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Paper 16
Entered: October 4, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2019-00896
Patent 9,545,278 B2

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

POLLOCK, *Administrative Patent Judge.*

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

I. INTRODUCTION

Paragon 28, Inc. ("Petitioner" or "Paragon") filed a Petition for an *inter partes* review challenging claims 1–9 of U.S. Patent No. 9,545,278 B2 ("the '278 Patent," Ex. 1005) as unpatentable as obvious under 35 U.S.C § 103.[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. Paper 13 ("Reply"); Paper 14 ("Sur-Reply").

We review the Petition, Preliminary Response, Reply, Sur-Reply, and accompanying evidence under 35 U.S.C. § 314. An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Further, a decision to institute may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). *See Trial Practice Guide Update* (July 2019), at 31 ("The Board will not institute on fewer than all claims or all challenges in a petition.") ("USPTO Guidance").[2]

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[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 '278 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.

[2] Available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trial-practice-guide-july-2019-update.

After considering the evidence and arguments presented in the Petition and Preliminary Response, Reply, and Sur-Reply, we determine that Petitioner demonstrates a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '278 Patent is unpatentable. Accordingly, we institute an *inter partes* review as to all the challenged claims of the '278 Patent on all grounds of unpatentability set forth in the Petition.

A. Real Parties-in-Interest

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

B. Related Proceedings

According to the parties, the '278 Patent is at issue in *Wright Medical Technology, Inc. v. Paragon 28, Inc.*, Case No. 18-cv-00691-PAB-STV (D. Colo.). Pet. 75; Paper 6, 2.

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

in section III(D), below, the parties dispute whether the claims of the '278 Patent are entitled to benefit of the 2006 Application.

C. The '278 Patent (Exhibit 1005)

The '278 Patent discloses "a series of orthopedic plates for use in repair of a bone" such as a clavicle. Ex. 1005, Abstract, 1:22–24, 2:19–21. Figure 1 of the '278 Patent is reproduced below:

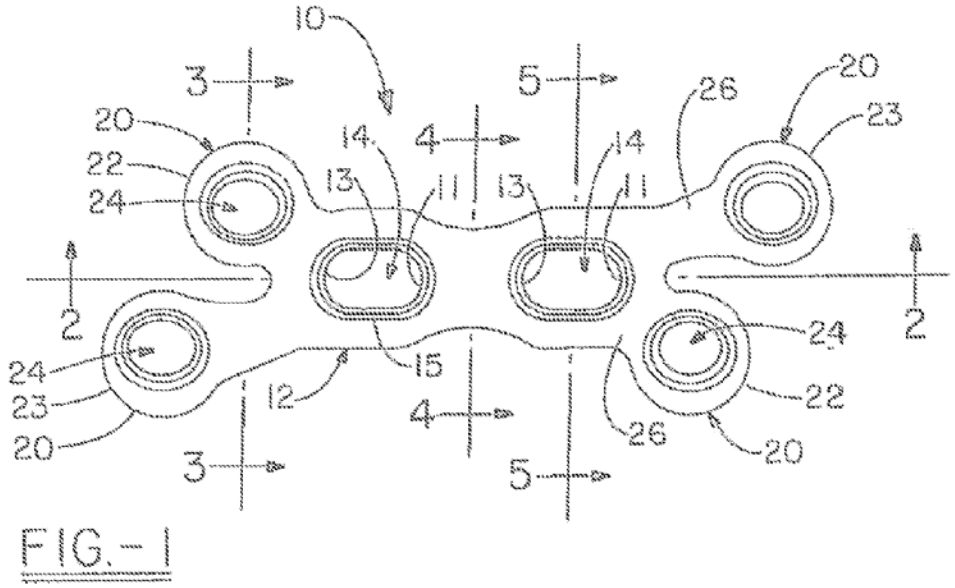

FIG.-1

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, 5:31–32, 6:48–51, 7:19–27. Central trunk portion 12 includes two screw holes or slots 14. *Id.* at 6:51–53. The opposing pairs of arms 20 each include short arm 22 and long arm 23, which extend from central trunk portion 12 at different angles of divergence relative to the longitudinal axis of trunk

portion 12.[3] *Id.* at 7:24–34. The differing angles of divergence ensure that screws inserted into respective screw holes 24 of short arm 22 and long 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 1:66–69, 3:54–4:2, 8:11–16.

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

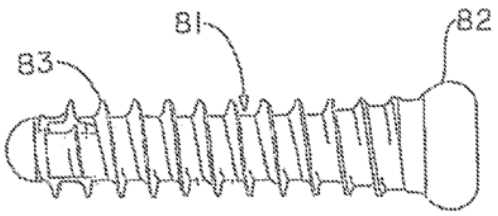

FIG.-6

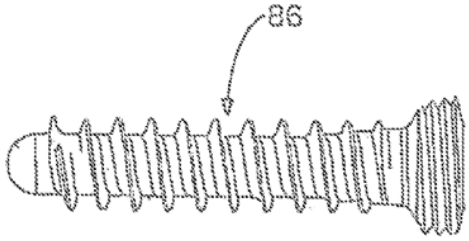

FIG.-7

Figure 6 illustrates screw 81 with head 82 that is devoid of threads, and Figure 7 illustrates "locking" screw 86 with a head that has threads. *Id.* at 8:55–9:3. Screw holes 24 in plate 10 "preferably . . . can include internal threads which mate with external threads on the head of the screws to cause locking of the screws relative to the plate." *Id.* at 4:32–36.

D. Challenged Claims

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

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[3] The '278 Patent suggests these angles are identified as α and β in Figure 1 of the '278 Patent (Ex. 1005, 7:27–36), 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.

> 1. An orthopedic plate system comprising at least one screw and a contoured plate having an inferior surface which is capable of engaging a bone surface in use and having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end and further including at the first end a pair of arms, each arm including an arm screw hole which defines a central screw hole axis and having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal axis of the trunk area, and wherein the longitudinal arm axis of the first of the pair of arms is different than the longitudinal arm axis of the second pair of arms; and
>
> wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis.

Ex. 1005, 12:7–25. Depending from claim 1, claim 2 requires that the orthopedic plate system comprise at least two screws, which "do not impinge on each other"; claim 3 relates to orientation angle of the screw axis in the arm screw hole; and claim 4 requires that "the arm screw hole includes internal threads."

> Independent claim 5 relates to an orthopedic plate system
>
> wherein the plate has a medial line which describes a curve in a lateral plane or in a longitudinal plane wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface such that said at least one screw can engage said arm screw hole so as to allow a plurality of angular orientations of said at least one screw axis relative to said screw hole axis.

Ex. 1005, 12:55–62. Depending from claim 5, claim 6 requires that the orthopedic plate system comprise at least two screws, which "do not impinge on each other"; claim 7 relates to the orientation of the plate arms; claim 8 relates to orientation angle of the screw axis in the arm screw hole; and claim 9 requires that "the curve in the lateral plane or in the longitudinal plane is an S-curve."

