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. 9,259,252

Case IPR2019-00895

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

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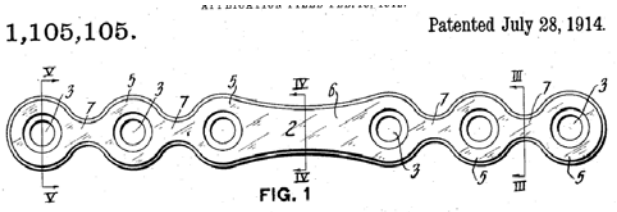
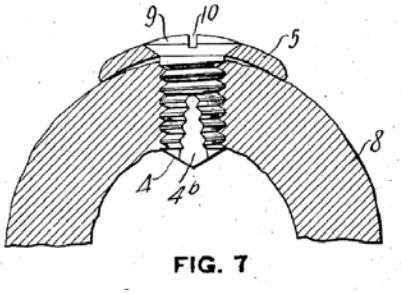
Paragon 28, Inc. ("Paragon") requests *inter partes* review ("IPR") of Claims 17-27 (the "Challenged Claims") of U.S. Patent No. 9,259,252 (the "'252 patent") (Ex. 1003).

I. INTRODUCTION

The '252 patent, titled "Orthopedic Plate for Use in Small Bone Repair," issued on February 16, 2016. Ex. 1003. The Challenged Claims combine two well-known and well-understood technologies—bone plates and bone screws—in a straightforward fashion that would have been obvious to a person of ordinary skill in the art ("POSITA"). For over a century, surgeons have utilized bone plates and bone screws to repair bone fractures, as shown in U.S. Patent No. 1,105,105, issued in 1914:





Ex. 1052, Figs. 1, 7.

The Challenged Claims utilize similar concepts and combine known plate shapes with known screw designs. The Challenged Claims include plates with divergent arms, yet such plate designs have been known since at least the 1980s. The Challenged Claims also include screws that can "lock" into place via a "threaded

head" at a variety of angles, yet such screws have been known since at least the early 2000s.

Though these plate designs were well-known since the 1980s, the non-provisional application that led to the '252 patent was not filed until January 2006 ("the 2006 application"), and was published on August 3, 2006. The initial application disclosed combining a well-known plate design (plates shaped like an X or Y) with a well-known screw design (non-locking screws without a threaded head). But there was nothing novel or non-obvious about this combination; POSITAs have been combining known plate shapes with known screw designs for over a century.

Despite the well-known nature of these screws, the 2006 application did not disclose screws with a threaded head that could "lock" into place. In 2009, seeking to expand its rights, the Applicant filed a continuation-in-part application ("CIP") in 2009 ("2009 CIP application") and added new material, including a screw with a threaded head that can "lock" into place. The law, however, does not allow an Applicant to expand its rights in this manner.

Once the 2006 application was published and available as prior art to the public, only novel or non-obvious subject matter could be patented. The subject matter added to the 2009 CIP application, however, is anything but novel and non-obvious. Locking screws 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. *E.g.* Ex. 1003, Claim 17. 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. 1003, Abstract. Below is an overview of the state of the art of bone plates and screws as of the priority date of the Challenged Claims.

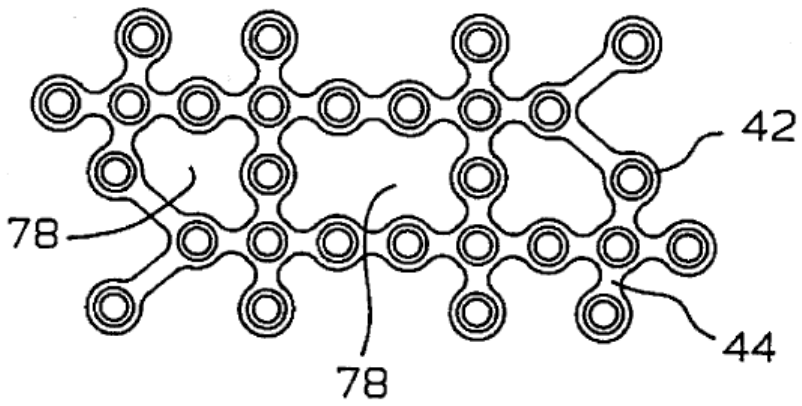
A. Bone Plates

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

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

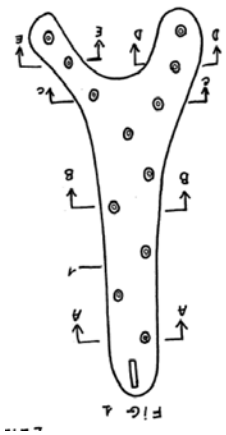
Bone plates come in a variety of materials and a variety of shapes depending on the fracture to be treated. *Id.*, ¶33. Plate materials vary based on the material's stiffness, strength, ductility, corrosion resistance, surface structure, and biocompatibility. *Id.* The majority, if not all, of bone plates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

Plate size varies based on the anatomy of the person and the bone to be healed. *Id.*, ¶35. Because bones have different shapes, and humans have differently sized anatomy, POSITAs understood that plates could and should be shaped in a variety of configurations to permit the plate to attach to the plate in an advantageous manner. *Id.*, ¶36. Surgeons commonly used "multi-configurable plating system[s]" to shape the plate the bone before or during surgery. *Id.*, ¶¶36-37. 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":

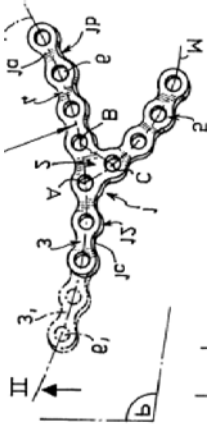


Ex. 1012, Abstract, Fig. 12, 2:59-65, 7:9-22; Ex. 1001 ¶¶36-38. Surgeons and POSITAs understood how to use these "linking members" to form "Y-shaped plates, T-shaped plates, X-shaped plates, and numerous other conventional and non-conventional shaped plates." Ex. 1012, 7:18-22.

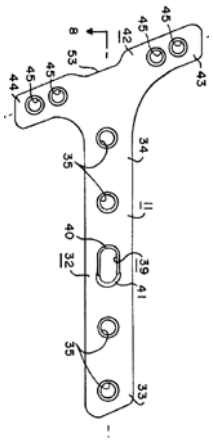
POSITAs also would have been familiar with bone plates having "two asymmetrical branches [] that diverge from each other" in which the "two branches have a different length and width." Ex. 1013, 3:21-24; Ex. 1001, ¶39. Numerous "diverging branch" plates were known in the art, prior to even the filing date of the provisional application that eventually led to the '252 patent, as shown below:



Ex. 1013, Fig. 1 (1977)

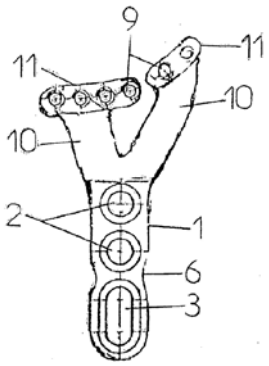


Ex. 1015, Fig. 1 (1987)



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:

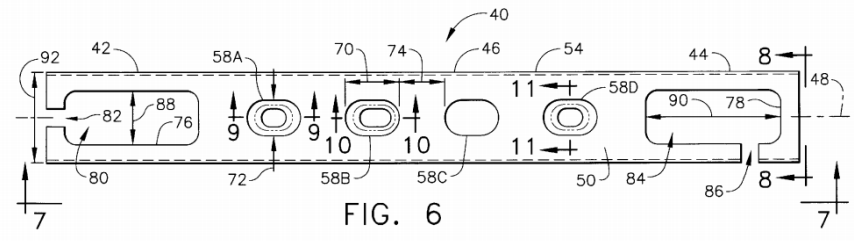


FIG. 6

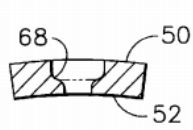


FIG. 11

(*Id.* at 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:

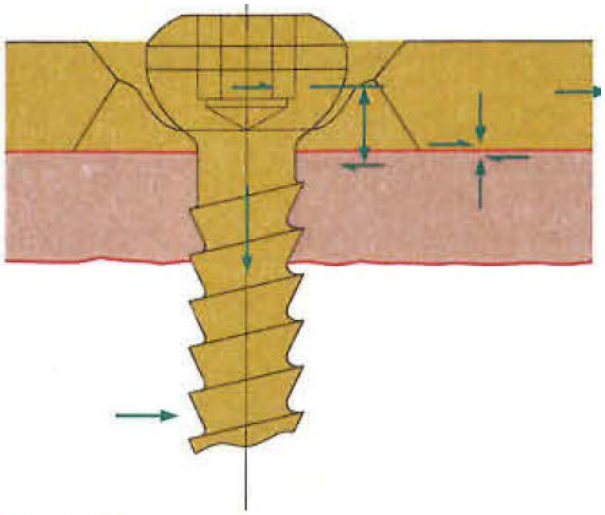


Fig. 1.2-20: Conventional plate screws

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:

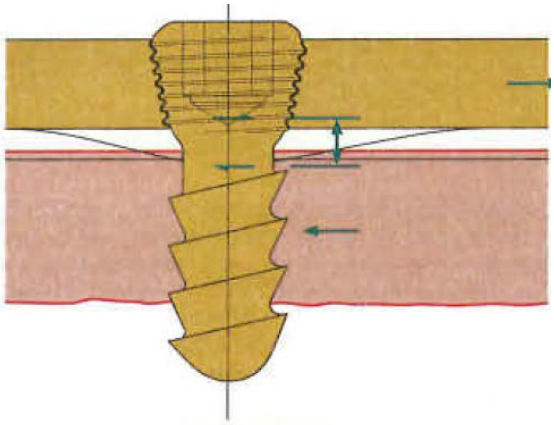
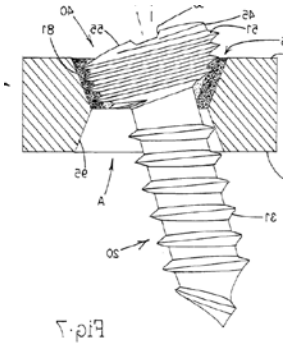


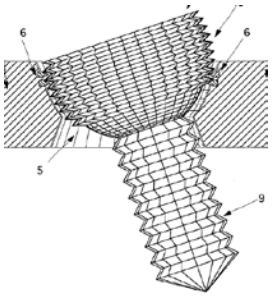
Fig. 1.2-21: Locked plate screws.

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.

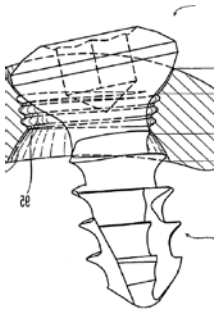
Screws can also be polyaxial, *i.e.* permitted to be inserted at a variety of angles, or monoaxial, *i.e.* permitted to be inserted at a single angle. *Id*., ¶46. POSITAs used polyaxial screws to permit screws to be inserted at an optimal angle to achieve optimal compression and avoiding hitting other 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 Challenged Claims. As a result, the earliest date to which the Challenged Claims can claim priority is February 24, 2009.

A. Legal Standard

To obtain the benefit of the priority date of an earlier application, the claims of the '252 patent must meet the requirements of 35 U.S.C. § 120. *In re Huston*, 308 F.3d 1267, 1276 (Fed. Cir. 2002). Section 120 permits a patent application to rely on the filing date of an earlier application "only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (quoting *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995)). Claims which depend on "[s]ubject matter that arises for the first time in [a] CIP application do[] not receive the benefit of the filing date of the parent application." *Id.* Thus, if "even

a single feature" of a claimed invention was first disclosed in a CIP, and that feature is not inherent in the parent application, then the claim is only entitled to the filing date of the CIP. *Lockwood v. Am. Airlines, Inc.*, 877 F. Supp. 500, 507 (S.D. Cal. 1994), aff'd 107 F.3d 1565 (Fed. Cir. 1997). Once the party asserting invalidity presents invalidating prior art, the patentee has "the burden [] to come forward with evidence to show entitlement to an earlier filing date." *Research Corp. Techs, Inc. v. Microsoft Corp.*, 627 F.3d 859, 871 (Fed. Cir. 2010). If a CIP application is not entitled to the priority date of the original application, the original application is prior art to the CIP application and can be used to find the claims obvious under § 103. 35 U.S.C. § 102(b); *In re Chu*, 66 F.3d at 297-298 (finding the claims of a CIP application obvious in light of the parent's disclosure because the CIP was not entitled to the parent's priority date); *Application of Van Langenhoven*, 458 F.2d 132, 137 (C.C.P.A. 1972) (an applicant's own prior application "may properly be relied upon for all it fairly teaches to establish obviousness" if the applicant cannot claim the benefit of a filing date that precedes its own application); MPEP § 2133.01 ("When [an] applicant files a [CIP] whose claims are not supported by the parent application,…[a]ny prior art disclosing the invention or an obvious variant thereof having a critical reference date more than 1 year prior to the filing date of the child will bar the issuance of a patent under" § 102(b)).

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

Claims 17-27 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 17 and its dependent claims 18-27 recite "inserting a first locking screw having a proximal end and a distal end into the threaded screw hole of the first arm, and a second locking screw having a proximal end and a distal end into the threaded locking screw hole of the second arm … ." Ex. 1003, Claim 17.

