

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*.

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, 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) 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). Moreover, in accordance with USPTO Guidance, “if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition.” *See Trial Practice Guide Update*

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 versions of 35 U.S.C. § 103 throughout this Decision.

(July 2019), at 31 (“The Board will not institute on fewer than all claims or all challenges in a petition.”) (“USPTO Guidance”).²

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 ’253 Patent is unpatentable. Accordingly, we institute an *inter partes* review as to all the challenged claims of the ’253 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. 81. Patent Owner, likewise, identifies only itself as the real party-in-interest. Paper 6, 2.

B. Related Proceedings

According to the parties, the ’253 Patent is at issue in *Wright Medical Technology, Inc. v. Paragon 28, Inc.*, Case No. 1:18-cv-00691-PAB-STV (D. Colo.). 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,

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

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 II(D), below, the parties dispute whether the claims of the '253 Patent are entitled to benefit of the 2006 Application.

C. 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:

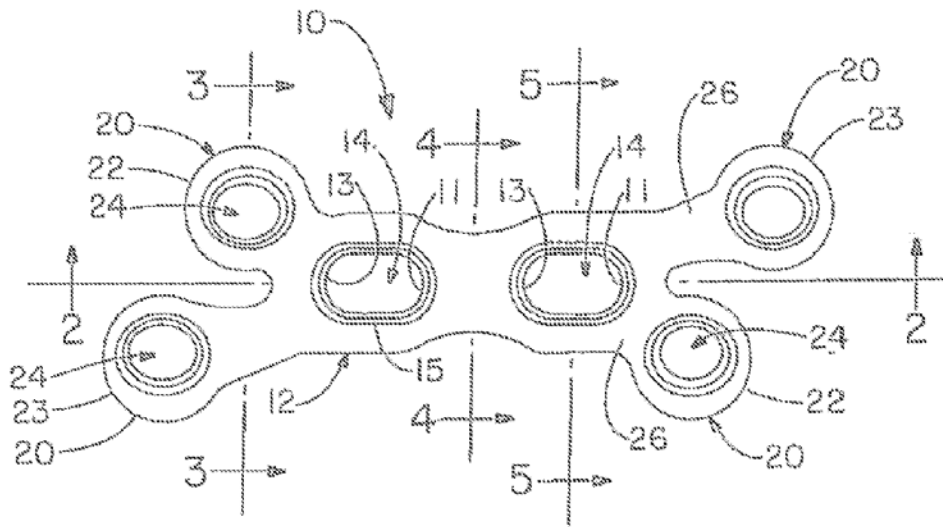


FIG. -1

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 12.³ *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.

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:

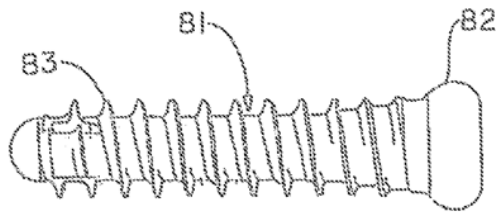


FIG. -6

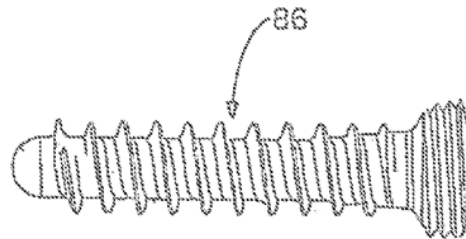


FIG. -7

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

³ 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.

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.

D. 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. 1005, 11:46–58.

Pertinent to our analysis, independent claims 13 and 46 are similarly directed to orthopedic plate systems 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.

Ex. 1005, 12:56–66, 16:8–15.

Patent Owner refers to claims 13, 46 and their dependent claims as “Plate+Screw” claims. Prelim. Resp. 18. 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,” 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 (indicting that a threaded-head screw is a locking screw). We adopt those conventions as convenient.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds for unpatentability (Pet. 17):

Ground	Claim(s)	Basis	Asserted Reference(s)
1	13–15, 17–19, 46–48, and 50–53	103	Kay ⁴ and Chan ⁵

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).

Ground	Claim(s)	Basis	Asserted Reference(s)
2	1, 3–9, and 12	103	Grusin ⁶ and Fernandez ⁷

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

⁶ Grusin et al., US 6,283,969 B1, issued Sept. 4, 2001 (Ex. 1010).