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds for unpatentability (Pet. 21):

Ground	Claim(s)	Basis	Asserted Reference(s)
1	1–8	103	Kay[4] and Chan[5]
2	9	103	Kay, Chan, and Heinl[6]
3	1–8	103	Grusin[7] and Fernandez[8]

[4] Kay et al., US 2006/0173459 A1, published Aug. 3, 2006 (Ex. 1006), originally filed as US Application No. 11/340,028 on January 26, 2006 (Ex. 2001).
[5] Chan et al., US 2008/0140130 A1, published June 12, 2008 (Ex. 1007).
[6] Heinl, US 4,903,691, issued Feb. 27, 1990 (Ex. 1009).
[7] Grusin et al., US 6,283,969 B1, issued Sept. 4, 2001 (Ex. 1010).
[8] Fernandez, US 2005/0165400 A1, published July 28, 2005 (Ex. 1011).

In support of its patentability challenges, Petitioner further relies on, *inter alia*, the Declaration of Javier E. Castañeda. Ex. 1001.

II. ANALYSIS

A. Principles of Law

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

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

obviousness, if presented.[9] *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).

B. Person of Ordinary Skill in the Art

Petitioner contends a person having ordinary skill in the art pertaining to the '278 Patent "would have had 2–3 years of experience in the design of orthopedic plates or 2–3 years of experience using orthopedic plates in surgery." Pet. 23; Ex. 1001 ¶¶ 28–29. Patent Owner does not dispute

[9] Patent Owner does not argue objective evidence of non-obviousness at this stage of the proceeding.

Petitioner's proposed definition "for the purposes of this Preliminary Response only." Prelim. Resp. 12. Because Petitioner's presently unopposed definition is not inconsistent with the '278 Patent and the prior art of record, we adopt that definition in deciding whether to institute trial. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579–80 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

C. Claim Construction

We interpret the claims of the '278 Patent "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,358 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective Nov.13, 2018). 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.*

The parties assert that no claim term requires express construction. Pet. 22; Prelim. Resp. 13. Based on the present record, we also agree that no claim term requires express construction at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed "only to the extent necessary to resolve the controversy") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Priority of Challenged Claims

The application that issued as the '278 Patent was filed as a continuation of U.S. Patent Application No. 13/348,888, which is a division of U.S. Patent Application No. 12/380,177 (filed February 24, 2009), which was filed as a continuation-in-part of U.S. Patent Application No. 11/340,028 (filed January 26, 2006). Ex. 1005, [60], 1:6–18. For consistency, we adopt the parties' convention of referring to the latter parent applications as the 2006 Application and the 2009 Application, reflecting their respective filing dates. *See* Pet. 2; Prelim. Resp. iii, 14.

Petitioner contends that Kay (the published version of the 2006 Application) qualifies as prior art because the challenged claims lack written description support in the 2006 Application for both the "threaded head limitation" common to claims 1–8, and the "S-curve limitation" specified in claim 9. Accordingly, Petitioner argues, the challenged claims are entitled to a priority date of no earlier than the filing date of the 2009 Application. Pet. 10–19. Patent Owner responds the challenged subject matter of claims 1–9 has written description support in the 2006 Application, such that Kay does not qualify as prior art. *See e.g.*, Prelim. Resp. 17–39.

1. Legal Standard

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. (if

pre-AIA) or § 112(a) (if post-AIA).[10] This requires that the earlier 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, ¶ 1, is whether the earlier application's disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description "test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.*

2. 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."

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[10] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, took effect on March 16, 2013. The application that issued as the '278 Patent was filed on June 24, 2014, and asserts continuation priority to the January 12, 2012 filing date of the '443 patent. *See* Ex. 1005, [22], [60]. Thus, whether the pre-AIA or post-AIA versions of these statutes applies is an involved issue. We need not resolve that issue, however, because we would reach the same conclusion as to written description support in the 2006 Application either way.

Ex. 2001, Abstract. "The plate is designed specifically for the small bone market, i.e. for use in bones distil 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:

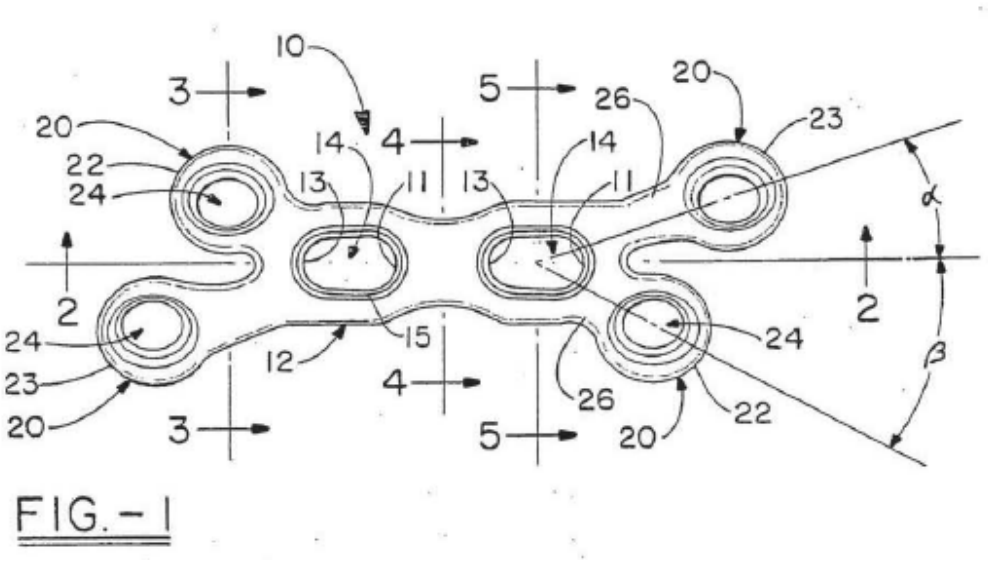

FIG. - 1

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. "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.

3. The Threaded Head Limitation (Claims 1–9)

According to Petitioner, "[c]laims 1–9 are not entitled to the priority date of the 2006 [A]pplication because they recite a 'threaded head' limitation that is not supported by the 2006 [A]pplication." Pet 12. In particular, Petitioner refers to the language of the independent claims "wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface" (claim 1), and "wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface" (claim 5). *See id.*

Petitioner states that "two broad categories of screws relevant here are non-locking and locking screws." Pet. 8 (citing Ex. 1001 ¶ 43). "Non-locking screws, or conventional screws, have a threaded shaft with an unthreaded head. . . . Locking screws, on the other hand, have a threaded head that 'locks into' the screw hole and firmly holds the screw in place." *Id.*[11]

With respect to the disclosure of such screws, Petitioner refers to Figures 6 and 7 of the '278 Patent, reproduced below.

