**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|---|
| United States Patent No.: 8,162,989 | § | Attorney Docket No.: 110432-0003-651 |
| Inventors: Farid Bruce Khalili | § | |
| Formerly Application No.: 10/693,698 | § | |
| Issue Date: Apr. 24, 2012 | § | Customer No. 28120 |
| Filing Date: Oct. 27, 2003 | § | |
| Former Group Art Unit: 3733 | § | Petitioner: Globus Medical, Inc. |
| Former Examiner: Mary C. Hoffman and Eduardo C. Robert | § | |

For: ORTHOPEDIC ROD SYSTEM

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**PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,162,989**

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| Ex. 1006 | U.S. Patent No. 6,077,262 ("Schläpfer '262") |
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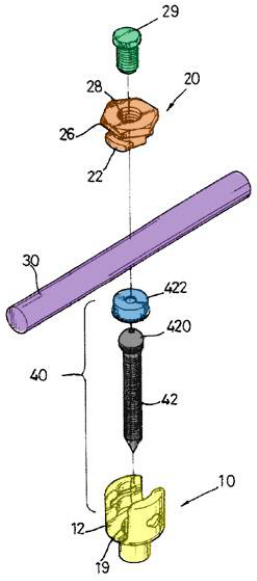
Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, the undersigned, on behalf of and acting in a representative capacity for petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review of claims 1, 2, and 5-11 of U.S. Patent No. 8,162,989 ("the '989 patent"), issued to Farid Bruce Khalili and currently assigned to Altus Partners, LLC ("Altus"). Petitioner hereby asserts that there is a reasonable likelihood that at least one of the challenged claims is unpatentable for the reasons set forth herein and respectfully requests review of, and judgment against, claims 1, 2, and 5-11 as unpatentable under § 103.[1]

## I. INTRODUCTION

The claims of the '989 patent are not directed to anything new. Rather, the claims cover known pedicle screw systems intended to be used in securing portions of a spine—such as the system shown in FIG. 8 (at right) of prior art U.S. Patent No. 6,786,903 ("Lin") (Ex. 1003).[2] Lin and the claims of the '989 patent are both directed to a pedicle screw system with a fastener (shown in gray) that is screwed into a vertebra, and a tulip (yellow) and cap (orange) used to secure a rod (purple) to the fastener. A surgeon can secure part of a spinal column by screwing multiple pedicle screws into multiple

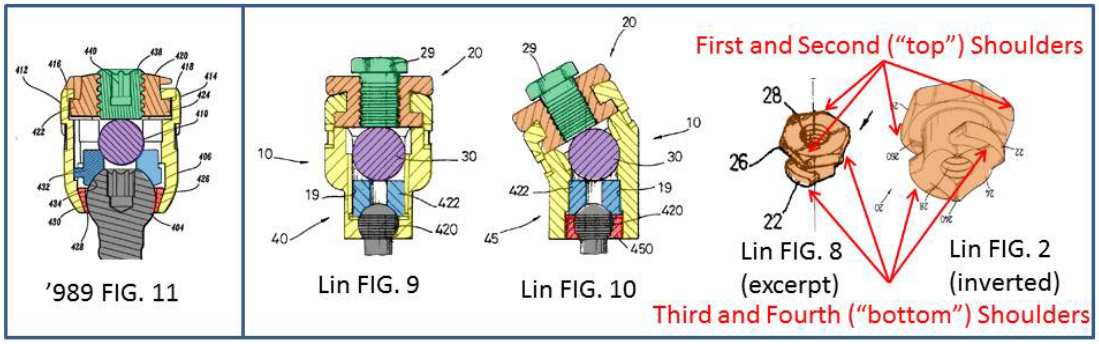


Lin FIG. 8

[1] All section citations are to Title 35 of the U.S. Code, unless otherwise noted.

[2] Emphasis and coloration added throughout, except as otherwise noted.

vertebrae and connecting those screws with a rod. The prior art renders obvious the supposed "invention" in each of the claims—a cap with upper "shoulders" that slide over the top of the tulip and lower "shoulders" that slide into grooves in the tulip when the cap is rotated. A comparison of FIG. 11 of the '989 patent with FIGS. 2, 8, 9 and 10 of Lin illustrates the presence or an obvious variant of each element:[3]




The dependent claims of the '989 patent merely add well-known elements from the prior art, such as: a locking screw (shown above in green) used to lock the rod and fastener into place by pressing the rod against a seat cap (blue), which in turn presses against the head of the fastener, which in turn presses against the seat ring (red).

The '989 patent itself concedes that many designs for pedicle screw systems were already well-known in the prior art. *See, e.g.*, Ex. 1001 at FIG. 10, 1:20-22 and 1:32-33. Indeed, pedicle screws with non-threaded caps (*e.g.*, with top or bottom shoulders) were commonplace prior to the filing date of the '989 patent. *See, e.g.*, Ex. 1007, WO 01/52758 to Yuan et al. ("Yuan"). It was also known that such non-threaded caps could have varying numbers of shoulders, such as 2 or 4 shoulders, on

[3] Throughout the Petition, all red text, arrows and circles in the figures were added.

the cap. *See, e.g.*, Ex. 1007, Yuan, FIG. 12A (showing two shoulders—elements 284 and 286); and Ex. 1008, Mueller, US 2006/0200128, FIGS. 9 and 12 (showing four shoulders – elements 317, 318, and two elements 323).

As discussed in more detail below, the supposed invention of the '989 claims, including the alleged point of novelty of a cap with bottom and top shoulders that are rotated into grooves in the tulip and over the top of the tulip, respectively, was well known in the art. *See, e.g.*, Ex. 1003, Lin (disclosing bottom and top shoulders); Ex. 1005, U.S. Patent No. 6,063,090 ("Schläpfer '090") (disclosing top shoulders); Ex. 1006, U.S. Patent No. 6,077,262 ("Schläpfer '262") (disclosing bottom shoulders). The '989 patent merely combines these well-known elements in a manner in which they had already been combined in the art and would have been obvious and predictable to one possessing ordinary skill in the art at the time the '989 patent was filed.

All the claims subject to this petition (claims 1, 2 and 5-11) recite nothing more than routine and predictable combinations of well-known elements and are thus invalid as obvious under § 103. For these reasons, as explained in more detail herein, Petitioner respectfully submits that there is at a minimum a reasonable likelihood that Petitioner will prevail on at least one claim. Accordingly, Petitioner respectfully requests that this Petition be granted and claims 1, 2, and 5-11 of the '989 patent be found unpatentable and canceled.

## II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

### A. Globus Is the Real Party In Interest Under 37 C.F.R. § 42.8(b)(1)

The real party-in-interest is Petitioner Globus Medical, Inc.

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

Altus Partners L.L.C. ("Altus") has asserted claims 1-2 and 5-11 of the '989 patent against Petitioner in *Altus Partners, L.L.C.* v. *Globus Medical, Inc.,* No. 2:13-cv-00822-RK (E.D. Pa., filed Feb. 14, 2013) ("E.D. Pa. Litigation").

### C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3) and Service Information under 37 C.F.R. § 42.8(b)(4)

Lead counsel, backup counsel, and service information for Petitioner are: Steven Baughman (Lead Counsel), Reg. No. 47,414, steven.baughman@ropesgray.com, P: 202-508-4606/F: 202-383-8371; Marc Cavan (Backup Counsel) Reg. No. 51,537, marc.cavan@ropesgray.com, P: 312-845-1282/F: 312-845-5500; Mailing address for all PTAB correspondence: ROPES & GRAY LLP, IPRM – Floor 43, Prudential Tower, 800 Boylston Street, Boston, MA 02199-3600.

## III. PETITIONER HAS STANDING

### A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies pursuant to 37 C.F.R. § 42.104(a) that the '989 patent is eligible for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review of the '989 patent. Petitioner was served with a Complaint asserting infringement of the '989 patent on or after February 14, 2013,

and neither Petitioner nor any other real party-in-interest, or privy of Petitioner was served with a complaint before that date, or has initiated a civil action challenging validity of the '989 patent.

### B. Claims and Statutory Grounds Under 37 C.F.R. § 42.22 and 37 C.F.R. § 42.104(b)

Petitioner requests *inter partes* review of '989 claims 1, 2, and 5-11 and asserts that these claims are unpatentable under 35 U.S.C. § 103 as set forth below.

- Ground 1: Claims 1, 2, and 5-11 are obvious under § 103 over Lin in view of the knowledge of a person having ordinary skill in the art ("POSITA").
- Ground 2: Claims 8-11 are obvious under § 103 over Lin in view of the Admitted Prior Art ("APA") (as illustrated by FIG. 10 of the '989 patent).
- Ground 3: Claims 8-11 are obvious under § 103 over Lin in view of Errico.
- Ground 4: Claims 1, 2, and 5-11 are obvious under § 103 over Schläpfer '090 in view of Schläpfer '262.

Every proposed ground contains art that was never previously considered by the Patent Office during earlier prosecution of the '989 patent – specifically, Lin, Errico, and Schläpfer '262.

Section V.D. below provides claim charts specifying how the relied upon prior art renders obvious claims 1, 2 and 5-11 of the '989 patent. In further support of the proposed grounds of rejection, this Petition is accompanied by a Declaration of technical expert Raymond P. Vito ("Vito Decl."), attached as Exhibit 1009.

## IV. SUMMARY OF THE '989 PATENT

### A. Overview of the '989 Patent

The '989 patent generally relates to "a pedicle screw and rod system and associated method for joining two or more bone segments, such as vertebrae." Ex. 1001 at 1:14-16. The '989 patent describes a tulip-shaped seat with a non-threaded cap "having transversely aligned wings that are passed through the slot and then, as the cap is rotated, positioned into dove-tail like grooves that prevent the cap from being backed out." *Id.* at 1:45-51. According to the '989 patent, the claimed design "allows loose retention of the components relative to the rod so a surgeon can easily make adjustments." *Id.* at 3:34-37.

Another feature claimed by the '989 patent, in dependent claims 9-11, is a seat ring (or sleeve) "for seating the screw head relative to the cup or tulip." *Id.* at 3:62-63.

As set forth in this Petition, these features and the remaining elements claimed by the '989 patent were already well known in the art before its earliest possible priority date (Nov. 4, 2002)—the date of the earliest cited provisional application.

### B. Brief Overview of the '989 Patent Prosecution History

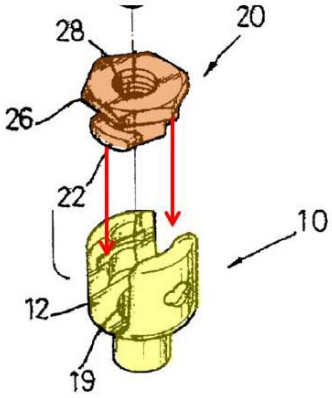
The application leading to the '989 patent was filed on October 27, 2003 and claims priority from two related U.S. Provisional Patent Applications: 60/423,168 (filed Nov. 4, 2002) and 60/479,822 (filed June 20, 2003). After nearly a decade of prosecution, including over six months when the application stood abandoned, and

several changes in ownership, the Examiner issued a Notice of Allowance on April 24, 2012. Specifically, the Reasons for Allowance stated that:

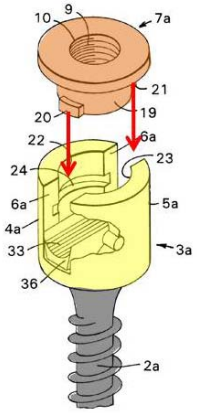
> The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest the claimed combination, specifically first, second, third, and fourth shoulders capable of performing the claimed function. Applicant has pointed out in an interview with the examiner that the prior art cited in the Non-final Office action does not have *third and fourth shoulders sized and shaped to be received into the first and second slots* (rather the prior art shows shoulders that are received into the central bore of the tulip and not into the slots formed in the sides of the tulip).

Ex. 1002 at 29. The Examiner had **not** considered either Lin or Schläpfer '262 (shown to the right)—both of which disclose a cap (orange) with "third and fourth shoulders sized and shaped to be received into the first and second slots."

Third and Fourth Shoulders
Received into First and Second Slots




Lin FIG. 8
(excerpt)




Schläpfer '262 FIG. 2
(excerpt)

## V. THERE IS A REASONABLE LIKELIHOOD THAT PETITIONER WILL PREVAIL WITH RESPECT TO AT LEAST ONE CLAIM OF THE '989 PATENT

Petitioner submits there is at least "a reasonable likelihood that the petitioner[ ] would prevail with respect to at least 1 of the claims challenged in the petition." § 314(a). Indeed, all of the '989 patent claims asserted against Petitioner in litigation

(claims 1, 2, and 5-11) are obvious under § 103 in light of the prior art, as explained below.

### A. Claim Construction Under 37 C.F.R. § 42.104(b)(3)

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purposes of this review, Petitioner construes the claim language such that it is "given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Because the standard for claim construction at the PTO is different than that used in U.S. District Court litigation, *see In re Am. Acad. Of Sci. Tech Ctr.,* 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004), MPEP § 2111, Petitioner has argued and expressly reserves the right to argue a different claim construction in a different forum for any term in the '989 patent as appropriate in that proceeding.

"**Grooves**": For review purposes, this term is construed to mean "long narrow channels or depressions." *See, e.g.,* Ex. 1001 at 5:23-29; FIG. 11 (elements 416, 418).

