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. 9,259,253

Case IPR2019-00898

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

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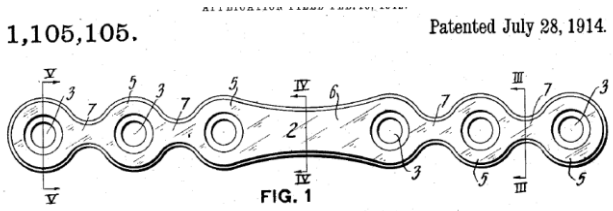
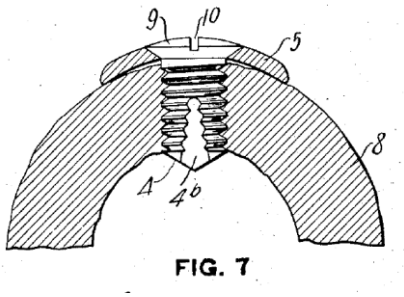
Paragon 28, Inc. ("Paragon") requests *inter partes* review ("IPR") of Claims 1, 3-9, 12-15, 17-19, 46-48, and 50-53 (the "Challenged Claims") of U.S. Patent No. 9,259,253 ("the '253 patent") (Ex. 1004).

I. INTRODUCTION

The '253 patent, titled "Orthopedic Plate for Use in Small Bone Repair," issued on February 16, 2016. Ex. 1004. 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 any person of ordinary skill in the art ("POSITA"). For over a century, surgeons have utilized bone plates and bone screws to repair bone fractures, as shown in U.S. Patent No. 1,105,105, issued in 1914:





Ex. 1052, Figs. 1, 7.

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

"lock" into place screws with threaded heads, yet such screw holes have been known since at least the early 2000s.

Though these plate designs were well-known since the 1980s the non-provisional application that led to the '253 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. Indeed, this is shown by the straight-forward combination of a plate available to the public since 2001 (Grusin) with screws patented in 2004 (Fernandez).

Not content with just claiming the plate and screws disclosed in its 2006 application, the Applicant filed a continuation-in-part application ("CIP") in 2009 ("2009 CIP application") and added new material not disclosed in its 2006 application, including a screw with a threaded head that can "lock" into place. While such screws are obvious, and have been known since the early 2000s, the law 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 were well-known and an obvious variation on the plate and screws 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. An untreated fractured, or broken, bone can lead to bone shortening, lack of bone alignment, formation of calluses, and limited mobility. Ex. 1001, ¶¶30-31. To prevent this, doctors treat bone fractures by stabilizing the bone in its correct position and alignment so that it behaves like an intact bone and can heal on its own. *Id.*

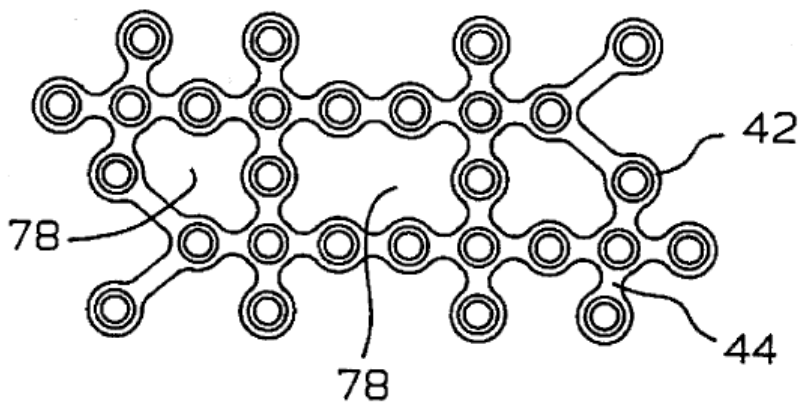
Stabilizing and repairing a fracture by attaching a mechanical device directly to the bone is known as "internal fixation." *Id.* The Challenged Claims are directed to an "orthopedic plate[]," which is an internal fixation device with two main components: the plate and the screws. Ex. 1004, Abstract. 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.*

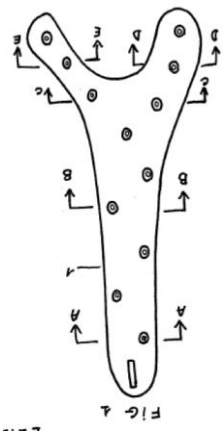
Bone plates come in a variety of materials and a variety of shapes depending on the fracture to be treated. *Id.*, ¶33. Plate materials vary based on the material's stiffness, strength, ductility, corrosion resistance, surface structure, and biocompatibility. *Id.* The majority, if not all, of bone plates 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 uniquely 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.*, ¶36. Surgeons commonly used "multi-configurable plating system[s]" to shape the plate to the bone before or during surgery. *Id.*, ¶¶36-37; Ex. 1012, Abstract. 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":

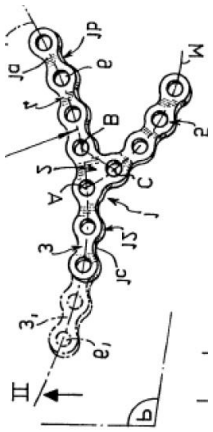


Ex. 1012, Abstract, Fig. 12, 2:59-65, 7:9-22; Ex. 1001, ¶¶36-38. Surgeons and POSITAs understood how to use these "linking members" to form "Y-shaped plates, T-shaped plates, X-shaped plates, and numerous other conventional and non-conventional shaped plates." Ex. 1012, 7:18-22.

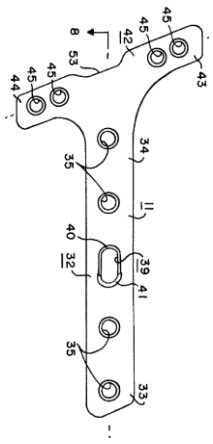
POSITAs also would have been familiar with bone plates having "two asymmetrical branches [] that diverge from each other" in which the "two branches have a different length and width." Ex. 1013, 3:21-24; Ex. 1001, ¶39. Numerous "diverging branch" plates were known in the art, prior to even the filing date of the provisional application that eventually led to the '253 patent, as shown below:



Ex. 1013, Fig. 1 (1977)

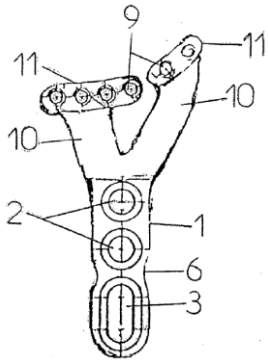


Ex. 1015, Fig. 1 (1987)



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; Ex. 1001, ¶¶39-40. Other plates that matched anatomic structures of the bones, such as plates with constant curves, were similarly known in the art. Ex. 1001, ¶40. For example, a "1/3 tubular" plate was "curved … to accommodate the cross-sectional shape of the particular bone" and was known to be "available in a variety of shapes, for use in stabilizing bones." Ex. 1055, 1:17-27. An example 1/3 tubular plate is depicted below:

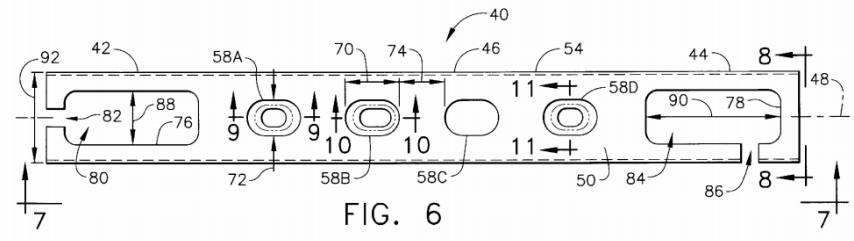


FIG. 6

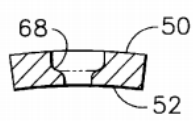


FIG. 11

(*Id.*, Figs. 6, 11.)

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 that accept 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:

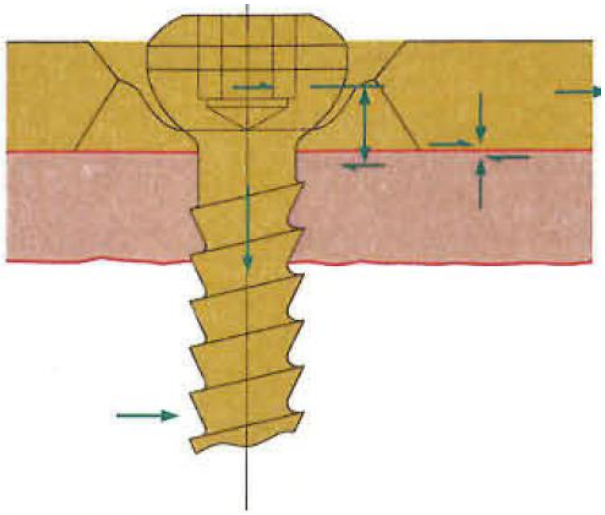


Fig. 1.2-20: Conventional plate screws

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

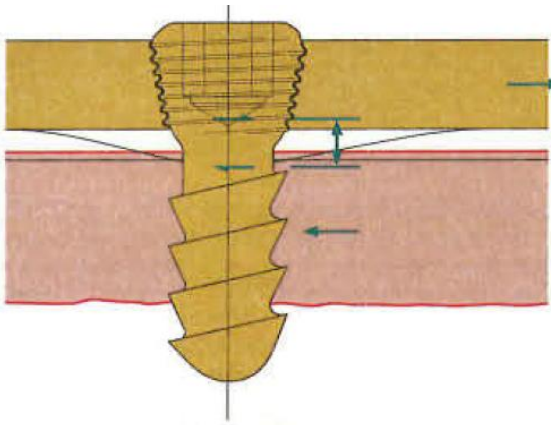
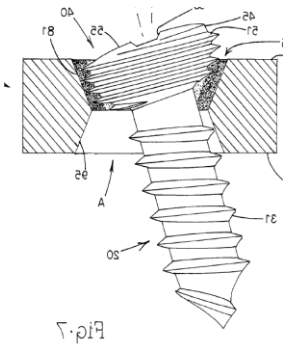


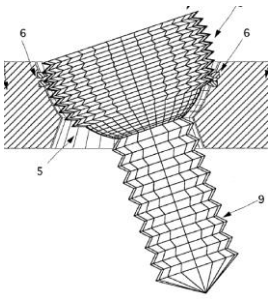
Fig. 1.2-21: Locked plate screws.

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

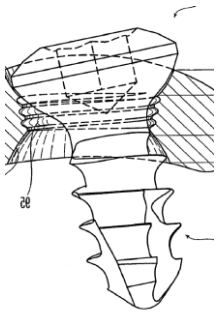
Screws can also be polyaxial, *i.e.* permitted to be inserted at a variety of angles, or monoaxial, *i.e.* permitted to be inserted at a single angle. *Id*., ¶46. POSITAs used polyaxial screws to permit screws to be inserted at an optimal angle to achieve optimal compression and avoiding hitting other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



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



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



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

III. PRIORITY DATE OF THE CHALLENGED CLAIMS

The 2009 CIP application added new matter to the 2006 application, including new matter claimed in the majority of Challenged Claims. As a result, the earliest date to which the majority of 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 '253 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 that

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 Majority Of The Challenged Claims Are Not Entitled To The Priority Date Of The 2006 Application

Claims 13-15, 17-19, 46-48, and 50-53 are not entitled to the priority date of the 2006 application because they recite a "locking screw" limitation that is not supported by the 2006 application.

Claim 13 of the '253 patent recites, "A plate system for use in bone comprising: a first locking screw and a second locking screw … ." (the "threaded head limitation"). Ex. 1004, Claim 13. Similarly, Claim 46 recites, "An orthopedic plate system for use in bone defining an axis and comprising: a first locking screw, and a second locking screw … ." *Id.*, Claim 46. Claims 14-15 and 18-19 depend from Claim 13, and Claims 47-48 and 50-53 depend from Claim 46, and thus these claims incorporate the locking screw limitation.

Figures 6 and 7 of the '253 patent depict the difference between threaded and unthreaded screw heads:

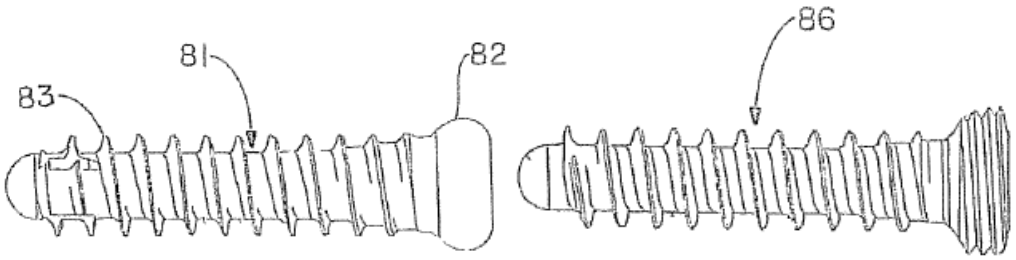


FIG.-6 FIG.-7

Ex. 1004, Fig. 6 (unthreaded screw head), Fig. 7 (threaded screw head). Figure 7 is the only of the two figures described as depicting a "locking screw." *Id.*, 8:41-55. The screw depicted in Figure 7 is described as "includ[ing] the same features as the screw in FIG. 6, except that the screw further includes external threads 88 on the screw head." *Id.*, 8:52-55. Thus, according to the '253 patent, the difference between a locking and a non-locking screw concerns the presence of "external threads … on the screw head." *Id.* Although the 2006 application and the '253 patent share many common figures (Figs. 1-5 of the 2006 application, for example, are either identical or practically identical to figures from the '253 patent), Figs. 6 and 7 of the '253 patent are not found in the 2006 application. *See* Ex. 1006, Figs. 1-31; Ex. 1004, 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:

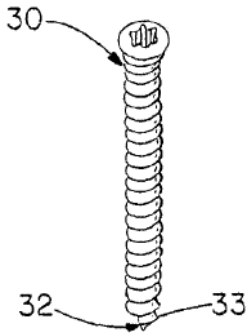


FIG.-6

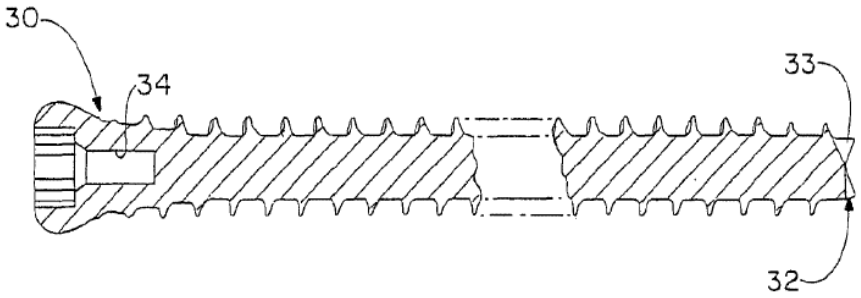


FIG.-8

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 of the 2006 application, 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 2006 application's screw head "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," nor is the screw described as a "locking screw," as required by Claims 13 and 46 of the '253 patent and their dependents. *See generally* Ex. 1006; Ex. 1004, Claims 13, 46.

The 2006 application states: "The corresponding mating heads of the screws are rounded and have a low profile so that the screws can be seated with their longitudinal axes at a variety of angles." Ex. 1006, ¶10. The '253 patent employs ***identical language***, reciting, "the corresponding mating heads of the screws are rounded and have a low profile so that the screws can be seated with their longitudinal axes at a variety of angles." Ex. 1004, 4:20-23. The '253 patent, however, further recites, "Alternatively and in many cases, preferably, the screw holes can include internal threads which mate with ***external threads on the head of the screws to cause locking of the screws*** relative to the plate." Ex. 1004, 4:29-32 (emphasis added). While the 2006 application discloses screw heads, they are never

described as "threaded," an apparent requirement of locking screws, according to the '253 patent. *See generally* Ex. 1006; Ex. 1004, 8:41-55.

Section 112 "requires that the written description actually or inherently disclose the claim element." *PowerOasis*, 522 F.3d at 1306-07 (citing *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118-20 (Fed. Cir. 2001)). "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed." *Lockwood*, 107 F.3d at 1571-72. 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 or to be locking screws. Ex. 1001 ¶¶80-82.