Figures 6 and 7 of the '252 patent depict the difference between threaded and unthreaded screw heads:

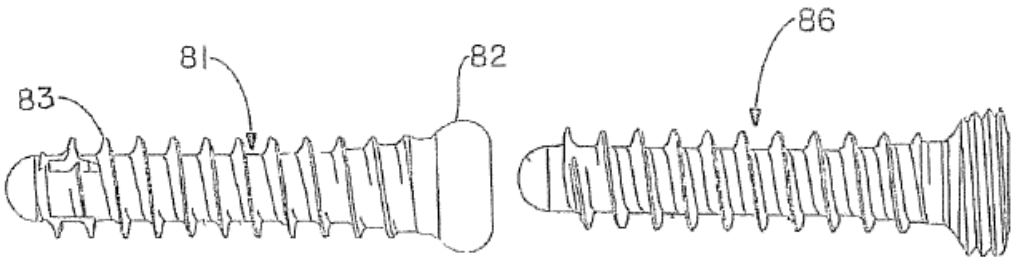


FIG.-6 FIG.-7

Ex. 1003, 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" in the '252 Patent. *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 '252 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 '252 patent share many common figures (Figs. 1-5 of the 2006 application, for example, are either identical or practically identical to figures from the '252 patent), Figs. 6 and 7 of the '252 patent are not found in the 2006 application. *See* Ex. 1006, Figs. 1-31; Ex. 1003, 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:

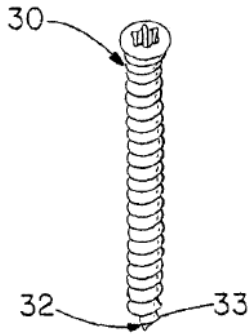


FIG.-6

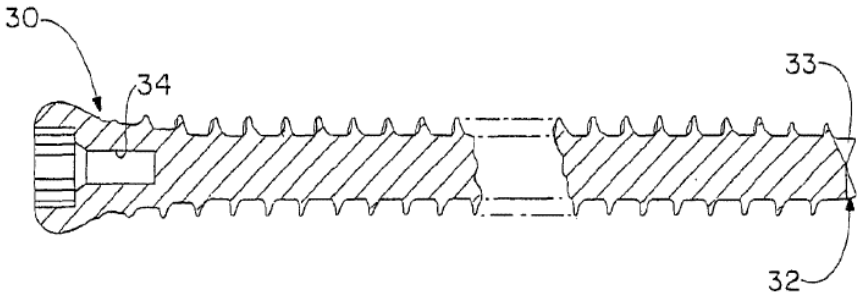


FIG.-8

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 screw head in the 2006 application "keeps the screw from having any sharp projecting edges which could provide an irritation to the tissue in the vicinity of the plate and further seats in the plate so that no more than 10% by volume of the screw head projects from the plate." *Id*. Yet despite the level of detail with which the 2006 application describes the screw heads, the screw head itself is never described as "threaded," nor is the screw described as a "locking screw," as required by Claim 17 of the '252 patent and its dependents. *See generally* Ex. 1006; Ex. 1003, Claim 17.

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 '252 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. 1003, 4:20-23. The '252 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." *Id.*, 4:29-32 (emphasis added). While the 2006 application discloses screw heads, they are never described as "threaded," a requirement of locking screws according to the '252 patent. *See generally* Ex. 1006; Ex. 1003, 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 detailed 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 Claim 17, which includes the "locking screw" limitation, is not entitled to the priority date of the 2006 application. Because Claims 18-27 depend from Claim 17, those claims also include the "locking screw" limitation and are also not entitled to the priority date of the 2006 application, and the earliest priority date for the Challenged Claims is the filing date of the 2009 CIP application: February 24, 2009.

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 '252 patent.

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

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

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

- U.S. Patent Pub. No. 2008/0140130 to Chan et al. ("Chan") (Ex. 1007), filed January 9, 2008 and published June 12, 2008. Chan is prior art under 35 U.S.C. § 102(a).

- U.S. Patent No. 6,283,969 to Grusin ("Grusin") (Ex. 1010), filed March 10, 2000, and issued September 4, 2001. Grusin is prior art under 35 U.S.C. § 102(b).

- U.S. Patent Pub No. 2005/0165400 to Fernandez ("Fernandez") (Ex. 1011), filed January 26, 2004 and published July 28, 2005. Fernandez is prior art under 35 U.S.C. § 102(b).

Even if the Challenged Claims were found to be entitled to the priority date of the 2006 application (January 6, 2006) or provisional application 60/648,209 (January 28, 2005), at least Grusin and Fernandez would both be prior art to the Challenged Claims under § 102(b) and § 102(a)/§102(e), respectively.

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

Ground	Claims	Description
1	17-27	Obvious under § 103 in view of Kay and Chan
2	17-21, 23-27	Obvious under § 103 in view of Grusin and Fernandez

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

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	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

The person of ordinary skill in the art contemplated by the '252 patent would have had 2-3 years of experience in the design of orthopedic plates or 2-3 years of experience using orthopedic plates in surgery. Ex. 1001, ¶¶28-29.

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

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

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

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

V. THE DISTRICT COURT LITIGATION

Paragon has filed this IPR after Patent Owner alleged that Paragon infringes 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.

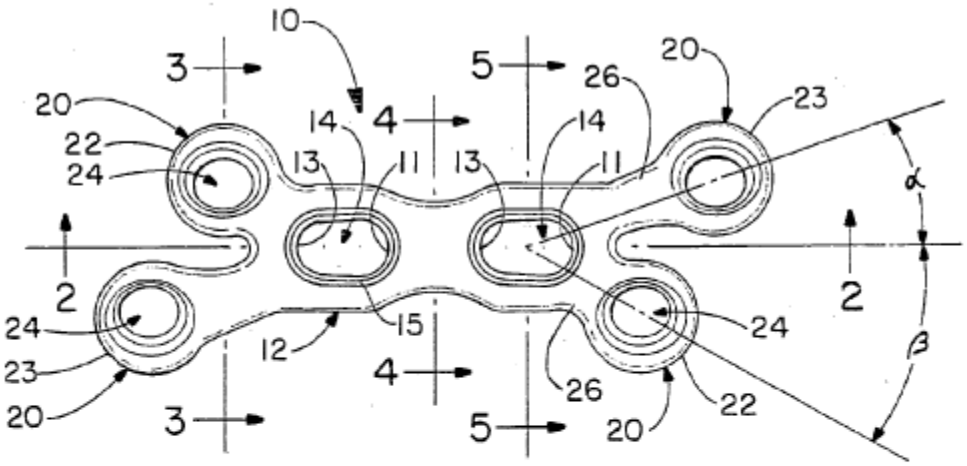


FIG.-1

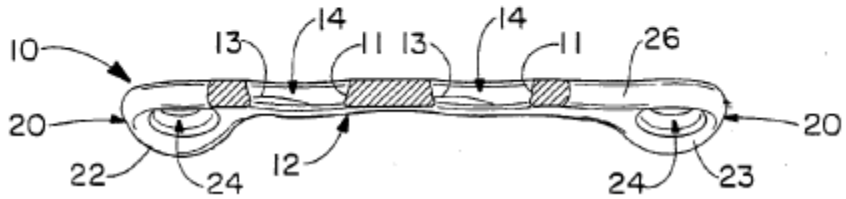


FIG.-2

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

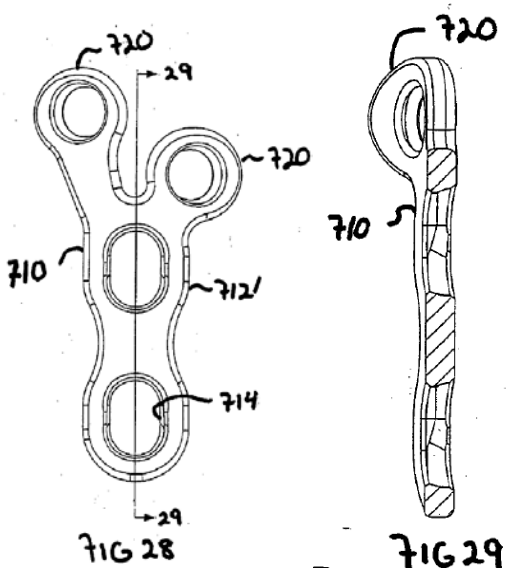
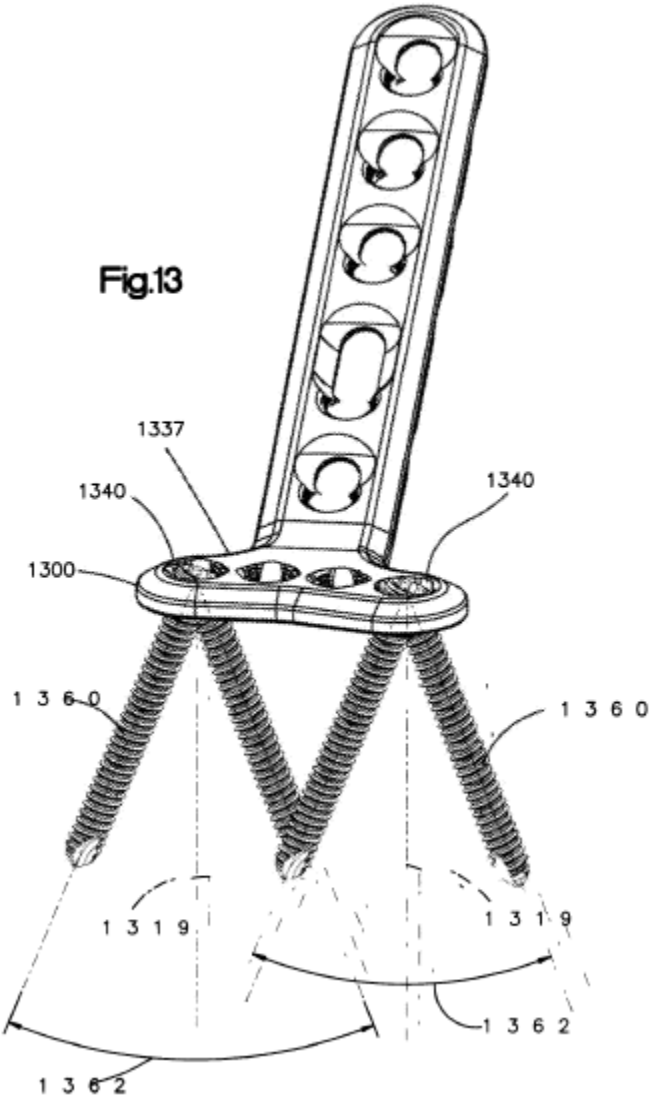


FIG 28 FIG 29

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.

B. Chan

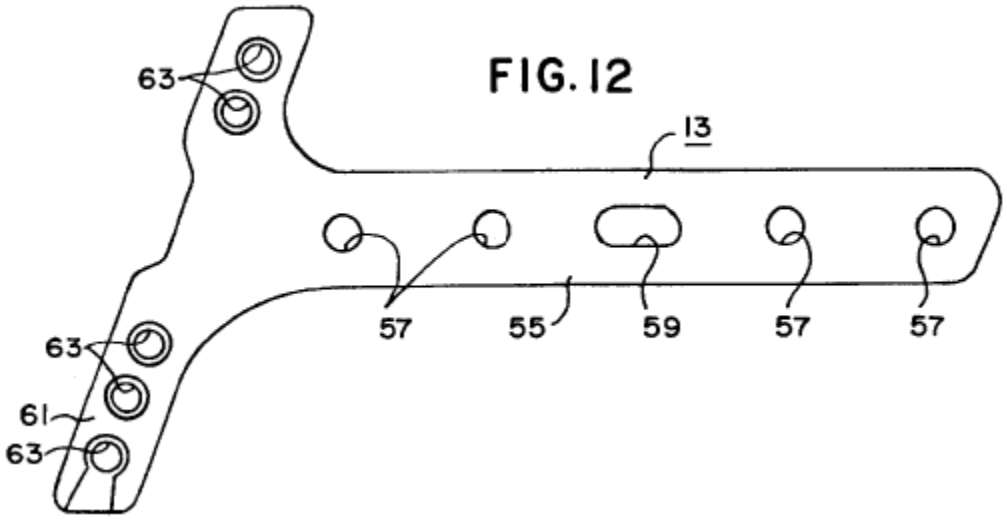
Chan is titled "Highly-Versatile Variable-Angle Bone Plate System" and generally describes "[a] bone plate system for internal fixation of bone fractures [that] includes a bone plate having a plurality of bone plate holes" that are "constructed to receive either a non-locking, locking or variable-angle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



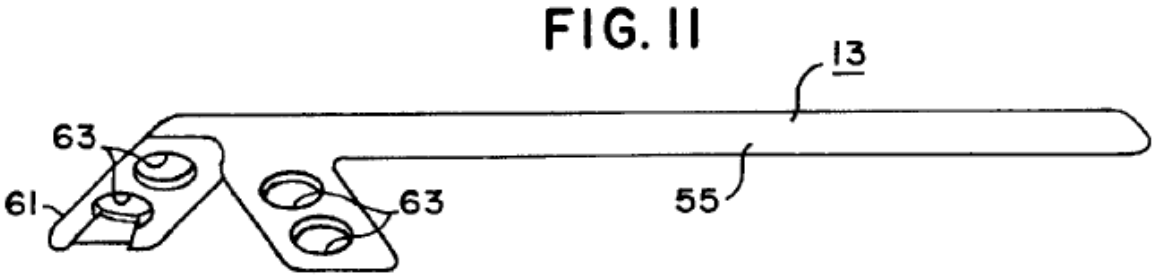
C. Grusin

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. *Id.*, 5:62–64, 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