"**Shoulders**": For review purposes, this term is construed to mean "projections that form an abutment on an object or limits motion." *See, e.g., id.* at 4:29-35; 5:23-29; FIGS. 11 and 13.

### B. Level of Ordinary Skill in the Art and State of the Art

Petitioner submits that the applicable level of ordinary skill in the art is an engineer, who, as of at least November 2002, had a degree in mechanical engineering, applied mechanics, or a related field, with 2-3 years of experience in the field of orthopedic devices, such as spinal implants. *See* Ex. 1009, Vito Decl. ¶¶ 12-18.

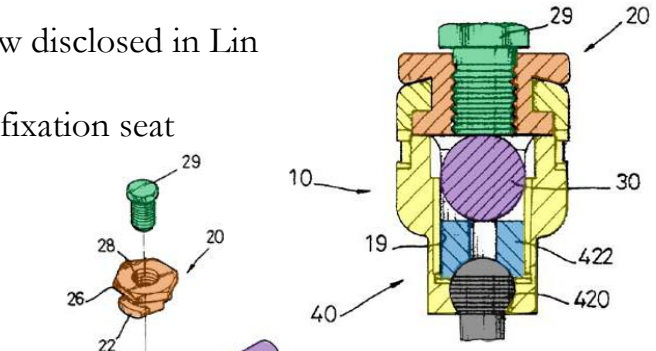
### C. Overview of the Prior Art and Grounds for Petition

#### 1. Claims 1, 2, and 5-7 Are Rendered Obvious by Lin (Ground 1)

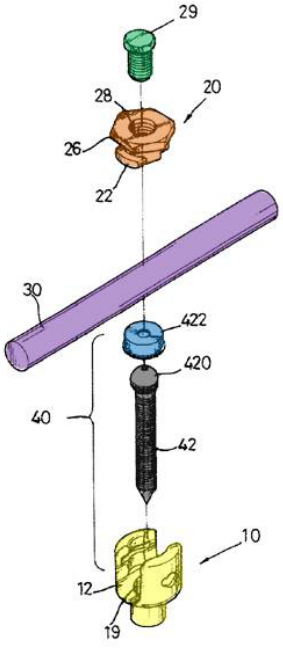
##### a. Overview of Lin

U.S. Patent No. 6,786,903 to Lin, "Rotary Device for Fixing Spinal Column Under Treatment," was filed on March 28, 2002 and issued on September 7, 2004, qualifying it as prior art to the '989 patent under at least § 102(e). Like the '989 patent, Lin discloses a pedicle screw designed to be used as part of an orthopedic rod system for bridging one or more vertebrae of a spine. *See, e.g.*, Ex. 1003 at 1:28-30 ("The primary objective of the present invention is to provide a rotary device for fixing spinal column under treatment"). Lin also discloses various pedicle screw embodiments that are similar in construction. *See, e.g.*, *id.* at 3:49-51.

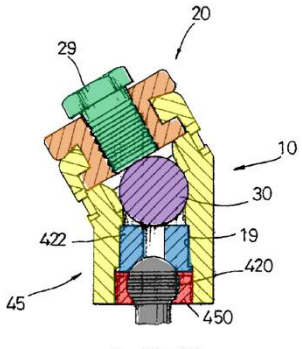
Like the '989 patent, the pedicle screw disclosed in Lin includes three basic components—a tulip ('fixation seat 10'— yellow), a cap ('fixation block 20'—orange), and a fastener ('fixation screw 42'—gray). *Id.* at FIGS. 8, 9. In one preferred embodiment, Lin's disclosed U-shaped fixation seat 10 has an axial bore through which the threaded shaft of the fixation screw 42—but not its spherical



Lin FIG. 9



Lin FIG. 8



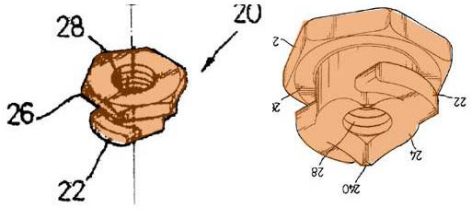
Lin FIG. 10

head 420—can pass. *See id.* at FIGS. 8, 9. In an alternative embodiment, a seat ring ('assembly ring 450'—red) is used to hold the head of the screw '420.' *See id.* at FIG. 10; Ex. 1009, Vito Decl. ¶¶ 23-36.

Once the fixation screw of Lin has been placed through the bore, a fitted seat cap ('press ring 422'—blue) is placed over the spherical head ('420') of the fastening screw ('42'). *See* Ex. 1003 at FIGS. 9, 10. The fixation rod '30' (purple) is then placed inside the U-shaped opening of the fixation seat so that the rod is held by the U-shaped walls and rests on top of the seat cap ('422'). *See id*; Ex. 1009, Vito Decl. ¶ 25.

Once these elements are in place, a non-threaded cap ('fixation block 20' - orange) is placed on top of the rod and turned. Lin discloses caps of varying configurations. *See, e.g.,* Ex. 1003 at FIG. 11 (element '60'), and FIG. 2 (element '20'); Ex. 1009, Vito Decl. ¶ 25-26.

In the first preferred embodiment, the cap disclosed in Lin has two lower shoulders and a hexagonal-shaped top. *See* Ex. 1003 at FIGS. 2, 8.



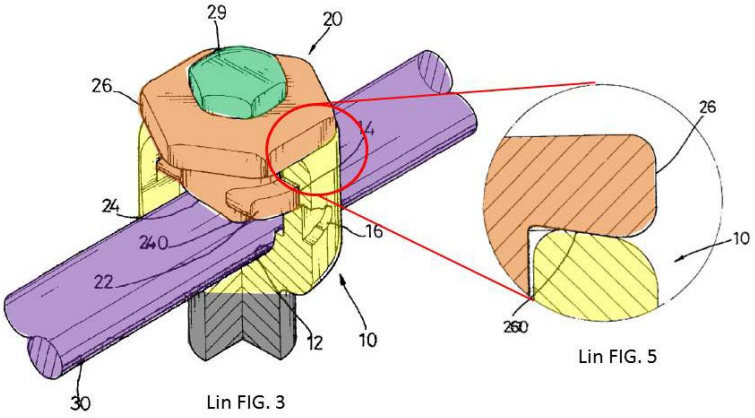
Lin FIG. 8 (excerpt)


Lin FIG. 2 (inverted)

Lin describes that when the cap ('fixation block 20') is placed on top of the tulip ('fixation seat 10'), it is rotated so that the two lower shoulders ('retaining edges 22') engage with complementary grooves ('recesses 14') in the U-shaped walls of the tulip ('fixation seat 10'), and the hexagonally-shaped end of the cap ('fixation block 20') engages with the top of the tulip ('fixation seat 10'). *See id.* at 4:50-59, FIG. 3; Ex.

1009, Vito Decl. ¶ 24-26.

As illustrated in FIGS. 3 and 5, the underside of the rotary control end of the cap in Lin has inclined surfaces, which produce an "inward push" when they come into contact with the lip of the tulip giving the tulip "added strength to hold securely" the cap and the rod. Ex. 1003 at 3:37-42 (red lines added above). This design element creates an inward bias, which reduces the risk of the tulip splaying and backing out the cap. *See* Ex. 1009, Vito Decl. ¶ 26.



Lin FIG. 3 Lin FIG. 5

To finally lock the pedicle screw in place, Lin teaches that a threaded locking screw ('fastening bolt 29' – green) is screwed through a hole in the top of the cap, forcing the rod downward and fixing the rod and the fastener in place. Ex. 1003 at 4:42-45; Ex. 1009, Vito Decl.¶ 25.

**b. Claims 1, 2, and 5-7 Are Rendered Obvious by Lin (Ground 1)**

The invention claimed in the '989 patent is at minimum obvious in light of Lin in view of the knowledge of a person of skill in the art ("POSITA") because all of the elements of the asserted claims of the '989 patent were well known, and one of skill in the art would have been motivated and able to make routine design modifications to Lin's disclosed pedicle screw system to meet any limitations of the claims of the '989

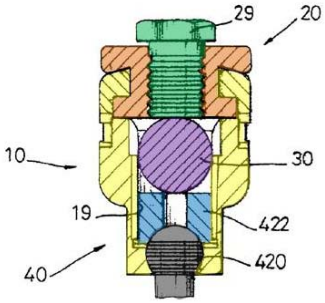
patent that are not found to be explicitly or inherently disclosed. For example, to the extent it may be argued that Lin does not disclose the first and second shoulders precisely as claimed, a POSITA would have found it obvious and a simple matter of design choice to include such shoulders. *See* Ex. 1009, Vito Decl. ¶¶ 33-36.

Indeed, Lin teaches the *same* solution to the *same* problem as the '989 patent. The '989 patent is purportedly aimed at providing a pedicle screw and rod system that overcomes a problem associated with threaded-cap designs: "the surgeon must manipulate and tighten the cap while holding the pedicle screw and rod at a particular desired angle." Ex. 1001 at 1:25-30; *see also* Ex. 1003 at 1:14-15 (providing a "means to locate temporarily the fixing rod in the surgical operation"). The '989 patent's solution to this problem is a pedicle screw with a non-threaded cap, which when closed by the surgeon, temporarily holds the components at a particular angle and relationship to one another. *See* Ex. 1001 3:34-36. The surgeon can then review the alignment and adjust the relative position of the components of the tulip and screw as needed before finally locking components completely via a locking screw. *Id.*

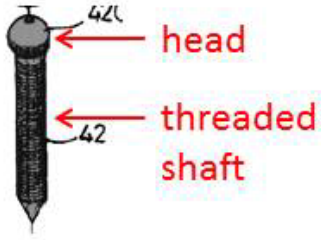
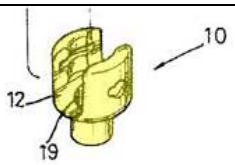
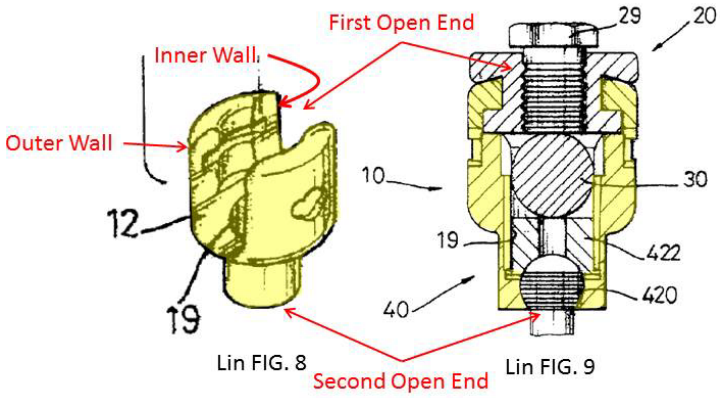
As discussed above, Lin also discloses the *same* solution to that *same* problem. In particular, Lin discloses a pedicle screw with a non-threaded cap, which, when closed by the surgeon, temporarily holds the components at a particular angle and relationship to one another. *See* Ex. 1009, Vito Decl. ¶¶ 37. The surgeon can then review the alignment and adjust the relative position of the components of the tulip

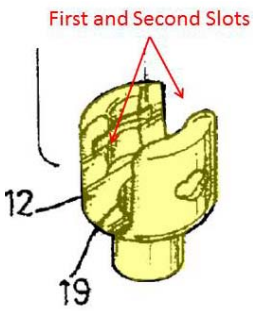
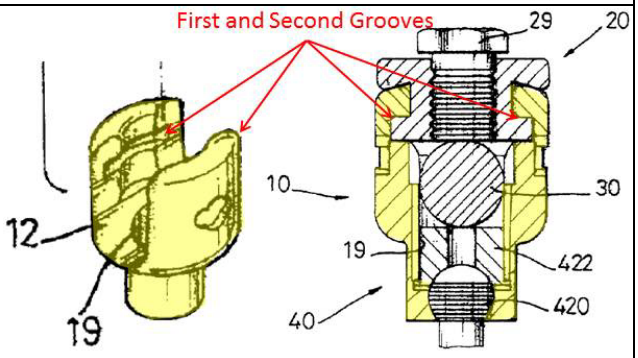
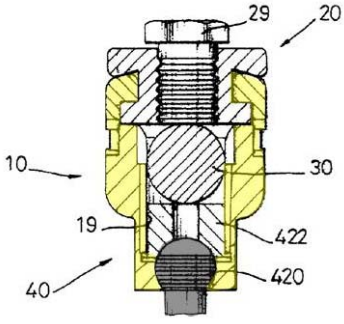
and screw as needed before finally locking the components permanently via a locking screw. *See* Ex. 1009, Vito Decl. ¶¶ 24, 37, 40.