Therefore, independent Claims 13 and 46, which include the "locking screw" limitation, are not entitled to the priority date of the 2006 application. Because Claims 14-15, 17-19, and 47-48, 50-53 depend from Claims 13 and 46 respectively, those claims also include the "locking screw" limitation and are also not entitled to

the priority date of the 2006 application. The earliest priority date for Claims 13-15, 17-19, 46-48 and 50-53 is the filing date of the 2009 CIP application: February 24, 2009. For the purposes of this IPR only, Petitioner does not challenge that Claims 1, 3-9 and 12 and entitled to the priority date of January 26, 2006.

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 '253 patent.

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

IPR of the Challenged Claims is requested in light of the prior art listed below. As explained above, the earliest priority date to which Claims 13-15, 17-19, 46-48 and 50-53 are entitled is February 24, 2009, and the earliest priority date to which Claims 1, 3-9 and 12 are entitled is January 28, 2005.

- 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 to Claims 13-15, 17-19, 46-48 and 50-53 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 to Claims 13-15, 17-19, 46-48 and 50-53 under 35 U.S.C. § 102(a).

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

- 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 to Claims 1, 3-9 and 12 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 to Claims 1, 3-9 and 12 under 35 U.S.C. § 102(e).

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

Ground	Claims	Description
1	13-15, 17-19, 46-48, and 50-53	Obvious under § 103 in view of Kay and Chan
2	1, 3-9, and 12	Obvious under § 103 in view of Grusin and Fernandez

C. 37 C.F.R. § 42.104(b)(3): Claim Construction

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, but Patent Owner has not submitted

its responsive brief yet. No trial date has currently been set for the pending district court litigation.

As Paragon explained in detail in that *Markman* brief, Ex. 1060, the manner in which Patent Owner is applying the claims to Paragon's products to support Patent Owner's allegations of infringement created a dispute over the scope of the claims as applied to Paragon's products. That same dispute is not present here, because as Paragon's expert explains in his declaration, the Challenged Claims are rendered obvious by the prior art whether Paragon's or Patent Owner's proposed construction is applied. Ex. 1001, ¶¶105-107. Thus, Paragon does not believe construction of any terms are necessary for this proceeding.

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

Term	Patent Owner Proposed Construction	Paragon's Proposed Construction
"arm"	no construction necessary	a plate appendage configured to be bent without deforming any of its screw holes.
"linking section"	no construction necessary or a "portion of the plate between plate features	portion of the plate that links two distinct parts of the plate
"waist"	no construction necessary or "area of the plate that is configured to facilitate bending of the plate"	portion of a linking section with a decreased width relative to the non-waist portion of the linking portion

"trunk" or "trunk portion"	no construction necessary or "a portion of the plate from which appendages extend."	the main body of the plate from which plate appendages extend
"end"	no construction necessary	the intersection of the edge of the plate and the longitudinal axis of the plate
"plate … that forms a Y-shape"	no construction necessary or, "a plate with features generally arranged in the shape of a 'Y'"	a plate that is shaped such that the entire outline of the plate forms only the shape of the letter Y

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 Appendix 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 Section VIII. Paragon submits the declaration of Javier E. Castañeda, attached as Exhibits 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 this family, including the Challenged Claims, in the related district court litigation. Paragon has repeatedly sought to reduce the number of claims at issue, 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 for April 2019, though there is no firm date set, and 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.

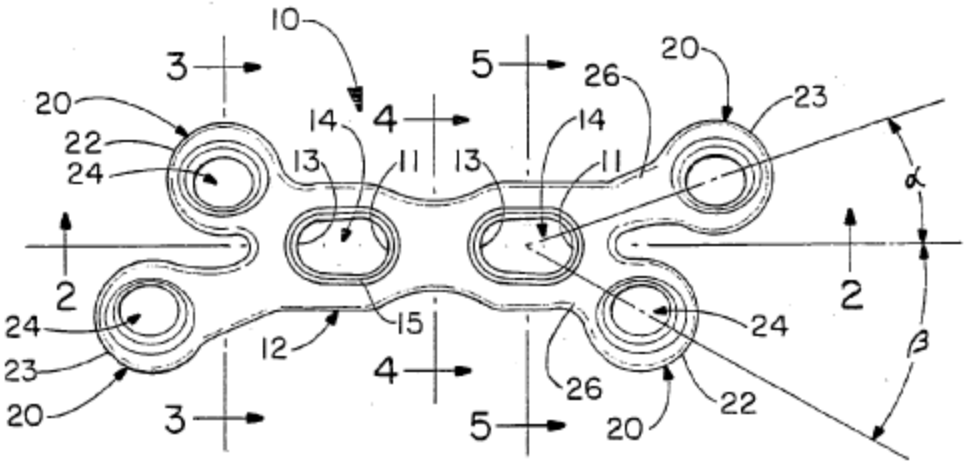


FIG.-1

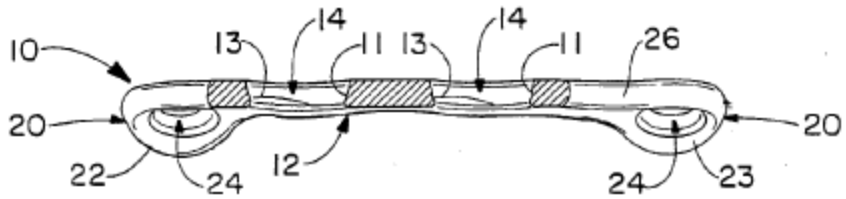


FIG.-2

Kay also describes a plate having only one pair of arms, as shown below in Figures 28-29:

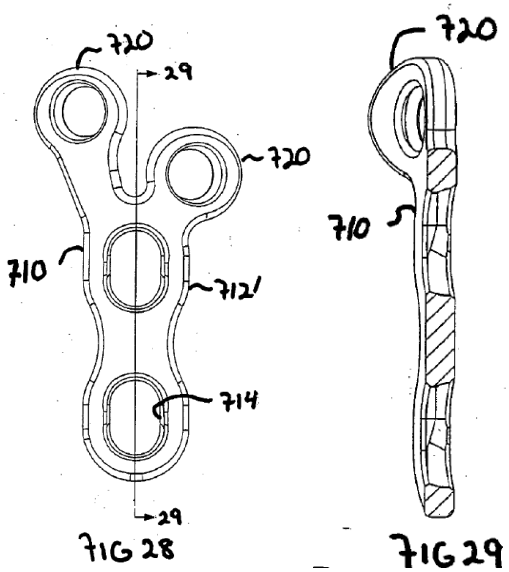
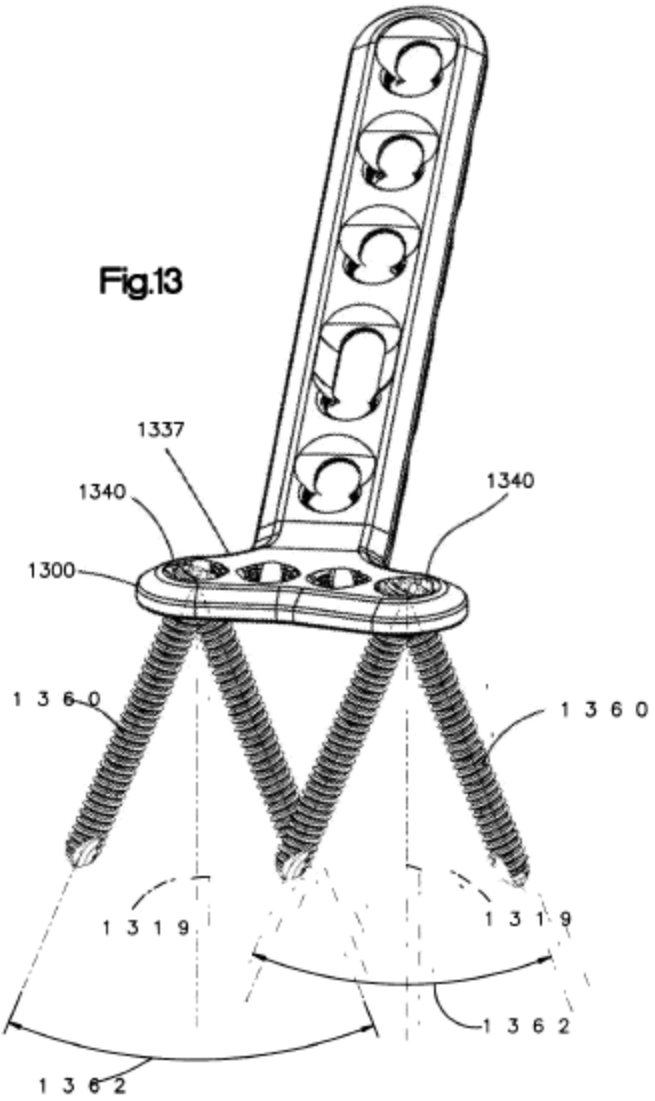


FIG 28 FIG 29

Aside from only including two arms, and optionally having a compression slot, Ex. 1006, ¶56, the plate features in Figures 28-29 are the same as examples elsewhere in the specification, and POSITAs would have recognized that these features would be readily combinable with features of the other examples disclosed in Kay. Ex. 1001, ¶87.

B. Chan

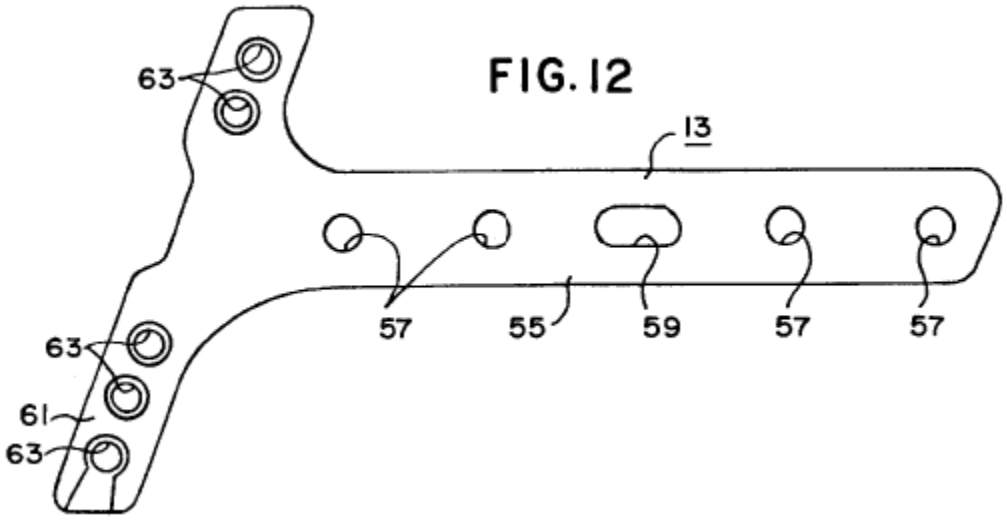
Chan is titled "Highly-Versatile Variable-Angle Bone Plate System" and generally describes "[a] bone plate system for internal fixation of bone fractures [that] includes a bone plate having a plurality of bone plate holes" that are "constructed to receive either a non-locking, locking or variable-angle locking 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:



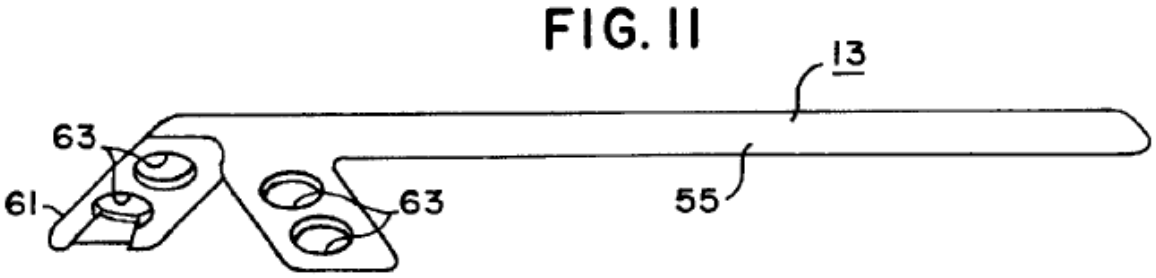
C. Grusin

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, 2:5-11. Grusin discloses a plate that includes a longitudinal segment and a transverse segment that is "preferably substantially T-shaped," as shown below. Ex. 1010, 1:56-62, 10:55-60.

The transverse segment includes "spherically recessed" arm screw holes which create "a locking feature …" (*id.*, 6:13-21), as shown below in Figure 12:



In addition, Grusin discloses a plate that "is preferably pre-bent" (*id.*, 6:36–40), with a transverse curve to conform to the distal radius, shown below in Figure 11:



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

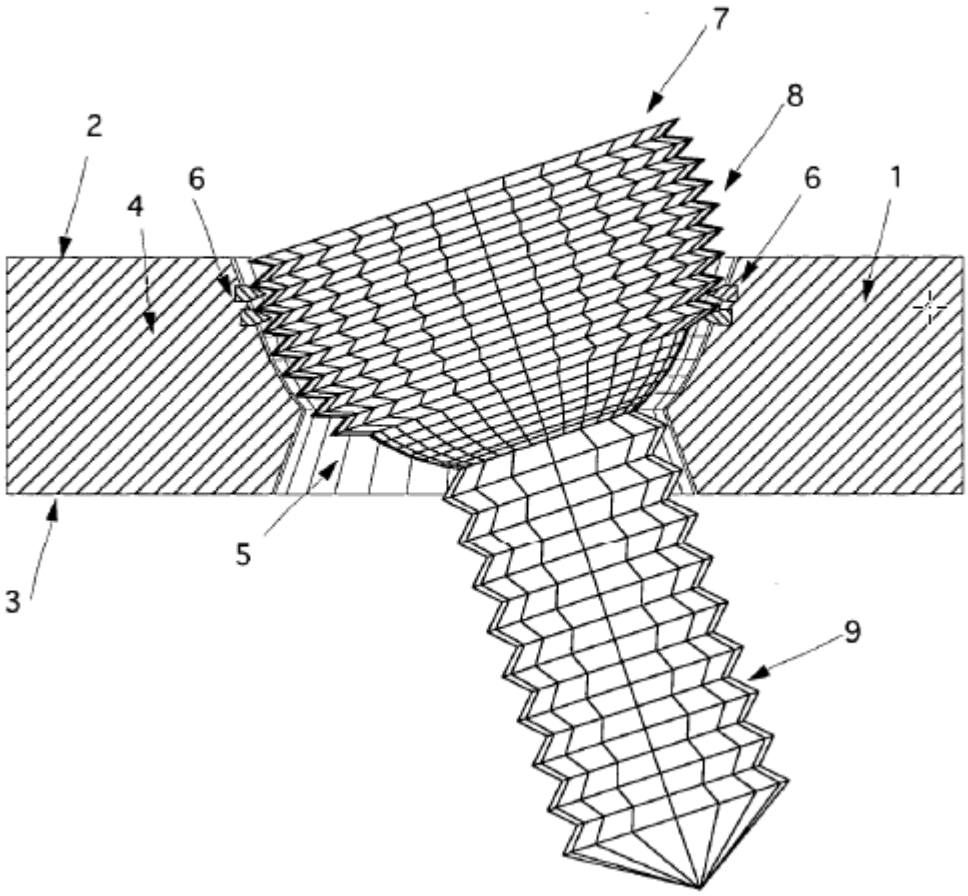
dorsal plate 11." *Id.*, 6:60-63. Grusin further clarifies that its "disclosure of the corresponding features, etc., of the small, left distal radial dorsal plate 11 will provide a full and enabling teaching of such features, etc., for the large left distal radial dorsal plate [13] to one of ordinary 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.*, 7-15. Aside from this exception, descriptions of plate 11 apply equally to plate 13. *Id.*, Figs. 12-18; Ex. 1001, ¶101.

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 the 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 bone plate hole disclosed by Fernandez:

FIG. 10



VII. PROSECUTION HISTORY

During prosecution, the examiner determined that the then-pending claims were not supported by the 2006 application, and considered their effective filing date to be February 24, 2009. Ex. 1043, 4-5. The Applicant did not contest this effective filing date. Grusin was discussed during prosecution, but the examiner only identified Grusin as a secondary reference for its disclosure of a compression slot

and did not evaluate whether it rendered obvious the Challenged Claims as a primary reference in combination with another reference. Ex. 1043, 10-11.