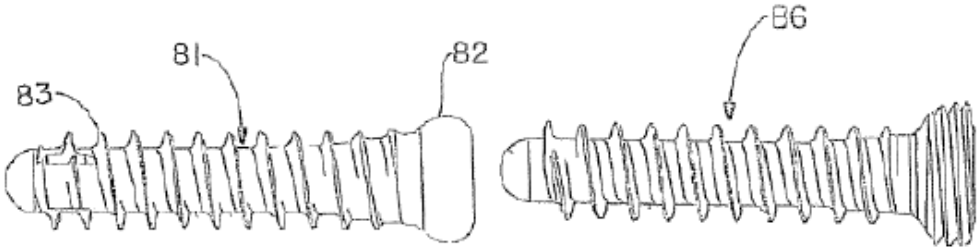

FIG.-6 FIG.-7

Pet. 12. Petitioner contends that Figures 6 and 7 of the '278 Patent depict screws with unthreaded and threaded screw heads, respectively. *Id.*

In contrast to the two types of screws illustrated in Figures 6 and 7 of the '278 Patent, Petitioner points to Figures 6 and 8 of the 2006 Application, reproduced below, as evidence that "the screw used with the 2006 application . . . does not have a threaded head:"

[11] We note that Grusin discloses a type of locking fastener that employs a "buttress pin" rather than the threaded-head type at issue here. *See* section II(F)(1), below.

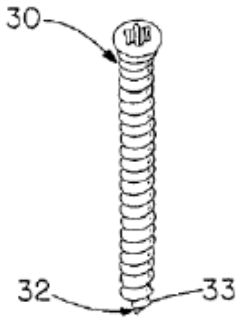

FIG.-6

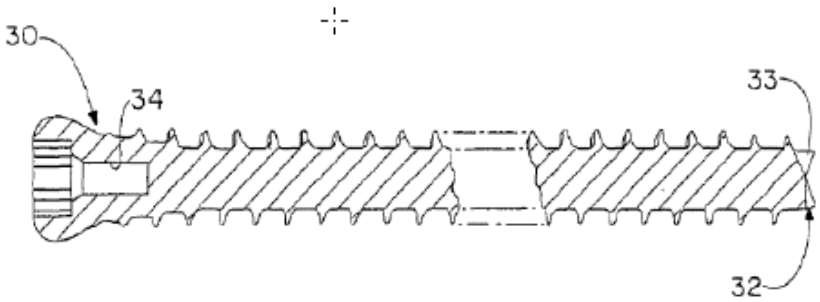

FIG.-8

Pet. 13. According to Petitioner, the above figures show that "the threads (or protrusions) on the shaft of the screw do not continue to the head of the screw." *Id.* Moreover, Petitioner contends, although "[t]he 2006 [A]pplication provides numerous details about the screws," "the screw head itself is never described as 'threaded' as required by claims 1 and 5 of the '278 [P]atent and their dependents." *Id.* at 13–14 (citations omitted).

Patent Owner argues that although the *figures* of the 2006 Application do not depict a threaded-head screw, "[t]he ***text*** of the 2006 Application expressly discloses an embodiment of an orthopedic plate having threaded screw holes: '**[*i*]*n a further embodiment, the bore could be threaded.*** '" Prelim. Resp. 21–22 (quoting Ex. 2001 ¶ 51) (emphasis added by Patent Owner). According to Patent Owner, this express disclosure "of an orthopedic plate system having 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." *Id.* at 22.

In response, Petitioner argues that Patent Owner's position is unsupported by expert testimony. Reply 1, 4. Petitioner further contends—without reference to expert testimony—that, "[t]here could be any number of reasons why a screw hole would be threaded," so "there is no basis to assume that a threaded screw hole 'necessarily demonstrates' threaded-head screws." *Id.* at 3–5.

Patent Owner points out that Petitioner has not identified any particular reason why a screw hole might be threaded, yet not be meant to receive a threaded-head screw. Sur-Reply 3. Patent Owner further argues that its own position is supported by the expert testimony of Petitioner's expert, insofar as Mr. Castañeda, indicates that the purpose of a screw hole with internal threads is to mate with external threads on the head of a threaded-head screw. *Id*. at 1–2 (citing Ex. 1001 ¶ 409), 4–5 (citing Ex. 1001 ¶¶ 43–44); Prelim. Resp. 24 (citing Ex. 1001 ¶ 58); Sur-Reply 1–5. Patent Owner also points to Chan as evidence that "a plate hole . . . is threaded so that it can accept and mate with a threaded-head screw." Prelim. Resp. 25.

Noting that the Petition is silent regarding the 2006 Application's statement that "the bore could be threaded," Patent Owner asserts that Petitioner "intentionally ignored the threaded screw hole embodiment because that embodiment undermines Petitioner's argument that the Challenged Claims are not entitled to priority of the 2006 Application." Sur-Reply 1; Ex. 2001 ¶ 51. Setting aside the question of Petitioner's intent, we find particularly relevant that Mr. Castañeda (1) failed to address the 2006 Application's disclosure that "the bore could be threaded," yet rendered detailed opinions regarding support for the "threaded screw head" limitation

in the 2006 Application (Ex. 1001 ¶¶ 80–82); (2) testified that a threaded screw head is what distinguishes a locking screw from a non-locking screw (*id.* ¶¶ 42–44, 58, 80); and (3) concluded that it would have been obvious "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." (*id.* ¶ 199).

Considering the scope of Mr. Castañeda's testimony, and his failure to address the 2006 Application's disclosure that "the [screw hole] bore could be threaded," we accord little weight to his opinion that the 2006 Application does not demonstrate possession of threaded screw heads, as recited in independent claims 1 and 5.

Based on the present record, Patent Owner has the better position. The 2006 Application describes 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. Petitioner has not identified any reason for a screw hole to be threaded, other than to engage a correspondingly threaded head of a screw. Chan also suggests a person of ordinary skill in the art would have understood that disclosure of a threaded screw hole demonstrates possession of a locking screw, having a threaded head to be received in the hole. Chan distinguishes between "locking" and "non-locking" screws based upon whether the head of the screw is threaded to be received within threaded "locking bone plate holes 832," or unthreaded to be received in "non-locking bone plate holes 834." Ex. 1007, Fig. 8, ¶ 64; *see also* Pet. 7–10 (explaining that threaded-head locking screws were known in the art).

In sum, the evidence of record suggests that a person of ordinary skill in the art would have understood that disclosure of a threaded screw hole demonstrates possession of a threaded-head screw to be received in the threaded screw hole. Because the 2006 Application discloses orthopedic plates having screw holes, where "the bore [of the screw hole] could be threaded," the ordinarily skilled artisan would have understood that it also discloses corresponding threaded-head screws. Accordingly, the record before us fails to support Petitioner's contention that claims 1–8 of the '278 Patent are not entitled to priority to the filing date of the 2006 Application based on the "threaded screw head" limitation. As such, Petitioner has not established that that Kay is prior art with respect to claims 1–8.

We address, below, priority with respect to the additional "S-curve" limitation of claim 9.

4. The S-Curve Limitation (Claim 9)

Claim 5 of the '278 Patent recites an orthopedic plate system "wherein the plate has a medial line which describes a curve in a lateral plane or in a longitudinal plane." Depending from claim 5, claim 9 requires that "the curve in the lateral plane or in the longitudinal plane is an S-curve." Petitioner contends that, in contrast to the express disclosure in the '278 Patent, the 2006 Application lacks written description support for an orthopedic plate describing the S-curve of claim 9.[12] Pet. 2–3, 16–19; *see*

[12] Given that the '278 Patent recites only 9 claims, reference to "dependent claims 10–11" on page 16 of the Petition appears to be a typographical error.

