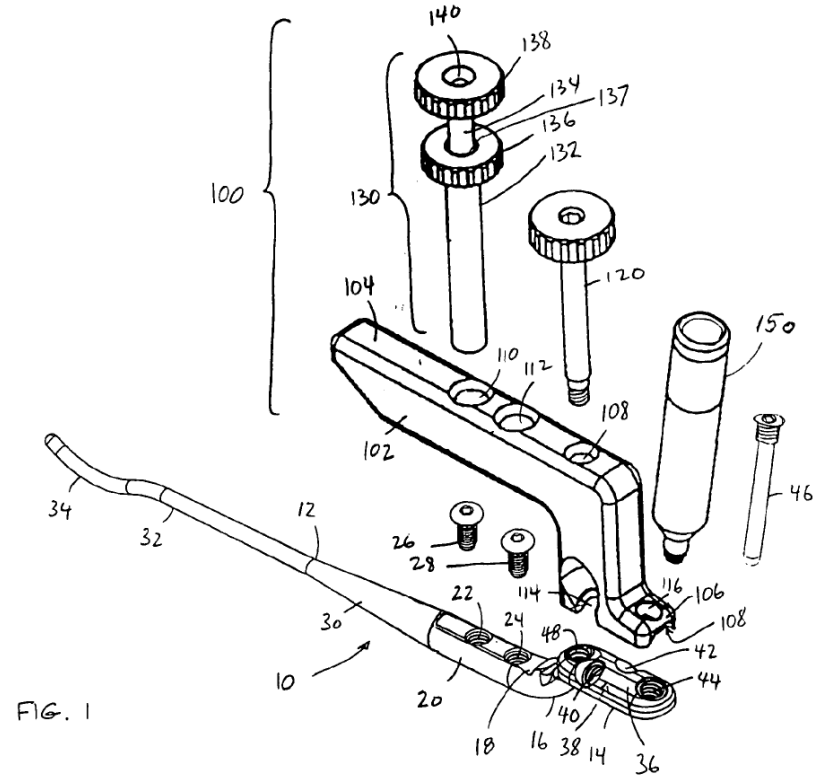


FIG. 1

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 5–6. The heads of screws 26, 28 are not threaded, so they are not locking screws. Ex. 1084, Fig. 1; Ex. 1087 ¶ 27. Thus, a person of ordinary skill in the art in

January 2006 would have known that a screw hole bore may be threaded to receive the threaded shaft of a non-locking screw, rather than the threaded head of a locking screw.

Patent Owner asserts the Castañeda Application does not aid Petitioner, because the 2006 Application discloses that its screw hole diameters are larger than its screw shaft diameters and that its screw shafts are tapered, both of which are inconsistent with the threaded shaft of the screw interfacing with the threads of the screw hole bore. Sur-reply 16–18 (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 18–19 (citing Ex. 1084, Fig. 12; Ex. 2023, 25:3–20, 27:15–28:19). Even acknowledging this difference in operation, however, the Castañeda Application still establishes that the threads of a screw hole bore in a bone fixation device may interact with the threads of a screw shaft (on a non-locking screw) rather than the threads of a screw head (on a locking screw). This is consistent with the 2006 Application, which reflects that the head of a non-locking screw is "rounded" but not threaded. Ex. 2001, Fig. 8, ¶¶ 9, 11, 52.

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

The evidence establishes a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive many instruments, such as a drill guide, a screw guide, and a plate positioner. The 2006 Application indicates its plate system may be used with "instruments" (Ex. 2001 ¶ 12), and allows a surgeon "to perfect a variety of techniques using a set of instruments" (*id.* ¶ 13). *See* Reply 6–7.

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.

Patent Owner points out that, after drill guide 150 is used to drill a hole into bone, guide 150 is removed and then peg 46 is inserted until the threaded head of peg 46 is received within threaded hole 44 of device 10. *See* Sur-reply 21; Ex. 2023, 29:12–30:13. However, we find that, viewing the state of the art as a whole in January 2006, a person of ordinary skill in the art would 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 ¶ 28 (citing Ex. 1082, Fig. 1, ¶ 7); Reply 5, 7. 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. 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 threaded 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 6–7. We acknowledge Mr. Harrigan's further testimony that, in his view, the "primary" purpose, use, or reason for having a threaded screw hole bore in a plate is to receive the threaded head of a locking screw. Ex. 1066, 191:22–23, 192:7–9. However, inherency requires that a locking screw is a necessary counterpart, and not just a probable counterpart or an obvious use, of a threaded screw hole bore.

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

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

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

(3) Jig Assembly

Petitioner argues a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive a jig assembly. *See* Reply 7–8 (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 18–19 (citing Ex. 1084, Fig. 12; Ex. 2023, 25:3–20, 27:15–28:19).

The Castañeda Application's jig assembly 100 is used to align fixation device 10 inside a bone, which involves the threaded end of locking screw 120 being inserted through hole 118 (mislabeled as "108" in Figure 1) of jig 102 and threaded into locking hole 48 of fixation device 10. Ex. 1084, Abstract, Fig. 1, ¶¶ 8–12, 41, 43–44; *id.* at Fig. 12 (illustrating the locking screw (unnumbered) received in device 10, which is inserted inside

bone 400); Ex. 1087 ¶ 25; Ex. 2023, 25:3–20, 27:15–28:19. The various bone plates of the 2006 Application, by contrast, are mounted on the exterior surface of the bone. *See, e.g.*, Ex. 2001 ¶ 8.

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

(4) Locking Peg

Petitioner additionally argues a person of ordinary skill in the art would have known in January 2006 that the 2006 Application's screw hole bore may have been threaded to receive the threaded head of a locking peg, rather than the threaded head of a locking screw. Reply 8–10; Ex. 1087 ¶¶ 20–24 (citing Ex. 1083 ¶¶ 13–15, 41, Figs. 1–2; Ex. 1085 ¶¶ 60, 73; Ex. 1086, 4–5, Fig. 6). Mr. Castañeda testifies in support that a locking peg differs from a locking screw because the peg has a smooth shaft, while the screw has a threaded shaft, even though both have a threaded head. Ex. 1087 ¶¶ 20, 23. Patent Owner argues in opposition that Petitioner and Mr. Castañeda draw a false dichotomy between locking pegs and locking screws, because the evidence reflects the same structure has been labeled as a locking peg and as a locking screw. Sur-reply 14–16 (citing Ex. 1086,

Fig. 6; Ex. 2024, 2:8–14, Figs. 2, 8a, 8c). Petitioner replies that Patent Owner's rebuttal overlooks that a "locking screw" in the context of the '253 Patent must have a threaded shaft, as well as Mr. Castañeda's deposition testimony distinguishing between pegs and screws. Sur-sur-reply 2–3.