Though the examiner believed the effective filing date of the claims was February 24, 2009, the examiner never evaluated whether Kay, alone or in combination with other art, rendered obvious the Challenged Claims under § 103. Chan and Fernandez are not cited on the face of the '253 Patent and were not discussed during prosecution. Therefore, neither the same nor substantially the same arguments as presented in this petition have previously been presented to the Patent Office.

VIII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The Challenged Claims are unpatentable on the following grounds: Claims 13-15, 17-19, 46-48 and 50-53 are rendered obvious by the combination of Kay and Chan (Ground 1), and Claims 1, 3-9, and 12 are rendered obvious by the combination of Grusin and Fernandez (Ground 2). As described below, the combinations of Kay/Chan and Grusin/Fernandez disclose every element of the Challenged Claims, and it would have been obvious to a POSITA to combine the teachings of these references.

A. Ground 1: Kay in View of Chan

1. POSITAs Would Have Been Motivated to Modify Kay in View of Chan.

POSITAs would have found it obvious to modify Kay's plates to add Chan's variable locking screws. Ex. 1001, ¶¶281-284, 290-91, 294, 302-303, 333. Kay and Chan each recognize loosening of screws is a potential issue and attempt to avoid that issue. Ex. 1006, ¶4, Ex. 1007, ¶3. For example, Kay emphasizes the advantages of a plate with "increase[d] pullout strength" and recognizes its plates call for "specialized implants and tools." Ex. 1006, ¶4. Chan similarly explains, if "non-locking screws" are used, they can "loosen or back out with respect to the plate," leading "to poor alignment and poor clinical results." Ex. 1007, ¶3. POSITAs would have been motivated by Kay to seek out features that would increase the pullout strength, such as Chan. Ex. 1001, ¶¶282-284.

As Chan explains, "locking screws" in which "the thread on the screw head mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate" were well-known as one solution to "provide high resistance to shear, torsional, and bending forces." Ex. 1007, ¶4. Indeed, Chan lists numerous well-known plate systems which used threaded and non-threaded screw holes at varying angles. Ex. 1007, ¶¶6-11. Recognizing a plate system with the advantages of both locking and non-locking screw holes is desirable, Chan discloses screw holes with "discrete columns of teeth or thread segments for engaging compatibly

dimensioned and configured threaded heads of locking and variable-angle locking bone screws," which would provide increased pullout strength. Ex. 1007, ¶¶5, 14; Ex. 1001, ¶¶281-283. Chan describes that "a number of so-called 'polyaxial' bone plate systems are known" in which a "variable-angle locking screw" is used. Ex. 1007 ¶¶9-12.

Chan also discloses that its variable locking screw eliminate cumbersome components of prior polyaxial bone plate systems. Ex. 1007 ¶12. POSITAs would have realized the benefit of combining the variable locking screws of Chan with Kay's plates to provide additional flexibility for the operator to orient the screw and to eliminate the cumbersome components of prior art polyaxial bone plate systems. Ex. 1001, ¶283.

Given Chan's disclosure of screws with threaded heads as a "known embodiment," POSITAs would expect that modifying the plate system of Kay to accept threaded screws would be successful. In view of the long history and known advantages of threaded screw holes, POSITAs would have expected Chan's locking and variable locking features could be incorporated into Kay successfully. Ex. 1001, ¶284; Ex. 1024, ¶2. Given the history and known advantages of variable locking screws, POSITAs would have expected Chan's variable locking screws could be successfully incorporated into Kay, particularly given that Kay and Chan both disclose screw holes allowing for 30º of conical rotation. Ex. 1006 ¶10; Ex. 1007

¶17. Finally, POSITAs would not have known of any particular reason why Kay could not be so modified. Ex. 1001, ¶¶284, 294.

POSITAs would also have understood that, once Kay has been modified to accept Chan's variable locking screws as taught by Chan, that locking screws could successfully be inserted at selected angles within the screw holes as described by Kay. Ex. 1001, ¶¶281-284, 294, 302-303, 333. Chan discloses that locking screws "are typically inserted coaxially with the central axis of the hole," Ex. 1007, ¶4, and POSITAs would have understood, that inserting locking screws coaxially into threaded screw holes oriented as described by Kay, Ex. 1006, ¶50, would successfully result in a threaded screw head locking into each threaded screw hole. Because Kay and Chan disclose screw holes allowing 30º of conical rotation of the screw axis in relation to the axis of the screw hole, Ex. 1006, ¶10; Ex. 1007, ¶17, POSITAs would have understood that using variable locking screws of Chan could be successfully incorporated into Kay. Ex. 1001, ¶¶281-284, 294, 302-303, 333.

2. Claim 13 is Rendered Obvious by Kay in View of Chan

a. Element 13[pre]: "A plate system for use in bone comprising"

To the extent the preamble is limiting, Kay and Chan disclose this element. Ex. 1001, ¶¶279. Kay discloses an "Orthopedic Plate for Use in Small Bone Repair," and "relates to an orthopedic plate and screw system and instruments for surgical fixation of a small bone or bones," Ex. 1006, Abstract, which is "designed to fit a

range of needs of the surgeon operating on the small bones to allow him or her to perfect a variety of techniques using a set of instruments and a customizable plate and screw construct." *Id.*, ¶14.

b. Element 13[a]: "a first locking screw and a second locking screw, and"

Kay in view of Chan discloses this element. Ex. 1001, ¶¶280-284. Kay describes the use of "self-starting, self-tapping screws" throughout its Figures and specification. Ex. 1006, Abstract, Figs. 6-8, ¶¶12, 53.

Chan discloses a plate with screw holes "constructed advantageously to receive either a non-locking, locking, or variable-angle locking bone screw," Ex. 1007, ¶14, and "preferably have four columns 942 of thread segments, as shown in Figs. 9A and 9B." *Id.*, ¶67. Chan also describes plates optionally having "conventionally threaded and/or non-threaded screw holes" that may be threaded all the way through, or "for only a portion of the vertical distance between the top and bottom surfaces of the bone plate." *Id.*, ¶¶21, 64.

As explained above, POSITAs would have been motivated to look for examples of bone plate systems which resist screws loosening or pulling out, given Kay's emphasis on the desirability of "increase[d] pullout strength," and its emphasis on obtaining "greater procedural precision" through the use of "specialized implants and tools." Ex. 1006 ¶4; Ex. 1001, ¶¶282-283. POSITAs would have known that threaded locking screws seated in threaded screw holes increase pullout

strength. Ex. 1001, ¶¶282-283. Chan recognizes the reduced strength of non-locking screws, and POSITAs would have found it obvious to apply the threaded locking screws and screw holes of Chan to the bone plate of Kay to achieve Kay's stated goal of increasing pullout strength. *Id.*; *see also supra*, Section VIII.A.1

c. Element 13[b]: "a bilaterally asymmetrical plate"

Kay discloses this element. Ex. 1001, ¶285. Kay discloses a plate with "bilateral asymmetry (meaning that the left half of the plate is not the same as the right half)." Ex. 1006, ¶7.

d. Element 13[c]: "having an elongate central trunk with a medial longitudinal axis and at least one set of arms disposed at a terminal end of the plate, wherein each arm of the at least one set of arms diverges asymmetrically away from the medial longitudinal axis relative to the other arm of the pair of arms"

Kay discloses this element. Ex. 1001, ¶¶286-288. The plate of Kay has "a central trunk portion," and has "a bilaterally asymmetric shape…with foreshortened opposing diagonal legs extending from a central trunk portion 12." Ex. 1006, ¶¶8, 46. Kay's plate further "includes at least one set … of arms 20 [which] can be viewed as a set of diagonally opposed short 22 and long arms 23." *Id.*, ¶48. Kay's arms "diverg[e] asymmetrically from the longitudinal axis of the plate." *Id.*, ¶48. Figures 1 and 28 of Kay, annotated below, depict a central trunk portion (blue), medial longitudinal axis (green), and a set of arms (orange) disposed at the terminal

end which diverge asymmetrically away from the medial longitudinal axis relative to the other:

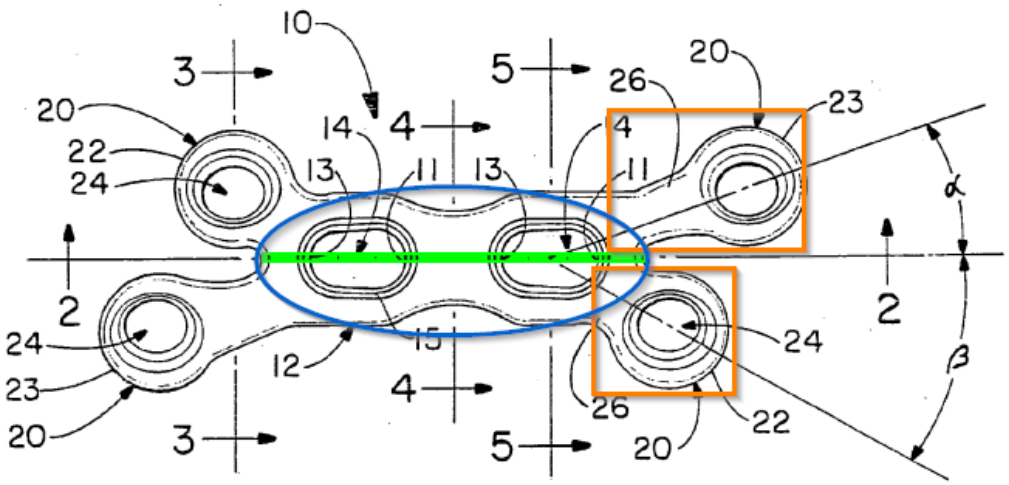


FIG.-1

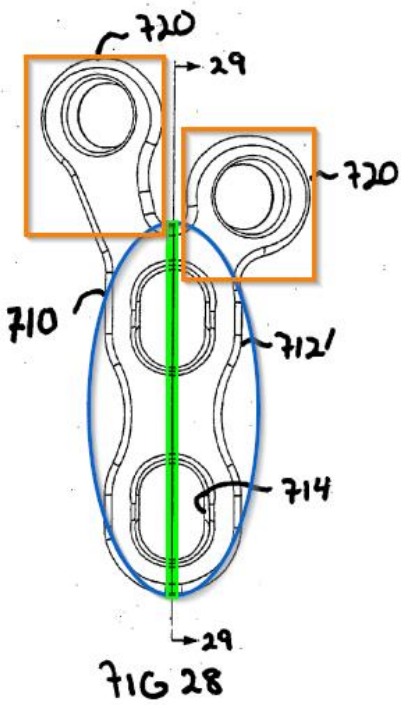


FIG 28

Ex. 1001, ¶¶286-288. As shown in the figures, Kay's trunk is elongated and includes a medial longitudinal axis running the length of the plate, and at least one set of arms

disposed at an end of the plate. Ex. 1006, Figs. 1-2, 9-12, 14, 16-31; *see also id.*, Claims 1, 9, 17, 22; Ex. 1001, ¶288.

e. Element 13[d]: "each arm of the asymmetrical pair including a threaded locking screw hole, and"

Kay in view of Chan discloses this element. Ex. 1001, ¶¶289-291. Kay discloses that "[e]ach of the arms in a set includes screw holes 24 … which diverg[e] asymmetrically… ." Ex. 1006 ¶48; *see also id.*, ¶ 52; Ex. 1004, claim 27.

Chan discloses screw holes with teeth "for engaging threads on the heads of locking and variable-angle locking bone screws." Ex. 1007, Abstract. These holes "are constructed advantageously to receive either a non-locking, locking, or variable-angle locking bone screw." Ex. 1007, ¶¶14, 67. Chan also describes plates optionally having "conventionally threaded and/or non-threaded screw holes." Ex. 1007, ¶21. Chan further states that "conventional locking plate holes" may be threaded completely or partially through. Ex. 1007, ¶64.

As described in Sections VIII.A.1 and VIII.A.2.b, POSITAs would have been motivated to modify the screw holes of Kay's plate with threads to accept locking screws, and would have expected such features to be successfully incorporated. Ex. 1001, ¶291.

f. Element 13[e]: "each of the threaded locking screw holes of the asymmetrical pair having one of the first locking screw and the second locking screw locked to the plate and each of the first locking screw and the second locking screw have a proximal end and a distal end which extends from the orthopedic plate, and the distal ends of the screw converge toward each other, but do not impinge and"

Kay in view of Chan discloses this element. Ex. 1001, ¶¶292-294. The "proximal" ends of the screws are the ends at or near the screw heads, and the "distal" ends are the ends away from the screw heads. Kay describes the screw "of the presentation invention" as having a "distil [sic] end of the screw including a cutting tip 32 which is self-starting and self-tapping." Ex. 1006, ¶53. Thus Kay's screws have a distal end which is cutting tip 32, and a proximal end which is the screw head. Ex. 1001, ¶292.

Kay further 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. Kay explains that this plate design allows "conflicts in the positions of paired screws [to be] avoided so that the screws of a set of arms typically do not impinge on each other." Ex. 1006, ¶50.

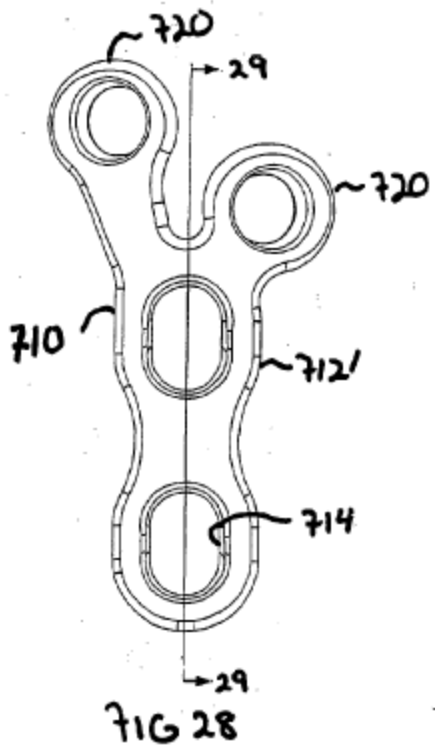
Chan discloses inserting locking screws "coaxially with the central axis of the hole," and that "the thread on the screw head mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate." Ex. 1007, ¶4.

When modifying Kay with locking screws as taught by Chan, POSITAs would have understood to insert locking screws coaxially with screw holes as described by Kay so that the proximal (threaded screw head) end of each screw locks to the plate, and the screw distal ends converge without impinging. Ex. 1001, ¶¶293-294.

POSITAs would also have recognized that because the screw holes of both Kay and Chan allow for 30º of conical rotation of the screw axis in relation to the axis of the screw hole, locking screws could be inserted at selected angles such that the screw proximal ends would lock into each threaded screw hole, and the screw distal ends would converge without impinging. Ex. 1006, ¶10; Ex. 1007, ¶17; Ex. 1001, ¶294.

g. Element 13[f]: "wherein the elongate central trunk has a compression slot having an internal edge which includes a shoulder that slopes toward the inferior side of the orthopedic plate as it extends away from the first end of the elongate central trunk."

Kay discloses this element. Ex. 1001, ¶¶295-298. Kay discloses a "plate 710, 710' having only a single pair of arms 720, 720' and a trunk portion 712, 712' optionally having one or more compression slots 714, 714'." Ex. 1006, ¶56. This is shown in Figure 28, below:



Ex. 1006, Fig. 28.

Kay discloses the trunk may have a number of screw holes, and "in one embodiment these holes are compression holes" which "may also or alternatively have a shallow shoulder or lip 16, which descends toward the inferior surface of the plate to allow the plate to be set initially and subsequently to be slide [sic] into a different position as the screws are tightened down." Ex. 1006, ¶46. POSITAs would have used a trunk with compression slots because Kay explicitly discloses their use and compression slots ensure adequate fracture repair. Ex. 1001, ¶296.