Ex. 1005, 5:21–23 ("The lateral plate has an S-curve of the medial line in the direction of the width of the plate.").

According to Petitioner, although the 2006 Application indicates a plate may "bend laterally (or 'curve') relative to the longitudinal axis . . . to form a curved area," there is no disclosure that such bending may describe an S-curve. Pet. 16 (quoting Ex. 2006 ¶ 46, also citing *id.* ¶ 7) (further noting that claim 17 of the 2006 Application recites a plate having "a single continuous radius of curvature"). Petitioner asserts the Examiner of the '278 Patent affirmatively decided that the 2006 Application lacks written description support for a plate describing an S-curve, which the applicant did not properly contest at the time. *Id.* at 18–19 (citing Ex. 1001 ¶¶ 77–79; Ex. 1049, 4; Ex. 1050, 6).[13] Petitioner further argues that, unlike Figures 21–23 of the '278 Patent, "none of the figures of the 2006 Application depict plates that have an S-curve." *Id.* at 17–18.

In response, Patent Owner presents three distinct arguments, which we consider in turn.

a) Prosecution History of the '278 Patent

Patent Owner asserts that "the priority of the Claim 9 on the basis of the 'S-curve limitation' was not an issue that required resolution in any rejection raised by the [E]xaminer." Prelim. Resp. 36. And although Patent Owner acknowledges the Examiner's statement during the '278 Patent prosecution that the 2006 Application "lacks any reference to an S-curve"

[13] Citations herein to prosecution history documents refer to the page numbering added by the parties when preparing the Exhibit.

(Ex. 1030, 4), Patent Owner contends that the lack of *in haec verba* support is not determinative of whether the 2006 Application supports the S-curve limitation of claim 9. Prelim. Resp. 36. Rather, Patent Owner argues, the prosecution history as a whole "illustrates that the examiner later accepted the applicant's argument that the 'S-curve limitation' was sufficiently described in the 2006 Application." Prelim. Resp. 37. In particular, Patent Owner argues, "by advancing only a double patenting rejection [over the '457 Patent], the examiner implicitly accepted that Kay was not prior art the then-pending claims of the 278 Patent." *Id.* at 36.

During the prosecution of the '278 Patent, then-pending claim 22, recited a plate "hav[ing] a medial line which describes an S curve in the lateral plane or in a longitudinal plane." *See* Ex. 1048, 3–4 (showing claim 22 with subsequent amendments). The Examiner rejected claim 22 for obviousness-type double-patenting over claims of the '846 Patent, and for obviousness in view of Austin et al., (U.S. 2008/0300637 A1) and Sixto, Jr. et al., (US 8,568,462 B2). Ex. 1049, 5–8, 12–14 (noting that "Sixto, Jr. et al. teach a bone plate describing an S-curve."). In response, Applicant filed a terminal disclaimer to the term of the '846 Patent, amended the claims such that the S-curve requirement was recited in new claim 26 (now claim 9 of the '278 Patent), and as quoted in the Petition, sought to overcome the rejections with respect to the S-curve limitation by establishing benefit of priority to the 2006 Application. *See* Prelim. Resp. 37–38 (quoting Ex. 1050, 6–7); Ex. 1050, 3–4; Ex. 1063. In addition to discussing enablement, Applicant stated that:

> The plates of the [2006 Application] are designed specifically for the small bone market including in bones distal to the clavicle, elbow and knee, including, for example, the ulna, radius, tibia, fibula, as well as the metacarpals, carpals, metatarsals, tarsals, and phalanges. *Id.* As noted in the present application, the clavicle has a S-curve contour. Therefore, one skilled in the art reading the disclosure of the [2006 Application] would recognize that the plates disclosed therein could be conformed to the S-shape of the clavicle which would require an S-shape curve in a lateral plane or in a longitudinal plane.

Ex. 1050, 6. In the next office action, the Examiner allowed the newly-submitted claim reciting the S-curve limitation to issue as claim 9 of the '278 application—which, in Patent Owner's view, establishes that the Examiner "accepted the applicant's argument" concerning priority. Prelim. Resp. 37–38.

We do not find Patent Owner's argument persuasive. First, the reference to "clavicle" in the above-quoted passage was added by amendment after the initial filing of the 2006 Application. Ex. 2005, 4. Moreover, the amendment indicates the disclosed plates may be used on bones that are *distal to* the clavicle, not on the clavicle itself. We also note that, contrary to Patent Owner's assertion, the Examiner's priority determination was necessary to the Examiner's reliance on the combination of Austin (filed in February 2008), Sixto (filed in October 2008), and Chreene (filed in November 2007), as *prima facie* prior art references to support obviousness rejections entered by the Examiner.[14] Ex. 1049, 12–14.

[14] These references do not appear in the record. We have, nevertheless, obtained *prima facie* filing date information from the cover page of each

Moreover, Applicant contested the obviousness rejection on two grounds: (1) by arguing entitlement to priority (Ex. 1050, 6–7, 10 (citing Ex. 2001 ¶ 6)) and, in the alternative (2), arguing that even if Austin and Sixto were prior art, they failed to disclose, teach, or suggest the claimed invention (*id.* at 10–12). In allowing claim 9 of the '278 Patent to issue, the Examiner did not indicate which of the applicant's two alternative arguments was found persuasive. Ex. 1051. Accordingly, there is no evidence of record to support Patent Owner's assertion that the Examiner reversed course as to priority during the '278 Patent prosecution.

b) 2006 Application Paragraphs 6 and 46

Patent Owner further contends the written description in paragraphs 6 and 46 of the 2006 Application discloses the S-curve limitation. Prelim. Resp. 34–36. Patent Owner asserts that paragraph 46 "describes the plate as being capable of 'bending longitudinally,' so as 'to form a curved area *in and out* of the plane of the plate,' thus disclosing an S-curve." *Id.* at 34 (quoting Ex. 2001 ¶46) (emphasis added by Patent Owner). Patent Owner argues that paragraph 6 of "the 2006 Application expressly discloses that the plates are 'designed to facilitate three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape.'" *Id.* at 34 (quoting Ex. 2001 ¶ 6). Patent Owner further points to

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reference. We note that the prior art status of each reference may, in fact, extend back to earlier filing dates, presenting a somewhat complicated inter-relationship with the priority chain of the '278 Patent. The point here, however, is simply that the Examiner's priority determination was necessary for these references to be *prima facie* prior art.

paragraph 6 of the 2006 Application as "stat[ing] that the 'plate is designed specifically for the small bone market, i.e., for use in bones distil [sic] to the elbow and knee, including, for example, the ulna, radius, tibia, fibula, as well as metacarpals, carpals, metatarsals, tarsals, and phalanges." *Id.* According to Patent Owner, one of ordinary skill "would have been motivated by this disclosure in Kay to seek out a number of different shapes of orthopedic bone plates to accommodate the variety of bone shapes" and "to use plates with an S-curve because the curve better matches the shape or contour of certain bones, for example the clavicle bone." *Id.* at 34–35 (quoting Pet. 31–32 and Ex. 1001 ¶ 44).

