UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,

Petitioner

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,

Patent Owner

US. PATENT NO. 9,144,443

Case IPR2019-00894

PETITION FOR INTER PARTES REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

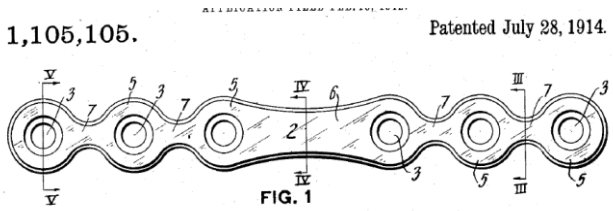
Regulations

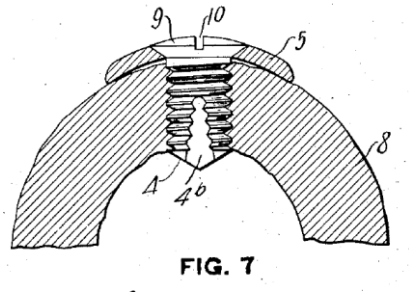
Other Authorities

Paragon 28, Inc. ("Paragon") requests *inter partes* review ("IPR") of Claims 1, 3-11, 15, 19, and 22-26 (the "Challenged Claims") of U.S. Patent No. 9,144,443 (the "'443 patent") (Ex. 1002.)

I. INTRODUCTION

The '443 patent, titled "Orthopedic Plates for Use in Clavicle Repair and Methods for Their Use," issued on September 29, 2015. Ex. 1002. The Challenged Claims combine two well-known and well-understood technologies—bone plates and bone screws—in a straightforward fashion that would have been obvious to a person of ordinary skill in the art ("POSITA"). For over a century, surgeons have utilized bone plates and bone screws to repair bone fractures, as shown in U.S. Patent No. 1,105,105, issued in 1914:





Ex. 1052, Figs. 1, 7.

The Challenged Claims utilize similar concepts and combine known plate shapes with known screw designs. The Challenged Claims include plates with divergent arms and S-curves, yet such plate designs have been known since at least the 1980s. The Challenged Claims also include screw holes with threads and cutouts

to help guide screws into place, yet such screw holes have been known since at least the early 2000s.

Though these plate designs were well-known since the 1980s, the non-provisional application that led to the '443 patent was not filed until January 2006 ("the 2006 application"), and was published on August 3, 2006. The initial application disclosed combining a well-known plate design (plates shaped like an X or Y) with a well-known screw design (non-locking screws without a threaded head). But there was nothing novel or non-obvious about this combination; POSITAs have been combining known plate shapes with known screw designs for over a century.

Despite the well-known nature of these shapes and screws, the 2006 application did not disclose a plate with an S-curve or screw holes with cutouts for guiding a screw. In 2009, seeking to expand its rights, the Applicant filed a continuation-in-part application ("2009 CIP application") and added new material, including a bone plate with an S-curve and a screw hole with guideways. The law, however, does not allow an Applicant to expand its rights in this manner. Once the 2006 application was published and available as prior art to the public, only novel or non-obvious subject matter could be patented.

The subject matter added to the 2009 CIP application, however, is anything but novel and non-obvious. S-curves and cutouts were well-known and an obvious variation on the plate design disclosed in the 2006 application. Using CIP

applications to patent obvious and non-novel variations of what was previously published and available to the public is counter to the law, and the Board should find the Challenged Claims unpatentable.

II. BACKGROUND OF INTERNAL FIXATION DEVICES

The Challenged Claims generally relate to the use of bone plates and screws to repair fractured bones. Ex. 1002, Claims. An untreated fractured, or broken, bone can lead to bone shortening, lack of bone alignment, formation of calluses, and limited mobility. Ex. 1001, ¶¶30-31. To prevent this, doctors treat bone fractures by stabilizing the bone in its correct position and alignment so that it behaves like an intact bone and can heal on its own. *Id*.

Stabilizing and repairing a fracture by attaching a mechanical device directly to the bone is known as "internal fixation." *Id.* The Challenged Claims are directed to an "orthopedic plate[]," which is an internal fixation device with two main components: the plate and the screws. *E.g.* Ex. 1002, Claim 1. Below is an overview of the state of the art of bone plates and screws as of the priority date of the Challenged Claims.

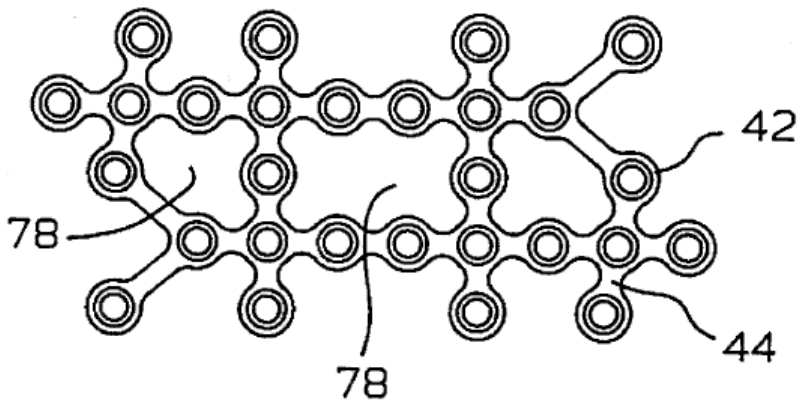
A. Bone Plates

Bone plates are useful to provide rigid fixation and compression, among other things. Ex. 1001, ¶32. Rigid fixation reduces the pressure applied to the bone,

stabilizes the fractures, and prevents further fracturing. *Id.* Compression aids in repairing the bone, while ensuring the bone is properly aligned. *Id.*

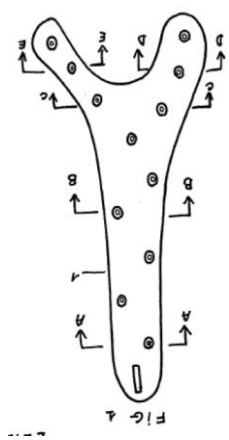
Bone plates come in a variety of materials and a variety of shapes depending on the fracture to be treated. *Id.*, ¶33. Plate materials vary based on the material's stiffness, strength, ductility, corrosion resistance, surface structure, and biocompatibility. *Id.* The majority, if not all, of bone plates have screw holes, including compression slots, to attach the plate to the bone. *Id.*, ¶34.

Plate size varies based on the anatomy of the person and the bone to be healed. *Id.*, ¶¶35-36. Because bones have different shapes, and humans have differently sized anatomy, POSITAs understood that plates could and should be shaped in a variety of configurations to permit the plate to attach to the bone in an advantageous manner. *Id.* Surgeons commonly used "multi-configurable plating system[s]" to shape the plate to the bone before or during surgery. *Id.*, ¶36. In one such system shown below, plates have screw holes connected by "linking members" that enable a user to "easily separate" the screw holes by "cutting along the appropriate linking members":

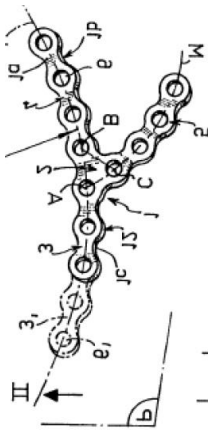


Ex. 1012, Abstract, Fig. 12, 2:59-65, 7:9-22; Ex. 1001, ¶¶37-38. Surgeons and POSITAs understood how to use these "linking members" to form "Y-shaped plates, T-shaped plates, X-shaped plates, and numerous other conventional and non-conventional shaped plates." Ex. 1012, 7:18-22.

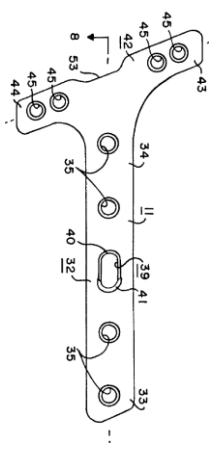
POSITAs also would have been familiar with bone plates having "two asymmetrical branches [] that diverge from each other" in which the "two branches have a different length and width." Ex. 1013, 3:21-24; Ex. 1001, ¶39. Numerous "diverging branch" plates were known in the art, prior to even the filing of the provisional application that eventually led to the '443 patent, as shown below:



Ex. 1013, Fig. 1 (1977)

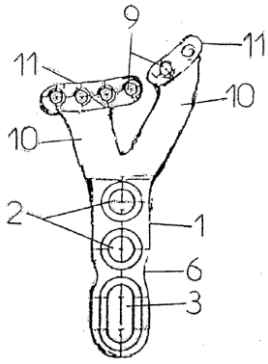


Ex. 1015, Fig. 1 (1987)



Ex. 1010, Fig. 1 (2000)

Ex. 1018, Fig. 1 (2001)



Ex. 1019, Fig. 3 (2004)

Plates with diverging branches were known to "ensure optimal adjustment to the bone structure without adversely affecting important anatomic structures of the bone." Ex. 1017, 2.

POSITAs also understood that plates forming an S-curve either in the lateral (i.e., when viewed from the top) or longitudinal plane (i.e., when viewed from the side), were particularly useful for treating fractures of the clavicle because its S-shape matched the contours of the clavicle bone. Ex. 1001, ¶41. Examples of plates with S-curves include:

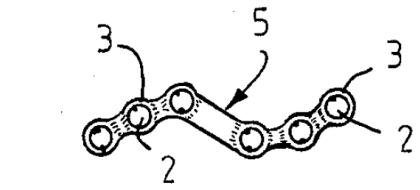
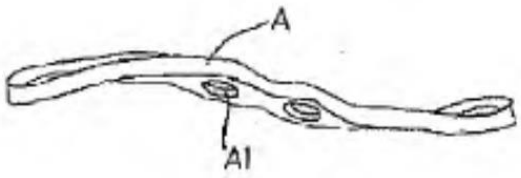
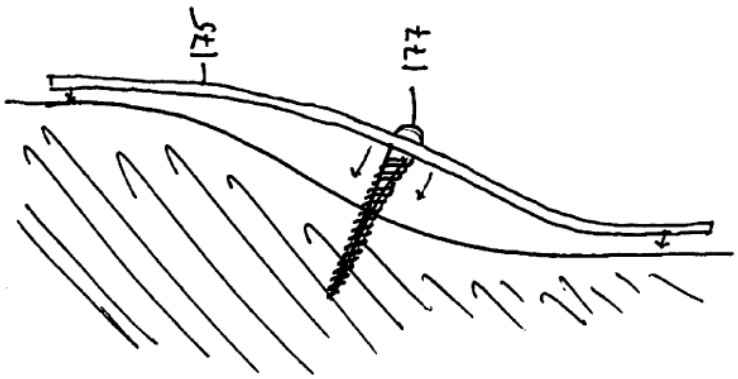


Fig. 3

Ex. 1009, Fig. 3 (1986) (S-curve in lateral plane)



Ex. 1020, Fig. 19 (2001) (S-curve in longitudinal plane)



Ex. 1022, Fig. 21b (2005) (S-curve in longitudinal plane)

B. Screws

POSITAs understood that bone plates should be fixed in position to be properly utilized. Ex. 1001, ¶42. One of the most common methods of ensuring bone plates remain fixed in position is to design a plate with screw holes and use screws to achieve fixation. *Id*. While there are many different types of screws used with bone plates, two broad categories of screws relevant here are non-locking and locking screws. *Id.*, ¶43. Non-locking screws, or conventional screws, have a threaded shaft with an unthreaded head, as shown below:

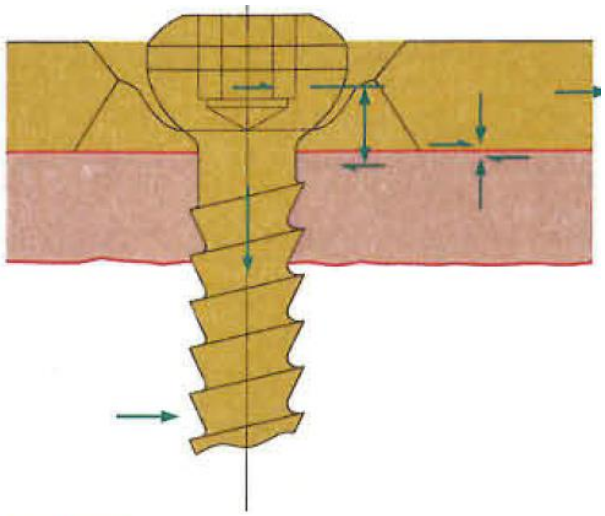


Fig. 1.2-20: Conventional plate screws

Ex. 1023, 18. Non-locking screws are held into position through compressive forces. Ex. 1001, ¶43. Locking screws, on the other hand, have a threaded head that "locks into" the screw hole and firmly holds the screw in place, as shown below:

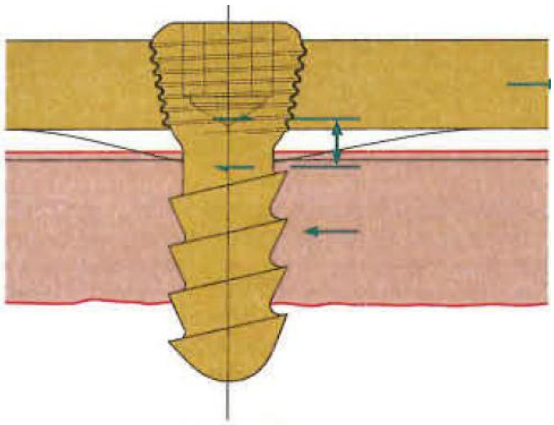
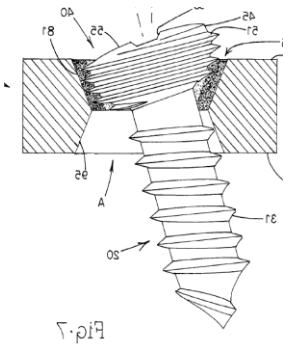


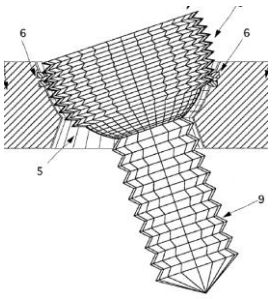
Fig. 1.2-21: Locked plate screws.