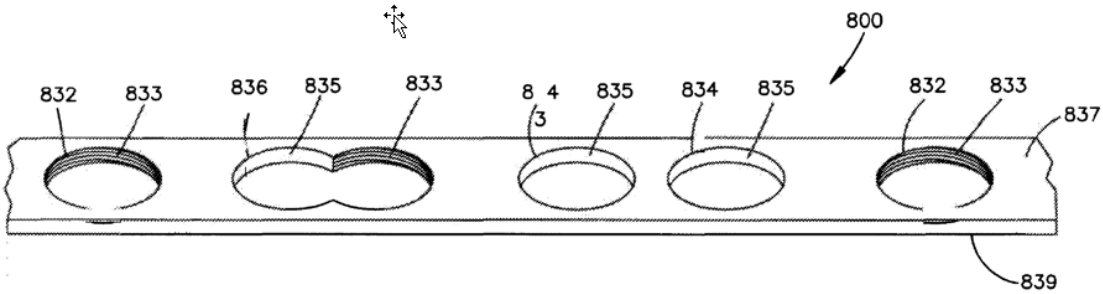
We conclude we need not resolve the foregoing dispute, because we have already concluded (*see supra* Sections III(C)(4)(a) and III(C)(4)(b)(1)–(2)) that a person of ordinary skill in the art in January 2006 would have known the 2006 Application's screw hole bore may have been threaded to receive several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

c) Conclusion

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

6. Chan (Ex. 1007)

Patent Owner further 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. 31–34 (emphasis by Patent Owner); Ex. 2017 ¶¶ 50–51; Ex. 2018 ¶¶ 48–49. Figure 8 of Chan is reproduced here:



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. 31–33; Ex. 2017 ¶¶ 50–51; Ex. 2018 ¶¶ 48–49.

Petitioner contends Chan merely establishes that a locking screw requires a threaded screw bore, and "does nothing to inform the discussion of whether a threaded bore, with nothing more [as in the 2006 Application], discloses a 'locking screw.'" Reply 11–12 (citing Ex. 1007 ¶ 64). Further: "the fact that Chan felt the need to call its holes 'locking bone plate holes' (as opposed to just 'threaded holes') . . . shows that POSITAs understood ***additional*** disclosure was required to understand the use of a 'threaded bore.'" *Id.* (emphasis by Petitioner).

We agree with Petitioner that Chan merely establishes a locking screw requires a threaded screw bore to receive the threaded head of a locking screw; Chan does not establish that disclosure of a threaded screw hole bore

demonstrates possession of a locking screw to be received in the bore. *See* Ex. 1007 ¶ 64, Fig. 8. For example, Chan specifically describes its threaded holes as "*locking* bone plate holes 832," and the hole's threads 833 as "for engaging the threads around *the head of a locking bone screw*." *Id.* ¶ 64 (emphases added). Chan's decision to describe a threaded screw hole bore functioning to receive the threaded head of a "locking" screw stands in stark contrast to the silence of the 2006 Application on this point. *See* Ex. 2001 ¶ 51. Chan thus supports Petitioner's position that a person of ordinary skill in the art would have known a threaded screw hole bore may receive various structures other than a locking screw, which led Chan to identify the locking screw from among the various structures in this regard, which the 2006 Application does not do. *See* Reply 12.

7. Prosecution History

Patent Owner next argues that, coextensive with the prosecution of the '253 Patent at issue here, "the same examiner determined that claims pending in the [related] 252 Patent prosecution directed to a method using a plate system having a ***plate plus locking screws*** were entitled to the priority of the 2006 Application." PO Resp. 18, 25–26 (citing Ex. 1037, 3–4).[13] Patent Owner asserts the same Examiner consistently maintained this position during prosecution of the related '278 Patent. *Id.* at 19–22 (citing Ex. 1049, 12; Ex. 1048, 2). Patent Owner, thus, concludes the prosecution history supports a finding that the claims of the '253 Patent challenged under Ground 1 are entitled to priority to the 2006 Application's filing date. *Id.* at 15–20.

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

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

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

8. Alleged Inconsistency in Petitioner's Arguments

Patent Owner lastly argues Petitioner takes inconsistent positions, on one hand, contending the 2006 Application does not demonstrate possession of a locking screw by disclosing a threaded screw hole bore, and on the other hand, contending a locking screw would have been obvious to implement in

Kay because Kay discloses a threaded screw hole bore. PO Resp. 2–3, 6, 22–23, 33–35 (citing Pet. 7–8, 11–12, 29–32, 34; Ex. 1001 ¶ 282). 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 and lock the screws to the plate.." Sur-Reply 6; *see* PO Resp. 2–3, 22–23, 34 (citing Ex. 1001 ¶ 282).

Petitioner replies that its arguments concerning priority and obviousness are not inconsistent. *See* Reply 10–11, 12–13 (citations omitted).

We disagree with Patent Owner's assertion that Petitioner takes inconsistent positions here. First, Patent Owner mischaracterizes Petitioner's position and Mr. Castañeda's testimony to be that the 2006 Application discloses its "screw holes are threaded ***so that*** they can accept locking screws." PO Resp. 2–3, 6, 22–23, 34 (emphasis by Patent Owner); Sur-reply 6; Ex. 1001 ¶ 282.

Petitioner's position instead is that "once Kay [the publication of the 2006 Application] *has been modified to accept Chan's variable locking screws as taught by Chan*," then the "locking screws could successfully be inserted at selected angles within the screw holes as described by Kay." Pet. 30 (emphasis added) (citing Ex. 1001 ¶¶ 281–284, 294, 302–303, 333); *see id.* at 36. Mr. Castañeda similarly testifies in support that: "*It would have been obvious* to a POSITA *to thread the screw holes of the plate disclosed by Kay using either the thread segments or conventional threading disclosed*

by Chan, so that the plate system could accept locking screws." Ex. 1001 ¶ 282 (emphases added); *id.* ¶¶ 294, 302–303, 333.

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.

9. Summary and Conclusion Regarding Priority

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 as recited in the claims. We

correspondingly conclude that the claims challenged under Ground 1, claims 13–15, 17–19, 46–48, and 50–53 of the '253 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.

D. Ground 1: Obviousness over Kay and Chan

Petitioner asserts claims 13–15, 17–19, 46–48, and 50–53 of the '253 Patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Kay and Chan. Pet. 17, 28–56. Patent Owner opposes on the sole basis that Kay and Chan are not prior art to the '253 Patent, because the '253 Patent is entitled to priority to the filing date of the 2006 Application. *See* PO Resp. 1–5, 36; Sur-reply 7; 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 '253 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 '253 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 13–15, 17–19, 46–48, and 50–53 of the '253 Patent would have been obvious over Kay and Chan.