We do not find Patent Owner's argument persuasive on the present record. Paragraph 46 pertinently reflects only that plate 10 of Figure 1 "will *bend laterally* (or 'curve') relative to the longitudinal axis," and "will *bend longitudinally* to form a curved area in and out of the plane of" plate 10. Ex. 2001 ¶ 46 (emphases added). This disclosure is too general to demonstrate possession of the S-curve limitation at issue here. Paragraph 6 indicates that the disclosed plates may be three-dimensionally contoured "to accommodate individual variation in bone shape," such as "for the small bone market" including the ulna, radius, metacarpals, and carpals. *Id.* ¶ 6. Contrary to Patent Owner's implication, the 2006 Application does not identify the clavicle as such a bone. *Id.*[15] On the present record, we are also

[15] Patent Owner asserts that "[t]he clavicle bone was added by amendment in the 2006 Application to the exemplary listing of small bones." Prelim. Resp. 35 n.4 (citing Ex. 2005). This is not entirely accurate. The relevant amendment recites: "The plate is designed specifically for the small bone

not persuaded that a person of ordinary skill in the art would have understood the disclosed small bones to define an S-curve. Patent Owner's position in this regard is supported only by attorney argument without any testimonial evidence in support, and some pictures of arm bones. *See* Prelim. Resp. 34–35; Ex. 1001 ¶ 41 (pertinently stating only that "it has long been commonly known to use plates with an S-curve because the curve better matches the shape or contour of *certain bones, for example the clavicle bone*" (emphasis added)). Patent Owner does not explain, and we are unable to discern from the present record, how the bone pictures provided by Patent Owner describe an S-curve. *See* Prelim. Resp. 35.

c) 2006 Application Figure 1 In Light of Paragraph 47

Patent Owner further asserts that Figure 1 and the accompanying written description in paragraph 47 of the 2006 Application disclose an S-curve. Prelim. Resp. 4–5, 29–34. Figure 1 of the 2006 Application is reproduced in section II(D)(2), above. The portion of paragraph 47 Patent Owner relies on states:

> The plate 10 also 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 . . . .

Ex. 2001 ¶ 47 (emphases added by Patent Owner); Prelim. Resp. 30. Patent

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market, i.e. for use in bones distal [[distil]] to the clavicle, elbow and knee, including, for example, the ulna" and other bones. Ex. 2005, 34. Accordingly, the amendment, on its face, indicates that the disclosed plates may be used on bones that are *distal to* the clavicle, not on the clavicle itself.

Owner interprets this passage as "clearly and expressly disclos[ing] that the plate 10 shown in Figure 1 *may include only one set of diagonally opposed arms — a set of short arms 22 . . . or a set of long arms 23 . . . .*" Prelim. Resp. 17–18.

Patent Owner illustrates this reading of paragraph 47 with alternative sets of annotations to Figure 1 highlighting pairs of diagonally opposed arms, one version of which is reproduced below. *Id.* at 31.

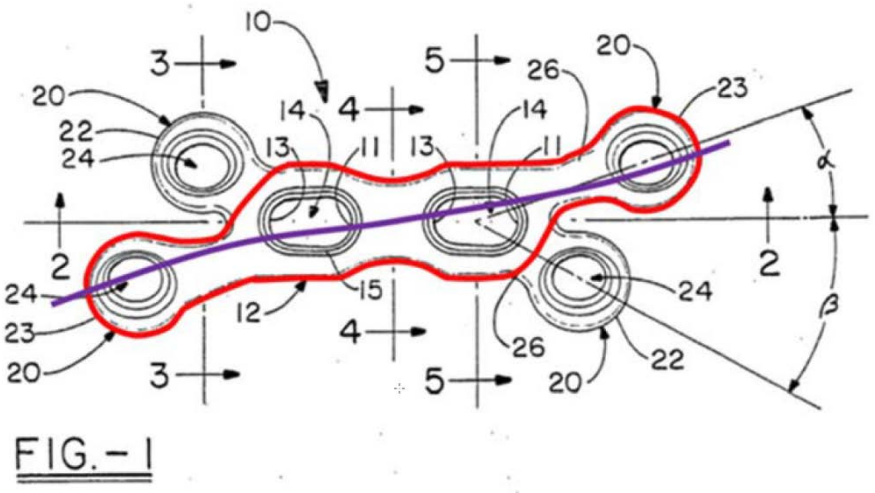

FIG. – 1

According to Patent Owner, the above annotations to Figure 1 show how paragraph 47 of the 2006 Application discloses "[a] plate having only the single set of diagonally opposed long arms 23 . . . outlined in red with a medial line in purple." *Id.* Patent Owner presents a similarly annotated version of Figure 1 to illustrate its position that paragraph 47 of the 2006 Application also discloses "[a] plate having only [a] single set of diagonally opposed short arms 22." *Id.* With reference to its annotated figures, Patent Owner contends that "plates having the disclosed configuration of a single set of diagonally opposed arms (outlined in red) define an 'S-curve' in a lateral plane (outlined in red)." *Id.* at 32. So

configured, Patent Owner contends that these versions of Figure 1 comprise a substantially similar S-curve shape as disclosed in Heinl, relied on by Petitioner. *Id.* at 32–33.

While Patent Owner's position is not unreasonable, it is also not accompanied by expert testimony. Because we are hesitant to rely on attorney argument in deciding how one of ordinary skill in the art would interpret Figure 1 in light of paragraph 47 of the 2006 Application, we defer our determination regarding the S-turn limitation of claim 9 pending further development of this issue at trial. In the interests of expediency and to address the substance of Ground 2, however, we *provisionally* assume that claim 9 is not entitled to the priority date of the 2006 Application such that Kay qualifies as prior art with respect to this claim. The parties are encouraged to further address at trial whether claim 9 is entitled to benefit of priority of the 2006 Application.

5. Conclusion

The record before us fails to support Petitioner's contention that claims 1–8 of the '278 Patent are not entitled to priority to the filing date of the 2006 Application based on the "threaded screw head" limitation. As such, Petitioner has not established that Kay qualifies as prior art with respect to at least claims 1–8.

In contrast, a determination of whether the S-curve limitation of dependent claim 9 is supported by the 2006 Application would benefit from further development. In order to address Petitioner's arguments with respect to Ground 2, however, we provisionally assume that claim 9 is not entitled to

the priority date of the 2006 Application such that Kay qualifies as prior art with respect to this claim.

E. The Board's Discretion to Deny Institution under 35 U.S.C. §§ 325(d)

Patent Owner argues that "[t]he Board should exercise its discretion under Section 325(d) and deny institution of Ground 1." Prelim. Resp. 41. As an initial matter, our decision whether to institute an *inter partes* review "require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition." *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018). We decline to base any analysis under § 325(d) on Ground 1 alone, but instead consider our discretion under § 325(d) in light of the record as a whole.