⁷ Fernandez, US 2005/0165400 A1, published July 28, 2005 (Ex. 1011).

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.⁸ *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).

⁸ Patent Owner does not argue objective evidence of non-obviousness at this stage of the proceeding.

B. Person of Ordinary Skill in the Art

The instant Petition does not directly address the standard of one of ordinary skill in the art. In copending proceedings involving the related patents with substantially the same specification, however, Petitioner contends a person having ordinary skill in the art “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.” *See e.g.*, IPR2019-00086, Paper 2 at Pet. 23; Ex. 1001 ¶¶ 28–29 (Petitioner’s expert expressly applying this definition of one of ordinary skill in the art in his opinions). Patent Owner does not dispute Petitioner’s proposed definition “for the purpose of this Preliminary Response only.” Prelim. Resp. 12. Because Petitioner’s presently unopposed definition is not inconsistent with the ’253 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 ’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).” *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. 17–18; Prelim. Resp. 12. 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 ’253 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. 1004, [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, 18.

Petitioner contends that Kay (the published version of the 2006 Application) qualifies as prior art to the Plate+Screw claims challenged in Ground 1 (claims 13–15, 17–19, 46–48, and 50–53) because these claims lack written description support in the 2006 Application for the “locking screw” (i.e., “threaded head”) limitation recited in independent claims 13 and 46. Pet. 11–16. Absent sufficient written description support, Petitioner argues, the Plate+Screw claims are entitled to a priority date of no earlier

than the filing date of the 2009 Application. *Id.* at 16. Patent Owner responds the challenged subject matter of claims 13–15, 17–19, 46–48, and 50–53 has written description support in the 2006 Application, such that Kay does not qualify as prior art with respect to these claims. *See e.g.*, Prelim. Resp. 18–33.

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).⁹ 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 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*

⁹ 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 ’253 Patent was filed on March 31, 2014, and asserts continuation priority to the January 12, 2012 filing date of the ’443 patent. *See* Ex. 1004, [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.

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.” Ex. 2001, Abstract. “The plate is designed specifically for the small bone market, i.e. for use in bones distal to the elbow and knee, including, for example, the ulna, radius, tibia, fibula, as well as the metacarpals, carpals, metatarsals, tarsals, and phalanges.” *Id.* ¶ 6. The plate is also “configured to bend laterally, longitudinally, and to wrap or spiral about its longitudinal axis so that it can be molded to an optimal shape for small bone procedures.” *Id.*

Figure 1 of the 2006 Application is reproduced below:

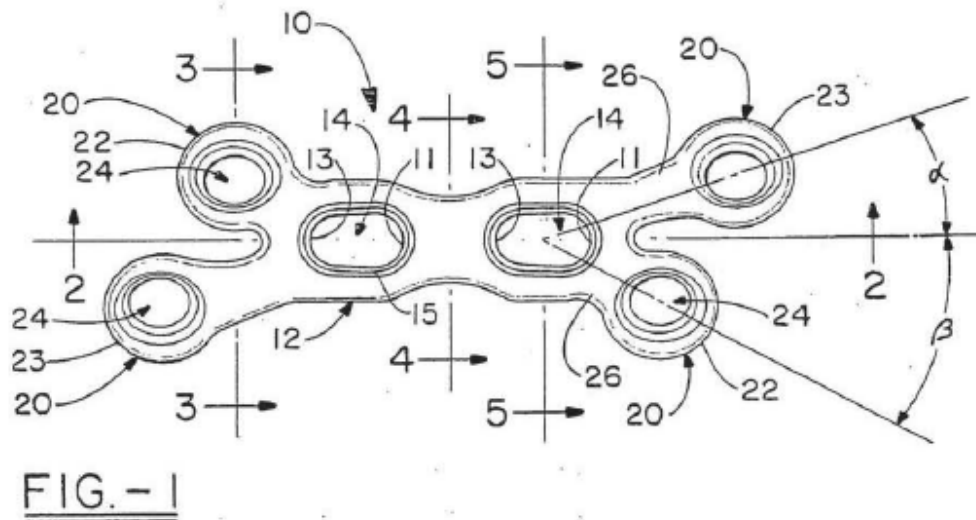


Figure 1 illustrates orthopedic plate 10 having a modified X-shaped profile, formed by central trunk portion 12 and two pairs of arms 20 extending diagonally from opposed terminal ends of central trunk portion 12. *Id.* at Abstract, ¶¶ 45, 47. In certain embodiments, plate 10