Ex. 1023, 18; Ex. 1001, ¶44. By the early 2000s, POSITAs were aware that both locking and non-locking screws could be utilized with bone plates depending on the type of fracture and desired fixation technique. Ex. 1001, ¶45.

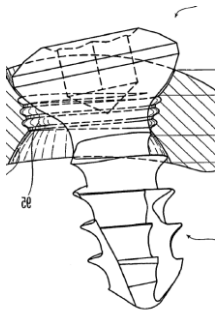
Screws can also be polyaxial, *i.e.* permitted to be inserted at a variety of angles, or monoaxial, *i.e.* permitted to be inserted at a single angle. *Id.*, ¶46. POSITAs used polyaxial screws to permit screws to be inserted at an optimal angle to achieve optimal compression and avoiding hitting other screws or problem areas (i.e., impingement). *Id.* Both locking and non-locking screws can be polyaxial, and POSITAs understood these were used to "secure[] [screws] to the bone plate at a selectable angle within a range of selectable angles." Ex. 1007, ¶72; Ex. 1001, ¶47. Below are examples of variable angle locking and non-locking screws:



Ex. 1024, Fig. 7 (2002) (polyaxial locking)

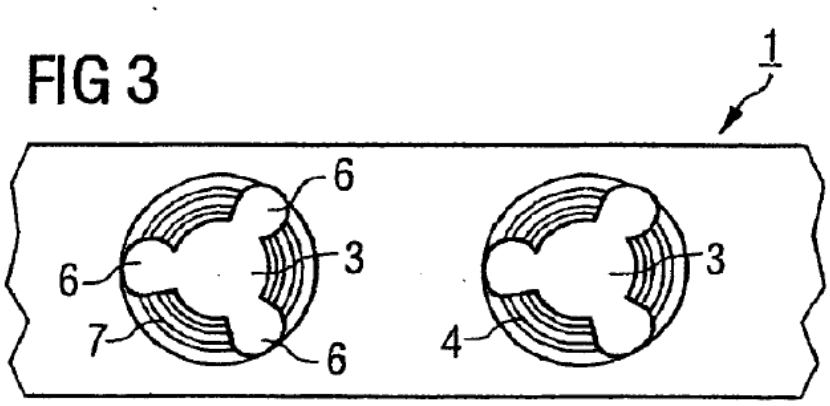


Ex. 1011, Fig. 10 (2004) (polyaxial locking)



Ex. 1025, Fig. 6B (2004) (polyaxial non-locking) (figure flipped)

In order to ensure the screw was guided into the screw hole at the desired angle, some plates also placed recesses in the screw hole so that "the bone screws can be guided during their insertion." Ex. 1008, ¶9; Ex. 1001, ¶48. An example of a plate with these recesses is shown below:



Id., Fig. 3; Ex. 1007, Figs. 20A-C, ¶80 (describing cutouts in a "cloverleaf design intended to accommodate a drill guide having a complementary drill-guide tip design").

III. PRIORITY DATE OF THE CHALLENGED CLAIMS

The 2009 CIP application added new matter to the 2006 application, including new matter claimed in the Challenged Claims. As a result, the earliest date to which the Challenged Claims can claim priority is February 24, 2009.

A. Legal Standard

To obtain the benefit of the priority date of an earlier application, the Challenged Claims must meet the requirements of 35 U.S.C. § 120. *In re Huston*, 308 F.3d 1267, 1276 (Fed. Cir. 2002). Section 120 permits a patent application to rely on the filing date of an earlier application "only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (quoting *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995)). Claims which depend on "[s]ubject matter that arises for the first time in [a] CIP application do[] not receive the benefit of the filing date of the parent application." *Id.* Thus, if "even a single feature" of a claimed invention was first disclosed in a CIP, and that feature is not inherent in the parent application, then the claim is only entitled to the filing date of the CIP. *Lockwood v. Am. Airlines, Inc.*, 877 F. Supp. 500, 507 (S.D. Cal. 1994), *aff'd* 107 F.3d 1565 (Fed. Cir. 1997). Once the party asserting invalidity presents invalidating prior art, the patentee has "the burden [] to come forward with

evidence to show entitlement to an earlier filing date." *Research Corp. Techs, Inc. v. Microsoft Corp.*, 627 F.3d 859, 871 (Fed. Cir. 2010)

If a CIP application is not entitled to the priority date of the original application, the original application is prior art to the CIP application and can be used to find the claims obvious under § 103. 35 U.S.C. § 102(b); *In re Chu*, 66 F.3d at 297-298 (finding the claims of a CIP application obvious in light of the parent's disclosure because the CIP was not entitled to the parent's priority date); *Application of Van Langenhoven*, 458 F.2d 132, 137 (C.C.P.A. 1972) (an applicant's own prior application "may properly be relied upon for all it fairly teaches to establish obviousness" if the applicant cannot claim the benefit of a filing date that precedes its own application); MPEP § 2133.01 ("When [an] applicant files a [CIP] whose claims are not supported by the parent application, …[a]ny prior art disclosing the invention or an obvious variant thereof having a critical reference date more than 1 year prior to the filing date of the child will bar the issuance of a patent under" § 102(b)).

B. Claims 1, 3-11, 15, 19, and 26 Are Not Entitled To The Priority Date Of The 2006 Application

Claims 1, 3-11, 15, 19, and 26 are not entitled to the priority date of the 2006 application because they recite an "S-curve" limitation that is not disclosed in the 2006 application.

Claim 1, and its dependent claims 3-11, 15, and 19, recite "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" (the "S-curve limitation"). Ex. 1002, Claim 1 (emphasis added). Similarly, Claim 26 recites "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." *Id*., Claim 26 (emphasis added).

In contrast, the 2006 application does not describe an S-curve, but instead describes the curvature of the claimed plate as being intended to "bend laterally (or 'curve') relative to the longitudinal axis," and to "bend longitudinally to form a curved area." Ex. 1006, ¶47; *see also id*., ¶7. The 2006 application discloses plates that "include[] a radial curve about the longitudinal axis" in Figures 3-5:

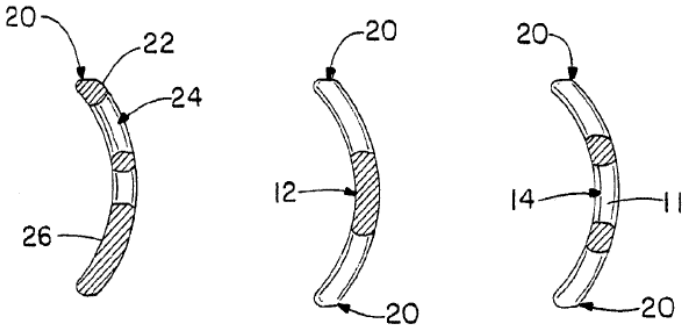


FIG.-3 FIG.-4 FIG.-5

Id., ¶52, Figs. 3-5. These figures from the 2006 application show what the '443 patent describes as "a c-shape lateral curve." Ex. 1002, 5:10-14.

However, the 2006 application does not disclose an S-curve. Review of the specification of the 2006 application confirms there is ***no*** reference to an S-curve, and there is no description in the 2006 application of why a POSITA would have wanted an orthopedic plate with an S-curve. *See generally* Ex. 1006. Indeed, the published claims of the 2006 application recite a plate with an "inferior surface…including a ***single continuous radius of curvature***." *Id.*, Claim 17 (emphasis added).

In contrast, the '443 patent specifically discloses an orthopedic plate with an S-curve, and why a POSITA would have wanted to have an orthopedic plate with an S-curve:

> Depending on the intended placement of the plate, the central trunk, and the plate itself includes a general topography (i.e. the contour in the z direction) designed to maximize the fit on a variety of shapes and sizes of clavicle while enabling, but reducing the need for individualized contouring. This topography includes a c-shape lateral curve in the superior and 4-hole anterior plates, a fishtail (i.e. having a broad curve in the direction of the bone-facing surface of the plate terminating in a short up-turned curve at the end of the plate) shape in the longer anterior plates. ***The lateral plate has an S-curve of the medial line in the direction of the width of the plate.***

Ex. 1002, 5:5-16 (emphasis added).

The figures of the 2006 application and '443 patent also illustrate the differences between the two disclosures. The 2006 application and '443 patent share many common figures. *Compare* Ex. 1006, Figs. 1-5, 28-31 *with* Ex. 1002, Figs. 1-5, 8-11. However, none of the figures of the 2006 application depict plates that have an S-curve. *See* Ex. 1006, Figs. 1-31. In contrast, Figures 21-23 of the '443 patent, which were added with the 2009 CIP application, depict an orthopedic plate with an S-curve:

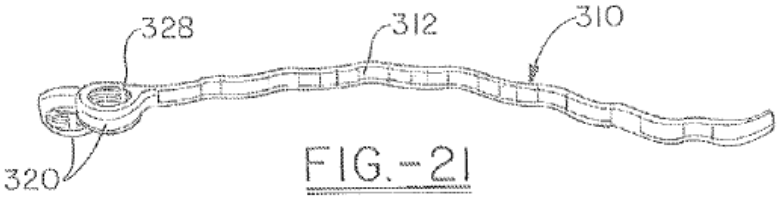


FIG.-21

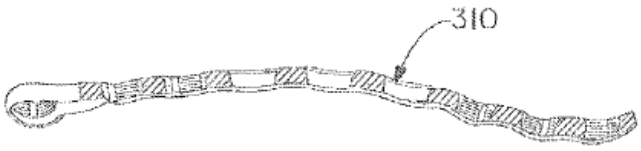


FIG.-22

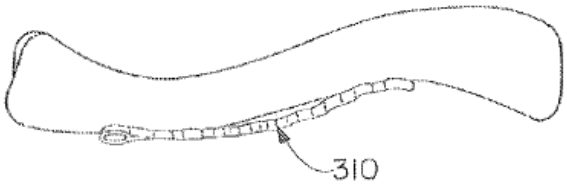


FIG.-23

Ex. 1002, Figs. 21-23.

Section 112 "requires that the written description actually or inherently disclose the claim element." *PowerOasis*, 522 F.3d at 1306-07 (citing *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111,

1118-20 (Fed. Cir. 2001)). "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed." *Lockwood*, 107 F.3d at 1571-72. Given that: (1) none of the figures in the 2006 application have an S-curve, (2) the detailed description of the 2006 application does not describe an orthopedic plate having an S-curve, and (3) the published claims of the 2006 application require its orthopedic plate only to have a "single continuous radius of curvature" (Ex. 1006, claim 17), a POSITA would not have understood the orthopedic plate disclosed in the 2006 application has an S-curve. Ex. 1001, ¶¶77-79. Absent any disclosure or description of an S-curve in the 2006 application, the written description of the 2006 application does not "actually or inherently disclose" an orthopedic plate with an S-curve. *See PowerOasis*, 522 F.3d at 1306-07.

The USPTO reached the same conclusion regarding the proper priority date of Challenged Claims 1, 3-11, 15, 19, and 26 during prosecution. The Examiner stated in a February 4, 2015 Office Action:

> The disclosure of the [2006 application] fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for [the claims] of this application. It is noted that the claimed subject matter has been presented for the first time in this application and is not supported in the prior-filed applications. For example, …***[the 2006 application] lacks any reference to an S-curve.***

…

> Accordingly, the effective filing date for the claimed subject matter in the current application is February 24, 2009.

Ex. 1030, 4. The Applicant did not contest this finding in its response to that Office Action. Ex. 1031, 8-10. In a Final Rejection, the Examiner again stated that the effective filing date for all claims of the '443 patent is February 24, 2009, and again the Applicant did not contest this finding. Ex. 1032, 3-4; Ex. 1033, 9-10; Ex. 1053, 2.

As independent Claims 1 and 26, and their dependent claims, include the "S-curve" limitation, they are not entitled to the priority date of the 2006 application. Therefore, the earliest priority date for Challenged Claims 1, 3-11, 15, 19, and 26 is the filing date of the 2009 CIP application: February 24, 2009.

C. Claims 9-11 and 22-25 Are Not Entitled To The Priority Date Of The 2006 Application

Independent Claim 22 of the '443 patent, its dependent Claims 23-25, and Claims 9-11, are not entitled to the priority date of the 2006 application for another reason: the claims recite that the system includes "a drill guide and the arm screw hole further includes guide ways for the drill guide." Ex. 1002, Claims 9, 22. The "drill guide [and] guide ways for the drill guide" limitation of Claims 9-11 and 22-25 is not supported by the 2006 application.

The words "drill," "guide," and "ways" do not appear anywhere in the 2006 application, let alone the phrases "drill guide" and "guide ways." *See generally* Ex. 1006. The figures of the 2006 application illustrate various orthopedic bone plates, and the screws used to secure them, but do not illustrate any sort of "drill guide" used to guide a drill. *Id.*, Figs. 1-31. The Abstract of the 2006 application states that the patent "relates to an orthopedic plate and screw system and instruments for surgical fixation of a small bone or bones," but nowhere does the 2006 application offer any description that these "instruments" include a drill guide. *Id*., Abstract.