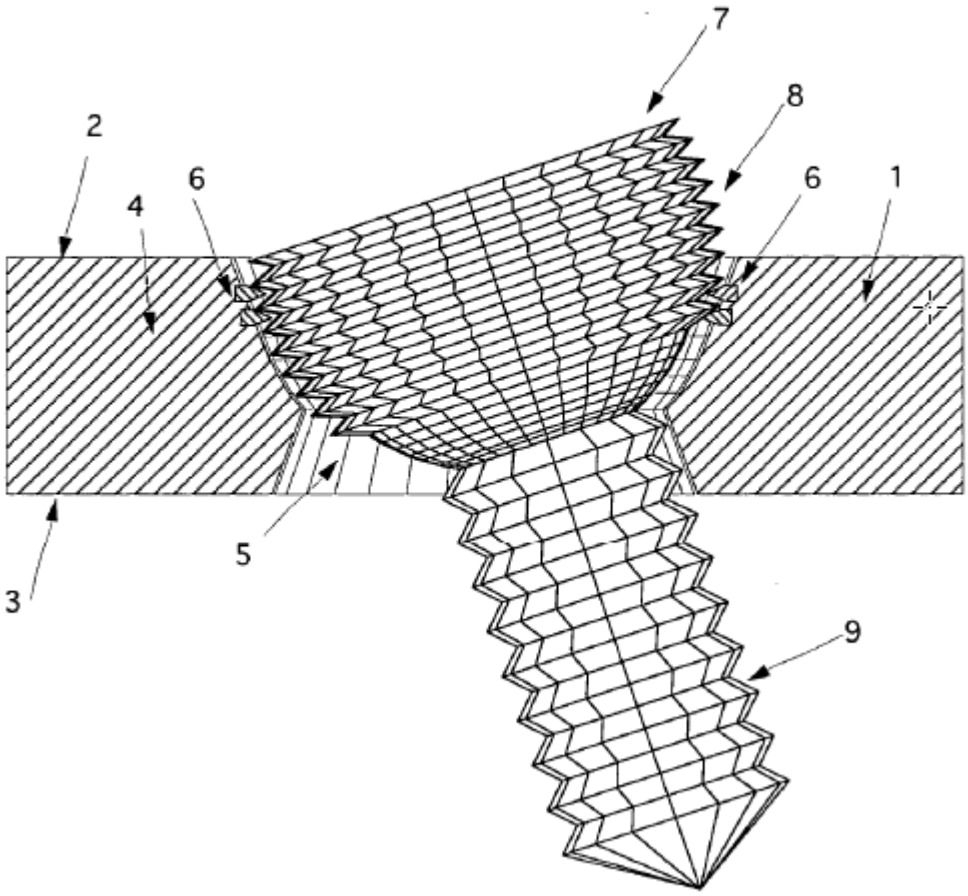
dorsal plate 11." *Id.*, 6:60-63. Grusin further clarifies that its "disclosure of the corresponding features, etc., of the small, left distal radial dorsal plate 11 will provide a full and enabling teaching of such features, etc., for the large left distal radial dorsal plate [13] to one of ordinary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

D. Fernandez

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

heads are spherical and "threaded with a constant pitch." *Id.*, ¶30. Below is an example of the screw and bone plate hole disclosed by Fernandez:

FIG. 10



VII. PROSECUTION HISTORY OF THE '252 PATENT

During prosecution, the examiner rejected the then-pending claims on the grounds that the claims covered subject matter not present in earlier applications, including "a pre-contoured plate having only two diverging arms." Ex. 1037, 3-4. The examiner also rejected the claims on the grounds of nonstatutory double patenting over claims of U.S. Patent No. 8,100,954 because at least one claim was

not "patentably distinct." *Id.*, 5. The '954 Patent is a continuation of the Kay application, U.S. Application No. 11/340,028, and contain the same disclosure. *Compare* Ex. 1006, 1 *with* Ex. 1062, 1. The applicant filed a terminal disclaimer to traverse the nonstatutory obviousness-type rejection, Ex. 1064, and the claims were eventually allowed.

The examiner never evaluated whether Kay, alone or in combination with other art, rendered obvious the Challenged Claims under § 103. Grusin, Chan, and Fernandez are not cited on the face of the '252 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 17-27 are rendered obvious by the combination of Kay and Chan (Ground 1) and Claims 17-21, 23-27 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 Found it Obvious to Modify Kay in view of Chan.

POSITAs would have found it obvious to modify Kay in view of Chan. Kay and Chan each recognize and attempt to avoid loosening of screws. Ex. 1006, ¶4, Ex. 1007, ¶3. For example, Kay emphasizes the advantages of designing a plate with "increase[d] pullout strength," but recognizes there are obstacles in "the less forgiving biological environment in which the small bone surgeon works" which "requires greater procedural precision and calls for specialized implants and tools." Ex. 1006, ¶4. Chan similarly explains that if "non-locking screws" are used, "dynamic loading on the bone and bone plate from physiological conditions can cause the screws to 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's disclosure to seek out features that would increase the pullout strength, and one such reference POSITAs would have been motivated to combine with Kay is Chan. Ex. 1001, ¶¶199-201.

As Chan explains, "locking screws" in which "the thread on the screwhead mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate" were already 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 combinations of threaded and non-threaded screw holes to accept locking or non-locking screws at varying angles. Ex. 1007, ¶¶6-11. Recognizing that it would be desirable to design a plate system with

the advantages of both locking and non-locking screw holes, 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 POSITAs would have understood would provide increased pullout strength. Ex. 1007, ¶¶5, 14; Ex. 1001, ¶200.

Given Chan's disclosure of screws with threaded heads as a "known embodiment," POSITAs would have expect that modifying the plate system of Kay with threaded screw holes 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, ¶201; Ex. 1024, ¶2. In addition, POSITAs would not have known of any particular reason why Kay could not be so modified. Ex. 1001, ¶201.

POSITAs would also have understood that, once Kay has been modified to accept the locking or 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, ¶¶199-201. 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 screwhead 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, ¶¶199-201.

2. **Claim 17**

a. **Element 17[pre]: "A method of conducting a surgery on a bone in a patient comprising the steps of"**

To the extent the preamble is limiting, both Kay discloses this element. Ex. 1001 ¶190. Kay is titled "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, ¶1. Kay specifically "relates to an orthopedic plate in particular for ***surgical repair*** or reconstruction of a small bone and to a system of orthopedic plates which are presented ***during surgery for use*** for a variety of indications." Ex. 1006, ¶2. The plate of Kay is "designed to fit a range of needs of the surgeon operating on the small bones," Ex. 1006, ¶14, and explains that the disclosed plate "is specifically intended to provide for the treatment of a broad range of indications including … complex surgeries…." Ex. 1006, ¶5. Kay further discloses that such surgery "often includes arthrodesis or partial or total fusion" or "an 'osteotomy.'" Ex. 1006, ¶¶5, 7. Kay further discloses "well-balanced and

ergonomically designed" instruments which are designed for use in an operating room. Ex. 1006, ¶13.

To the extent Patent Owner argues that a method of conducting a surgery on a bone in a patient is not disclosed by Kay, POSITAs would have found it obvious to use those Kay's plates in surgery because Kay explicitly describes using those plates in surgery. Ex. 1001, ¶190.

b. **Element 17[a]: "using a plate system on the bone, the plate system comprising a pre-contoured plate having an elongate trunk which extends along a longitudinal medial axis"**

Kay discloses this element. Ex. 1001, ¶¶191-195. Kay "relates to an orthopedic plate and screw system and instruments for surgical fixation of a small bone or bones" which is "designed to fit a range of needs of the surgeon operating on the small bones…." Ex. 1006, ¶¶1-2.

Figures 1-5 and 9-31 of Kay depict examples of pre-contoured plates. Ex. 1006, Figs. 1-5, 9-31. Kay states that "the plate is configured to bend laterally, longitudinally, and to wrap or spiral about its longitudinal axis" and "is radiiused about the inferior surface, (i.e. the surface which faces towards and which may, but does not have to fully contact the bone), with a curvature corresponding generally to the curvature of a bony surface." Ex. 1006, ¶¶7, 9. Kay further describes that "the plate includes a radial curve about the longitudinal axis" and provides examples in

which "the bottom side is radiiused as for the small bone area, but with a gentler curvature of radius." Ex. 1006, ¶54.

The plate of Kay has "a central trunk portion including one or more screw holes." Ex. 1006, Abstract; *see also id.* ¶9. In Figure 1 of Kay, annotated below, "plate 10 of the present invention" includes "a central trunk portion 12" (outlined in blue) which defines "the longitudinal axis of the plate," (a longitudinal medial axis, annotated in green). Ex. 1006, Fig. 1, ¶46.

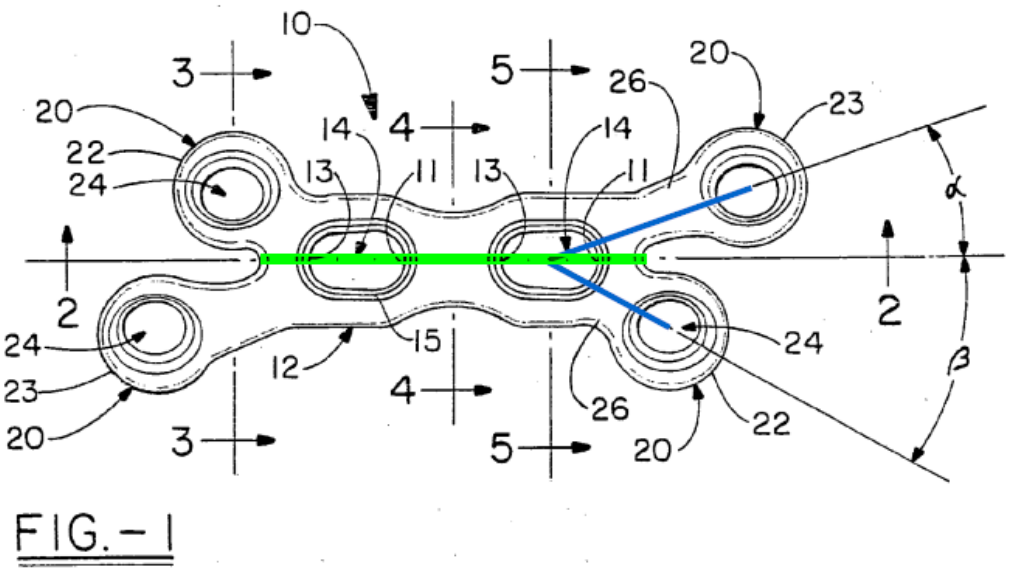
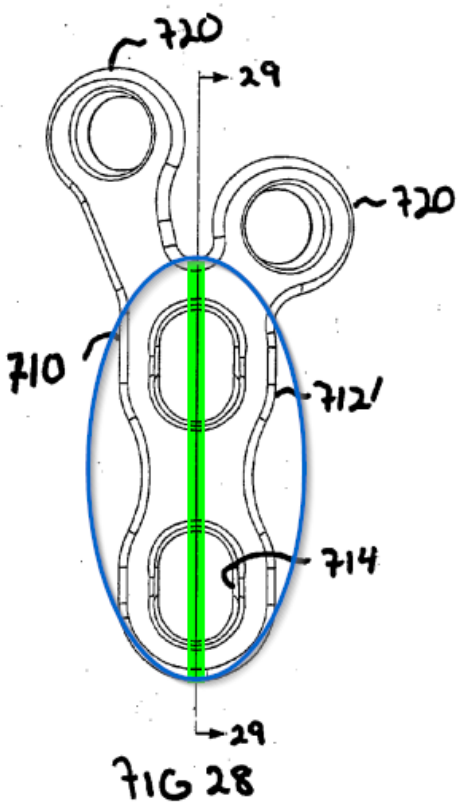


FIG. – 1

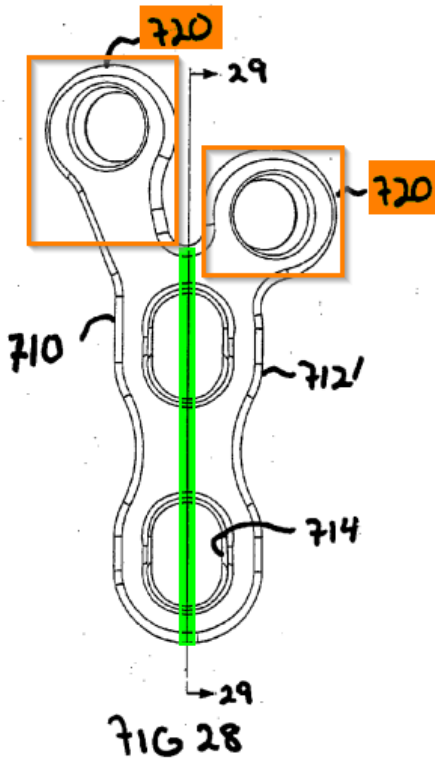
Ex. 1001, ¶193. Figure 28 of Kay, also annotated below, similarly shows a trunk portion 712 outlined in blue and a longitudinal medial axis annotated in green:



Ex. 1001, ¶ 193. As shown in these figures, the trunk disclosed by Kay is elongated and includes a longitudinal medial axis running the length of the plate, such that the trunk extends along a longitudinal medial axis. Ex. 1001, ¶194; Ex. 1006, Figs. 2, 9-12, 14, and 16-31 also show an orthopedic plate defining a longitudinal trunk axis that extends between a first end and a second end, and the published claims of Kay claims recite a plate having a trunk defining a longitudinal axis with a first end and a second end. Ex. 1006, Figs. 1-2, 9-12, 14, and 16-31, claims 1, 9, 17, 22.

c. **Element 17[b]: "at one end of the longitudinal medial axis only a first arm and a second arm which diverge from the end of the trunk asymmetrically relative to the other arm"**

Kay discloses this element. Ex. 1001, ¶196. Kay discloses a plate including "at least one set… of arms 20 [which] can be viewed as a set of diagonally opposed short 22 and long arms 23." Ex. 1006, ¶48. According to Kay, "each of the arms in a set includes screw holes 24 which are placed at a radially equal distance but which diverg[e] asymmetrically from the longitudinal axis of the plate 10," Ex. 1006, ¶48, and each arm includes "a linking portion 26 that joins the screw hole to the trunk portion" which "facilitates the desired bending while resisting deformation of the screw holes." Ex. 1006, ¶51. Figures 28-31 of Kay, such as shown in annotated Figure 28 below, disclose a plate having a first and second arm (orange) at only one end of the longitudinal medial axis (green), which diverge from the end of the trunk asymmetrically relative to each other. Ex. 1006, ¶56; Ex. 1001, ¶196.



d. **Element 17[c]: "the first arm and second arm each including at least one threaded screw hole"**

Kay in view of Chan discloses this element. Ex. 1001 ¶¶197-201. Kay discloses that "[e]ach of the arms in a set includes screw holes 24." Ex. 1006 ¶48. Kay states that "corresponding screw holes could be sized to range from a 1.5 mm diameter screw up to a 7.5 mm diameter screw," and that "[i]n a further embodiment, the bore could be threaded." Ex. 1006 ¶52.

Chan discloses a bone plate system including at least one threaded screw hole. Chan discloses screw holes with "discrete columns of teeth or threaded segments arranged around the inner surface of the hole 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, and "preferably have four columns 942 of thread segments, as shown in Figs. 9A and 9B." Ex. 1007 ¶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 all the way through, or "for only a portion of the vertical distance between the top and bottom surfaces of the bone plate." Ex. 1007 ¶64.

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, ¶¶199-201. POSITAs would have known that threaded screw holes for use with locking screws could be used to increase pullout strength. Ex. 1001 ¶¶199-201. One example of a system using threaded screw holes for locking screws is Chan, which also recognizes the reduced strength of non-locking screws, and POSITAs would have found it obvious to apply the threaded 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

e. **Element 17[d]: "inserting a first locking screw having a proximal end and a distal end into the threaded screw hole of the first arm, and a second locking screw having a proximal end and a distal end into the threaded locking screw hole of the second arm so that the proximal end of the first locking screw is locked in the threaded screw hole of the first arm and the proximal end of the second locking screw is locked in the threaded hole of the second arm and so that the distal ends of the first and the second locking screws converge toward each other but do not impinge"**

Kay in view of Chan discloses this element. Ex. 1001, ¶¶202-203. The "proximal" ends of the screws are the ends at or near the screwhead, and the "distal" ends of screws are the ends away from the screwhead. Ex. 1001 ¶102. Kay discloses that the screws have a "dist[a]l end … including a cutting tip 32 which is self-starting

and self-tapping" and Figure 6 of Kay shows that the screw also includes a proximal end at or near the screwhead. Ex. 1001 ¶203.

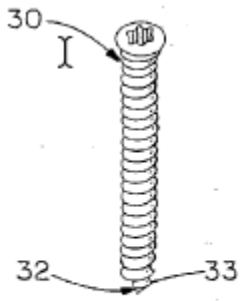


FIG.-6

Kay further explains 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," and "since the arms are asymmetrical relative to each other, and in particular since they diverge from the longitudinal axis of the trunk portion at differing angles, conflicts in the positions of paired screws is avoided so that the screws of a set of arms typically do not impinge on each other." Ex. 1006 ¶50.

Chan discloses inserting locking screws "coaxially with the central axis of the hole," and that "the thread on the screwhead mates with a corresponding thread on the inner surface of a bone plate hole to lock the screw to the plate." Ex. 1007 ¶4. Both Kay and Chan also allow for 30º of conical rotation of a screw axis relative to the axis of the screw hole. Ex. 1006, ¶10; Ex. 1007, ¶17. POSITAs would have understood that modifying the plate of Kay to use either conventional or variable

locking screws and corresponding threaded screw holes taught by Chan, in combination, would result in locking screws which could be inserted coaxially or at selected angles so that the proximal end of each screw would lock into each threaded screw hole, and the distal ends of each screw would converge without impinging. Ex. 1001, ¶204. When inserted the locking screws of Chan are inserted coaxially into the plate of Kay, the screws would be inserted along "the longitudinal axes of the screws" and thus, "since the arms are asymmetrical relative to each other, and in particular since they diverge from the longitudinal axis of the trunk portion at differing angles, conflicts in the positions of paired screws is avoided so that the screws of a set of arms typically do not impinge on each other." Ex. 1006 ¶50; Ex. 1001, ¶204.

f. **Element 17[e]: "also so that the distal end of the screw is secured in cortical bone."**

Kay discloses this element. Ex. 1001, ¶205. Kay states "some surgeons prefer bicortical fixation in which a screw is sized so that the distil [sic] end is secured in cortical bone giving the screw better purchase." Ex. 1006, ¶4. POSITAs would have understood that Kay encourages the use of bicortical fixation to provide a better hold, and POSITAs would have been motivated to secure the distal end of the screw in cortical bone to provide greater pullout strength. Ex. 1001 ¶205.

3. **Claim 18**

a. **"The method of conducting a surgery on a bone in a patient as set forth in claim 17, including the further step of providing a plate bender in the surgical tray, and whereby the plate bender can be used during surgery to further contour the two arms without distorting the threaded screw hole."**

As explained above, Kay in view of Chan renders obvious claim 17. Kay discloses the additional limitation of claim 18. Ex. 1001, ¶207.

Kay discloses screw holes with "increased annular area around the through bores" that "resists deformation when a bending device is used to apply a force to the plate through the screw holes." Ex. 1006, ¶47. The arms disclosed in Kay "also each include a screw hole 24 which … has a linking portion 26 that joins the screw hole to the trunk portion" and which "facilitates the desired bending while resisting deformation of the screw holes 24 when they are used with the bending instrument to contour the plate." Ex. 1006, ¶51. Thus Kay discloses contouring the two arms without distorting the threaded screw hole. Ex. 1001, ¶207. Kay's published claims further recite contouring the plate system "before or during surgery." Ex. 1006, claims 5-6. The "bending device" referenced in Kay that bends plates is a "plate bender" and PHOSITAs would have understood that surgical instruments, such as plate benders, are provided in surgical trays. Ex. 1001, ¶207.

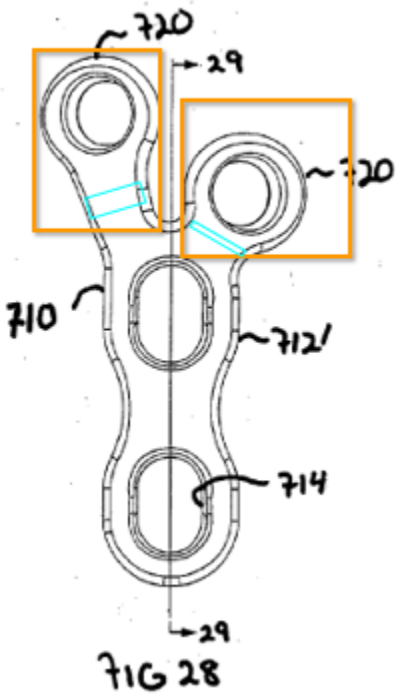
4. **Claim 19**

a. **"The method of conducting a surgery on a bone in a patient as set forth in claim 17, wherein each arm**

includes a linking section joining the arms to the elongate trunk and each linking section has a waist."

As explained above, Kay in view of Chan renders obvious claim 17. Kay discloses the additional limitation of claim 19. Ex. 1001 ¶209.

Kay discloses that "the area linking the screw holes has a decreased width so as to define a waist area 26 that will bend laterally (or "curve") relative to the longitudinal axis and which will bend longitudinally to form a curved area in and out of the plane of the plate." Ex. 1006, ¶47. The arms disclosed in Kay "also each include a screw hole 24 which … has a linking portion 26 that joins the screw hole to the trunk portion" and which "facilitates the desired bending while resisting deformation of the screw holes 24 when they are used with the bending instrument to contour the plate." Ex. 1006, ¶51. Annotated Figure 28 below shows the linking portions and waists (light blue):



Ex. 1001, ¶209.

5. **Claim 20**

a. **"The method of conducting a surgery on a bone in a patient as set forth in claim 19, wherein the waist of the linking section of the first arm and the second arm is configured to bend relative to the elongate trunk in response to a force applied to at least one of before or during surgery without deforming the threaded screw hole of that arm."**

As explained above, Kay in view of Chan renders obvious claim 19. Kay discloses the additional limitation of claim 20. Ex. 1001 ¶201.

Kay discloses that the arms have "a linking portion 26 that joins the screw hole to the trunk portion," which "facilitates the desired bending while resisting deformation of the screw holes 24 when they are used with the bending instrument

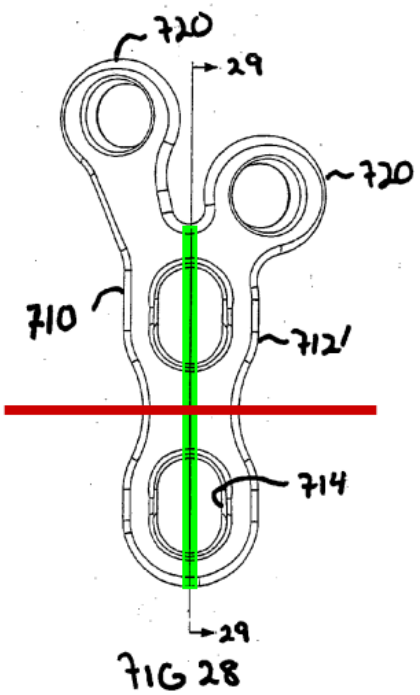
to contour the plate." Ex. 1006, ¶51. Kay discloses "a bending device" to be "used to apply a force to the plate through the screw holes," Ex. 1006, ¶47, and that the plate "can be molded to an optimal shape for small bone procedures." Ex. 1006, ¶7. Published claim 6 of Kay recites "bending between the arm through hole and the trunk in response to a force applied before or during surgery." Ex. 1006, claim 6.

6. **Claim 21**

a. **"The method of facilitating surgery on a small bone as set forth in claim 17, wherein the plate further defines a transverse axis and the plate is bilaterally asymmetrical about the transverse axis."**

As explained above, Kay in view of Chan renders obvious claim 17. Kay discloses the additional limitation of claim 21. Ex. 1001 ¶¶213-215.

Kay discloses "a plate with bilateral asymmetry (meaning that the left half of the plate is not the same as the right half)" and also having some embodiments "a mid-plane which is perpendicular to the longitudinal or medial axis." Ex. 1006, ¶¶7-8. Kay's disclosure of a mid-plane perpendicular to the longitudinal medial axis discloses a transverse axis where the mid-plane intersects the plate. Ex. 1001, ¶214. A transverse axis (red) is shown in annotated Figure 28, crossing the longitudinal medial axis (green):



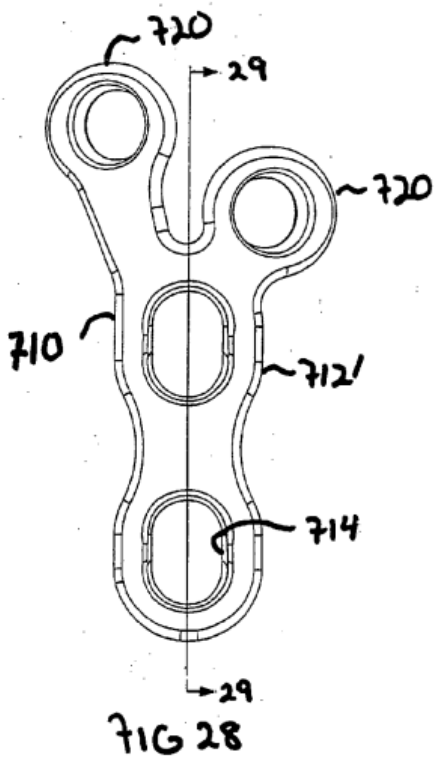
Ex. 1001, ¶213. As shown in annotated Figure 28, above, Kay discloses discloses a plate which is bilaterally asymmetrical about the transverse axis with arms disposed at only one end of the trunk. Because the side of the plate with arms is different from the side of the plate without arms, which is across the transverse axis, POSITA would have understood that the plate was bilaterally asymmetrical across the transverse axis. Ex. 1001, ¶215.