"The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented." *LG Elecs., Inc. v. Conversant Wireless Licensing S.A.R.L.*, 759 F. App'x 917, 925 (Fed. Cir. 2019) (quoting *In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir.

2016)).[14] Nonetheless, to provide a complete record, we summarize our findings and conclusions as to obviousness below.

1. Overview of 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.).[15] In the interest of efficiency, we refer to section II(D)(2), above, for an overview of the shared disclosure and adopt Mr. Castañeda's overview of Kay as set forth in paragraphs 84–89 of Exhibit 1001.

2. Overview of 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

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

[15] *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 plates to add Chan's variable locking screws." Pet. 28 (citing Ex. 1001 ¶¶ 281–284, 290–91, 294, 302–303, 333). Petitioner contends that one of ordinary skill in the art "would also have understood that, once Kay has been modified to accept the locking or variable locking screws as taught by Chan, that locking screws could

successfully be inserted at selected angles within the screw holes as described by Kay." *Id.* at 30 (citing Ex. 1001 ¶¶ 281–284, 294, 302–303, 333). With respect to motivation, Petitioner contends that a person of ordinary skill in the art would have known that locking screws such as disclosed in Chan resist loosening of the screw, better than non-locking screws being received in non-threaded screw hole bores, and so would have been motivated to use Chan's locking screws and threaded plate holes in Kay's plate to increase pullout resistance. *See id.* at 28–32; Ex. 1001 ¶¶ 282–284; Ex. 1006 ¶ 4; Ex. 1007 ¶¶ 5–11, 14. Moreover, "[g]iven Chan's disclosure of screws with threaded heads as a 'known embodiment,' POSITAs would expect that modifying the plate system of Kay to accept threaded screws would be successful." *Id.* at 29 (citing Ex. 1001 ¶ 284; Ex. 1024 ¶ 2). We find Petitioner's arguments persuasive and supported by the evidence of record.

Petitioner and Petitioner's expert sufficiently address each limitation of claims 13–15, 17–19, 46–48, and 50–53 in view of Kay and Chan. Pet. 28–56; Ex. 1001 ¶¶ 279–346. As indicated above, Patent Owner does not oppose on the merits. *See* PO Resp. 36; *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.") (quoting *NuVasive, Inc.*, 841 F.3d at 974); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. 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 13–15, 17–19, 46–48, and 50–53, so the claims are unpatentable under 35 U.S.C. § 103.

E. Ground 2: Obviousness over Grusin and Fernandez

In Ground 2, Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, in support of its contentions that independent claim 1 and its dependent claims 3–9 and 12 would have been obvious in view of Grusin and Fernandez. Pet. 56–81; Reply 15–23; Sur-sur-reply 3–5; Ex. 1001 ¶¶ 347–392; Ex. 1087 ¶¶ 32–38. Patent Owner provides arguments and evidence in opposition, including testimony from Dr. Neufeld and Mr. Harrigan. PO Resp. 5, 36–62; Sur-reply 6, 22–32; Ex. 2017 ¶¶ 55–71; Ex. 2018 ¶¶ 53–87.

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. Overview of 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:

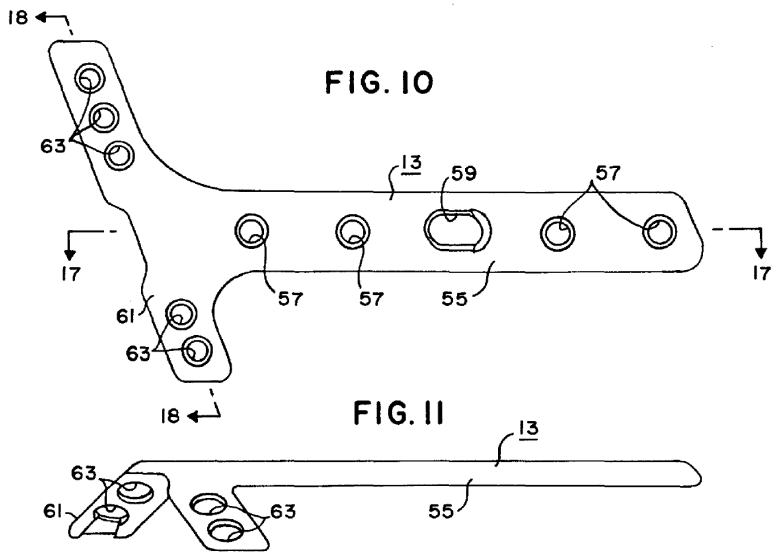


FIG. 10

FIG. 11

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:

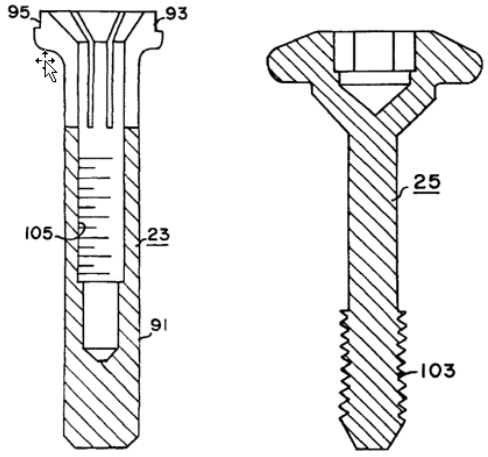


FIG. 45

FIG. 50

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. Overview of Fernandez (Ex. 1011)

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

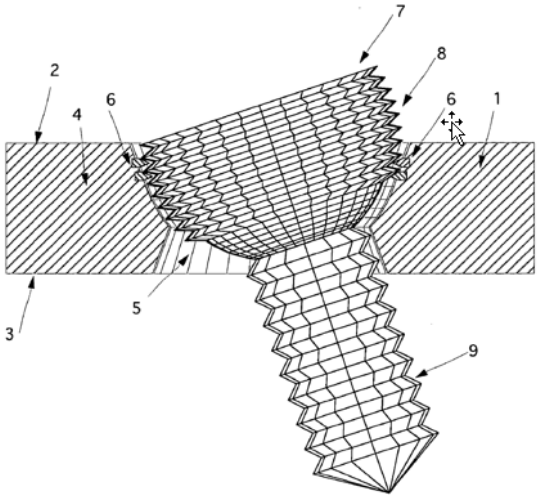


Figure 10 is a sectional view of screw 7 driven through hole 5 of bone plate 1, into bone underneath plate 1 (not shown), and locked at a tilt. *Id.* ¶¶ 27, 29, 30. Screw 7 has head 8, which "is threaded with a constant pitch." *Id.* ¶ 30. Further, the wall of plate hole 5 "has a small number of isolated 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. Construction of "threaded screw hole"

Petitioner relies on Fernandez as disclosing, e.g., claim element 1[b][16] directed to an orthopedic plate having divergent arms, "each arm including a threaded screw hole." *See* Pet. 59–62; Reply 15–21. Patent Owner, however, contends "Petitioner has failed to demonstrate that either Fernandez or Grusin discloses 'threaded screw hole[s]' in a bone plate as recited in Claim 1." PO Resp. 37. Ascertaining whether Fernandez discloses this limitation, as Petitioner contends, requires a construction of the claim term. As is evident from the Patent Owner response, this construction issue arises in connection with determining whether Fernandez's protrusions 6 in plate hole 5 define or suggest a threaded screw hole. *See id.* at 13–15, 40–57.

