

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,

Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,

Patent Owner

Case: IPR2019-00894

U.S. Patent No. 9,144,443

PATENT OWNER'S NOTICE OF APPEAL

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

Pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. §§90.2 and 90.3, Patent Owner, Wright Medical Technology, Inc., hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board (“Board”) entered September 23, 2020 (Paper 41) and from all underlying orders, decisions, rulings, and opinions adverse to Patent Owner regarding U.S. Patent 9,144,443 (“the ’443 Patent”) at issue in *inter partes* review IPR2019-00894.

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

1. Whether the Board erred in finding Patent Publication No. 2006/0173459 (“Kay”) is prior art to Claims 1, 3-8, 15, 19 and 26 of the ’443 Patent and any finding or determination supporting or related to this issue.
2. Whether the Board erred in finding the Petitioner met its burden to show unpatentability by a preponderance of the evidence that Claims 1, 3-8, 15, 19 and 26 of the ’443 Patent would have been obvious under 35 U.S. C. §103 over Patent Publication No. 2006/0173459 (“Kay”) in view of Patent No. 4,903,691 (“Heinl”) and any finding or determination supporting or related to this issue.

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

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

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

Respectfully submitted,

Dated: November 23, 2020

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

ATTORNEY FOR PATENT OWNER

CERTIFICATE OF SERVICE

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

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

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

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

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

Respectfully submitted,

Dated: November 23, 2020

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

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

ATTORNEY FOR PATENT OWNER

Attachment A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2019-00894
Patent 9,144,443 B2

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

HOSKINS, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

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

I. INTRODUCTION

Paragon 28, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 1, 3–11, 15, 19, and 22–26 of U.S. Patent No. 9,144,443 B2 (Ex. 1002, “the ’443 patent”).

Wright Medical Technology, Inc. (“Patent Owner”) filed a Preliminary Response (Paper 8, “Prelim. Resp.”). Contemporaneously with the Preliminary Response, Patent Owner disclaimed claims 9–11 and 22–25. *See* Prelim. Resp. 1 n.1 (citing Ex. 2006); Paper 13 (Order authorizing Patent Owner to file Supplemental Preliminary Response with further evidence of disclaimer); Paper 15 (Supplemental Preliminary Response, citing Exs. 2013–2016).

We instituted a trial to determine whether claims 1, 3–8, 15, 19, and 26 are unpatentable, on the sole challenge to those claims presented in the Petition. Paper 17 (“Institution Decision” or “Inst. Dec.”), 2, 6, 31. We did not institute trial as to claims 9–11 and 22–25 due to Patent Owner’s disclaimer of those claims. *Id.* at 2, 27–31; 37 C.F.R. § 42.107(e) (2018).

Patent Owner filed a Patent Owner Response (Paper 23, “PO Resp.”) to the Petition. Petitioner filed a Reply (Paper 31, “Reply” or Pet. Reply”) to the Patent Owner Response. Patent Owner filed a Sur-reply (Paper 33, “Sur-reply”) to the Reply.

Patent Owner filed a Motion to Exclude Evidence (Paper 37). Petitioner filed an Opposition (Paper 38) to the Motion. Patent Owner filed a Reply (Paper 39). We dismiss the Motion as moot as to Exhibits 1057–1060, 1073–1075, and 1081, and we deny the Motion as to Exhibit 1070.

An oral hearing was held, for which the transcript was entered into the record (Paper 40, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of claims 1, 3–8, 15, 19, and 26 of the ’443 patent.

We determine Petitioner has shown by a preponderance of the evidence that claims 1, 3–8, 15, 19, and 26 are unpatentable.

II. BACKGROUND

A. *Real Parties-in-Interest and Related Proceedings*

Petitioner identifies itself as the sole real party-in-interest. Pet. 67. Patent Owner identifies itself as the sole real party-in-interest. Paper 7, 2.

The parties identify one U.S. District Court litigation as related to this proceeding: *Wright Medical Technology, Inc. v. Paragon 28, Inc.*, Case No. 18-cv-00691-PAB-STV (D. Colo.) (“the District Court Litigation”). Pet. 68; Paper 7, 2.

There are three related IPR proceedings, each challenging different continuations of the ’443 patent. Pet. 68; Paper 7, 2; Paper 26, 1; Ex. 1002, code (21); Ex. 1003, code (60); Ex. 1004, code (60); Ex. 1005, code (60). They are IPR2019-00895 challenging U.S. Patent No. 9,259,252 B2;

IPR2019-00894
Patent 9,144,443 B2

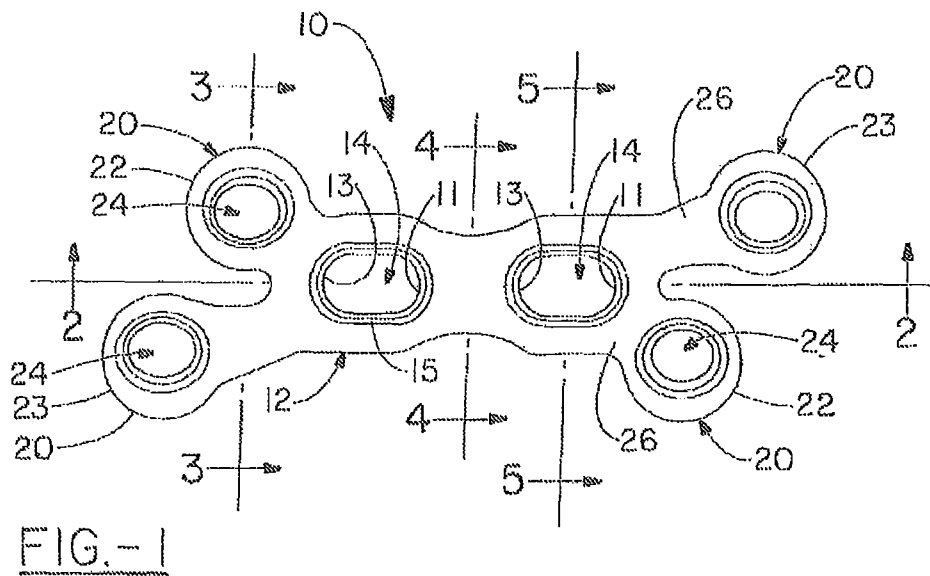
IPR2019-00896 challenging U.S. Patent No. 9,545,278 B2; and
IPR2019-00898 challenging U.S. Patent No. 9,259,253 B2.

*B. Patent Owner's Pre-Institution Disclaimer of
Claims 9–11 and 22–25 of the '443 Patent*

The Petition asserts claims 9–11 and 22–25 of the '443 patent are unpatentable under 35 U.S.C. § 103. Pet. 22–23, 55–67. Patent Owner disclaimed these claims prior to institution of trial. *See* Inst. Dec. 2, 27–30. We did not institute trial as to these claims. *Id.* at 30–31. Therefore, we do not address these claims any further in this Decision.

C. The '443 Patent Disclosure

The '443 patent discloses “a series of orthopedic plates for use in repair of a clavicle.” Ex. 1002, Abstract, 1:20–22, 2:16–18. Figure 1 of the '443 patent is reproduced here:



'443 Patent Figure 1 (Ex. 1002).

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, 6:35–38, 7:4–6. Central trunk portion 12 includes two screw holes 14 to receive screws secured in bone underneath plate 10. *Id.* at 1:60–64, 6:38–40, 8:37–51. The area between screw holes 14 includes a decreased width waist area “that will bend laterally (or ‘curve’) relative to the longitudinal axis and which will bend longitudinally to form a curved area in and out of the plane of” plate 10. *Id.* at 6:60–66.

The opposing pairs of arms 20 each include short arm 22 and long arm 23. *Id.* at 7:4–13. The arms are configured so screws inserted into respective screw holes 24 of the arms will not impinge on each other inside a bone underneath plate 10. *Id.* at 1:53–56, 3:54–65, 7:62–8:2.

Plate 10 is “pre-contoured” into the shape shown in Figure 1. *Id.* at 3:21–24. The ’443 patent also discloses several other plates, having various different pre-contoured shapes. *Id.* at Figs. 8–47, 5:38–6:31. The ’443 patent recognizes that the small bones in the human body have “a wide variety in the[ir] exact shape and mass,” and indicates that the plates disclosed in the ’443 patent are particularly useful for repair or reconstruction of the clavicle. *Id.* at 1:20–22, 1:28–40, 2:4–7, 2:16–18.

“[W]hile the plates are pre-contoured, the plate[s] are designed to facilitate three dimensional contouring . . . to accommodate individual variation in bone shape” such as by “bend[ing] laterally, longitudinally, and to wrap or spiral about the longitudinal axis or medial line.” *Id.* at 3:21–27; *see also id.* at 1:40–42 (“[I]ndividual variations become more problematic for orthopedic plates of stock design.”); *id.* at 6:62–7:3 & 8:3–8 (discussing individual contouring of plate 10). Further, several differently pre-contoured plates are “provided in a number of variations in a surgical tray,” which

“allows the surgeon to select his plate during surgery after opening the wound area and considering the plating needs.” *Id.* at 3:37–45. In this way, the surgeon picks out a pre-contoured plate that most closely matches a need for a particular patient, and the surgeon may then bend the chosen plate into a different shape to provide an even more optimal match for the patient’s need. This “reduc[es] the need for individualized contouring” by the surgeon in the operating room. *Id.* at 5:9–10.

The principal disputes between the parties focus on claim limitations requiring a pre-contoured plate to have a medial line describing an S-curve in a lateral or longitudinal plane. The ’443 patent discloses that a “lateral plate” for use on the clavicle may have “an S-curve of the medial line in the direction of the width of the plate.” *Id.* at 5:5–16. Also according to the ’443 patent, Figures 42–47 illustrate plate 510 “for use on the lateral aspect of the clavicle” and having “a shallow S shape along the medial line with the more proximal of the two translation slots [516] marking the transition between the lobes of the S.” *Id.* at 11:17–37, 6:23–31. Further, Figure 21 of the ’443 patent depicts plate 310 exhibiting an S-curve medial line when viewed from the side, although the ’443 patent does not use the terms “S-curve” or “S-shape” in connection with plate 310. *Id.* at 10:18–20, 10:30–36; *see also* Pet. 15 (arguing Figures 21–23 “depict an orthopedic plate with an S-curve”).