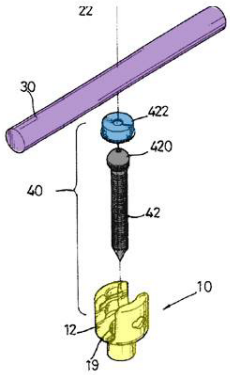
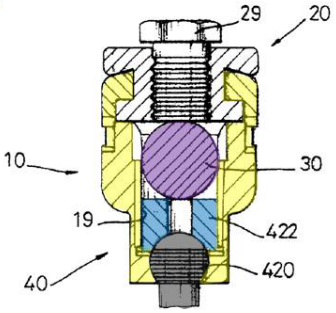
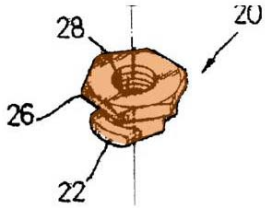
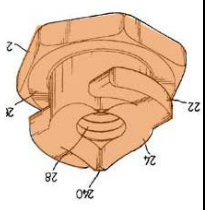
As detailed in the charts below, Lin discloses (in the exemplary excerpts and cites provided herein) each and every limitation of claims 1, 2 and 5-7 rendering them invalid as at least obvious under § 103.[4]

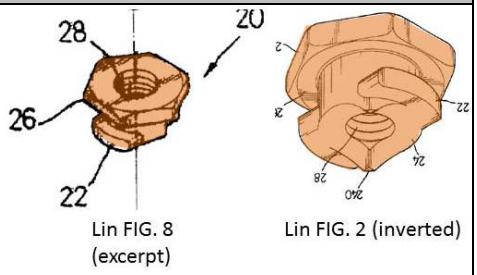
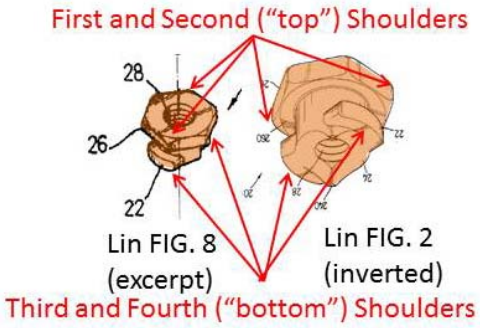
| **'989 Patent Claim 1** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| An apparatus for bridging one or more vertebrae of a spine, the apparatus comprising: | To the extent the preamble is limiting:<br><br>Lin discloses an apparatus for bridging one or more vertebrae of a spine, describing "a rotary device for fixing [a] spinal column under treatment." *See, e.g.*, Ex. 1003 at 1:28-30; 2:65-68 ("a backbone fixing device of the present invention"); FIGS. 2, 8, 9; Ex. 1009, Vito Decl. ¶¶ 23-36.<br><br>The elements of Lin have been colored according to the following key:<br><br>Tulip ('fixation seat 10') is yellow;<br>Cap ('fixation block 20') is orange;<br>Screw ('fastening bolt 29') is green;<br>Rod ('fixation rod 30') is purple;<br>Fastener ('fixation screw 42') is gray; and<br>Seat Cap ('press ring 422') is blue.<br><br>  <br>Lin FIG. 9 |

[4] Petitioner's arguments under § 103 should not be taken as admission that the claims are not also invalid under § 102 in view of Lin—especially with respect to claims 1 and 5-7.

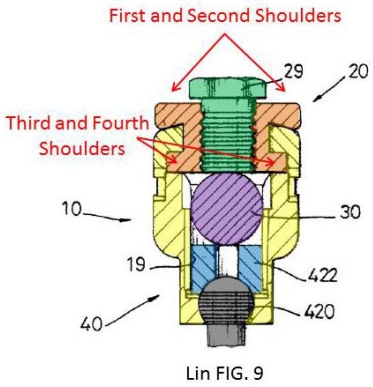
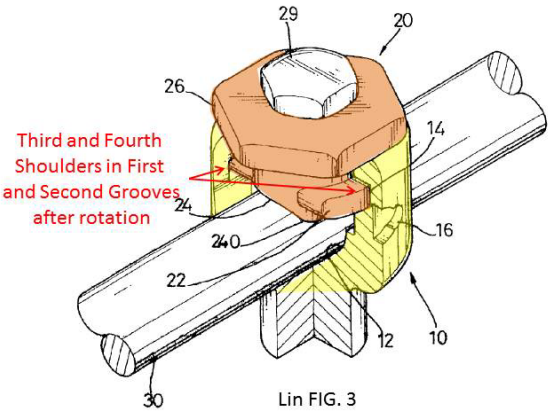
| '989 Patent Claim 1 | Rendered Obvious by Lin (exemplary excerpts below) |
|---|---|
| **a fastener** having a threaded shaft adapted to be driven into the vertebrae and a head at a proximal end of the shaft; | Lin discloses a fastener ('fixation screw 42') having a threaded shaft adapted to be driven into the vertebrae and a head ('420') at a proximal end of the shaft. Ex. 1003 at 2:22-25 ("Preferably, [the] spherical head is provided with a fastening screw made integrally therewith for fastening onto a bone or spinal segment"); 3:44-45; 3:48-51; *id.* at FIGS. 2, 8, and 9.<br>  <br>Lin FIG. 8 (excerpt) |
| **a tulip** having: | Lin discloses a tulip ('fixation seat 10'). Ex. 1003 at 2:65-68; 4:32-34; *id.* at FIGS. 2, 8, and 9.<br>  <br>Lin FIG. 8 (excerpt) |
| (a) outer and inner walls defining opposing, and generally circularly open, first and second ends, | The tulip ('fixation seat 10') of Lin has outer and inner walls defining opposing, and generally circularly open, first and second ends. Ex. 1003 at 2:10-11; 3:1-2; 4:32-34; FIGS. 2, 8, and 9; Ex. 1009, Vito Decl. ¶ 27.<br>  <br>Lin FIG. 8 Lin FIG. 9 |

| **'989 Patent Claim 1** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| (b) opposing first and second slots extending from the open first end toward the open second end, and | The tulip ('fixation seat 10') of Lin has opposing first and second slots ('12'). Ex. 1003 at 3:1-2; 4:32-34 ("fixation seat provided with a receiving slot for receiving the fixation rod, said receiving slot having two opposite side walls"); FIGS. 2 and 8; Ex. 1009, Vito Decl. ¶ 28, 31.   Lin FIG. 8 (excerpt) |
| (c) first and second grooves, each extending in opposing relation to one another along the inner wall from at least one of the first and second slots toward the other of the first and second slots, wherein: | The tulip ('fixation seat 10') of Lin has first and second grooves ('retaining recesses 14'), each extending in opposing relation to one another along the inner wall from at least one of the first and second slots toward the other of the first and second slots. Ex. 1003 at 3:2-3 ("fixation seat 10" has "two retaining recesses 14 on the two inner walls"); 4:46-49 ("said retaining recesses of said fixation seat are located in inner sides of the two side walls of said receiving slot"); FIGS. 2, 8, and 9; Ex. 1009, Vito Decl. ¶ 30.   Lin FIG. 8 (excerpt) Lin FIG. 9 |
| (i) the head of the fastener is retained within the tulip and proximate to the second end thereof, with the threaded shaft extending out of the tulip through the second opening thereof, and | Lin discloses that the head of the fastener ('fixation screw 42'—shown in gray) is retained within the tulip ('fixation seat 10'—shown in yellow) and proximate to the second end thereof. Ex. 1003 at 3:57-59 ("the head 420 is held by the edge of the through hole 19 to prevent the escape of the fixation screw 42").   Lin FIG. 9 |

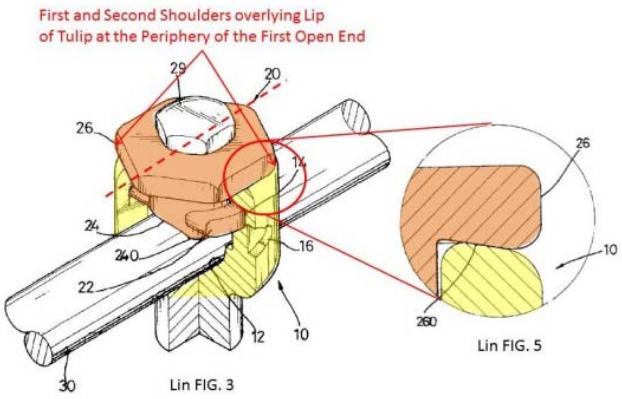
| **'989 Patent Claim 1** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| | The threaded shaft of the fastener disclosed in Lin also extends out of the tulip through the second opening thereof. *Id.* at 3:54-57 ("[t]he shank of the fixation screw 42 is put through the through hole 19 of the fixation seat 10 such that the shank is fastened onto a spinal segment under treatment"); FIG. 9; Ex. 1009, Vito Decl. ¶ 30. |
| (ii) the opposing first and second slots are sized and shaped to receive a rod therethrough in a transverse orientation with respect to the threaded shaft of the fastener, such that the rod passes over the head; and | Lin discloses that the opposing first and second slots ('receiving slots' '12') in the tulip ('fixation seat 10' – yellow) are sized and shaped to receive a rod ('fixation rod 30' – purple)   Lin FIG. 8 (excerpt)   Lin FIG. 9 therethrough in a transverse orientation with respect to the threaded shaft of the fastener ('fixation screw 42' – gray), such that the rod passes over the head of the fastener. Ex. 1003 at 3:1-2 ("fixation seat 10 is provided with a U-shaped receiving slot 12"); *id.* at 4:32-34 ("fixation seat [is] provided with a receiving slot for receiving the fixation rod"; FIGS. 2, 8 and 9; Ex. 1009, Vito Decl. ¶ 31. |
| **<u>a cap</u>** including: | Lin discloses a cap ('fixation block 20' – orange). Ex. 1003 at 2:38-39; 2:65-68; FIGS. 2, 8, and 9.   Lin FIG. 8 (excerpt)  Lin FIG. 2 (inverted) |
| (a) a generally cylindrical body having first and second opposing ends, an outer surface, and a bore extending through the | The cap ('fixation block 20') disclosed in Lin has a generally cylindrical body having first and second opposing ends, and an outer surface, and a bore extending through the first and second opposing ends of the body along a central, longitudinal axis. Ex. 1003 at 3:4-8 ("fixation block 20 has a cylindrical body, and is provided with a rotary control end |

| **'989 Patent Claim 1** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| first and second opposing ends of the body along a central, longitudinal axis, | 26 at one end of the cylindrical body…[and] two opposite retaining edges 22 protruding radially from the cylindrical body at the other end thereof"); FIGS. 2 and 8; Ex. 1009, Vito Decl. ¶¶ 32-36.   Lin FIG. 8 (excerpt)  Lin FIG. 2 (inverted) |
| (b) first and second shoulders disposed in opposing relationship to one another proximate to the first end of the body, and extending radially away, and circumferentially along, the outer surface of the body,<br><br>(c) third and fourth shoulders disposed in an opposing relationship proximate | Lin discloses a cap ('fixation block 20') that has first and second shoulders disposed in opposing relationship to one another proximate to the first end of the body, and extending radially away, and circumferentially along, the outer surface of the body. Ex. 1003 at 3:4-10 ("fixation block 20 has a cylindrical body, and is provided with a rotary control end 26 at one end of the cylindrical body"); FIGS. 2, 8 and 9. Ex. 1009, Vito Decl. ¶ 25.[5]   |

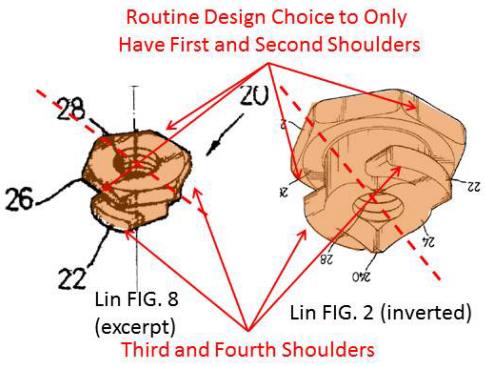
[5] To the extent it is argued that the claimed first and second shoulders are not explicitly taught in Lin, it would at a minimum have been an obvious design choice to include first and second shoulders similar to the third and fourth shoulders in Lin discussed below—to take advantage of the lower manufacturing cost required to make the simpler shoulders (relative to the hex) and allow compatibility with a broader range of tools. Ex. 1009, Vito Decl. ¶ 25,32-39. This routine and predictable

| '989 Patent Claim 1 | Rendered Obvious by Lin (exemplary excerpts below) |
|---|---|
| to the second end of the body, and extending radially away, and circumferentially along, the outer surface of the body, wherein: | Lin also discloses that the cap ('fixation block 20') has third and fourth shoulders disposed in an opposing relationship proximate to the second end of the body, and extending radially away, and circumferentially along, the outer surface of the body. Ex. 1003 at 3:4-8 ("fixation block 20 has . . . two opposite retaining edges 22 protruding radially from the cylindrical body at the other end thereof"); 4:37-42 ("two retaining edges opposite to each other"); FIGS. 2, 8, and 9. *See* Ex. 1009, Vito Decl. ¶¶ 32-36.   Lin FIG. 9 |
| the third and fourth shoulders are sized and shaped to be: (i) received into the first and second slots, respectively, to positions adjacent to the first and second grooves, respectively, and (ii) slidingly received into the first and second grooves by rotation of the cap about the longitudinal axis; and | Lin discloses third and fourth shoulders ('retaining edges 22') that are sized and shaped to be (i) received into the first and second slots, respectively, to positions adjacent to the first and second grooves, respectively, and (ii) slidingly received into the first and second slots by rotation of the cap about the longitudinal axis. Ex. 1003 at 3:26-29 ("As the rotary control end 26 of the fixation block 20 is turned, the two retaining edges 22 will be retained in the two retaining recesses 14 on the inner walls of the receiving slot 12 of the fixation seat 10."); 3:37-43 ("two retaining edges opposite   Lin FIG. 3 |

combination of well-known elements would have been well understood to yield a predictable result—rendering the claims obvious under § 103. *See* MPEP 2143(c).