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. 14 (citing Ex. 2017 ¶ 37; Ex. 2018 ¶ 35); Sur-reply 25–26 (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.

Petitioner responds that "Fernandez's protrusions mate with the threaded head of a screw, and thus are threads *under any reasonable meaning*." Reply 16 (emphasis added). Petitioner argues "[t]here is no basis to accept PO's narrow construction," because it is supported only by

[16] For convenience, we apply Petitioner's convention of referring to certain claim phrases by claim number and bracketed letter. *See*, *e.g.*, Pet. 39.

dictionary definitions rather than intrinsic evidence. *Id.* n.6. Petitioner further asserts Patent Owner's expert witness Dr. Neufeld "testified that a thread ***does not*** require a helical structure." *Id.* (emphasis by Petitioner) (citing Ex. 1072, 148:3–5).

We construe the term "threaded screw hole" to require "a helical structure such as a rib or ridge for receiving a screw," as proposed by Patent Owner. This construction is supported by the plain and ordinary meaning of the term "thread," as established by the dictionary definitions and witness testimony cited by Patent Owner. *See* Ex. 1087 ¶ 33; Ex. 2008, 4; Ex. 2009, 4; Ex. 2010, 4; Ex. 2017 ¶ 37; Ex. 2018 ¶ 35; Ex. 2019, 85:10–86:24. Thus, Dr. Neufeld's statement during deposition that "[a] thread could be helical or not" is contrary to his own declaration and the weight of other evidence presented in this proceeding and is not persuasive. Ex. 1072, 148:3–5; Ex. 2017 ¶ 37.

Our construction also is supported by the '253 Patent's illustration of "cancellous thread 83" and "external threads 88" as helical structures of a screw. Ex. 1004, Figs. 6–7, 4:29–32, 8:41–55. It is further supported by the '253 Patent's illustration of plate 210 in Figures 12, 13, and 15 having locking holes 232 with "internal threads," wherein the threads are helical structures to match the helically threaded structure of a screw. *Id.* at 9:14–16; *see also id.* at 10:12–14 (describing plate 312 illustrated in Figs. 18 and 19 as including an elongate central trunk with screw holes having "internal threads").

We further determine that the helical structure formed by the threaded screw hole in claim 1 may be either continuous or interrupted. The '253 Patent itself indicates a threaded screw hole may be formed by a series

of interrupted structures. Figures 12 and 13 of the '253 Patent are reproduced below:

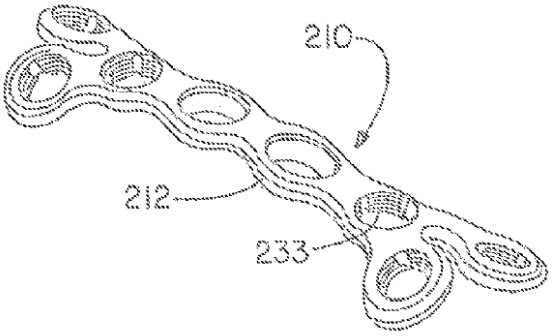


FIG.-12

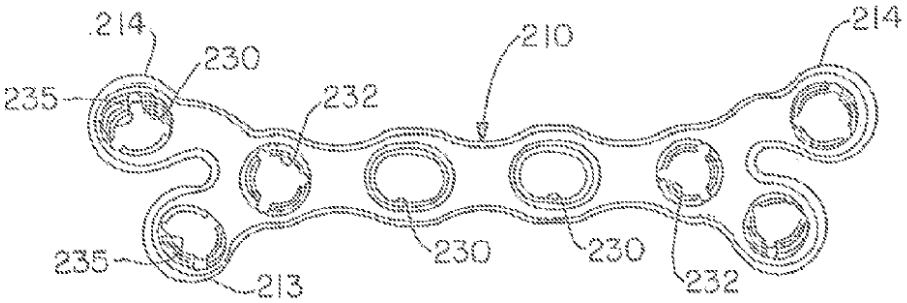


FIG.-13

Figure 12 is a perspective view, and Figure 13 is a top view, of plate 210. Ex. 1004, 5:50–53, 8:64–67. Plate 210 exhibits "locking holes [232] having internal threads" and "keyways 233 for the mating portion of a drill guide." *Id.* at 9:14–19; *see also id.* at Figs. 18 and 19, 10:12–14 (plate 312 has screw holes with internal threads interrupted by keyway grooves). In light of these disclosures, the extrinsic dictionary definition of "thread" being limited to "[a] *continuous* helical rib" is not consistent with the intrinsic evidence. *See* Ex. 2008, 4 (emphasis added).

Extrinsic evidence also indicates the helical structure formed by the threaded screw hole in claim 1 may be either continuous or interrupted. Mr. Castañeda testified via declaration that Fernandez's protrusions 6 form "internal threads" (Ex. 1001 ¶¶ 352–353) 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 85:23–86:8; 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 acknowledge Mr. Castañeda's struggle with the '253 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. 13–15; Sur-reply 25–26. We do not discern such a minimum amount from our independent review of the '253 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 1 simply requires the individual structures, taken together, form a helical structure, which may be an interrupted helical structure.

Patent Owner additionally contends that the "threaded screw hole" of claim 1, 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. 49–52, 57 (citing Ex. 2018 ¶¶ 68–73; Ex. 1011, Fig. 10, ¶ 33; Ex. 2019, 88:8–10); Sur-reply 26–29 (further citing Ex. 1011, Fig. 9, ¶¶ 6, 15; Ex. 2023, 44–45, 63–64). We have reviewed Mr. Harrigan's testimony in support. Ex. 2018 ¶¶ 64–73, 83. However, Patent Owner and Mr. Harrigan do not cite any intrinsic evidence to support this narrow view of the "threaded screw hole" recited in claim 1. 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 1 or in the '253 Patent's intrinsic evidence for the threaded screw hole to receive the screw at only one fixed angle within the plate.