7. **Claim 22**

a. **"The method of facilitating surgery on a small bone as set forth in claim 17, wherein the plate has only one set of arms and an outline that forms a Y-shape."**

As explained above, Kay in view of Chan renders obvious claim 17. Kay discloses the additional limitation of claim 22. Ex. 1001, ¶217.

Figure 28 of Kay depicts a "version of the 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. The outline of the plate in Figure 28 forms the shape of the letter Y. Ex. 1001, ¶217.



8. **Claim 23**

a. **"The method of facilitating surgery on a small bone as set forth in claim 17, wherein the threaded locking screw holes of a set of arms are placed a radially equal distance from the medial line of the elongate trunk."**

As explained above, Kay in view of Chan renders obvious claim 17. Kay in view of Chan discloses the additional limitation of claim 23. Ex. 1001, ¶219.

Kay discloses that includes "screw holes which are placed at a radially equal distance but which diverg[e] asymmetrical[ly] from the longitudinal axis relative to its paired upper or lower mate." Ex. 1006, Abstract, *see also* ¶¶9, 48. As a longitudinal axis of the plate of Kay is a medial line of the elongate trunk, Kay discloses this limitation. Ex. 1001, ¶219. While Kay discloses that its "screw holes" are at a "radially equal distance," as described above it would have been obvious to use threaded locking screw holes of Chan in the screw holes of the arms of disclosed by Kay. *See supra*, Section VIII.A.1.

9. **Claim 24**

a. **"The method of facilitating surgery on a small bone as set forth in claim 17, wherein the plate defines a medial line and the elongate trunk plate has an inferior surface defining a curve transverse to the medial line."**

As explained above, Kay in view of Chan renders obvious claim 17. Kay discloses the additional limitation of claim 24. Ex. 1001, ¶¶221-222.

Kay discloses a plate that "includes a radial curve about the longitudinal axis … typically about 10 mm with a transverse dimension." Ex. 1006 ¶52. Kay further discloses a plate having "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. Figures 3-5, 13, and 15 of Kay depict these disclosures in a plate having with an inferior surface defining a curve transverse to the medial line:

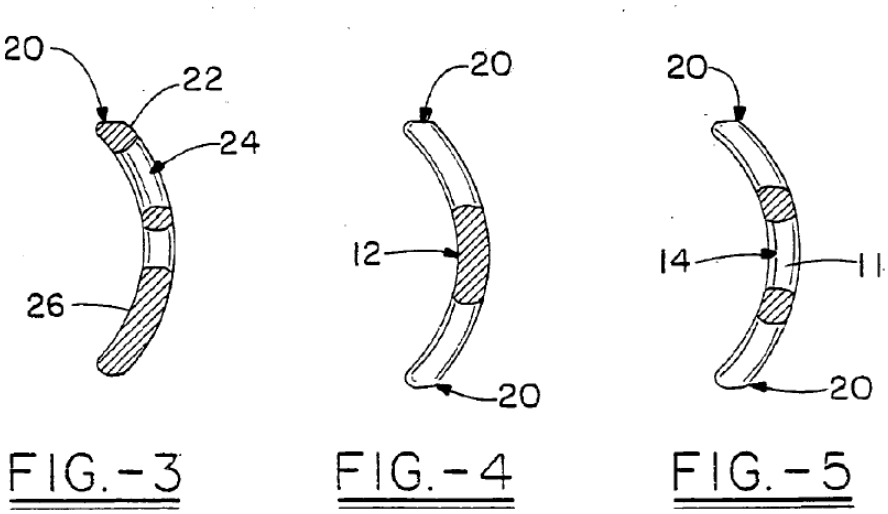


FIG.-3 FIG.-4 FIG.-5

Ex. 1006, Figs. 3-5. Thus Kay discloses this limitation. Ex. 1001, ¶¶221-222.

10. **Claim 25**

a. **"The method of conducting a surgery on a bone in a patent as set forth in claim 24, wherein the curve is constant along the medial line."**

As explained above, Kay in view of Chan renders obvious claim 24. Kay discloses the additional limitation of claim 25. Ex. 1001, ¶224.

Kay discloses a plate "radiiused about the inferior surface … with a curvature corresponding generally to the curvature of a bony surface," having a pair of arms which "continue this curvature." Ex. 1006, ¶9. Kay further discloses a plate including "a radial curve about the longitudinal axis" of "about 10 mm." Ex. 1006, ¶52. Kay's published claim 17 also recites an "inferior surface of the plate including a single continuous radius of curvature." As Kay's plates have a "single continuous radius of curvature," Kay discloses a constant curve along the medial line. Ex. 1001 ¶224. The Figures of Kay, e.g. Figure 29 below, show such a plate:

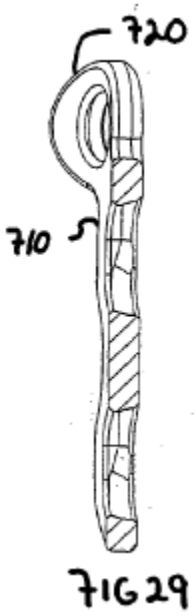


FIG 29

11. **Claim 26**

a. **"The method of conducting a surgery on a bone in a patient as set forth in claim 25, wherein the curve is a portion of a circle and the plate defines a segment of a cylinder."**

As explained above, Kay in view of Chan renders obvious claim 25. Kay discloses the additional limitation of claim 26. Ex. 1001, ¶226.

As discussed above in Section VI.A.9, Kay discloses a plate with a constant curve along the medial line. Kay further discloses, "as shown in Figs. 3-5, [that] the plate includes a radial curve about the longitudinal axis," and that "the radius is typically about 10 mm." Ex. 1006, ¶52. A radial curve defines a portion of a circle, as shown in Figures 3-5, and Kay's disclosure of a radial curve constant along longitudinal axis, continuing into the arms, defines a segment of a cylinder. Ex. 1001, ¶226. The Figures of Kay, e.g. Figures 3-5 and 29 below, show such plate:

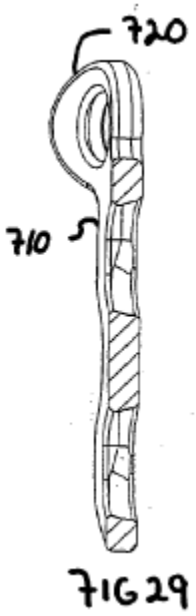


FIG. 29

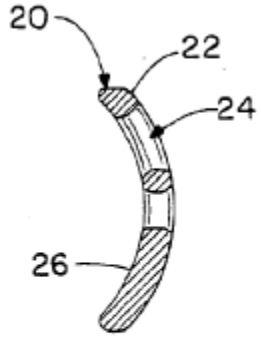


FIG.-3

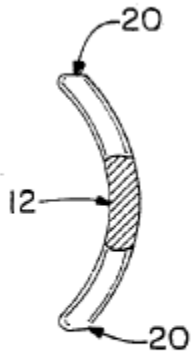


FIG.-4

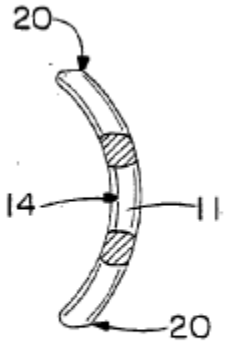


FIG.-5

12. **Claim 27**

a. **"The method of conducting a surgery on a bone in a patient as set forth in claim 17, wherein the surgery is selected from the group consisting of an osteotomy and a fusion surgery."**

As explained above, Kay in view of Chan renders obvious claim 17. Kay discloses the additional limitation of claim 27. Ex. 1001, ¶228.

Kay discloses that "small bone surgeons may be called upon to achieve soft-tissue balancing … in a procedure known as an "***osteotomy***." Ex. 1006, ¶¶5, 7. Kay discloses its plates are "specifically intended to provide for the treatment of a broad range of indications including … more complex surgeries such as reconstruction to correct congenital or age related deformation." Ex. 1006, ¶5. Such "reconstruction often includes arthrodesis or partial or total fusion," and Kay's plate is "designed to accelerate fusion success." Ex. 1006, ¶¶5, 7.

B. Ground 2: Grusin in view of Fernandez

Grusin in view of Fernandez disclose all limitations of Claims 17-21 and 22-27, and POSITAs would have found it obvious to modify Grusin in view of Fernandez.

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

POSITAs would have found it obvious to modify Grusin in view of Fernandez. Grusin discloses bone plates that include spherically recessed screw holes which can accept a variety of bone screws, as well as a "locking feature," Ex. 1010, 6:13–21. POSITAs would have understood the screws of a plate 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 or manipulate objects stresses the screws. Ex. 1001, ¶¶240-241. POSITAs would therefore have been motivated by Grusin's disclosure of a fastening mechanism to seek out fastening mechanisms that increase

the hold strength, maintain position through a locking mechanism, and maintain a low profile. Ex. 1001, ¶240. One such reference is Fernandez, which includes these advantages and also provides the freedom to choose the most desirable angle to direct the bone screw. Ex. 1011 ¶12.

Fernandez explains that its variable locking screws and threaded screw holes improve on a variety of prior fasteners, including screws, threaded bolts or pins, and "expansion-head screws." Ex. 1011 ¶¶5, 10-13. Both Grusin and Fernandez disclose spherically recessed screw holes, Ex. 1010, 6:13–21; Ex. 1011 ¶¶15, 32, and POSITAs would have recognized that they could be successfully combined to provide Grusin with a low-profile, threaded locking screw hole that provides a solid hold between the bone and plate as well as flexibility to choose a desirable screw angle. Ex. 1001, ¶240.

Given Fernandez's disclosure that screws with threaded heads to engage threaded screw holes were among the many known ways to secure screws to a bone plate, Ex. 1011 ¶5, POSITAs would have expected that modifying the plate system of Grusin to accept threaded screws would be successful. Ex. 1001, ¶241. The screw holes of Grusin could remain spherically recessed as modified by Fernandez, which would minimize the portion of the screw head protruding above the edge of the plate and provide a low-profile as sought by Grusin. *Id.* POSITAs would not have known of any particular reason why Grusin could not be so modified, and in

view of the long history and known advantages of threaded screw holes, Ex. 1001, ¶241 (citing Ex. 1024, ¶2), POSITAs would have expected Fernandez's variable locking features could be incorporated into Grusin successfully.

POSITAs would also have understood that, once Grusin has been modified to accept variable locking screws as taught by Fernandez, that the screws could successfully be inserted at selected angles within the screw holes as described by Grusin with the result that the screws converge without impinging. Ex. 1001, ¶246. POSITAs would have understood from Grusin's disclosure that screw size should not be selected until after the contour of the plate is determined, Ex. 1010, 10:3-12, and so would have known to select appropriately-sized threaded-head screws, as disclosed by Fernandez to ensure the screws would not impinge on each other when locked in place. Ex. 1001, ¶246. Fernandez further discloses that its system "provides the surgeon with the greatest freedom to choose the most desirable angle to direct the bone screw," Ex. 1011, ¶12, and recognizes that it is "often desirable to insert the screws at an angle relative to the fixation device." Ex. 1011, ¶6. Fernandez recognizes that polyaxial systems were already known in the art, Ex. 1011, ¶6, and POSITAs would have found it obvious to incorporate Fernandez's polyaxial locking screws with Grusin's plate and would have expected to succeed in doing so. In particular, POSITAs would have understood that variable locking screws of the proper length and diameter could be inserted at select angles into threaded screw

holes described by Grusin, Ex. 1006, Fig. 13., which would successfully result in the threaded screwhead of each screw locking into each threaded screw hole, such that the screws converge without impinging. Ex. 1001, ¶246.