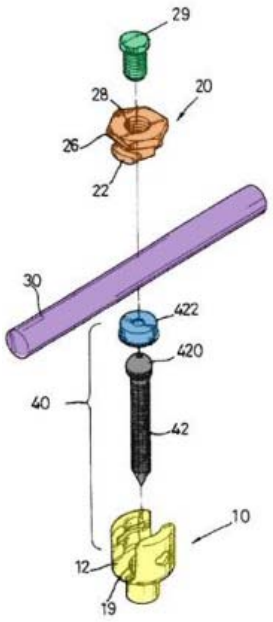
| '989 Patent Claim 1 | Rendered Obvious by Lin (exemplary excerpts below) |
|---|---|
| | to each other, wherein said fixation block is engaged with said fixation seat such that the fixation rod is pressed against by said fixation block, and the two retaining edges are retained in said retaining recesses of said fixation seat"); FIGS. 2, 3, 8. *See* Ex. 1009, Vito Decl. ¶¶ 34-35. |
| at least portions of the first and second shoulders are sized and shaped to slide over, and overlie, respective portions of a lip of the tulip at the periphery of the first open end of the tulip by the rotation of the cap about the longitudinal axis. | Lin also discloses that at least portions of the first and second shoulders (portions of 'rotary control end 26') are sized and shaped to slide over, and overlie, respective portions of a lip of the tulip ('fixation seat 10') at the periphery of the first open end of the tulip by the rotation of the cap about the longitudinal axis. Ex. 1003 at FIGS. 3, 5, and 9; 3:44-48 ("As illustrated in FIG. 5, the inclined surfaces of the underside 260 of the rotary control end 26 of the fixation block 20 and the top edge of the side walls of the fixation seat 10 come in contact with each other to produce an inward push, which gives the fixation seat 10 an added strength to hold securely the fixation block 20 and the fixation rod 30."). *See* Ex. 1009, Vito Decl. ¶¶ 26, 33.   Lin FIG. 3 Lin FIG. 5 |

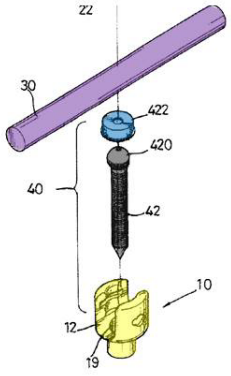
| '989 Patent Claim 2 | Rendered Obvious by Lin (exemplary excerpts below) |
|---|---|
| The apparatus of **claim 1**, wherein | *See* claim 1 above. |
| the cap includes no further shoulders beyond the first, second, third, and fourth shoulders. | The cap ('fixation block 20') of Lin has no further shoulders proximate to its bottom end beyond the third and fourth shoulders. With respect to the top, 'rotary control end' '26' of the cap disclosed in Lin also contemplates different shapes for the top of the cap used |

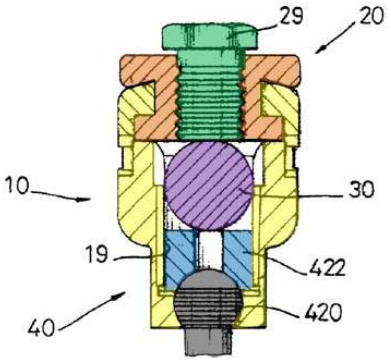
| | |
|---|---|
| | with various embodiments (*see*, *e.g.*, elements '60' and '66' in FIG. 11), including ones that would have no further shoulders beyond the first and second shoulders proximate to the top end under the broadest reasonable interpretation of that claim phrase. *See* Ex. 1009, Vito Decl. ¶ 38.[6]   |

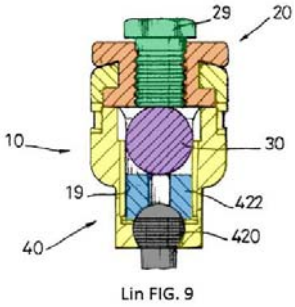
| '989 Patent Claim 5 | Rendered Obvious by Lin (exemplary excerpts below) |
|---|---|
| The apparatus of **claim 1**, further comprising | *See* claim 1 above. |

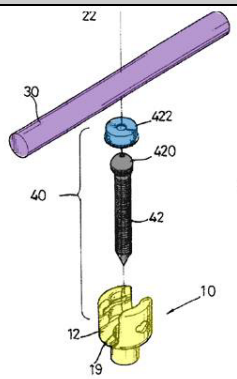
[6] To the extent the cap in Lin is considered to disclose more than first and second shoulders, a POSITA would at minimum have found it obvious to implement a pedicle screw system as disclosed in Lin but utilizing first and second top shoulders similar in shape to Lin third and fourth shoulders ('retaining edges 22') located near the bottom end of the cap. Ex. 1009, Vito Decl. ¶ 33, 38. For example, and without limitation, a POSITA would have found it obvious to use the truncated, top shape of the cap disclosed in Lin's FIG. 11 in lieu of the hexagonally-shaped top as shown in the embodiment of Lin's FIG. 8 or to use a cap with any number of shoulders based on routine design choice— to take advantage of the lower manufacturing cost required to make the simpler shoulders (relative to the hex) and allow compatibility with a broader range of tools. *See* Ex. 1009, Vito Decl. ¶¶ 25, 38, 39.

| **'989 Patent Claim 5** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| a screw operating to thread into the bore of the cap, to urge the rod toward the second end of the tulip, and to tighten such that the rod, the head of the fastener, and the tulip are rigidly fixed and locked into position. | The apparatus for fixing a spinal column under treatment disclosed by Lin further comprises a screw ('fastening bolt 29' – green) that operates to thread into the bore of the cap, to urge the rod toward the second end of the tulip, and to tighten such that the rod, the head of the fastener, and the tulip are rigidly fixed and locked into position. Ex. 1003 at 2:65-68 ("a backbone fixing device of the present invention comprises a fixation seat 10, a fixation block 20, and a fastening bolt 29"); 4:24-26 ("fastening bolt" is put through a threaded through hole of the control end of the fixation block to press against the fixation rod 30); FIGS. 1, 2, 4, and 8-11; *See* Ex. 1009, Vito Decl. ¶ 40.   Lin FIG. 8 |

| **'989 Patent Claim 6** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 5**, further comprising | *See* claim 5 above. |
| a seat cap having first and second opposing surfaces disposed within the tulip, the first surface being oriented toward the first end of the tulip and operating to engage the rod, and the second surface being oriented toward the second end of the tulip and operating to permit sliding engagement with, and articulation of, the head when the screw | The apparatus for fixing a spinal column under treatment disclosed by Lin further comprises a seat cap ('press ring 422' – blue) which has first and second opposing surfaces disposed within the tulip. Ex. 1003 at 3:49-54; FIGS. 8 and 9. The first surface of the seat cap ('press ring 422' – blue) is oriented toward the first end of the tulip and operates to engage the rod, and the second surface is oriented toward the second end of the tulip and operates to permit sliding engagement   Lin FIG. 8 (excerpt) |

| **'989 Patent Claim 6** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| is not tight. | with, and articulation of, the head when the screw is not tight. *Id.* at 3:59-61 ("[t]he press ring 422 is rested on the spherical head 420 to secure the spherical head 420, and is pressed by the fixation rod 30); 5:20-26 (the device as in claim 1 of the '903 patent, wherein the "fixation apparatus comprises a spherical head and a press ring, wherein said spherical head and said press ring are adapted to be received in said through hole with said press ring resting on said spherical head, and said spherical head and said press ring will be pressed securely in the fixation seat by the fixation rod, when the fixation block is joined with said fixation seat"); FIGS. 8 and 9; *See* Ex. 1009, Vito Decl. ¶ 41.  Lin FIG. 9 |

| **'989 Patent Claim 7** | **Rendered Obvious by Lin (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 6**, wherein | *See* claim 6 above. |
| a surface of the head that engages the second surface of the seat cap includes a generally dome-shaped contour, and the second surface of the seat cap includes a complementary contour in a manner permitting sliding articulation of the head within the tulip when the screw is not tight. | Lin teaches that a surface of the head that engages the second surface of the seat cap ('press ring 422' – blue) includes a generally dome-shaped contour, and the second surface of the seat cap includes a complementary contour (shown in FIG. 9) in a manner permitting sliding articulation of the head within the tulip when the screw is not tight. Ex. 1003 at 3:49-54; 3:59-63 ("The press ring 422 is rested on the spherical head 420 to secure the spherical head 420, and is pressed by the fixation rod 30. The fixation rod 30 is then fastened by the fixation block 20."); 5:20-26 ("fixation apparatus comprises a spherical  Lin FIG. 9 |

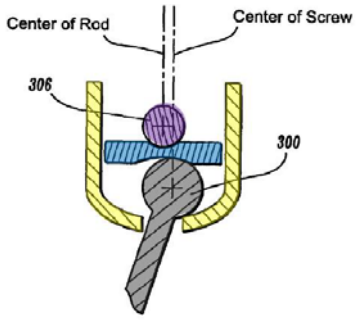
| '989 Patent Claim 7 | Rendered Obvious by Lin (exemplary excerpts below) |
|---|---|
| | head and a press ring, wherein said spherical head and said press ring are adapted to be received in said through hole with said press ring resting on said spherical head, and said spherical head and said press ring will be pressed securely in the fixation seat by the fixation rod, when the fixation block is joined with said fixation seat"); FIGS. 8 and 9. *See* Ex. 1009, Vito Decl. ¶ 42.   Lin FIG. 8 (excerpt) |

### 2. Lin Renders Obvious Claims 8-11 in View of the Knowledge in the Art (Ground 1), in View of the APA (Ground 2), and/or in View of Errico (Ground 3)

Petitioner notes that the cited prior art references all relate to designs for pedicle screws for use in an orthopedic rod system. As the '989 patent itself acknowledges, several different designs for pedicle screw systems were already well known in the art at the time of the claimed invention. *See* Ex. 1001 at 1:23-25. Further, "[a] person of ordinary creativity [is] not an automaton" and "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420-21 (2007). A POSITA would have been motivated to look to the teachings of Lin and the other prior art references disclosing pedicle screw designs in implementing a pedicle screw system and would have found it obvious design choice in doing so to arrive at the purported invention. *See* Ex. 1009, Vito Decl. ¶¶ 47-60.

**a. Overview of the APA**

As disclosed in the '989 patent itself and depicted in Figure 10 of the '989 patent, it was known in the prior art to have a seat cap (blue) on the head of the fastener ('300'—gray), with the seat cap having a U-shaped contour to accommodate a rod ('306'—purple).



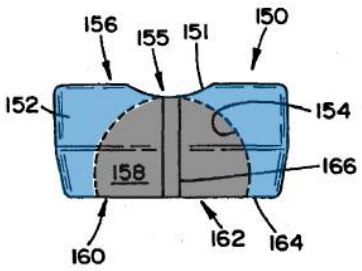
'989 Patent: **FIG. 10 (Prior Art)**

**b. Overview of Errico**

U.S. Patent No. 5,669,911 to Errico et al., entitled "Polyaxial Pedicle Screw" (Ex. 1004) was filed on June 13, 1996 and issued on September 23, 1997, making it prior art to the '989 patent under at least § 102(b).

Like the '989 patent and Lin, Errico has a tulip (shown in yellow below) and a locking cap (shown in orange). While Errico discloses a threaded locking cap, a POSITA would have found it obvious to apply Errico's other features in a pedicle screw system having a non-threaded locking cap and tulip with grooves (such as those taught in Lin), as a routine design choice. *See* Ex. 1009, Vito Decl. ¶¶ 52-60.

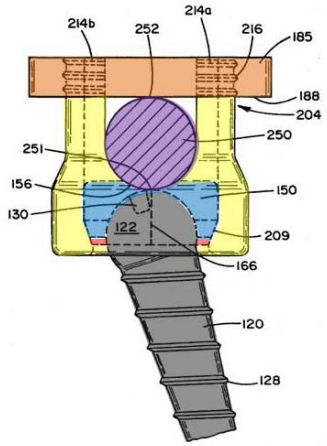
Like the '989 patent and Lin, Errico also describes a polyaxial pedicle screw for use in an orthopedic fixation system. Errico describes a pedicle screw (shown in gray) with a threaded shaft and a spherical head and a U-shaped receiving member (shown in blue) with an axial, cylindrical bore that tapers at the bottom. *See* Errico,



Errico FIG. 5

Ex. 1005 at FIGS. 5 & 6, 3:48-51; 7:3-15; 7:44-50. In a preferred embodiment of Errico, the head has a greater diameter than the shaft so that the shaft may pass through a hole at the base of the coupling device but the head may not. *Id.* at 6:61-67; *see* Ex. 1009, Vito Decl. ¶¶ 52.

Errico also discloses a cylindrical, tapered locking collar (shown in blue) shaped so that it may "slide loosely" from the top of the axial bore in the coupling element to the bottom. Ex. 1005 at 3:49-51. The locking collar has a semi-circular interior surface "ideally suited for holding therein the semi-spherical head of the screw." *Id.* at 3:31-32; *see id.* at FIG. 5.



Errico FIG. 9

When the screw and the unlocked locking collar of Errico are assembled into the coupling element the screw and the collar "remain free to swing relative to one another." *Id.* at 3:42-44; *see also* FIG. 9. Forcing the locking collar of Errico downward then "causes the interior surface of the collar to contract against the head of the screw, thereby crush locking the two elements together." *Id.* at 3:44-46.