For the foregoing reasons, we construe the "threaded screw hole" of independent claim 1 to require a helical structure such as a rib or ridge for receiving a screw. The helical structure may be continuous or interrupted,

and if it is interrupted then there is no minimum amount by which an individual structure forming the interrupted helical structure of the thread must extend around the periphery of the hole. The helical structure may function to receive a screw at several different angles or at one fixed angle.

4. Whether Grusin Discloses Claimed Subject Matter

Focusing first on independent claim 1, Petitioner contends Grusin discloses each and every limitation of the claim, except for (a) threaded screw holes to receive first and second locking screws and (b) the distal end of the screw being secured in cortical bone. Pet. 56–66; Ex. 1001 ¶¶ 352–355, 389–392. Prior to institution of trial, there was some question as to whether Petitioner might be relying on Grusin as disclosing threaded screw holes. *See* Inst. Dec. 32 n.17. It is now clear from the Reply that Petitioner does not rely on Grusin as disclosing threaded screw holes. *See* PO Resp. 45 (arguing Petitioner relies solely on Fernandez as disclosing threaded screw holes); Reply 15–23 (relying solely on Fernandez as disclosing threaded screw holes).

Patent Owner does not dispute Petitioner's foregoing contentions. PO Resp. 30–59; *see LG Elecs.,* 759 F. App'x at 925 ("The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented."); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. Nonetheless, to provide a complete record, we summarize representative findings comparing Grusin with the subject matter of claim 1.

Figures 12 and 13 of Grusin are reproduced here, with annotations added by Petitioner. Pet. 63.

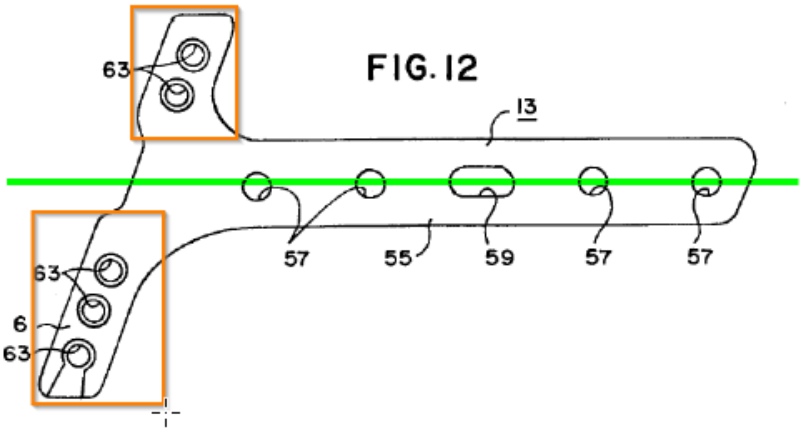


FIG. 12

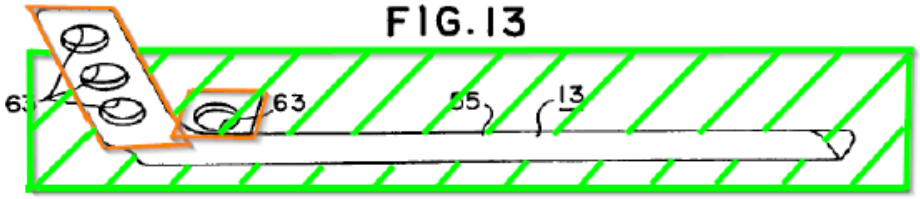


FIG. 13

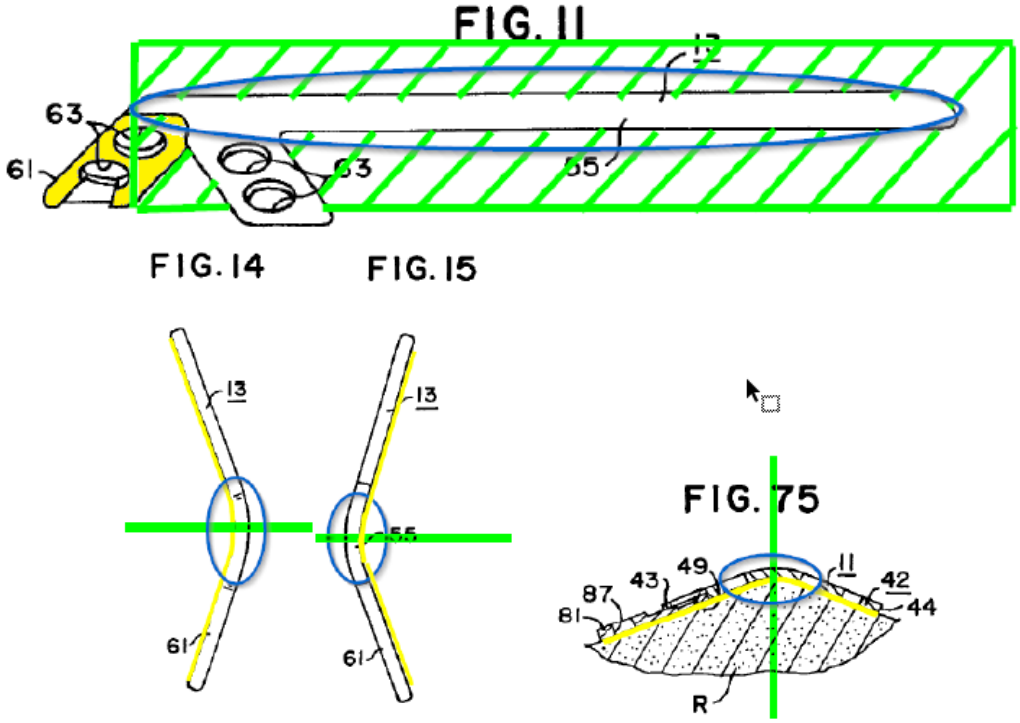
As set forth at pages 58–59 and 62–63 of the Petition, these annotations to Figures 12 and 13 of Grusin reflect how Grusin's plate 13 has an elongate central trunk portion having a medial longitudinal plane and

> a pair of divergent arms (orange) which diverge asymmetrically away from the medial longitudinal plane (green) relative to the other arm. *See, e.g.*, Ex.1010, Figs. 12, 13; Ex. 1001, ¶¶ 357-358. Because the transverse segment is angled with respect to the longitudinal segment, each end of the transverse segment will form a different angle with respect to the longitudinal medial axis. Ex. 1001, ¶357. And because the angles are different as well as the lengths of each end (arm) of the transverse segment, the arms diverge asymmetrically away from the medial longitudinal axis relative to each other. *Id.*

Pet. 62–63. We further find a person of ordinary skill in the art would have known, based on Grusin's disclosure, to choose screws having a length and diameter such that the screws inserted into one arm will converge toward,

but not impinge upon, the screws inserted into the other arm. Ex. 1001 ¶¶ 242–243; Pet. 59–60.