D. The ’443 Patent Claims at Issue During Trial

We instituted trial as to claims 1, 3–8, 15, 19, and 26 of the ’443 patent. Inst. Dec. 2, 31. Claim 1 illustratively recites:

1. An orthopedic plate system comprising
at least one screw and
an orthopedic plate having an inferior side including an inferior surface which is capable of facing a bone surface in use,
the plate having a central trunk portion having at least a first and a second screw hole and defining a longitudinal trunk axis extending between a first end and a second end,
said plate including at the first end a pair of divergent arms which extend so as to form a first arm and a second arm,
each arm including an arm screw hole which defines a central screw hole axis and
wherein *the plate has a medial line and is pre-contoured such that the medial line describes an S-curve in a lateral plane or in a longitudinal plane*, and
the S-curve has an inflection point that is located between the first and the second screw hole.

Ex. 1002, 11:43–56 (emphasis and line breaks added).

E. Tried Ground of Unpatentability

Petitioner challenges claims 1, 3–8, 15, 19, and 26 of the '443 patent solely under 35 U.S.C. § 103 as having been obvious over Kay¹ and Heinl.² See Pet. 22–23; Inst. Dec. 2, 6, 31.

F. Testimonial Evidence

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

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

² Ex. 1009, U.S. Patent No. 4,903,691, iss. Feb. 27, 1990.

| Witness | Role | Exhibits |
|----------------------------|--|---|
| Javier E. Castañeda | Petitioner's engineering expert ³ | Ex. 1001 (declaration of Mar. 28, 2019). Ex. 2019 (transcript of deposition of Dec. 5, 2019). |
| Steven K. Neufeld, M.D. | Patent Owner's medical expert ⁴ | Ex. 2017 (declaration of Dec. 21, 2019). Ex. 1072 (transcript of deposition of Mar. 10, 2020). |
| Timothy P. Harrigan, Sc.D. | Patent Owner's engineering expert ⁵ | Ex. 2018 (declaration of Dec. 23, 2019). Ex. 1066 (transcript of deposition of Mar. 5, 2020). |

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner has moved to exclude Petitioner's Exhibits 1057–1060, 1070, 1073–1075, and 1081 from evidence, citing several reasons grounded in the Federal Rules of Evidence. *See* Paper 37. We do not rely on any of Exhibits 1057–1060, 1073–1075, and 1081 in this Decision, so we dismiss the motion as moot in relation to those Exhibits.

We rely on Exhibit 1070 to support our determination of obviousness. Patent Owner asserts Exhibit 1070 “purports to be an article on the Scapula and Clavicle,” and “is irrelevant, unfairly prejudicial, misleading, . . . of no probative value . . . , inadmissible because it contains hearsay,” and not authenticated. Paper 37, 3 (citing Fed. R. Evid. 401, 402, 403, 801, 802, and 901). The sole analysis offered in support of Patent Owner's position is

³ *See* Ex. 1001 ¶¶ 1, 3, 8.

⁴ *See* Ex. 2017 ¶¶ 2, 6, 10, 12, 14, 16; Tr. 38:23–39:5.

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

that “Petitioner has failed to make *any* showing that [Ex. 1070 is] authentic,” because “Petitioner offers no proof as to the authorship . . . or integrity of the reproduction[.]” *Id.* at 6.

Petitioner responds that Patent Owner has failed to meet its burden to establish that Exhibit 1070 contains inadmissible hearsay, or is irrelevant. Paper 38, 1–2, 3–4 (citing 37 C.F.R. §§ 42.20(c) & 42.64(c)). Petitioner also asserts Exhibit 1070 is authentic. *Id.* at 4–6.

Patent Owner replies that Petitioner improperly “attempts to shift the burden to Patent Owner to prove” Exhibit 1070 is “not authentic,” when the Federal Rules of Evidence require “the proponent” of an item to “produce evidence sufficient to support a finding that the item is what the proponent claims it is.” Paper 39, 3 (quoting Fed. R. Evid. 901). Patent Owner maintains Petitioner did not produce such evidence. *Id.* at 3–4.

Patent Owner’s relevancy, unfair prejudice, misleading, and hearsay objections are unsupported by any analysis at all applying the law to the substance of Exhibit 1070, so these objections are not persuasive.

We further conclude Exhibit 1070 is authentic under Rule 901 of the Federal Rules of Evidence. The rule requires “evidence sufficient to support a finding that [Exhibit 1070] is what [Petitioner] claims it is.” Fed. R. Evid. 901(a). As Petitioner points out, this is a low bar, simply requiring a rational basis for Petitioner’s claim. Paper 38, 4 (citing *Caterpillar Inc. v. Wirtgen Am., Inc.*, IPR2018-01091, Paper 49 at 72 (PTAB Nov. 27, 2019) (further citations omitted)). An item may be authenticated by: “Distinctive Characteristics and the Like. The appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances.” Fed. R. Evid. 901(b)(4); *see also id.* Advisory

Committee’s Notes (“Example (4). The characteristics of the offered item itself, considered in the light of circumstances, afford authentication techniques in great variety.”).

Here, Exhibits 1023 and 1070 combine to satisfy the authenticity requirement as to Exhibit 1070. Exhibit 1023, which Petitioner submitted with the Petition and to which Patent Owner has not objected, contains excerpts from a textbook created to teach surgeons how to manage bone fractures. *See* Ex. 1023, 1 (Cover Page and Title); *id.* at 2, 4–7 (identifying various editors of and contributors to the textbook); *id.* at 8–10 (Foreword and Introduction); *id.* at 11 (Acknowledgments); *id.* at 12–15 (Table of Contents); *id.* at 16–42 (substantive excerpts). Exhibit 1023 further includes a page containing standard types of information and disclaimers often seen in published books. *See id.* at 3.

Petitioner submitted Exhibit 1070 with the Reply, claiming Exhibit 1070 provides additional excerpts from the same textbook previously excerpted in Exhibit 1023. *See* Pet. Reply 14–15, 17. Petitioner’s claim is supported by the evidence. The Table of Contents in Exhibit 1023 lists item “4.1” as an article entitled “Scapula and clavicle” authored by “C.W. Geel” and beginning on page 255. Ex. 1023, 14. The pages of Exhibit 1070 contain headings at the top of each page stating either “4.1 Scapula and clavicle—C.W. Geel” and bearing page numbers closely following page 255, or simply “4.1.” Ex. 1070. Further, the look and overall presentation of content is the same in Exhibits 1023 and 1070. In light of this combined evidence, and Patent Owner’s failure to identify any evidence that might suggest Exhibit 1070 is anything other than the textbook excerpt it appears to be, we conclude Exhibit 1070 is authentic.

IV. ANALYSIS

A. *Level of Ordinary Skill in the Art*

Petitioner contends a person having ordinary skill in the art pertaining to the '443 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. 24; Ex. 1001 ¶¶ 28–29. Patent Owner “does not dispute Petitioner’s definition of a person of ordinary skill in the art” in this proceeding. PO Resp. 17. We determine the level of ordinary skill proposed by Petitioner is consistent with the '443 patent and the prior art of record. We, therefore, adopt that level in this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579–80 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

B. *Claim Construction*

We interpret the claims of the '443 patent “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This “includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

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

1. “*the plate has a medial line and is pre-contoured such that the medial line describes an S-curve in a lateral plane or in a longitudinal plane*”

Independent claims 1 and 26 both recite “the plate has a medial line and is pre-contoured such that the medial line describes an S-curve in a lateral plane or in a longitudinal plane.” Ex. 1002, 11:52–54 (claim 1), 13:27–29 (claim 26). This proceeding implicates the meaning of several aspects of this limitation; the parties agree as to some aspects, and disagree as to other aspects.

First, the parties agree a “pre-contoured” plate refers to the plate as made by a manufacturer and presented to a surgeon, prior to any individualized contouring made by the surgeon bending or otherwise modifying the plate for use within a particular patient. PO Resp. 11, 14–15, 25–30; Pet. Reply 13–15, 19–21; Tr. 35:3–17. We concur. *See supra* Section II.C (discussing pertinent disclosures of ’443 patent).

Second, the parties agree the shape described by a plate’s medial line *in a lateral plane* is determined from a *top view* of the plate, such as shown in Figures 1, 8, 10, 13, 19, 25, 31, 35, 37, and 43 of the ’443 patent. *See* Pet. 6 (citing Ex. 1001 ¶ 41); PO Resp. 1 n.1 (citing Ex. 2017 ¶ 32; Ex. 2018 ¶ 31), 16. The parties also agree the shape described by a plate’s medial line *in a longitudinal plane* is determined from a *side view* of the plate, such as shown to varying extents in Figures 2, 9, 11, 15, 17, 21, 23, 27–29, 33, 39, and 45 of the ’443 patent. *See* Pet. 6 (citing Ex. 1001 ¶ 41); PO Resp. 1 n.1

(citing Ex. 2017 ¶ 32; Ex. 2018 ¶ 31), 16. We do not find any disclosure in the '443 patent that contradicts the parties' mutual understanding, so we apply this understanding here.

Third, Patent Owner emphasizes the claims require the medial line of the plate, and not the plate itself, to be S-shaped. PO Resp. 18–20, 23–25. According to Patent Owner, Petitioner and Mr. Castañeda both interpret the claims incorrectly to require the plate itself to be S-shaped. *Id.* (citing Ex. 2019, 25:2–25, 33:18–23; Ex. 1001 ¶¶ 41, 77, 114–116). Although the Petition and Mr. Castañeda's Declaration often refer loosely to “a plate with an S-curve” or employ similar phrases, Petitioner does not dispute that the claims require specifically that the plate's medial line describes an S-curve. *See* Pet. 2, 6–7, 13–15; Ex. 1001 ¶¶ 41, 77–79. Based on the plain claim language, we agree.

Fourth, the parties disagree as to how the “medial line” of a plate is to be determined. PO Resp. 20–25, 41–48; Pet. Reply 2, 5–10; Sur-reply 11–21. We do not resolve this dispute, because claim terms need to be construed “only to the extent necessary to resolve the controversy.” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). This dispute arises in connection with whether the 2006 Application demonstrates possession of a plate having a medial line describing an S-curve in the lateral plane. *See* PO Resp. 20–25, 41–48; Pet. Reply 2, 5–10; Sur-reply 11–21. As discussed below, we determine the 2006 Application does not demonstrate possession of a plate having a medial line describing an S-curve in the longitudinal plane, so we need not reach the lateral plane issue to resolve the parties'

priority dispute. *See infra* Section IV.C. Also, as to obviousness, there is no dispute that Heintl discloses a plate having a medial line describing an S-curve in the lateral plane, regardless of which parties' understanding of how to determine the medial line is applied. *See infra* Section IV.D.4(c).