Pursuant to 35 U.S.C. § 325(d), when determining whether to institute an *inter partes* review, we "may take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). In *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, the Board enumerated non-exhaustive factors to be considered in exercising discretion under 35 U.S.C. § 325(d) on whether to institute *inter partes* review. IPR2017-01586, slip op. at 17–18 (PTAB Dec. 15, 2017) (Paper 8) (precedential as to § III.C.5, first paragraph). The non-exhaustive *Becton* factors are:

> 1. the similarities and material differences between the asserted art and the prior art involved during examination;

> 2. the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> 3. the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
>
> 4. the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
>
> 5. whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
>
> 6. the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Id. (numbering added). The *Becton* factors are not dispositive, but are part of a balanced assessment of the relevant circumstances in a particular case and we do not simply default to a tally of each factor to determine whether or not an IPR should be instituted.

With respect to Ground 1, Patent Owner argues that the Examiner considered—and made a determination in Patent Owner's favor—regarding entitlement to priority of the 2006 Application with respect to the threaded head limitation. Prelim. Resp. 40–42. In particular, Patent Owner points to the Examiner's statement that "**[a]ccordingly, the effective filing date for the claimed subject matter (claims 1, 2, 6, and 8) in the current application is January 26, 2006 and will be treated as such for examination purposes**," which would remove the asserted Kay reference as prior art. *See id.* at 41–42 (quoting Ex. 1049, 4); Sur-Reply 5. We note, however, that in making this determination, the Examiner focused on "contoured plate" and "pre-contoured plate" limitations without specific

reference to any other claim element. *See* Ex. 1049, 3–4; *see also* Reply 5 (noting "the Examiner never expressly examined whether the 2006 application discloses 'locking screws,' nor did she make any kind of factual finding that the 2006 application discloses 'locking screws'"). In light of the Examiner's silence with respect to the threaded head limitation, we accord only modest weight to Patent Owner's argument. *See, e.g.*, *Becton* factors 1–4.

With respect to Ground 2, we note that the benefit of priority of the S-curve limitation of claim 9 was expressly discussed during prosecution. *See* section II(D)(4), above. Nevertheless, the prosecution history does not clearly establish that the Examiner accorded claim 9 the benefit of priority of the 2006 Application in allowing the claims to issue. *Id.*

Further, although Kay (as the published version of the 2006 Application) was inherently at issue during prosecution of the '278 Patent, Patent Owner does not argue, nor do we discern, that the Examiner raised either Chan or Heinl,[16] or anything cumulative thereto, in any rejection. Accordingly, the Examiner never considered whether claim 9 was obvious in view of Kay, Chan, and Heinl. Moreover, "[t]he Board has consistently declined exercising its discretion under Section 325(d) when the only fact a Patent Owner can point to is that a reference was disclosed to the Examiner during the prosecution." *Amgen Inc. v. Alexion Pharm., Inc.*, IPR2019-00739, Paper 15 (PTAB Aug. 30, 2019) (collecting cases).

[16] Heinl is, however, cited on the face of the '278 Patent. Ex. 1005, (56).

Accordingly, the evidence relating to Ground 2 does not weigh in favor of exercising our discretion. *See Becton* factors 1–6.

With respect to Ground 3, Patent Owner does not argue, nor do we discern, that Fernandez was even cited during the prosecution of the '278 Patent.[17] This evidence weighs against exercising our discretion to deny the Petition under §325(d). *See Becton* factors 1–5.

Taken as a whole, the above factors do not weigh in favor of exercising our discretion to deny institution. Therefore, based on the evidence cited by Patent Owner and for the reasons above, we decline to exercise our discretion under section 325(d) to deny institution here.

F. Obviousness of Claims 1–8 in view of Kay and Chan (Ground 1)

In Ground 1, Petitioner challenges claims 1–8 as obvious in view of Kay and Chan. Pet. 31–49. Patent Owner opposes. Prelim. Resp. 40–42.

According to Petitioner, one of ordinary skill in the art "would have found it obvious to use screws with a threaded head and threaded screw holes, as disclosed by Chan, with Kay's plate system." Pet. 32 (citing Ex. 1001, ¶¶ 408–10). As noted in section II(D)(3), above, Petitioner has not established that challenged claims 1–8 are not entitled to the benefit of priority of the 2006 Application. Accordingly, on the present record, Kay does not qualify as prior art with respect to these claims. In the absence of

[17] Although not raised by Patent Owner in this proceeding, in a copending *inter partes* review Petitioner admits that Grusin was discussed during prosecution "as a secondary reference for its disclosure of a compression slot." IPR2019-00898, Paper 2 at 26–27.

Kay, Petitioner cannot demonstrate a reasonable likelihood that it would prevail with respect Ground 1.

G. Obviousness of Claim 9 in view of Kay, Chan, and Heinl (Ground 2)

In Ground 2, Petitioner challenges claim 9 as obvious in view of Kay, Chan, and Heinl. Pet. 50–51. Patent Owner opposes. Prelim. Resp. 43–46.

As an initial matter, Patent Owner contends that Ground 2 fails because claim 9 is entitled to the priority of the 2006 Application such that Kay is not prior art. Prelim. Resp. 43.[18] As noted in section II(D)(3), above, Petitioner has not established that challenged claims 1–8 are not entitled the benefit of priority of the 2006 Application based on the threaded-head limitation, as a result, Kay does not qualify as prior art with respect to these claims. Dependent claim 9, however, recites the S-curve limitation, which entails additional analysis. As discussed in section II(D)(4), above, on the present record we *provisionally* assume that claim 9 is not entitled to the priority date of the 2006 Application such that Kay qualifies as prior art with respect to claim 9. On this basis, we address below the merits of Ground 2.

We begin with an overview of the cited references.

1. Overview of Kay (Exs. 1006 and 2001)[19]

As noted above, Kay (Exhibit 1006) is the USPTO's publication of the 2006 Application (Exhibit 2001), such that the two disclosures are

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[18] Patent Owner further asserts that Chan is not prior art but provides no analysis. *Id.* at n.6.

[19] 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. As noted by Patent Owner in a parallel proceeding, the two disclosures "are

substantially the same but for pagination. Accordingly, we refer to section II(D)(2), above, for an overview of the shared disclosure.

2. Overview of Chan (Ex. 1007)

Chan discloses "[a] bone plate system for internal fixation of fractures include[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. 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." *Id.* ¶ 3. In contrast, locking screws are in a fixed relationship to the plate, and "provide high resistance to shear, torsional, and bending 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

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substantially identical." IPR2019-00895, Prelim. Resp. 16 n.3; *but see* Ex. 2005 (amendments dated Nov. 10, 2008). To minimize confusion, we recast Petitioner's arguments in terms of the corresponding disclosure in the application as originally filed and refer herein to Exhibit 2001.