As shown in annotated Figure 11, below, the shoulder (yellow) "describes towards the inferior surface of the plate," the shoulder slopes as it extends away from an end of the trunk:

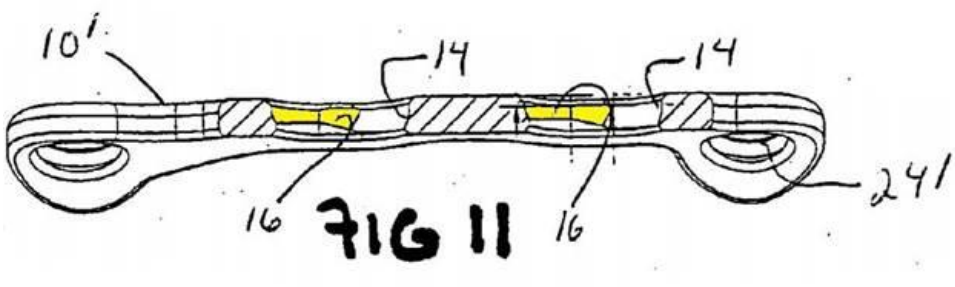


FIG 11

Ex. 1001, ¶¶296-297.

3. Claim 14 is Rendered Obvious by Kay in View of Chan

a. "The plate system as set forth in claim 13, wherein one or both of the first locking screw and the second locking screw are variable locking screws."

Kay in view of Chan renders obvious claim 14. Ex. 1001, ¶¶299-303. As described above, POSITAs would have been motivated to incorporate the variable locking screws of Chan with the plate of Kay. *See supra* Section VIII.A.1. 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.

4. Claim 15 is Rendered Obvious by Kay in View of Chan

a. "The plate system as set forth in claim 13, wherein the orthopedic plate is bilaterally asymmetrical about the medial line or a transverse axis."

Kay in view of Chan renders obvious claim 15. Ex. 1001, ¶¶304-308. Kay describes that "[t]he present invention provides a plate with bilaterally asymmetrical [sic] (meaning that the left half of the plate is not exactly the same as the right half

of plate taken from the medial axis)." Ex. 1006, ¶7. Asdepicted in annotated Figures 1 and 28 below, with the medial line in green, Kay shows such a plate:

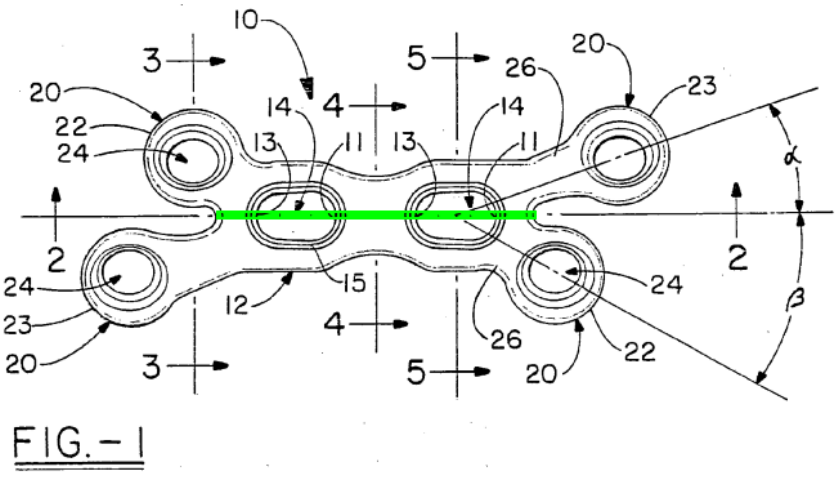


FIG.-1

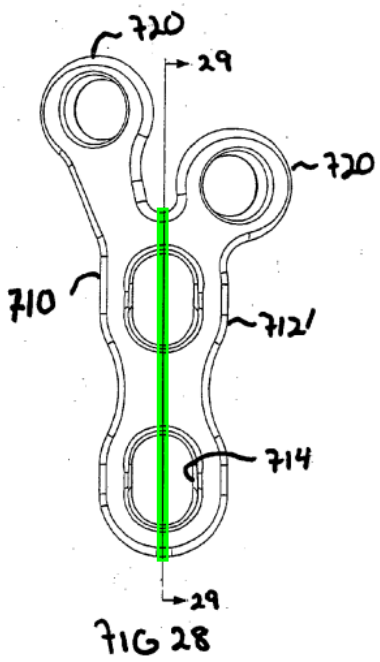
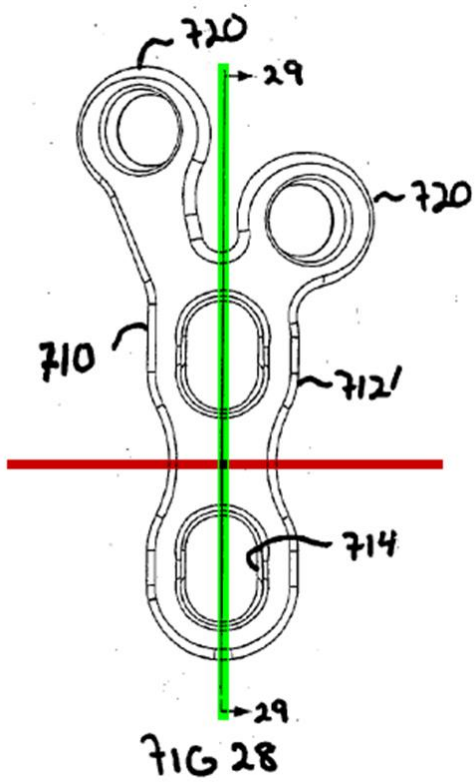


FIG 28

Ex. 1001, ¶¶304-305.

Kay also discloses a plate that is bilaterally asymmetrical about the transverse axis. Ex. 1001, ¶¶306-308. Annotated Figure 28, below shows an axis transverse to the medial line, where the side of the plate above the transverse axis includes

arms, and so is different from the opposite side of the plate across the transverse axis.

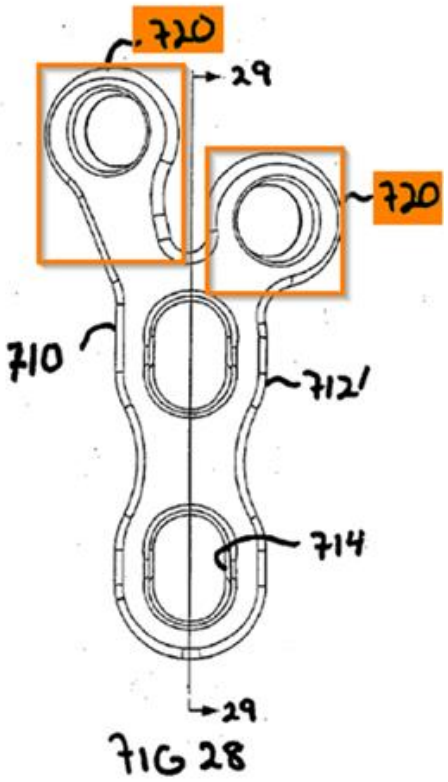


Ex. 1001, ¶¶306-308.

5. Claim 17 is Rendered Obvious by Kay in View of Chan

a. "The plate system as set forth in claim 13, wherein the orthopedic plate has only one set of arms and an outline that forms a Y-shape or the orthopedic plate has only two sets of terminal arms which are at either end of the elongate trunk and an outline that forms an X-shape."

Kay in view of Chan renders obvious claim 17. Ex. 1001, ¶¶309-311. Kay describes that Figure 28, annotated below, illustrates a plate "having only a single pair of arms." Ex. 1006, ¶56. This plate forms the shape of a Y, as shown below:



Ex. 1001, ¶310.

Kay further discloses a plate having two sets of terminal arms at either end of the elongate trunk and an X-shape outline. Ex. 1001, ¶311. As shown in annotated Figure 1, below, Kay describes a plate with a shape "similar to the Greek letter X" that includes "two opposing set of arms":

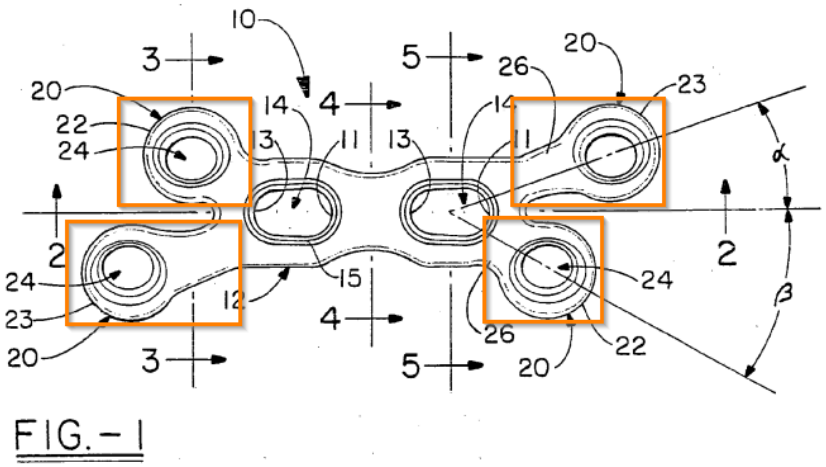


FIG.-1

Ex. 1001, ¶311; Ex. 1006, ¶46-48.

6. Claim 18 is Rendered Obvious by Kay in View of Chan

a. "The plate system as set forth in claim 13, wherein the central trunk portion has an inferior surface defining a curve transverse to the medial longitudinal plane and the curve is a portion of a circle and the orthopedic plate defines a segment of a cylinder."

Kay in view Chan renders obvious claim 18. Ex. 1001, ¶¶312-315. Kay discloses a plate with an "inferior side, or the side that would be facing (which contemplates opposing or touching or partially touching the) bone surface in use." Ex. 1006, ¶50.

Kay further describes that "the plate includes a radial curve about the longitudinal axis … typically about 10 mm with a transverse dimension." Ex. 1006, ¶52. Kay discloses that "the plate is radiiused about the inferior surface … with a curvature corresponding generally to the curvature of a bony surface," and that "the upper pair of arms, and the lower pair of arms continue this curvature." Ex. 1006,

¶9. Kay also explains that "the plate includes a radial curve about the longitudinal axis." Ex. 1006, ¶52.

Kay's disclosure of a single 10 mm radius curve "about the longitudinal axis" with the arms continuing the curvature discloses a curve that is constant along the medial line, and that this radial curve defines a portion of a circle. Ex. 1001, ¶315. And because Kay discloses a single radius about the longitudinal axis that continues into the arms, the plate defines a segment of a cylinder. *Id.* Figures 1-5, 13, 15, and 28-31 of Kay illustrate this curvature:

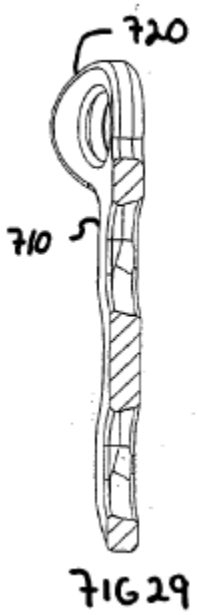


FIG 29

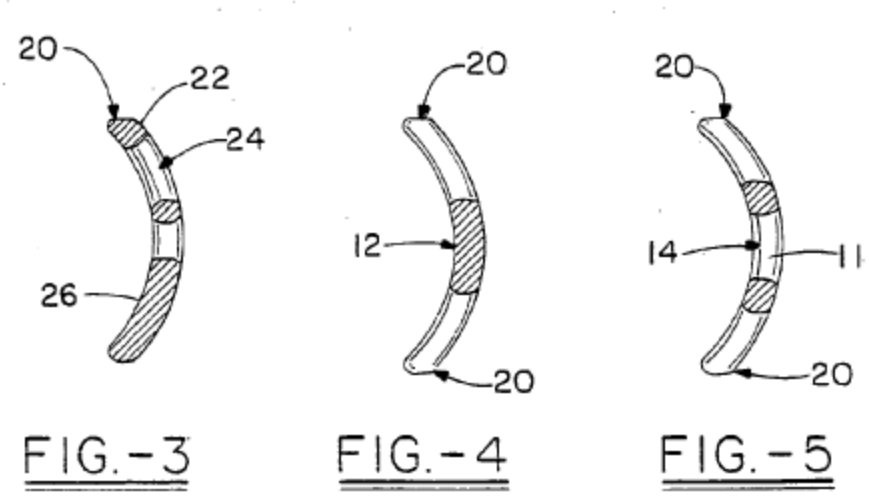


FIG.-3 FIG.-4 FIG.-5

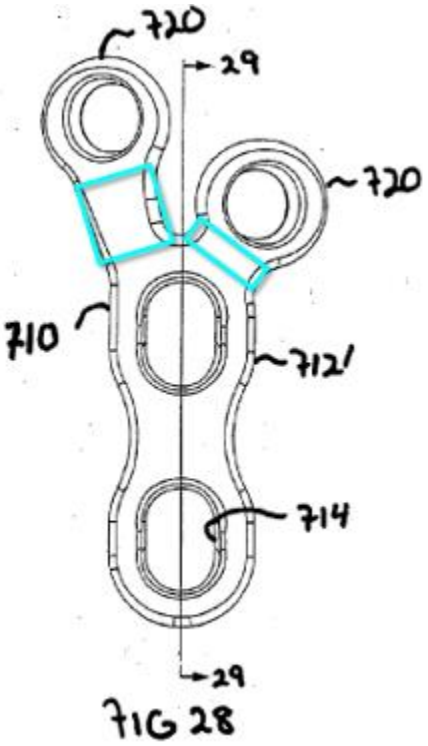
Ex. 1006, Figs. 3-5, 29.

7. Claim 19 is Rendered Obvious by Kay in View of Chan

a. "The plate system as set forth in claim 13, wherein each arm includes a linking section joining the arms to the elongate central trunk and each linking section has a waist and the waist of the linking section of the first arm and of the second arm is configured to bend relative to the elongate central trunk in response to a force applied at least to one of before or during surgery without deforming the threaded screw hole of the first or second arm."

Kay in view of Chan renders obvious claim 19. Ex. 1001, ¶¶316-319. Kay discloses that its plates have an "area linking the screw holes" that "has a decreased width so as to define a waist area 26 that will bend laterally (or 'curve') relative to the longitudinal axis and which will bend longitudinally to form a curved area in and out of the plane of the plate." Ex. 1006, ¶47. Kay describes that "this design facilitates the desired bending while resisting deformation of the screw holes 24

when they are used with the bending instrument to contour the plate" and that this force may be "applied before or during surgery." Ex. 1006, ¶51, claim 6. Annotated Figure 28 below shows the linking sections with waists:



Ex. 1001, ¶¶318-19.