2. **Claim 17**

a. **Element 17[pre][2]**

To the extent the preamble is limiting, Grusin discloses this element. Ex. 1001, ¶229. Grusin is titled "Bone Plating System," is directed to a "distal radial plate," and relates to "bone plating systems and, more specifically, to a plating system for fractures of the distal radius." Ex. 1010, Cover, Abstract, 1:18–20. The system disclosed in Grusin "is designed to give a surgeon a low contour, stainless steel, and volar distal radius plating system for both intra- and extra articular fractures of the distal radius." Ex. 1010, 2:5-11. Grusin discloses instructions for performing surgery with the disclosed system, e.g. "with a dorsal approach, typically a straight longitudinal incision is made over the dorsal radius between the second and third dorsal extensor compartments … . [T]he surgeon can then decide what size plate, 11, 13, etc., to use." Ex. 1010, 9:57-10:1; *see also* 5:36-44. Grusin also discloses that "[a]ttachment of the plate 15 with screws and buttress pins, etc., can

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

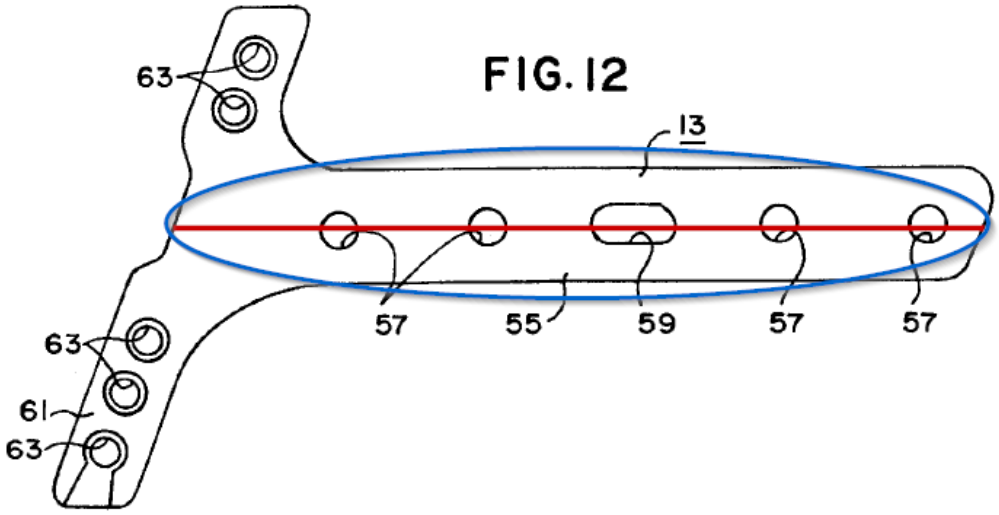
follow the same procedures described hereinabove relative to the dorsal approach." Ex. 1010, 10:46-10:48.

b. **Element 17[a]**

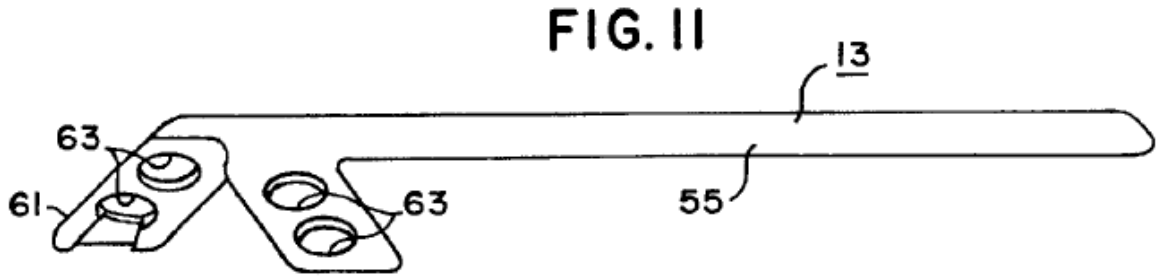
Grusin discloses this element. Ex. 1001, ¶¶230-233. Grusin relates to "bone plating systems and, more specifically, to a plating system for fractures of the distal radius." Ex. 1010, Cover, Abstract, 1:18–20.

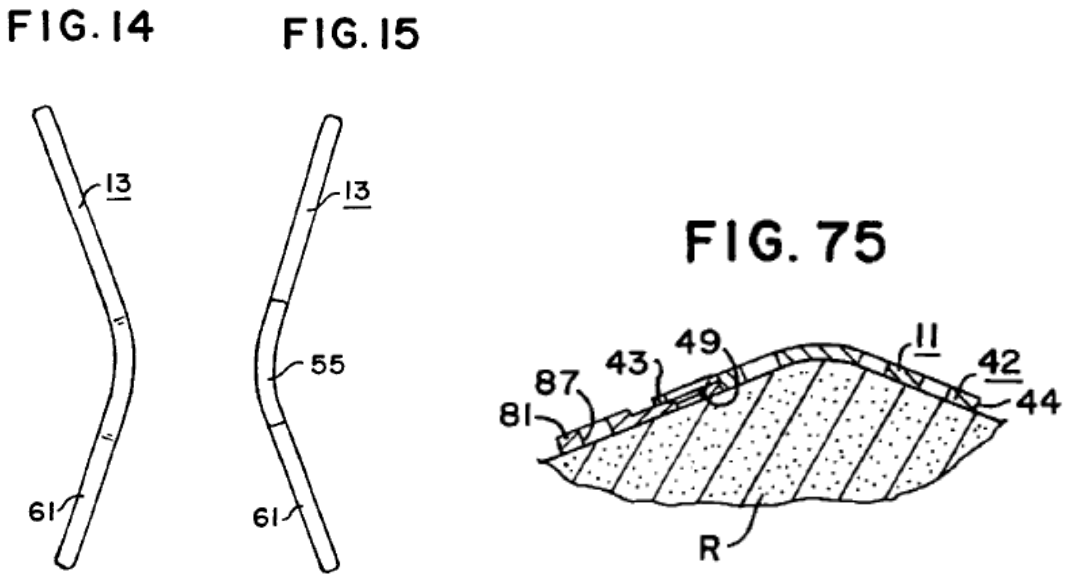
Grusin discloses a "distal radial plate including a longitudinal segment" which is attached to a "transverse segment intermediate … to form a T-shape." Ex. 1010, Abstract. Grusin also discloses that "[t]he transverse segment 42 of the plate 11 is preferably angled with respect to the longitudinal segment 32 to further match the anatomy of the distal radius R," and that "the plate 11 is preferably pre-bent to approximately a 140º angle … so that its bottom face 51 conforms as closely as possible to the surface of the distal radius R." Ex. 1010, 6:33-40.

The Figures of Grusin, as demonstrated in annotated Figure 12 below, show an elongate central trunk portion (dark blue) having a medial longitudinal axis (red) and at least one pair of divergent arms extending therefrom, and with the longitudinal medial axis running the length of the plate from end to end, such that the trunk extends along a longitudinal medial axis. *See*, *e.g.*, Ex. 1010, Fig. 12; Ex. 1001, ¶232.



As depicted by the Figures of Grusin, the plate is also pre-contoured. *See, e.g.*, Ex. 1010, Figs. 11, 14–15, 75; Ex. 1001, ¶233.

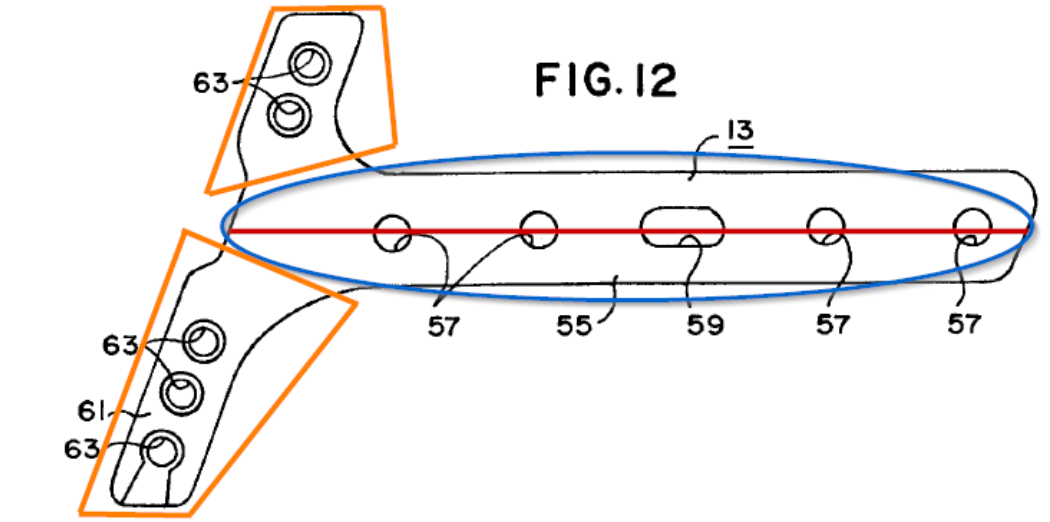


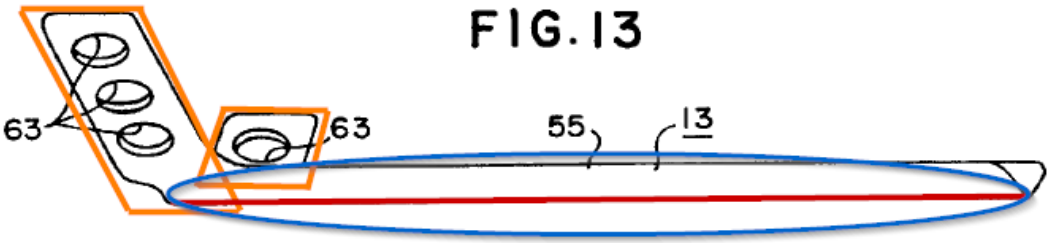


c. **Element 17[b]**

Grusin discloses this element. Ex. 1001, ¶234-236. Grusin states that its plate is "preferably substantially T-shaped," Ex. 1010, 5:62–64, 10:55-60, and as shown in Figure 11, Grusin's plate has arms at only one end of the longitudinal medial axis. *Id.*, Fig. 11; Ex. 1001, ¶234. Grusin also discloses that "[t]he transverse segment 42 of the plate 11 is preferably angled with respect to the longitudinal segment 32 to further match the anatomy of the distal radius R," Ex. 1010, 6:33-40, and provides an example in which "the lateral end of the distal transverse segment 61 is extended proportionally a greater distance from the proximal longitudinal segment 55… ." Ex. 1010, 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." Ex. 1010, 10:3-11.

The Figures of Grusin, as shown in annotated Figures 12 and 13 below, show a plate having at one end of the longitudinal medial axis (red) only a first arm and a second arm (orange) which diverge from the end of the trunk (blue) asymmetrically relative to the other arm. *See, e.g.*, Ex. 1010, Figs. 12, 13. 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, ¶234. 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.*, ¶235. This is shown in annotated Figure 12 and 13:





d. **Element 17[c]**

Grusin in view of Fernandez discloses this element. Ex. 1001 ¶¶237-341. Grusin discloses "spherically recessed" arm screw holes for a variety of screws or pins which "ha[s] 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 discloses a "buttress pin screw lock pin shank" having an "internally threaded aperture ... for receiving the screw portion." Ex. 1010, 8:67–9:6.

Fernandez describes a "bone plate" with "a through hole shaped like an hourglass" that "is provided with multiple isolated protrusions," and matches with a spherical screw head where "the atrial head of the screw engages in the protrusions of the plate hole resulting in the strong locking of the screw at the selected orientation within the through hole." Ex. 1011, Abstract; *see also* ¶32, claim 1. The through hole in Fernandez is preferably "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.

Figures 1, and 4–10 of Fernandez depict threaded screw holes. *See, e.g.*, Ex. 1011, Figs. 4, 5.

FIG. 4

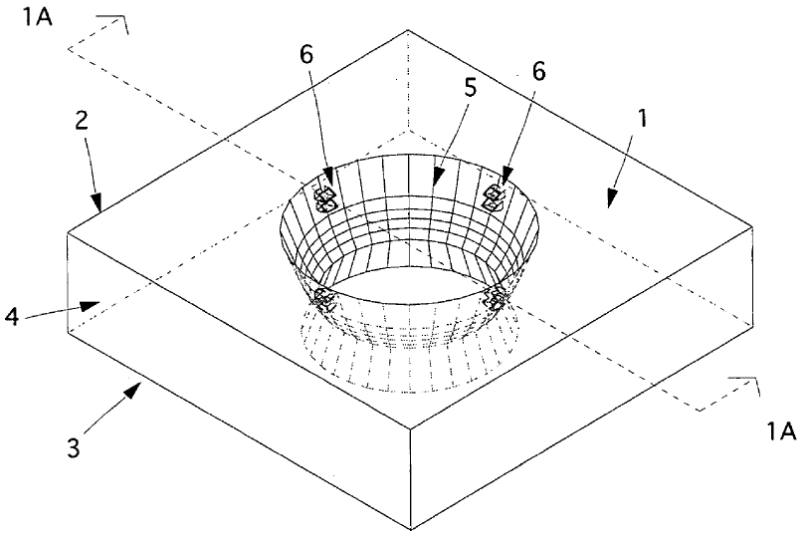
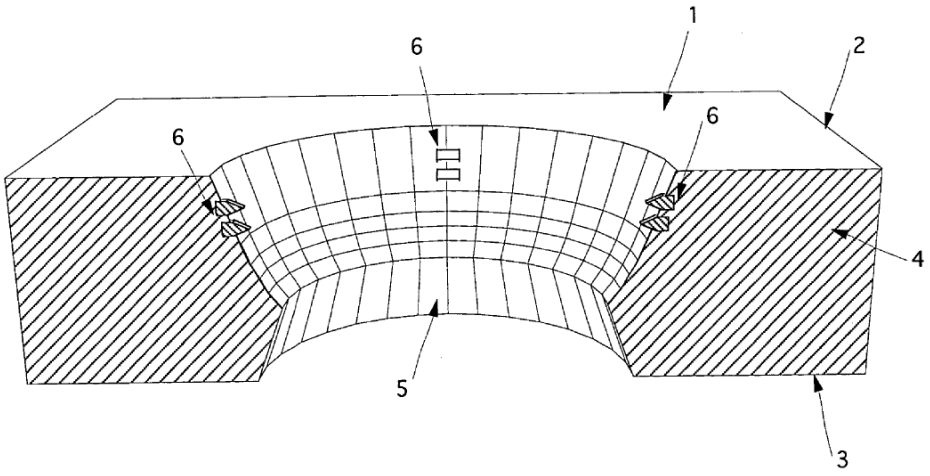