2. *Other Claim Terms*

No further explicit claim construction of any claim term is needed to resolve the patentability issues presented in this proceeding. *See Nidec*, 868 F.3d at 1017.

C. *Priority of Claims 1, 3–8, 15, 19, and 26 of the '443 Patent*

1. *Legal Standards*

Pursuant to 35 U.S.C. § 120, a patent application is entitled to assert priority to the filing date of a prior application only for an invention disclosed in the prior application in the manner provided by 35 U.S.C. § 112, ¶ 1.⁶ This requires that the prior application provides written description support for the invention claimed by the later application. *See Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306–11 (Fed. Cir. 2008); *Augustine Medical, Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1302–03 (Fed. Cir. 1999). The test for sufficiency of a written description under 35 U.S.C. § 112, ¶ 1, is whether the prior application's disclosure “reasonably conveys

⁶ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, amended 35 U.S.C. § 112 effective September 16, 2012. *See* AIA § 4, 125 Stat. 296–97. The application that issued as the '443 patent was filed on January 12, 2012, so we cite the pre-AIA version. *See* Ex. 1002, code (22). However, we would reach the same conclusion as to written description support in the 2006 Application regardless of which version applies.

to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description “test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.*

2. *Parent Applications at Issue*

The application that issued as the ’443 patent was filed as a division of U.S. Patent Application No. 12/380,177 (filed February 24, 2009), which was filed as a continuation-in-part of U.S. Patent Application No. 11/340,028 (filed January 26, 2006). Ex. 1002, code (60), 1:5–12. The parties refer to those two parent applications as the 2006 Application and the 2009 Application, reflecting their respective filing dates. *See* Pet. 2; PO Resp. 30–31. For consistency in the record, we will do likewise.

We must decide whether the ’443 patent is entitled to priority to the 2006 Application, because this determines whether Kay is prior art to the ’443 patent. Kay (Ex. 1006) is the August 3, 2006, publication of the 2006 Application (Ex. 2001). Thus, the respective disclosures of Kay and the 2006 Application “are substantively identical.” PO Resp. 35 n.6.

3. *2006 Application Disclosure*

Petitioner contends the challenged ’443 patent claims lack written description support in the 2006 Application, so the claims have a priority date of no earlier than the filing date of the 2009 Application. Pet. 2–3, 11–17. According to Petitioner, the 2006 Application lacks written description support for a plate having a medial line that “*describes an S-curve* in a lateral plane or in a longitudinal plane,” as recited in

independent claims 1 and 26. *Id.* at 13 (emphasis by Petitioner). Petitioner challenges the priority of dependent claims 3–8, 15, and 19 on the same basis. *Id.*

Petitioner asserts that, while the 2006 Application indicates a plate may “bend laterally (or ‘curve’) relative to the longitudinal axis . . . to form a curved area” and “bend longitudinally to form a curved area,” there is no disclosure that such bending may result in an S-curve medial line. *Id.* (quoting Ex. 2001 ¶ 46, also citing *id.* ¶ 6).⁷ Petitioner argues the Figures of the 2006 Application do not illustrate a plate having an S-curve medial line, in either the lateral plane or the longitudinal plane. *Id.* at 13, 15, 16; Ex. 1001 ¶¶ 77–78. Petitioner contends the ’443 patent’s explicit disclosure concerning S-curves (Ex. 1002, 5:5–16) and figures depicting a plate with an S-curve medial line (*id.* at Figs. 21–23) are not in the 2006 Application. Pet. 14–15; Ex. 1001 ¶¶ 77–78.

Patent Owner responds that the challenged ’443 patent claims have written description support in the 2006 Application, so the claims have a priority date of no later than the filing date of the 2006 Application. PO Resp. 3, 30–51. Patent Owner states the 2006 Application provides written description support for a plate having an S-curve medial line “in either the lateral plane or the longitudinal plane.” *Id.* at 36. However, the arguments presented in support of this contention in the Patent Owner Response discuss only the lateral plane; they do not address the longitudinal

⁷ Petitioner cites to the disclosure of Kay (Ex. 1006) rather than the 2006 Application (Ex. 2001). We have re-cast Petitioner’s citations to refer to corresponding disclosures in the 2006 Application, which “are substantively identical” to Kay. PO Resp. 35 n.6.

plane. *Id.* at 3 (stating Patent Owner “contends that the X-shaped plates illustrated in [the 2006 Application] each possess a medial line describing an S-curve in the lateral plane”), 35–51. In particular, Patent Owner cites Figures 1, 9, 10, 12, 14, 16, 18, 20, 22, 24, and 26 of the 2006 Application, which are all top views of various plates, as demonstrating possession of “an X-shape in the lateral plane . . . such that each plate possesses a medial line describing an S-curve in the lateral plane.” *Id.* at 36. Patent Owner’s analysis then focuses on Figure 1 as representative of the contention that the 2006 Application discloses an S-curve medial line in the lateral plane. *Id.* at 36–48.

Petitioner’s Reply correctly points out that the Patent Owner Response does not cite any evidence that might indicate the 2006 Application demonstrates possession of an S-curve medial line in the longitudinal plane. Pet. Reply 1, 2, 3–5. Petitioner asserts that, for priority to be found, the 2006 Application must demonstrate possession of both alternatives recited in claims 1 and 26: an S-curve medial line in the lateral plane, and an S-curve medial line in the longitudinal plane. *Id.* at 3–4 (citing *D Three Enterprises, LLC v. SunModo Corp.*, 890 F.3d 1042, 1051–52 (Fed. Cir. 2018); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158–60 (Fed. Cir. 1998)).

Patent Owner replies that its Response properly addresses only the lateral plane because “Petitioner’s challenge to priority . . . focuse[s] substantively on the alleged lack of support for the ‘S-curve’ limitation in the lateral plane,” and Petitioner’s obviousness challenge similarly focuses on the lateral plane. Sur-reply 3–4; *id.* at 1, 9–10. Patent Owner further asserts the 2006 Application “provides sufficient support for the ‘S-curve’

limitation in either the lateral plane or the longitudinal plane,” if we construe the “pre-contoured” claim term broadly to allow for the S-curve medial line to be formed by an individualized contouring achieved by a surgeon bending the plate for use with a particular patient. *Id.* at 2–4, 5–9.

Upon review of the foregoing, we first note it is undisputed that the 2006 Application must demonstrate possession of both claimed S-curve medial line alternatives (lateral and longitudinal planes) for priority to be found. *See* Pet. Reply 1, 2, 3–5; Tr. 44:22–45:6 (Patent Owner’s counsel agrees); *see also D Three*, 890 F.3d at 1051–52 (where earlier application disclosed only a washer above the flashing, it did not provide written description support for later-filed application claiming washers that could be either above or below the flashing); *Tronzo*, 156 F.3d at 1158–60 (application disclosing only conical cup did not provide written description support for later-filed claims, which were generic as to cup shape).

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

demonstrate possession of a plate having an S-curve medial line in a longitudinal plane.

Patent Owner has misconstrued Petitioner's claim construction position to be that a "pre-contoured" plate broadly allows for the S-curve medial line to be formed by individualized contouring of a plate by a surgeon bending the plate for use with a particular patient. *See supra* Section IV.B.1. As neither party advocates for such a claim construction, we do not apply it here. *See id.* Therefore, we need not consider Patent Owner's argument that the 2006 Application demonstrates possession of an S-curve medial line in the longitudinal plane applying that construction.

Patent Owner presents additional arguments in the Sur-reply. *See* Sur-reply 2–4, 5–9. Here, Patent Owner asserts "Petitioner agrees that [the 2006 Application's] pre-contoured plates *would embody* the S-curve." *Id.* at 2 (emphasis added). This argument relies on statements in the Petition and the Reply made in support of the asserted obviousness of modifying plate 10 in Figure 1 of Kay (which is the same as Figure 1 of the 2006 Application) to have an S-curve medial line. *Id.* at 2–4, 5–9 (citing Pet. Reply 20; Pet. 31–32; Ex. 1001 ¶¶ 41, 121–122; Ex. 2001 ¶ 6; Ex. 1086, Fig. 1⁸); Tr. 40:14–41:5, 43:18–44:21, 54:16–55:19. Specifically, in that context, Petitioner states a person of ordinary skill in the art "*would have known that some small bones would require an S-shape plate* in order for the plate to be molded to the optimal shape for those bones," and "for some bones, the

⁸ There is no Exhibit 1086 in this proceeding. We believe Patent Owner meant to cite Exhibit 1086 from a related proceeding, IPR2019-00895, challenging a continuation of the '443 patent.

pre-contoured plate would require an S-shape.” Pet. Reply 20 (emphases modified in part) (citing Pet. 39–40).

Patent Owner’s Sur-reply is not persuasive. As Petitioner points out (Pet. 15–16): “Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed,” such that “[i]t extends only to that which is disclosed.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997); *see also PowerOasis*, 522 F.3d at 1306–07 (same). “While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification,” and “a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.” *Lockwood*, 107 F.3d at 1572 (citations omitted).

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

Patent Owner cites Exhibit 1086 from IPR2019-00895 as establishing such bones might benefit from being repaired with a plate having an S-curve

medial line. *See* Sur-reply 8 (citing Exhibit 1086, Fig. 1). Even overlooking the fact that this Exhibit has not been introduced as evidence in this proceeding, we conclude this Exhibit establishes, at best, the obviousness of using a plate having an S-curve medial line in the longitudinal plane to heal some fractures that might occur in the radius bone. *See id.* It does not reflect that the inventors of the 2006 Application had possession of using such a plate in such a manner. *See id.*

Patent Owner also cites the testimony of Dr. Neufeld and Mr. Harrigan that “[a] POSA understood that a plate that was customized by bending longitudinally to form a curved area in and out of the plane of the plate,” as described in the ’443 patent, “*would have a medial line that described an S-curve in the longitudinal plane.*” *Id.* at 8; Ex. 2017 ¶ 46 (emphasis added) (citing Ex. 1002, 4:40–41, 5:5–10, 6:63–66); Ex. 2018 ¶ 45 (same). While this testimony relates to disclosures in the challenged ’443 patent, there are somewhat overlapping disclosures in the 2006 Application. *See* Ex. 2001 ¶¶ 10, 13, 46. Importantly, however, the overlap does not include the ’443 patent’s disclosure at column 5, lines 5–16, directed to how a clavicle might benefit from applying “a lateral plate [having] an S-curve of the medial line” *Compare* Ex. 1002, 5:1–16, *with* Ex. 2001 ¶¶ 12–13. As we concluded in the Institution Decision, and which has not been materially disputed by Patent Owner during trial, the 2006 Application does not demonstrate possession of using its plates on the clavicle. *See* Inst. Dec. 14–15 & n.8; Ex. 2001 ¶ 6.

