UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.

Petitioner,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.

Patent Owner.

U.S. PATENT NO. 9,545,278

Case IPR2019-00896

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

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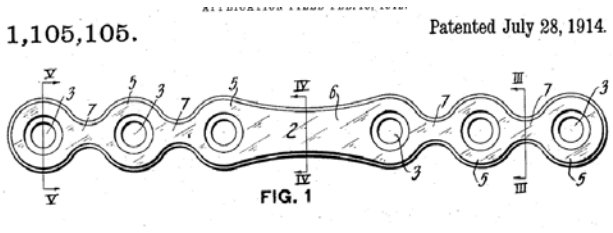
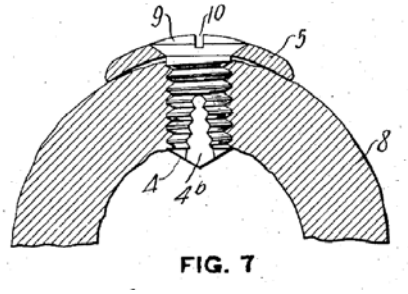
Paragon 28, Inc. ("Paragon") requests *inter partes* review ("IPR") of claims 1-9 (the "Challenged Claims") of U.S. Patent No. 9,545,278 ("the '278 patent") (Ex. 1005).

I. INTRODUCTION

The '278 patent, titled "Orthopedic Plate for Use in Small Bone Repair," issued on January 17, 2017. Ex. 1005, 1. 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 the same 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 screws that can "lock" into place

via a "threaded head" at a variety of angles, yet such screws 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 '278 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 screws with a threaded head that could "lock" into place. In 2009, seeking to expand its rights, the Applicant filed a continuation-in-part application in 2009 ("2009 CIP application") and added new material, including a screw with a threaded head that can "lock" into place and a bone plate with an S-curve. 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. Locking screws and S-curves 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. *E.g.* Ex. 1005, Claim 1. An untreated fractured, or broken, bone can lead to bone shortening, lack of bone alignment, formation of calluses, and limited mobility. Ex. 1001, ¶30. 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.* ¶31.

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. Ex. 1005, Abstract. Below is an overview of the state of the art of bone plates and screws as of the priority date of the Challenged Claims.

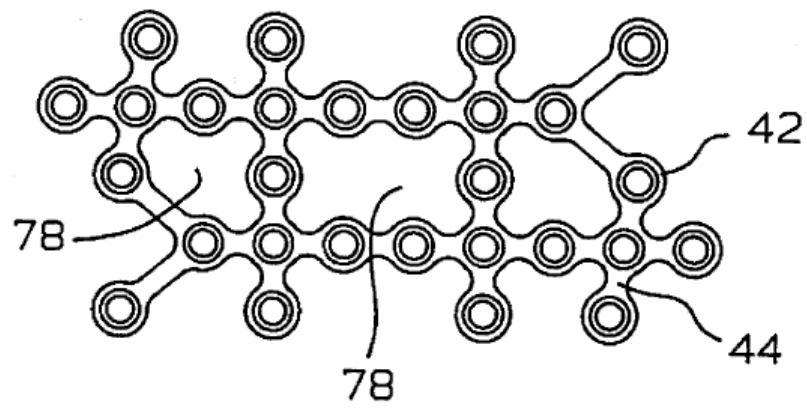
A. Bone Plates

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,

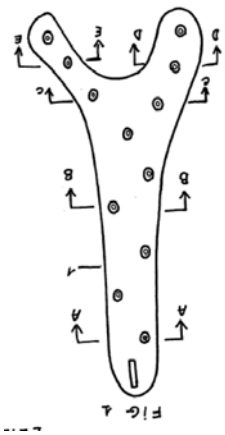
stabilizes the fractures, and prevents further fracturing. *Id.* Compression aids in repairing the bone, while ensuring the bone is properly aligned. *Id.*

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.

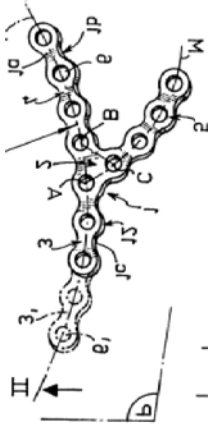
Plate size varies based on the anatomy of the person and the bone to be healed. *Id.*, ¶35. Because bones have different shapes, and humans have differently sized anatomy, POSITAs understood that plates could and should be shaped in a variety of configurations to permit the plate to attach to the bone in an advantageous manner. *Id.*, ¶¶35-36. 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":



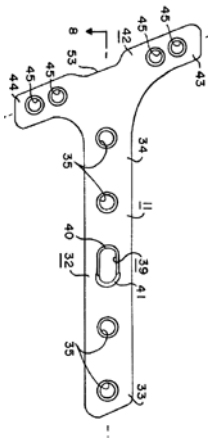
Ex. 1012, Abstract, Fig. 12, 2:59-65, 7:9-22; Ex. 1001, ¶37. Surgeons and POSITAs understood how to use these "linking members" to form "Y-shaped plates, T-shaped plates, X-shaped plates, and numerous other conventional and non-conventional shaped plates." Ex. 1012, 7:18-22. POSITAs also would have been 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 '278 patent, as shown below:



Ex. 1013, Fig. 1 (1977)

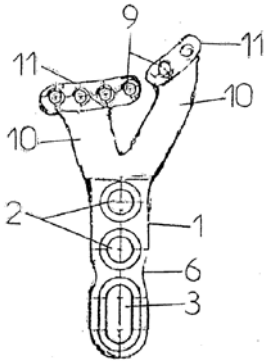


Ex. 1015, Fig. 1 (1987)



Ex. 1010, Fig. 1 (2000)

Ex. 1017, 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:

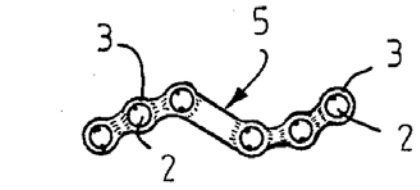
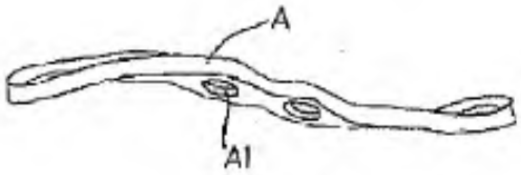
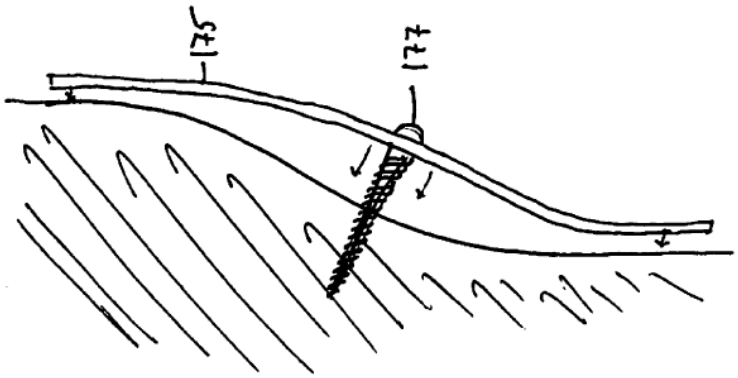


Fig. 3

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:

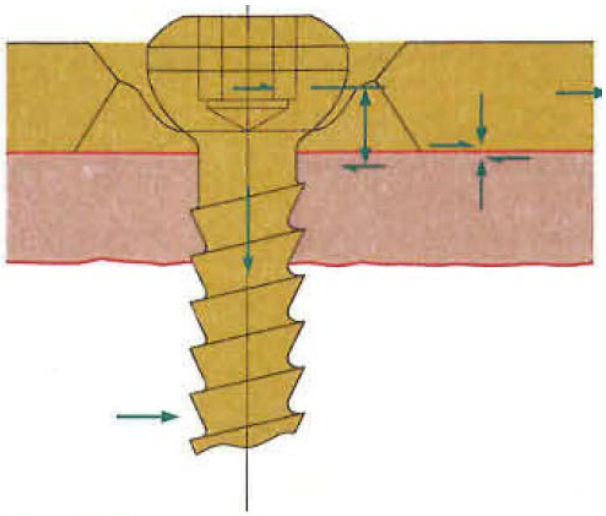


Fig. 1.2-20: Conventional plate screws

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:

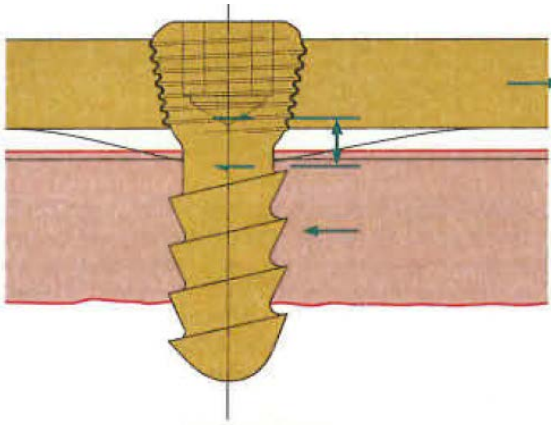
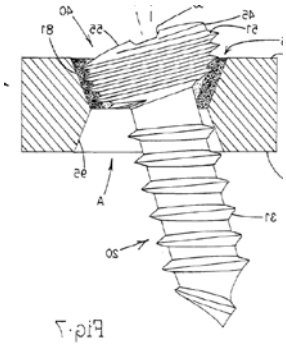


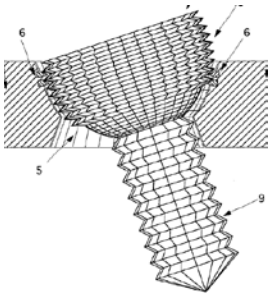
Fig. 1.2-21: Locked plate screws.

Ex. 1023, 18. 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.

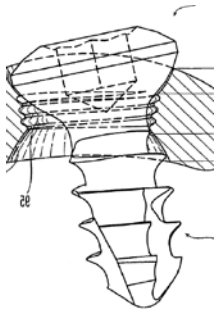
Screws can also be polyaxial, *i.e.* permitted to be inserted at a variety of angles, or monoaxial, *i.e.* permitted to be inserted at a single angle. *Id*., ¶¶46-47. POSITAs used polyaxial screws to permit screws to be inserted at an optimal angle to achieve optimal compression and avoiding hitting 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, ¶¶46-47. Below are examples of variable angle locking and non-locking screws:



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



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



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

III. PRIORITY DATE OF THE CHALLENGED CLAIMS

The 2009 CIP application added new matter to the 2006 application, including matter found 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 claims of the '278 patent 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. The Challenged Claims Are Not Entitled To The Priority Date Of The 2006 Application

Claims 1-9 are not entitled to the priority date of the 2006 application because they recite a "threaded head" limitation that is not supported by the 2006 application.

Claim 1 and its dependent claims 2-4 recite "wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface" (the "threaded head limitation"). Ex. 1005, Claim 1. Similarly, Claim 5 and its dependent claims 6-9 recite "wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface." *Id.*, Claim 5.

Figures 6 and 7 of the '278 patent depict the difference between threaded and unthreaded screw heads:

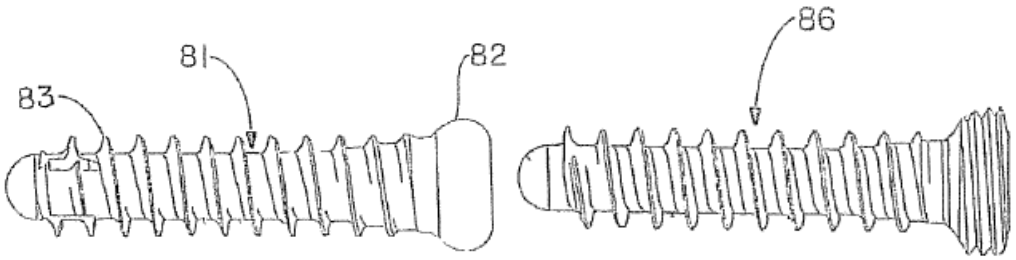


FIG.-6 FIG.-7

Ex. 1005, Fig. 6 (unthreaded screw head), Fig. 7 (threaded screw head). Although the 2006 application and the '278 patent share many common figures (Figs. 1-5 of

the 2006 application, for example, are either identical or practically identical to figures from the ’278 patent), Figs. 6 and 7 of the ’278 patent are not found in the 2006 application. *See* Ex. 1006, Figs. 1-31; Ex. 1005, Figs. 1-47.

The 2006 application does include figures illustrating “a screw used with the present system.” Ex. 1006, ¶¶20-22. However, the screw used with the 2006 application, illustrated in Figures 6-8, does not have a threaded head:

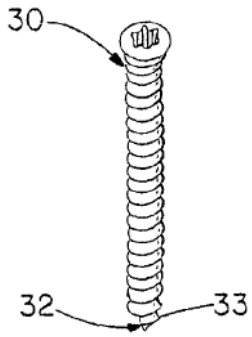


FIG.-6

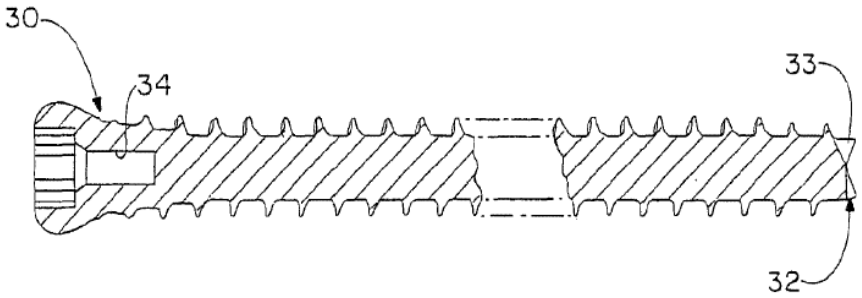


FIG.-8

Id., Figs. 6, 8, ¶22 (Fig. 8 is “a cross-section of the screw of FIG.**6** taken along line 6-6.”). As can be seen most clearly in Figure 8, the threads (or protrusions) on the shaft of the screw do not continue to the head of the screw

The 2006 application provides numerous details about the screws “used with the plate system of the present invention.” Ex. 1006, ¶53. For example, the screws are oriented so as to “avoid impinging on each other,” while still allowing the “longitudinal axes of the screws [to] converge in the direction of the [distal] end of

the screw." *Id.*, ¶9. The "[distal] end of the screw includes a cutting tip," the cutting tip is "self-starting and self-tapping," the screws "can optionally include partial or full cannulation," and the "screw has a cancellous thread." *Id*., ¶53. The 2006 application even provides details regarding the "screw head," reciting that the "head of the screw is spherical and includes a torque driving recess" (*id.*), explaining the screw heads have "a low profile so that the screws can be seated with their longitudinal axes at a variety of angles" (*id.*, ¶10), and describing that the screw heads are "rounded at the junction of the head and the shaft" (*id.*, ¶12). The rounded low profile of the screw head in the 2006 application "keeps the screw from having any sharp projecting edges which could provide an irritation to the tissue in the vicinity of the plate and further seats in the plate so that no more than 10% by volume of the screw head projects from the plate." *Id*. Yet despite the level of detail with which the 2006 application describes the screw heads, the screw head itself is never described as "threaded," as required by claims 1 and 5 of the '278 patent and their dependents. *See generally* Ex. 1006; Ex. 1005, claims 1, 5.