**c. Combination of Lin with either the APA or Errico**

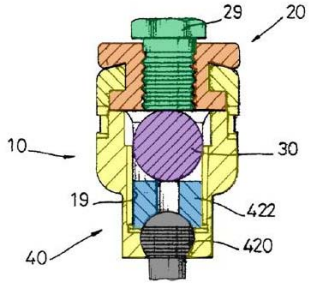
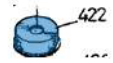
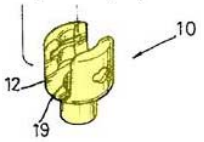
A POSITA would have been motivated to combine Lin with the APA disclosed in Figure 10 of the '989 patent, including without limitation, to take advantage of the U-shaped contour in the seat cap to accommodate the rod. *See* Ex. 1009, Vito Decl. ¶¶ 47-51. The same holds true for the combination of Lin with the

U-shaped contour of the seat cap to accommodate the rod in Errico. *See id.* ¶ 56.

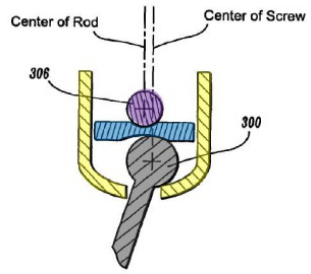
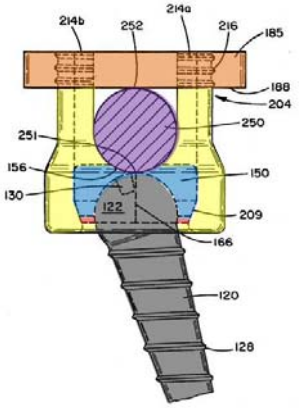
Because the seat cap is functionally independent of whether the cap is threaded or non-threaded, a POSITA would have understood that these cap designs were interchangeable. In particular, a POSITA would have been motivated to combine the tulip and cap of Lin with the seat cap surface, seat ring, and fastener in the Errico pedicle screw design because non-threaded locking caps were known to solve the problem of cross-threading, while threaded caps, such as the cap disclosed in Errico, were known to back out. *See, e.g.*, Ex. 1003, Lin, at 1:11-13, 1:37-45; Ex. 1004, Errico, at FIG. 9; *see* Ex. 1009, Vito Decl. ¶¶ 26, 54. The combination of the Lin tulip and cap design with Errico's seat cap, seat ring, and fastener design amounts to the use of known techniques to improve a similar device in the same way. *See, e.g.*, MPEP 2143(c); Ex. 1009, Vito Decl. ¶¶ 53-60.

### D. Claims 8-11: Rendered Obvious by Lin (Ground 1), Rendered Obvious by Lin in View of APA (Ground 2) and Rendered Obvious by Lin in View of Errico (Ground 3)

As detailed in the charts below, Lin, the APA, and Errico disclose and render obvious (in the exemplary excerpts and cites below and throughout) each and every limitation of claims 8-11, thus rendering asserted claims 8-11 unpatentable as obvious under § 103. In addition to rendering obvious claims 8-11 as discussed below, the combination of Lin and Errico would also render obvious claims 6 and 7, from which claims 8-11 depend.

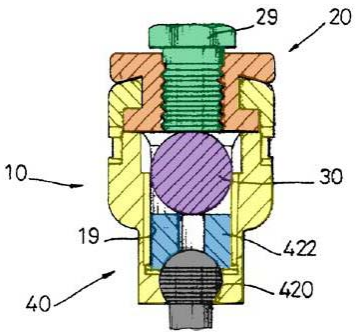
| **'989 Patent Claim 8** | **Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 7**, wherein | *See* claim 7 above.<br><br>The elements of Lin have been colored according to the following key:<br><br>Tulip ('fixation seat 10') is yellow;<br>Cap ('fixation block 20') is orange;<br>Screw ('fastening bolt 29') is green;<br>Rod ('fixation rod 30') is purple;<br>Fastener ('fixation screw 42') is gray;<br>Seat Cap ('press ring 422') is blue.<br><br>  <br><br>Lin FIG. 9 |
| the first surface of the seat cap includes a U-shaped contour that complements and engages a contour of the rod in a manner permitting sliding and rotational articulation of the rod within the tulip when the screw is not tight. | See also discussion for claim 5 above in § V.1.b.<br><br>  <br><br>Lin FIG. 8 (excerpt)<br><br>**Lin**: The slots of the tulip ('fixation seat 10') of Lin are U-shaped to accommodate the rod. Ex. 1003 at FIGS. 2, 8, and 9; *see* Ex. 1009, Vito Decl. ¶ 28.[7]<br><br>  <br><br>Lin FIG. 8 (excerpt)<br><br>* * *<br><br>**'989 Admitted Prior Art**: The '989 patent acknowledges |

[7] A POSITA would have found it obvious to include a U-shaped contour on the first surface (the top surface) of the seat cap ('press ring 422') disclosed in Lin as a routine design choice, just as the slots of the tulip ('fixation seat 10') of Lin are U-shaped to accommodate the rod—to advantageously distribute the stress from the rod to the seat cap across more surface area of the rod and cap, thus reducing lateral buckling and failure risks. Ex. 1003 at FIGS. 2, 8, 9; *see* Ex. 1009, Vito Decl. ¶ 43.

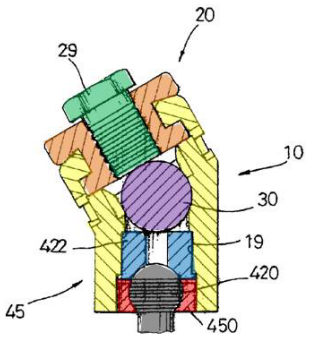
| **'989 Patent Claim 8** | **Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below)** |
|---|---|
| | that the claimed seat cap (blue) with a U-shaped contour that complements and engages a contour of the rod (purple) in a manner permitting sliding and rotational articulation of the rod was known in the prior art. *See* Ex. 1001 at FIG. 10 (Prior Art).[8]<br>  <br><br>'989 Patent: **FIG. 10 (Prior Art)**<br>* * *<br>**Errico**: Errico teaches a seat cap ('locking collar 150' – blue) having a U-shaped first (top) surface. Ex. 1004 at FIGS. 5 and 9; 7:13-15 ("the top surface 156 of the collar 150 may also comprise a pair of *opposing notches 151 which are curvate and ideally suited for the rod 250 to seat thereon*"); 9:55-60 ("the rod is locked between the bottom surface 188 of the locking device 185 and top surface 156 of the locking collar 150. This locking prevents the rod 250 from sliding relative to the assembled structure (along an axis which is perpendicular to the plane of FIG. 9). The full insertion of the top locking nut 185, therefore, locks the rod 250 in the channel of the receiving member 200 as well as the screw<br>  <br><br>Errico FIG. 9 |

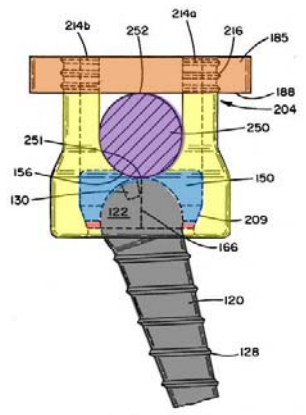
[8] A POSITA would have found it obvious to incorporate the U-shaped first (top) surface of the seat cap, as in the admitted prior art, in implementing Lin to advantageously complement the shape of the rod for the reasons discussed above. *See* Ex. 1009, Vito Decl. ¶¶ 28, 50.

| '989 Patent Claim 8 | Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below) |
|---|---|
| | 120 within the locking collar 150."). *See* Ex. 1009, Vito Decl. ¶ 52.[9] |

| '989 Patent Claim 9 | Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below) |
|---|---|
| The apparatus of **claim 8**, further comprising | *See* claim 8 above. |
| a seat ring having an annular configuration defined by inside and outside surfaces and opposing first and second open ends,<br><br>the inside surface being sized and shaped to receive and permit articulation of the head when the screw is not tight,<br><br>the second open end having a diameter | *See also* discussion for claim 5 above in Section V.C.1.b.<br><br>**Lin** further discloses a seat ring ('assembly ring 450' – red). *See, e.g.*, Ex. 1003 at FIG. 10. The seat ring ('assembly ring 450' – red) has an annular configuration defined by inside and outside surfaces and opposing first and second open ends. *See id.* at 3:63-4:7 ("As shown in FIG. 10, a second spherical head fixation apparatus 45 is used in conjunction with the fixation seat 10 and an assembly ring 450. The head 420 is joined with the assembly ring 450 before the fixation screw 42 (shown in FIG. 8) is fastening onto a<br><br>  <br><br>Lin FIG. 9 |

[9] To the extent Lin's disclosed seat cap ('press ring 422'), does not include a U-shaped first surface, it would also have been obvious to apply Errico's teaching of a seat cap ('locking collar 150' – blue) having a U-shaped first (top) surface for the reasons discussed above. Ex. 1004 at FIG. 5; Ex. 1009, Vito Decl. ¶ 56.

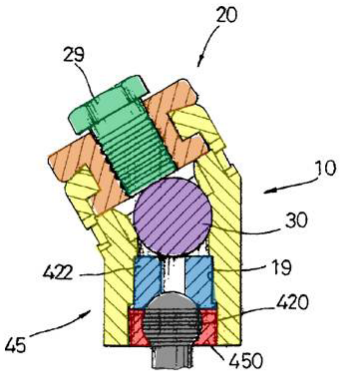
| **'989 Patent Claim 9** | **Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below)** |
|---|---|
| sufficiently large to permit the threaded shaft to extend therethrough but not sufficiently large to permit the head to pass therethrough, and<br><br>an outside surface being sized and shaped to engage the inner wall of, and prevent the head from extending through, the second open end of the tulip. | bone. The press seat 422 is joined with the assembly ring 450, thereby enclosing the head 420 . . . . In order to fixedly connect the assembly ring 450 to the fixation seat 10, threads may be formed on the inner wall of the through hole 19 and on the outside surface of the assembly ring 450."); FIGS. 8-10.<br><br>  <br><br>Lin FIG. 10<br><br>The inside surface of the seat ring is sized and shaped to receive and permit articulation of the head when the screw ('fastening bolt 29' – green) is not tight. *See id.*<br><br>The second open end of the seat ring has a diameter sufficiently large to permt the threaded shaft (of 'fixation screw 42' – gray) to extend therethrough, but is not sufficiently large to permit the head ('420' – gray) to pass therethrough. *See id.*<br><br>The outside surface of the seat ring being sized and shaped to engage the inner wall of, and prevent the head from extending through, the second open end of the tulip. *See id.* |

| '989 Patent Claim 9 | Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below) |
|---|---|
| | *See also* Ex. 1009, Vito Decl. ¶¶ 30, 44, 57.[10]<br><br>* * *<br><br>**Errico** also discloses a seat ring (red) at the distal end of the seat cap ('locking collar 150' – blue). Ex. 1004 at 7:6-12 ("[t]he locking collar 150 comprises a slotted and tapered cylindrical body 152 having a semi-spherical interior surface 154").<br><br>The seat ring (bottom (red) of 'locking collar 150' – blue) disclosed in Errico has an annular configuration defined by inside and outside surfaces and opposing first and second open ends. Ex. 1004 at 7:6-12 ("[t]he top surface 156 of the locking collar 150 has an opening 155 through which the screwdriving tool which is used to insert the screw 120 into the bone may access and rotate the screw 120 through the collar 150"); 7:20-26 ("the annular lip 164 defines the circular opening which has a diameter less than the diameter of the semi-spherical head of the screw").<br>  <br><br>Errico FIG. 9 |

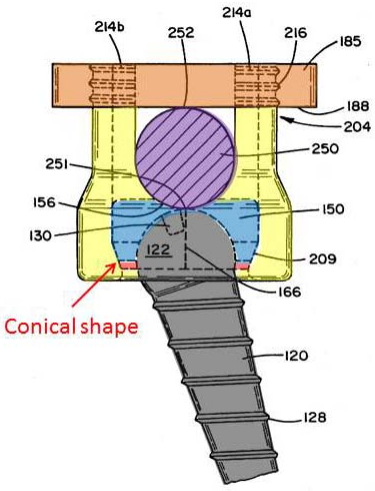
[10] While the claimed seat ring is at least obvious in view of Lin, to the extent it is argued that Lin fails to disclose this in any respect, a POSITA would have found it obvious to apply a seat ring in implementing Lin to advantageously distribute the load from the fastener head to the tulip in a more controlled and predictable way and allow for a greater lock-down force. *See* Ex. 1009, Vito Decl. ¶ 44-45.

| **'989 Patent Claim 9** | **Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below)** |
|---|---|
| | The inside surface of the seat ring disclosed in Errico is sized and shaped to receive and permit articulation of the head when the screw is not tight, and the second open end has a diameter sufficiently large to permit the threaded shaft to extend therethrough, but is not sufficiently large to permit the head to pass therethrough, and the outside surface is sized and shaped to engage the inner wall of, and prevent the head from extending through, the second open end of the tulip. Ex. 1004 at 7:15-18 ("[t]he interior semi-spherical volume is ideally suited for holding the head portion 122 of the screw 120, and permitting the screw 120 to rotate through a range of angles"); 7:20-25 ("It is understood that the head of the screw is held within the interior semi-spherical volume by the relative size of the head as compared with the openings. More specifically, the annular lip defines the circular opening which has a diameter less than the diameter of the semi-spherical head of the screw."); 3:16-24 ("the lower portion [of the assembly ring] has an axially tapered interior surface portion for retaining, and providing radial compression force against the slotted and tapered locking collar. The locking collar 150 initially flexibly retains the head 122 of the polyaxial screw, but upon compression downward along the tapered portion of the receiving member, the locking collar 150 compresses inwardly to lock the head of the screw."). *See* Ex. 1009, Vito Decl. ¶¶ 55-59.[11] |

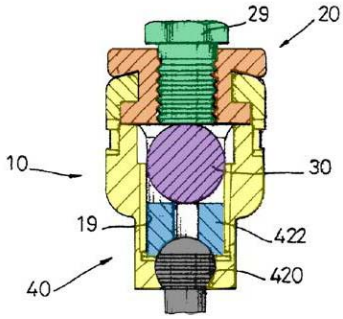
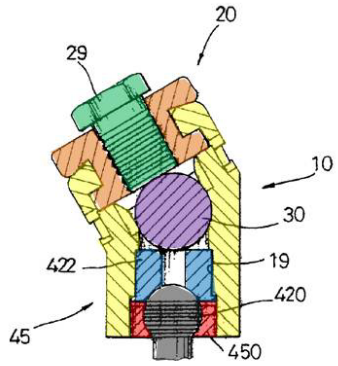
[11] While the claimed seat ring is at least obvious in view of Lin, to the extent it is argued that Lin fails to disclose this in any respect, the seat ring is disclosed by Errico and a POSITA would have found it obvious to apply Errico's teaching of a seat ring in implementing Lin for the reasons discussed above. *See* Ex. 1009 ¶¶ 44-45, 55-59.