In contrast, the '443 patent specifically discloses a drill guide and guide ways, also called "keyways": "These holes [in the plate] further include keyways 233 for the mating portion of a drill guide." Ex. 1002, 9:12-15; *see also id.*, 9:23-26, 9:41-45, 10:8-10, 10:52-54. Not only does the '443 patent disclose a drill guide and guide ways, it provides details about that drill guide that are entirely absent from the 2006 application, such as the why drill guides might be used: "to set the pilot hole for a locking screw received in these holes" and to set "the angle for the locking screw." *Id.*, 9:12-15, 9:23-26; *see also id.*, 9:41-45, 10:52-54. At least Figures 30-31, 37 (depicted below), and 42-43 of the '443 patent illustrate screw holes in the plate with guide ways for the drill guide:

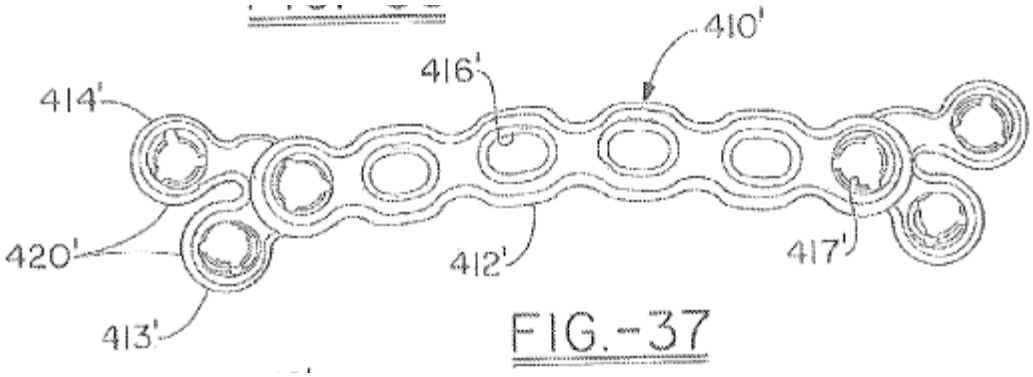


FIG.-37

Ex. 1002, Fig. 37. These figures are notably absent from the 2006 application.

The same legal requirements that preclude Patent Owner from being entitled to the 2006 priority date for S-curve limitations preclude Patent Owner from being entitled to the 2006 priority date for the "guideway" limitations. *See PowerOasis*, 522 F.3d at 1306-07; *Lockwood*, 107 F.3d at 1571-72 ("Entitlement to a filing date…extends only to that which is disclosed."). Given the lack of disclosure in the 2006 application regarding a drill guide, or guide ways for a drill guide, a POSITA would not have understood that the 2006 application discloses an orthopedic plate that included these features. Ex. 1001, ¶83. Absent any disclosure or description of guide ways for a drill guide (or even a drill guide) in the 2006 application, the written description of the 2006 application does not "actually or inherently disclose" a drill guide or an orthopedic plate with arm screw holes having guide ways for the drill guide. *See PowerOasis*, 522 F.3d at 1306-07.

The USPTO reached the same conclusion regarding the proper priority date of Challenged Claims 9-11 and 22-25 during prosecution. The Examiner stated in a February 4, 2015 Office Action:

> The disclosure of the [2006 application] fails to provide adequate support or enablement in the manner provided by the 35 U.S.C. 112 for [the claims] of this application. It is noted that the claimed subject matter has been presented for the first time in this application and is not supported in the prior-filed applications. For example, …[claim 22] includes the limitation of a "drill guide and an arm screw hole including guide ways for the drill guide." The [2006 application] also lack any reference to a drill guide.
>
> Accordingly, the effective filing date for the claimed subject matter in the current application is February 24, 2009."

Ex. 1030, 4. The Applicant did not contest this finding in its response to that Office Action. Ex. 1031, 8-10. In a Final Rejection, the Examiner again stated that the effective filing date for all claims of the '443 patent is February 24, 2009, and again the Applicant did not contest this finding. Ex. 1032, 3-4; Ex. 1033, 9-10; Ex. 1053, 2.

Therefore, Claims 9 and 22, and their dependent Claims 10-11 and 23-25, which include the "a drill guide and the arm screw hole further includes guide ways for the drill guide" limitation, are not entitled to claim priority to the 2006

application, and the earliest priority date is the filing date of the 2009 CIP application: is February 24, 2009.

D. Patent Owner Has Admitted Claims 10, 11, And 23 Are Not Entitled To The Priority Date Of The 2006 Application

In the related district court action, Case No. 1:18-cv-00691-PAB-STV (D. Colo.), the Local Patent Rules required Patent Owner to file a Response to Paragon's Invalidity Contentions, and to include an "identification of each limitation of a claim that [Patent Owner] believes is absent from the prior art." D.C.COLO.LPtR 10(b)(1).

In its Response to Paragon's Invalidity Contentions, Patent Owner stated the 2006 application "does not expressly disclose 'the guide ways are radially spaced grooves that form interruptions in the threads of the screw hole,'" as required by Claim 10 of the '443 patent and its dependent Claim 11. Ex. 1054, 62-65; *see also id*., 64-65. Patent Owner made a similar admission with respect to Claim 23. *Id.* (admitting the 2006 application "does not expressly disclose 'wherein the guideways include three equally spaced grooves wherein the grooves extend the length of the screw hole'")

By admitting that the 2006 application does not expressly disclose these limitations of Claims 10, 11, and 23 of the '443 patent, Patent Owner admitted that these claims are not entitled to claim priority to the 2006 application. Therefore,

these claims are only entitled to claim priority to February 24, 2009, both for the reasons stated above ***and*** because of Patent Owner's admission.

IV. IDENTIFICATION OF CHALLENGE: 37 C.F.R. § 42.104(B)

A. 37 C.F.R. § 42.104(b)(1): Claims for Which IPR is Requested

Paragon requests IPR of the Challenged Claims of the '443 patent.

B. 37 C.F.R. § 42.104(b)(2): The Specific Art and Statutory Ground(s) on Which the Challenge is Based

IPR of the Challenged Claims is requested in light of the prior art listed below. As explained above, the earliest priority date to which the Challenged Claims are entitled is February 24, 2009.

- U.S. Patent Pub. No. 2006/0173459 to Kay et al. ("Kay") (Ex. 1006), filed January 26, 2006, and published August 3, 2006. Kay is prior art under 35 U.S.C. § 102(b).[1]

- U.S. Patent No. 4,903,691 to Heinl ("Heinl") (Ex. 1009), filed January 21, 1987, and issued February 27, 1990. Heinl is prior art under 35 U.S.C. § 102(b).

- U.S. Patent Pub. No. 2006/0235400 to Schneider ("Schneider") (Ex. 1008), filed February 24, 2006, and published October 19, 2006. Schneider is prior art under 35 U.S.C. § 102(b).

Paragon requests IPR of the Challenged Claims on the following grounds:

[1] Cites to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version applicable here.

Ground	Claims	Description
1	1, 3-8, 15, 19, 26	Obvious under § 103 in view of Kay and Heinl
2	9-11	Obvious under § 103 in view of Kay, Heinl, and Schenider
3	22-25	Obvious under § 103 in view of Kay and Schneider

C. 37 C.F.R. § 42.104(b)(3): Claim Construction And Definition Of POSITA

Claims in an IPR are construed using the same claim construction standard used to construe claims in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). Claims should be construed in accordance with their ordinary and customary meaning as understood by one of ordinary skill in the art based on the intrinsic evidence. *Id.*

The parties have proposed constructions for some terms in the Challenged Claims in the related district court litigation. Paragon has submitted its opening brief, and Patent Owner has not yet submitted its responsive brief. A trial date has not yet been set for the pending district court litigation.

As Paragon explained in detail in that *Markman* brief (Ex. 1060), the manner in which Patent Owner is applying the claims to Paragon's products to support Patent Owner's allegations of infringement created a dispute over the scope of the claims as applied to Paragon's products. That same dispute is not present here, because as Paragon's expert explains in his declaration, the Challenged Claims are rendered

obvious by the prior art whether Paragon's or Patent Owner's proposed construction is applied. Ex. 1001, ¶¶105-107. Thus, Paragon does not believe construction of any terms are necessary for this proceeding.

For reference, the two parties' proposed constructions of terms relevant to the Challenged Claims are below:

Term	Patent Owner Proposed Construction	Paragon's Proposed Construction
arm	no construction necessary	a plate appendage configured to be bent without deforming any of its screw holes.
screw hole axis	no construction necessary or an "axis that extends longitudinally through the center of a bore through the plate	line through the center of a screw hole that is perpendicular to the top surface of the plate surrounding the screw hole
linking portion or link	no construction necessary or a "portion of the plate between plate features	portion of the plate that links two distinct parts of the plate
waist	no construction necessary or "area of the plate that is configured to facilitate bending of the plate"	portion of a linking section with a decreased width relative to the non-waist portion of the linking portion
trunk or trunk portion	no construction necessary or "a portion of the plate from which appendages extend."	the main body of the plate from which plate appendages extend
end	no construction necessary	the intersection of the edge of the plate and the longitudinal axis of the plate

The person of ordinary skill in the art contemplated by 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. Ex. 1001, ¶¶28-29.

D. 37 C.F.R. § 42.104(b)(4): How the Claims are Unpatentable

Paragon details in Section VIII below how the Challenged Claims are unpatentable.

E. 37 C.F.R. § 42.104(b)(5): Evidence Supporting Challenge

An Index of Exhibits is attached. Relevance of the evidence, including identifying the specific portions of the evidence that support the challenge, may be found in Section VIII. Paragon submits the declaration of Javier E. Castañeda, attached as Exhibit 1001, in support of this Petition in accordance with 37 C.F.R. § 1.68.

V. THE DISTRICT COURT LITIGATION

Paragon has filed this IPR after Patent Owner alleged that Paragon infringed over 140 claims from various patents in the family of the ’443 patent, including the Challenged Claims, in the related district court litigation. Paragon has repeatedly sought to reduce the number of claims at issue in that case, but Patent Owner has refused to limit its asserted claims, and the district court has refused to impose any limits. Ex. 1057; Ex. 1058. The District Court has rescheduled the month of its tentative *Markman* hearing to April 2019, though there is no firm date set, and the District Court has not yet scheduled a trial date. Ex. 1059.

VI. THE ASSERTED PRIOR ART

A. Kay

Kay is titled "Orthopedic Plate for Use in Small Bone Repair" and generally describes an "orthopedic plate and screw system and instruments for surgical fixation of a small bone or bones." Ex. 1006, 1. Kay is the published version of the 2006 application discussed above.

Kay discloses a plate system designed to allow a surgeon operating on small bones to use a variety of techniques and a customizable plate and screw. Ex. 1006, Abstract. Kay describes a bilaterally asymmetrical plate that allows for bi-planar screw fixation. *Id.*, ¶¶2-4. The plate can be bent laterally, longitudinally, or to "wrap or spiral about its longitudinal axis." *Id.*, ¶7. An example of one of the plates described by Kay is shown below in Figures 1-2.

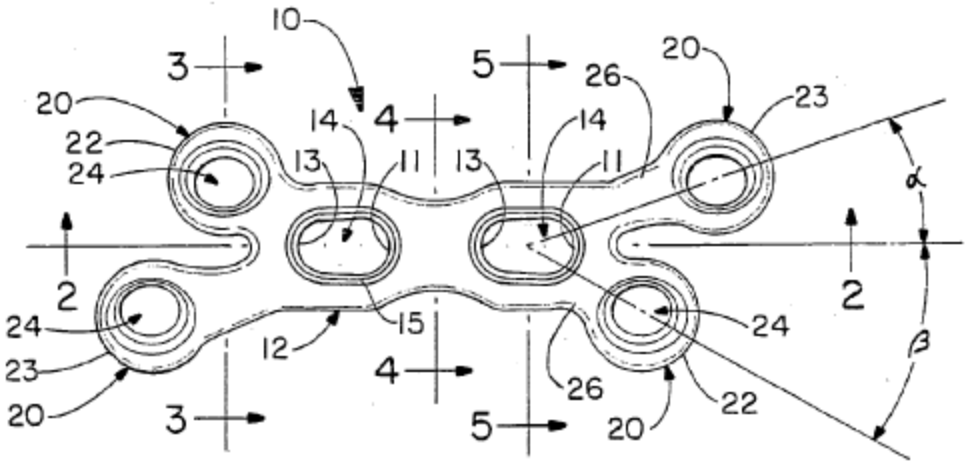


FIG.-1

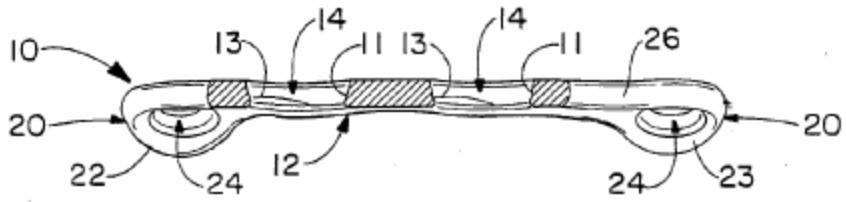


FIG.-2

B. Heinl

Heinl is a U.S. patent titled "Set of Surgical Instruments for Joining Bone Fragments." Ex. 1009, 1. Heinl describes a set of surgical instruments for joining bone fragments by screw fastening, comprising plates of different shapes and curvatures. *Id.*, Abstract. Heinl discloses a set of bone plates having different shapes and curvatures that can be adapted to a particular fracture during surgery, and discloses using screws and a screwdriver for affixing the bone plates. *Id.*, 1:22-26, 1:42-55. Figures 1-5 of Heinl illustrate five different configurations of Heinl's bone plate, including L form, double-Y form, S form, a multifragment plate, and a nasal

plate. *Id.*, Figs. 1-5, 8:41-9:13. Of note, Figure 3 of Heinl shows an S-shaped plate, which is shown below:

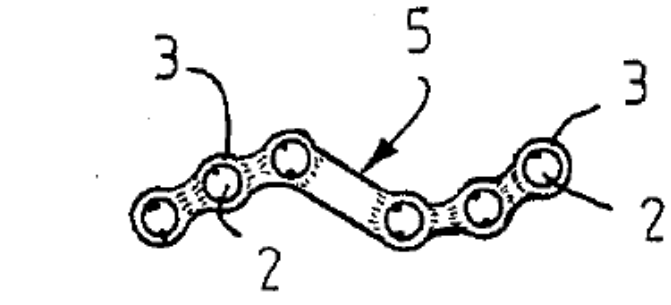
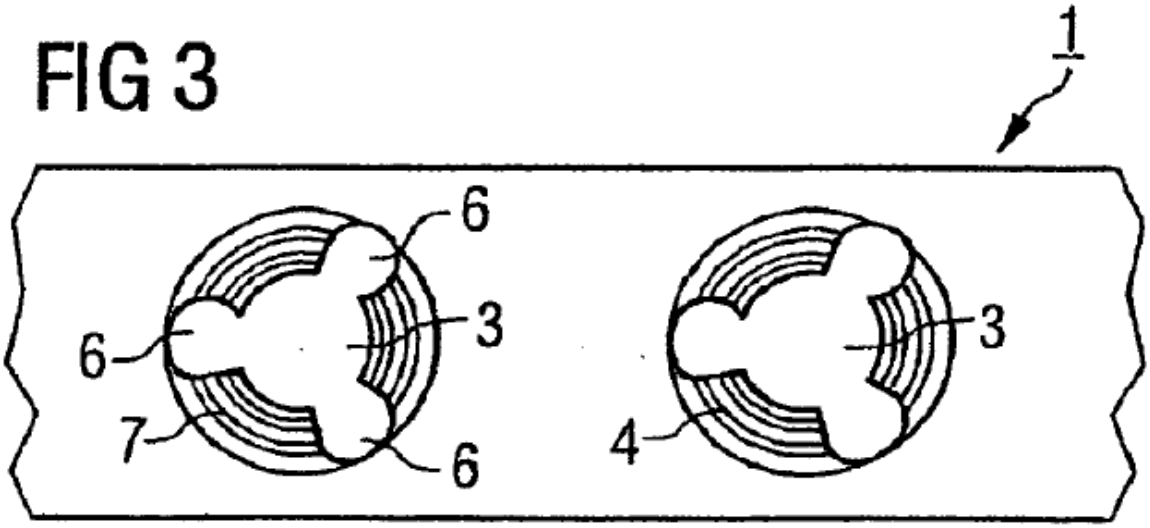


Fig. 3

C. Schneider

Schneider is a published U.S. patent application titled "Bone Plate." Ex. 1008, 1. Schneider describes a bone plate for use in repairing bone fractures that can accommodate conventional locking capscrews. *Id.*, ¶5. Schneider discloses a bone plate in which the screw holes of the plate have an internal jacket surface with at least three recesses that secure the screw. *Id.*, ¶¶6-7. These three recesses "guide drilling bushings or guide bushings, by which the bone screws can be guided during their insertion" (*id.*, ¶9), and are shown in Figure 3:

FIG 3



VII. PROSECUTION HISTORY OF THE '443 PATENT

During prosecution, the examiner rejected the then-pending claims on the grounds of nonstatutory obviousness-type double patenting over claims of U.S. Patent No. 7,7741,457 ("the '457 patent") in view of Heinl because "it would have been obvious to [a POSITA]…to incorporate an S-curve." Ex. 1030, 8. The examiner also rejected the "drill guide" claims as obvious based on the '457 Patent in view of a U.S. Publication No. 2008/0300637 ("Austin") because "it would have been obvious to [a POSITA] to include a drill guide…in order to properly align screws with the openings in the plate during the fastening step." Ex. 1030, 8-9. The '457 Patent and Kay are the same application, U.S. Application No. 11/340,028, and contain the same disclosure. *Compare* Ex. 1006, 1 *with* Ex. 1061, 1. The applicant

filed a terminal disclaimer to the ’457 patent to traverse the nonstatutory obviousness-type rejection. Ex. 1033, 11.

As explained above, the examiner determined the 2006 application failed to disclose an S-curve or a drill guide and thus determined the priority date for those claims was February 24, 2009. *Supra* Section III. Despite the fact that the examiner (1) believed the priority date of the “S-curve” and “drill guide” claims was February 24, 2009, and (2) believed the “S-curve” and “drill guide” claims were obvious based on the ’457 Patent in view of Heinl and Austin, the Applicant never disclosed to the examiner that the published application corresponding to the ’457 Patent, *i.e.* Kay, was prior art under § 102(b) to any claims with a February 24, 2009 priority date because it was published on August 3, 2006. The examiner therefore ***never*** evaluated whether Kay, alone or in combination with other art, rendered obvious the Challenged Claims under § 103.

Thus, while Kay was cited on the face of the ’443 patent, the Examiner did not discuss Kay during prosecution. Schneider is not cited on the face of the ’443 Patent. And, as explained above, Heinl was discussed during prosecution. Therefore, neither the same nor substantially the same arguments as presented in this petition have previously been presented to the Patent Office.

VIII. THE CHALLENGED CLAIMS OF THE '443 PATENT ARE UNPATENTABLE

The Challenged Claims are unpatentable on the following grounds: Claims 1, 3-8, 15, 19, and 26 are rendered obvious by the combination of Kay and Heinl (Ground 1), Claims 9-11 are rendered obvious by the combination of Kay, Heinl and Schneider (Ground 2), and Claims 22-25 are rendered obvious by the combination of Kay and Schneider (Ground 3). As described below, the combinations of Kay, Heinl, and/or Schneider discloses every element of the Challenged Claims, and it would have been obvious to a POSITA to combine the teachings of these references.

A. Ground 1: Kay in view of Heinl Renders Claims 1, 3-8, 15, 19, and 26 Obvious

1. POSITAs Would Have Found It Obvious to Modify Kay in View of Heinl

POSITAs would have been motivated to modify Kay in view of Heinl. Kay states that its orthopedic plate "facilitates three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape," Ex. 1006, Abstract, and describes that the portion of the trunk of its plate "linking the screw holes [through holes 14 in Figure 1] has a decreased width so as to define a waist area 26 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 the plate," *Id.*, ¶47. POSITAs would have been motivated by this disclosure in Kay to seek out a number of different shapes of orthopedic bone plates to accommodate

the variety of bone shapes of the human body, and would have understood that the bone plate of Kay could be bent in a number of different ways. Ex. 1001, ¶¶121-122.

One such reference POSITAs would have been motivated to combine with Kay is Heinl. *Id*. Heinl provides examples of orthopedic plates of different shapes, including a plate with an S-curve in the longitudinal plane, and explains that the varying shapes allow a surgeon to "tak[e] into account the particular anatomical conditions [and] to select the plate best suited for its shape and form and use it immediately." Ex. 1009, 1:62-2:3. POSITAs would have understood that the S-form plate disclosed in Heinl would be one way the plate of Kay could "accommodate individual variation in bone shape," and 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 in view of the teachings of Heinl. Ex. 1001, ¶¶121-122. Because Kay describes that the waist area of the trunk of its plate "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 the plate" (1006 ¶47), POSITAs further would have understood that Kay's plate could be successfully bent in such a manner, and would still work for its intended purpose. Ex. 1001 ¶¶121-122.

2. Claim 1

a. Element 1[pre]: "An orthopedic plate system comprising"

To the extent the preamble is limiting, Kay discloses an orthopedic plate system. Ex. 1001, ¶111. Kay is titled "Orthopedic Plate for Use in Small Bone Repair," and "relates to an orthopedic plate and screw system." Ex. 1006, 1.

b. Element 1[a]: "at least one screw"

Kay discloses an orthopedic plate system with at least one screw. Ex. 1001, ¶112. Kay describes that "[t]he screws of the system are self-starting, self-tapping screws." Ex. 1006, Abstract. Figures 6-8 of Kay depict the screws used with its orthopedic plate system, and Kay's specification further describes the screws. *Id.*, Figs. 6-8, ¶¶12, 53.

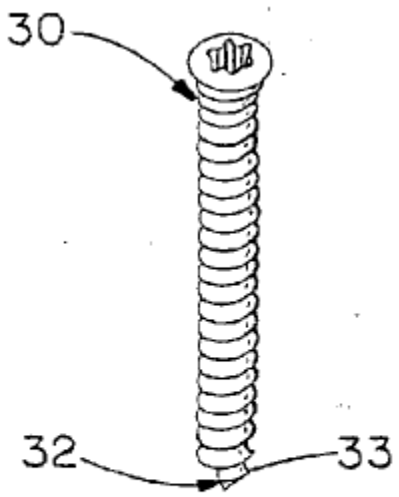
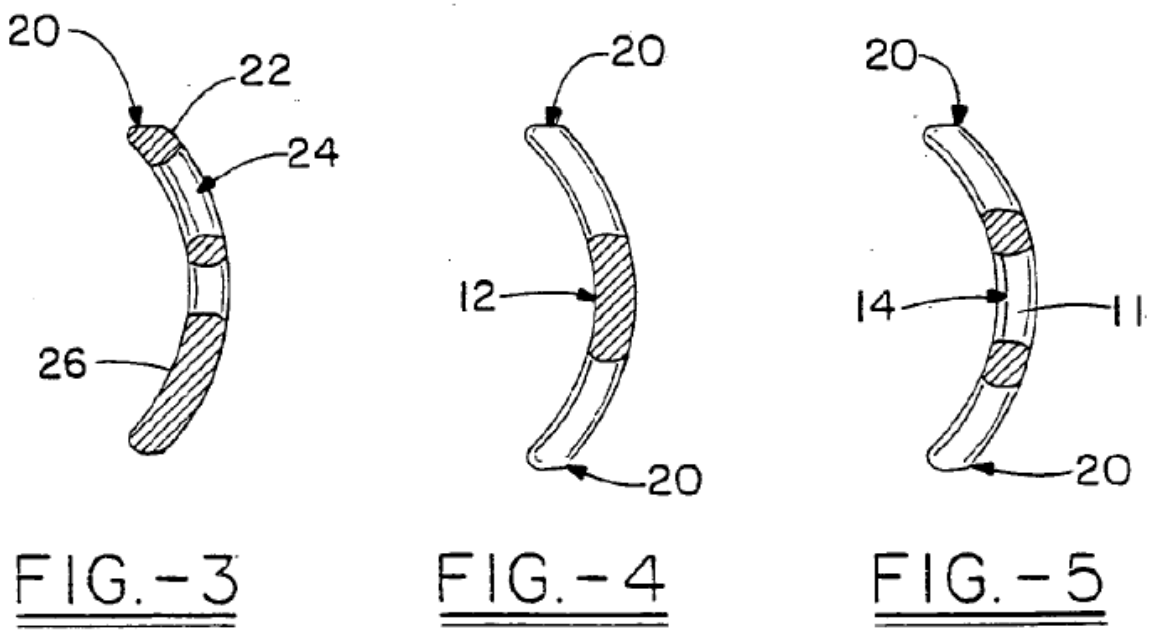


FIG.-6

c. Element 1[b]: "an orthopedic plate having an inferior side including an inferior surface which is capable of facing a bone surface in use,"

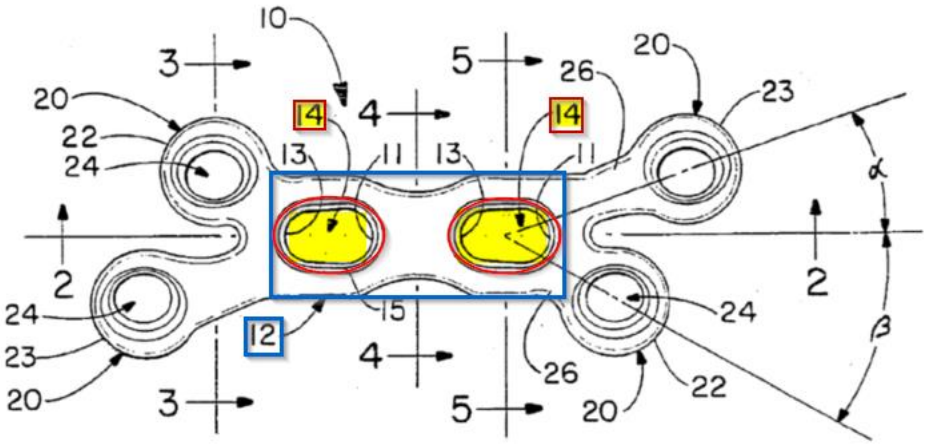
Kay discloses an orthopedic plate having an inferior side including an inferior surface which is capable of facing a bone surface in use. Ex. 1001, ¶113. Kay describes that its orthopedic plate "is radiiused about the inferior surface, (i.e. the surface which faces toward and which may, but does not have to fully contact the bone)." Ex. 1006, ¶9. Kay also states that the plate has an "inferior side, or the side that would be facing (which contemplates opposing or touching or partially touching the) bone surface in use." *Id.*, ¶50. This inferior side is the left side of the plate as shown in Figures 3-5:



Ex. 1006, Figs. 3-5.

d. Element 1[c]: "the plate having a central trunk portion having at least a first and a second screw hole"

Kay discloses an orthopedic plate having a central trunk portion having at least a first and a second screw hole. Ex. 1001, ¶114. Kay describes that its plate includes "a central trunk portion including one or more screw holes." Ex. 1006, Abstract; *see also id.*, ¶9. Figure 1 of Kay is described as "plate 10 of the present invention," with "a central trunk portion 12" including "two screw holes or slots 14." *Id.*, Fig. 1, ¶46. In the annotated version of Kay's Figure 1 below, central trunk portion 12 is outlined in blue, and the two screw holes 14 are highlighted and outlined in red:

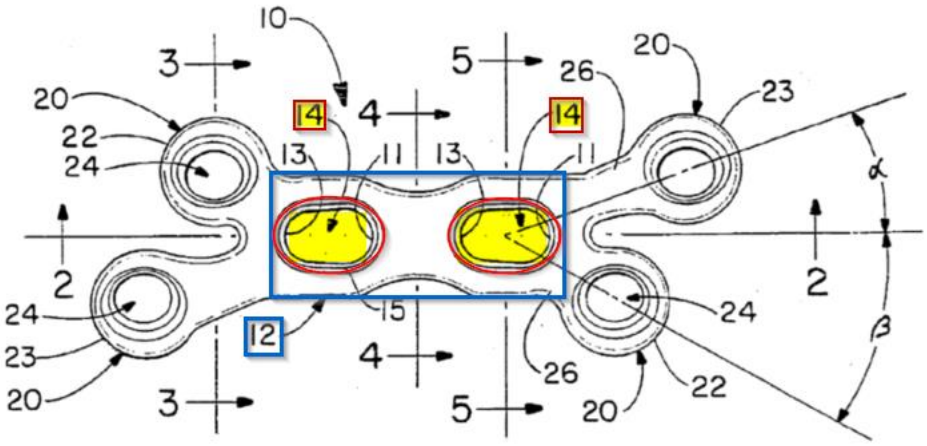


Id., Fig. 1 (annotated); Ex. 1001, ¶114.

e. Element 1[d]: "defining a longitudinal trunk axis extending between a first end and a second end,"

Kay discloses an orthopedic plate having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end. Ex. 1001,

¶115. Kay describes that "plate 10 of the present invention is shown having…a central trunk portion 12 defining the longitudinal axis of the plate," which is the axis that runs the length of the plate from one end to the other. Ex. 1006, Fig. 1, ¶46; Ex. 1001, ¶115. The central trunk portion extends between a first end and a second end, as shown in Figure 1 of Kay. *See id.*, Fig. 1; Ex. 1001, ¶115:

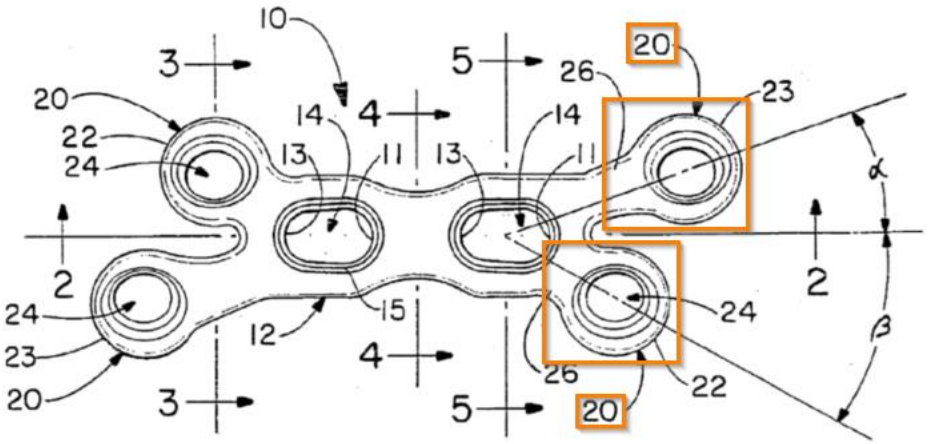


Id., Fig. 1 (annotated); Ex. 1001, ¶115. Figures 2, 9-12, 14, and 16-31 also show an orthopedic plate defining a longitudinal trunk axis that extends between a first end and a second end, and the published claims of Kay claims recite a plate having a trunk defining a longitudinal axis with a first end and a second end. Ex. 1006, Figs. 1-2, 9-12, 14, and 16-31, Claims 1, 9, 17, 22.

f. Element 1[e]: "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,"

Kay discloses an orthopedic plate including at the first end a pair of divergent arms which extend so as to form a first arm and a second arm. Ex. 1001, ¶116. Kay describes that "plate 10 of the present invention is shown having a bilaterally

asymmetric shape which can be thought of as being similar to the Greek letter X with foreshortened opposing diagonal legs extending from a central trunk portion 12." Ex. 1006, ¶46. Plate 10 "includes at least one set, and preferably two opposing sets of arms 20 [which] can be viewed as a set of diagonally opposed short 22 and long arms 23." *Id.*, ¶48. The annotated version of Kay's Figure 1 below outlines in orange a pair of divergent arms 20 that extend to form divergent arms 22 and 23.



Id., Fig. 1 (annotated); Ex. 1001, ¶116.

g. Element 1[f]: "each arm including an arm screw hole which defines a central screw hole axis and wherein the plate has a medial line"

Kay discloses an orthopedic plate system in which each arm includes an arm screw hole which defines a central screw hole axis and wherein the plate has a medial line. Ex. 1001, ¶¶117-118. Kay describes that "[e]ach of the arms in a set includes screw holes 24 which are placed at a radially equal distance but which diverg[e] asymmetrically from the longitudinal axis of the plate 10." Ex. 1006, ¶48. The

screw holes in each arm "are placed with the longitudinal axis perpendicular to a tangent to the top surface of the arm" (*id.*, ¶9), and thus Kay discloses a "central screw hole axis." Ex. 1001, ¶117.

Kay also discloses that its invention "provides a plate with bilateral[] asymmetr[y] (meaning that the left half of the plate is not exactly the same as the right half of the plate taken from the medial axis)" and that "while the plate exhibits a bilateral asymmetry (meaning that the left half is not the same as the right half), it exhibits a transverse mirror symmetry (meaning that one end of the plate is a mirror image of the other end of the plate relative to a mid-plane which is perpendicular to the longitudinal or medial axis)." Ex. 1006, ¶¶7-8. Thus Kay's plate has a medial axis, which includes a medial line. Ex. 1001, ¶118.

h. Element 1[g]: "is pre-contoured such that the medial line describes an S-curve in a lateral plane or in a longitudinal plane"

Kay in view of Heinl discloses an orthopedic plate is pre-contoured such that the medial line describes an S-curve in a lateral plane or in a longitudinal plane. Ex. 1001, ¶¶119-122. Kay discloses that its 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." Ex. 1006, ¶7. Figures 1-5 and 9-31 illustrate varying plates disclosed by Kay, all of which are pre-contoured. *Id.*, Figs. 1-5, 9-31.

Heinl discloses S-shaped orthopedic plates. Ex. 1009, 2:18-22. Heinl explains that "[o]ne of the crucial concepts of the present invention is to replace the presently used flat plates…with an assortment of differently shaped and curved plates provided with multiple holes to subsequently receive screws. It is thus possible for the surgeon, taking into account the particular anatomical conditions…, to select the plate best suited for its shape and form and use it immediately." *Id.*, 1:62-2:3. Figure 3 of Heinl, shown below, illustrates "a plate of approximately S-form." *Id.*, Fig. 3, 8:53-55.

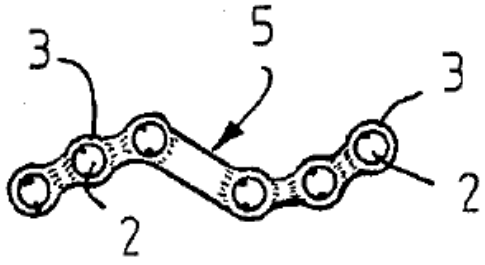


Fig. 3

POSITAs would have been motivated to look for examples of bone plates of various shapes given that Kay discloses that its 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." Ex. 1006, ¶7; Ex. 1001, ¶¶121-122. POSITAs 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. Ex. 1001, ¶121-122. One example of a bone plate with an S-shape plate is Heinl, and a POSITA would have been motivated to apply the S-shape of Heinl to the bone plate of Kay. *Id.*; *supra* Section VIII.A.1.

i. Element 1[h]: "the S-curve has an inflection point that is located between the first and the second screw hole."

Kay in view of Heinl discloses that the S-curve has an inflection point that is located between the first and second screw hole. Ex. 1001, ¶¶123-126. As an S-curve changes directions twice, an S-curve includes a point at which the direction of a curve changes, *i.e.* an inflection point. *Id.* Therefore, an orthopedic plate pre-contoured such that the medial line describes an S-curve in a lateral or longitudinal plane would have at least one inflection point. *Id.*

Heinl describes that the S-form of Figure 3 has "three holes 2 with the accompanying screw rings" at its outer ends, and in "the center region in between lies the parting surface between the two bone fragments to be connected, so that the provision of holes in this area appears unnecessary." Ex. 1009, 8:53-58. In the S-shaped plate of Figure 3 of Heinl, 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 in Figure 3:

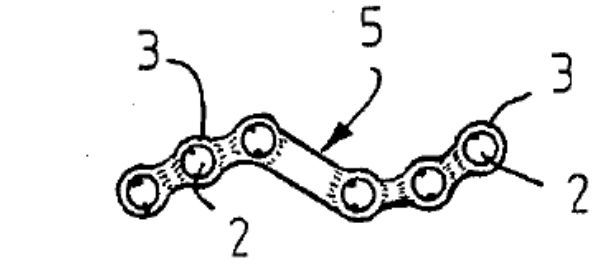


Fig. 3

Id., Fig. 3.

Kay describes that the portion of its trunk "linking the screw holes [through holes 14 in Figure 1] has a decreased width so as to define a waist area 26 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 the plate. This thinner area also facilitates twisting of the plate so as to allow the plate to spiral, or wrap around it[s] longitudinal axis." Ex. 1006, ¶47.

POSITAs desiring to bend Kay's plate to form a lateral S-curve, like that shown in Heinl Figure 3, would have understood that the bending should be done at the waist section of the trunk of Kay because, as Kay itself discloses, the decreased width of the "waist area" facilitates the bending or curving of the orthopedic plate. Ex. 1001, ¶126; Ex. 1006, ¶47. As the plate is bent at the waist section and the waist section is between the first and second screw holes of the trunk, the inflection point

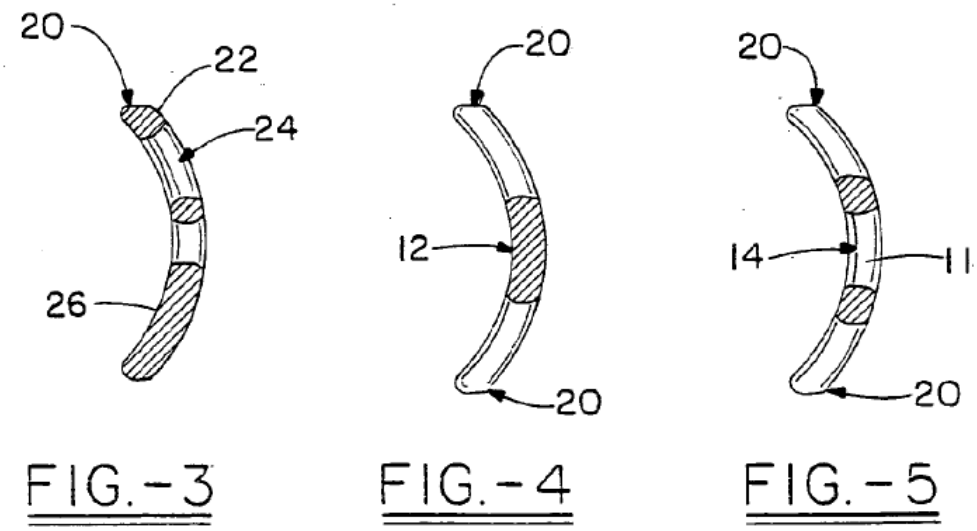
of Kay's plate bent in an S-curve based on Heinl would be located at a "waist area" between the first and second screw holes of the trunk. Ex. 1001, ¶¶123-126; *see also supra* Section VIII.A.1.

3. Claim 3

a. "The orthopedic plate system as set forth in claim 1, wherein the orthopedic plate comprises an oppositely facing concentric superior surface."

As explained above, Kay in view of Heinl renders obvious claim 1. Kay discloses the additional limitation of claim 3. Ex. 1001, ¶128.

Kay describes that its orthopedic plate has "an inferior radius of curvature of about 8 mm to about 12 mm and a concentric radius on the superior side," and that the "superior or top side of the plate has a similar radius of curvature as the top surface of the plate has an outline that corresponds with the shape of the bottom of the plate." Ex. 1006, ¶¶49- 50. This "superior or top side of the plate" is an "oppositely facing superior surface" of an orthopedic plate because it faces the opposite direction of the inferior or bottom surface of the plate. Ex. 1001, ¶128. This is shown below on the right side surface of Figures 3-5:



Ex. 1006, Figs. 3-5.

4. Claim 4

a. "The orthopedic plate system as set forth in claim 3, wherein the screws each have a longitudinal axis and a distal end and the screw holes of each arm are placed with the longitudinal axis perpendicular to a tangent to the concentric superior surface with the effect that the longitudinal axes of the screws converge in the direction of the distal ends."

As explained above, Kay in view of Heinl renders obvious claim 3 of the '443 patent. Kay discloses the additional limitation of claim 4. Ex. 1001, ¶¶130-131.