8. Claim 46 is Rendered Obvious by Kay in View of Chan

As explained above, POSITAs would have found it obvious to combine Kay in Chan. *See supra* Section VIII.A.1. The combination of Kay and Chan also disclose every limitation of claim 46. Ex. 1001, ¶¶320-333.

a. Element 46[pre]: "An orthopedic plate system for use in bone defining an axis and comprising"

To the extent the preamble is limiting, Kay discloses an "Orthopedic Plate for Use in Small Bone Repair," and "relates to an orthopedic plate and screw system and instruments for surgical fixation of a small bone or bones," Ex. 1006, Abstract. Kay also discloses a plate having "a central trunk portion 12 defining the longitudinal axis of the plate." Ex. 1006, Fig. 1, ¶46. As shown in annotated Figures 1 and 28, below, Kay discloses both a longitudinal axis (green) and transverse axis (red):

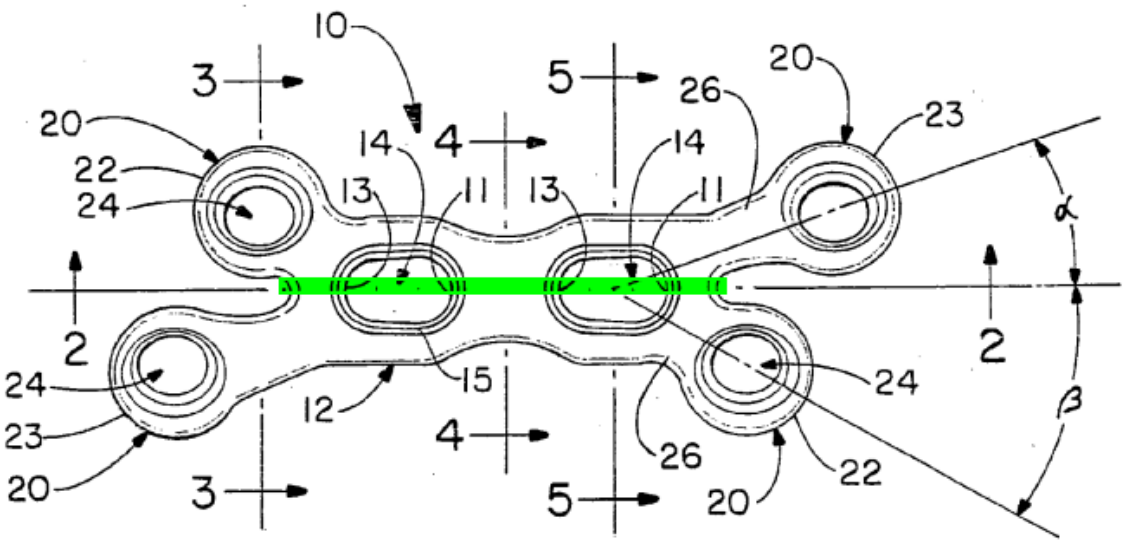
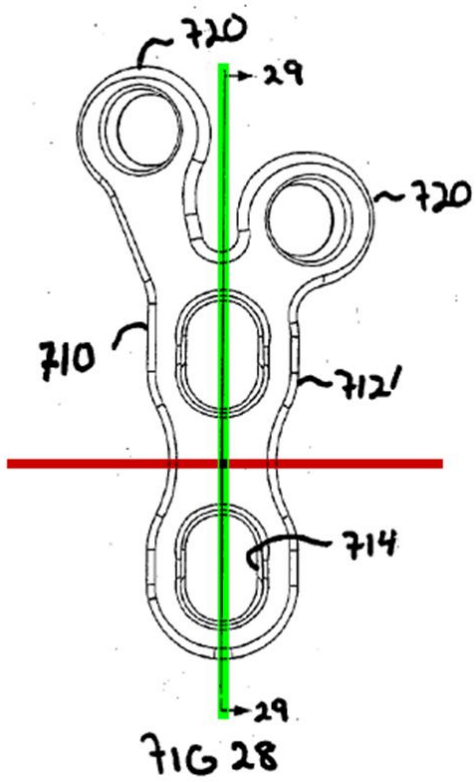


FIG. – 1



Ex. 1001, ¶¶320-323

b. Element 46[a]: "a first locking screw, and a second locking screw"

See Section VIII.A.2.a, Element 13[a], and Ex. 1001, ¶¶280-284, 324.

c. Element 46[b]: "and a plate having a trunk, and at least one pair of terminal arms wherein each terminal arm diverges asymmetrically outward from the trunk relative to the other terminal arm of the pair of terminal arms and"

See Section VIII.A.2.d, Element 13[c], and Ex. 1001, ¶¶286-288, 325.

d. Element 46[c]: "each of the terminal arms having a threaded locking hole which is in locked communication respectively with one of the first and the second locking screw"

See Sections VIII.A.2.e and VI.A.2.f, Elements 13[d] and 13[e], and Ex. 1001, ¶¶289-294, 326.

e. Element 46[d]: "the plate being contoured in three dimensions so that the terminal arms spiral so as to wrap around the bone axis in a portion of a double helix extending through an arc of less than 50º"

Kay discloses this element. Ex. 1001, ¶¶327-329. Kay discloses that "the plate is configured to bend laterally, longitudinally, and to wrap or spiral about its longitudinal axis so that it can be molded to an optimal shape for small bone procedures." Ex. 1006, ¶7. Kay also describes that "the plate is radiiused about the inferior surface…with a curvature corresponding generally to the curvature of a bony surface," and further explains that "the upper pair of arms, and the lower pair of arms continue this curvature." Ex. 1006, ¶9.

As shown below in Figures 3-5, the plates of Kay further "include[] a radial curve about the longitudinal axis,":

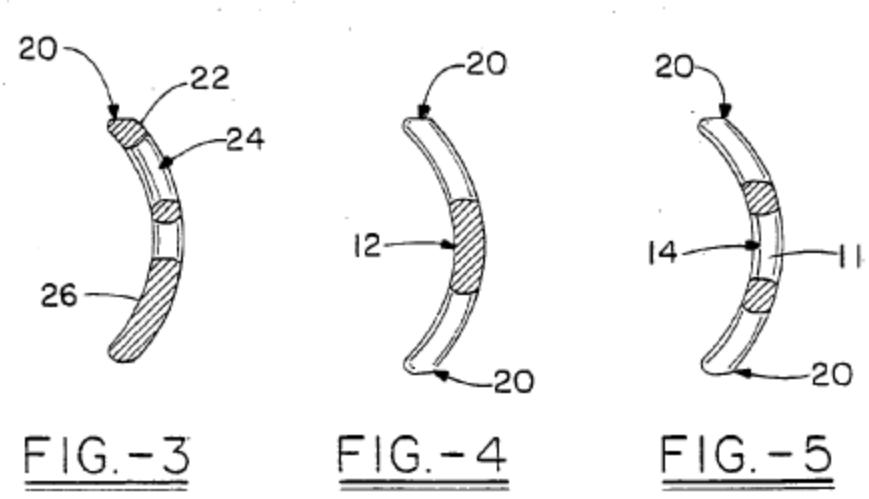


FIG.-3 FIG.-4 FIG.-5

Ex. 1006, ¶52, Figs. 3-5.

As Kay's plate has a radius corresponding to the curvature of a bony surface and Kay's arms wrap around the bone and continue the curvature, POSITAs would understand Kay's plate to wrap in a portion of a double helix less than 50º. Ex. 1001, ¶¶328-329. This is confirmed by the '253 patent, which correlates "wrapp[ing] around the bone like a small portion of a double helix (i.e. extending through an arc of less than about 50º)" with a plate that is "curved about the inferior surface … with a curvature corresponding generally to the curvature of a bony surface" and with arms that "continue this curvature." Ex. 1004, 3:65-4:9.

To the extent that Patent Owner argues Kay does not expressly describe a portion of a double helix with an arc less than 50º, choosing such an arc length would have been obvious to POSITAs. Ex. 1001, ¶¶328-329. As described by Kay, "there is less room on and about the bone for the surgeon to place and fix the construct" in

small bone applications, and "these bones are finer and have less surface area for placement of an implant." Ex. 1006, ¶3. POSITAs would have understood that, the greater the arc covered by a plate, the greater the difficulty for the surgeon in accessing and fixing screws from different sides of the bone, and the greater the chance for a screw to interfere with ligaments and tendons. Ex. 1001, ¶328; Ex. 1006, ¶4. POSITAs thus would have found it obvious to modify Kay's plate to include an arc of less than 50º for small bone applications. Ex. 1001, ¶328.

As Kay discloses that "a bending device" may be "used to apply a force to the plate through the screw holes" and that its plates "can be molded to an optimal shape for small bone procedures," POSITAs would also have expected that the plate could be successfully bent into a plate with an arc of less than 50º. Ex. 1001, ¶329; Ex. 1006, ¶¶7, 47.

f. Element 46[e]: "and wherein the plate has an inferior side and each of the first locking screw and the second locking screw have a proximal end and a distal end which extends from the plate, and the distal ends of the screws converge toward each other on the inferior side of the plate, but do not impinge."

Kay in view of Chan discloses this limitation. Ex. 1001, ¶¶330-333. Kay describes that the plate has an "inferior side" and arms. Ex. 1006, ¶50. As explained above, Kay's Figure 6 discloses a screw with cutting tip 32 being the distal end and the screw head being the proximal end. Ex. 1006, ¶53; Ex. 1001, ¶331; *see supra* Section VIII.A.2.f. Kay explains that "since the arms are asymmetrical relative to

each other…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." Ex. 1006, ¶50. As the "inferior" side of the plate is the side facing the bone, and the screws are to be inserted into the bone, Kay discloses that the distal ends of the screws converge on the inferior side. Ex. 1001, ¶¶330-332.

As described above, POSITAs would have been motivated to use Chan's threaded screw holes to allow for the use of locking screws in the arms of Kay to increase pullout strength, and would have expected that such features could be successfully incorporated into Kay. Ex. 1001, ¶333; *see supra* Sections VIII.A.1, VIII.A.2.b and VIII.A.2.e. Chan explains that locking screws "are typically inserted coaxially with the central axis of the hole," and that "the thread on the screw head mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate." Ex. 1007, ¶4. POSITAs would also have recognized that both Kay and Chan's screw holes allow for 30º of conical rotation of the screw axis relative to the axis of the screw hole. Ex. 1006, ¶10; Ex. 1007, ¶17. Thus when the screws are inserted "coaxially with the central axis of the hole," or at selected angles within the screw holes as described by Kay, the proximal end of each screw would lock to the plate, and the distal ends of each screw would converge without impinging. Ex. 1001, ¶333.

9. Claim 47 is Rendered Obvious by Kay in View of Chan

a. "The orthopedic plate system as set forth in claim 46, wherein one or both of the first locking screw and the second locking screw are variable locking screws."

Kay in view of Chan renders obvious claim 47. Ex. 1001, ¶¶299-303, 334-335. See Section VIII.A.3, Claim 14.

10. Claim 48 is Rendered Obvious by Kay in View of Chan

a. "The orthopedic plate system as set forth in claim 46, wherein the plate defines a medial line and the plate is bilaterally asymmetrical about the medial line or the transverse axis."

Kay in view of Chan renders obvious claim 48. Ex. 1001, ¶¶304-308, 336-337. *See* Section VIII.A.4, Claim 15.

11. Claim 50 is Rendered Obvious by Kay in View of Chan

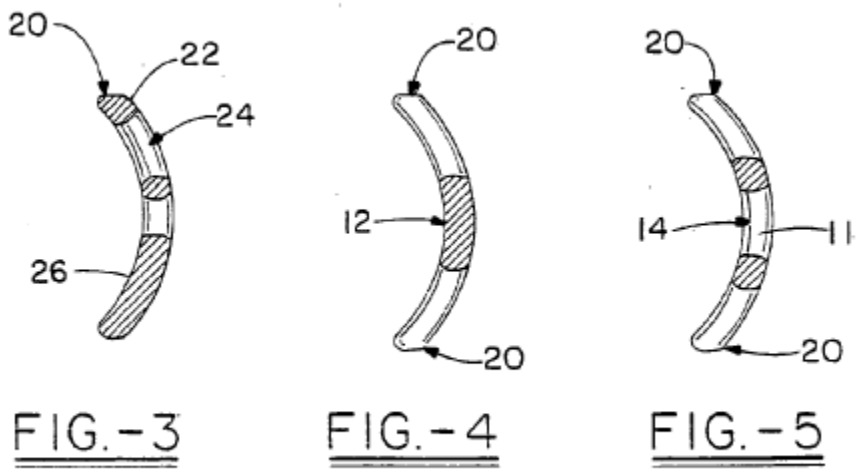
a. "The orthopedic plate system as set forth in claim 46, wherein the plate has only one set of arms and an outline that forms a Y-shape or the plate has only two sets of terminal arms which are at either end of the trunk and an outline that forms an X-shape."

Kay in view of Chan renders obvious claim 50. Ex. 1001, ¶¶309-311, 338-339. *See* Section VIII.A.5, Claim 17.

12. Claim 51 is Rendered Obvious by Kay in View of Chan

a. "The orthopedic plate system as set forth in claim 46, wherein the trunk defines a medial line and the trunk has an inferior surface defining a curve transverse to the medial line."

Kay in view of Chan renders obvious claim 51. Ex. 1001, ¶¶340-342. Kay discloses that its plates include "a radial curve about the longitudinal axis … typically about 10 mm with a transverse dimension." Ex. 1006, ¶52. Kay further discloses that its plate has an "inferior side…that would be facing [the] bone surface in use." *Id.*, ¶50. Figures 3-5, 13, and 15 of Kay illustrate the orthopedic plate having an inferior surface defining a curve transverse to the medial line:

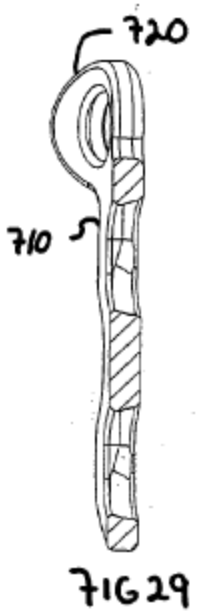


Ex. 1001, ¶342; Ex. 1006, Figs. 3-5.

13. Claim 52 is Rendered Obvious by Kay in View of Chan

a. "The orthopedic plate system as set forth in claim 46, wherein the curve is constant along the medial line."

Kay in view of Chan renders obvious claim 52. Ex. 1001, ¶¶343-344. Although claim 46 does not refer to a particular curve, Kay discloses a curve transverse to the medial line that is constant along the medial line. Kay discloses that "the plate is radiiused about the inferior surface … with a curvature corresponding generally to the curvature of a bony surface," and further explains that "the upper pair of arms, and the lower pair of arms continue this curvature." Ex. 1006, ¶9. Kay also discloses that "the plate includes a radial curve about the longitudinal axis" which "is typically about 10 mm." *Id.*, ¶52. As Kay discloses a single 10 mm radius curve "about the longitudinal axis" with the arms continuing the curvature, that the curve is constant along the medial line. Ex. 1001, ¶344. Figures 1-5, 13, 15, and 28-31 of Kay all illustrate the orthopedic plate in which the curve is constant along the medial line, and exemplary Figure 29 is shown below:



Ex. 1001, ¶344; Ex. 1006, Fig. 29.

14. Claim 53 is Rendered Obvious by Kay in View of Chan

a. "The plate system as set forth in claim 52, wherein the curve is a portion of a circle and the plate defines a segment of a cylinder."

Kay in view of Chan renders obvious claim 53. Ex. 1001, ¶¶345-346. Although claim 46 does not refer to a particular curve, as described above for Claims 51 and 52, Kay discloses a curve transverse to the medial line that is constant along the medial line. Because Kay discloses that the curve is constant, the curve is a portion of a circle, and, as the curves continue across the plate, the plate defines a segment of a cylinder. Ex. 1001, ¶346. Figures 1-5, 13, 15, and 28-31 of Kay depict this:

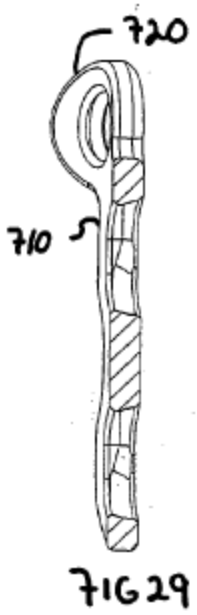


FIG 29

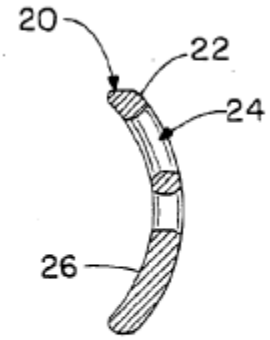


FIG.-3

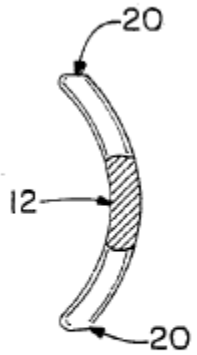


FIG.-4

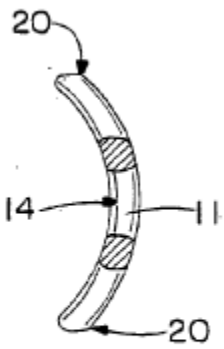


FIG.-5

Ex. 1006, Figs. 3-5, 29.