Comparing the claims in the published version of the 2006 application to the claims of the '278 patent further illustrates the differences between the patents. In the 2006 application, both published claim 15 and claim 27 recite the claimed plate system includes "screws ***having [] threaded shafts and a head*** wherein the screw holes and the screw heads have a mating interface such that the screws can engage

the screw hole so as to allow a plurality of angular orientations of the screw axis." Ex. 1006, claims 15, 27 (emphasis added). The '278 patent uses nearly identical language, but instead recites "wherein said at least one screw ***has a threaded shaft and a threaded head*** wherein said arm screw hole and said ***threaded*** head comprise a mating interface such that said at least one screw can engage said arm screw hole so as to allow a plurality of angular orientations." Ex. 1005, Claim 5; *see also id.*, Claim 1.

Section 112 "requires that the written description actually or inherently disclose the claim element." *PowerOasis v. T-Mobile USA, Inc.*, 522 F.3d 1299, 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 v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997). Absent any disclosure or description of a threaded head in the 2006 application, the written description of the 2006 application does not "actually or inherently disclose" an orthopedic plate using a screw having a threaded head. *See PowerOasis*, 522 F.3d at 1306-07. Given that: (i) none of the figures of the 2006 application illustrate a screw with a threaded head, and (ii) the 2006 application describes the screw head as "rounded," "spherical," and "low profile," but ***not*** threaded, a POSITA would not

have understood the screws used with the orthopedic plate described by the 2006 application to have threaded heads. Ex. 1001, ¶¶80-82.

As independent claims 1and 5, and their dependent claims, include the "threaded head" limitation, they are not entitled to the priority date of the 2006 application. Therefore, the earliest priority date for the Challenged Claims is the filing date of the 2009 CIP application: February 24, 2009.

C. Claim 9 Is Not Entitled to the Priority Date of the 2006 Application

Claim 9 and its dependent claims 10-11 recite an orthopedic plate system "wherein the curve in the lateral plane or in the longitudinal plane is an S-curve" (the "S-curve limitation"). Ex. 1005, Claim 9.

The 2006 application describes the curvature of the claimed plate, stating that the claimed plate is meant 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. However, the 2006 application does not disclose an S-curve. A search 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 ’278 patent specifically discloses an orthopedic plate with an S-curve, and why a person of ordinary skill in the art (“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. 1005, 5:12-23 (emphasis added).

The figures of the 2006 application and the ’278 patent also illustrate the differences between the two disclosures. The 2006 application and the ’278 patent share many common figures. *Compare* Ex. 1006, Figs. 1-5 and 28-31 *with* Ex. 1005, Figs. 1-5 and 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 ’278 patent, which were added with the 2009 CIP application, depict an orthopedic plate with an S-curve:

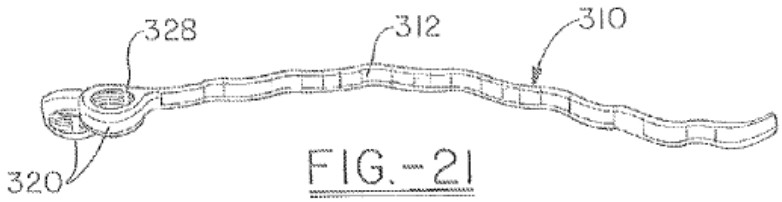


FIG.-21

FIG.-22

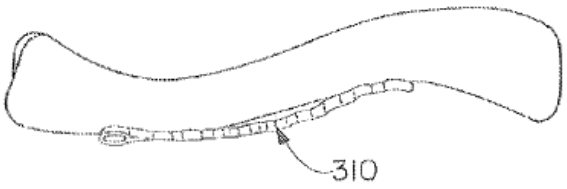


FIG.-23

Ex. 1005, Figs. 21-23.

The U.S. Patent and Trademark Office ("USPTO") agreed that the proper priority date of Claim 9 is February 24, 2009. The Examiner stated in her April 4, 2016 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 [then-pending] claims 22-25 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, independent claim 22 includes the recitation of an "S-curve in a lateral plane or in a longitudinal plane." [The 2006 application] lacks any reference to an S-curve.

> **Accordingly, the effective filing date for the claimed subject matter (claims 22-25) in the current application is February 24, 2009**.

Ex. 1049, 4. The applicant admitted that the 2006 application "does not include a direct textual reference to an S-curve," but argued that the 2006 application "would still enable one skilled in the art to make and use a plate having an S-curve in a lateral plane or in a longitudinal plane." Ex. 1050, 6. But "[e]ntitlement 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. Section 112 "requires that the written description actually or inherently disclose the claim element." *PowerOasis*, 522 F.3d at 1306-07 (citing *TurboCare*, 264 F.3d at 1118-20).

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 of the 2006 application to have 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.

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 '278 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. The earliest priority date to which the Challenged Claims are entitled is February 24, 2009. *Supra* Section III.

- 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 Pub. No. 2008/0140130 to Chan et al. ("Chan") (Ex. 1007), filed January 9, 2008 and published June 12, 2008. Chan is prior art under 35 U.S.C. § 102(a).
- U.S. Patent No. 6,283,969 to Grusin ("Grusin") (Ex. 1010), filed March 10, 2000, and issued September 4, 2001. Grusin is prior art under 35 U.S.C. § 102(b).
- U.S. Patent Pub No. 2005/0165400 to Fernandez ("Fernandez") (Ex. 1011), filed January 26, 2004 and published July 28, 2005. Fernandez is prior art under 35 U.S.C. § 102(b).

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

- 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).

Even if the Challenged Claims were found to be able to claim priority to the filing date of the 2006 application (January 6, 2006), or provisional application 60/648,209 (January 28, 2005), at least Heinl, Grusin, and Fernandez would be prior art to the Challenged Claims.

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

Ground	Claims	Description
1	1-8	Obvious under § 103 in view of Kay and Chan
2	9	Obvious under § 103 in view of Kay, Chan, and Heinl
3	1-8	Obvious under § 103 in view of Grusin and Fernandez

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, Case No. 1:18-cv-00691-PAB-STV (D.

Colo.). Paragon has submitted its opening brief, and a *Markman* hearing is scheduled for April 2019.

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 prior art Challenged Claims are rendered obvious by the prior art whether Paragon's or Patent Owner's proposed construction is applied. Ex. 1001, ¶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 a "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
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

A person of ordinary skill in the art contemplated by the ’278 patent would have had 2-3 years of experience in the design of orthopedic plates or 2-3 years of experience using orthopedic plates in surgery. Ex. 1001, ¶28.

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 ’278 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.

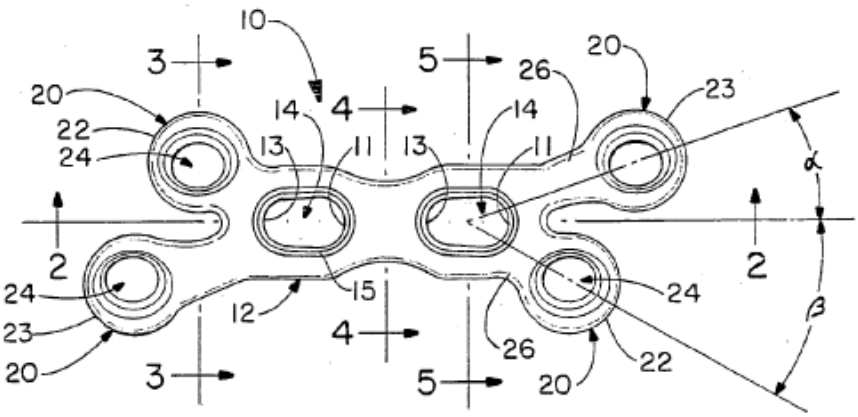


FIG.-1

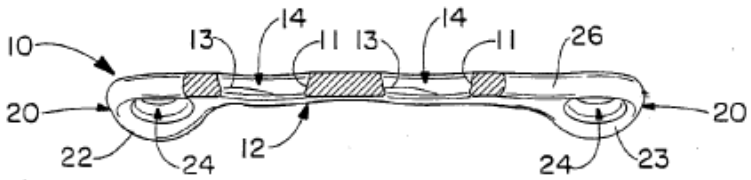


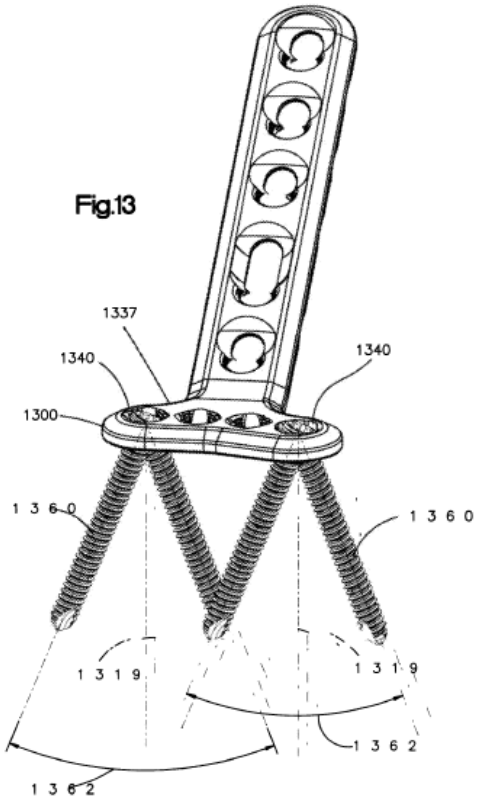
FIG.-2

Though Kay describes other examples of plates having varying lengths or a single set of arms, POSITAs would recognize that the features of the plate depicted in Figures 1-2 (such as the arms and screw holes) are otherwise the same as examples elsewhere in the specification, and that these features would be readily combinable with features of other examples disclosed in Kay.

B. Chan

Chan is titled "Highly-Versatile Variable-Angle Bone Plate System" and generally describes "[a] bone plate system for internal fixation of bone fractures [that] includes a bone plate having a plurality of bone plate holes" that are "constructed to receive either a non-locking, locking or variable-angle locking bone screw." Ex. 1007, 1. Chan discloses that the inner surface of the screw holes has

"columns of teeth or thread segments" that are configured to engage the threaded heads of locking and variable-angle locking screws. *Id.*, ¶14. An example of a plate with threaded screw holes disclosed by Chan is shown below:



C. Grusin

Grusin is titled "Bone Plating System" and generally describes "a plating system for fractures of the distal radius" that "is designed to give a surgeon a low contour, stainless steel" system "while preserving the strength of the current more bulky prior art distal radial plating systems." Ex. 1010, 1, 1:18-20, 2:5-10. Grusin discloses a plate that includes a longitudinal segment and a transverse segment that form a T-shape. *Id.*, 1:56-2:2. The longitudinal segment includes several recessed

holes and a slot with a beveled edge, and the transverse segment also includes recessed holes. *Id.*, 1:62-2:2.

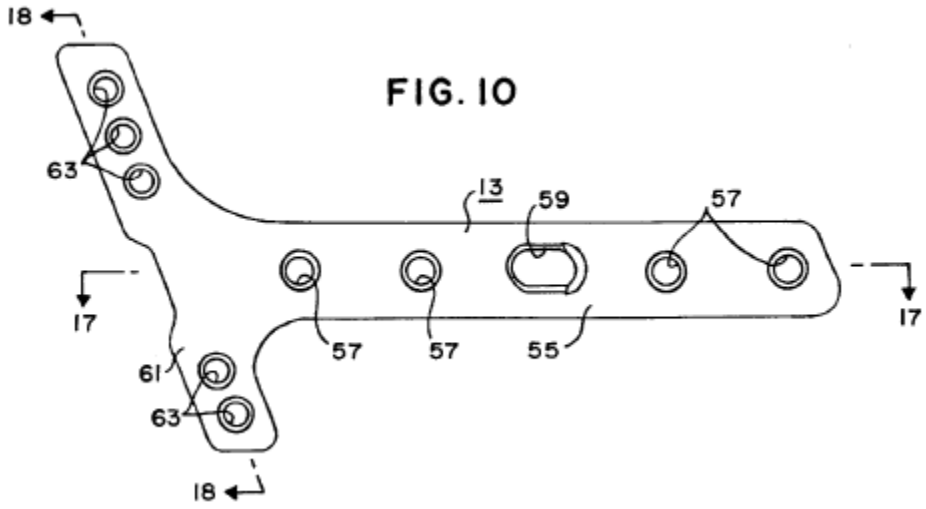


FIG. 10

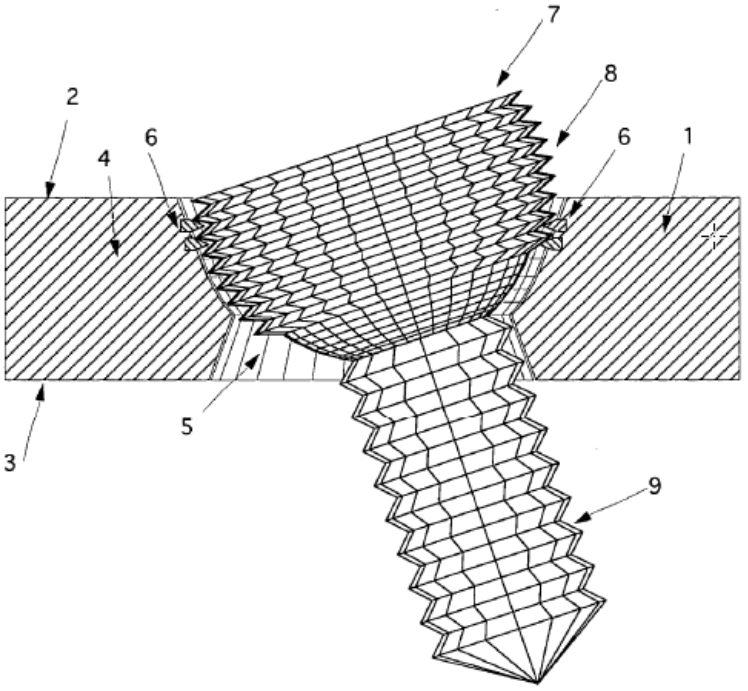
Grusin discloses, in part, distal radial dorsal plates 11 and 13. *See, e.g., id.*, Figs. 10, 12.) Plates 11 and 13 represent separate disclosed embodiments, but Grusin states, "[o]ther than size and one exception . . . the large, left distal radial dorsal plate 13 is preferably identical in design and construction to the small, left distal radial dorsal plate 11." *Id.*, 6:60-7:2. Grusin further clarifies that its "disclosure of the corresponding features, etc., of the small, left distal radial dorsal plate 11 will provide a full and enabling teaching of such features, etc., for the large left distal radial dorsal plate [13] to one of ordinary skill in the art." *Id.*, 7:2-6. The "one exception" is that "the lateral end of the distal transverse segment 61 [of plate 13] is extended proportionally a greater distance from the proximal longitudinal segment 55 than [in]…plate 11, and an additional spherically recessed hole 63 is provided through the lateral end 43 of the distal transverse segment 42."