FIG. 5

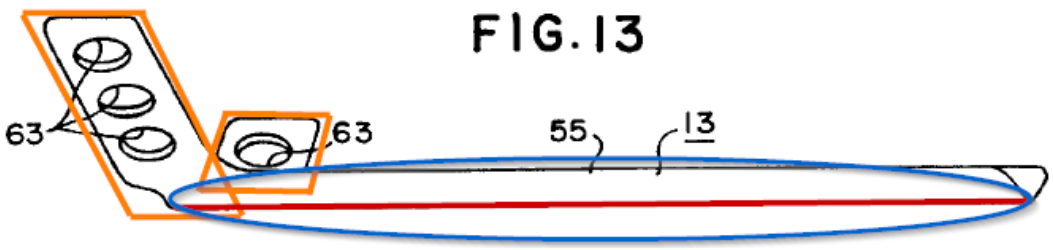


As explained in detail above, POSITAs would have been motivated to look for features of bone plate systems which resist screws loosening or pulling out, particularly given Grusin's application to the end of the radius where use of a patient's hand could increase stress on the screws, and Grusin's disclosure of locking

features. POSITAs would have known that threaded screw holes for use with locking screws could be used to increase pullout strength. Ex. 1001, ¶¶240-241. One example of a system using threaded screw holes for locking screws is Fernandez, which like Grusin also uses spherically recessed holes, and POSITAs would have been motivated to apply the threaded screw holes of Fernandez to the bone plate of Grusin. Ex. 1001, ¶¶240-241.

e. **Element 17[d]**

Grusin in view of Fernandez discloses this element. The "proximal" ends of the screws are the ends at or near the screwhead, and the "distal" ends of screws are the ends away from the screwhead. Ex. 1001 ¶¶242-246. Grusin discloses that the "transverse segment 42 preferably has a plurality of spherically recessed holes 45 to accept … bone screws." Ex. 1010, 6:14–17. Grusin further discloses the "[a]ppropriate screw size as well as screw and pin placement," such that "[s]crew and pin holes must be predrilled in the radius R with the appropriate drill and drill guide," and that "[t]he screws should be self-tapping and can be inserted directly into their corresponding drilled holes." Ex. 1010, 10:11–31. Grusin also explains that the plate "is preferably pre-bent … so that its bottom face 51 conforms as close as possible to the surface of the distal radius R," and as seen in annotated Figure 13, screws inserted through the arm screw holes would thus converge. Ex. 1001, ¶242.

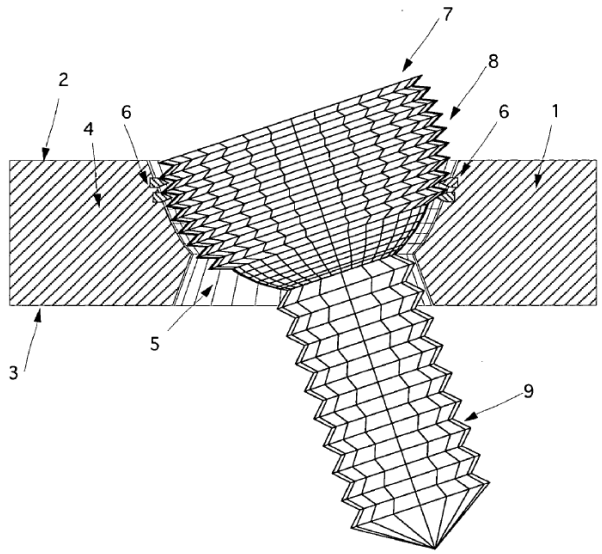


Grusin also discloses that "[a]ppropriate screw size as well as screw and pin placement" can be determined after using a template "to determine the appropriate contour of the fractured radius R," Ex. 1010, 10:3-12, and that "[s]crew and pin holes must be predrilled in the radius R with the appropriate drill and drill guide." *Id.*, 10:12-15. POSITAs would have understood from Grusin's disclosure to select screws of a proper diameter and length based on the contour of the fractured radius such that the screws do not impinge on each other when locked into their screw holes. Ex. 1001 ¶¶242-246.

Fernandez discloses threading a variable threaded screw "into the bone, through the hole of the bone plate at a selected angle," and that the "partial sphere head of the screw engages in the protrusions of the plate hole … in just one single surgical action." Ex. 1011, Abstract, ¶15. The method disclosed by Fernandez "provides the surgeon with the greatest freedom to choose the most desirable angle to direct the bone screw while maintaining an effective locking mechanism." Ex. 1011, ¶12. Fernandez states that "up to 20 degrees of angulation in any direction is allowed" in fixing the bone screws. Ex. 1011, ¶33.

The figures of Fernandez depict a screw having a length and a diameter such that when a first and second screw are locked in their respective screw holes, the two screws would not impinge on each other. *See, e.g.*, Ex. 1011, Fig. 10.

FIG. 10



The variable bone screws of Fernandez would have allowed POSITAs to fix the screws at variable orientations within Grusin such that when the two screws are locked in their respective screw holes, the two screws converge but do not impinge on each other. Ex. 1001, ¶¶242-246. As discussed above, POSITAs would have been motivated to replace the screw holes of Grusin with the variable threaded screw holes of Fernandez to obtain the advantages of choosing a desirable angle for the bone screw with a solid locking mechanism. Ex. 1011, ¶¶6, 12. POSITAs, therefore, would have understood that modifying the plate of Grusin to use the variable locking screws and corresponding threaded screw holes taught by Fernandez would result in

locking screws which could be inserted at selected angles through the plate of Grusin, which conforms to the underlying radius R, so that they converge but do not impinge when locked into their respective screw holes. Ex. 1001 ¶¶242-246.

f. **Element 17[e]**

Grusin in view of Fernandez discloses this element. Fernandez explains that it is "often desirable to insert the screws at an angle relative to the fixation device selected by the surgeon," and that prior art "polyaxial" systems were already known. Ex. 1011, ¶6. POSITAs would thus have been motivated to use variable locking screws as disclosed by Fernandez of the proper length and at an angle so that their distal ends were secured in cortical bone for a secure hold in the radius bone. Ex. 1001, ¶247. Grusin's plate systems are directed to the radius bone, where movement of a patient's hand or arm would increase the stress on the screws and require a more secure hold. *Id.* Because the patient's hand and arm are likely to move, POSITAs would have been motivated to secure the distal end of a bone screw in cortical bone for the plate system and method disclosed by Grusin in view of Fernandez.

3. **Claim 18**

As explained above, Grusin and Fernandez renders obvious claim 17. Grusin discloses the additional limitation of claim 18. Ex. 1001, ¶249.

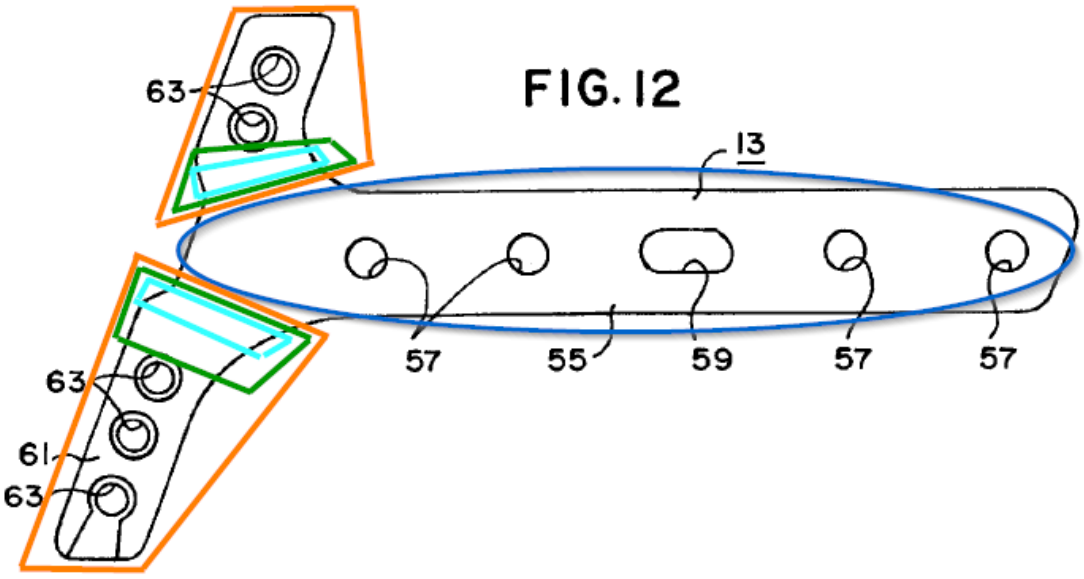
Grusin discloses a "slotted plate bender … designed for use in bending and molding a fracture fixation plate to match the anatomy of a specific radius R." Ex.

1010, 9:16–24. The plate bender disclosed in Grusin also "has a first slot 119 extending through the end surface 115 for receiving an end of the transverse segment 42 of the plate 11." Ex. 1010, 9:31-37. Grusin also states that when the plate bender is "used to match the selected plate ... to the contoured template," that "[c]are should be taken not to bend the selected plate 11, 13, etc. across the holes 45, etc., designed for use with buttress pins 19, 21 or buttress pin combinations 23, 25." Ex. 1010, 10:3-11. Grusin thus discloses that the plate bender provided could be used during surgery to contour the arms without distorting the threaded screw hole, and and PHOSITAs would have understood that surgical instruments, such as plate benders, are provided in surgical trays. Ex. 1001, ¶249.

4. **Claim 19**

As explained above, Grusin and Fernandez renders obvious claim 19. Grusin discloses the additional limitation of claim 18. Ex. 1001 ¶250-255.

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) having a linking section (green), and show that each linking section also includes a waist (light blue). *See, e.g.*, Ex. 1010, Fig. 12.



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 ¶253.

To the extent Patent Owner argues that Grusin does disclose a waist, it would have been obvious to POSITAs to modify the linking sections 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, ¶253; *see also* Ex. 1001, ¶39; Ex. 1013, Fig. 1; Ex. 1015, Fig. 1; Ex. 1018, Fig. 1; Ex. 1019, Fig. 3.

5. **Claim 20**

As explained above, Grusin and Fernandez renders obvious claim 19. Grusin discloses the additional limitation of claim 20. Ex. 1001 ¶257.

As described above, Grusin discloses a "slotted plate bender … designed for use in bending and molding a fracture fixation plate to match the anatomy of a specific radius R," Ex. 1010, 9:16–24, and which can "be used to match the selected plate 11, 13, etc., to the contoured template." Ex. 1010, 10:3–8. Grusin also discloses that "[c]are should be taken not to bend the selected plate 11, 13, etc. across the holes 45, etc." Ex. 1010, 10:8-11. Grusin therefore discloses that the plate is

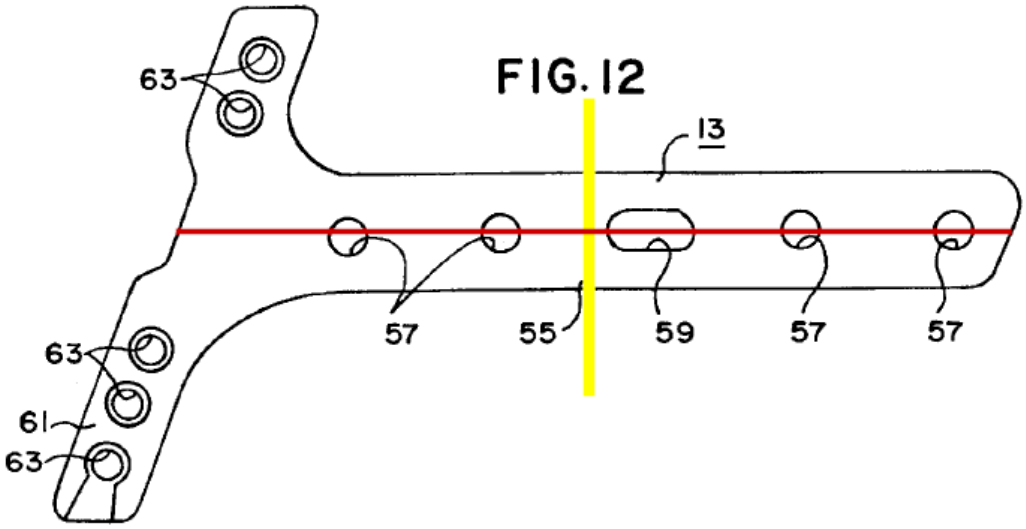
configured to be bent at a portion of the linking section linking the holes to the trunk, and thus discloses bending at the waist of the linking section. Ex. 1001, ¶257.

To the extent Patent Owner argues Grusin does not disclose a waist, POSITAs would have found it obvious to include a waist in the linking section of Grusin. As explained above, Grusin discloses that a portion of the linking section is configured to be bent such that the holes are not bent. Ex. 1010, 10:8-11. PHOSITAs understood that waists encouraged bending because the less material at a particular plate location, the easier the plate is to bend at that location. Ex. 1001, ¶253. Plates with such designs were well-known in the art, as explained in Section II, and POSITAs would have been motivated, and expected to succeed, in removing some material to create a waist to encourage bending because Grusin explicitly contemplates this goal and this design was well-known. *Id.*; *see also* Ex. 1001, ¶39; Ex. 1013, Fig. 1; Ex. 1015, Fig. 1; Ex. 1018, Fig. 1; Ex. 1019, Fig. 3.