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. Overview of Heinl (Ex. 1009)

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

Figure 3 of Heinl is reproduced below:

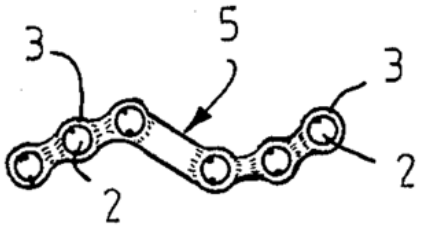

Fig. 3

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

4. Analysis of Ground 2

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

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

Accordingly, one of ordinary skill in the art "would have understood that the S-form plate disclosed in Heinl would be one way the plate of Kay could 'accommodate individual variation in bone shape.'" *Id.* (citing Ex. 1001 ¶ 440). In addition to its arguments for priority to the 2006 Application, Patent Owner contends that, to the extent "Kay fails to disclose a plate embodying the S-curve then so does Heinl since Kay discloses an embodiment that is materially the same shape as the embodiment in Heinl relied on by Petitioner." Prelim. Resp. 44–46.

At this stage of the proceeding we do not find Patent Owner's argument persuasive. On the present record, Petitioner relies on the unopposed testimony of Mr. Castañeda to establish that Heinl discloses an orthopedic plate comprising an S-curve. Prelim. Resp. 50 (citing Ex. 1001 ¶¶ 437–40); *see, e.g.*, Ex. 1001 ¶ 439 ("Figure 3 of Heinl illustrates 'a plate of approximately S-form.' (*Id.* at Fig. 3, 8:53–55.)"). Petitioner likewise relies on the testimony of Mr. Castañeda in asserting that "a POSITA would not have understood the orthopedic plate of the 2006 Application to have an S-curve." Pet. 19 (citing Ex. 1001 ¶¶ 77–79). Patent Owner, in contrast, has not provided persuasive evidence of how one of ordinary skill in the art would have understood these disclosures. Thus, solely in view of the record before us, Petitioner has demonstrated a reasonable likelihood that it would prevail with respect Ground 2.

H. Obviousness of Claims 1–8 in view of Grusin and Fernandez (Ground 3)

In Ground 3, Petitioner challenges claims 1–8 as obvious in view of Grusin and Fernandez. Pet. 51–74. Patent Owner opposes. Prelim. Resp. 46–58. We begin our analysis with an overview of the asserted references.

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:

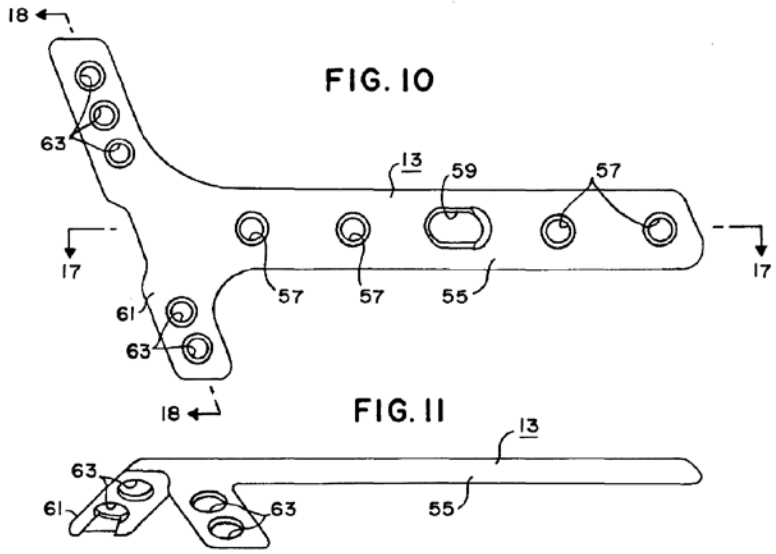

FIG. 10

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:

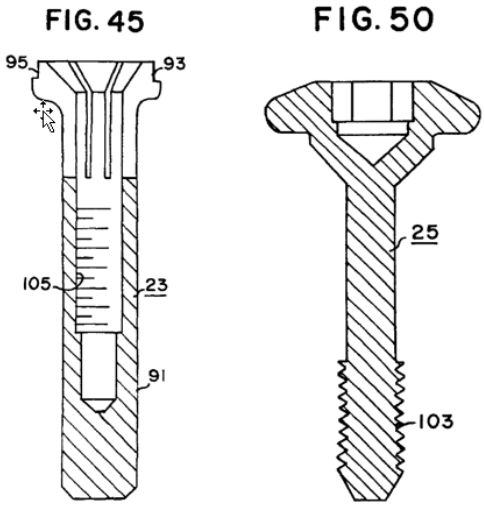

Figure 45 is a sectional view of buttress pin shank 23, and Figure 50 is a sectional view of pin head 25. *Id.* at 4:5–23, 8:63–67. In use, pin shank 23 is inserted into hole 57 or 63 of plate 13, until the flange of collar 93 is caught underneath plate 13, "to lock" pin shank 23 to plate 13. *Id.* at 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:

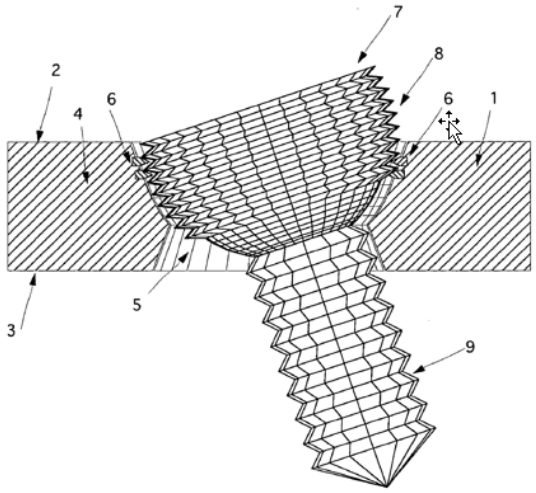

Figure 10 is a sectional view of screw 7 driven through hole 5 of bone plate 1, into bone underneath plate 1 (not shown), and locked at a tilt. *Id.* ¶¶ 27, 29, 30. Screw 7 has head 8, which "is threaded with a constant pitch." *Id.* ¶ 30. Further, the wall of plate hole 5 "has a small number of isolated 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. Analysis of Ground 3

Petitioner relies on Grusin as disclosing every element of claim 1–8, except for certain limitations relating to threaded screw holes and corresponding threaded-head screws. Pet. 51–74. With respect to these

limitations, Petitioner relies on Fernandez as disclosing element 1[g][20] ("wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis) (*id.* at 60–62); element 2[a], relating to "screws . . . locked in their respective screw holes" (*id.* at 62); element 4[a] reciting an "arm screw hole includ[ing] internal threads" (*id.* at 64–65); element 5[h] "wherein the plate has a medial line which describes a curve in a lateral plane or in a longitudinal plane wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface such that said at least one screw can engage said arm screw hole so as to allow a plurality of angular orientations of said at least one screw axis relative to said screw hole axis" (*id.* at 73).