Id., 7:8-15. Aside from this exception, descriptions of plate 11 apply equally to plate 13. *Id.*, Figs. 12-18.

D. Fernandez

Fernandez is titled "Variable Angle Locked Bone Fixation System," and describes a "bone fixation assembly" that allows a screw to be threaded into bone through the bone plate hole at a selected angle. Ex. 1011, 1. Fernandez discloses a locking bone screw and plate "having a polyaxial coupling of the screw to the fixation device, whereby a single fixation device is compatible with a wide range of screw-in angles." *Id.*, ¶¶10-11. The plate system described in Fernandez includes hourglass-shaped screw holes that have an inner wall with a small number of isolated protrusions that lock against the threaded heads of the screws. *Id.*, ¶32. The screw heads are spherical and "threaded with a constant pitch." *Id.*, ¶30. Below is an example of the screw and plate hole disclosed by Fernandez:

FIG. 10



E. Heinl

Heinl is a U.S. patent that issued on February 27, 1990 and is 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 several plates of different shapes and curvatures." *Id.*, Abstract. Heinl discloses a set of 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 plates. *Id.*, 1:22-26, 1:42-55. Figures 1-5 of Heinl illustrate five different configurations of Heinl's 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:

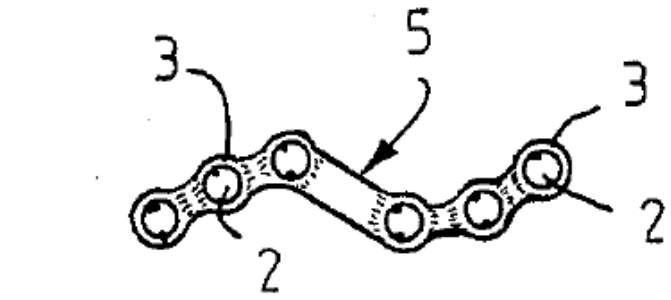


Fig. 3

VII. PROSECUTION HISTORY OF THE ’278 PATENT

During prosecution, the examiner rejected the then-pending claims of the ’278 patent on the grounds of nonstatutory double patenting over U.S. Patent No. 7,771,457 (“the ’457 patent”), which is the patented version of Kay. Ex. 1049, 6-8. The ’457 Patent was filed as U.S. Application No. 11/340,028 (“the ‘028 application”), and contains the same disclosure as Kay. *Compare* Ex. 1006, 1 *with* Ex. 1061, 1. The applicant filed a terminal disclaimer to the ’457 Patent to traverse the nonstatutory double patenting rejection. Ex. 1063.

The examiner determined the 2006 application failed to disclose “an S-curve in a lateral plane or in a longitudinal plane,” and thus determined the priority date for those claims was February 24, 2009. Ex. 1049, 3-4. Despite the fact that the examiner believed (1) the priority date of the “S-curve” claims was February 24,

2009 (*id.*, 4), and (2) believed then-pending claims 1 and 22 were obvious based on the ’457 patent in view of Dayan (Ex. 1013), 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 ’278 patent, the examiner did not discuss Kay during prosecution. Heinl is also cited on the face of the ’278 patent, but Chan, Grusin, and Fernandez are not. 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 ’278 PATENT ARE UNPATENTABLE

The Challenged Claims are unpatentable on the following grounds: claims 1-8 are rendered obvious by the combination of Kay and Chan (Ground 1), claim 9 is rendered obvious by the combination of Kay, Chan, and Heinl (Ground 2), and claims 1-8 are rendered obvious by the combination of Grusin and Fernandez (Ground 3). As described below, the combinations of Kay and Chan; Kay, Chan, and Heinl; and Grusin and Fernandez disclose every element of the Challenged

Claims, and it would have been obvious to POSITAs to combine the teachings of these references.

A. Ground 1: Kay in view of Chan

1. POSITAs Would Have Found it Obvious To Modify Kay in View of Chan.

POSITAs would have found it obvious to use screws with a threaded head and threaded screw holes, as disclosed by Chan, with Kay's plate system. Ex. 1001, ¶¶408-10.

Kay uses non-locking screws and a plate design that it claims "increase[s] the pullout strength." Ex. 1006, ¶4. Chan recognizes that "non-locking screws" in a plate "can cause the screws to loosen or back out with respect to the plate" (Ex. 1007, ¶3), and found the solution in "locking screws," in which "the thread on the screwhead mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate" (*id.*, ¶4). Chan lists numerous bone-plate systems in which various combinations of threaded and non-threaded screw holes are used to accept locking or non-locking screws at varying angles. *Id*., ¶¶6-11. Chan thus recognizes that it would be desirable to design a plate system with both locking and non-locking screws, and include screw holes that feature "discrete columns of teeth or thread segments for engaging compatibly dimensioned and configured threaded heads of locking and variable-angle locking bone screws." *Id*. ¶¶5, 14.

POSITAs would have been motivated by the disclosure in Kay to seek out ways to improve pullout strength. Ex. 1001, ¶408. POSITAs would have understood that a way to achieve increased pullout strength would be to use the known combination of non-locking screws and locking screws with a threaded head as disclosed by Chan, and thread the screw holes of the plate disclosed by Kay using either the thread segments or conventional threading disclosed by Chan, so that the plate system could accept locking screws with threaded heads. *Id.*, ¶409. And POSITAs would have expected this modification would be successful. *Id.*, ¶410. Screws with threaded heads that mate and engage threaded screw holes were a known way to secure screws to a plate. Ex. 1007, ¶4; Ex. 1024, ¶2 (2004 publication listing multiple earlier disclosures of screws with threaded heads that mate with and engage threaded screw holes to "lock" to the plate); Ex. 1001, ¶410. Given the long history and known advantages of screws with threaded heads that engage threaded screw holes, POSITAs would have expected that those teachings of Chan could be successfully incorporated into Kay, and would have seen no reason why such screws with threaded heads, and threaded screw holes, could not be used with the plate system of Kay. Ex. 1001, ¶410.

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, ¶ 396. 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 in view of Chan discloses at least one screw. Ex. 1001, ¶¶397-98. Kay's plate "relates to an orthopedic plate and screw system," and Kay describes that "[t]he screws of the system are self-starting, self-tapping screws." Ex. 1006, Abstract; *see also id.*, Figs. 6-8, ¶¶12, 53.

Chan describes that "[v]ariable-angle locking bone screws can engage the bone plate at a selectable angle within a range of selectable angles relative to the central axis of the bone plate hole." Ex. 1007, Abstract. The holes in Chan's plate "receive either a non-locking, locking, or variable-angle locking bone screw," and "[a] variable-angle locking bone screw according to the invention is inserted through a bone plate hole and locked to the bone plate at a selectable angle within a range of selectable angles." *Id.*, ¶¶14, 17.

c. Element 1[b]: "a contoured plate having an inferior surface which is capable of engaging a bone surface in use"

Kay discloses a contoured plate having an inferior surface which is capable of engaging a bone surface in use. Ex. 1001, ¶399. Kay describes "orthopedic plates" where "[t]he plate facilitates three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape." Ex. 1006, Abstract. Kay further describes the plate as being "radiiused about the inferior surface, (*i.e.* the surface which faces toward and which may, but does not have to fully contact the bone), with a curvature corresponding generally to the curvature of a bony surface." *Id*., ¶9; *see also id.*, ¶50.

d. Element 1[c]: "having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end"

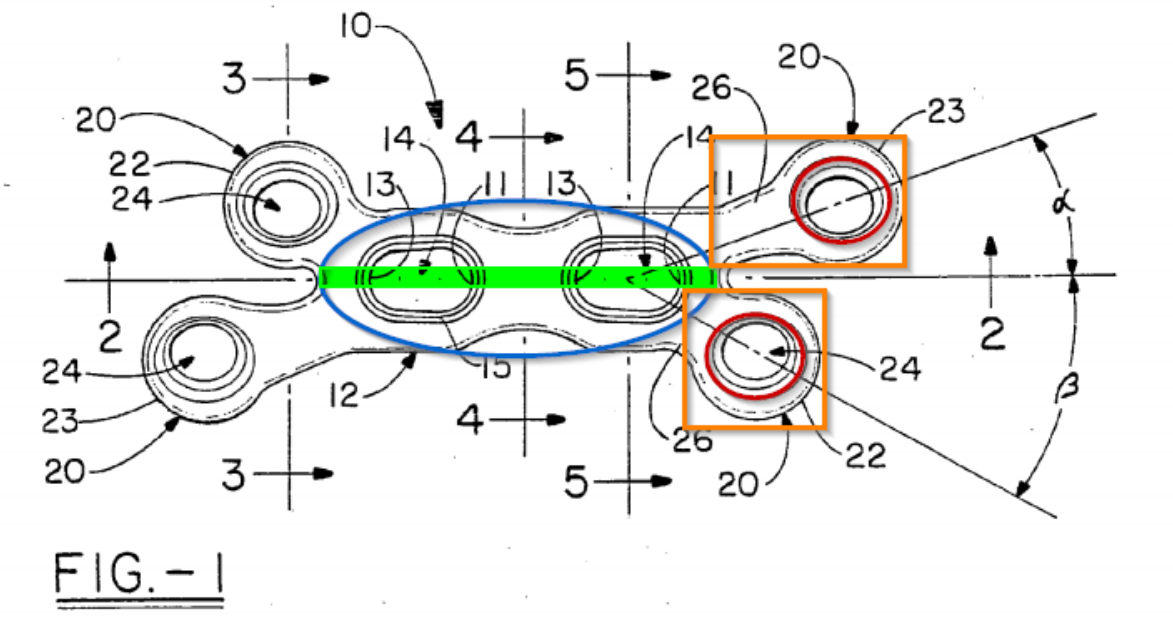
Kay discloses an orthopedic plate system having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end. Ex. 1001, ¶400. Kay states that its plate includes "a central trunk portion" and a "longitudinal axis." Ex. 1006, Abstract; *see also id.*, ¶9. Kay describes that its plate "is shown having … a central trunk portion 12 defining the longitudinal axis of the plate." *Id*., Fig. 1, ¶46; *see also id.*, Figs. 2, 9-12, 14, 16-31. The published claims of Kay describe a "plate having a trunk defining a longitudinal axis with a first end and an opposing second end" and "[a]n orthopedic plate comprising a central trunk

including a central longitudinal axis extending between a first end and a second end." *Id.*, claims 1, 9. As the "longitudinal trunk axis" of Kay's plate is the axis that runs the length of the trunk as defined by the central trunk portion, Kay discloses this limitation. Ex. 1001, ¶400.

e. Element 1[d]: "further including at the first end a pair of arms, each arm including an arm screw hole which defines a central screw hole axis"

Kay discloses an orthopedic plate that includes at the first end a pair of arms, each arm including an arm screw hole which defines a central screw hole axis. Ex. 1001, ¶¶401-03. Kay describes its plate as "having a bilaterally asymmetric shape…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 "screw holes [of the arms] are placed with the longitudinal axis perpendicular to a tangent to the top surface of the arm." *Id.*, ¶50.