B. Ground 2: Grusin in View of Fernandez

1. POSITAs Would Have Been Motivated to Modify Grusin in View of Fernandez

POSITAs would have found it obvious to modify Grusin in view of Fernandez. Ex. 1001, ¶¶ 352-355, 389-392. Grusin discloses bone plates with

spherically recessed screw holes which can accept a variety of bone screws, including with a "locking feature," Ex. 1010, 6:13–21. POSITAs would have understood screws are used to create a strong hold, particularly for a fracture at the end of the radius where the patient's use of their hand or arm to grasp objects stresses the screws. Ex. 1001, ¶354. POSITAs would therefore have been motivated to combine Grusin's fastening mechanism with Fernandez's, as Fernandez's fastening mechanism includes the advantages of increased hold strength, maintaining position through a locking mechanism, and maintaining low profile. Ex. 1001, ¶¶354-355, 392. Fernandez's fastening mechanism also provides freedom to select the desirable screw angle. Ex. 1011, ¶12.

Fernandez explains its variable locking screw system improves on prior fasteners, including screws, threaded bolts or pins, and "expansion-head screws." *Id.*, ¶¶5, 10-13. Both Grusin and Fernandez disclose spherically recessed screw holes, Ex. 1010, 6:13–21; Ex. 1011, ¶15, and POSITAs would have recognized they could be successfully combined to provide Grusin with a low-profile, locking screw hole that provides a solid hold between bone and plate, and flexibility to choose a desirable screw angle. Ex. 1001, ¶¶354-355, 392.

Fernandez discloses screws with threaded heads to engage threaded screw holes was a well-known way to secure screws to a plate, Ex. 1011, ¶5, and POSITAs would have expected modifying Grusin's plate system to accept threaded screws

would be successful. Ex. 1001, ¶355. Grusin's screw holes could remain spherically recessed, modified by Fernandez, which minimizes the screw head's protrusion above the edge of the plate, providing the low-profile sought by Grusin. *Id.*. POSITAs would not have known of a reason why Grusin could not be so modified, and in view of the long history and known advantages of threaded screw holes, *id.*, (citing Ex. 1024, ¶2), would have expected Fernandez's variable locking features could be incorporated into Grusin successfully.

2. Claim 1 is Rendered Obvious By Grusin in View of Fernandez

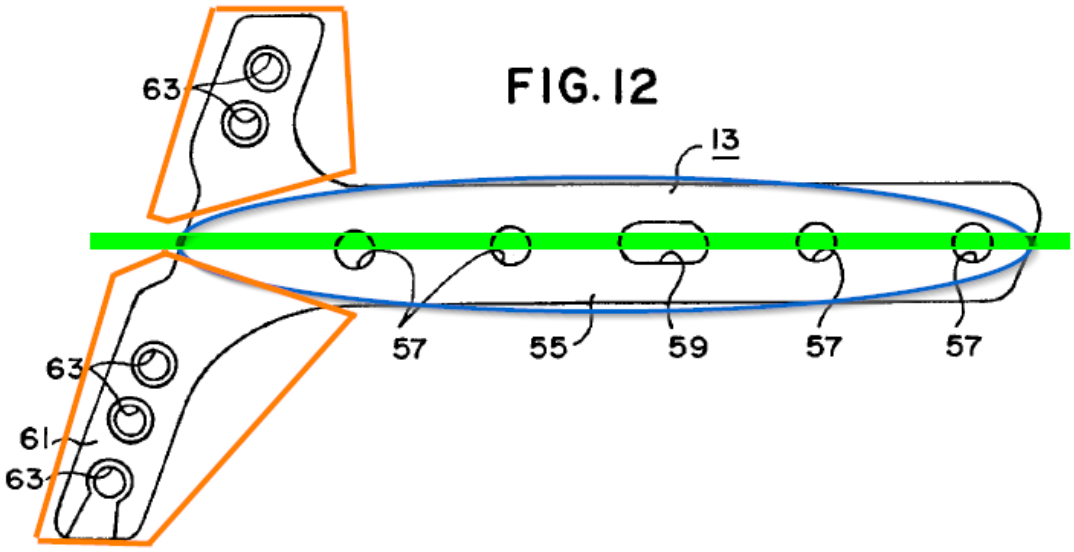
a. Element 1[pre]: "An orthopedic plate comprising"

To the extent the preamble is limiting, Grusin discloses this element. Ex. 1001, ¶347. Grusin, titled "Bone Plating System," relates to "a plating system for fractures of the distal radius." Ex. 1010. Cover, Abstract, 1:18–20.

b. Element 1[a]: "an elongate central trunk portion having a medial longitudinal plane and at least one pair of divergent arms"

Grusin discloses this element. Ex. 1001, ¶¶348-350. Grusin discloses "a longitudinal segment" attached to a "transverse segment" to "form a T-shape." Ex. 1010, Abstract. Grusin also discloses the transverse segment "is preferably angled with respect to the longitudinal segment 32 to further match the anatomy of the distal radius R." Ex. 1010, 6:33-40. Grusin discloses "the lateral end of the distal transverse segment 61 is extended proportionally a greater distance from the

proximal longitudinal segment … ." *Id.*, 7:6-15. Grusin also discloses using a plate bender "to match the selected plate … to the contoured template," noting that "[c]are should be taken not to bend the selected plate 11, 13, etc. across the holes 45, etc." *Id.*, 10:3-11. POSITAs would have understood that Grusin has an elongate central trunk (blue) having a medial longitudinal plane (green), and that the transverse segment includes arms (orange), as shown in annotated Figure 12, below:



Ex. 1001, ¶350.

c. Element 1[b]: "each arm including a threaded screw hole"

Grusin in view of Fernandez discloses this element. Ex. 1001, ¶¶351-355. Grusin describes "spherically recessed" screw holes that "have a counterbore 47 on the bottom side of the plate 11 in order to create a locking feature." Ex. 1010, 6:13–21. Grusin also describes a "buttress pin screw lock pin shank," preferably having an "internally threaded aperture." *Id.*, 8:67–9:6.

Fernandez discloses an "hourglass"-shaped through hole with "multiple isolated protrusions," that engage with the screw head "resulting in the strong locking of the screw at the selected orientation." Ex. 1011, Abstract; *see also* ¶ 32, claim 1. Fernandez's through hole is preferably "made by the combination of a partial sphere and two frustoconical holes" which include "a number of isolated protrusions." *Id.*, ¶ 15. Fernandez describes protrusions that are "designed to lock against the threaded spherical head of the screws," *Id.*,¶ 32, Claim 1, as shown below:

FIG. 4

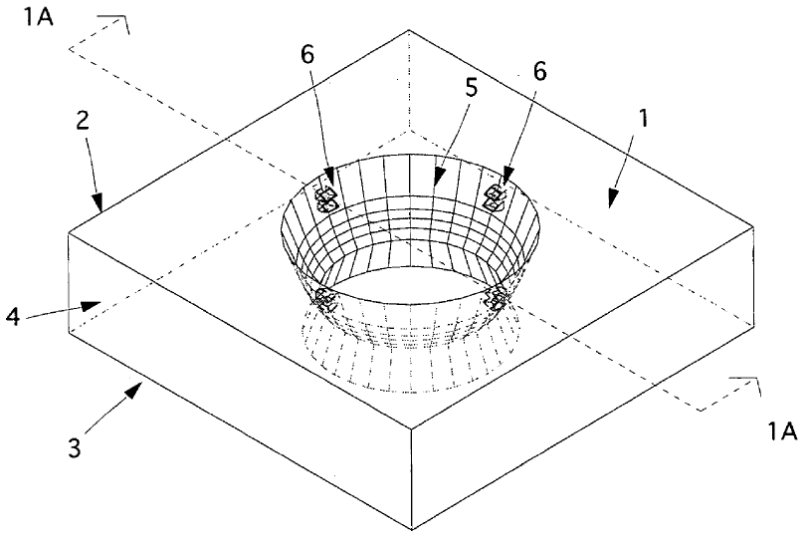
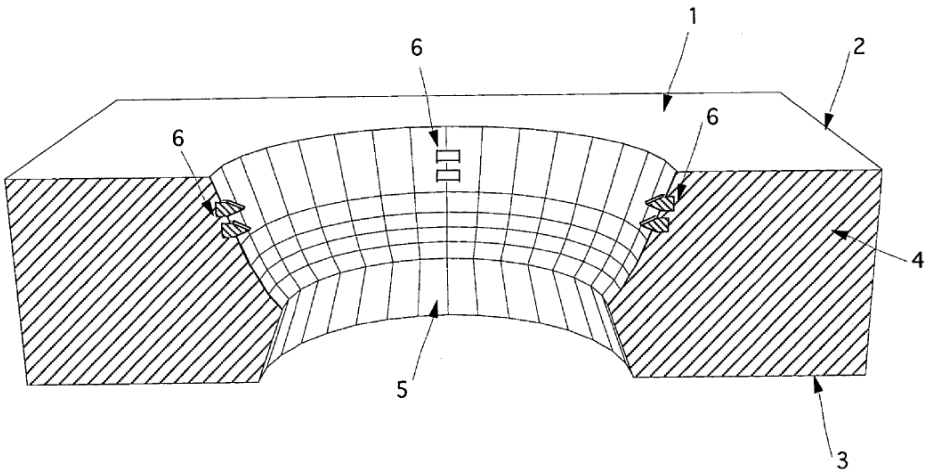


FIG. 5



Ex. 1011, Figs. 4-5.

As explained in detail above, POSITAs would have been motivated to look for features of bone plate systems which increase hold strength and resist screws loosening or pulling out, particularly given Grusin's application to the end of the radius where use of a patient's hand could increase stress on the screws, and Grusin's disclosure of locking features. Ex. 1001, ¶354. It would therefore have been obvious to POSITAs to thread Grusin's plate screw holes, as taught by Fernandez, so the plate could accept locking screws with threaded heads at a plurality of angular orientations while maintaining a strong hold on the bone. Ex. 1011, ¶ 12. Grusin and Fernandez both disclose spherically recessed screw holes, Ex. 1010, 6:13–21; Ex. 1011, ¶¶ 15, 32, and POSITAs would Grusin could be readily modified with Fernandez's screw holes to provide a low-profile screw hole that allows for a solid connection between bone and plate.

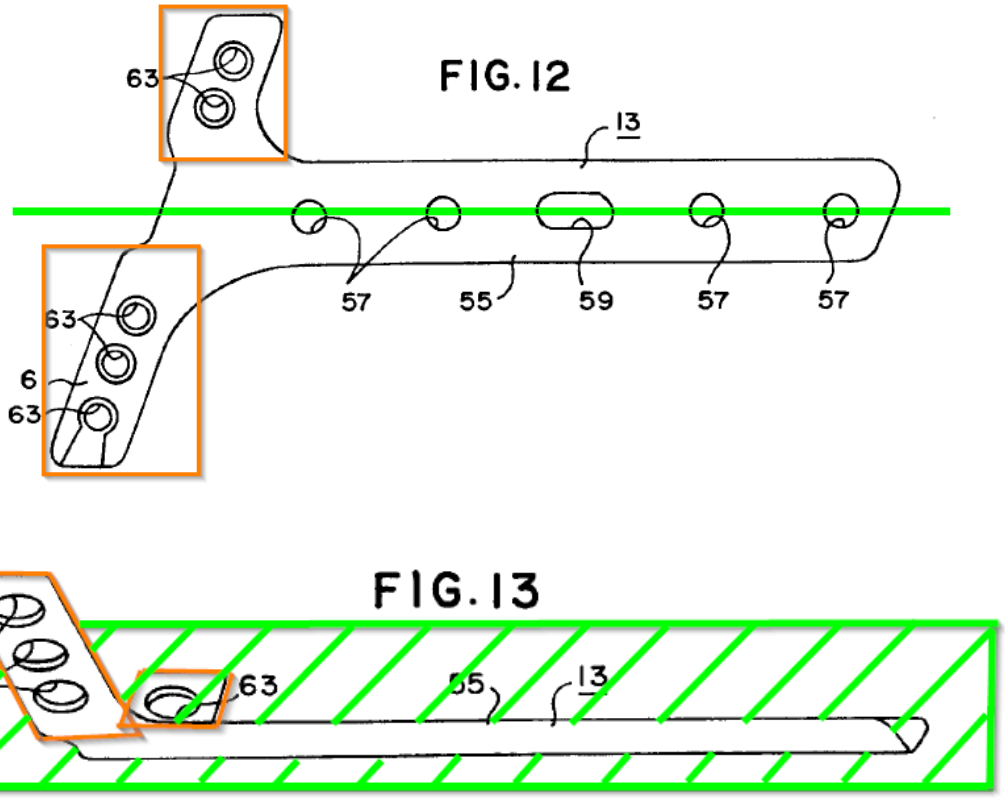
Further, POSITAs would have expected incorporating Fernandez's threaded screw holes and locking screws into Grusin's plate would be successful, given Fernandez's disclosure that threaded screw heads that engage threaded screw holes were well-known, Ex. 1011, ¶ 5, the fact that both Grusin and Fernandez teach spherical recesses that would minimize the screw's protrusion above the plate, and the long history and known advantages of threaded screw holes. Ex. 1001, ¶355 (citing Ex. 1024, ¶2.)

d. Element 1[c]: "and each arm of the pair of divergent arms diverging asymmetrically away from the medial longitudinal plane relative to the other arm of the pair of divergent arms and"

Grusin discloses this element. Ex. 1001, ¶¶356-358. Grusin discloses a "substantially T-shaped" plate with a "transverse segment," angled with respect to the longitudinal segment." Ex. 1010, 5:62–64; 6:33-40. Grusin discloses one end of the transverse segment is ""extended proportionally a greater distance" from the proximal longitudinal segment … ." *Id.*,7:6-15.

The Figures of Grusin, as shown in annotated Figures 12 and 13 below, show a plate having a pair of divergent arms (orange) which diverge asymmetrically away from the medial longitudinal plane (green) relative to the other arm. *See, e.g.*, Ex. 1010, Figs. 12, 13; Ex. 1001, ¶¶ 357-358. Because the transverse segment is angled with respect to the longitudinal segment, each end of the transverse segment will form a different angle with respect to the longitudinal medial axis. Ex. 1001, ¶357.

And because the angles are different as well as the lengths of each end (arm) of the transverse segment, the arms diverge asymmetrically away from the medial longitudinal axis relative to each other. *Id.*

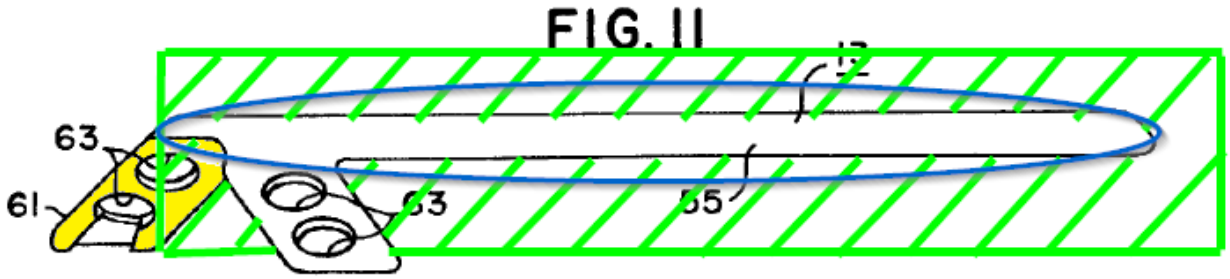


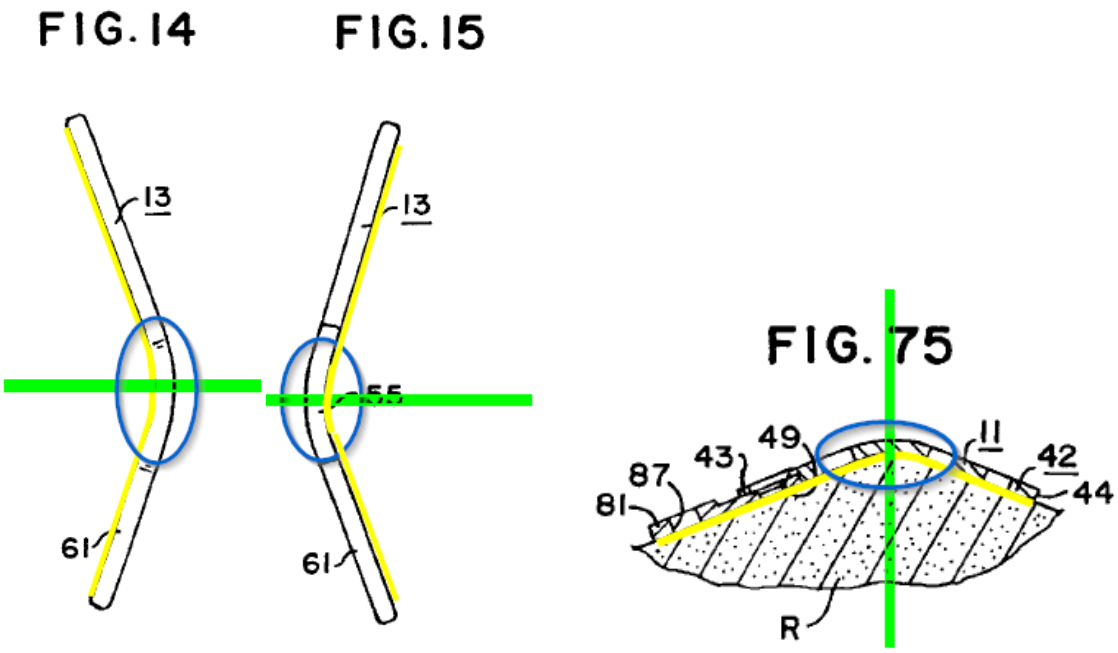
Ex. 1001, ¶358.

e. Element 1[d]: "wherein the central trunk portion has an inferior surface defining a curve transverse to the medial longitudinal plane and"

Grusin discloses this element. Ex. 1001, ¶¶359-360. Grusin discloses a "longitudinal segment" attached to a "transverse segment" forming a "T shape." Ex. 1010, Abstract. Grusin discloses the plating system is "designed to give a surgeon a low contour" that still "preserv[es] the strength" of existing "more bulky" systems.