Figures 11, 14, 15, and 75 of Grusin are reproduced below, with annotations added by Petitioner. *See* Pet. 64–65.



As set forth at pages 63 and 64 of the Petition, these annotations to Figures 11, 14, 15, and 75 of Grusin reflect how

> Grusin describes the plate as "preferably pre-bent to approximately a 140° angle . . . so that its bottom face 51 conforms as closely as possible to the surface of the distal radius R." [Ex. 1010,] 6:36–40. POSITAs would have understood a curve "transverse" to the medial plane is curve crossing the plate's medial longitudinal plane in the lateral direction. Ex. 1001, ¶359. POSITAs would therefore have understood Grusin's plate, which has a medial longitudinal plane running along the length of a bone, and which is curved so that the bottom face conforms as closely as possible to the surface of a radius

> bone, would have an inferior surface defining a curve transverse to the medial longitudinal plane.

In sum, considering the evidence of record, we find Grusin's plate system embodies the subject matter of claim 1 that Petitioner cites Grusin as disclosing.

5. Whether Fernandez Discloses Claimed Subject Matter

Petitioner contends Fernandez discloses a threaded screw hole (i.e., hole 5 with protrusions 6) for receiving a locking screw (i.e., screw 7) at a selected angle. *See* Pet. 57–62, 79–81 (citing Ex. 1011, Abstract, Figs. 4, 5, 10 ¶¶ 5, 12, 15, 32, claim 1); Ex. 1001 ¶¶ 351–355, 389–392. According to Petitioner:

> Fernandez discloses screws with threaded heads to engage threaded screw holes was a well-known way to secure screws to a plate, Ex. 1011, ¶5, and POSITAs would have expected modifying Grusin's plate system to accept threaded screws would be successful. Ex. 1001, ¶355. Grusin's screw holes could remain spherically recessed, modified by Fernandez, which minimizes the screw head's protrusion above the edge of the plate, providing the low-profile sought by Grusin. *Id.* POSITAs would not have known of a reason why Grusin could not be so modified, and in view of the long history and known advantages of threaded screw holes, *id.,* (citing Ex. 1024, ¶2), would have expected Fernandez's variable locking features could be incorporated into Grusin successfully.

Id. at 57–58.

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 ("[P]rotrusions 6 [are] designed to lock

against the threaded spherical head of screws 8," and "screw 7 . . . locks tightly against the protrusions 6 . . . in different positions").

Patent Owner disputes Petitioner's contention that Fernandez's protrusions 6 form "a threaded screw hole," as is required by claim 1. PO Resp. 44–58; Ex. 2017 ¶¶ 59–61; Ex. 2018 ¶¶ 57–85. 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. 45; Ex. 2017 ¶¶ 38, 48; Ex. 2018 ¶¶ 65. 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. 45–50 (citing Ex. 1011 ¶¶ 32, 35, Figs. 4–5); Ex. 2018 ¶¶ 66–68. 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. 46, 53 (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 ¶¶ 69–73; PO Resp. 50–53. 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 ¶¶ 70–72; PO Resp. 50–52. 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 ¶¶ 73–74, 85 (citing Ex. 1011 ¶ 33; Ex. 2019, 88:8–10); PO Resp. 52–53, 57.

In reply, Petitioner maintains Fernandez discloses threaded screw holes, even applying Patent Owner's claim construction. Reply 18–19; Ex. 1087 ¶¶ 32–36. In support, Petitioner notes the parties agree that Fernandez's screw head 8 has a helically pitched thread and, therefore, "a POSITA would have considered it obvious that Fernandez's protrusions also have a helical pitch," because Fernandez describes how the interaction between screw head 8 and protrusions 6 "provide[s] a simple effective and strong locking mechanism for locking the bone screw to the fixation device." Reply 18–19 (quoting Ex. 1011 ¶ 10); Ex. 1087 ¶¶ 33–36. Fernandez also, according to Petitioner, describes prior art "locking screws" having "threaded heads 'that ***match[] with*** corresponding threading on the surface of a plate hole,'" which is how screw 7 of Fernandez's invention also works because it is also a locking screw. Reply 18 (quoting Ex. 1011 ¶ 5), 20–21; Ex. 1087 ¶¶ 33–36 (citing Ex. 1011 ¶¶ 5–7, 9, 11, 15); 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 19–20 (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 16–17 (citing Ex. 1001 ¶¶ 239–240; Ex. 2019, 85:10–86:24, 88:1–11, 89:20–90:8). According to Petitioner, Mr. Castañeda's full deposition testimony "shows he was simply stating his preference for the *terminology* of Fernandez [i.e., 'protrusion' rather than 'thread'], but his opinion was that Fernandez discloses threaded screw holes, even under PO's narrow construction." *Id.* at 17 (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 21 (citing PO Resp. 50).

Patent Owner replies that Petitioner presents "a veiled inherency argument" that the "protrusions were necessarily helically arranged," which is not supported by the evidence. Sur-reply 23–25. Patent Owner asserts Fernandez's variable angle locking feature is inconsistent with, and precludes, a finding that protrusions 6 are helically arranged, because a helical arrangement can provide only one fixed angle of entry for the screw. *Id.* at 26–29 (citing Ex. 1011 ¶¶ 6, 15, 33, Figs. 9–10; Ex. 2018 ¶¶ 64, 67–71; Ex. 2023, 44–45, 63–064). Patent Owner also asserts Mr. Harrigan's testimony does not rely on any scale being provided in Fernandez's figures. *Id.* at 29–30 (citing Ex. 1011 ¶¶ 30–32; Ex. 2018 ¶ 68).

Patent Owner further cites the prosecution history of Fernandez as establishing Fernandez's protrusions 6 are *not* "interrupted or partial threads," as Petitioner would have it. *Id.* at 23–24, 29 (citing Ex. 2026, 5:23–

25, Fig. 6; Ex. 2027, 12; Ex. 2028, Abstract, 1:39–45, Fig. 1).[17] 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. *Id.* at 29 (citing Ex. 2026, 5:23–25, Fig. 6). Patent Owner also argues Mr. Castañeda "testified that the protrusions [in Figure 6 of Fernandez] could be in a helical pattern *if* the screw head had a quadruple lead (entry) thread," but "Fernandez explicitly discloses that the screw head engaging the hole of Figure 6 only has a double entry thread." *Id.* (citing Ex. 1011 ¶ 30); *see also* Ex. 2023, 56:21–59:2 (Mr. Castañeda's testimony concerning Figure 6).