The annotated figure below shows the central trunk portion (blue), the longitudinal trunk axis (green), a pair of arms at the first end (orange), and an arm screw hole (red):

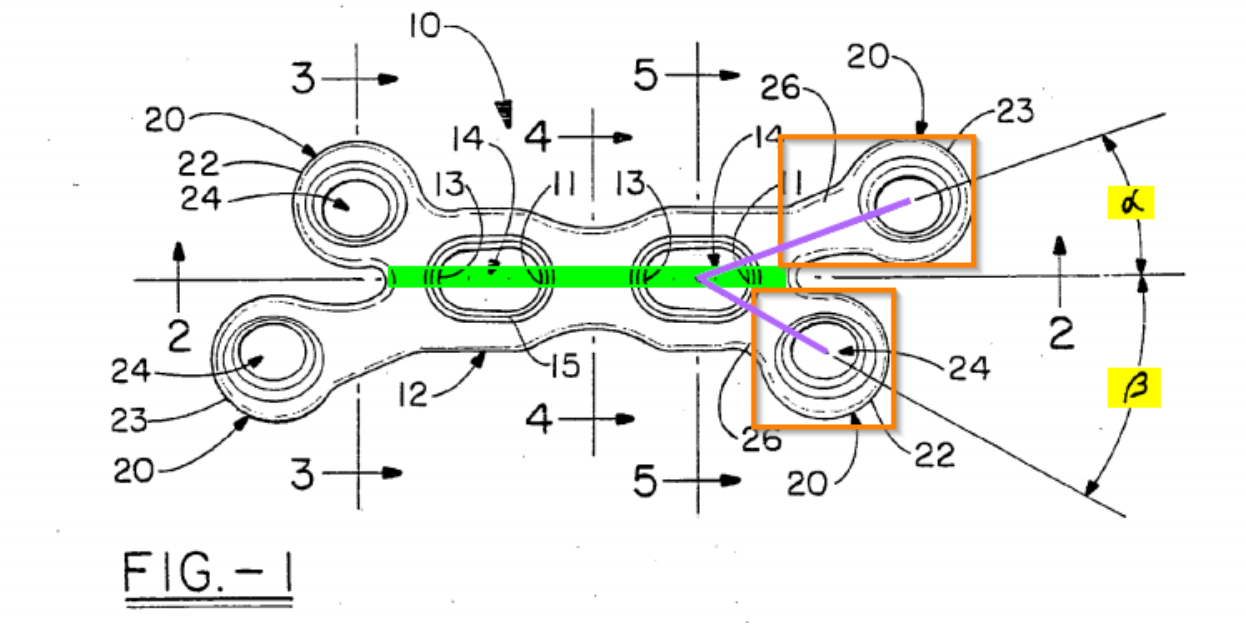


Ex. 1006, Fig. 1 (annotated); Ex. 1001, ¶402.

f. Element 1[e]: "having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal axis of the trunk area"

Kay discloses an orthopedic plate having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal axis of the trunk area. Ex. 1001, ¶403. Kay describes the arms of its plate as "diverging asymmetrically from the longitudinal axis," 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. Kay describes each of the "first and second" arms as "having a screw hole and a longitudinal axis which defines an angle relative to the central longitudinal axis of the trunk." *Id.*, claim 9.

In the annotated figure below, the arms of Kay's plate (orange) each have a longitudinal arm axis (purple) extending between the central screw hole axis and the longitudinal trunk axis (green), and each longitudinal arm axis forms an angle (yellow) with respect to the longitudinal axis of the trunk area.



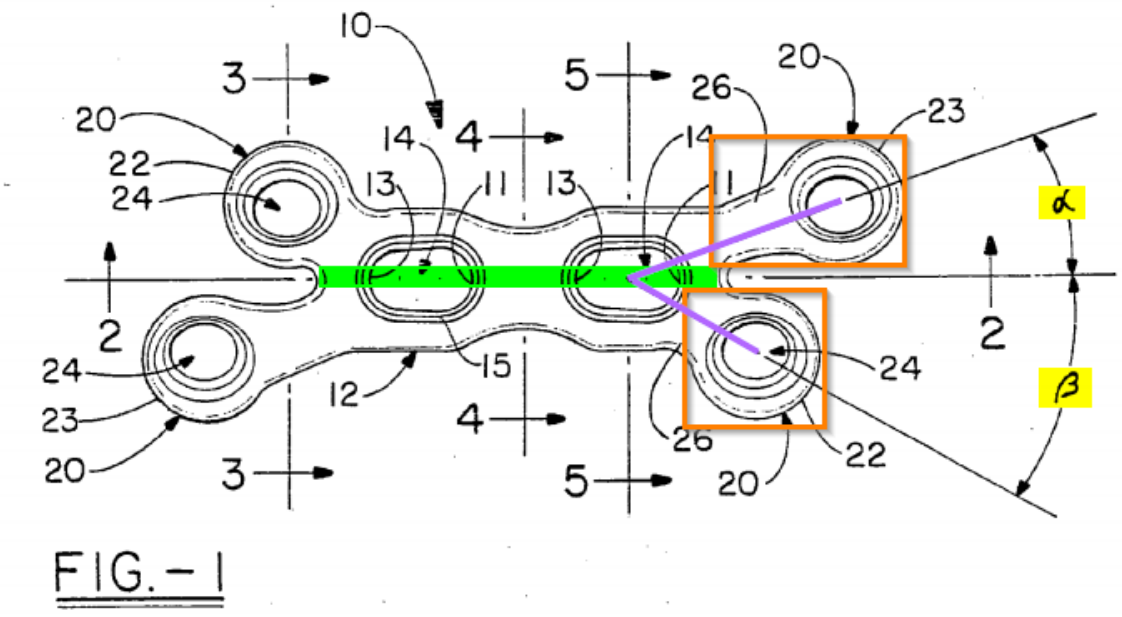
Id., Fig. 1 (annotated); Ex. 1001, ¶403.

g. Element 1[f]: "wherein the longitudinal arm axis of the first of the pair of arms is different than the longitudinal arm axis of the second pair of arms"

Kay discloses an orthopedic plate wherein the longitudinal arm axis of the first of the pair of arms is different than the longitudinal arm axis of the second of the pair of arms. Ex. 1001, ¶404. Kay describes the arms of its plate as "a set of diagonally opposed short 22 and long arms 23," and states 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; *see also id.*, ¶7 (describing the plate as "bilaterally asymmetrical"). Kay further describes that "the arms are asymmetrical relative to each other," and that "they diverge from the longitudinal axis of the trunk portion at differing angles." *Id.* ¶50.

Annotated Figure 1 below shows a plate wherein a longitudinal arm axis of the first of the pair of arms is different than a longitudinal arm axis of the second pair of arms:



Id., Fig. 1 (annotated); Ex. 1001, ¶404.

h. Element 1[g]: "wherein said at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the

screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis."

Kay in view of Chan discloses an orthopedic plate wherein at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis. Ex. 1001, ¶¶405-10. Both Kay and Chan disclose at least one screw. *Supra* Section VIII.A.2.b.

Kay describes that "[t]he screws of the system are self-starting, self-tapping screws." Ex. 1006, Abstract. The screw described by Kay has a threaded shaft and a screw axis along the shaft. *Id.*, Figs. 6-8, ¶¶12, 53; Ex. 1001, ¶406. Kay describes a plate with screw holes and screw heads "wherein the screw holes and the screw heads have a mating interface such that the screws can engage the screw hole so as to allow a plurality of angular orientations of the screw axis." Ex. 1006, claim 27.

While Kay does not disclose a screw with a threaded head, Chan describes "[v]ariable-angle locking screws" that "have a head that is at least partially spherically shaped," and that "has an external screw thread on its outer surface." *Id.*, ¶18; *see also id.*, Abstract, ¶58. Chan's plate includes screw holes which "are constructed advantageously to receive either a non-locking, locking, or variable-angle locking bone screw" (*id.* ¶14) and which "preferably have four columns 942

of thread segments, as shown in Figs. 9A and 9B" (*id.* ¶67). The threads may extend completely or partially through the screw hole. *Id.*, ¶64, Fig. 8.

POSITAs would have been motivated to use locking screws with threaded heads, and threaded screw holes to engage them, as disclosed by Chan, with Kay's plate system to increase pullout strength and would have expected such a combination to work. Ex. 1001, ¶¶408-10; *supra* Section VIII.A.1.

3. Claim 2

a. "The orthopedic plate system as set forth in claim 1, comprising at least two screws, wherein the two screws each have a length and a diameter such that when the two screws are locked in their respective screw holes, the two screws do not impinge on each other."

Kay in view of Chan renders obvious claim 2. Ex. 1001, ¶¶411-13. 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 distil [sic] end." Ex. 1006, ¶50. "Since the arms are asymmetrical relative to each other, and in particular since they diverge from the longitudinal axis of the trunk portion at differing angles, conflicts in the positions of paired screws is avoided so that the screws of a set of arms typically do not impinge on each other." *Id*.

POSITAs would have been motivated to use screws with threaded heads, such as those described in Chan, to lock the screws and increase pullout strength. *Supra*

Section VIII.A.1. Because Kay describes that "the screws of a set of arms typically do not impinge on each other" (Ex. 1006, ¶50), and because POSITAs would have understood that using Chan's threaded-head screws with Kay's orthopedic plate would not change the geometry of the screw holes described in Kay, POSITAs would have known to select a length and diameter for Chan's threaded-head screws that would ensure the two screws would not impinge on each other when locked into the arm holes of Kay's plate, based on Kay's explicit disclosure that those are the preferred screws. Ex. 1001, ¶413.

4. Claim 3

a. "The orthopedic plate system as set forth in claim 1, wherein the mating interface between the screw head and the arm screw holes allows for at least 30° of conical orientation of the screw axis in the screw hole."

Kay in view of Chan renders obvious claim 3. Ex. 1001, ¶¶414-16. Kay describes that the screws have "mating heads…so that the screws can be seated with their longitudinal axes at a variety of angles…most preferably [there is] 30° of conical rotation of the screw axis in relation to the longitudinal axis of the screw hole (i.e. the longitudinal axis of the screw can be rotated through a conical shape about the axis of the screw hole where the apex of the cone describes an angle of 30°)." Ex. 1006, ¶10. Kay describes a plate system "wherein the mating interface

between the screw heads and the screw holes allow for at least 30° of conical orientation of the screw axis in the screw hole." *Id.*, claim 28.

Chan also describes that "[t]he range of selectable angles" for bone screws "forms a cone of about 30 degrees about the central axis of the hole." Ex. 1007, ¶17. Therefore, once Kay is modified in view of Chan, inserting threaded-head screws coaxially with threaded screw holes would still allow for at least 30° of conical orientation of the screw axis in the screw hole, because both Kay and Chan explicitly state that 30° of conical orientation is permitted. Ex. 1001, ¶416.

5. Claim 4

a. "The orthopedic plate system as set forth in claim 1, wherein the arm screw hole includes internal threads."

Kay in view of Chan renders obvious claim 4. Ex. 1001, ¶¶417-20. In Kay's plate system, "the screws and corresponding screw holes" vary in size, and "the bore could be threaded." Ex. 1006, ¶52; *see also id.*, claim 27.

In Chan's plate system, the screw holes "are constructed advantageously to receive either a non-locking, locking, or variable-angle locking bone screw" (Ex. 1007, ¶14), and "preferably have [] thread segments" (*Id.*, ¶67, Figs. 9A-B). Chan's plates may optionally have "conventionally threaded and/or non-threaded screw holes." *Id.*, ¶21. "[C]onventional locking plate holes" may be completely or partially threaded. *Id.*, ¶64; *see also* Ex. 1001, ¶419.

POSITAs would have been motivated to incorporate screw holes with an internal thread and screws with a threaded head, as disclosed by Chan, into the plate taught by Kay, and would have expected the combination to succeed. *Supra* Section VIII.A.1; Ex. 1001, ¶420.

6. Claim 5

a. Element 5[pre]: "An orthopedic plate system comprising"

See Section VIII.A.2.a.

b. Element 5[a]: "at least one screw"

See Section VIII.A.2.b.

c. Element 5[b]: "an orthopedic plate having an inferior surface which is capable of facing a bone surface in use and which is pre-contoured to accommodate the shape of the bone surface and an oppositely facing concentric superior surface"

Kay discloses an orthopedic plate having an inferior surface which is capable of facing a bone surface in use and which is pre-contoured to accommodate the shape of the bone surface and an oppositely facing concentric superior surface. Ex. 1001, ¶423. As described above, Kay discloses a contoured plate with an inferior surface capable of engaging a bone surface in use. *Supra* Section VIII.A.2.c. The "inferior surface" is "the surface which faces toward…the bone." Ex. 1006, ¶9. Kay's plate also is "designed to facilitate three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape." *Id.*, ¶7; *see*

also id., claim 2. Kay also states its plate has "a concentric radius on the superior side," opposite the inferior side. *Id.*, ¶49, Figs. 3-5.

d. Element 5[c]: "the plate having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end and defining at least a portion of the inferior surface which includes a curve transverse to the longitudinal trunk axis"

Kay discloses a plate having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end and defining at least a portion of the inferior surface which includes a curve transverse to the longitudinal trunk axis. Ex. 1001, ¶424. As described above, Kay discloses a central trunk portion defining a longitudinal trunk axis extending between a first and second end. *Supra* Section VIII.A.2.d. Kay's plate, including the central trunk portion, "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), with a curvature corresponding generally to the curvature of a bony surface." Ex. 1006, ¶9. As a curve transverse to the longitudinal trunk axis runs perpendicular to the longitudinal trunk axis, a radius about the inferior surface of the plate could create a curve transverse to the longitudinal trunk axis. Ex. 1001, ¶424. Figures 3-5 of Kay are cross-sections of the plate of Figure 1 taken along lines 3, 4, and 5 respectively (transverse to the longitudinal trunk axis), and each illustrate a curve of Kay's plate that is transverse to the longitudinal trunk axis. Ex. 1006, Fig. 1, Figs. 3-5, ¶¶17-19, 52.

e. Element 5[d]: "the first end including a first arm and a second arm, each arm including an arm screw hole which defines a central screw hole axis"

See Section VIII.A.2.e.

f. Element 5[e]: "each arm having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal trunk axis, the angle of the first arm being α and the angle of the second arm being β"

Kay discloses a plate wherein each arm has a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal trunk axis, the angle of the first arm being α and the angle of the second arm being β. Ex. 1001, ¶426. As described above, Kay discloses a pair of arms, each arm having a longitudinal arm axis extending between the central screw hole axis and the longitudinal trunk axis and defining an angle with respect to the longitudinal trunk axis. *Supra* Sections VIII.A.2.e, VIII.A.2.f. Kay describes the arms as "diverging asymmetrically from the longitudinal axis of the plate," and states "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; *see also id.*, Fig. 1.

g. Element 5[f]: "where α is different than β such that the central screw hole axis of the right arm converges

toward but does not impinge on the central screw hole axis of the left arm"

Kay discloses that α is different than β such that the central screw hole axis of the right arm converges toward but does not impinge on the central screw hole axis of the left arm. Ex. 1001, ¶¶427-28. Kay states that "each set of arms includes one arm that defines a smaller [*i.e.*, different] 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. The arms "diverge asymmetrically from the longitudinal axis to avoid conflicts in the screw placement of the paired arm." *Id.*, ¶9. "While the screws are at convergent angles, the screws typically do not in fact impinge on each other, or conflict in their placement since each of the arms of the plate in a pair form a different angle to the central trunk so that the longitudinal axis of the screws are offset from each other along the length of the plate." *Id.*, ¶11.

h. Element 5[g]: "wherein the plate has a medial line which describes a curve in a lateral plane or in a longitudinal plane"

Kay discloses a plate having a medial line which describes a curve in a lateral plane or in a longitudinal plane. Ex. 1001, ¶429. Kay's plate is "bilaterally asymmetrical (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 also "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. As the "medial axis" of Kay is parallel to the longitudinal axis, the medial axis describes a medial line. Ex. 1001, ¶429. Kay's 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; *see also id.*, ¶47 (Kay's 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."

i. Element 5[h]: "wherein said at least one screw has a threaded shaft and a threaded head wherein said arm screw hole and said threaded head comprise a mating interface such that said at least one screw can engage said arm screw hole so as to allow a plurality of angular orientations of said at least one screw axis relative to said screw hole axis."