Id., 2:5–11. Grusin describes the plate as "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.*, 6:36–40. POSITAs would have understood a curve "transverse" to the medial plane is curve crossing the plate's medial longitudinal plane in the lateral direction. Ex. 1001, ¶359. POSITAs would therefore have understood Grusin's plate, which has a medial longitudinal plane running along the length of a bone, and which is curved so that the bottom face conforms as closely as possible to the surface of a radius bone, would have an inferior surface defining a curve transverse to the medial longitudinal plane, as shown in annotated figures 11, 14-15 and 75 below:



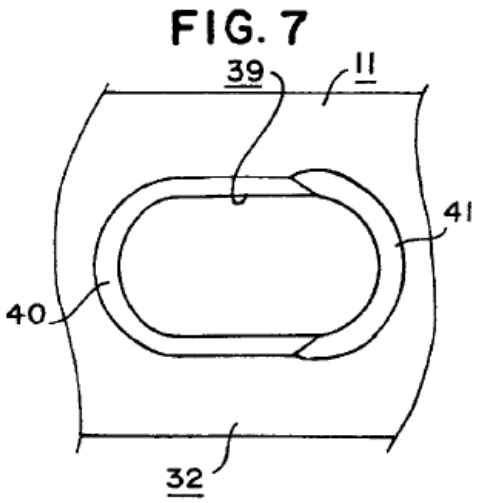


Ex. 1001, ¶¶359-360.

f. Element 1[e]: "has a compression slot having an internal edge which includes a shoulder that slopes toward the inferior side of the orthopedic plate as it extends away from the first end of the central trunk portion."

Grusin discloses this element. Ex. 1001, ¶¶361-362. Grusin discloses "a compression slot" with "a beveled edge which converges distally with the spherical edges or recess of the distal end 40 of the slot 39 to create a compression feature." Ex. 1010, 2:11–18, 6:5–9, 10:26-32. POSITAs would have understood, to provide compression, a compression slot's shoulder must slope toward the inferior side of a plate as it extends away from the plate's end, and would also have understood the shoulder of a compression slot located within the trunk would slope as it extends

away from an end of the trunk. As shown for example in Figure 7, below, Grusin depicts this element:



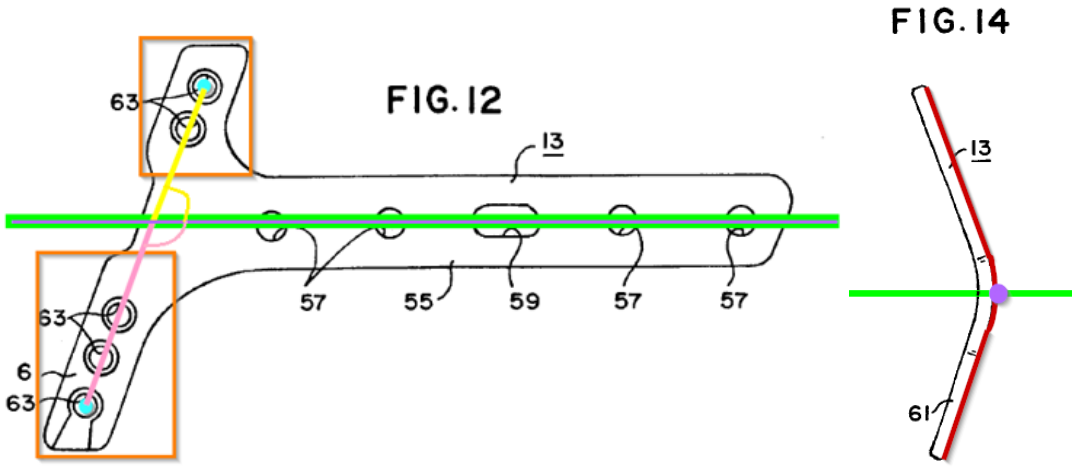
Ex. 1001, ¶ 362; Ex. 1010, Fig. 7.

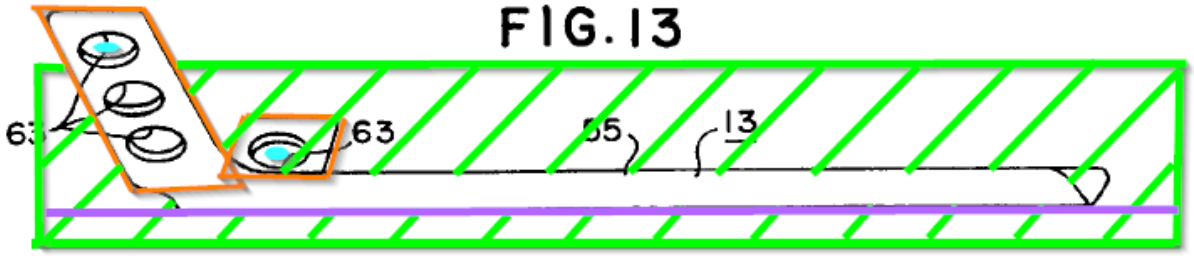
3. Claim 3 is Rendered Obvious By Grusin in View of Fernandez

a. "The orthopedic plate as set forth in claim 1, wherein the orthopedic plate has a top surface and the medial longitudinal plane intersects the top surface of the orthopedic plate in a longitudinal plate axis, each of the pair of divergent arm threaded screw holes has a mid-point, and the pair of divergent arms comprise a first arm which has a longitudinal arm axis that intersects the mid-point of the first arm threaded screw hole and the longitudinal plate axis to form a first angle with the longitudinal plate axis and a second arm which has a longitudinal arm axis that intersects the mid-point of the second arm threaded screw hole and the longitudinal plate axis to form a second angle with the longitudinal plate axis, and the first angle is different than the second angle."

Grusin in view of Fernandez renders obvious Claim 3. Ex. 1001, ¶¶363-365. Grusin discloses "a longitudinal segment" and "a transverse segment" that "form a T-shape." Ex. 1010, Abstract. Grusin discloses a "dorsal plate" with "a transverse segment," and "spherically recessed holes." *Id.*, 6:12–17. As explained above in Section VIII.B.2.c, it would have been obvious to modify the arm holes of Grusin to with threads in view of Fernandez. Grusin also discloses the "transverse segment" "form[s] an angle" with the "longitudinal segment," as shown below. Ex. 1010, Figs. 12-14, 12:16–17. As shown for example in Figures 12-14 of Grusin, annotated below, POSITAs would have understood that the medial longitudinal plane (green) intersects the top surface (red) in a longitudinal medial axis (purple). POSITAs would also have understood that each of the arms (orange) have a screw hole with a

mid point (light blue), and that the longitudinal arm axis (yellow) of the first arm forms a different angle with the longitudinal plane axis than the longitudinal arm axis (pink) of the second arm.



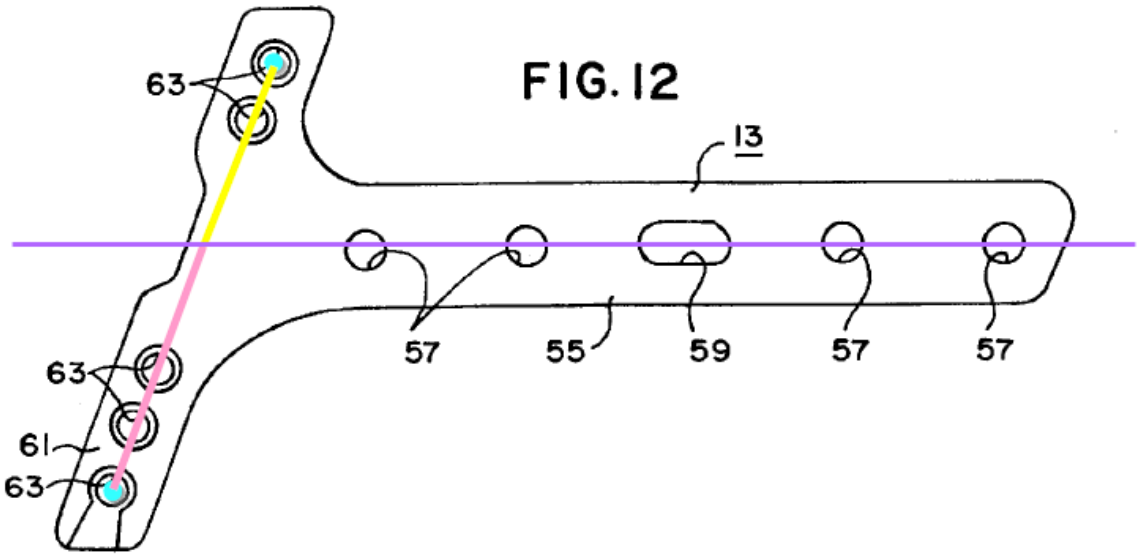


Ex. 1001, ¶365.

4. Claim 4 is Rendered Obvious By Grusin in View of Fernandez

a. "The orthopedic plate as set forth in claim 3, wherein the first longitudinal arm axis and the second longitudinal arm axis respectively have a first length and a second length each respectively defined from the intersection of the threaded screw hole mid-point and the intersection of the longitudinal plate axis and the first length is different from the second length."

Grusin in view of Fernandez renders obvious Claim 4. Ex. 1001, ¶¶366-68. Grusin discloses a "transverse segment" that is "preferably angled with respect to the longitudinal segment." Ex. 1010, 6:33–40. Grusin discloses the one end of the "transverse segment" is "extended proportionally a greater distance" from the longitudinal segment than the other, allowing for "an additional spherically recessed hole" on the transverse segment. *Id.,* 7:6-15. Grusin discloses that the transverse segment "form[s] an angle" with the longitudinal segment. *Id.,* 12:16–17. As shown in annotated Figure 12, below, POSITAs would therefore have understood Grusin discloses a first and second longitudinal arm axis (yellow and pink) with different lengths as shown below.



Ex. 1001, ¶368.

5. Claim 5 is Rendered Obvious By Grusin in View of Fernandez

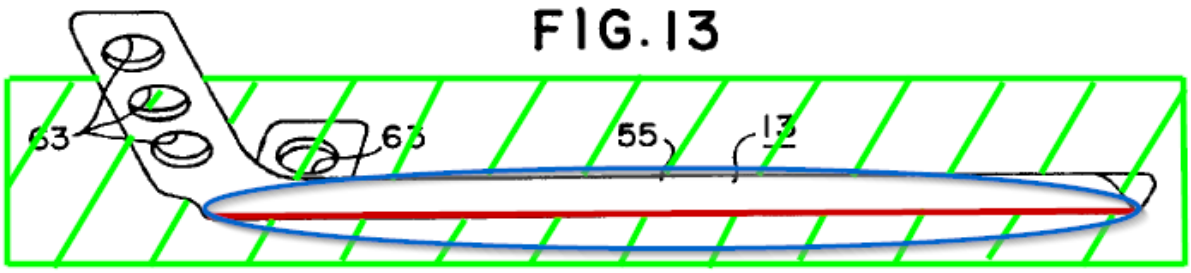
a. "The orthopedic plate as set forth in claim 1, wherein the medial longitudinal plane defines a medial axis in the central trunk portion and the curve is constant along the medial axis."

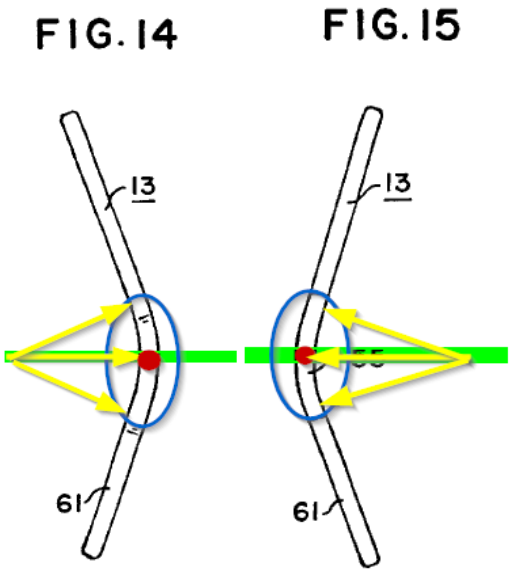
Grusin in view of Fernandez renders obvious Claim 5. Ex. 1001, ¶¶369-373. As discussed above, Grusin discloses an elongate central trunk having a medial longitudinal plane. POSITAs would have understood the medial longitudinal plane corresponds to a medial axis where the plane intersects with the middle of the trunk. *Id.* ¶370.

Grusin discloses a "longitudinal segment" and "a transverse segment," which "form a T-shape." Ex. 1010, Abstract. Grusin discloses the plate gives "a low contour" and is designed for "both intra- and extra-articular fractures of the distal

radius." *Id.*, 2:5–11. Grusin discloses a plate 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.*, 6:36–40.

As shown in annotated Figures 13-15, belowPOSITAs would have understood Grusin to disclose a medial axis (red) defined by the medial longitudinal plane (green) and a constant curve constant along the medial axis:





Ex. 1001, ¶372.

The top of the radius bone is rounded and extends along an axis, and therefore the plate of Grusin, which is pre-bent so that the bottom face conforms closely to the bone underneath, would have a constant curve along the medial axis. Ex. 1001, ¶373. The surgery disclosed in Grusin may also require "[r]emoval of the Lister's tubercle," which would result in a more uniform curvature of the underlying anatomy. Ex. 1010, 10:5-6. Given Grusin's disclosure of a plate bender "for use in bending and molding a fracture fixation plate to match the anatomy of a specific radius," *id.*, 9:16-18, POSITAs would also have been motivated to bend the plate to have a constant curve along the medial line. POSITAs would have expcted that a constant curve along the medial line would be successful, given that plates with a constant curve were generally well known to work in the prior art. Ex. 1001, ¶373 (citing Ex. 1055.) Thus it would have been obvious to POSITAs to bend the plate to a constant curve matching the underlying anatomy. Ex. 1001, ¶373.

6. Claim 6 is Rendered Obvious By Grusin in View of Fernandez

a. "The orthopedic plate as set forth in claim 5, wherein the curve is a portion of a circle and the orthopedic plate defines a segment of a cylinder."

Grusin in view of Fernandez renders obvious claim 6. Ex. 1001, ¶¶374-375.

As explained above, POSITAs would have understood that Grusin discloses a plate with a constant curve along the medial axis because the whole plate is pre-bent so that the bottom face conforms as closely as possible to the surface of the

bone underneath, or would have been motivated to bend the plate to such curvature. *See supra*, Section VIII.B.5. This curvature is a portion of a circle because it is constant and, similarly, the plate defines defines a segment of a cylinder because it is a constant curvature along the medial axis. Ex. 1001, ¶375.