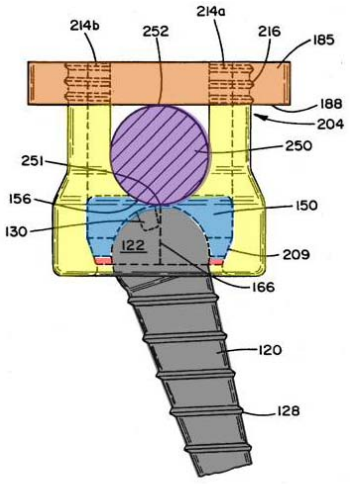
| **'989 Patent Claim 10** | **Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 9**, wherein: | *See* claim 9 above. |
| the inner wall of the tulip includes a conical surface formed annularly about the open second end thereof; and<br><br>the outside surface of the seat ring is sized and shaped to slidingly engage the conical surface and permit articulation of the head of the fastener when the screw is not tight. | *See also* discussion for claim 5 above in Section V.C.1.b.<br><br>**Lin** discloses that the inner wall of the tulip ('fixation seat 10' – yellow) includes a conical surface formed annularly about the open second end. Ex. 1003 at FIG. 9. Lin also discloses a seat ring that is sized and shaped to slidingly engage the inner surface of the tulip and permit articulation of the head of the fastener when the screw is not tight. *Id.* at FIG.10; 3:63-4:1 ("As shown in FIG. 10, a second spherical head fixation apparatus 45 is used in conjunction with the fixation seat 10 and an assembly ring 450. The head 420 is joined with the assembly ring 450 before the fixation screw 42 (shown in FIG. 8) is fastening onto a bone. The press seat 422 is joined with the assembly ring 450, thereby enclosing the head 420.").[12]<br><br>  <br>Lin FIG. 10 |

[12] While the claimed seat ring is obvious in view of Lin, to the extent it is argued that Lin fails to disclose this in any respect, it would have been obvious to a POSITA to apply implement the claimed seat ring and a conical surface of the tulip to distribute the load from the fastener head to the tulip in a more controlled and predictable way and allow for a greater lock-down force. *See* Ex. 1009 ¶¶ 44-45, 55-59.

| | |
|---|---|
| | * * *<br><br>**Errico** discloses that the inner wall of the tulip ('receiving member 200' – yellow) includes a conical surface formed annularly about the open second end. Ex. 1004 at FIG. 9. Errico also discloses a seat ring (bottom (red) of 'locking collar 150' – blue) that is sized and shaped to slidingly engage the inner surface of the tulip and permit articulation of the head of the fastener when the screw is not tight. *Id.* at FIG. 9; 3:16-24 ("the lower portion [of the assembly ring] has an axially tapered interior surface portion for retaining, and providing radial compression force against the slotted and tapered locking collar. The locking collar initially flexibly retains the head of the polyaxial screw, but upon compression downward along the tapered portion of the receiving member, the locking collar compresses inwardly to lock the head of the screw."); 7:6-8 ("The locking collar 150 comprises a slotted and tapered cylindrical body 152 having a semi-spherical interior surface 154."); 7:15-18 ("The interior semi-spherical volume 158 is ideally suited for holding the head portion 122 of the screw 120, and permitting the screw to rotate through a range of angles.").[13]<br>  <br><br>Errico FIG. 9 |

[13] While the claimed seat ring is obvious in view of Lin, to the extent it is argued that Lin fails to disclose this in any respect, the seat ring is disclosed by Errico and a POSITA would have found it obvious to apply Errico's teaching of a seat ring in implementing Lin for the reasons discussed above. *See* Ex. 1009 ¶¶ 44-45, 55-59.

| **'989 Patent Claim 11** | **Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 10**, wherein | *See* claim 10 above. |
| tightening the screw into the bore of the cap causes:<br><br>(i) a distal end of the screw to engage and urge the rod against the first surface of the seat cap;<br><br>(ii) the second surface of the seat cap to engage and urge the head of the fastener toward and engage the inside surface of the seat ring; and<br><br>(iii) the outside surface of the seat ring to engage the conical surface of the tulip, such that the cap, the rod, the seat cap, the head of the fastener, and the tulip are rigidly fixed and locked into position. | *See also* discussion for claim 5 above in Section V.C.1.b.<br><br>**Lin**: In the apparatus disclosed in Lin, tightening the screw ('fastening bolt 29' – green) into the bore of the cap ('fixation block 20' – orange) causes (i) the distal end of the rod against the first surface of the seat cap; and (ii) the second surface of the seat cap ('fixation block 20') to engage and urge the head of the fastener toward and engage the inside surface of the seat ring. Lin at FIG. 9; 3:33-36 ("The fixation rod 30 is held securely in the fixation seat 10, when it is pressed against by the fastening bolt 29 which is engaged with the threaded through hole 28 of the fixation block 20."). *See* Ex. 1009, Vito Decl. ¶ 40.<br><br>In the apparatus disclosed in Lin, tightening the screw ('fastening bolt 29' – green) into the bore of the cap also causes (iii) the outside surface of the seat ring ('assembly ring 450' – red) to engage the conical surface of the tulip ('fixation seat 10' – yellow), such that the cap ('fixation block 20' – orange), the rod ('fixation rod 30' – purple), the seat cap ('press ring 422' – blue), the head ('420') of the fastener ('fixation screw 42' – gray), and the tulip ('fixation seat 10' – yellow) are rigidly fixed and locked into position. Lin at FIGS. 9 and 10; Lin at 3:63-4:7 ("As shown in FIG. 10, a second spherical head fixation apparatus 45 is<br><br>  <br>Lin FIG. 9<br><br>  <br>Lin FIG. 10 |

| '989 Patent Claim 11 | Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below) |
|---|---|
| | used in conjunction with the fixation seat 10 and an assembly ring 450. The head 420 is joined with the assembly ring 450 before the fixation screw 42 (shown in FIG. 8) is fastening onto a bone. The press seat 422 is joined with the assembly ring 450, thereby enclosing the head 420. The press seat 422 and the assembly ring 450 together the head 420 are received in the through hole 19 of the fixation seat 10. In order to fixedly connect the assembly ring 450 to the fixation seat 10, threads may be formed on the inner wall of the through hole 19 and on the outside surface of the assembly ring 450."). *See* Ex. 1009, Vito Decl. ¶¶ 41-42.<br><br>* * *<br><br>**Errico**: In the apparatus disclosed in Errico, tightening the locking device causes (i) the distal end of the rod ('rod 250' – purple) to press against the first surface of the seat cap ('locking collar 150' – blue); and (ii) the second surface of the seat cap ('locking collar 150' – blue) to engage and urge the head of the fastener toward and engage the inside surface of the seat ring (bottom (red) of 'locking collar 150' – blue). Errico at FIG. 9; 4:15-33 ("If a rod is disposed in the channel, the downward translation of the locking device provides a corresponding downward force onto the rod. The downward force on the rod translates into a downward force on the locking collar causing it to be forced downward into the tapered bottom of the bore . . . . This relative motion of the locking collar into the tapered bottom of the bore causes the rod to seat against the curved bottom of the channel,<br>  <br><br>Errico FIG. 9 |

| '989 Patent Claim 11 | Rendered Obvious by Lin, Rendered Obvious by Lin in view of APA, and Rendered Obvious by Lin in view of Errico (exemplary excerpts below) |
|---|---|
| | the screw to be angularly locked in the locking collar, and the locking collar to be locked within the bottom of the receiving member."); *see* Ex. 1009, Vito Decl. ¶ 52.<br><br>In the apparatus disclosed in Errico, tightening the locking device also causes (iii) the outside surface of the seat ring ('locking collar 150' – blue) to engage the conical surface of the tulip ('receiving member 200' – yellow), such that the cap ('locking device 185' – orange), the rod ('rod 250' – purple), the seat cap ('locking collar 150' – blue), the head of the fastener ('screw 120' – gray), and the tulip ('receiving member 200' – yellow) are rigidly fixed and locked into position. Errico at FIG. 9; 9:55-60 ("the rod is locked between the bottom surface 188 of the locking device 185 and the top surface 156 of the locking collar 150. This locking prevents the rod 250 from sliding relative to the assembled structure (along an axis which is perpendicular to the plane of FIG. 9). The full insertion of the top locking nut 185, therefore, locks the rod 250 in the channel of the receiving member 200, as well as the screw 120 within the locking collar 150."); *see* Ex. 1009, Vito Decl. ¶ 60.[14] |

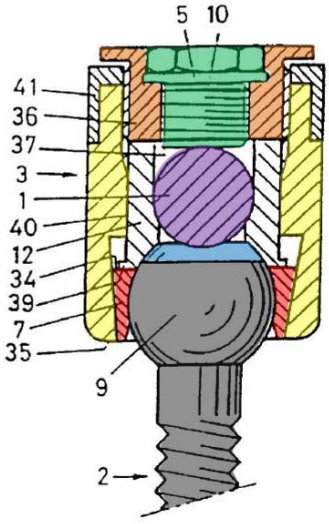
[14] While the claimed seat cap and seat ring combination are obvious in view of Lin, to the extent it is argued that Lin fails to disclose this in any respect, the seat cap and seat ring combination are disclosed by Errico and a POSITA would have found it obvious to apply Errico's teaching of a seat cap and seat ring combination in implementing Lin for the reasons discussed above. *See* Ex. 1009, Vito Decl. ¶¶ 44-46, 53-60.

### 1. Schläpfer '090 in View of Schläpfer '262 Renders Obvious Claims 1, 2 and 5-11 (Ground 4)

U.S. Patent No. 6,063,090 to Schläpfer *et al.* ("Schläpfer '090"), "Device for Connecting a Longitudinal Support to a Pedicle Screw" (Ex. 1005), issued on May 16, 2000, making it prior art to the '989 patent under at least § 102(b). U.S. Patent No. 6,077,262 to Schläpfer et al. ("Schläpfer '262"), "Posterior Spinal Implant" (Ex. 1006), issued on June 20, 2000, making it prior art to the '989 patent under at least § 102(b). Like the '989 patent and other prior art discussed above, Schläpfer '090 and Schläpfer '262 relate to a device for the connection of a longitudinal rod with a bone anchoring element. Ex. 1005, Schläpfer '090 at Abstract; Ex. 1006, Schläpfer '262 at Abstract. *See* Ex. 1009, Vito Decl. ¶¶ 61-63.

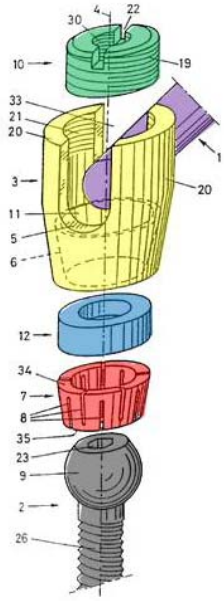
#### a. Overview of Schläpfer '090

Similar to the designs discussed above and as shown in Figure 7 of Schläpfer '090 (depicting a cross-section of a cap, tulip, and fastener), Schläpfer '090 discloses a fastener ('pedicle screw 2'—gray) with a fastener head ('pedicle screw head 9'—gray). The fastener is screwed into a vertebra. A tulip ('retainer head 3'—yellow) containing a seat ring ('spring chuck 7'—red) and a seat cap (unlabeled—blue) is placed over the fastener head ('pedicle screw head 9'—gray) and the seat ring encloses the fastener head – retaining the fastener head in the tulip ('retainer head 3'—yellow).