See Section VIII.A.2.h.

7. Claim 6

a. "The orthopedic plate system as set forth in claim 5, comprising at least two screws wherein the two screws each have a length and a diameter such that when the two screws are locked in their respective screw holes, the two screws do not impinge on each other."

See Section VIII.A.3.

8. Claim 7

a. "The orthopedic plate system according to claim 5, wherein the longitudinal arm axis of each of the first arm and the second arm intersects a longitudinal trunk axis medial to the respective first arm or second arm."

Kay in view of Chan renders obvious claim 7. Ex. 1001, ¶¶433-34. Kay's plate includes a longitudinal trunk axis. *Supra* Sections VIII.A.2.d, VIII.A.6.e. The axis shown in Figure 1 of Kay running the length of the trunk between arms 22 and 23 is a longitudinal trunk axis because it is "medial" to the first or second arm. Ex. 1001, ¶434. Each arm has at least one longitudinal arm axis. *Supra* Sections VIII.A.2.f, VIII.A.6.f. The arms of Kay's plate "diverg[e] asymmetrically from the longitudinal axis of the plate 10." Ex. 1006, ¶48. Figure 1 of Kay illustrates lines through arms 22 and 23, which form longitudinal arm axes, and those lines intersect a longitudinal trunk axis medial to the first and second arms. *Id.*, Fig. 1; Ex. 1001, ¶434. As the arms of Kay's plate diverge from the longitudinal axis of the central trunk portion, a longitudinal arm axis of each arm would intersect the longitudinal axis of the plate. Ex. 1001, ¶434.

9. Claim 8

a. "The orthopedic plate system as set forth in claim 7, wherein the mating interface between the screw head and the arm screw holes allows for at least 30° of conical orientation of the screw axis in the screw hole."

See Section VIII.A.4.

B. Ground 2: Kay in view of Chan and Heinl

1. POSITAs Would Have Found It Obvious To Combine Kay, Chan, and Heinl

POSITAs would have found it obvious to modify Kay's plates to add Chan's locking screws. *Supra* Section VIII.A.1. POSITAs also would have found it obvious to modify Kay's plates to form an S-curve based on Heinl. Ex. 1001, ¶¶437-40. Kay states that its plate "facilitates three dimensional contouring to provide for a variety of applications and to accommodate individual variation in bone shape." Ex. 1006, Abstract. POSITAs would have been motivated by this disclosure in Kay to seek out a number of different shapes of orthopedic plates to accommodate the variety of bone shapes of the human body. One such reference is Heinl, which provides examples of orthopedic plates with 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." Ex. 1001, ¶440.

2. Claim 9

a. "The orthopedic plate system as set forth in claim 5, wherein the curve in the lateral plane or in the longitudinal plane is an S-curve."

Kay in view of Chan and Heinl renders obvious claim 9. Ex. 1001, ¶¶437-40. Kay's 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. While Kay does not disclose an S-curve, *see supra* Section III.C, POSITAs would have found it obvious to contour Kay's plates, as shown in Figures 1-5, and 9-31, into an S-curve in the lateral plane or in the longitudinal plane based on Heinl. *Id.*, Figs. 1-5, 9-31; Ex. 1001, ¶438.

Heinl discloses an S-shaped plate. Ex. 1009, 2:18-22. Heinl discloses "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 illustrates "a plate of approximately S-form." *Id.*, Fig. 3, 8:53-55.

C. Ground 3: Grusin in view of Fernandez

1. POSITAs Would Have Found it Obvious to Modify Grusin in View of Fernandez

POSITAs would have found it obvious to modify the plate system of Grusin to use screws with a threaded head and threaded screw holes, as disclosed by

Fernandez, so that Grusin's plates accept locking screws with threaded heads at variable angles. Ex. 1001, ¶¶456-58.

Grusin emphasizes the desirability of designing a plate so that the "screw lock pin head" is "screwed into the screw lock pin shank 23 and tightened," in order to "lock[] the unit…together in a very solid connection." Ex. 1010, 9:5–14. Fernandez recognizes that "the use of so-called 'locking screws'" was a known method of coupling an orthopedic fixation device to a bone (Ex. 1011, ¶5) and that it is "often desirable to insert the screws at an angle relative to the fixation device selected by the surgeon," and that "[t]he prior art discloses a number of these so-called 'polyaxial' systems" (*id.*, ¶6). Fernandez emphasizes the desirability of allowing the surgeon the freedom to select the most desirable angle for a bone screw. *Id.*, ¶12.

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

and threading the screw holes of Grusin's so that the screw can engage the arm screw hole at a variety of angular orientations, would be successful. Ex. 1001, ¶458. "Locking screws" were a known method of coupling a plate to a bone. Ex. 1011 ¶5; Ex. 1024, ¶2 (2004 publication listing multiple earlier disclosures of screws with threaded heads that mate with and engage threaded screw holes to "lock" to the plate). Given the long history and known advantages of screws with threaded heads that engage threaded screw holes, POSITAs would have expected that those teachings of Fernandez could be successfully incorporated into Grusin. Ex. 1001, ¶458. And POSITAs would have seen no reason why such screws with threaded heads and threaded screw holes could not be used with the plate system of Grusin. *Id.*

2. Claim 1

a. Element 1[pre][2]

To the extent the preamble is limiting, Grusin discloses an orthopedic plate. Ex. 1001, ¶441. Grusin is titled "Bone Plating System" and relates to "bone plating systems…for fractures of the distal radius." Ex. 1010, 1, 1:18–20.

b. Element 1[a]

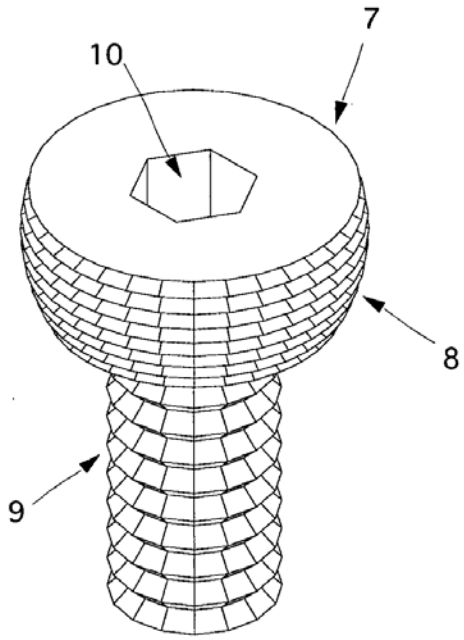
Both Grusin and Fernandez disclose at least one screw. Ex. 1001, ¶¶442-43. Grusin describes "specially designed screws with low profile heads to complement

[2] The text of the challenged claims is set forth in Ground 1, above.

the plates." Ex. 1010, 2:11–14. The "transverse segment" of Grusin's plate has "spherically recessed holes" that are designed "to accept…bone screws." *Id*., 6:14–17. "The screws…can be inserted directly into their corresponding drilled holes." *Id*., 10:14–15. Figure 76 of Grusin shows its plate with a screw. *Id.*, Fig. 76.

Fernandez describes a screw that "has a shank with a thread for engaging bone and a partial sphere head with a thread configured and dimensioned to match with the isolated protrusions of the hour glass shaped through holes of the bone plate." Ex. 1011, Abstract. Fernandez recites a method wherein "the bone screw" has "a threaded partial sphere head" and "a threaded shank." *Id.*, claim 2; *see also id.*, Figs. 1–3 and 7–10. This is depicted below:

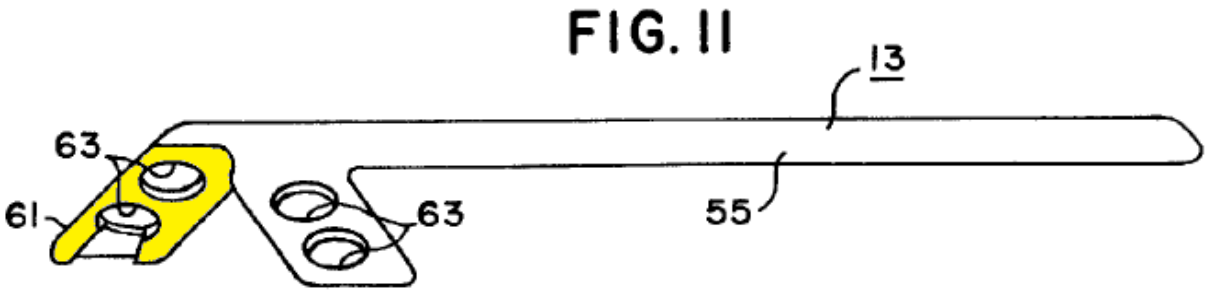
FIG. 2

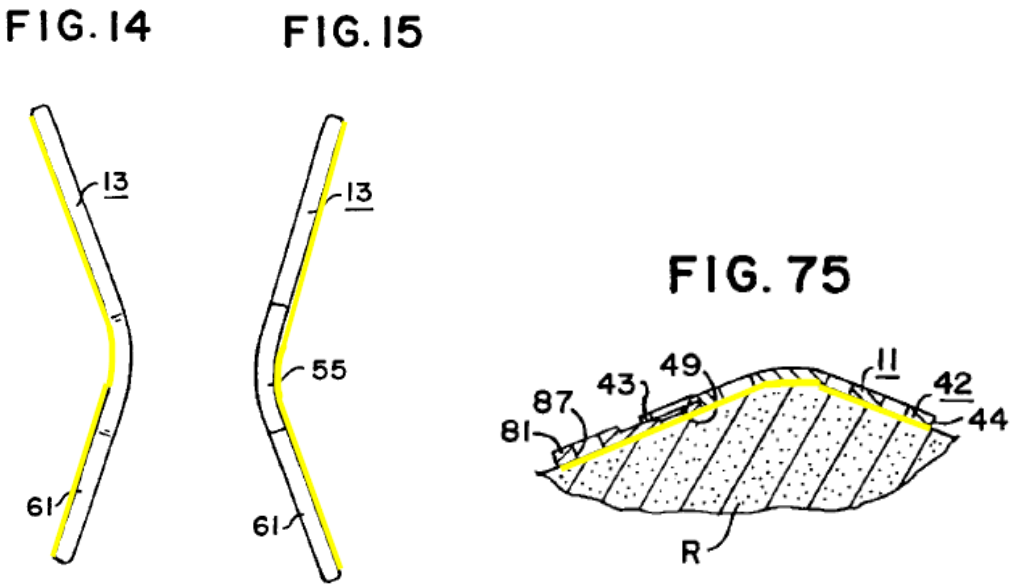


Id., Fig. 2.

c. Element 1[b]

Grusin discloses a contoured plate having an inferior surface which is capable of engaging a bone surface in use. Ex. 1001, ¶444. Grusin describes plates that are "preferably pre-bent" so that they "conform[] as closely as possible to the surface of the distal radius R." Ex. 1010, 6:36–40; *see also id.*, 7:44–50. Grusin also discloses a "slotted plate bender" that "is designed for use in bending and molding a fracture fixation plate to match the anatomy of a specific radius R." *Id.*, 9:16–24. Thus Grusin has an inferior surface (*i.e.*, a side facing the bone) that is capable of engaging a bone surface in use. Ex. 1001, ¶444. This is shown in the annotated figures below, in which the inferior surface is highlighted in yellow:



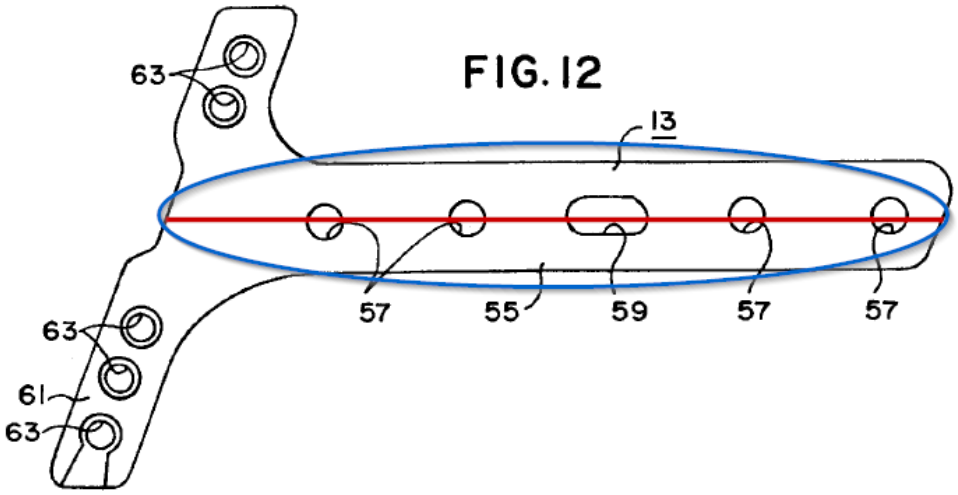


Ex. 1010, Figs. 11, 14-15, 75 (annotated); Ex. 1001, ¶444.

d. Element 1[c]

Grusin 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, ¶¶445-46. Grusin describes a "distal radial plate including a longitudinal segment having a proximal end and a distal end; a transverse segment having a lateral end and a med[ial] end; the distal end of the longitudinal segment attached to the transverse segment intermediate the lateral and medial ends of the transverse segment to form a T-shape." Ex. 1010, Abstract; *see also id.*, 5:62–65. Grusin's plate comprises "a longitudinal segment having a proximal end and a distal end." *Id.*, 10:55–59; *see also id.*, 11:16–17.