Kay discloses an orthopedic plate system wherein the screws each have a longitudinal axis and a distal end. Kay states that "FIG. 6 shows a screw 30 used with the plate system of the present invention. The [distal] end of the screw including a cutting tip 32 which is self-starting and self-tapping." Ex. 1006, ¶53. Figure 6 of Kay shows that the longitudinal axis of the screw runs from the head of

the screw to cutting tip 32, and that the distal end of the screw is cutting tip 32. Ex. 1001, ¶130. This is shown in Figure 6, below:

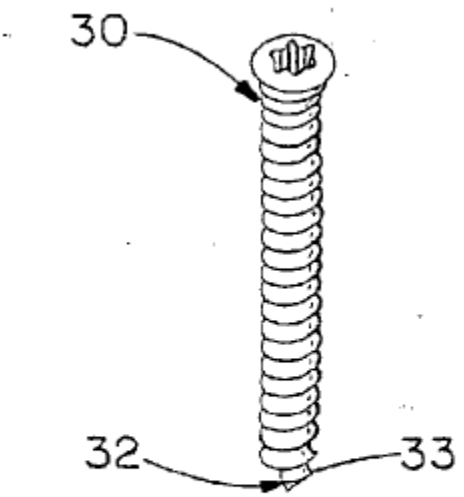


FIG.-6

Kay also discloses an orthopedic plate system wherein the screw holes of each arm are placed with the longitudinal axis perpendicular to a tangent to the concentric superior surface, with the effect that the longitudinal axes of the screws converge in the direction of the distal ends. Kay describes that the "screw holes [of the arms] are placed with the longitudinal axis perpendicular to a tangent to the top surface of the arm with the effect that the longitudinal axes of the screws converge in the direction of the [distal] end." Ex. 1006, ¶9. The arms of the orthopedic plate "continue th[e] curvature" of the concentric superior surface, and the "tangent to the

top surface of the arm" is a tangent to the concentric superior surface. *Id.*; Ex. 1001, ¶131.

5. Claim 5

a. "The orthopedic plate system as set forth in claim 1, wherein the orthopedic plate having at least a portion of the inferior surface which includes a curve transverse to the longitudinal trunk axis."

As explained above, Kay in view of Heinl renders obvious claim 1. Kay discloses the additional limitation of claim 5. Ex. 1001, ¶133.

A curve "transverse" to the longitudinal trunk axis of an orthopedic plate is a curve along the plate in the direction across the longitudinal trunk axis—i.e., in the lateral, rather than longitudinal, direction. *Id.* Kay describes that its orthopedic 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." Ex. 1006, ¶7. In particular, Kay states that "the plate includes a radial curve about the longitudinal axis…typically about 10 mm with a transverse dimension." *Id.*, ¶52. Figures 3-5, 13, and 15 of Kay all illustrate the orthopedic plate having at least a portion of the inferior surface which includes a curve transverse to the longitudinal trunk axis. *Id.*, Figs. 3-5, 13, 15.

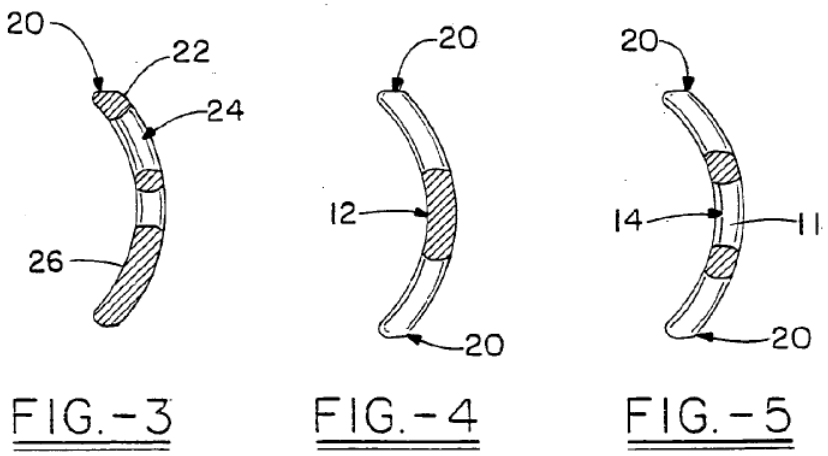


FIG.-3 FIG.-4 FIG.-5

Ex. 1006, Figs. 3-5.

6. Claim 6

a. "The orthopedic plate system as set forth in claim 1, wherein the central screw hole axis of each arm converges towards the central screw hole axis of the other arm of the divergent pair on the inferior side of the plate."

As explained above, Kay in view of Heinl renders obvious claim 1. Kay discloses the additional limitation of claim 6. Ex. 1001, ¶135.

Kay describes that the screw hole of each arm is "placed with the longitudinal axis perpendicular to a tangent to the top surface of the arm with the effect that the longitudinal axes of the screws converge in the direction of the [distal] end." Ex. 1006, ¶9. As described above, POSITAs would have understood that the central screw hole axis of each screw hole is the longitudinal axis that runs perpendicular to a tangent to the top surface of the arm. *See supra* Section VIII.A.2.g. Thus Kay

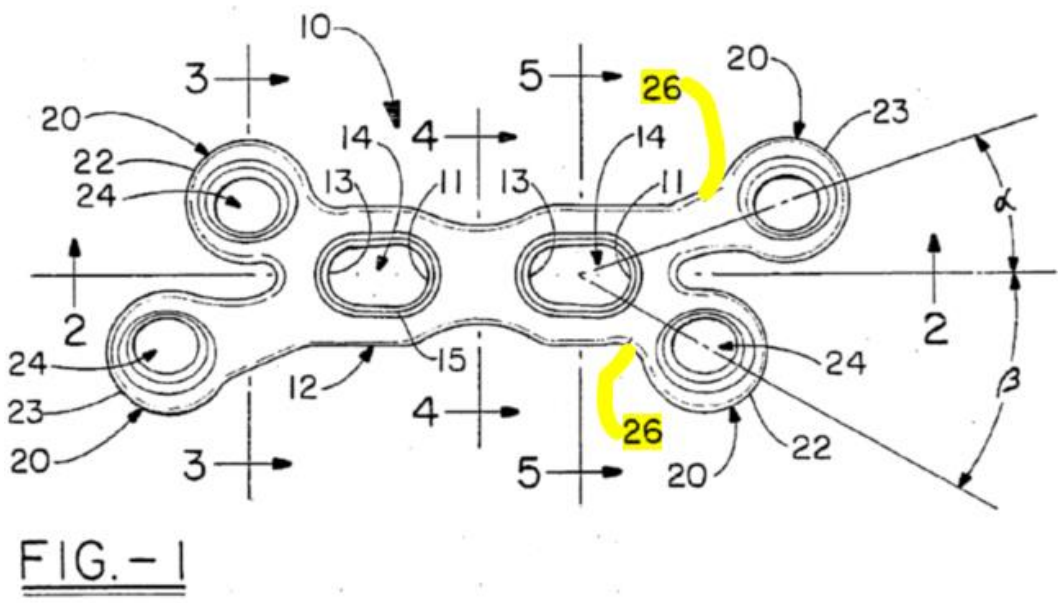
discloses that the central screw hole axis of each arm converges towards the central screw hole axis of the other arm. Ex. 1001, ¶135.

7. Claim 7

a. "The orthopedic plate system as set forth in claim 1, wherein the arm being joined to the trunk portion by a link, 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."

As explained above, Kay in view of Heinl renders obvious claim 1. Kay discloses the additional limitation of claim 7. Ex. 1001, ¶¶137-138.

Kay states "arms 20 also each include a screw hole 24 which, like the trunk portion 12 has a linking portion 26 that joins the screw hole to the trunk portion." Ex. 1006, ¶51. POSITAs would have understood from this description and Figure 1, annotated below, that the "linking portion 26" links arms 20 to trunk portion 12.



Id., Fig. 1 (annotated); Ex. 1001, ¶137.

Kay also describes that "[e]ach of the arms in a set includes screw holes 24 which are placed at a radially equal distance but which diverg[e] asymmetrically from the longitudinal axis of the plate 10." Ex. 1006, ¶48. "[E]ach set of arms includes one arm that defines a smaller angle of divergence α from the longitudinal axis of the trunk portion than the angle of divergence of the other arm β." *Id*. In annotated Figure 1 of Kay below, the longitudinal arm axis of each arm 22, which extends between the central screw axis of screw hole 24 and a point on the longitudinal trunk axis, is highlighted in blue. An angle defined by a longitudinal axis of the central trunk portion and the longitudinal arm axis is highlighted in green.

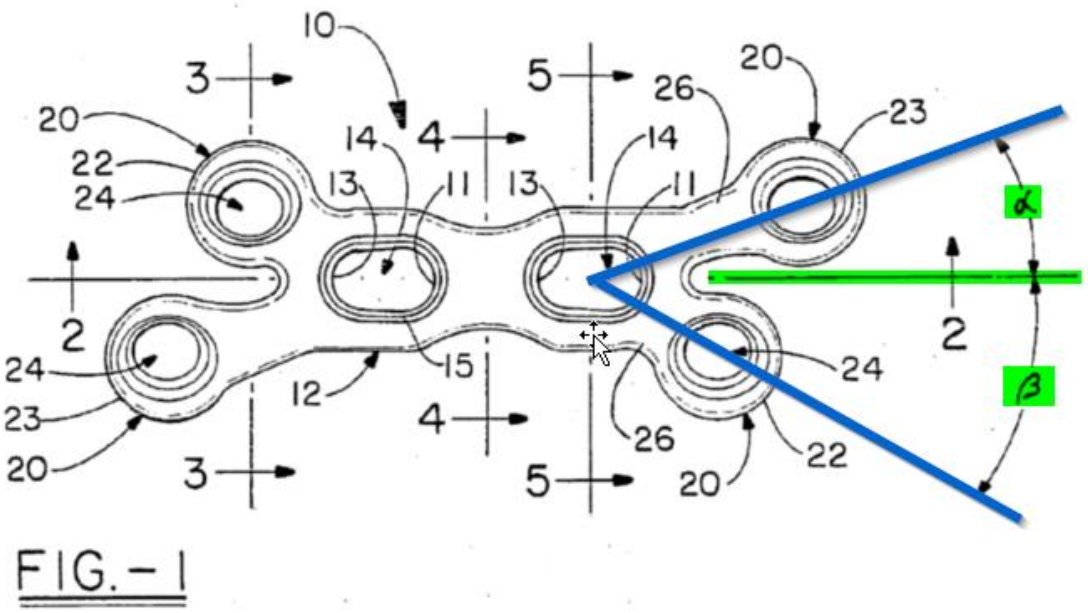


FIG. – 1

Id., Fig. 1 (annotated); Ex. 1001, ¶138.

8. Claim 8

a. "The orthopedic plate system as set forth in claim 7, wherein each pair of arms includes a first arm that defines a smaller angle of divergence α from the medial line of the elongate central trunk than the angle of divergence β of a second arm."

As explained above, Kay in view of Heinl renders obvious claim 7 of the '443 patent. Kay discloses the additional limitation of claim 8. Ex. 1001, ¶¶140-141.

As explained above, Kay describes a pair of arms that "diverg[e] asymmetrically" from the longitudinal axis of the plate, with an angle of divergence of the first arm described as α and an angle of divergence of the second arm described as β. Kay further describes that "each set of arms includes one arm that defined a smaller angle of divergence α from the longitudinal axis of the trunk

portion than the angle of divergence of the other arm β." Ex. 1006, ¶48. These angles disclosed in Kay extend from the "medial line of the elongate central trunk," which is a line following the longitudinal axis of the central trunk, and thus Kay discloses this limitation. *Id.*, ¶¶140-141.

9. Claim 15

a. "The orthopedic plate system as set forth in claim 1, wherein the plate is configured to bend laterally, longitudinally, or to wrap or spiral about the medial line."

As explained above, Kay in view of Heinl renders obvious claim 1. Kay discloses the additional limitation of claim 15. Ex. 1001, ¶156.

Kay states that its 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." Ex. 1006, ¶7. The "medial line" is a line that follows the longitudinal axis of the orthopedic plate, and therefore Kay describes a plate that is configured to bend laterally, longitudinally, or to wrap or spiral about the medial line. Ex. 1001, ¶156.

10. Claim 19

a. "The orthopedic plate system as set forth in claim 1, wherein the first and second screw holes are separated by a waist shaped linking portion."

As explained above, Kay in view of Heinl renders obvious claim 1. Kay discloses the additional limitation of claim 19. Ex. 1001, ¶158.

Claim 1 of the ’443 patent states that the first and second screw holes are two screw holes in the trunk of the orthopedic plate system. Ex. 1002, Claim 1. Kay describes that its orthopedic plate “has a central trunk portion including one or more screw holes separated by a waist shaped linking portion along a longitudinal axis.” Ex. 1006, ¶9. Kay further describes that “[t]he area linking the screw holes has a decreased width so as to define a waist area 26 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 the plate.” *Id.*, ¶47.

11. Claim 26

a. Element 26[pre]: “An orthopedic plate system comprising”

See Section VIII.A.2.a.

b. Element 26[a]: “at least one screw”

See Section VIII.A.2.b.

c. Element 26[b]: “an orthopedic plate having an inferior surface which is capable of facing a bone surface in use,

See Section VIII.A.2.c.

d. Element 26[c]: “the plate having a central trunk portion having at least a first and a second screw hole”

See Section VIII.A.2.d.

e. Element 26[d]: "defining a longitudinal trunk axis extending between a first end and a second end,"

See Section VIII.A.2.e.

f. Element 26[e]: "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"

See Sections VIII.A.2.f and VIII.A.2.g.

g. Element 26[f]: "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"

See Sections VIII.A.2.g and VIII.A.2.h.

h. Element 26[g]: "including a first lobe which includes the first screw hole and which bows in a first direction"

Kay in view of Heinl discloses an orthopedic plate including a first lobe which includes the first screw hole and which bows in a first direction. Ex. 1001, ¶¶183-184. Kay states that its orthopedic plate "has a central trunk portion including one or more screw holes separated by a waist shaped linking portion along a longitudinal axis." Ex. 1006, ¶9. Kay discloses that in Figure 1, "[t]he area linking the screw holes has a decreased width so as to define a waist area 26 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 the plate." *Id.*, ¶47.