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



Patent Owner’s Demonstrative Exhibit (Slide 2).

According to counsel, the picture above shows the size of one plate embodying the claimed invention in relation to a penny, to illustrate how small the plates can be. *Id.* at 37:18–38:2. Counsel argued, “Petitioner fails to appreciate the relative dimensions of the bone plate in the longitudinal direction.” *Id.* at 39:13–17. In counsel’s view, “[b]ecause the plate is so thin in relation to the lateral direction, the medial line takes the same shape as the plate in the longitudinal direction,” so “[i]t’s clear that [the 2006 Application] discloses an S-shaped medial line in a longitudinal direction.” *Id.* at 39:17–40:13 (citing PO Resp. 36–37; Ex. 2001 ¶¶ 1, 6); Ex. 2017 ¶¶ 61–62; Ex. 2018 ¶¶ 60–61.

We reject this argument for two reasons. First, it was presented untimely. The Petition satisfied Petitioner’s burden of production, sufficiently raising the issue of whether the 2006 Application demonstrates possession of an S-curve medial line in *either* the lateral plane *or* the

longitudinal plane. *See* Pet. 13 (challenging whether the 2006 Application discloses plates having a medial line that “*describes an S-curve* in a lateral plane or in a longitudinal plane” (emphasis by Petitioner)); *Dynamic Drinkware*, 800 F.3d at 1378–81 (discussing burdens of production and persuasion in the context of determining the effective date of a prior art patent that asserts priority to a provisional application).

We disagree with Patent Owner’s assertion that the Petition was limited to challenging whether the 2006 Application demonstrates possession of an S-curve medial line in the lateral plane. It is true that the Petition’s obviousness challenge largely focuses on modifying Kay’s plate 10 to have an S-curve medial line in the lateral plane, in light of Heintl. *See* Sur-reply 10 (citing Ex. 2019, 30:18–32:6); Pet. 39 (relying on Heintl’s Figure 3, which is a top view of a plate in the lateral plane, as disclosing the S-curve medial line limitation). However, priority and obviousness are different issues, and the Petition discusses both the lateral plane and the longitudinal plane in connection with the priority issue. *See* Pet. 2–3, 12–17.

Thus, we conclude the Petition shifted the burden of production to Patent Owner, to present argument and evidence that the 2006 Application demonstrates possession of an S-curve medial line in *both* the lateral plane *and* the longitudinal plane. *See Dynamic Drinkware*, 800 F.3d at 1379 (discussing shifting burdens of production). The Patent Owner Response analyzes an S-curve medial line only in the lateral plane. *See* PO Resp. 3, 30–51. The argument presented for the first time at the hearing addressing an S-curve medial line in the longitudinal plane was untimely presented, thereby impairing Petitioner’s ability to respond given the expeditious nature of IPR proceedings.

Second, the argument presented for the first time at the hearing—that the thinness of a plate in its lateral direction means the medial line will take the same shape in the lateral and longitudinal planes—is not persuasive. The '443 patent figures demonstrate that the shape of a plate's medial line in the lateral plane (shown in a top view) provides very little information as to the shape of the medial line in the longitudinal plane (shown in a side view). For example, the top view of Figure 1 does not convey the curvature of plate 10 as seen in the lateral side view of Figure 2 and the end side views of Figures 3–5. *See* Ex. 1002, 5:24–33, 7:47–55. Also, the top view of Figure 13 does not convey “the slight longitudinal curve” of plate 210 seen in the lateral side view of Figure 15, reflecting the medial line of plate 210 in the longitudinal plane. *See id.* at 5:45–50, 8:60–9:4. And the top view of Figure 19 does not convey the curvature of plate 310 seen in the lateral side views of Figures 21 and 22, reflecting the medial line of plate 310 in the longitudinal plane. *See id.* at 5:54–61, 9:62–65, 10:17–25. The same is true in the other evidence of record. *See, e.g.,* Ex. 1070, 4 (Figure 4.1-7(a), illustrating a top view and a side view of a 9-hole reconstruction plate used to fix a midshaft fracture of the clavicle).

In conclusion, we find the 2006 Application fails to demonstrate possession of a plate having an S-curve medial line in a longitudinal plane.

4. *Prosecution History of the '443 Patent*

Petitioner asserts the Examiner of the '443 patent affirmatively decided that the 2006 Application lacks written description support for a plate's medial line describing an S-curve in a lateral plane or in a longitudinal plane, which was not contested by the applicant at the time.

Pet. 16–17 (citing Ex. 1030, 4; Ex. 1031, 8–10; Ex. 1032, 3–4; Ex. 1033, 9–10; Ex. 1053, 2);⁹ Pet. Reply 10–12. Further according to Petitioner, the applicant admitted during prosecution that Figure 1 of the 2006 Application does not have the claimed S-curve medial line. Pet. Reply 11–12 (citing Ex. 1031, 9; Ex. 1002, Figs. 30–47, 5:21–6:31, 11:17–37).

Patent Owner asserts in opposition that “the priority of the claims was not an issue that required resolution in any rejection raised by the examiner,” and “the examiner did not consider that plates having a modified X-shape (for example the plate of Figure 1 [of the 2006 Application]) possessed a medial line describing an S-curve.” PO Resp. 48–50. Patent Owner acknowledges the Examiner’s statement that the 2006 Application “lacks *any reference to an S-curve*” (Ex. 1030, 4 (emphasis added)), but contends it is not determinative because written description does not require *in haec verba* support. PO Resp. 49. Patent Owner argues the Examiner’s rejection of two claims for double patenting over U.S. Patent No. 7,771,457 B2 (“the ’457 patent”), which is the patent that issued from the 2006 Application, “did not rely on Kay as prior art” and therefore “implicitly accepted that Kay was not prior art.” *Id.*; *see* Ex. 1030, 8–9 (double patenting rejections citing the ’457 patent). Patent Owner also accuses Petitioner of mischaracterizing the prosecution history in relation to alleged admissions by the applicant. Sur-reply 21.

We determine the prosecution history of the ’443 patent is consistent with our finding that the 2006 Application fails to demonstrate possession of

⁹ Our page citations to prosecution history documents in the record refer to the page numbering added to the bottom of each page by Petitioner when preparing the Exhibit.

a plate having an S-curve medial line in a longitudinal plane. The Examiner expressly found the 2006 Application failed to demonstrate possession of a claim limitation reciting “an S-curve in a lateral plane or in a longitudinal plane.” Ex. 1030, 3–4. On that basis, the Examiner determined “the effective filing date for the claimed subject matter” was the February 24, 2009, filing date of the 2009 Application. *Id.* (emphasis omitted). We concluded in the Institution Decision that “[t]he Examiner’s priority determination was necessary to the Examiner’s reliance on 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.” Inst. Dec. 16–17 (footnote omitted) (citing Ex. 1030, 10, 13). Patent Owner’s conclusory statement that priority was not an issue that required resolution in any rejection raised by the Examiner does not address that conclusion (PO Resp. 49), and is not persuasive. Further, there is no suggestion that the applicant contested the Examiner’s priority determination. *See* Exs. 1031 & 1033.

The fact that the Examiner did not cite Kay as prior art does not mean, as Patent Owner would have it, that the Examiner implicitly accepted Kay was not prior art. The Examiner found Austin, Sixto, and Chreene all qualified as prior art based on the determined February 24, 2009 priority date, so the same is necessarily true for Kay, which was published on August 3, 2006.

We do not agree with Petitioner’s argument that the applicant admitted during prosecution that Figure 1 of the 2006 Application does not have the claimed S-curve medial line. Petitioner here relies on the applicant’s statement that: “*The s-shaped plate of the present invention is*

meant for use on the superior aspect of a clavicle,” and “[t]he other plates in the application are also meant for use on a clavicle, but do not include the s-shaped medial line.” Ex. 1031, 9 (emphases added). However, Petitioner does not cite, and we cannot find, any disclosure in the ’443 patent indicating that plate 10 shown in Figure 1 is, or is not, meant for use on any particular aspect of the clavicle, such as the superior aspect. *See, e.g.,* Ex. 1002, 3:47–53, 5:5–16, 5:24–37. Therefore, it is not clear whether plate 10 falls inside or outside the claimed invention, based on the applicant’s statement during prosecution.

In summary, based on the Examiner’s explicit determination of the proper priority afforded the ’443 patent claims, we conclude the prosecution history of the ’443 patent is consistent with our finding that the 2006 Application fails to demonstrate possession of a plate having an S-curve medial line in the longitudinal plane.

5. *Conclusion Regarding Priority of Claims 1, 3–8, 15, 19, and 26 of the ’443 Patent*

For the foregoing reasons, we find a preponderance of the evidence establishes that the 2006 Application fails to demonstrate possession of a plate having an S-curve medial line in the longitudinal plane. Thus, we conclude claims 1, 3–8, 15, 19, and 26 of the ’443 patent do not have priority to the filing date of the 2006 Application. Those claims instead have a priority date of no earlier than the filing date of the 2009 Application, which is February 24, 2009.

D. Obviousness over Kay and Heinl

Petitioner asserts claims 1, 3–8, 15, 19, and 26 of the '443 patent are unpatentable under 35 U.S.C. § 103 as having been obvious over Kay and Heinl. Pet. 22–23, 31–54. Patent Owner opposes. PO Resp. 51–65.

We determine Petitioner has demonstrated, by a preponderance of the evidence, that each of these claims would have been obvious over Kay and Heinl. We begin our analysis with a brief summary of the law of obviousness, next we summarize pertinent disclosures of Kay and Heinl, and then we address Petitioner's and Patent Owner's contentions as to obviousness.