According to Petitioner, "'[l]ocking screws' were a known method of coupling a plate to a bone" and a person of ordinary skill in the art "would have found it obvious to modify the plate system of Grusin to use screws with a threaded head and threaded screw holes, as disclosed by Fernandez, so that Grusin's plates accept locking screws with threaded heads at variable angles." *Id.* at 51–53 (citing Ex. 1001, ¶¶ 454, 456–458; Ex. 1011 ¶¶ 5, 6, 12; Ex. 1024 ¶ 2). Relying on the testimony of Dr. Fernandez, Petitioner further asserts that the skilled artisan would have seen no reason why screws

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

with threaded heads and threaded screw holes taught in Fernandez could not be used with the plate system of Grusin. Pet. 53 (citing Ex. 1001 ¶ 458). Moreover, Petitioner contends, one of ordinary skill in the art

> would have been motivated by the disclosure in Grusin to seek out screws that would increase the strength with which the plate is locked, and would have understood the benefits of using at least one screw that has a threaded head and forms a mating interface with a threaded screw hole that allows variable angles as disclosed by Fernandez. Ex. 1001, ¶¶456-57. Such a combination is a way to achieve a very solid connection between the plate and the bone, as desired by Grusin, and gives the advantage of allowing a surgeon to choose the most desirable angular orientation for a screw while still locking.

Pet. 52. Petitioner similarly argues that persons of ordinary skill in the art "would have been motivated to use screws with a threaded head and threaded screw holes, as disclosed by Fernandez, with Grusin's plate system so that the plate could accept locking screws with threaded heads at a plurality of angular orientations and increase pullout strength." *Id.* at 61 (citing Ex. 1001 ¶¶ 456–458).

In response, Patent Owner contends that Ground 3 fails because it "is based on the erroneous premise that Fernandez discloses a ***threaded screw hole*** for receiving a threaded-head screw at a plurality of angular orientations," whereas, "[c]ontrary to Petitioner's contention, the alleged '***threaded screw holes***' of Fernandez are holes with protrusions – not threads." Prelim. Resp. 55. In particular, Patent Owner contends that Petitioner has failed to establish one of ordinary skill in the art would have understood the "isolated protrusions" of Fernandez's screw hole to be threads. Pet. 55–57. To the contrary, Patent Owner argues, "[t]he ordinary

and customary meaning of a thread is understood as ***a helical structure*** such as a rib or ridge," as confirmed by three dictionary definitions of the term "thread." *Id.* at 56 (citing Exs. 2008, 2009, & 2010).

Patent Owner's contentions are presently unsupported by testimony from a person of ordinary skill in the art. On behalf of Petitioner, by contrast, Mr. Castañeda testifies that Fernandez's protrusions 6 correspond to "internal threads" in hole 5 of plate 1. Ex. 1001 ¶¶ 417–420.

Some evidence of record supports Mr. Castañeda's interpretation. In particular, Fernandez indicates the interaction between protrusions 6 and the threaded head 8 of screw 7 is "designed to lock" protrusions 6 against head 8, 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.

In addition, the Petition cites Dahners[21] as disclosing a polyaxial locking screw arrangement. *See* Pet. 10 (citing Ex. 1024, Fig. 7,); Ex. 1001 ¶¶ 410, 458. Dahners discloses screw fastener 10 having helical threading 51 on head 40. Ex. 1024, Fig. 1, ¶¶ 27, 29. Screw head 40 is received in aperture A of orthopedic plate 60. *Id.* at Figs. 2B & 3, ¶¶ 32–34. As described in Dahners, "the invention departs from the conventional use of a thread formed on inside surface 81 of aperture A for mating with the thread of a screw head." *Id.* ¶ 35, Fig. 2B. Dahners thus provides tappable contact

[21] Dahners, U.S. Patent App. Pub. No. 2004/0073218 A1, pub. Apr. 15, 2004 (Ex. 1024).

region 85 on the surface of aperture A, comprised of a matrix of protrusions 87 such as pegs, bristles or tines, which allows threading 51 on head 40 "to form, in effect, a custom internal thread in contact region 85" as screw 10 is driven through aperture A. *Id.* at Figs. 2B & 3, ¶¶ 35–36, 43, 44. This tapping process may or may not cause deformation of protrusions 87. *Id.* ¶¶ 38, 44. Accordingly, and as we presently understand the reference, Dahners discloses that protrusions within a screw hole, e.g. pegs, bristles, or tines, comprise "a custom internal thread" and, thus, further supports Petitioner's contention that Fernandez's protrusions 6 correspond to "internal threads."

In light of Mr. Castañeda's testimony, and the record as a whole, Petitioner has advanced sufficient evidence to support its contention that Fernandez discloses a threaded screw hole to justify institution of trial on this issue. This may also be the case were we to adopt Patent Owner's construction of a threaded screw hole to require a helical structure, because protrusions 6 are configured to mate with the helical threading on head 8 of screw 7.

Patent Owner also asserts "Petitioner fails to carry its burden of identifying any reason that a skilled artisan using the plate system of Grusin would even be motivated to seek a means for inserting screws into the arms of Grusin's plate at a plurality of angular orientations," as set forth in independent claims 1 and 5. Prelim. Resp. 58. We do not find Patent Owner's argument persuasive in light of Petitioner's evidence, including a plain reading of Fernandez. With respect to the latter, Fernandez discloses a "variable angle locked bone fixation system," including orthopedic plates

having a multiplicity of screw holes for fixing the plates to bone, and employing variable angle locking screws, that can be fixed in a "perpendicular or tilted position." *See* section II(H)(2), above. Fernandez, on its face, thus, discloses a means for inserting screws into the arms of an orthopedic plate at a plurality of angular orientations.

On the present record, we further credit Petitioner's arguments that the combination of Grusin's plates with Fernandez's variable angle locking screw system provides "a way to achieve a very solid connection between the plate and the bone, as desired by Grusin, and gives the advantage of allowing a surgeon to choose the most desirable angular orientation for a screw while still locking." *See* Pet. 52 (citing Ex. 1001, ¶¶ 456–57); *see also id*. at 61 (arguing that persons of ordinary skill in the art "would have been motivated to use screws with a threaded head and threaded screw holes, as disclosed by Fernandez, with Grusin's plate system so that the plate could accept locking screws with threaded heads at a plurality of angular orientations and increase pullout strength") (citing Ex. 101 ¶¶ 456–458).

For the above reasons, we find Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to Ground 3.

III. CONCLUSION

On the record before us at this stage in the proceeding, Petitioner has demonstrated a reasonable likelihood of prevailing on Grounds 2 and 3. Given this determination, we institute trial on all challenged claims and all Grounds raised in the Petition. *See PGS Geophysical*, 891 F.3d at 1360; USPTO Guidance.

Our decision at this stage derives from our preliminary review of the challenged claims, the asserted prior art, and the opinions set forth in the as-yet-unrebutted Castañeda Declaration. We emphasize that at this stage of the proceeding, we have not made a final determination as to the construction of any claim term or the patentability of the instituted claims. Our final decision will be based on the full record developed during trial.

IV. ORDER

Accordingly, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1–9 of U.S. Patent No. 9,545,278 B2, in accordance with each ground on which the challenge to each claim is based in the Petition, is hereby *instituted*; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the ’278 Patent will commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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