As discussed above, POSITAs would have been motivated to and expected to succeed in bending the plate of Kay into the S-curve illustrated in Heinl to better conform to bone anatomy, and would have understood that the narrowed waist area of the central trunk portion of Kay's orthopedic plate would be the desired location to bend the plate because it is configured to encourage bending. *Supra* Section VIII.A.1. POSITAs would have understood based on the disclosure of Kay that bending the waist area of the trunk of Kay into an S-shape would result in a "first lobe" that bends in a "first direction," similar to how an S has "two lobes" that bow in "two directions." Ex. 1001, ¶184. Figure 3 of Heinl illustrates a "first lobe" that bends in a "first direction," and the plate shape of Kay when modified as taught by Heinl would also result in a lobe that includes a screw hole, because the bending occurs between the two screw holes. *Id.* Thus Kay in view of Heinl discloses a first lobe which includes the first screw hole and which bows in a first direction. *Id.*

i. Element 26[h]: "a second lobe which bows in the opposite direction and which includes the second screw hole."

Kay in view of Heinl discloses an orthopedic plate including a second lobe which bows in the opposite direction and which includes the second screw hole. Ex. 1001, ¶¶185-186. Kay describes an orthopedic plate with "a central trunk portion," which has "one or more screw holes separated by a waist shaped linking portion along a longitudinal axis," and the waist shaped linking portion "will bend laterally

(or 'curve') relative to the longitudinal axis and [] will bend longitudinally to form a curved area in and out of the plane of the plate. Ex. 1006, ¶¶9, 47.

As discussed above, POSITAs would have been motivated and expected to succeed in bending the plate of Kay into the S-curve illustrated in Heinl to better conform to bone anatomy, and would have further understood that the narrowed waist area of the central trunk portion of Kay's orthopedic plate would be the desired location to bend the plate because it is configured to encourage bending. *Supra* Section VIII.A.1. POSITAs would have understood based on the disclosure of Kay that bending the waist area of the trunk of Kay into the S-shape disclosed by Heinl would result in a "second lobe" that bends in a "second direction," similar to how an S has "two lobes" that bows in "two directions." Ex. 1001, ¶186. Figure 3 of Heinl illustrates a "second lobe" that bends in a "second direction," and the plate shape of Kay when modified as taught by Heinl would also result in a lobe that includes a screw hole, because the bending occurs between the two screw holes. *Id.* Thus Kay in view of Heinl discloses a second lobe which includes the second screw hole and which bows in the opposite direction. *Id.*

B. Ground 2: Kay in view of Heinl and Schneider Renders Obvious Claims 9-11

1. POSITAs Would Have Found It Obvious To Modify Kay in view of Heinl and Schneider

As described above in Section VIII.A, POSITAs would have found it obvious to modify the shape of Kay's plates into an S-curve based on Heinl. POSITAs would also have found it obvious to add Schneider's guideways to Kay's S-shaped plate. Kay states that there are "instruments for use with the [plate] system," but does not disclose any details about those instruments. Ex. 1006, ¶13; *see also id.*, Abstract, ¶14. Based on this disclosure, a POSITA would have been motivated to look to bone plate instruments to improve Kay's plate system, and Schneider's drill guide is just such an instrument. Ex. 1001, ¶¶145-148. POSITAs would have been motivated to use Schneider's drill guide with Kay's plate system and modify Kay's plate design to add recesses as guideways to allow surgeons to "insert[] [the drill guide] into the holes in the plate." Ex. 1001, ¶¶145-148; Ex. 1008, ¶9. POSITAs would have been further modified to combine Kay and Schneider because Schneider discloses that its system eliminates "the need for additional components," thereby reducing manufacturing costs, improving functionality, and eliminating potential waste. Ex. 1001, ¶147.

POSITAs would also have expected to succeed in adding Schneider's drill guide and three recesses to Kay's plate system because Schneider and Kay describe

similar plate systems. Ex. 1001, ¶148. Both describe plate systems with variable angle screws, and both describe similarly shaped screw holes. *Id.* In light of the shared characteristics, POSITAs would have expected to succeed in adding recesses to the screw holes of Kay's plates and using the drill guide to guide screws into the screw holes at the desired angle. *Id.*

2. Claim 9

a. "The orthopedic plate system as set forth in claim 1 further including a drill guide and the arm screw hole further includes guide ways or the drill guide which set the angle for the drill guide relative to the plate."[2]

As explained above, Kay in view of Heinl renders obvious claim 1 of the '443 patent. Schneider discloses the additional limitation of claim 9. Ex. 1001, ¶144.

Schneider states that an advantage of its bone plate is "us[ing] the at least three recesses in the hole in the plate to guide drilling bushings or guide bushings, by which the bone screws can be guided during their insertion." Ex. 1008, ¶9. These recesses improve the process by which "drilling bushings or guide bushings" are attached to the plate by permitting the guide bushings "to be inserted into the holes in the plate." *Id.* A "bushing" is "a usually removable cylindrical lining for an

[2] Paragon understands this claim should read "the arm screw hole includes guide ways ***for*** the drill guide which set the angle for the drill guide relative to the plate."

opening (as of a mechanical part) used to limit the size of the opening, resist abrasion, or serve as a guide," and a POSITA would have understood the term to have its ordinary meaning in the context of Schneider. Ex. 1027; Ex. 1001, ¶144. Thus Schneider discloses a drill guide (the bushings) and guide ways for the drill guide (the three recesses in the hole that guide the bushings). *Id.*

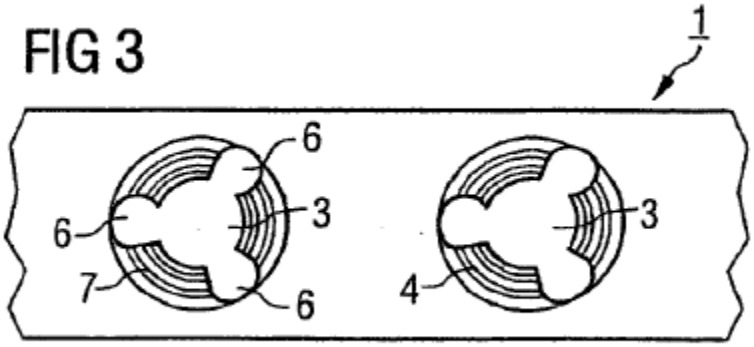
POSITAs would also have been motivated to combine the drill guide and guideways of Schneider (i.e., the bushings and recesses) with Kay's S-shaped plate. *Id.*, ¶¶145-148; *see also supra* Section VIII.B.1. Because Kay states that there are "instruments for use with the [plate] system" (Ex. 1006, ¶13), but does not provide any details, a POSITA would have been motivated to look for bone plate instruments to improve Kay's plate system. Ex. 1001, ¶¶145-148. Schneider's drill guide is just such an instrument, and a POSITA would have been motivated to uses Schneider's design and expected to succeed in doing so because of the similarities between Kay and Schneider and Schneider's emphasis that its system eliminates the need for additional components. *Id.*, ¶147.

3. Claim 10

a. "The orthopedic plate system as set forth in claim 9, wherein the screw holes are threaded and the guide ways are radially spaced grooves that form interruptions in the threads of the screw hole."

As explained above, Kay in view of Heinl and Schneider renders obvious claim 9 of the '443 patent. Schneider discloses the additional limitation of claim 10. Ex. 1001, ¶¶150-151.

Schneider describes "bone screws with a threaded head and holes in the plate with an inner thread." Ex. 1008, ¶8. Schneider further describes that its screw hole has an internal jacket surface, which "includes N recesses extending radially away from the central axis, where $N \geq 3$." *Id.*, ¶6. In Figure 3 of Schneider, below, "bone plate 1" has an "internal jacket surface 4 ha[ving] three recesses 6 which extend radially away from the hole axis 5 of the hole." *Id.*, Fig. 3, ¶32.



As explained above, POSITAs would have found it obvious to use the screw holes disclosed in Schneider with the orthopedic plate system of Kay. *See supra*

Section VIII.B.1. In particular, Kay discloses screw holes with "a rounded concavity to mate with the rounded shape of the head of the screw to allow of variable axis positioning." Ex. 1006, ¶50. Schneider describes that its "internal jacket surface can have a concave, preferably spherical, tapered or ellipsoidal shape." Ex. 1008, ¶12. A POSITA would have understood that it would be straightforward to substitute Schneider's concave, threaded screw holes with recesses for Kay's concave screw holes, and would be motivated to do so because of the angular and axial stability provided by Schneider's screw holes. Ex. 1001, ¶151.

4. Claim 11

a. "The orthopedic plate system as set forth in claim 10, wherein the guide ways include three equally spaced grooves wherein the grooves extend a length of the screw hole."

As explained above, Kay in view of Heinl and Schneider renders obvious claim 10 of the '443 patent. Schneider discloses the additional limitation of claim 11. Ex. 1001, ¶¶153-154.

Schneider describes its screw hole has an internal jacket surface, which "includes N recesses extending radially away from the central axis, where $N \geq 3$." Ex. 1008, ¶6. Schneider further describes that where N = 3, as in Figure 3, "internal jacket surface 4 has three recesses 6 which extend radially away from the hole axis 5 of the hole at a uniform distance of 120° from one another." *Id.*, ¶32. Recesses at a "uniform distance [] from each other" are equally spaced. Ex. 1001, ¶153. "The

recesses can extend from the upper side to the underside over the entire height of the bone plate," meaning the grooves extend the length of the screw hole. Ex. 1008, ¶17.

As explained above, POSITAs would have found it obvious to use the screw holes disclosed in Schneider, including grooved guide ways, with the orthopedic plate system of Kay. *Supra* Section VIII.B.1.

C. Ground 3: Kay in view of Schneider Renders Obvious Claims 22-25

1. POSITAs Would Have Found It Obvious To Modify Kay in view of Schneider

Claims 22-25 are rendered obvious by Kay in view of Schneider. As explained above with reference to Grounds 1 and 2, POSITAs would have found it obvious to combine Kay, Heinl, and Schneider. For the same reasons explained above, POSITAs would also have found it obvious to combine Kay and Schneider. POSITAs would have been motivated to combine Schneider's recesses and drill guide with Kay's plates because Schneider discloses that its system eliminates "the need for additional components," thereby reducing manufacturing costs, improving functionality, and eliminating potential waste. Ex. 1001, ¶¶145-147. Similarly, POSITAs would also have expected to succeed in adding Schneider's drill guide and three recesses to Kay's plate system because of the shared characteristics of the systems, including screws, screw holes. Ex. 1001, ¶148.

2. Claim 22

a. Element 22[pre]: "An orthopedic plate system for use on a bone"

To the extent the preamble is limiting, Kay discloses an orthopedic plate system for use on a bone. Ex. 1001, ¶159. Kay is titled "Orthopedic Plate for Use in Small Bone Repair," and "relates to an orthopedic plate and screw system." Ex. 1006, 1.

b. Element 22[a]: "having a side that faces the bone and a side which faces away from the bone"

Kay discloses an orthopedic plate system with a side that faces the bone and a side which faces away from the bone. Ex. 1001, ¶160. Kay describes that its orthopedic plate has an "inferior side, or the side that would be facing (which contemplates opposing or touching or partially touching) the bone surface in use" and a "superior or top side." Ex. 1006 ¶50; *see also id.*, ¶51. This is shown below in Figures 3-5:

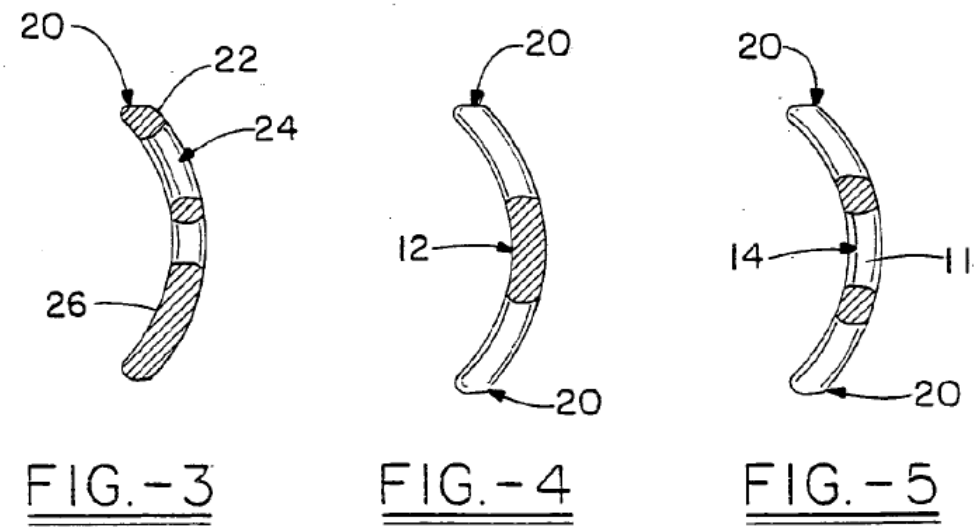


FIG.-3 FIG.-4 FIG.-5

Ex. 1006, Figs. 3-5.

c. Element 22[b]: "a footprint having an elongate central trunk with a medial line and at least one pair of terminal asymmetric arms and"

Kay discloses an orthopedic plate system with a footprint having an elongate central trunk with a medial line and at least one pair of terminal asymmetric arms. Ex. 1001, ¶161. Kay states that its orthopedic plate "is shown having a bilaterally asymmetric shape which can be thought of as being similar to the Greek letter X with foreshortened diagonal legs extending from a central portion 12 defining the longitudinal axis of the plate." Ex. 1006, ¶46. As explained above, Kay discloses an orthopedic plate with a central trunk with a "medial line," *i.e.* a line following the longitudinal axis of the plate. Ex. 1001, ¶161. Kay's central trunk is elongated, as shown in numerous figures. Ex. 1006, Figs. 1, 9, 10, 20, 22, 24, 26, 28, 30. Kay further describes that its orthopedic plate has "sets of arms [that] can be viewed as a

set of diagonally opposed short 22 and long arms 23," and the varying lengths of the arms such that they are asymmetric. *Id.*, ¶48; Ex. 1001, ¶161.

d. Element 22[c]: "wherein each arm extends from the elongate central trunk at a differing angle relative to the medial line from the other arm of the pair and having a differing length than the other arm of the pair and"

Kay discloses an orthopedic plate system wherein each arm extends from the elongate central trunk at a different angle relative to the medial line from the other arm of the pair and having a differing length than the other arm of the pair. Ex. 1001, ¶162. Kay describes that its orthopedic plate has "sets of arms [that] can be viewed as a set of diagonally opposed short 22 and long arms 23" and that "each set of arms includes one arm that defines a smaller angle of divergence α from the longitudinal axis of the trunk portion than the angle of divergence of the other arm β." Ex. 1006, ¶48. As there is a "short" and a "long" arm, and the angles are different, Kay discloses arms with differing angles and different lengths as set forth in the claim. Ex. 1001, ¶162.

e. Element 22[d]: "the plate having a contour in a z direction and"

Kay discloses an orthopedic plate having a contour in a z direction. Ex. 1001, ¶¶163-164. Kay describes that its plate is "designed to facilitate three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape." Ex. 1006 ¶7. Kay does not define or explain which

direction is the z direction, but from Kay's disclosure that 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.*, ¶7), POSITAs would have understood that Kay's plate was contoured in any direction, including a "z-direction," or found it obvious to do so because Kay explicitly informs POSITAs to bend the plate in all three directions. Ex. 1001, ¶164.

f. Element 22[e]: "each arm including a threaded screw hole for a screw having threads on a screw head, and"

Kay in view of Schneider discloses an orthopedic plate system with arms, each arm including a threaded screw hole for a screw having threads on a screw head. Ex. 1001, ¶165. Kay states that each of the arms of its plate "includes screw holes 24." Ex. 1006, ¶48. Schneider describes "bone screws with a threaded head and holes in the plate with an inner thread," and further describes that the internal jacket surface of the screw hole "preferably comprises partial or complete pitches of a thread." Ex. 1008, ¶¶8, 10.