1. Law of Obviousness

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if made available in the record.¹⁰ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

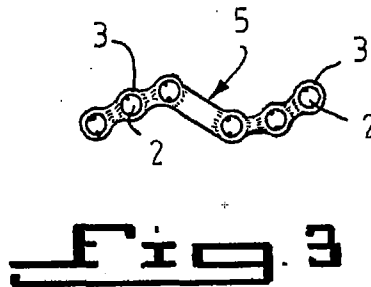
¹⁰ The Patent Owner Response discusses the needs met by the '443 patent, and the "great commercial success" of products embodying the '443 patent claims. PO Resp. 4–7. However, during the hearing, Patent Owner's

2. *Kay Disclosure*

Kay is the USPTO publication of the 2006 Application. *See* Ex. 1006; Ex. 2001. The summary of the '443 patent provided above in Section II.C applies equally as well to Kay, except that the '443 patent's disclosures of an S-curve medial line in the lateral or longitudinal plane are not found in Kay.

3. *Heinl Disclosure*

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. Several plates are presented to the surgeon as "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 here:



Heinl Figure 3 (Ex. 1009).

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.

counsel confirmed Patent Owner is not relying on objective indicia of nonobviousness. Tr. 56:12–20.

4. *Claim 1*

Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, in support of contending claim 1 is unpatentable as having been obvious over Kay and Heinl. Pet. 31–42; Pet. Reply 13–23; Ex. 1001 ¶¶ 84–89, 95–97, 111–126. Patent Owner provides arguments and evidence in opposition, including testimony from Dr. Neufeld and Mr. Harrigan. PO Resp. 51–62; Sur-reply 1–5, 22–26; Ex. 2017 ¶¶ 80–97; Ex. 2018 ¶¶ 79–96.

a) *Whether Kay is Prior Art to the '443 Patent*

Patent Owner argues Kay is not prior art, because the '443 patent is entitled to priority to the filing date of the 2006 Application, which published as Kay. PO Resp. 51–52. For reasons provided above in Section IV.C, we disagree. Kay was published on August 3, 2006, before the '443 patent's priority filing date of February 24, 2009. Ex. 1006, code (43); *supra* Section IV.C. Therefore, we determine Kay is prior art to the '443 patent.

b) *Whether Kay Discloses Claimed Subject Matter*

Petitioner contends Kay discloses an orthopedic plate system embodying each and every limitation of claim 1, except Kay's plate does not have an S-curve medial line in a lateral plane or a longitudinal plane, with the S-curve having an inflection point located between two screws holes of the central trunk portion. Pet. 33–42; Ex. 1001 ¶¶ 111–126.

Patent Owner does not dispute Petitioner's foregoing contentions. PO Resp. 34–35 & n.6, 52–62. "The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented." *LG Elecs., Inc. v. Conversant Wireless Licensing S.A.R.L.*,

759 F. App'x 917, 925 (Fed. Cir. 2019) (quoting *In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016)).¹¹ Nonetheless, to provide a complete record, we summarize our findings comparing Kay with the subject matter of claim 1.

Figure 1 of Kay is reproduced here:

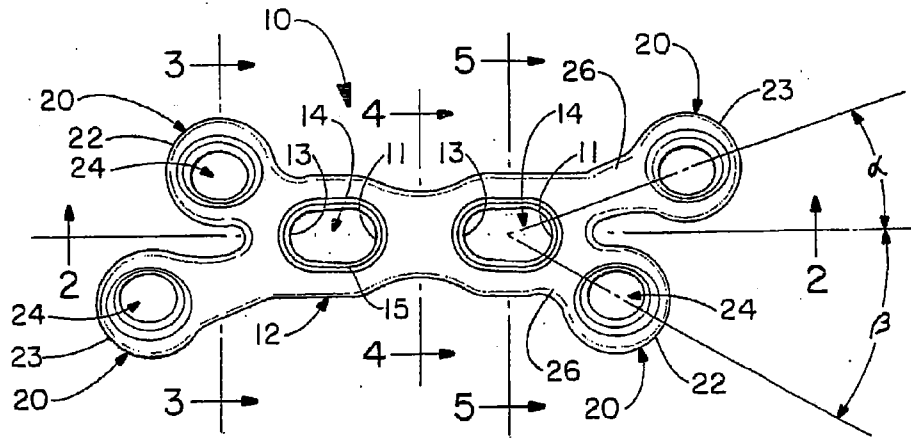


FIG. - 1

Kay Figure 1 (Ex. 1006).

Figure 1 of Kay is a top view of plate 10, “having a bilaterally asymmetric shape which can be thought of as being similar to the Greek letter [χ],” comprising central trunk portion 12 and four arms 20. Ex. 1006 ¶¶ 46, 48.

We find Kay discloses an orthopedic plate system including plate 10 and at least one screw. *See id.* at Abstract (“[t]he present invention relates to an orthopedic plate and screw system”); *id.* ¶ 46 (“[t]he plate 10 of the present invention”); Pet. 33; Ex. 1001 ¶¶ 111–112. In particular, plate 10

¹¹ *See also Papst Licensing GmbH & Co. v. Samsung Elecs. Am.*, 924 F.3d 1243, 1250 (Fed. Cir. 2019) (holding that patentee forfeited argument for patentability because it did not present it to the Board); *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1048 (Fed. Cir. 2019) (explaining that arguments not presented to the Board are waived).

includes six screw holes 14 or 24, each of which receives a screw secured in bone underneath plate 10. *See* Ex. 1006, Abstract, ¶¶ 4, 9, 46, 48; Pet. 33; Ex. 1001 ¶¶ 111–112.

We find Kay's plate 10 has an inferior surface that faces a bone surface in use. Kay's Figures 3–5 illustrate the concave curvature of plate 10 where it faces bone. *See* Ex. 1006 ¶¶ 9, 50; Pet. 34; Ex. 1001 ¶ 113.

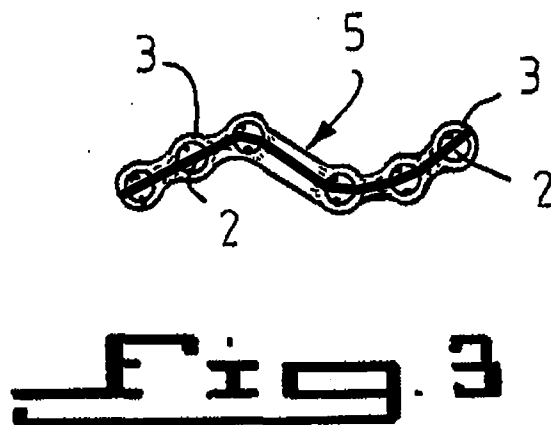
We find Kay's plate 10 includes central trunk portion 12 having two screw holes 14 and defining a longitudinal trunk axis extending between a first end (at the left in Figure 1) and a second end (at the right in Figure 1). *See* Ex. 1006 ¶¶ 9, 46; Pet. 35–36; Ex. 1001 ¶¶ 114–115. We find Kay's plate 10 has, at both ends, a pair of divergent arms 20, each including a screw hole 24 defining a central screw hole axis. *See* Ex. 1006 ¶ 48; Pet. 36–38; Ex. 1001 ¶¶ 116–118.

We find Figure 1 of Kay illustrates plate 10 in a pre-contoured shape, prior to any individualized contouring achieved by a surgeon bending plate 10 for use with a particular patient. *See* Ex. 1006 ¶¶ 7, 51; Pet. 38; Ex. 1001 ¶ 119.

c) Whether Heintl Discloses Claimed Subject Matter

In the Petition, Petitioner contends Heintl's plate 5 is pre-contoured to have an S-curve medial line in a lateral plane, with the S-curve having an inflection point located between two screws holes of the central trunk portion. Pet. 39–42; Ex. 1001 ¶¶ 119–120, 123–124. In opposition, Patent Owner disputes only whether Heintl's plate 5 has the recited inflection point. *See* PO Resp. 61–62.

We find Figure 3 of Heintl illustrates a pre-contoured, S-shaped bone plate 5. Ex. 1009, 1:62–2:3, 2:18–22, 8:41–58. We also find Figure 3 demonstrates that the medial line of plate 5 describes an S-curve in the lateral plane, regardless of whether the medial line is determined by applying Patent Owner’s or Petitioner’s understanding. *See, e.g.*, PO Resp. 41–48 (discussing Patent Owner’s view of how to determine a plate’s medial line); Pet. 38–40 (discussing Heintl’s S-shaped plate); Pet. Reply 13–14 (discussing how Heintl’s S-shaped plate has an S-curve in a lateral plane). Figure 3 of Heintl is reproduced here, with our annotation to identify the S-curve medial line in the lateral plane:



**Heintl Figure 3 (Ex. 1009)
(Annotated to Identify Medial Line in Lateral Plane).**

Figure 3 of Heintl above illustrates “a plate [5] of approximately S-form.” Ex. 1009, 8:53. Indeed, Patent Owner does not dispute that plate 5 has an S-curve medial line in the lateral plane.

Patent Owner argues Petitioner errs in relying on Heintl’s plate 5 as having an S-curve medial line “inflection point that is located between” two screw holes of a central trunk portion, as recited in claim 1. PO Resp. 61–62 (citing Pet. 40–41). Patent Owner contends Petitioner’s position is belied by

Mr. Castañeda’s deposition testimony “that the medial line of Heintl would be a straight line through the segment between the third and fourth holes.” *Id.* (citing Ex. 2019, 38:23 & Ex. 2¹²); Ex. 2019, 38:23 (“I intend to draw it relatively straight.”). Patent Owner asserts “Petitioner provides no explanation or basis for its contention that a straight line can have an inflection point.” PO Resp. 62.

Petitioner replies: “In fashioning an argument based on where the inflection point of the S-curve in Figure 3 of *Heintl* would be, [Patent Owner] ignores Petitioner’s actual argument and evidence.” Pet. Reply 21 (emphasis by Petitioner). Petitioner asserts “Petitioner did not rely on the inflection point of Heintl, but rather” relied on Kay’s disclosure to establish the obviousness of locating an S-curve medial line inflection point in the waist section of Kay’s central trunk 12 between screw holes 14. *Id.* (quoting Pet. 41–42, and citing Ex. 1001 ¶¶ 123–126 and Ex. 1006 ¶ 47).