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

3. Support for the Locking Screw Limitation in the 2006 Application

According to Petitioner, “[c]laims 13–15, 17–19, 46–48, and 50–53 are not entitled to the priority date of the 2006 application because they recite a ‘locking screw’ limitation that is not supported by the 2006 application.” Pet. 11; Reply 3–5. As indicated in section I(D), above, Petitioner equates the genus of “locking screws” with the species of threaded head locking screws, i.e., screws having a threaded head designed to mate with threads in a locking screw hole.¹⁰

Petitioner states that “two broad categories of screws relevant here are non-locking and locking screws.” Pet. 7 (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.*

¹⁰ We note that Grusin appears to disclose another type of locking fastener, which employs a “buttress pin” rather than the threaded-head type at issue here. *See* section II(F)(1), below.

With respect to the disclosure of such screws, Petitioner refers to Figures 6 and 7 of the '253 Patent, reproduced below (*id.* at 12).

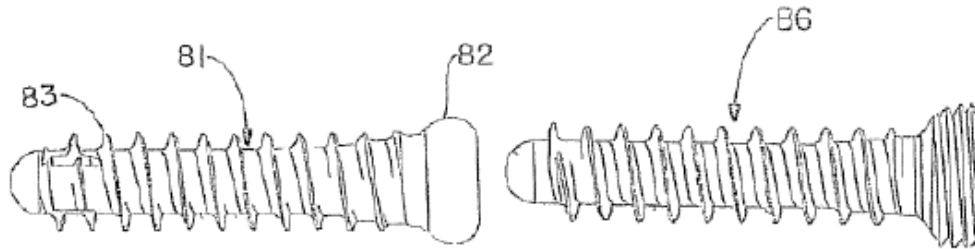
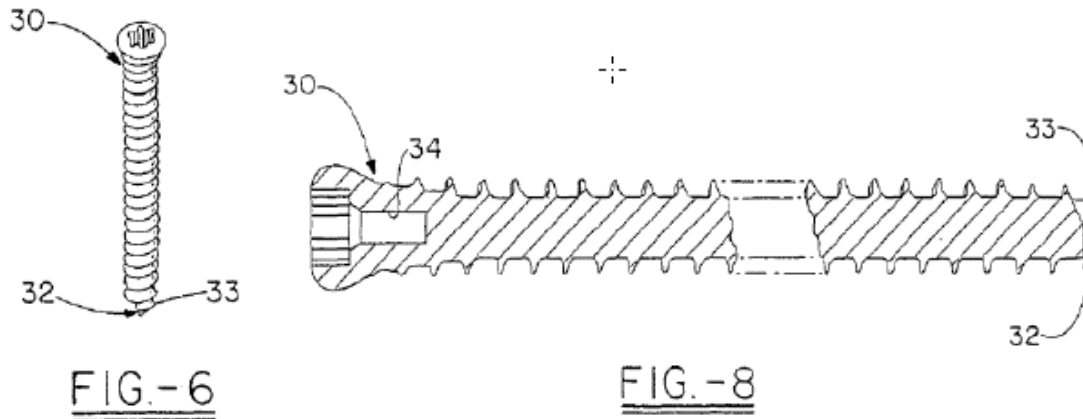


FIG.-6

FIG.-7

Petitioner contends that Figure 6 of the '253 Patent depicts a (non-locking) screw with an unthreaded head, whereas the '253 Patent describes the screw of Figure 7 “as ‘includ[ing] the same features as the screw in FIG. 6, except that the screw further includes external threads 88 on the screw head.’” *Id.* (citing Ex. 1004, 8:52–55). Thus, Petitioner contends, “according to the '253 Patent, ‘the difference between a locking and a non-locking screw concerns the presence of ‘external threads ... on the screw head.’” *Id.*

In contrast to the two types of screws illustrated in Figures 6 and 7 of the '253 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:”



Pet. 12–13. 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.* at 13. Moreover, Petitioner asserts, although “despite the level of detail with which the 2006 application describes the screw heads, the screw head itself is never described as ‘threaded,’ nor is the screw described as a ‘locking screw,’ as required by Claims 13 and 46 of the ’253 patent and their dependents.” *Id.* at 14.