As explained above, POSITAs would have been motivated to combine the threaded screw holes and screws disclosed by Schneider with the orthopedic plate disclosed by Kay. *Supra* Sections VIII.B.1 and VIII.C.1.

g. Element 22[f]: "a screw in the threaded screw hole providing bi-planar screw fixation and"

Kay in view of Schneider discloses an orthopedic plate system with a screw in the threaded screw hole providing bi-planar screw fixation. Ex. 1001, ¶167. Schneider describes "bone screws with a threaded head and holes in the plate with an inner thread," and further describes that the internal jacket surface of the screw hole "preferably comprises partial or complete pitches of a thread." Ex. 1008, ¶¶8, 10. Kay discloses an orthopedic plate with "bi-planar screw fixation (meaning that the screws do not lie in a single plane)." Ex. 1006, ¶7. POSITAs would have been motivated to replace the screw holes of Kay with the threaded screw holes of Schneider. *See supra* Section VIII.B.1. Furthermore, POSITAs would have understood that modifying the screw holes of Kay as disclosed by Schneider would not have modified the location of the Kay's screw holes, and thus Kay's plate would still provide bi-planar screw fixation. Ex. 1001, ¶167.

h. Element 22[g]: "the system further includes a drill guide and"

See Section VIII.B.2.

i. Element 22[h]: "the arm screw hole further includes guide ways for the drill guide which sets the angle for the drill guide relative to the plate and wherein the guide ways are radially spaced grooves that form interruptions in the threads of the screw hole."

See Sections VIII.B.2 and VIII.B.3.

3. Claim 23

a. "The orthopedic plate system as set forth in claim 22, wherein the guideways include three equally spaced grooves wherein the grooves extend the length of the screw hole."

As explained above, Kay in view of Schneider renders obvious claim 22. Schneider discloses the additional limitation of Claim 23, as explained in Section VIII.B.3 (Claim 11).

4. Claim 24

a. "The orthopedic plate system as set forth in claim 22, wherein the medial line divides the plate in half laterally."

As explained above, Kay in view of Schneider renders obvious claim 22. Kay discloses the additional limitation of Claim 24. Ex. 1001, ¶173.

Kay discloses that while its orthopedic plate "exhibits a bilaterally asymmetry (meaning that the left half is not the same as the right half), it exhibits a transverse mirror symmetry (meaning that one end of the plate is a mirror image of the other end of the plate relative to a mid-plane which is perpendicular to the longitudinal or medial axis)." Ex. 1006, ¶8. Because Kay's orthopedic plate exhibits transverse mirror symmetry relative to a mid-plane perpendicular to the medial line, the medial line of Kay's plate divides the plate in half laterally. Ex. 1001, ¶173.

5. Claim 25

a. "The orthopedic plate system as set forth in claim 22, wherein the plate has a transverse curve along the medial line about the side which faces the bone."

As explained above, Kay in view of Schneider renders obvious claim 22. Kay discloses the additional limitation of Claim 25. Ex. 1001, ¶175.

Kay states that its 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." Ex. 1006, ¶7. Kay further describes that "the plate includes a radial curve about the longitudinal axis…typically about 10 mm with a transverse dimension." *Id.*, ¶52. Kay specifies this radial curve is about the side which faces the bone when it explains that the plate "is radiiused about the inferior surface, (i.e. the surface which faces toward and which may, but does not have to fully contact the bone." *Id.*, ¶9. Figures 3-5, 13, and 15 of Kay all illustrate the orthopedic plate having at least a portion of the inferior surface facing the bone which includes a curve transverse to the longitudinal trunk axis. *Id.*, Figs. 3-5, 13, 15.

IX. MANDATORY NOTICES

A. 37 C.F.R. § 42.8(b)(1): Real Party-in-Interest

Paragon is the real party in interest for Petitioner.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

Patent Owner asserted the '443 patent against Paragon in Case No. 1:18-cv-00691-PAB-STV (D. Colo.), filed March 23, 2018. This case may affect, or be affected by, this proceeding. Paragon is not aware of any other proceedings involving the '443 patent.

Other patents in the same family as the '443 patent have also been asserted in the above-referenced case and are, or will be, the subject of IPRs filed by Paragon.

C. 37 C.F.R. § 42.8(b)(3): Lead and Back-Up Counsel

Lead Counsel	Back-Up Counsel
Joel R. Merkin (Reg. No. 58,600) KIRKLAND & ELLIS LLP 300 North LaSalle Chicago, IL 60654 Telephone: (312) 862-2000 Facsimile: (312) 862-2200 jmerkin@kirkland.com	Luke L. Dauchot (*pro hac vice*, pending) Greg Polins (*pro hac vice*, pending) KIRKLAND & ELLIS LLP 300 North LaSalle Chicago, IL 60654 Telephone: (312) 862-2000 Facsimile: (312) 862-2200 luke.dauchot@kirkland.com greg.polins@kirkland.com

A Power of Attorney pursuant to 37 C.F.R. § 42.10(b) is filed herewith.

D. 37 C.F.R. § 42.8(b)(4): Service Information.

Please direct all correspondence regarding this Petition to lead counsel at the above address. Paragon consents to service by email at: Paragon28_PTAB@kirkland.com.

X. GROUNDS FOR STANDING

Paragon certifies that the '443 patent is available for IPR and Paragon is not barred or estopped from requesting IPR of the '443 patent on the grounds identified. Paragon was served with a complaint asserting infringement of the '443 patent on March 29, 2018, and this Petition is being filed within one year of that date. Ex. 1056.

XI. PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15(A) AND 42.103

Review of 17 claims is requested. The undersigned authorizes the Office to charge the fee set forth in 37 C.F.R. § 42.15(a) for this Petition to Deposit Account No. 506092, as well as any additional fees due in connection with this petition.

XII. CONCLUSION

For the reasons set forth above, the Challenged Claims of the '443 patent are unpatentable. Paragon therefore requests that an IPR of these claims be instituted.

DATED: March 28, 2019

Respectfully submitted,

/s/ Joel R. Merkin

Joel R. Merkin (Reg. No. 58,600)
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, Illinois 60654
P: 312.862.2000; F: 312.862.2200
jmerkin@kirkland.com

Attorney for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. § 42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 12,900 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

DATED: March 28, 2019

Respectfully submitted,

/s/ Joel R. Merkin
Joel R. Merkin (Reg. No. 58,600)
KIRKLAND & ELLIS LLP
Attorney for Petitioner

INDEX OF EXHIBITS

Exhibit No.	Description
1001	Declaration of Javier E. Castaneda
1002	U.S. Patent No. 9,144,443 to Leither et al.
1003	U.S. Patent No. 9,259,252 to Kay et al.
1004	U.S. Patent No. 9,259,253 to Kay et al.
1005	U.S. Patent No. 9,525,278 to Ducharme et al.
1006	U.S. Patent Application No. 2006/0173459 to Kay et al.
1007	U.S. Patent Application No. 2008/0140130 to Chan et al.
1008	U.S. Patent Application No. 2006/0235400 to Schneider
1009	U.S. Patent No. 4,903, 691 to Heinl
1010	U.S. Patent No. 6,283,969 to Grusin et al.
1011	U.S. Patent Application No. 2005/0165400 to Fernandez
1012	U.S. Patent No. 5,690,631 to Duncan et al.
1013	French Patent No. 2,405,706 to Dayan (English Translation)
1014	French Patent No. 2,405,706 to Dayan
1015	French Patent No. 2,622,431 to Letournel (English Translation)
1016	French Patent No. 2,622,431 to Letournel
1017	German Patent No. 10,125,092 to Nicoloff (English Translation)
1018	German Patent No. 10,125,092 to Nicoloff
1019	U.S. Patent Application No. 2007/0123886 to Meyer et al.

Exhibit No.	Description
1020	Japanese Patent Application No. 2003-102743 to Nishiyama (English Translation)
1021	Japanese Patent Application No. 2003-102743 to Nishiyama
1022	U.S. Patent Application No. 2008/0300637 to Austin et al.
1023	Ruedi, Thomas P., and William M. Murphy. AO Principles of Fracture Management. Thieme, 2000.
1024	U.S. Patent Application No. 2004/0073218 to Dahners
1025	U.S. Patent No. 7,776,076 to Grady, Jr. et al.
1026	U.S. Provisional Patent Application 60/648364 to Kay
1027	Definition of "Bushing", Merriam-Webster's Collegiate Dictionary, Tenth Edition, p. 154
1028	Sept. 26, 2014 Office Action in Patent '443
1029	Oct. 23, 2014 Resp. to Office Action in Patent '443
1030	Feb. 4, 2015 Office Action in Patent '443
1031	May 4, 2015 Resp. to Office Action in Patent '443
1032	May 14, 2015 Office Action in Patent '443
1033	July 14, 2015 Resp. to Office Action in Patent '443
1034	July 24, 2015 Notice of Allowance in Patent '443
1035	Apr. 15, 2015 Office Action in Patent '252
1036	May 7, 2015 Resp. to Office Action in Patent '252
1037	May 20, 2015 Office Action in Patent '252
1038	Aug. 20, 2015 Resp. to Office Action in Patent '252
1039	Sept. 30, 2015 Amend. in Patent '252
1040	Oct. 14, 2015 Notice of Allowance in Patent '252

Exhibit No.	Description
1041	Apr. 15, 2015 Office Action in Patent '253
1042	May 7, 2015 Resp. to Office Action in Patent '253
1043	May 21, 2015 Office Action in Patent '253
1044	Aug. 20, 2015 Resp. to Office Action in Patent '253
1045	Oct. 7, 2015 Amendment in Patent '253
1046	Oct. 13, 2015 Notice of Allowance in Patent '253
1047	Jan. 20, 2016 Office Action in Patent '278
1048	Mar. 16, 2016 Resp. to Office Action in Patent '278
1049	Apr. 4, 2016 Office Action in Patent '278
1050	Aug. 4, 2016 Amendment in Patent '278
1051	Sept. 12, 2016 Notice of Allowance in Patent ‘278
1052	U.S. Patent No. 1,105,105 to Sherman
1053	July 16, 2015 Interview Summary in Patent '443
1054	Wright Medical’s U.S. Patent Application 2006/017349 Validity Claims Chart
1055	U.S. Patent No. 5,951,557 to Luter
1056	District Case 18-cv-00691 Dkt. 11, 2018-03-30 Summons In A Civil Matter Return of Service
1057	District Case 18-cv-00691 Dkt. 82, 2018-09-19 Brief in Support of P28's Motion for Early Claim Construction
1058	District Case 18-cv-00691 Dkt. 123, 2018-12-21 P28's Motion for Clarification of Claim Construction
1059	District Case 18-cv-00691 Dkt. 133, 2019-03-04 Minute Order re Motion to Strike and Motion for Clarification of Claim Construction Denied
1060	District Case 18-cv-00691 Dkt. 134, 2019-03-11 P28's Opening Claim Construction Brief

Exhibit No.	Description
1061	U.S. Patent No. 7,771,457 to Kay et al.
1062	U.S. Patent No. 8,100,954 to Kay et al.
1063	Aug. 4, 2016 Terminal Disclaimers in Patent ‘278
1064	Sept. 29, 2015 Terminal Disclaimers in Patent ‘252
1065	Sept. 29, 2015 Terminal Disclaimers in Patent ‘253

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I certify that I caused to be served a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,144,443 (and accompanying Exhibits) by overnight courier on the Patent Owner at the correspondence address of the Patent Owner as follows:

Hudak, Shunk, & Farine Co.
30B Northwest Avenue, Suite 210
Tallmadge OH 44278

Duane Morris LLP
IP Department
30 South 17th Street
Philadelphia, PA 19103

A courtesy copy of the foregoing was also served via email on the counsel of record for Patent Owner in the related district court action.

DATED: March 28, 2019

Respectfully submitted,

/s/ Joel R. Merkin
Joel R. Merkin (Reg. No. 58,600)
KIRKLAND & ELLIS LLP
Attorney for Petitioner