We determine Petitioner’s Reply overlooks the assertion in the Petition that, in Heintl’s Figure 3, “the inflection point where the direction of the curve changes is located at the mid-point of the orthopedic plate, between the screw holes, at approximately the location to which the arrow from element 5 is pointing.” Pet. 40–41; Ex. 1001 ¶ 124. Patent Owner challenged this assertion in the Preliminary Response, but we determined the assertion was sufficiently supported to justify institution of trial. Inst. Dec. 24–25. Based on Petitioner’s Reply, we understand Petitioner now to have withdrawn any reliance on Heintl as disclosing an S-curve medial line having an inflection point located between two screws holes of a central

¹² We have been unable to locate Exhibit 2 from Mr. Castañeda’s deposition in the record of this proceeding.

trunk portion. We consider Petitioner's contentions as to obviousness in this regard below in Section IV.D.4(e).

d) Whether It Would Have Been Obvious to Modify Kay's Plate to Have an S-Curve Medial Line, in light of Heintl

The Petition contends, as to the obviousness of modifying Kay in light of Heintl, that Kay discloses several plates having various pre-contoured shapes, each of which can be bent or molded into a more optimal shape for a particular small bone procedure. Pet. 31, 38 (citing Ex. 1006, Abstract, Figs. 1–5 & 9–31, ¶¶ 7, 47); Ex. 1001 ¶¶ 86, 119, 121. The Petition asserts this disclosure would have motivated a person of ordinary skill in the art to look for other examples of pre-contoured plate shapes that are appropriate for use in small bone procedures. Pet. 31–32, 39; Ex. 1001 ¶¶ 121–122. The Petition then points to Heintl's Figure 3 as demonstrating an S-shape is an appropriate pre-contoured plate shape for use with some small bones, so a person of ordinary skill in the art "would have been motivated to apply the S-shape of Heintl to the bone plate of Kay." Pet. 32, 39–40 (citing Ex. 1009, 1:62–2:3); Ex. 1001 ¶¶ 120–122. The Petition concludes this could be accomplished by bending plate 10 at its central waist area, either laterally, or longitudinally in and out of the plane of the plane of plate 10. Pet. 32, 41–42 (citing Ex. 1006 ¶ 47); Ex. 1001 ¶¶ 122, 125–126.

Patent Owner responds, in part, that the foregoing contentions of obviousness overlook that claim 1 specifies the plate must be "pre-contoured" to have an S-curve medial line. PO Resp. 60–61; Sur-reply 2–3, 5. According to Patent Owner, the Petition is limited to asserting the obviousness of reaching the claimed invention by the individualized contouring achieved by a surgeon bending a pre-contoured

plate, in which case, the plate is not pre-contoured to have an S-curve medial line. PO Resp. 60–61 (citing Pet. 38, 40); *see also id.* at 52–54 (same, citing Pet. 31–32); Sur-reply 2–3, 5.

Petitioner replies that Patent Owner “ignores or selectively excerpts the Petition,” thereby mischaracterizing the Petition’s contentions. Pet. Reply 1, 13–15, 19–21. Petitioner cites the Petition’s contention that “it would have been obvious to POSITAs to *pre-contour* Kay’s orthopedic plate such that the medial line describes an S-curve in a lateral or longitudinal plane.” *Id.* at 15, 19 (quoting Pet. 32) (emphasis added in Reply). Petitioner acknowledges that the Petition cites disclosures of Kay pertaining to a surgeon’s bending of a pre-contoured plate in relation to obviousness, but asserts this merely establishes that Kay recognizes the need to provide a plate having an optimal shape that matches the bone to be repaired, regardless of whether the shape is provided in a pre-contoured plate or the subsequent individualized contouring of a pre-contoured plate. *Id.* at 19–21 (stating “the same features that would make a plate suitable for individual contouring would be of assistance when pre-contouring the plate”).

Upon review of the foregoing, we conclude that while the Petition could have more clearly articulated Petitioner’s position on obviousness, the clarifications provided in the Reply properly respond to objections raised in the Patent Owner Response without improperly exceeding the scope of the Petition. Reading the Petition and the Reply together, Petitioner’s position is that it would have been obvious, in light of the combined disclosures of Kay and Heintl, to provide a pre-contoured plate having the shape of plate 10 with the addition of an S-curve medial line in the lateral plane, prior to any

individualized contouring achieved by a surgeon bending plate 10 for use with a particular patient. *See* Pet. 31–32, 38–40; Pet. Reply 13–17, 19–21; Tr. 35:17–36:12. For the following reasons, we determine this contention is supported by a preponderance of the evidence.

We find Kay discloses plate 10 is pre-contoured into the shape shown in Kay’s Figure 1. Ex. 1006 ¶¶ 7–8, 46, 51; *see* Pet. 31–32, 38; Pet. Reply 14–15. Kay also discloses several other plates, having various different pre-contoured shapes. Ex. 1006, Figs. 9–31, ¶¶ 23–45; *see* Pet. 38; Ex. 1001 ¶ 119. These various shapes accommodate a wide variety in the exact shape and mass of various small bones. Ex. 1006 ¶¶ 5, 7–8.

Thus, according to Kay, several differently pre-contoured plates are “presented for example in a surgical tray as a system of plates,” which “allows the surgeon to select his plate during surgery after opening the wound area and considering the plating needs.” *Id.* ¶ 8. In this way, the surgeon picks out a pre-contoured plate that most closely matches a need within a particular patient, and the surgeon may bend the chosen plate into a different shape to provide an even more optimal match for the patient’s need. *Id.* at Abstract (“The plate facilitates three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape.”); *id.* ¶ 7 (“The plate is 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.* ¶ 11 (“The radiused [sic., radiused] configuration of the plate is designed to increase operating room efficiency by facilitating commonly desirable shapes while maintaining the required strength and by permitting bending without

deforming the screw holes,” which “results in making customization in anticipation or during surgery easier.”); *id.* ¶¶ 14, 47, 51.

Heinl, meanwhile, discusses how pre-contoured plates that are flat “must be adapted to specific requirements by, at least partially, bending them, during the operation with a suitable set of instruments,” which can disadvantageously add “a considerable extension to the operation time.” Ex. 1009, 1:22–32; *see* Pet. 32, 39; Pet. Reply 15, 19–20. Heinl seeks to reduce the time required to bend plates in the operating room by providing “a set of surgical instruments for joining bone fragments . . . comprising several plates of different shapes and curvatures.” Ex. 1009, Abstract, 1:42–50; *see* Pet. 32, 39; Pet. Reply 15, 17; Ex. 1001 ¶¶ 95–97, 120. “It is thus possible for the surgeon, taking into account the particular anatomical conditions and also the particular statical proportions, . . . to select the plate best suited for its shape and form and use it immediately.” Ex. 1009, 1:66–2:6; *see* Pet. 32, 39; Pet. Reply 15, 17, 19–20.

Heinl also contemplates that, once the surgeon selects a pre-contoured plate, the surgeon may modify the selected plate by bending it for use with a particular patient. Ex. 1009, Abstract (disclosing that Heinl’s set of surgical instruments may include “a bending instrument”), 1:47–51 & 8:8–29 (same). According to Heinl, by allowing the surgeon to select an optimally pre-contoured plate before performing any bending operations, “[t]he adapting or bending operation, which was previously generally necessary, is then largely made superfluous, so that much faster work is possible.” *Id.* at 1:62–2:6; *id.* at 2:11–17 (“[T]he curvature of the plates will be approximately adapted to subsequent conditions” so that “[a]daptation of the

plates with the aid of the bending instrument to the respective curvatures is then largely eliminated.”); *see* Pet. 32, 39; Pet. Reply 15, 19–20.

In light of the foregoing, we agree with Mr. Castañeda’s testimony that Kay’s stated goal, to provide a set of plates that are pre-contoured differently to suit the different shapes of small bones, would have motivated a person of ordinary skill in the art to seek out other pre-contoured plate shapes to supplement Kay’s collection. Ex. 1001 ¶¶ 119, 221; Pet. 31–32, 38–40; Pet. Reply 14, 20–21. Heintl provides several such pre-contoured plates, one of which is shown in Heintl’s Figure 3 to have a medial line that describes an S-curve in the lateral plane, to match the individual contours of particular bones. Ex. 1001 ¶¶ 95–97, 120; Pet. 32, 39–40. Based on the overlapping disclosures of Kay and Heintl in this regard, Mr. Castañeda’s testimony that “[i]t would have been obvious to a POSITA to pre-contour Kay’s orthopedic plate such that the medial line describes an S-curve in a lateral or longitudinal plane in view of the teachings of Heintl” is persuasive and supported by the evidence. Ex. 1001 ¶ 121; Pet. 32, 39–40; Pet. Reply 13–14, 16–17, 19–20.

Further, and in the alternative to the foregoing, we acknowledge Patent Owner’s position that Kay’s plate 10 includes a medial line describing an S-curve in the lateral plane. PO Resp. 36–48. Even if we were to agree with this position over Petitioner’s opposition (*see* Pet. Reply 5–12), the result would be that Kay is prior art because the 2006 Application does not disclose any plate having a medial line describing an S-curve in a longitudinal plane. *See supra* Section IV.C. Further, there would be no need to modify Kay’s plate 10 to have an S-curve in the lateral or longitudinal plane, because the plate already exhibits an S-curve medial

line in the lateral plane. Thus, even if we were to agree with Patent Owner's position that Kay's plate 10 includes a medial line describing an S-curve in the lateral plane, still claim 1 would be obvious over Kay and Heintl, even though Heintl would not be needed to establish obviousness in this regard.

We have considered Patent Owner's counter-arguments concerning obviousness, but we do not find them persuasive. *See* PO Resp. 3–4, 52–60, 61–62; Sur-reply 1–5, 22–26. Patent Owner firstly argues Petitioner has not established a motivation for combining Kay and Heintl to reach the invention of claim 1. *See* PO Resp. 52–57; Sur-reply 22–23. Patent Owner asserts Petitioner provides no reason why a person of ordinary skill in the art would have modified “the trunk of Kay to include the shape of the entire plate (trunk and arms) of Heintl.” PO Resp. 54. Patent Owner also asserts Heintl teaches “away from individualized contouring of bone plates,” such as is disclosed by Kay. *Id.* at 56–57 (citing Ex. 1009, 1:27–33, 1:38–41, 2:4–6, 2:15–17); Ex. 2017 ¶ 88; Ex. 2018 ¶ 87.