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. 26 (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. Given that Petitioner agrees that a threaded-head screw is a locking screw, Petitioner's priority argument fails.

Id.

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’ locking 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 2. 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 ¶ 282), 4–5 (citing Ex. 1001 ¶¶ 43–44); Prelim. Resp. 28 (citing Ex. 1001 ¶ 58); *see generally* Sur-Reply 1–5. Patent Owner similarly 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. 29–30.

Noting that the Petition is silent regarding the 2006 Application's statement that “the bore could be threaded,” Patent Owner suggests that Petitioner “intentionally ignored the threaded screw hole embodiment because that embodiment undermines Petitioner's argument that the Plate+Screw Claims are not entitled to priority of the 2006 Application.”

Prelim. Resp. 26; Sur-Reply 1; Ex. 2001 ¶ 51. Setting aside the question of Petitioner’s intent, we find particularly relevant that Mr. Castañeda (1) rendered detailed opinions regarding support for the “locking crew” limitation in the 2006 Application, yet failed to address the 2006 Application’s disclosure that “the bore could be threaded” (Ex. 1001 ¶¶ 80–82); (2) testified that a threaded screw head is what distinguishes a locking screw from a non-locking screw (*id.* at ¶¶ 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” (*see* Sur-Reply (quoting Ex. 1001 ¶ 282)).

Considering the scope of Mr. Castañeda’s testimony and, in particular, 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 13 and 46.

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. In addition, Chan suggests a person of ordinary skill in the art would have understood that disclosure of a threaded screw hole demonstrates possession of a threaded head locking screw 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. 7–9 (explaining that threaded-head locking screws were known in the art).

We also address Petitioner’s contention that: “During prosecution [of the ’253 Patent], the examiner determined that the then-pending claims were not supported by the 2006 application, and considered their effective filing date to be February 24, 2009.” Pet. 26 (citing Ex. 1043, 4–5). Other than stating that “[t]he Applicant did not contest this effective filing date,” Petitioner does not elaborate its contention. *Id.*; Reply 5. Patent Owner, however, argues persuasively that the Examiner’s priority determination was directed to elements of then-pending claims not recited in those challenged by Petitioner. *See* Prelim. Resp. 13–15. In short, the statement Petitioner relies on (but fails to quote in its Petition) reads:

The disclosure of the prior-filed application, Application No. 11/340,028, fails to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph **for elected Species 5**, shown in Figs. 30-41 of this application.

Accordingly, the effective filing date **for claims directed to elected Species 5** in the current application is February 24, 2009 and will be treated as such for examination purposes.

Ex. 1043, 3–4 (emphasis added). The Examiner describes the elected species 5 as “includ[ing] a longer central trunk with translation slots flanked by two locking screw holes.” Ex. 1041, 3. Patent Owner contends that because “the examiner’s statement pertains only to claims directed to Species 5, and none

of the Challenged Claims are directed to Species 5, the examiner’s statement regarding priority is not relevant to the Challenged Claims.” Prelim Resp. 14–15 (citing Ex. 2011, claims 1–45); *see* Sur-Reply 5. We do not discern how the claims before us fall within the Species 5 election, and Petitioner does not challenge Patent Owner’s explanation in its Reply except to restate the same position set forth in the Petition.¹¹ *Cf.* Pet. 26 *with* Reply 5.

In sum, we find Patent Owner’s argument persuasive on the present record.¹² The evidence of record suggests that a person of ordinary skill in the art would understand that disclosure of a threaded screw hole demonstrates possession of a locking 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 skill artisan would understand that it also discloses corresponding threaded-head screws. Accordingly, the record before us fails to support Petitioner’s contention that claims 13–15, 17–19, 46–48, and 50–53 of the

¹¹ In reviewing the prosecution history of the ’253 and related Patents, Petitioner’s expert discusses the Examiner’s species designations, and the Applicant’s selections. *See* Ex. 1001 ¶¶ 59–74. Mr. Castañeda does not opine on whether any of the claims ultimately allowed in the ’253 Patent correspond to Species 5. *See, e.g., id.* ¶¶ 75–76.