Schläpfer '090 FIG. 7

The seat cap (blue) sits on top of the fastener head ('pedicle screw head 9'—gray) and has a U-shaped contour for receiving a rod and a dome-shaped contour corresponding to the dome shaped contour of the fastener head. The tulip ('retainer head 3'—yellow) has two slots to receive the rod ('longitudinal support 1'—purple). The rod ('longitudinal support 1'—purple) slides over and rests upon a U-shaped contour in the seat cap (blue). A screw ('tension means 10'—green), which screws into a cap ('tensioning screw 36'—orange), is screwed into the top of the tulip ('retainer head 3'—yellow) to enclose the rod ('longitudinal support 1'—purple). The cap ('tensioning screw 36'—orange) has two shoulders that rotate longitudinally to slide over and overlie the tulip ('retainer head 3'—yellow)—reaching to the periphery of the lip of the tulip. Alternatively, as shown in Figure 1, the screw ('tension means 10'—green) can be used without the cap ('tensioning screw 36'—orange in FIG. 7). *See* Ex. 1009, Vito Decl. ¶¶ 63, 67-76.



Schläpfer '090 FIG. 1

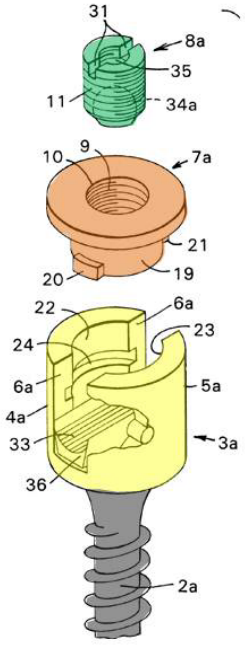
As taught in Schläpfer '090, when the screw ('tension means 10'—green) is tightened, it presses down on the rod ('longitudinal support 1'—purple), which presses down on the seat cap (blue—insert 12 in Figure 1), which presses down on the fastener head ('pedicle screw head 9'—gray), which presses down on the seat ring ('spring chuck 7'—red), which presses down on the conical slope of the inner wall of

the tulip ('retainer head 3'—yellow). Thus, tightening the screw ('tension means 10'—green) locks both the rod ('longitudinal support 1'—purple) and the fastener head ('pedicle screw head 9'—gray) into place. *See* Ex. 1009, Vito Decl. ¶¶ 78.

During prosecution of the '989 patent, Schläpfer '090 was considered by the Patent Office. In the interview summary that led to the Notice of Allowance during prosecution, the examiner noted that, "Applicant also pointed out that Schlapfer I and II [U.S. Patent No. 6,248,105 and Schläpfer '090] do not have all the claimed limitations, in particular shoulders that are capable of being received into the first and second slots." Ex. 1002 at 26. As discussed below, however, another patent from the same lead inventor (Schläpfer '262)—which the Patent Office did not consider—does expressly teach such a cap, whose shoulders are capable of being received into the first and second slots.

**b. Overview of Schläpfer '262**

Schläpfer '262 teaches an alternative cap ('tensioning screw 36'— orange ) to the cap of Schläpfer '090. As shown in Figure 2 of Schläpfer '262, the cap ('closure 7a'—orange) is cylindrical and has two shoulders ('studs 20, 21') on the bottom of the cylinder. The cap ('closure 7a'—orange) is designed to fit into a tulip ('head 3a'—yellow) similar to the tulip ('retainer head 3'—yellow) of Schläpfer '090. However, rather than screwing the cap



Schläpfer '262 FIG. 2

('closure 7a'—orange) into the tulip ('head 3a'—yellow) (as was done with the cap ('tensioning screw 36'—orange ) and tulip ('retainer head 3'—yellow) in Schläpfer '090), Schläpfer '262 teaches instead that the tulip has two slots in either side of the tulip and two grooves ('arcuate channels such as 24') in the sides of the tulip, such that the shoulders of the cap ('closure 7a'—orange) is dropped down into the slots of the tulip and rotated into the grooves to lock the cap into place. *See* Ex. 1009, Vito Decl. ¶¶ 64-65. Just as with Schläpfer '090 (*e.g.*, FIG. 7), Schläpfer '262 teaches a screw ('fastener 8a'— green) that is screwed into the cap ('closure 7a'— orange). *See* Ex. 1009, Vito Decl. ¶¶ 61-65.

**c. Combination of Schläpfer '090 and Schläpfer '262**

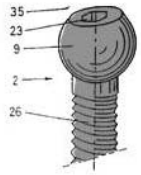
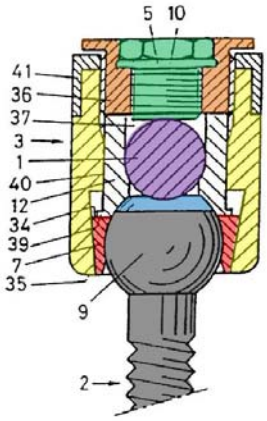
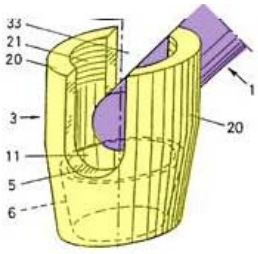
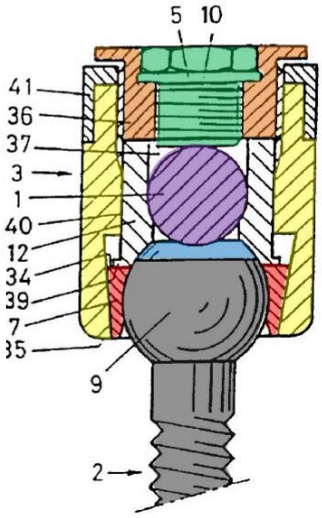
A POSITA would have found it obvious to combine Schläpfer '090 and Schläpfer '262. As taught in Schläpfer '262, the non-threaded cap disclosed in Schläpfer '262 was specifically provided as an alternative to threaded caps such as the cap of Schläpfer '090 ('tensioning screw 36'—orange ) as described in the background and summary of the invention in Schläpfer '262. (Ex. 1006 at 1:19-2:5.) It would have thus been obvious to combine the references from this express teaching of Schläpfer '262, and it would have also been obvious because non-threaded locking caps were known to solve the problem of cross-threading and thus a POSITA would have been motivated to use a non-threaded cap to lock with the tulip. *See* Ex. 1009, Vito Decl. ¶¶ 65-66. The combination amounts to the use of known techniques to

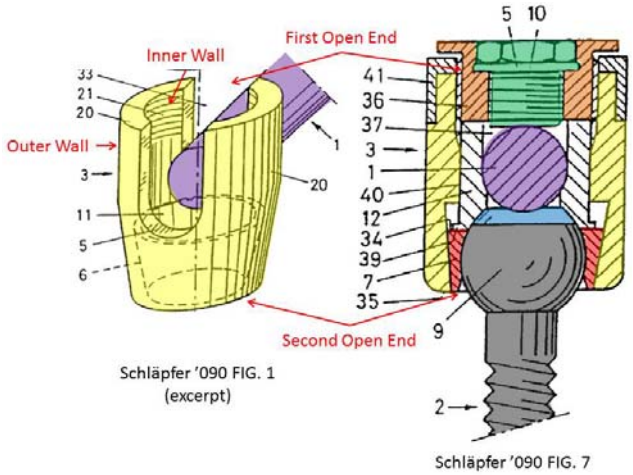
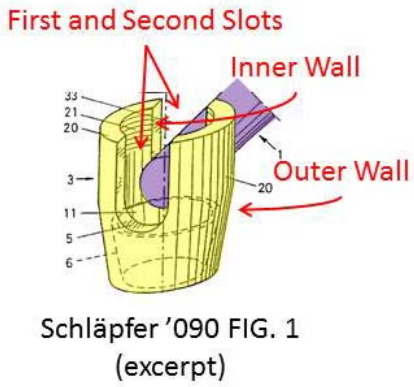
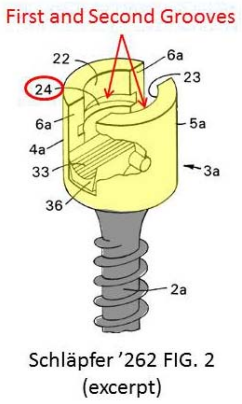
improve a similar device in the same way. *See, e.g.*, MPEP 2143(c); Ex. 1009 ¶¶ 65-66.

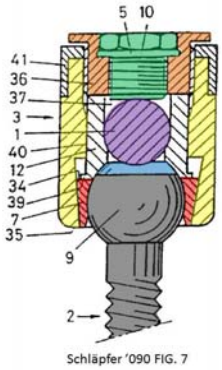
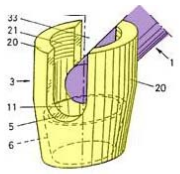
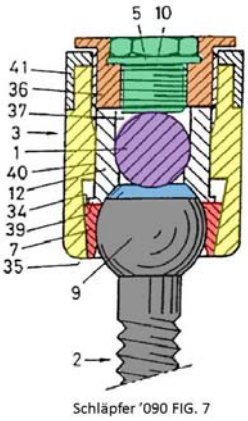
### d. Claims 1, 2, and 5-11: Rendered Obvious by Schläpfer '090 in View of Schläpfer '262 (Ground 4)

As detailed in the charts below, Schläpfer '090 in view of Schläpfer '262 discloses and renders obvious (in the exemplary excerpts and cites below and throughout) each and every limitation of the challenged claims, thus rendering asserted claims 1, 2, and 5-11 unpatentable as obvious under § 103.

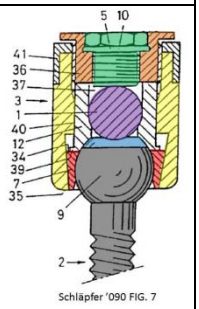
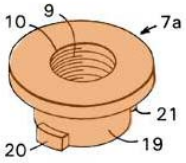
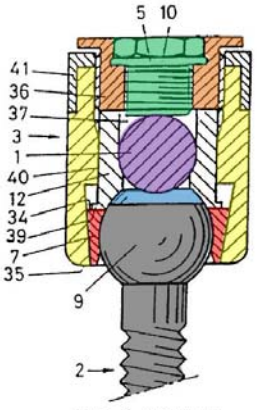
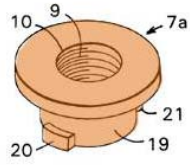
| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| An apparatus for bridging one or more vertebrae of a spine, the apparatus comprising: | To the extent the preamble is limiting:<br><br>**Schläpfer '090** discloses an apparatus for bridging one or more vertebrae of a spine, stating that "[t]he invention relates to a spinal fixation system, and in particular to a device for connecting a longitudinal support to a pedicle screw." Ex. 1005 at 1:5-7; FIGS. 1 and 7; *see* Ex. 1009, Vito Decl. ¶ 63.<br><br>The elements of **Schläpfer '090** have been colored according to the following key:<br><br>Tulip ('retainer head 3') is yellow;<br>Cap ('tensioning screw 36') is orange;<br>Screw ('tension means 10') is green;<br>Rod ('longitudinal support 1') is purple;<br>Fastener ('pedicle screw 2') is gray; and<br>Seat Cap (FIG. 1: 'insert 12' / FIG. 7: not labeled) is blue.<br><br>The elements of **Schläpfer '262** are colored as follows:<br><br>Tulip ('head 3a') is yellow;<br>Cap ('closure 7a') is orange. |

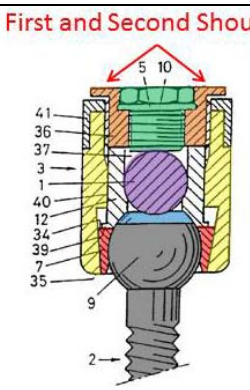
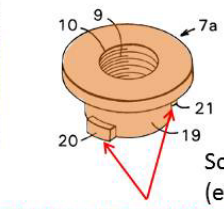
| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| **a fastener** having a threaded shaft adapted to be driven into the vertebrae and a head at a proximal end of the shaft; | **Schläpfer '090** discloses a fastener ('pedicle screw 2' – gray) having a threaded shaft adapted to be driven into the vertebrae and a head ('spherical head 9') at a proximal end of the shaft. Ex. 1005 at FIGS. 1 and 7; 6:1-3 ("spherical head 9 of the pedicle screw 2"). *See* Ex. 1009, Vito Decl. ¶ 63.<br>  <br>Schläpfer '090 FIG. 1 (excerpt)<br>  <br>Schläpfer '090 FIG. 7 |
| **a tulip** having: | **Schläpfer '090** discloses a tulip ('retainer head 3'—yellow). Ex. 1005 at FIGS. 1 and 7; 6:8-10 ("The acceptance of the longitudinal support 1 in the retainer head 3 can be realized as shown in FIG. 1 through a upwardly open channel 5"). *See* Ex. 1009, Vito Decl. ¶ 63.<br>  <br>Schläpfer '090 FIG. 1 (excerpt)<br>  <br>Schläpfer '090 FIG. 7 |
| (a) outer and inner walls defining opposing, and generally circularly open, first and second ends, | **Schläpfer '090**: The tulip ('retainer head 3'—yellow) of Schläpfer '090 has outer and inner walls defining opposing, and generally circularly open, first and second ends. Ex. 1005 at 4:16-21 ("The device according to the invention represented in FIGS. 1 and 2 essentially consists of a retainer head 3 with the central axis 4 and upwardly open channel 5 shaped as a yoke and running transversely to the central axis 4 as well as a downwardly open cavity 6 shaped |

| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| | as a truncated cone tapering downwardly with the central axis 4."); FIGS. 1 and 7; *See* Ex. 1009, Vito Decl. ¶ 67.   |
| (b) opposing first and second slots extending from the open first end toward the open second end, and | **Schläpfer '090**: The tulip ('retainer head 3'—yellow) of Schläpfer '090 has opposing first and second slots. Ex. 1005 at 4:17-21 ("upwardly open channel 5 shaped as a yoke and running transversely to the central axis 4"); FIGS. 1 and 2; Ex. 1009, Vito Decl. ¶68.   |
| (c) first and second grooves, each extending in opposing relation to one another along the inner wall from at least one of the first and second slots toward the other of the first and second slots, wherein: | **Schläpfer '262**: The tulip ('retainer head 3a' ) of Schläpfer '262 has first and second grooves ('two arcuate channels' '24'), each extending in opposing relation to one another along the inner wall from at least one of the first and second slots toward the other of the first and second slots. Ex. 1006 at FIG. 2; 3:55-62 ("Referring specifically to FIG. 2, …[i]n the inner walls 22, 23 of the legs 4a, 5a, of the U-shaped slot 6a, of head 3a, are provided two arcuate channels such as 24…. After the closure 7a has been axially inserted, it is rotated in the slot 6a and in the process the studs 20 and 21 are inserted into the channels   |