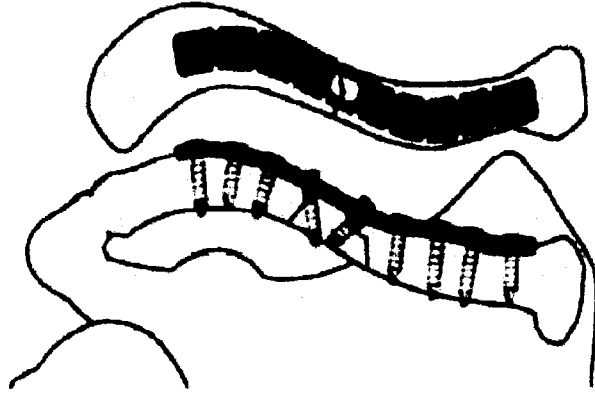
Petitioner replies that Patent Owner misinterprets Petitioner's arguments as relying on the bodily incorporation of Heintl's plate 5 into Kay's plate 10, which is not required by the law. Pet. Reply 1–2, 13, 16 (citing *In re Mouttet*, 686 F.3d 1322, 1332–33 (Fed. Cir. 2012)). Petitioner also argues Heintl's disclosure supports, rather than teaches away from, the proposed combination with Kay. *Id.* at 15.

We agree with Petitioner. As discussed in detail above, Kay and Heintl disclose respective bone plate systems that both present several pre-contoured plates to a surgeon in an operating room, with the plates having different shapes, which may likely be useful in repairing small bone fractures. This overlapping disclosure would have motivated a person of

ordinary skill in the art to consider improving upon Kay's system by incorporating one or more pre-contoured plate shapes disclosed by Heintl, thereby increasing the usefulness and efficiency of Kay's system. This includes incorporating Heintl's S-shape into Kay's plate 10, as Petitioner proposes. Further, Kay and Heintl both indicate the surgeon may fine tune the selected plate shape by bending it for use with a particular patient, with the pre-contouring reducing the amount of time such individualized contouring in the operating room will require. *See* Ex. 1006, Abstract, ¶¶ 7–8, 11, 14; Ex. 1009, Abstract, 1:62–2:17, 8:8–29. In short, Kay and Heintl would lead a person of ordinary skill in the same direction, not different directions.

Patent Owner secondly argues “Petitioner fails to provide any explanation or supporting evidence as to *how*” Kay's plate 10 could be modified, to “transform the plate from having an X-shape in the lateral plane to having an S-shape in the lateral plane as disclosed by Heintl.” PO Resp. 57–58; Ex. 2017 ¶ 92; Ex. 2018 ¶ 91. According to Patent Owner, “Petitioner has failed to carry its burden” to set forth an obviousness analysis “in sufficient detail to demonstrate that the result of the proposed combination meets the limitations recited in” claim 1. Sur-reply 4, 10, 22–23.

In reply, Petitioner cites Mr. Castañeda's testimony 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.” Ex. 1001 ¶¶ 41, 121 (citing Exs. 1009, 1020, & 1022); Pet. Reply 14. As further support for this testimony, Petitioner cites the following figure from Exhibit 1070. Pet. Reply 14–15, 17.



Excerpt from Exhibit 1070 (page 4), Figure 4.1-7(a).

The above figure shows how a midshaft fracture of a clavicle may be fixed with a 9-hole reconstruction plate, which according to Petitioner has an S-curve medial line in the lateral plane (top view at top of figure) and in the longitudinal plane (side view at bottom of figure). Ex. 1070, 4; Pet.

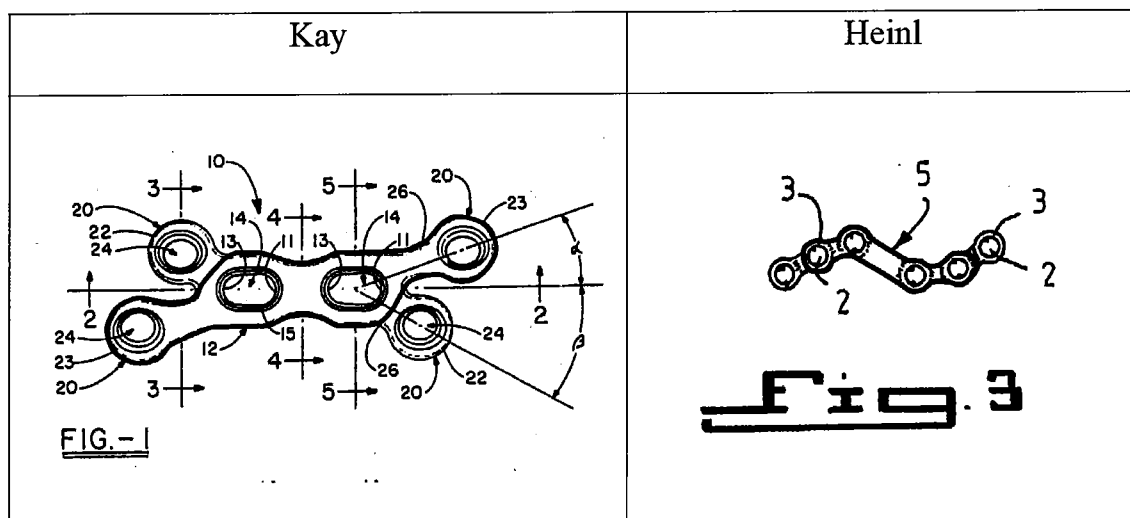
Reply 17. Petitioner also cites Mr. Harrigan's deposition testimony that persons of ordinary skill in the art in February 2009 "would have known how to use plates in general and S-shaped plates when they're appropriate," and "the clavicle generally has an S shape." Ex. 1066, 110:18–111:13; Pet. Reply 17. Petitioner concludes: "POSITAs starting with Kay's plate (a plate similar to the plate shown in [Exhibit 1070] above, but straight and with two added asymmetrical 'arms' at each end of the plates) would have known to pre-contour the Kay plate into the shape shown in [Exhibit 1070], but with arms at the ends, based on the disclosure of Heidl" Pet.

Reply 17 (citing Pet. 6, 31–32, 38–42; Ex. 1001 ¶¶ 41, 119–122).

Upon review of the foregoing, we conclude Petitioner has met its burden to explain, with particularity and with supporting evidence, how the combination of Kay and Heidl would have led a person of ordinary skill in the art to the invention recited in claim 1. 35 U.S.C. §§ 312 & 316(e);

37 C.F.R. § 42.22(a)(2). Petitioner contends it would have been obvious to modify the central trunk portion 12 of Kay's plate 10 to exhibit an S-curve medial line in the lateral plane, such as shown for example in the top view of Exhibit 1070 reproduced above, while retaining Kay's four diverging arms 20 at the terminal ends of trunk portion 12. *See* Pet. Reply 17; Tr. 36:13–37:4, 72:16–73:7. This exemplary modification of Kay's plate 10, in light of Heintl's disclosure, would embody the invention of claim 1.

In contrast to the above-discussed position that Kay's plate 10 has an X-shape, Patent Owner thirdly argues Petitioner and Mr. Castañeda “ignore[] the fact that the pre-contoured plate of Kay includes the same S-shaped footprint of Heintl, including the location of the screw holes, without the need for further” modification. PO Resp. 54–55 (citing Pet. 3–7, 31–32; Ex. 1001 ¶¶ 121–122; Ex. 1009, 4:8–16; Ex. 2019, 36:23–24); Sur-reply 22–24; Ex. 2017 ¶¶ 85–86; Ex. 2018 ¶¶ 84–85. In support, Patent Owner provides the following annotated comparison of Kay's Figure 1 and Heintl's Figure 3 (PO Resp. 55):



Kay Figure 1 and Heintl Figure 3 (Annotated by Patent Owner).

As illustrated above, Patent Owner has outlined in red the respective portions of Kay's plate 10 and Heintl's plate 5 that Patent Owner contends achieve the same result when attached to a bone, such that there is no need to modify the former in light of the latter. PO Resp. 55–56; Sur-reply 22–24; Ex. 2017 ¶¶ 85–87; Ex. 2018 ¶¶ 84–86. According to Patent Owner: “the selection of plates is driven by concordance of the shape of the plate and location of the screw holes with the particular bone to be repaired.” PO Resp. 55 (citing Ex. 1009, 4:8–16; Ex. 1001 ¶¶ 121–122; Ex. 2017 ¶ 86; Ex. 2018 ¶ 85).

Petitioner disputes Patent Owner's contention that Kay's plate 10 has an S-curve that would accommodate the same anatomical conditions as Heintl's S-curve plate 5, referring back to Petitioner's arguments relating to priority, discussed above. Pet. Reply 15, 16; *see supra* Section IV.C.

On this point, we find Mr. Castañeda's testimony to be more persuasive than that of Dr. Neufeld and Mr. Harrigan. We, like Mr. Castañeda, perceive a material difference in the curvature of the screw hole configurations respectively provided by Kay's plate 10 and Heintl's plate 5, such that modifying the former in light of the latter would have achieved a material benefit. Ex. 1001 ¶¶ 119–121. In particular, we do not agree with Dr. Neufeld's and Mr. Harrigan's testimony that the portions of the two plates circled in red in Patent Owner's annotations above are “the same . . . without the need for further bending.” Ex. 2017 ¶¶ 85–87; Ex. 2018 ¶¶ 84–86. Instead, we perceive that the shape defined by the screw hole alignment in Heintl's plate 5 has a much more pronounced curvature than the shape defined by the screw hole alignment in Kay's plate 10. That is, even assuming Kay's plate 10 incorporates an S-shaped screw hole

pattern as is found by Dr. Neufeld and Mr. Harrigan, it is a much flatter S than the S provided in Heintl's plate 5.

Patent Owner fourthly argues Petitioner fails to establish that the combination of Kay and Heintl would lead to a plate having "a central trunk portion . . . defining a longitudinal trunk axis extending between a first end and a second end," as recited in claim 1. PO Resp. 58–60 (citing Pet. 35–36, 52; Ex. 1001 ¶ 115). Patent Owner points out Petitioner cites Kay's plate 10 as having the claimed central trunk portion 12, but then Petitioner proposes to *modify* plate 10 to have the claimed S-curve medial line, by adding a bend in the plate in the waist area of trunk 12 between screw holes 14. *Id.* at 58–59. According to Patent Owner, "Petitioner provides no explanation or supporting evidence" that modifying Kay's plate 10 in this manner would maintain a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end in the pre-contoured plate. *Id.* at 59–60; Ex. 2017 ¶ 94; Ex. 2018 ¶ 93.