¹² We accord little weight to Patent Owner’s argument that, in allowing claims reciting “locking screws” and “a threaded head” in the ’252 and ’278 Patents, respectively, the Examiner expressly accorded those claims the filing date of the 2006 application. *See* Prelim. Resp. 15–20. In particular, the Examiner’s discussion of priority in those cases focused on elements other than locking screws or threaded screw heads. Ex. 1037, 4 (addressing “a pre-contoured plate having only two diverging arms”); Ex. 1049, 3–4 (addressing “contoured plate” and “pre-contoured plate” limitations).

'253 Patent are not entitled to priority to the filing date of the 2006 Application based on the “locking screw” limitations. As such, Petitioner has not established that Kay is prior art with respect to at least claims 13–15, 17–19, 46–48, and 50–53.

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. 34–36. 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 locking screw limitation. Prelim. Resp. 34–35. In particular, Patent Owner points to the Examiner’s statement from the prosecution of the related, copending ’252 Patent that “[a]ccordingly, the effective filing date for the claimed subject matter in the current application is January 26, 2006 and will be treated as such for examination purposes,” which would remove the

asserted Kay reference as prior art. *See id.* at 41–42 (quoting Ex. 1037, 4).¹³ Although Patent Owner argues that the then-pending claims in the '252 Patent application recited a plate plus locking screws, in making her determination, the Examiner focused on the claim language, “a pre-contoured plate having only two diverging arms,” without specific reference to any other claim element. *Id.*; Ex. 1037, 3–4; *see also* Ex. 1049, 3–4 (similarly addressing only “contoured plate,” and “pre-contoured plate” limitations in according then-pending claims of '278 Patent priority to the 2006 Application); Reply 5 (noting “the Examiner never made any kind of factual finding in any of the related patent prosecutions 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.

Further, although Kay (as the published version of the 2006 Application) was inherently at issue during prosecution of the '253 Patent, Patent Owner does not argue, nor do we discern, that Chan was before the Examiner during prosecution of the '253 Patent. Accordingly, the Examiner never considered the patentability of claims 13–15, 17–19, 46–48, and 50–53 over the combination of Kay and Chan, as set forth in Ground 1. This weighs in favor of rejecting Patent Owner’s request. *See, Becton* factor 3.

Accordingly, the evidence relating to Ground 1, does not weigh in

¹³ Patent Owner admits that the Examiner’s statement of priority claims directed to elected Species 5 “is not relevant” to the priority of the challenged claims, and, thus, similarly not relevant to our § 325 analysis. *See id.* at 35; section II(D)(3), above.

favor of exercising our discretion. *See, Becton* factors 1–5.

With respect to Ground 2, Patent Owner does not argue, nor do we discern, that Fernandez was cited during the prosecution of the '253 Patent. Petitioner, however, admits, “Grusin was discussed during prosecution but the examiner only identified Grusin as a secondary reference for its disclosure of a compression slot.” Pet. 26–27. Patent Owner does not dispute Petitioner’s characterization. Accordingly, even though Grusin was raised in some context during prosecution, the Examiner never addressed the combination of Grusin with Fernandez, nor the arguments set forth in Ground 2. *See, Becton* factors 1–6. This evidence weighs strongly against exercising our discretion to deny the Petition under §325(d).

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 in light of the analysis above, we decline to exercise our discretion under section 325(d) to deny institution here.

F. Obviousness of Claims 13–15, 17–19, 46–48, and 50–53 in view of Kay and Chan (Ground 1)

In Ground 1, Petitioner challenges claims 13–15, 17–19, 46–48, and 50–53 as obvious in view of Kay and Chan. Pet. 28–56. Patent Owner opposes. Prelim. Resp. 33–36. We begin with an overview of the cited references.

1. Overview of Kay (Exs. 1006 and 2001)¹⁴

As noted above, Kay (Exhibit 1006) is the USPTO's publication of the 2006 Application (Exhibit 2001), such that the two disclosures are substantially the same but for pagination.¹⁵ 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 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. 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

¹⁴ 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 identical.” IPR2019-00895, Prelim. Resp. 16 n.3

¹⁵ *But see* Ex. 2005 (text added to the 2006 Application by amendment dated Nov. 10, 2008).