The annotated figure below depicts a central trunk portion (blue) with a longitudinal trunk axis extending between a first and second end (red):

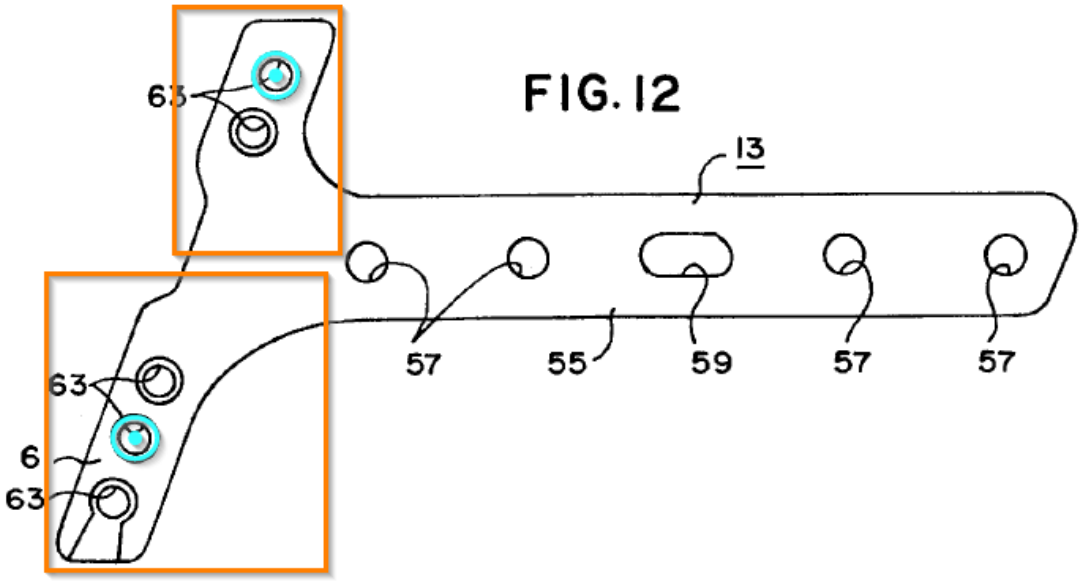


Id., Fig. 12 (annotated); *see also id.*, Figs 1-4, 10-13, 19-22, 68, 71, 74; Ex. 1001, ¶446.

e. Element 1[d]

Grusin discloses a plate having at the first end a pair of arms, each arm including an arm screw hole which defines a central screw hole axis. Ex. 1001, ¶¶447-48. Grusin describes a plate that is "preferably substantially T-shaped." Ex. 1010, 5:62–64; 10:55–65. "The transverse segment 42 of the plate 11 is preferably angled with respect to the longitudinal segment 32 to further match the anatomy of the distal radius R." *Id.*, 6:33-40. Grusin's plate has "a plurality of spherically recessed holes 63 in the distal transverse segment 61." *Id.*, 6:60–7:2.

This is depicted in the annotated figure below, showing a pair of arms at the first end (orange), with each arm including an arm screw hole which defines a central screw hole axis (light blue).



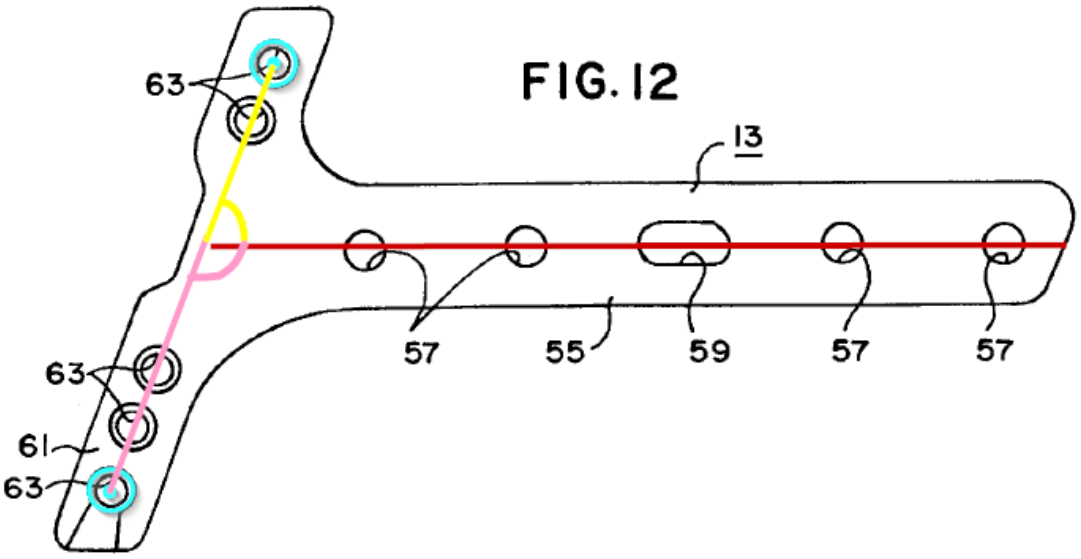
Id., Fig. 12 (annotated); *see also id.*, Figs. 1-4, 10-13, 19-22, 68, 71; Ex. 1001, ¶448.

f. Element 1[e]

Grusin discloses plates having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal axis of the trunk area. Ex. 1001, ¶¶449-50. Grusin discloses a "dorsal plate" that "includes a transverse segment 42 having a lateral end 43 and a medial end 44," as well as "a plurality of spherically recessed holes 45 to accept…bone screws." Ex. 1010, 6:12–17. Grusin also describes "transverse segments" of the plate as "forming an angle of approximately 113° with said longitudinal segment." *Id.*, 12:16–17.

As shown in the annotated figure below, Grusin discloses arms with a longitudinal arm axis (yellow and pink), extending between the central screw hole

axis (light blue) and a longitudinal trunk axis (red) defining an angle (yellow and pink) with respect to the longitudinal axis of the trunk area.



Id., Fig. 12 (annotated); *see also id.*, Figs. 1-4, 10-13, 19-22, 68, 71; Ex. 1001, ¶450.

g. Element 1[f]

Grusin discloses that the longitudinal arm axis of the first of the pair of arms is different than the longitudinal arm axis of the second pair of arms. Ex. 1001, ¶451. Grusin discloses that the "lateral end of the distal transverse segment 61 is extended proportionally a greater distance from the proximal longitudinal segment 55 than the lateral end 43 of the distal transverse segment 42 is extended from the proximal longitudinal segment." Ex. 1010, 7:6–15. The "transverse segment" in Grusin is "preferably angled with respect to the longitudinal segment 32 to further match the anatomy of the distal radius R," and that is "preferably pre-bent to approximately a

140° angle…so that its bottom face 51 conforms as closely as possible to the surface of the distal radius R." *Id.*, 6:33–40.

h. Element 1[g]

Grusin in view of Fernandez discloses a plate where at least one screw has a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole the threaded screw head forms a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis. Ex. 1001, ¶¶452-58. Both Grusin and Fernandez disclose at least one screw. *Supra* Section VIII.C.2.b.

Grusin's plate "preferably has a plurality of spherically recessed holes" that are designed "to accept…bone screws." Ex. 1010, 6:14–17. "The screws…can be inserted directly into their corresponding drilled holes." *Id.*, 10:14–15. As shown in Figure 76, Grusin describes a screw that has a threaded shaft and a screw axis. *Id.*, Fig. 76.

Fernandez describes a screw that "has a shank with a thread for engaging bone and a partial sphere head with a thread." Ex. 1011, Abstract. Fernandez's screw includes "a threaded partial sphere head" and "a threaded shank." *Id.*, claim 2. Fernandez also describes "a polyaxial coupling of the screw to the fixation device, whereby a single fixation device is compatible with a wide range of screw-in angles." *Id.*, ¶11. This method "provides the surgeon with the greatest freedom to

choose the most desirable angle to direct the bone screw while maintaining an effective locking mechanism." *Id.*, ¶12. Figures 1–3 and 7–10 of Fernandez show screws that have a threaded shaft, a screw axis, and a threaded head so that when engaged in the arm screw hole they form a mating interface such that the screw can engage the arm screw hole so as to allow a plurality of angular orientations of the screw axis.

FIG. 10

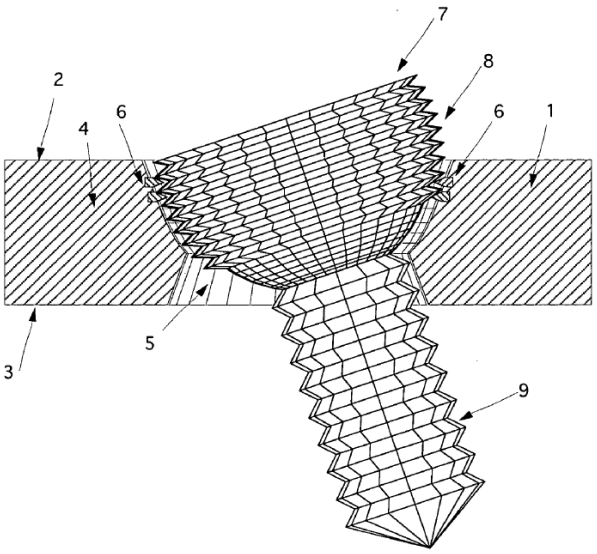
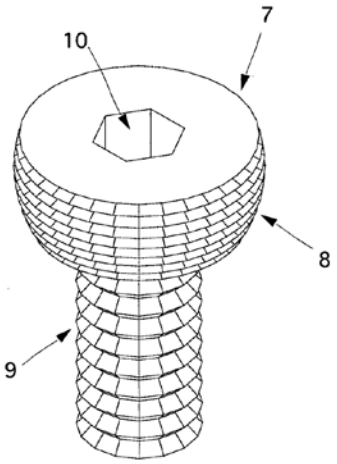


FIG. 2



E.g., id., Figs. 2, 10; Ex. 1001, ¶455.

As described above, POSITAs would have been motivated to use screws with a threaded head and threaded screw holes, as disclosed by Fernandez, with Grusin's plate system so that the plate could accept locking screws with threaded heads at a plurality of angular orientations and increase pullout strength. Ex. 1001, ¶¶456-58; *supra* Section VIII.C.1.

3. Claim 2

Grusin in view of Fernandez renders obvious claim 2. Ex. 1001, ¶¶459-61. Grusin describes that after a template is "used to determine the appropriate contour of the fractured radius R," the "[a]ppropriate screw size as well as screw and pin placement" can be determined. Ex. 1010, 10:3-12. "Screw and pin holes must be predrilled in the radius R with the appropriate drill and drill guide." *Id.*, 10:12-15. Thus the length and diameter of the screws used in Grusin should ensure the screws do not impinge on each other when locked into their screw holes. Ex. 1001, ¶460.

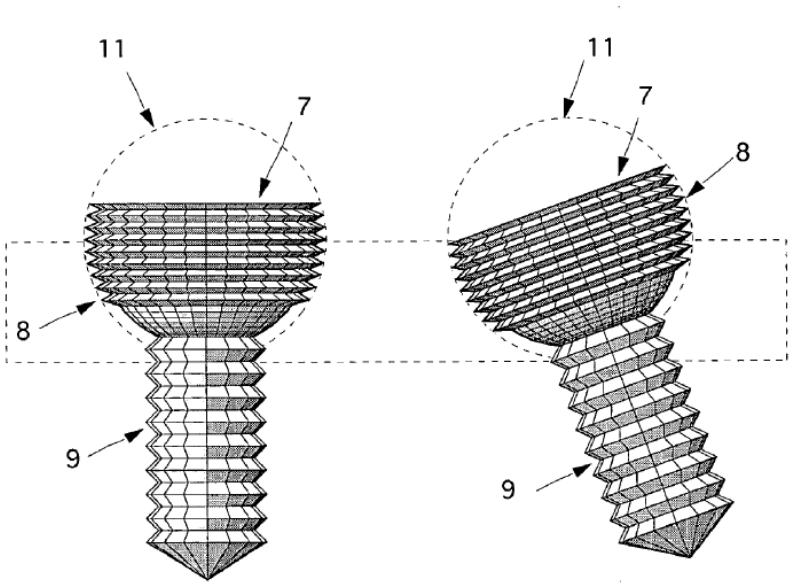
POSITAs would have been motivated to use screws with threaded heads, such as those disclosed by Fernandez, to allow the screws used in Grusin to lock and increase pullout strength. *Supra* Section VIII.C.1. Because Grusin explains that the appropriate screw size should not be selected until after the contour of the plate is determined, POSITAs would have known to select threaded-head screws from Fernandez that have a length and diameter that ensures the screws do not impinge on each other when locked into Grusin's screw holes. Ex. 1001, ¶461. Using Fernandez's threaded-head screws would not have changed the geometries of Grusin's plate, and thus those screws still would not have impinged on each other when locked in their respective arm screw holes. *Id.*

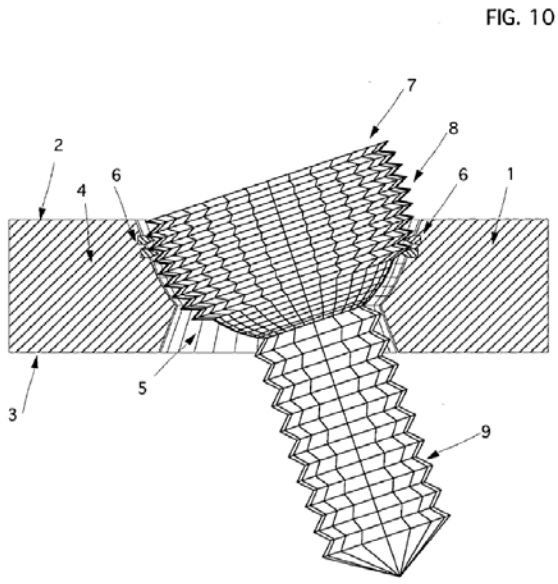
4. Claim 3

Grusin in view of Fernandez renders obvious claim 3. Ex. 1001, ¶¶462-65. Grusin's plate "preferably has a plurality of spherically recessed holes" that are designed "to accept…bone screws." Ex. 1010, 6:14–17; *see also id.*, 10:11-31; Ex. 1001, ¶463.