Petitioner replies that, "regardless of whether the trunk of Kay's plate is straight or includes an S-curve along the medial line in the lateral or longitudinal plane, it includes a longitudinal trunk axis." Pet. Reply 18–19 (citing Ex. 1002, 3:24–27, 6:62–66; Ex. 1006 ¶ 7). In support, Mr. Castañeda testifies that "a POSITA would have understood that the 'longitudinal trunk axis' of an orthopedic plate is the axis that runs the length of the plate from one end to the other." Ex. 1001 ¶ 115.

We agree with Petitioner. As discussed in detail above, Petitioner proposes modifying Kay's plate 10 to have a medial line describing an S-curve in the lateral plane. Even if this modification results in central trunk portion 12 having one or more curves or bends in the lateral plane, similar to

the top view illustration of the clavicle plate shown in Exhibit 1070 (reproduced above), the modified trunk would still have a longitudinal axis. Patent Owner does not cite, and we cannot find, any disclosure in the '443 patent that requires the longitudinal axis of the trunk to be straight, without any curves. Indeed, the '443 patent disclosure is to the contrary. *See, e.g.*, Ex. 1002, 3:7–11, 3:24–27, 6:62–7:1, 8:67–9:30 (describing central trunk 212 of plate 210 shown in Figures 12–17 as having “a longitudinal axis” despite the “slight longitudinal curve” seen in Figure 15), 10:40–11:16 (describing central trunk 412' of plate 410' shown in Figures 36–41 as having “a longitudinal axis” despite “curv[ing] gently in the direction of the shorter arms” 413' as seen in Figure 37).

Patent Owner fifthly argues that modifying Heintl's plate 5 or the plate of Exhibit 1070 by adding an arm at each end of the respective plate would lead to “an X-shaped plate—not an S-shaped plate.” Sur-reply 24–26 (annotating the figures for illustration). This argument is not persuasive because it misconstrues Petitioner's case, which posits that it would have been obvious to modify Kay's plate 10 in the fashion claimed, not Heintl's plate 5 or the plate of Exhibit 1070. Also, as Patent Owner points out in connection with the priority dispute, claim 1 requires the medial line of the plate, and not the plate itself, to be S-shaped. *See* PO Resp. 18–20, 23–25.

For the foregoing reasons, we determine a preponderance of the evidence establishes that it would have been obvious to modify Kay's pre-contoured plate 10 to have an S-curve medial line, in light of Heintl.

e) *Whether It Would Have Been Obvious for an Inflection Point of the S-Curve Medial Line to be Located Between Two Screw Holes of the Central Trunk Portion*

Petitioner argues that, when modifying Kay's plate 10 to have an S-curve medial line in the lateral plane in light of Heintl, it would have been obvious to locate an inflection point of the S-curve between screw holes 14 of central trunk portion 12 of Kay's plate 10. *See* Pet. 31–32, 40–42; Pet. Reply 21. Specifically, Petitioner asserts it would have been obvious to locate the inflection point at the “decreased width . . . waist area” between screw holes 14, because Kay discloses this area is designed to bend laterally or longitudinally to form a curved area in plate 10, and to facilitate twisting of plate 10. Pet. 31–32, 35, 41–42 (citing Ex. 1006 ¶ 47); Pet. Reply 21; Ex. 1001 ¶¶ 114, 122–123, 125–126.

Patent Owner's opposition is limited to disputing whether Petitioner errs in citing Heintl's S-shaped plate 5 as having an inflection point located between two screw holes of a central trunk portion. *See* PO Resp. 61–62. Patent Owner does not address Petitioner's additional obviousness analysis relying on Kay in this regard. *See id.* As discussed above in Section IV.D.4(c), in response to Patent Owner's argument, Petitioner has withdrawn any reliance on Heintl as disclosing the claimed location of an S-curve inflection point, opting instead to rely on the combination of Kay and Heintl leading to obviousness. *See* Pet. Reply 21.

We determine Petitioner's case for obviousness is supported by a preponderance of the evidence. Based on the overall shape of Kay's plate 10 as shown in Figure 1 of Kay, a person of ordinary skill in the art, when modifying plate 10 to have an S-curve medial line in the lateral plane as suggested by Heintl, would naturally provide an inflection point of the

S-curve in the central region of plate 10 between screw holes 14. Kay itself discloses that this region is an easy and beneficial location to implement variations in the shape of plate 10 to conform to bone shapes found in the human body. Ex. 1006 ¶ 46; Ex. 1001 ¶¶ 122–123, 125–126.

Thus, we determine a preponderance of the evidence establishes it would have been obvious to locate an inflection point of the S-curve medial line between screw holes 14 of central trunk portion 12 of Kay's plate 10.

f) Conclusion as to Claim 1

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

5. Claim 7

Claim 7 depends from claim 1 and recites: “each arm of the pair having a longitudinal arm axis which extends between the central screw axis and a point on the longitudinal trunk axis so as to define an angle with respect to the longitudinal axis of the central trunk portion.” Ex. 1002, 12:9–14.

Petitioner relies on the arguments above in relation to the subject matter recited in parent claim 1, and contends “Kay discloses the additional limitation of claim 7.” Pet. 47; Ex. 1001 ¶¶ 136–138. In particular, Petitioner asserts Kay's plate 10 has four arms 20, each of which is joined to trunk portion 12. Pet. 47–48 (citing Ex. 1006, Fig. 1, ¶ 51); Ex. 1001 ¶ 137. Further according to Petitioner, each arm 20 has a longitudinal axis extending from the trunk's longitudinal axis to a screw hole 24 on arm 20, such that the arm's longitudinal axis defines an angle with respect to the

trunk's longitudinal axis. Pet. 48–49 (citing Ex. 1006, Fig. 1, ¶ 48); *id.* at 49 (annotating Kay's Figure 1 to identify the two arms' longitudinal axes in blue, and the trunk's longitudinal axis in green); Ex. 1001 ¶ 138.

Patent Owner argues: “Petitioner bases all of its arguments [for claim 7] on the plate of Figure 1 of Kay without any consideration as to how the plate of Kay, contorted in view of Heinl to meet the S-curve limitation [recited in parent claim 1], also meets the additional limitation recited in” claim 7. PO Resp. 62–65 (citing Pet. 48). According to Patent Owner, a person of ordinary skill in the art “would have understood any compound bending of Kay at the waist as relied upon by Petitioner in order to achieve the S-shape of Heinl would result in a longitudinal trunk axis non-congruent with the longitudinal trunk axis of Kay in Figure 1.” *Id.* at 64; Ex. 2017 ¶ 97; Ex. 2018 ¶ 96.

Petitioner replies that it “does not matter” that central trunk 12 of Kay's plate 10 will have a different longitudinal axis than the one identified by Petitioner in the (unmodified) plate 10 shown in Figure 1. Pet. Reply 22. Petitioner asserts that, even if plate 10 is modified to include an S-curve medial line, each arm 20 will still have its own longitudinal axis, and each arm longitudinal axis will define an angle with the modified longitudinal axis of the central trunk, “because the arms extend asymmetrically from the trunk.” *Id.*

We agree with Petitioner. As discussed above in Section IV.D.4(d) in connection with the central trunk longitudinal axis limitation of claim 1, the modified trunk in Petitioner's combination would still have a longitudinal axis, and each arm 20 would still extend diagonally away from the central trunk. Thus, the modified plate would satisfy the additional limitation in

claim 7 for an angle to exist between each arm's longitudinal axis and the central trunk's longitudinal axis. We conclude a preponderance of the evidence establishes it would have been obvious to combine Kay and Heintl in the manner recited in claim 7, so the claim is unpatentable under 35 U.S.C. § 103.

6. *Claims 3–6, 8, 15, 19, and 26*

Petitioner provides arguments and evidence, including testimony from Mr. Castañeda, in support of contending claims 3–6, 8, 15, 19, and 26 are unpatentable as having been obvious over Kay and Heintl. *See* Pet. 42–47, 49–54; Ex. 1001 ¶¶ 127–135, 139–141, 155–158, 176–186.

Patent Owner asserts, in a general fashion, that “Petitioner bases all of its arguments on the plate of Figure 1 of Kay without any consideration as to how the plate of Kay, contorted in view of Heintl to meet the S-curve limitation [recited in parent claim 1], also meets the additional limitation recited in” dependent claims 3–6, 8, 15, and 19. PO Resp. 62–65. Petitioner replies, correctly, that Patent Owner's analysis in support of this assertion addresses only claim 7. Pet. Reply 22 n.2.

Patent Owner also does not address independent claim 26 separately from the arguments discussed above in connection with similar subject matter recited claim 1. *See, e.g.*, PO Resp. 1, 15–16, 51, 58, 60 (treating claims 1 and 26 together as a group).

Thus, Patent Owner does not present any argument for claims 3–6, 8, 15, 19, and 26 other than what we have already considered above with respect to claim 1. *See LG Elecs.*, 759 F. App'x at 925 (“The Board is ‘not required to address undisputed matters’ or arguments about limitations with

which it was never presented.”); *Papst*, 924 F.3d at 1250; *Bradium*, 923 F.3d at 1048. After considering the evidence and arguments of record, we determine Petitioner has demonstrated by a preponderance of the evidence that these claims would have been obvious over Kay and Heintl.

V. SUMMARY OF CONCLUSIONS

In summary, we determine a preponderance of the evidence establishes claims 1, 3–8, 15, 19, and 26¹³ of the ’443 patent are unpatentable,¹⁴ as shown in the following table:

| Claims | 35 U.S.C. § | References | Claims Shown Unpatentable | Claims Not Shown Unpatentable |
|--------------------|--------------------|-------------------|----------------------------------|--------------------------------------|
| 1, 3–8, 15, 19, 26 | 103 | Kay, Heintl | 1, 3–8, 15, 19, 26 | |

¹³ As explained above in Section II.B, we do not address Petitioner’s challenges to claims 9–11 and 22–25 under 35 U.S.C. § 103, because Patent Owner disclaimed those claims prior to institution of trial.

¹⁴ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1, 3–8, 15, 19, and 26 of the '443 patent have been proven by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot as to Exhibits 1057–1060, 1073–1075, and 1081, and is denied as to Exhibit 1070; and

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

IPR2019-00894
Patent 9,144,443 B2

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