6. **Claim 21**

As explained above, Grusin and Fernandez renders obvious claim 17. Grusin discloses the additional limitation of claim 21. Ex. 1001 ¶¶259-260.

As shown in annotated Figure 12 of Grusin below, the transverse axis, or the axis in the lateral direction crossing the longitudinal medial axis, (yellow) is transverse to the longitudinal medial axis (red).



Ex. 1001, ¶259. As shown in annotated Figure 12, above, Grusin discloses a plate which is bilaterally asymmetrical about the transverse axis. *Id.* Because the side of the plate with the transverse segment is different from the side of the plate without arms, which is across the transverse axis, the plate is bilaterally asymmetrical across the transverse axis. Ex. 1001, ¶260.

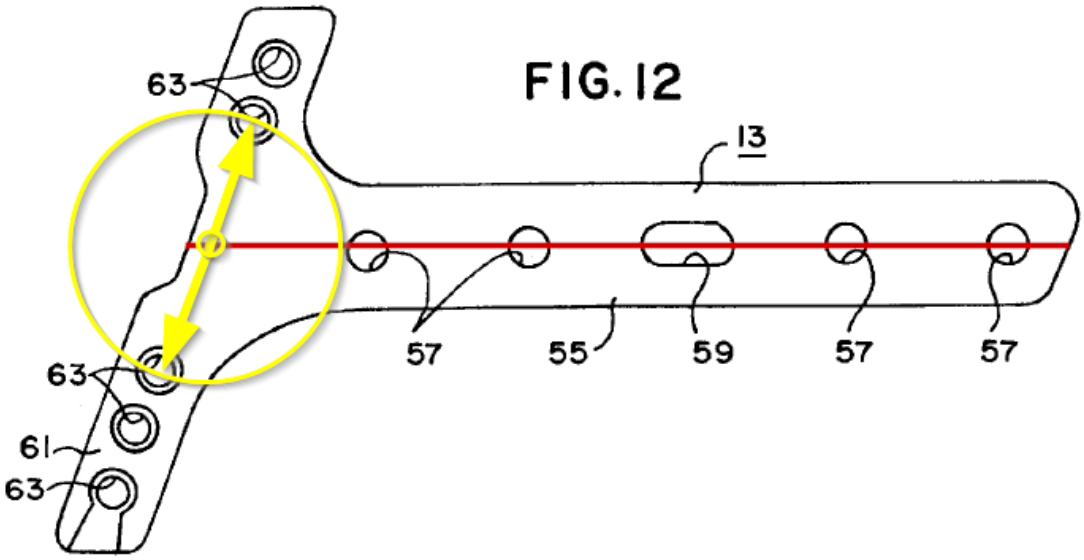
7. **Claim 23**

As explained above, Grusin and Fernandez renders obvious claim 17. Grusin discloses the additional limitation of claim 23. Ex. 1001 ¶¶262-264.

The plate of Grusin "is preferably substantially T-shaped in plan, … with a distal transverse segment 61, a plurality of spherically recessed holes 63 in the distal transverse segment 61, etc." Ex. 1010, 6:60-70:2. Grusin also states that "the lateral end of the distal transverse segment 61 is extended proportionally a greater distance from the proximal longitudinal segment 55 … and an additional spherically recessed

hole 63 is provided through the lateral end 43 of the distal transverse segment 42." Ex. 1010, 7:6-15.

Annotated Figure 12, below, shows a substantially T-shaped plate, from which POSITAs would have understood that the nearest threaded locking screw holes on each arm are placed a radially equal distance from the medial line.



Ex. 1001, ¶263; Ex. 1010, Fig. 12.

To the extent Patent Owner argues that Grusin does not expressly disclose this limitation, POSITAs would have been motivated to place the arm screw holes radially equidistant from the medial line. Ex. 1001, ¶264. For example, POSITAs would have recognized that placing the arm screw holes at a radially equal distance from the medial line would balance the forces across the medial line such that one of the screws would not be prone to loosening due to unequal leverage, and there

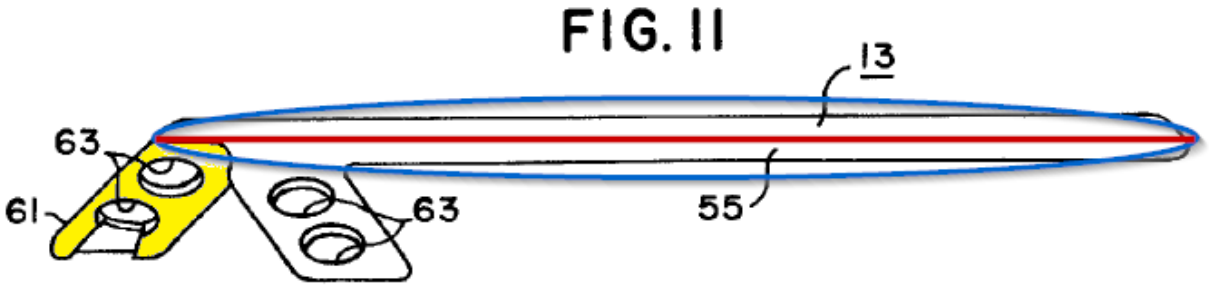
would be no additional manufacturing and design difficulty in placing the screw holes in such a way. *Id.*

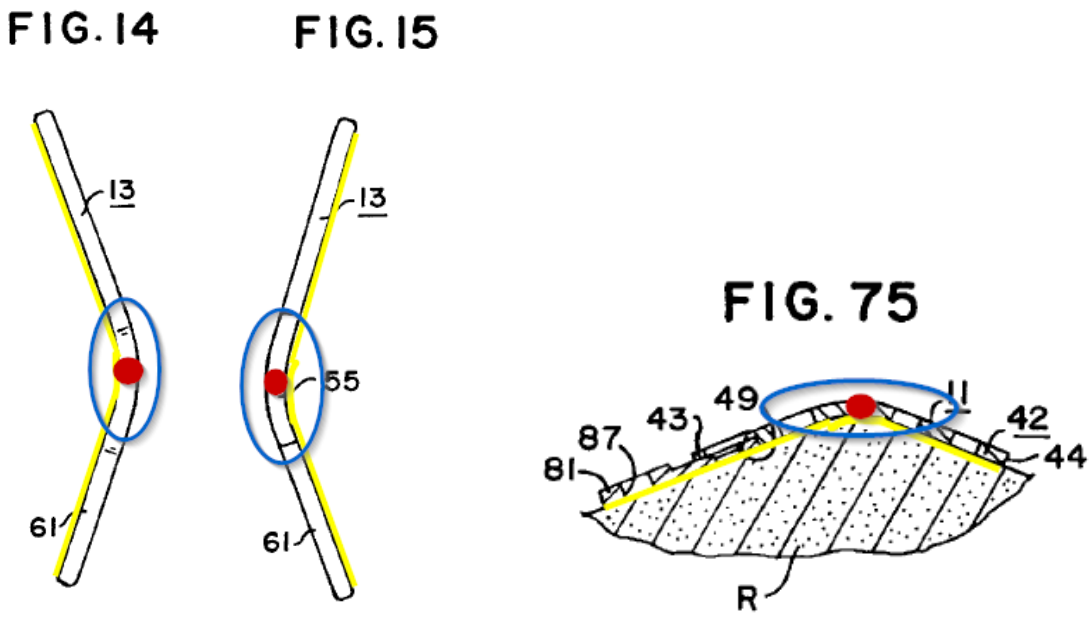
8. **Claim 24**

As explained above, Grusin and Fernandez renders obvious claim 17. Grusin discloses the additional limitation of claim 24. Ex. 1001 ¶¶266-267.

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." Ex. 1010, 6:36–40. Grusin's plate, which has a medial line running along the length of a bone, has a curve transverse to the medial line on its inferior surface so that the bottom face conforms as closely as possible to the surface of a bone. Ex. 1001, ¶266.

Annotated Figures 11, 14, 15, and 75 of Grusin, below, show the plate defining a medial line (red) and the central trunk portion (dark blue) having an inferior surface (yellow) defining a curve transverse to the medial longitudinal line (green). *See, e.g.*, Ex. 1010, Figs. 11, 14, 15, 75.



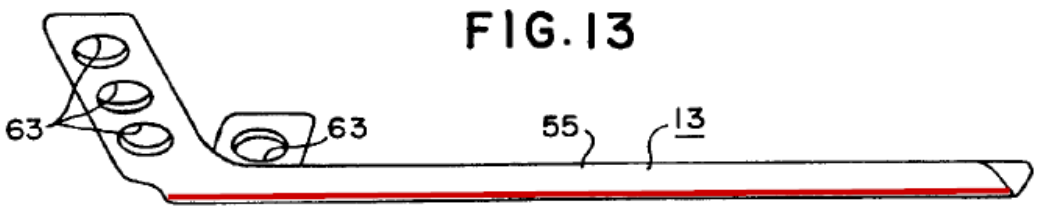


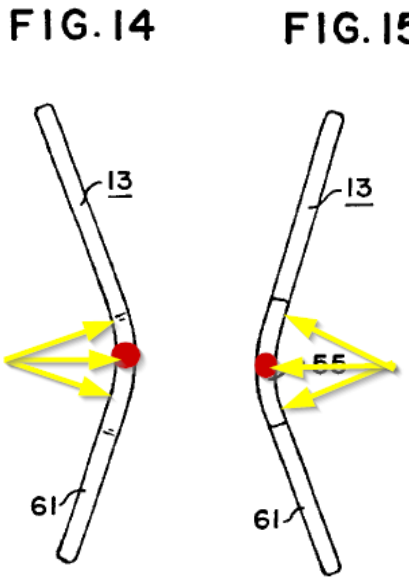
Ex. 1001, ¶267.

9. **Claim 25**

As explained above, Grusin and Fernandez renders obvious claim 24. Grusin discloses the additional limitation of claim 25. Ex. 1001, ¶¶269-271.

As discussed above, 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," Ex. 1010, 6:36–40, such that it has a curve transverse to the medial line. The Figures of Grusin, e.g. annotated Figures 13-15 below, also demonstrate that the curve is constant along the medial line. Ex. 1001, ¶¶270-271; *see, e.g.*, Ex. 1010, Figs. 13–15.





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 line. Ex. 1001, ¶271. The surgery disclosed in Grusin may also require "[r]emoval of the Lister's tubercle may be necessary," which would result in a more uniform curvature of the underlying anatomy. 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," POSITAs would have been motivated to bend the plate to have a constant curve

along the medial line. POSITAs would have expected 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, ¶271 (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, ¶271.

10. **Claim 26**

As explained above, Grusin and Fernandez renders obvious claim 25. Grusin discloses the additional limitation of claim 26. Ex. 1001 ¶273.

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.9. 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. Ex. 1001, ¶273.

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 to bend the plate to a constant curve which is a portion of a circle and defines a segment of a cylinder. 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. Ex. 1001, ¶273 (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. Ex. 1001, ¶273.

11. **Claim 27**

As explained above, Grusin and Fernandez renders obvious claim 17. Grusin discloses the additional limitation of claim 27. Ex. 1001 ¶275.

Grusin discloses a surgery including where "[r]emoval of the Lister's tubercle may be necessary." Ex. 1010, 10:5-6. Lister's tubercle is a portion of the radius bone, and POSITAs would have understood that an osteotomy involves reshaping a bone. Ex. 1001, ¶275. Thus, Grusin discloses a surgery selected from the group consisting of an osteotomy and fusion. *Id.* In addition, repair of many fractures involves osteotomies, and POSITAs would have understood that the internal fixation bone plate disclosed by Grusin could be used for osteotomies just as for any other type of fracture-repair. Ex. 1001, ¶275.

IX. MANDATORY NOTICES

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

Paragon is the real party in interest for Petitioner.

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

Patent Owner asserted the '252 patent against Paragon in Case No. 1:18-cv-00691-PAB-STV (D. Col.), filed March 23, 2018. This case may affect, or be affected by, this proceeding. Paragon is not aware of any other proceedings involving the '252 patent.

Other patents in the same family as the '252 patent, have also been asserted in the above-referenced case and are, or will be, the subject of 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 consent to service by email at the email address: Paragon28_PTAB@kirkland.com.

X. GROUNDS FOR STANDING

Paragon certifies that the '252 patent is available for IPR and Paragon is not barred or estopped from requesting IPR of the '252 patent on the grounds identified. Paragon was served with a complaint asserting infringement of the '252 patent on March 29, 2018, and this Petition is being filed within one year of that date. Ex. 1056.

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

Review of 9 claims is requested. The undersigned authorizes the Office to charge the fee set forth in 37 C.F.R. § 42.15(a) for this Petition to Deposit Account No. 506092, as well as any additional fees due in connection with this petition.

XII. CONCLUSION

For the reasons set forth above, the Challenged Claims of the '252 patent are unpatentable. Paragon therefore requests that an IPR of these claims be instituted.

DATED: March 28, 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 13,456 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

DATED: March 28, 2019

Respectfully submitted,

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

INDEX OF EXHIBITS

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

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

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

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I certify that I caused to be served a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,259,252 (and accompanying Exhibits) by overnight courier on the Patent Owner at the correspondence address of the Patent Owner as follows:

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

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

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

DATED: March 28, 2019

Respectfully submitted,

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