In reply, Petitioner asserts statements made by Fernandez's attorney during the prosecution history of Fernandez "do not offer any clarification" to what a person of ordinary skill in the art would have understood Fernandez to disclose. Sur-sur-reply 4–5. Petitioner faults Patent Owner for providing only one Amendment from the prosecution history (Exhibit 2027), and argues "the Examiner did not allow the claims after this amendment, providing evidence that the Examiner did not find applicant's statements persuasive." *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 18–21; Ex. 1087 ¶¶ 33–36). Petitioner finally argues the scope of the Fernandez patent's dependent

[17] 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 34; Sur-sur-reply 4–5.

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(E)(3) (claim construction). This finding is based on Fernandez's descriptions of the interaction between protrusions 6 and the helical structure of Fernandez's screw head 8, and the related testimony of Mr. Castañeda.

It is undisputed that Fernandez's screw head 8 has threads, and the threads of screw head 8 have a helical pitch, so the screw head 8 threads are helical structures. PO Resp. 50; Reply 18–19. 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 ¶¶ 353–355; 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 independent claim 1. Ex. 1087 ¶¶ 33, 36; *see supra* Section III(E)(3) (claim construction). No doubt, the interrupted structures illustrated in the '253 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(E)(3) (claim construction).

Mr. Harrigan's declaration testimony that Fernandez's protrusions 6 do not form a thread is not persuasive because it is undeveloped, confusing, and largely unsupported by citation to evidence. *See* Ex. 2018 ¶¶ 72–74. 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 several different angles. *See supra* Section III(E)(3) (claim construction).

We have considered Petitioner's argument that Mr. Harrigan's testimony improperly relies on measuring scaled dimensions of screw 7 as depicted in Figure 3 of Fernandez. *See* Reply 21–22. However, we agree with Patent Owner's rebuttal that Petitioner mischaracterizes the testimony as being premised upon a scale in Figure 3. *See* Sur-reply 29–30; Ex. 2018 ¶¶ 66–74. Therefore, we do not rely on this as a basis for our Decision.

We have also considered Patent Owner's citation to the prosecution history of Fernandez. There, the applicant representatively amended claim 21 to recite a method for fixing bone, using a bone plate opening "provided with non-thread protrusions configured and dimensioned to have the same pitch and mate with the threads on a bone screw head." Ex. 2027, 6 (underlined verbiage added by amendment). The applicant argued this amendment was supported by Fernandez's specification "describ[ing] the protrusions as non-thread elements such as pegs or spikes." *Id.* at 12 (citing Ex. 1011 ¶ 32). The applicant asserted the Examiner's prior finding that the "partial threads 3 of Talos[18]" 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.

This issue presented here, however, is whether Fernandez's protrusions 6 form a "threaded screw hole," as recited in claim 1 of the '253 Patent. We have adopted Patent Owner's construction of that term as requiring "a helical structure such as a rib or ridge for receiving a screw."

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

See supra Section III(E)(3) (claim construction). Further, based on the record of this proceeding, the helical structure may be interrupted, and there is no minimum amount by which an individual structure forming the interrupted helical structure of the thread must extend around the periphery of the hole. *See id.* Applying this construction, we find Fernandez's protrusions 6 form an interrupted helical structure, as encompassed by claim 1. Further, we agree with Petitioner's position that even if the scope of dependent claim 12 in the Fernandez patent (Ex. 2026) excludes threads, this does not necessarily mean that the disclosure of Fernandez (Ex. 1011) is correspondingly limited; it is quite often the case that a dependent claim is more narrow than the full scope of disclosure of a patent.

For the foregoing reasons, we find Fernandez's protrusions 6 form a threaded screw hole, as recited in claim 1.

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

For obviousness, Petitioner contends Grusin discloses spherically recessed holes 63 in the arms of plate 13, which receive either bone screws 37, or pin shank 23 and pin head 25 to create a locking feature. *See* Pet. 56–57, 59, 77; Ex. 1010, 5:67–6:3, 6:12–21, 6:60–7:6, 8:67–9:6, 10:11–31; Ex. 1001 ¶ 388. 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. 57–58, 60; 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. 56 (citing Ex. 1001 ¶¶ 352–355, 389–392).

Petitioner argues that a person of ordinary skill in the art would have been motivated "to look for features of bone plate systems which increase hold strength and resist screws loosening or pulling out" for use with Grusin's plate 13, "particularly given Grusin's application to the end of the radius where use of a patient's hand could increase stress on the screws." Pet. 61(citing Ex. 1001 ¶¶ 354).

According to Petitioner, "Fernandez discloses screws with threaded heads to engage threaded screw holes was a well-known way to secure screws to a plate," and further discloses a variable locking screw system that improves on prior screws and other fasteners. *Id*. at 57 (citing 1011 ¶ 5, 10–13, 15. 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).

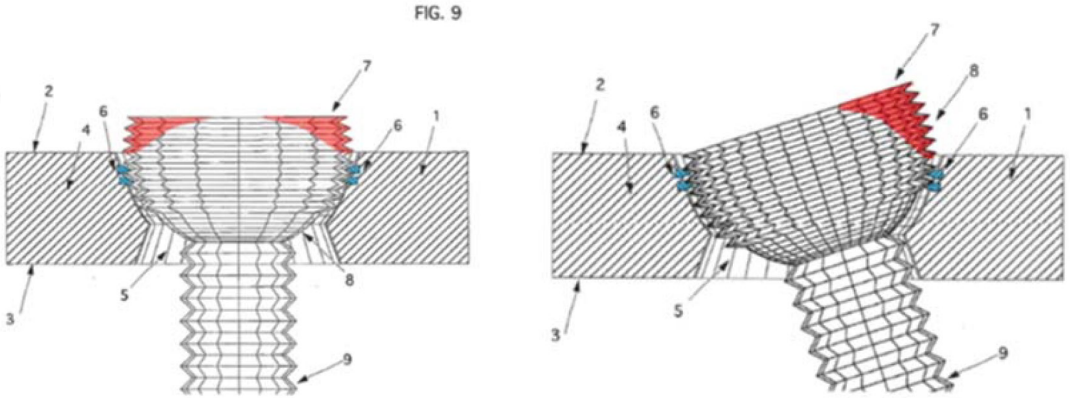
Noting that "Grusin and Fernandez both disclose spherically recessed screw holes," Petitioner further contends that one of ordinary skill in the art could have, "readily modified with Fernandez's screw holes to provide a low-profile screw hole that allows for a solid connection between bone and plate," as well as the "flexibility to choose a desirable screw angle." *Id.* at 57, 61–62 (citing Ex. 1010, 6:13–21; Ex. 1011, ¶¶ 5, 15, 32). Further with respect to reasonable expectation of success, Petitioner argues that one of ordinary skill in the art

> would have expected incorporating Fernandez's threaded screw holes and locking screws into Grusin's plate would be successful, given Fernandez's disclosure that threaded screw heads that engage threaded screw holes were well-known, Ex. 1011, ¶ 5, the fact that both Grusin and Fernandez teach spherical recesses that

> would minimize the screw's protrusion above the plate, and the long history and known advantages of threaded screw holes. Ex. 1001, ¶ 355 (citing Ex. 1024, ¶ 2.)