Fernandez describes a screw that "is threaded into the bone…at a selected angle," where the "partial sphere head of the screw engages in the protrusions of the plate hole resulting in the strong locking of the screw at the selected orientation." Ex. 1011, Abstract; *see also id.*, ¶¶12, 15. The screw can be "introduced perfectly perpendicular or at a tilt," and in the preferred embodiment "up to 20 degrees of angulation [*i.e.* 40 degrees of conical rotation] in any direction is allowed." *Id.*, ¶33; Ex. 1001, ¶464.

FIG. 3





Ex. 1011, Figs. 3, 10; *see also id.* at Figs. 1-10; Ex. 1001, ¶464; *supra* Section VIII.C.1.

5. Claim 4

Grusin in view of Fernandez renders obvious claim 4. Ex. 1001, ¶¶466-70. Grusin describes its arm screw holes as preferably being "spherically recessed" to accept a variety of screws or pins and preferably "hav[ing] a counterbore 47 on the bottom side of the plate 11 in order to create a locking feature… ." Ex. 1010, 6:17–21. Grusin further states that "buttress pin screw lock pin head 25 preferably has a male screw portion 103, and the buttress pin screw lock pin shank 23 preferably has a internally threaded aperture 105…for receiving the screw portion." *Id.*, 8:67–9:6, Figs. 44-45, 50-51.

Fernandez's screw "engages in the protrusions of the plate hole resulting in the strong locking of the screw at the selected orientation." Ex. 1011, Abstract.

Fernandez describes "the inner wall of each plate hole" as having "a small number of isolated protrusions…designed to lock against the threaded spherical head of the screws 8 when the said screws 7 are driven in through the said plate holes 5." *Id.*, ¶32. Fernandez recites a "method for securing bone screws to a bone plate that the so called plate having through holes provided with isolated protrusions able to lock into the thread of the screw head." *Id.*, claim 1.

FIG. 4

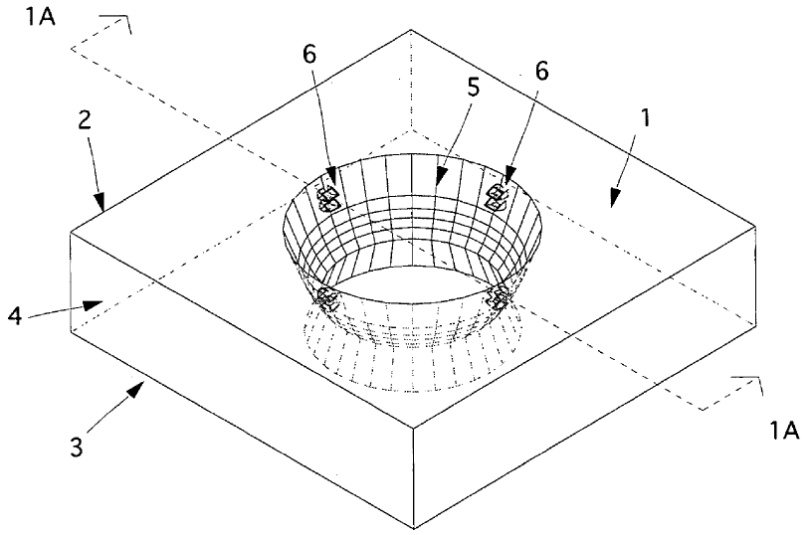
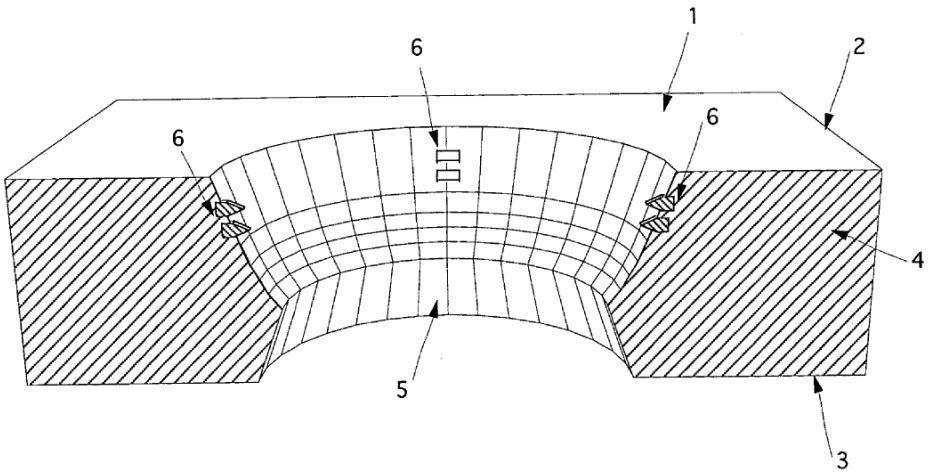


FIG. 5



Id., Figs. 4-5; *see also id.* Figs. 1, 6-10; Ex. 1001, ¶470; *supra* Section VIII.C.1.

6. Claim 5

a. Element 5[pre]

See Section VIII.C.2.a.

b. Element 5[a]

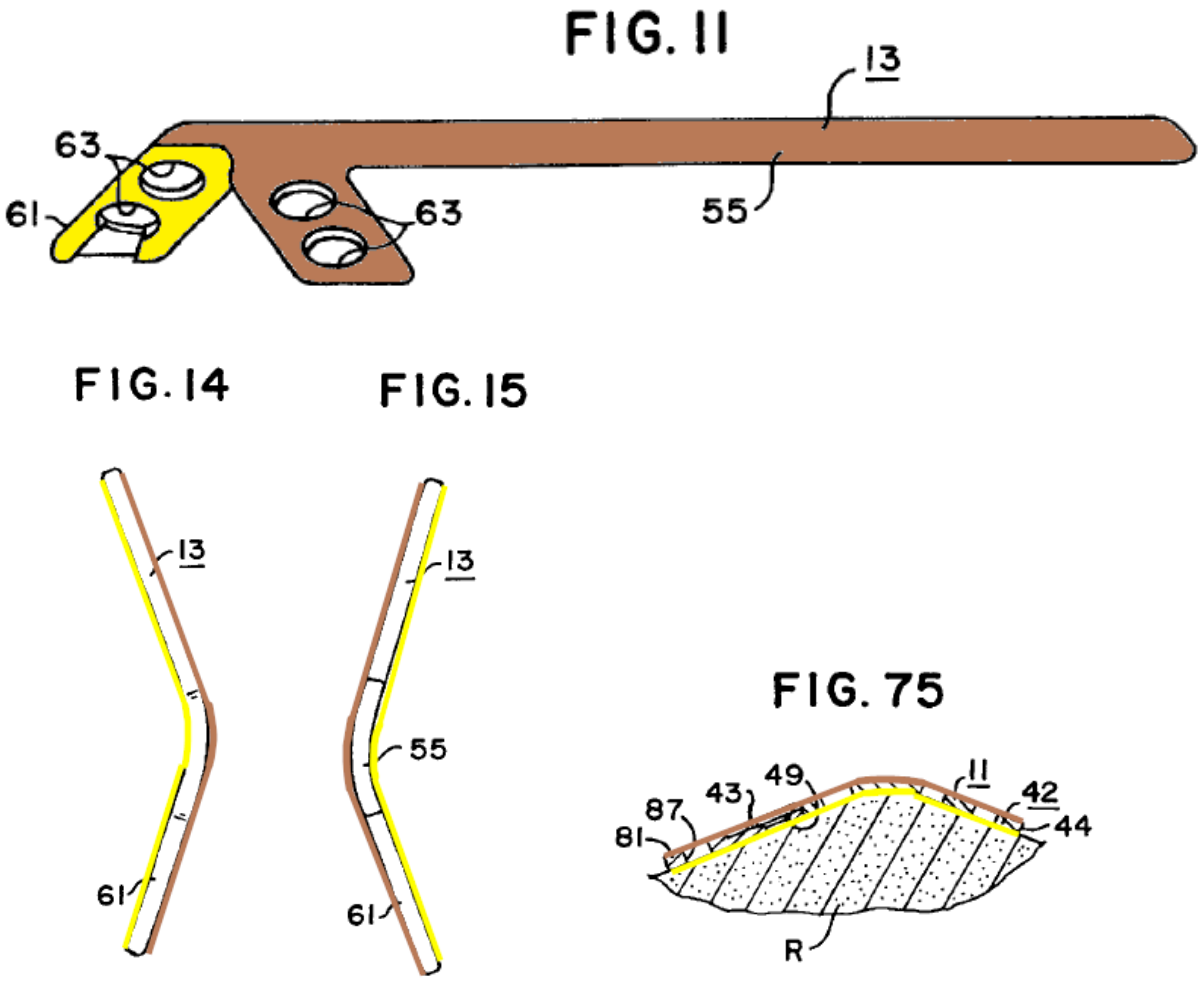
See Section VIII.C.2.b.

c. Element 5[b]

Grusin discloses an orthopedic plate having an inferior surface which is capable of facing a bone surface in use and which is pre-contoured to accommodate the shape of the bone surface and an oppositely facing concentric superior surface. Ex. 1001, ¶¶473-74. Grusin discloses a contoured plate having an inferior surface capable of engaging a bone surface in use. *Supra* Section VIII.C.2.c. Grusin describes plates that are "preferably pre-bent" so that they "conform[] as closely as

possible to the surface of the distal radius R." Ex. 1010, 6:36–40; *see also id.*, 7:44–50. Grusin also discloses a "slotted plate bender" that "is designed for use in bending and molding a fracture fixation plate to match the anatomy of a specific radius R." *Id.*, 9:16–24.

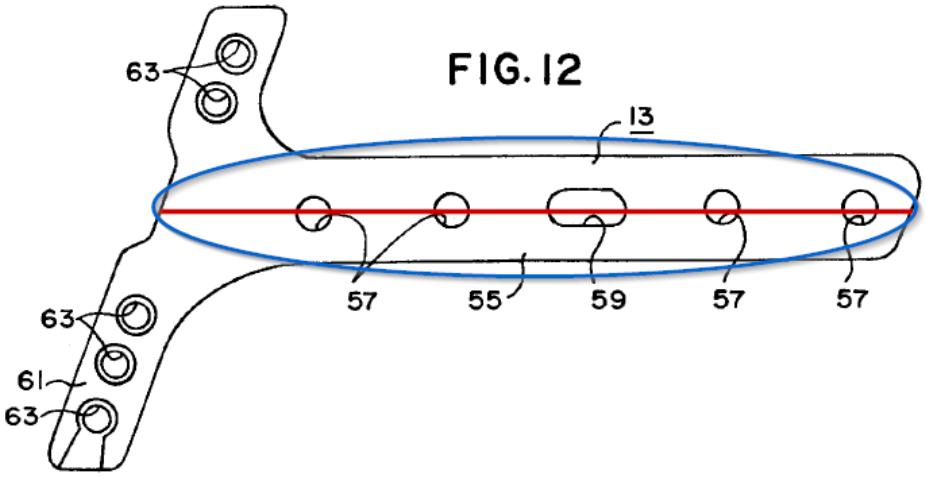
As shown in the annotated figures below, Grusin discloses a plate having an inferior surface (yellow) and an oppositely facing concentric superior surface (brown).

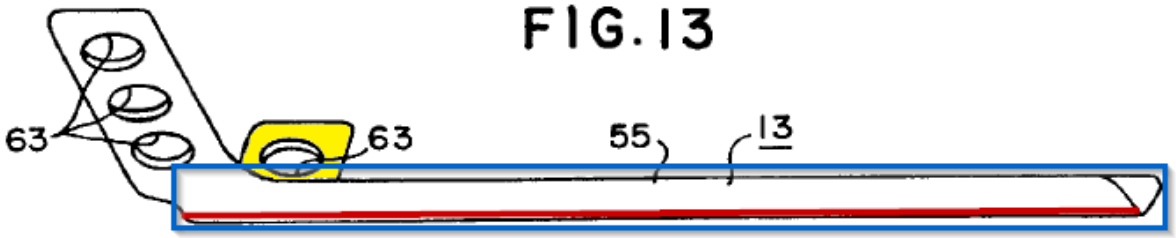


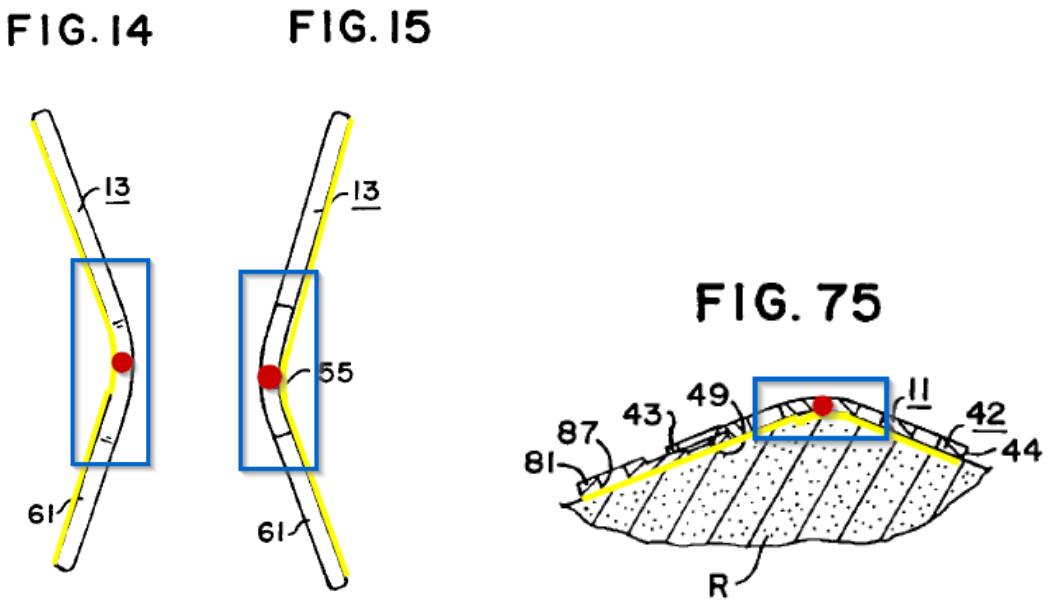
Id., Figs. 11, 14–15, 75 (annotated); Ex. 1001, ¶474.

d. Element 5[c]

Grusin discloses a plate having a central trunk portion defining a longitudinal trunk axis extending between a first end and a second end and defining at least a portion of the inferior surface which includes a curve transverse to the longitudinal trunk axis. Ex. 1001, ¶¶475-76. Grusin discloses a plate having a central trunk portion defining a longitudinal trunk axis extending between a first and second end and. *Supra* Section VIII.C.2.d. Grusin further discloses that its plate is "pre-bent" to "conform[] as closely as possible to the surface of the distal radius R," and includes Ex. 1010, 6:36–40; *see supra*, Section VII.C.6.c. Thus Grusin's plate has a longitudinal trunk axis running along the length of a bone and a curve so that the bottom face conforms as closely as possible to the surface of a bone with an inferior surface defining a curve transverse to the longitudinal trunk axis. Ex. 1001, ¶475. This is illustrated at least in Figures 12–15 and 75 below, in which the central trunk portion (dark blue) defines a longitudinal trunk axis extending between a first end and a second end (red) and defines at least a portion of the inferior surface (yellow) which includes a curve transverse to the longitudinal trunk axis.