To the extent Patent Owner argues this curvature is not a portion of a circle or Grusin's plate does not define a segment of a cylinder, POSITAs would have found it obvious to use the plate bender disclosed in Grusin, Ex. 1010, 9:16-18, to bend the plate to a constant curve which is a portion of a circle and defines a segment of a cylinder. *Id.*. POSITAs would also have expected that a curve that is a portion of a circle and which defines a segment of a cylinder would be successful, given that plates with such a profile were well known to work in the prior art. *Id.*, ¶375 (citing Ex. 1055.) Thus it would have been obvious to POSITAs to bend the plate to a constant curve which is a portion of a circle and defining a segment of a cylinder to match the underlying anatomy. *Id.*

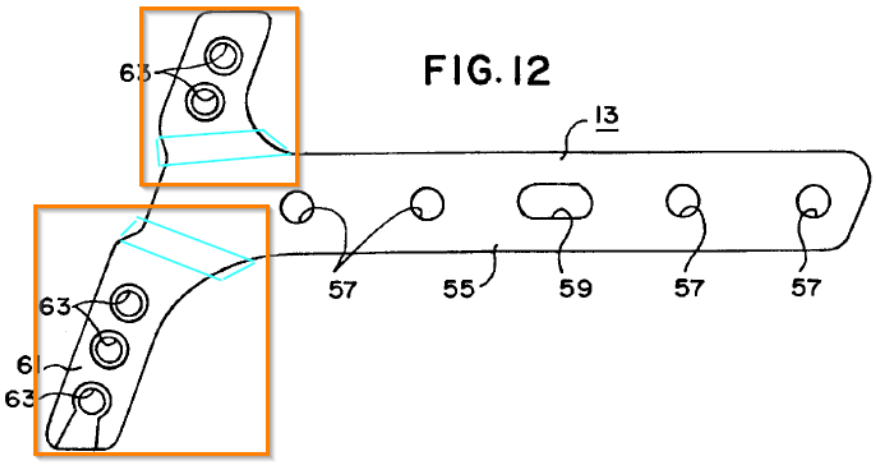
7. Claim 7 is Rendered Obvious By Grusin in View of Fernandez

a. "The orthopedic plate as set forth in claim 1, wherein each arm of the pair of divergent arms includes a waist."

Grusin in view of Fernandez renders obvious Claim 7. Ex. 1001, ¶¶376-380.

Grusin discloses a plate with a "longitudinal segment" and "transverse segment" in which "the distal end of the longitudinal segment [is] attached to the

transverse segment intermediate the lateral and medial ends of the transverse segment to form a T-shape." Ex. 1010, Abstract. The Figures of Grusin, e.g. annotated Figure 12 below, depict each end of the transverse segment (arm, in orange) including a waist (light blue):



Ex. 1001, ¶380.

Grusin further 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," and that "is specifically designed for use with a distal radial dorsal or volar plate … ." Ex. 1010, 9:16–24. Grusin further describes that the plate bender has slots "for receiving an end of the transverse segment 42 of the plate 11" and "for receiving an end of the longitudinal segment 32 of the plate 11 … ." *Id.*, 9:31-37. Grusin also explains that when the plate bender is "used to match the selected plate 11, 13, etc., to the contoured template," that "[c]are should be taken not to bend the selected plate 11, 13, etc. across the holes 45, etc. … ." *Id.*, 10:3-11. POSITAs

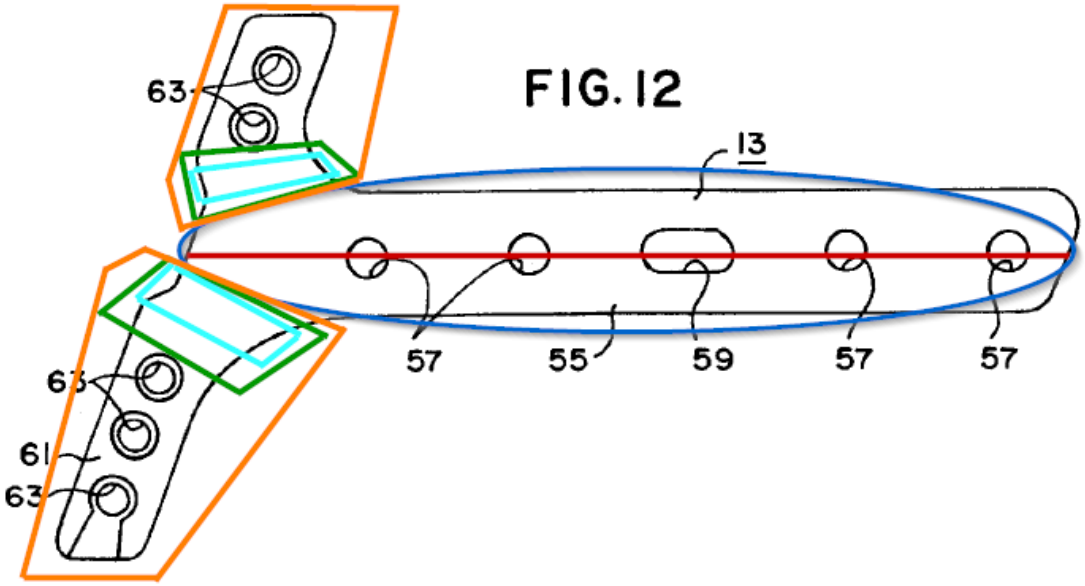
would have understood from Grusin's disclosure that the plate was designed to be bent at the most easily bent portion of the linking section without deforming the holes, and that the less material there is at a particular plate section, the easier it is to bend. POSITAs would therefore have understood that Grusin's linking sections would have waists to permit bending. Ex. 1001, ¶¶377-78.

To the extent Patent Owner argues that Grusin does not disclose a waist, it would have been obvious to POSITAs to modify the arms of Grusin with a waist, given Grusin's statement that bending to avoid deforming the holes is encouraged. POSITAs well understood the use of waists to encourage bending, and would have understood that cinching an area of the linking section to add a waist would successfully encourage bending based on the numerous well-known examples of prior waists. Ex. 1001, ¶¶379-380; *see also* Ex. 1001, ¶39; Ex. 1013, Fig. 1; Ex. 1015, Fig. 1; Ex. 1018, Fig. 1; Ex. 1019, Fig. 3.

8. Claim 8 is Rendered Obvious By Grusin in View of Fernandez

a. "The orthopedic plate as set forth in claim 7, wherein the pair of divergent arms comprise a first arm and a second arm each having a linking section joined to the central trunk portion and the waist of the linking section of the first arm and of the second arm is configured to bend relative to the central trunk portion in response to a force applied to at least one of before or during surgery without deforming the threaded screw holes of the pair of divergent arms."

Grusin in view of Fernandez renders obvious Claim 8. Ex. 1001, ¶¶381-383. Grusin discloses "a transverse segment" and a "longitudinal segment" that "form a T-shape." Ex. 1010, Abstract. Grusin describes a "plate bender" for "bending and molding a fracture fixation plate to match the anatomy of a specific radius R." *Id.,* 9:16–24. Grusin's plate bender has a slot "for receiving an end of the transverse segment" and slots "for receiving an end of the longitudinal segment." *Id.,* 9:31-37. Grusin discloses the plate bender can "be used to match the selected plate 11, 13, etc., to the contoured template," and "[c]are should be taken not to bend the selected plate 11, 13, etc. across the holes … ." *Id.,* 10:8-11. As depicted in annotated Figure 12, below, POSITAs would have understood that Grusin discloses linking sections (green) included in the arms (orange) joined to the central trunk (dark blue), and to bend Grusin's plate at the waist (light blue) of the linking section (green), before or during surgery, without deforming the arm screw holes. Ex. 1001, ¶383.

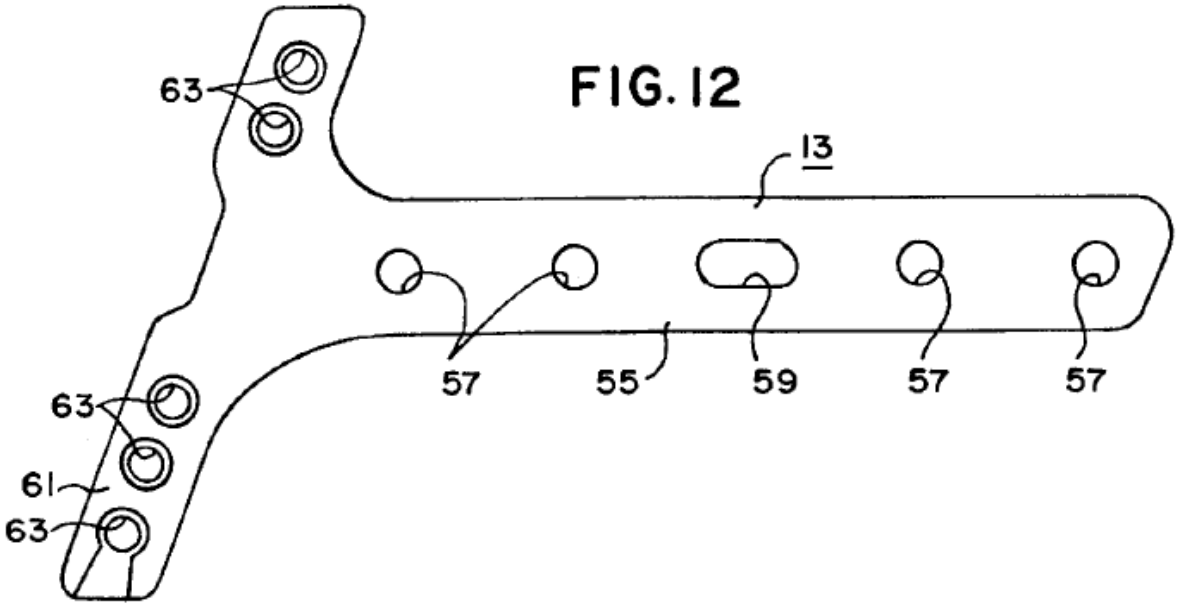


Ex. 1001, ¶383.

9. Claim 9 is Rendered Obvious By Grusin in View of Fernandez

a. "The orthopedic plate as set forth in claim 1, wherein the central trunk portion has a through hole."

Grusin in view of Fernandez renders obvious claim 9. Ex. 1001, ¶¶384-385. Grusin discloses a "longitudinal segment" with "spherically recessed holes" for bone screws and "a longitudinal slot . . . to compress fractures." Ex. 1010, 5:67–6:3, 6:60-67. This is shown in Grusin Figure 12:



Ex. 1010, Fig. 12.

10. Claim 12 is Rendered Obvious By Grusin in View of Fernandez

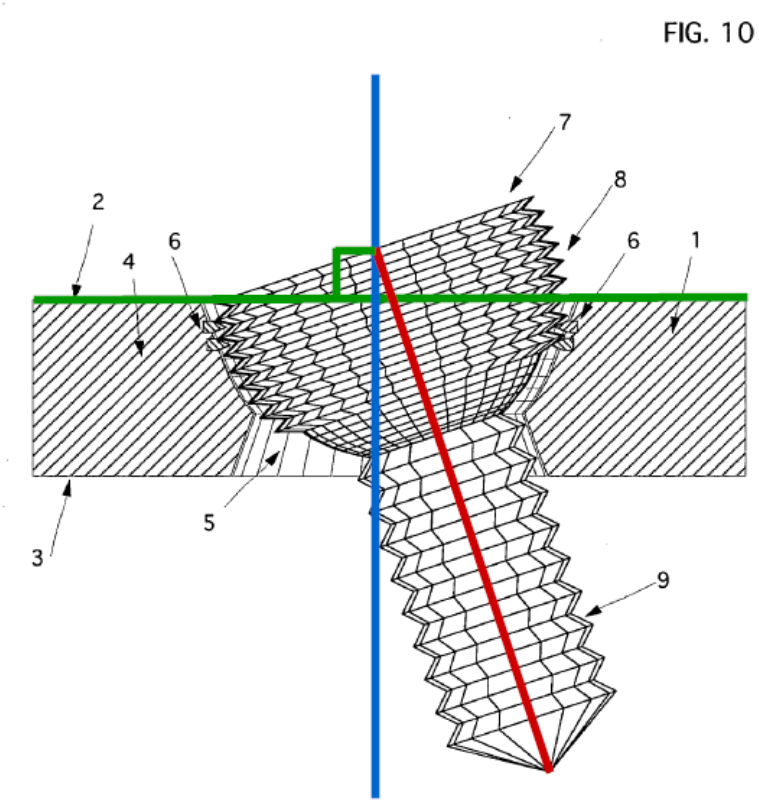
a. "The orthopedic plate as set forth in claim 1, wherein the threaded screw holes have a screw axis and further including screws having a threaded shaft and a head wherein the threaded screw holes and the screw heads of each screw have a mating interface such that the screw can engage a threaded screw hole so as to allow a plurality of angular orientations of the screw axis of that threaded screw hole."

Grusin in view of Fernandez renders obvious claim 12. Ex. 1001, ¶¶387-392. Grusin discloses a "spherically recessed" arm screw hole "hav[ing] a counterbore . . . in order to create a locking feature" for screws or pins. Ex. 1010, 6:14–21.

Fernandez discloses a screw with "a shank with a thread" and "a partial sphere head with a thread configured and dimensioned to match with the isolated

protrusions of the hour-glass shaped through holes," for "strong locking of the screw at the selected orientation within the through hole." Ex. 1011. Abstract. Fernandez describes a through hole "made by the combination of a partial sphere and two frustoconical holes, to which a number of isolated protrusions are coupled into." Ex. 1011, ¶ 15. Fernandez's plate holes have an inner wall with "a small number of isolated protrusions … designed to lock against the threaded spherical head of the screws." Fernandez's system "allows for a surgeon-selected angle of a bone screw relative to the fixation device," where the screw can be inserted "at variable orientations." *Id.,* ¶¶ 9, 15. Fernandez states the screw angle "does not affect the position of the thread of the screw head." *Id.,* ¶ 31.

POSITAs would have understood Fernandez discloses screws with threaded shaft and threaded screw holes, allowing for a plurality of angular orientations of the screw axis (red) with reference to an axis (blue) perpendicular to the top surface (green), as shown in annotated Figure 10, below:



Ex. 1001, ¶¶389-391.

As discussed above in Sections VIII.B.1 and VIII.B.2.c, it would have been obvious for POSITAs to have used the variable angle threaded screw holes and screws disclosed in Fernandez in Grusin's plate to obtain Fernandez's advantages of freedom to choose the desirable screw angle while maintaining an effective locking mechanism, and POSITAs would have expected Fernandez's features could be successfully incorporated into Grusin. Ex. 1001, ¶392. For example, POSITAs would have recognized that Grusin and Fernandez disclose spherically recessed screw holes, Ex. 1010, 6:13–21; Ex. 1011, ¶ 15, and could be readily combined to

provide a low-profile screw hole, still allowing a very solid connection between bone and plate. Ex. 1001, ¶392.

IX. MANDATORY NOTICES

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

Paragon 28 is the real party in interest for Petitioner.

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

WMT asserted the ’253 patent against Paragon in Case No. 1:18-cv-00691-PAB-STV (D. Colorado), filed March 23, 2018. This case may affect, or be affected by, this proceeding. Paragon is not aware of any other proceedings involving the ’253 patent.

Other patents, related to and in the same family as the ’253 patent, have also been asserted in the above-referenced case and are the subject of concurrently-filed IPRs 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 '253 patent is available for IPR and Paragon is not barred or estopped from requesting IPR of the '253 patent on the grounds identified. Paragon was served with a complaint asserting infringement of the '253 patent on March 29, 2018, and this Petition is being filed within one year of that date.

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 '253 patent are unpatentable. Paragon therefore requests that an IPR of these claims be instituted.

DATED: March 29, 2019

Respectfully submitted,

/s/ Joel R. Merkin

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Attorney for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. § 42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 13,772 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.

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
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
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. 9,259,253 (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