Id. at 62.

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. 58–62; Ex. 2017 ¶¶ 62–72. 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 ¶¶ 62–64 (citing Ex. 1010, 2:10–15, 2:20–33; Ex. 2018 ¶ 85); PO Resp. 58–59 (further citing Ex. 2019, 82:20–83:5); *see* Sur-reply 30–32. To illustrate his conclusion, Dr. Neufeld annotates Figures 9 and 10 of Fernandez, as reproduced below:



Dr. Neufeld's annotations to 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 ¶¶ 65–67; PO Resp. 59–60. Dr. Neufeld testifies this would traumatize tendons and soft tissue in the region of the patient's wrist. Ex. 2017 ¶¶ 66–67; PO Resp. 59–60.

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 ¶ 69 (citing Ex. 1010, 2:11–14); PO Resp. 37, 59–60; Sur-reply 30. Dr. Neufeld's view is that a person of ordinary skill in the art would, therefore, not have been motivated to replace Grusin's pins with Fernandez's screws to increase hold strength, because this would be "anathema to the teaching of Grusin" which already provides a "very solid connection." Ex. 2017 ¶¶ 66, 69–71 (citing Ex. 1010, 2:11–14); PO Resp. 37–39, 60–62; Sur-reply 30–32

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 22–23 (citing Ex. 1010, Figs. 76–77, 5:25–33, 5:66–6:17). Petitioner asserts there is no evidence to indicate that threads traumatize tendons, and if this were the case, then "threaded-headed screws would be of no use to surgeons." *Id.* at 22.

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 23 (citing Ex. 1010, 6:13–17). Petitioner also asserts there is no teaching away from a more secure connection in Grusin, because Grusin contemplates a "locking feature." *Id.* at 23 (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). Sur-reply 31.

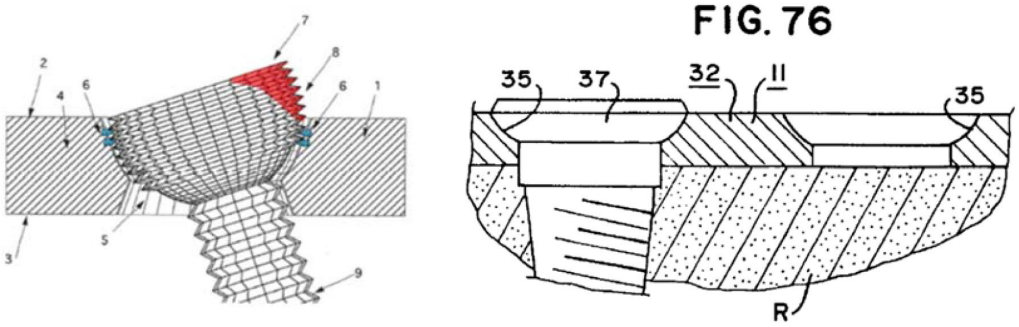


Figure 10 is an annotated front view of Fernandez's bone fixation assembly where the screw is locked at a tilt (i.e., non-perpendicular relative to the plate). Figure 76 is a front view of Grusin's bone fixation assembly where the screw is perpendicularly locked relative to the plate. Patent Owner argues 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 31–32 (quoting Ex. 2017 ¶ 66).

We determine a preponderance of the evidence supports Petitioner's contentions of obviousness. First, Petitioner provides a rational underpinning for the proposed obviousness of modifying holes 63 in Grusin's plate 13 to include protrusions 6 to receive Fernandez's screw 1—to permit the fastener to be locked at a selected angular orientation in Grusin's plate, *i.e,* the addition of Fernandez's polyaxial screw system beneficially adds "flexibility to choose a desired screw angle." *See* Ex. 1011, Abstract, ¶¶ 10–12, 32–33; Ex. 1001 ¶ 354; Pet. 56–58; *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). 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. 57 (citing Ex. 1001 ¶¶ 354–355). 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.

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 radial plating 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. *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 ¶ 66. However, Dr. Neufeld does not provide any reasons or analysis in support of this conclusion. *Id.* ¶¶ 66–67. For example, he does not compare an expected range of sizes for Fernandez's screw 7 if used with the radius bone, versus the size and durability of tendons and soft tissue in the wrist region. Thus, his opinion is too conclusory to be persuasive on this record.

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 ¶¶ 67–71. 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 1, 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.

7. Conclusion

We conclude a preponderance of the evidence establishes that it would have been obvious to combine Grusin and Fernandez in the manner recited in claim 1, so the claim is unpatentable under 35 U.S.C. § 103.

Petitioner provides further arguments and evidence, including testimony from Mr. Castañeda, in support of its contention that claims 3–9 and 12, depending from claim 1, are unpatentable as having been obvious over Grusin and Fernandez. *See* Pet. 67–81; Ex. 1001 ¶¶ 363–392. Patent Owner does not address these claims separately from arguments addressed above in connection with their common parent independent claim 1. *See* PO Resp. 22–32; *LG Elecs.,* 759 F. App'x at 925 ("The Board is 'not

required to address undisputed matters' or arguments about limitations with which it was never presented."); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that these claims would have been obvious over Grusin and Fernandez.

IV. SUMMARY OF CONCLUSIONS

In summary, we determine a preponderance of the evidence establishes claims 1, 3–9, 12–15, 17–19, 46–48, and 50–53 of the '253 Patent are unpatentable,[19] as shown in the following table:

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
13–15, 17–19, 46–48, and 50–53	103	Kay, Chan	13–15, 17–19, 46–48, and 50–53	
1, 3–9, and 12	103	Grusin, Fernandez	1, 3–9, and 12	
Overall Outcome			1, 3–9, 12–15, 17–19, 46–48, and 50–53	

[19] 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, 3–9, 12–15, 17–19, 46–48, and 50–53 of the ’253 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.

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