Ex. 1010, Figs. 12-15, 75 (annotated); Ex. 1001, ¶476.

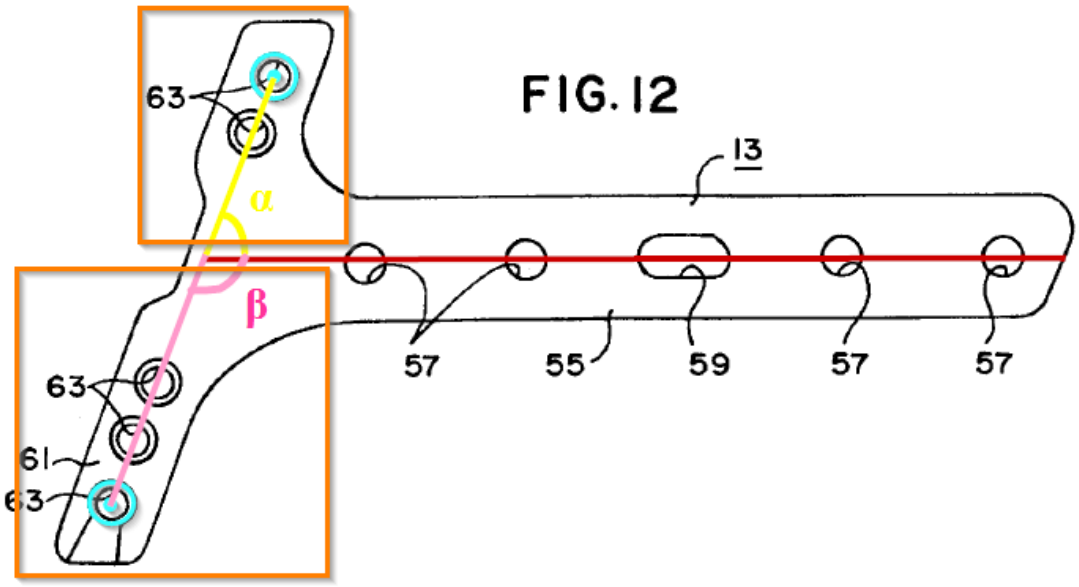
e. Element 5[d]

See Section VIII.C.2.e.

f. Element 5[e]

Grusin discloses each arm having a longitudinal arm axis which extends between the central screw hole axis and the longitudinal trunk axis defining an angle with respect to the longitudinal trunk axis, the angle of the first arm being α and the angle of the second arm being β. Ex. 1001, ¶¶478-79. Grusin discloses plates having a longitudinal arm axis, each arm's axis being different, extending between the central screw hole axis and the longitudinal trunk axis and defining an angle with respect to the longitudinal trunk axis. *Supra* Sections VIII.C.2.f, VIIIA.C.2.g; *see also* Ex. 1010, 7:7–15 (the two ends of the transverse segment of Grusin's plate extend different distances). To indicate their difference, these angles can be identified as α and β. Ex. 1001, ¶478.

As shown in the annotated figure below, Grusin discloses each arm (orange) having a longitudinal arm axis (yellow and pink) which extends between the central screw hole axis (light blue) and the longitudinal trunk axis (red) defining an angle with respect to the longitudinal trunk axis, the angle of the first arm being α (yellow) and the angle of the second arm being β (pink).



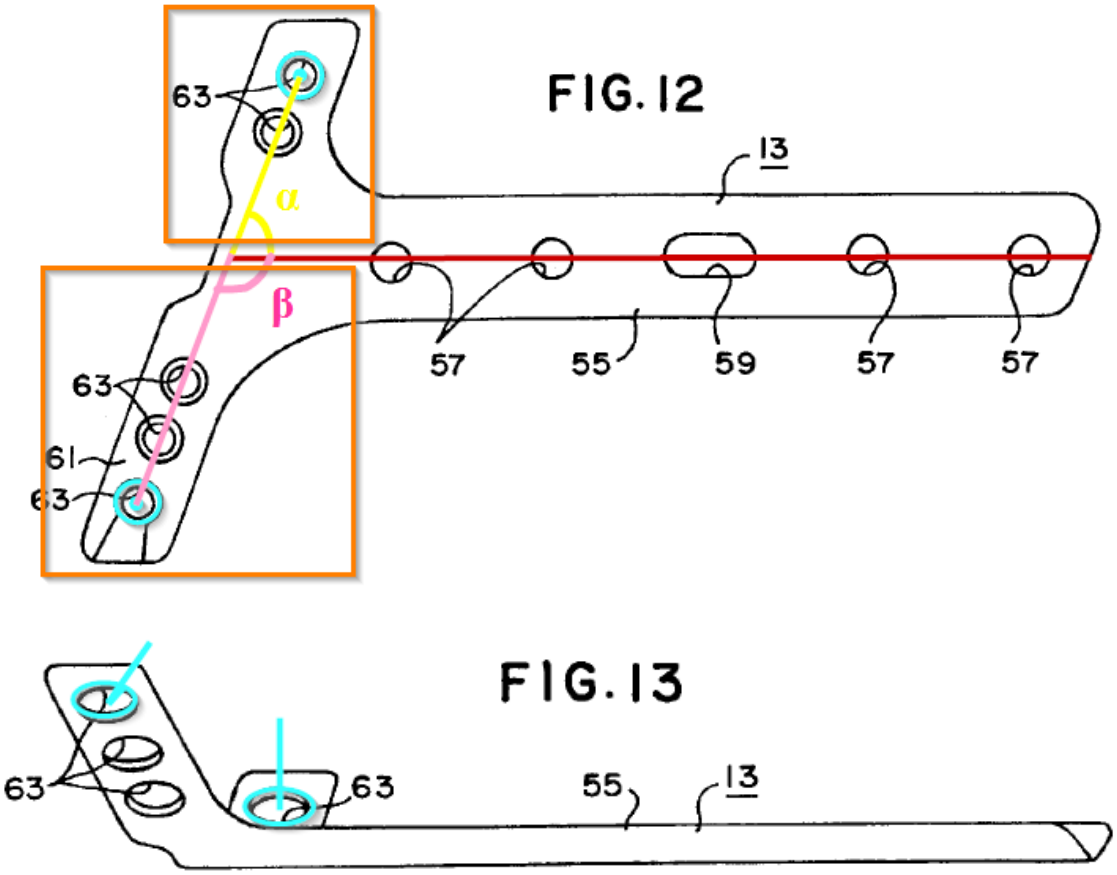
Ex. 1010, Fig. 12 (annotated); Ex. 1001, ¶479.

g. Element 5[f]

Grusin discloses that α is different than β such that the central screw hole axis of the right arm converges toward but does not impinge on the central screw hole axis of the left arm. Ex. 1001, ¶¶480-82. Grusin discloses plates with different angles with respect to a longitudinal trunk axis, identified as α and β to indicate that they are different. *Supra* Section VIII.C.6.f. Grusin discloses plates that are "preferably pre-bent" so as to "conform[] as closely as possible to the surface of the distal radius R," and that after a template is "used to determine the appropriate contour of the fractured radius R," the "[a]ppropriate screw size as well as screw and pin placement" can be determined. Ex. 1010, 6:33–40, 10:3-12. Thus, Grusin discloses that the screws should not impinge on each other, and that the central screw

hole axis of the right arm converges toward but does not impinge on the central screw hole axis of the left arm. Ex. 1001, ¶481.

As shown in the annotated figures below, Grusin discloses a plate wherein α (yellow) is different than β (pink) such that the central screw hole axis of the right arm converges toward but does not impinge on the central screw hole axis of the left arm (both light blue).



Id., Figs. 12-13 (annotated); Ex. 1001, ¶482.

h. Element 5[g]

Grusin discloses a plate that has a medial line which describes a curve in a lateral plane or in a longitudinal plane. Ex. 1001, ¶¶483-84. Grusin's plate is generally "T-shape[d]" and "preferably pre-bent" so that it "conforms as closely as possible to the surface of the distal radius R." Ex. 1010, Abstract, 6:36–40; *see also id.*, 7:44–50. Grusin further describes a "slotted plate bender" that "is designed for use in bending and molding a fracture fixation plate to match the anatomy of a specific radius R." *Id.*, 9:16–24. The slotted plate bender "provides leverage for bending the plate 11." *Id.*, 9:31-39; *see also id.*, 9:19-25.

As Grusin discloses a slotted plate bender, POSITAs would have found it obvious to bend Grusin's plate such that a medial line of the plate would describe a curve in a lateral plane or a longitudinal plane. Ex. 1001, ¶484. Because Grusin states its plates should conform as closely as possible to the bone surface, Grusin explicitly informs POSITAs to bend Grusin's plate such that the medial line would describe a curve in a lateral plane or a longitudinal plane to match the contour, and would have expected to succeed in doing so for the same reason. *Id.*

i. Element 5[h]

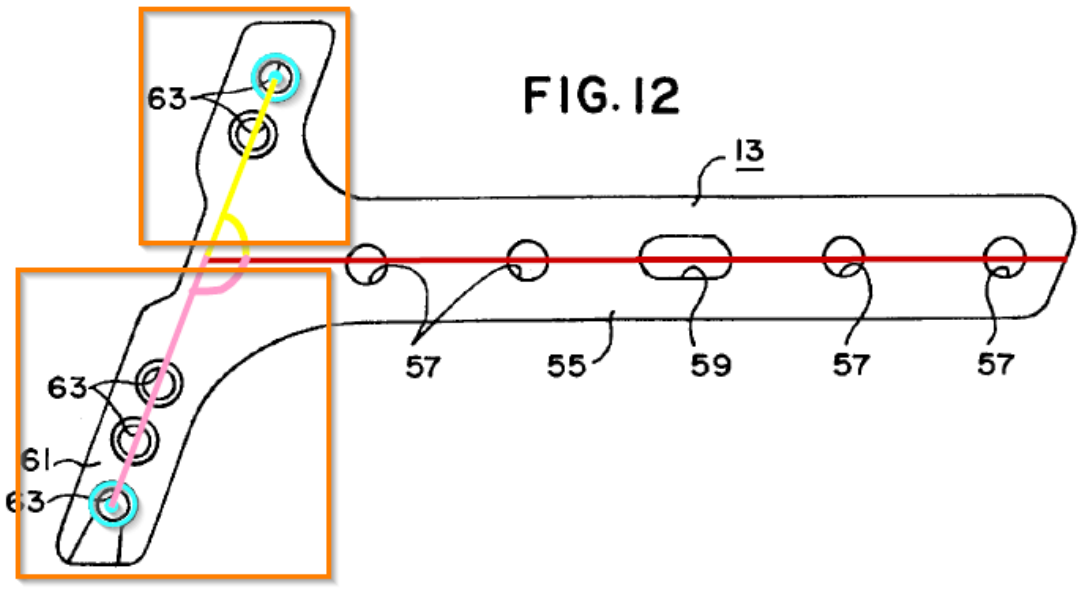
See Section VIII.C.2.h.

7. Claim 6

See Section VIII.C.3.

8. Claim 7

Grusin in view of Fernandez renders obvious claim 7. Ex. 1001, ¶¶488-90. Grusin's plate includes a longitudinal trunk axis. *Supra* Sections VIII.C.2.d, VIII.C.6.d. In Grusin's plate, each arm has at least one longitudinal arm axis, such as the axes shown in yellow and pink in the annotated version of Grusin's Figure 12 below. *See supra* Sections VIII.C.2.f, VIII.C.6.f.



Ex. 1010, Fig. 12 (annotated); Ex. 1001, ¶489.

Grusin discloses a plate that "is preferably substantially T-shaped." *Id.*, 5:62–64; *see also id.*, Abstract, 6:60-7:2. In Grusin's figures, including Figure 12 (annotated above), the T-shape plate is shown with a longitudinal arm axis of each arm intersecting a longitudinal axis of the plate. Ex. 1001, ¶490.

9. Claim 8

See Section VIII.C.4.

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 ’278 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 ’278 patent.

Other patents in the same family as the ’278 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 the email address: Paragon28_PTAB@kirkland.com.

X. GROUNDS FOR STANDING

Paragon certifies that the ’278 patent is available for IPR and Paragon is not barred or estopped from requesting IPR of the ’278 patent on the grounds identified. Paragon was served with a complaint asserting infringement of the ’278 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 9 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 ’278 patent are unpatentable, and Paragon requests that an IPR of these claims be instituted.

DATED: March 29, 2019

Respectfully submitted,

/s/ Joel R. Merkin

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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 13,821 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

DATED: March 29, 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 of Petition For *Inter Partes* Review of U.S. Patent No. 9,545,278 (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 29, 2019

Respectfully submitted,

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