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 of Ground 1

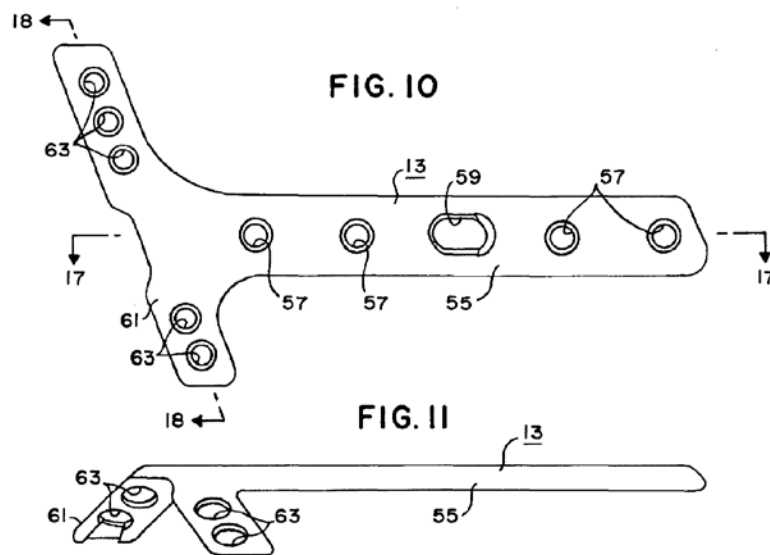
According to Petitioner, one of ordinary skill in the art “would have found it obvious to modify Kay’s plates to add Chan’s variable locking screws.” Pet. 28 (citing Ex. 1001 ¶¶ 281–284, 290–91, 294, 302–303, 333). But as noted in section II(D)(3), above, Petitioner has not established that challenged claims 13–15, 17–19, 46–48, and 50–53 are not entitled the benefit of priority of the 2006 Application such that, on the present record, Kay does not qualify as prior art with respect to these claims. And in the absence of Kay, Petitioner cannot demonstrate a reasonable likelihood that it would prevail with respect Ground 1.

G. Obviousness of Claims 1, 3–9, and 12 in view of Grusin and Fernandez (Ground 2)

In Ground 2, Petitioner challenges claims 1, 3–9, and 12 as obvious in view of Grusin and Fernandez. Pet. 56–81. Patent Owner opposes. Prelim. Resp. 36–48. 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:



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:

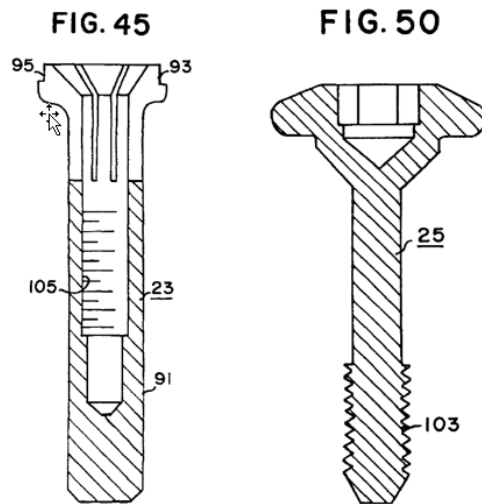


Figure 45 is a sectional view of buttress pin shank 23, and Figure 50 is a sectional view of pin head 25. *Id.* at 4:5–23, 8:63–67. In use, pin shank 23 is inserted into hole 57 or 63 of plate 13, until the flange of collar 93 is caught underneath plate 13, “to lock” pin shank 23 to plate 13. *Id.* at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

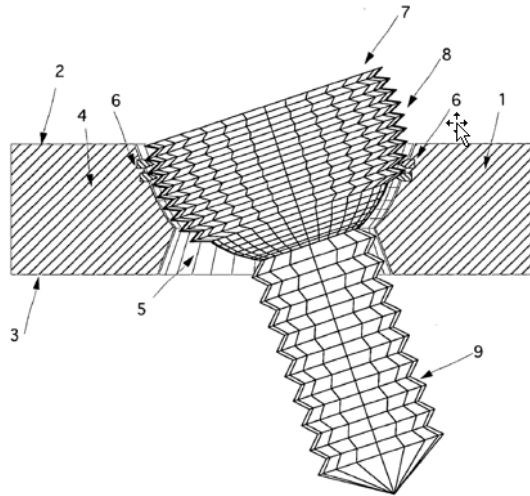


Figure 10 is a sectional view of screw 7 driven through hole 5 of bone plate 1, into bone underneath plate 1 (not shown), and locked at a tilt. *Id.* ¶¶ 27, 29, 30. Screw 7 has head 8, which “is threaded with a constant pitch.” *Id.* ¶ 30. Further, the wall of plate hole 5 “has a small number of isolated 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 2

Petitioner relies on Grusin as disclosing every element of claims 1, 3–9, and 12, 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, e.g., element 1[c]¹⁶ directed to an orthopedic plate having divergent arms, “each arm including a threaded screw hole.” *See id.* at 59–62.

Relying on the testimony of expert, Mr. Castañeda, Petitioner takes the position that:

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.

Pet. 57–58. Petitioner further argues that it would 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” and one of ordinary skill in the art would “have been motivated to combine Grusin’s fastening mechanism with Fernandez’s, as Fernandez’s fastening mechanism includes the advantages of increased hold strength, maintaining position

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.

through a locking mechanism, and maintaining low profile.” *Id.* at 57 (citing Ex. 1001 ¶¶ 354–355, 392); *id.* at 61 (citing Ex. 1001 ¶¶ 12, 354).

In response, Patent Owner contends that Ground 2 fails because it is based on the erroneous premise that Fernandez discloses a threaded screw hole in a bone plate whereas, “contrary to Petitioner’s arguments, the alleged ‘threaded screw holes’ of Fernandez are holes with protrusions – not threads.” Prelim. Resp. 43–48.¹⁷ In support of this position, 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 43–44 (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 and that “a POSITA would have expected that such screws and screw holes, as taught by Fernandez, could be successfully incorporated into Grusin.” Ex. 1001 ¶¶ 351–355; *see* Prelim. Resp. 44–45.

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

¹⁷ Patent Owner also contends that Petitioner’s reference to Grusin’s “buttress pin screw lock pin shank” implies that Petitioner asserts that “Grusin somehow discloses a threaded screw hole in a bone plate.” Prelim. Resp. 46–47 (referencing Pet. 59). We do not understand Petitioner to take that position.

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 Dahnners¹⁸ as disclosing a polyaxial locking screw arrangement. *See* Pet. 9 (citing Ex. 1024, Fig. 7.); Ex. 1001 ¶¶ 284, 355. Dahnners 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 Dahnners, “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. Dahnners thus provides tappable contact 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, Dahnners 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.”

¹⁸ Dahnners, U.S. Patent App. Pub. No. 2004/0073218 A1, pub. Apr. 15, 2004 (Ex. 1024).

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 be the case even 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 further argues that, because Fernandez does not disclose threaded screw holes, one of ordinary skill in the art would not expect the combination of Fernandez and Grusin to result in the invention of claim 1. Prelim. Resp. 48. For the above reasons, we do not agree with Patent Owner’s premise. To the contrary, on the present record we credit Petitioner’s arguments that one of ordinary skill in the art “would have recognized that Grusin and Fernandez disclose spherically recessed screw holes, Ex. 1010, 6:13–21; Ex. 1011, ¶ 15, and could be readily combined to provide a low-profile screw hole, still allowing a very solid connection between bone and plate. Ex. 1001 ¶392.” Pet. 80–81.

For the above reasons, we find Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to Ground 2.

III. CONCLUSION

On the record before us at this stage in the proceeding, Petitioner has demonstrated a reasonable likelihood of prevailing on Ground 2. Given this determination, we institute trial on all challenged claims and on all Grounds

raised in the Petition. *See, e.g., 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, 3–9, 12–15, 17–19, 46–48, and 50–53 of U.S. Patent No. 9,259,253 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 '253 Patent will commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2019-00898
Patent 9,259,253 B2

PETITIONER:

Joel R. Merkin
KIRKLAND & ELLIS LLP
jmerkin@kirkland.com

PATENT OWNER:

Joseph English
Patrick Craig Muldoon
Patrick D. McPherson
DUANE MORRIS LLP
DJEnglish@duanemorris.com
PCMuldoon@duanemorris.com
PDMcpherson@duanemorris.com