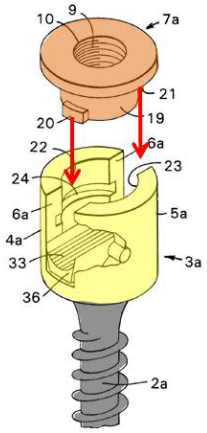
| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| | such as 24."). *See* Ex. 1009, Vito Decl. ¶ 69.[15] |
| (i) the head of the fastener is retained within the tulip and proximate to the second end thereof, with the threaded shaft extending out of the tulip through the second opening thereof, and | **Schläpfer '090** discloses that the head of the fastener ('pedicle screw 2'—gray) is retained within the tulip ('retainer head 3'—yellow) and proximate to the second end thereof, with the threaded shaft extending out of the tulip through the second opening thereof. Ex. 1005 at FIG. 7, 6:1-3; Ex. 1009, Vito Decl. ¶ 70.   Schläpfer '090 FIG. 7 |
| (ii) the opposing first and second slots are sized and shaped to receive a rod therethrough in a transverse orientation with respect to the threaded shaft of the fastener, such that the rod passes over the head; and | **Schläpfer '090** discloses that the first and second slots ('upwardly open channel 5') are sized and shaped to receive a rod thereth rough in a transverse orientation with respect to the threaded shaft of the fastener, such that the rod passes over the head. Ex. 1005 at FIGS. 1 and 7; 6:8-10 ("The acceptance of the longitudinal support 1 in the retainer head 3 can be  Schläpfer '090 FIG. 1 (excerpt)   Schläpfer '090 FIG. 7 |

[15] As detailed above, a POSITA would have found it obvious to substitute the means to engage the locking cap of Schläpfer '262 with the means to engage the locking cap of Schläpfer '090, such that the tulip ('retainer head 3'—yellow) of Schläpfer '090 has first and second grooves ('two arcuate channels' '24') of the tulip ('retainer head 3a') as taught in Schläpfer '262 to take advantage of the non-threaded cap to prevent cross-threading, for example. *See* Ex. 1009, Vito Decl. ¶¶ 64-66.

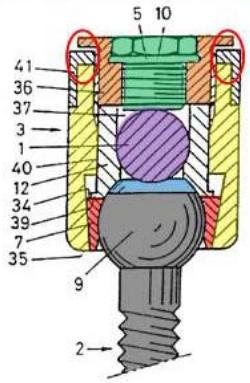
| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| | realized as shown in FIG. 1 through a upwardly open channel 5."). *See* Ex. 1009, Vito Decl. ¶ 71. |
| **a cap** including: | **Schläpfer '090** discloses a cap ('tensioning screw 36' —orange). Ex. 1005 at 6:1-2 ("The tensioning screw 36 is screwed into the retainer head …."); FIG. 7. *See* Ex. 1009, Vito Decl. ¶¶ 72-73, 76.<br>  <br>Schläpfer '090 FIG. 7<br>* * *<br>**Schläpfer '262** discloses a cap ('closure 7a'—orange). Ex. 1006 at FIG. 2; 3:51-57 ("In FIGS. 2-5, the closures are affixed to the head by bayonet locks rather than screws….Referring specifically to FIG. 2, the closure 7a is fitted with two diametrically opposite studs 20, 21 on its surface 19." *See* Ex. 1009, Vito Decl. ¶¶ 74-75.<br>  <br>Schläpfer '262 FIG. 2 (excerpt) |
| (a) a generally cylindrical body having first and second opposing ends, an outer surface, and a bore extending through the first and second opposing ends of the body along a central, longitudinal axis, | **Schläpfer '090**: The cap ('tensioning screw 36'—orange) disclosed in Schläpfer '090 has a generally cylindrical body having first and second opposing ends, an outer surface, and a bore extending through the first and second opposing ends. Ex. 1005 at FIG. 7; 6:1-2'; s*ee* Ex. 1009, Vito Decl. ¶¶ 72-73.<br>  <br>Schläpfer '090 FIG. 7<br>* * *<br>**Schläpfer '262**: The cap ('closure 7a' —orange) disclosed in Schläpfer '262 has a generally cylindrical body having first and second opposing ends, an outer surface, and a bore extending<br>  <br>Schläpfer '262 FIG. 2 (excerpt) |

| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| | through the first and second opposing ends. Ex. 1006 at FIG. 2; 3:51-57. |
| (b) first and second shoulders disposed in opposing relationship to one another proximate to the first end of the body, and extending radially away, and circumferentially along, the outer surface of the body,<br><br>(c) third and fourth shoulders disposed in an opposing relationship proximate to the second end of the body, and extending radially away, and circumferentially along, the outer surface of the body, wherein: | **Schläpfer '090** discloses a cap ('tensioning screw 36' — orange) that has first and second shoulders disposed in opposing relationship to one another proximate to the first end of the body, and extending radially away, and circumferentially along, the outer surface of the body. Ex. 1005 at FIG. 7; 6:1-2.<br><br>  <br>Schläpfer '090 FIG. 7<br><br>**Schläpfer '262** discloses a cap ('closure 7a'—orange) that has third and fourth shoulders ('two diametrically opposite studs 20, 21') disposed in an opposing relationship proximate to the second end of the body, and extending radially away, and circumferentially along, the outer surface of the body. Ex. 1006 at FIG. 2; 3:55-57 ("Referring specifically to FIG. 2, the closure 7a is fitted with two diametrically opposite studs 20, 21."). *See* Ex. 1009, Vito Decl. ¶¶ 74-75.[16]<br><br>  <br>Schläpfer '262 FIG. 2 (excerpt) |

[16] As discussed above, a POSITA would have found it obvious to include a cylindrical cap as taught by Schläpfer '090 and Schläpfer '262, having first and second top shoulders as taught by Schläpfer '090 and third and fourth bottom shoulders as taught by Schläpfer '262. *See* Ex. 1009, Vito Decl. ¶¶ 73-76. In addition to the first and second "top" shoulders being taught in the Schläpfer '090 at FIG. 7 (showing the

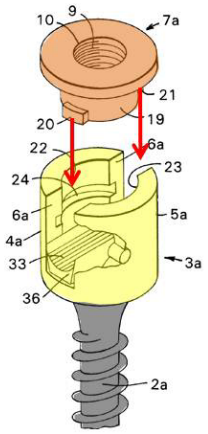
| **'989 Patent Claim 1** | **Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| the third and fourth shoulders are sized and shaped to be: (i) received into the first and second slots, respectively, to positions adjacent to the first and second grooves, respectively, and (ii) slidingly received into the first and second grooves by rotation of the cap about the longitudinal axis; and | **Schläpfer '262** discloses third and fourth shoulders ('two diametrically opposite studs 20, 21'—orange) that are sized and shaped to be (i) received into the first and second slots, respectively, to positions adjacent to the first and second grooves ('two arcuate channels' '24'—yellow), respectively, and (ii) slidingly received into the first and second slots by rotation of the cap about the longitudinal axis. Ex. 1006 at FIG. 2; 3:55-62 ("Referring specifically to FIG. 2, the closure 7a is fitted with two diametrically opposite studs 20, 21 on its surface 19. In the inner walls 22, 23 of the legs 4a, 5a, of the U-shaped slot 6a, of head 3a, are provided two arcuate channels such as 24, for said studs 20, 21. After the closure 7a has been axially inserted, it is rotated in the slot 6a and in the process the studs 20 and 21<br>  <br><br>Schläpfer '262 FIG. 2 (excerpt) |

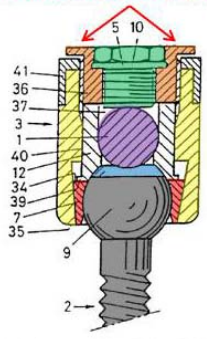
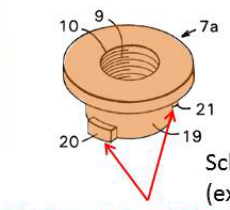
cross-section of the cap), a POSITA would have found it obvious to utilize first and second top shoulders similar in shape to the third and fourth shoulders ('two diametrically opposite studs 20, 21') located near the bottom end of the cap disclosed in FIG. 2 of the Schläpfer '262 patent – to take advantage lower manufacturing cost required to make the shoulders and allow compatibility with a broader range of tools. *See* Ex. 1009, Vito Decl. ¶ 73. This is a routine and predictable combination of well-known elements would have been understood by a POSITA to be a straightforward design choice and to yield a predictable result—rendering the claims obvious under § 103. *See, e.g.*, MPEP 2143(c); Ex. 1009, Vito Decl. ¶¶ 73-76.

| '989 Patent Claim 1 | Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below) |
|---|---|
| | are inserted into the channels such as 24."); *See* Ex. 1009, Vito Decl. ¶ 74.[17] |
| at least portions of the first and second shoulders are sized and shaped to slide over, and overlie, respective portions of a lip of the tulip at the periphery of the first open end of the tulip by the rotation of the cap about the longitudinal axis. | **Schläpfer '090** discloses that at least portions of the first and second shoulders (on 'tensioning screw 36'—orange) are sized and shaped to slide over, and overlie, respective portions of a lip of the tulip ('retainer head 3'—yellow) at the periphery of the first open end of the tulip by the rotation of the cap about the longitudinal axis. Ex. 1005 at FIG. 7; s*ee* Ex. 1009, Vito Decl. ¶ 76.[18]<br><br>First and Second Shoulders overlying Lip of Tulip at the Periphery of the First Open End<br>  <br><br>Schläpfer '090 FIG. 7<br><br>**Schläpfer '262** similarly discloses that, if the shapes of the third and fourth shoulders are used as the first and second |

[17] A POSITA would have found it obvious and a routine design choice to include a device with the cap ('closure 7a' —orange) and tulip ('retainer 3a'—yellow) of Schläpfer '262, with its corresponding shoulders and grooves, with the pedicle screw system otherwise disclosed in Schläpfer '090, for the reasons discussed above. *See* Ex. 1009, Vito Decl. ¶¶ 62, 64-66.

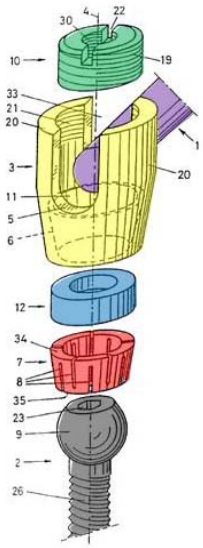
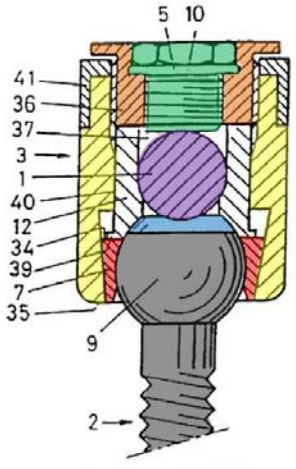
[18] To the extent it is argued that this element is not disclosed, it would have been an obvious design choice to model the shoulders of Schläpfer '090 after the shoulders in Schläpfer '262, as discussed above. *See* Ex. 1009, Vito Decl. ¶¶ 73-76.

| '989 Patent Claim 1 | Rendered Obvious by Schläpfer '090 in view of Schläpfer '262 (exemplary excerpts below) |
|---|---|
| | shoulders in place of the round top of the cap (as discussed above), then at least portions of the first and second shoulders would be sized and shaped to slide over, and overlie, respective portions of a lip of the tulip ('head 3a' —yellow) at the periphery of the first open end of the tulip by the rotation of the cap about the longitudinal axis. Ex. 1006 at FIG. 2; *See* Ex. 1009, Vito Decl. ¶¶ 75-76.<br>  <br><br>Schläpfer '262 FIG. 2 (excerpt) |

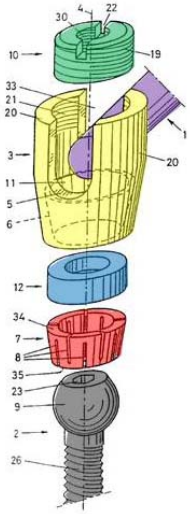
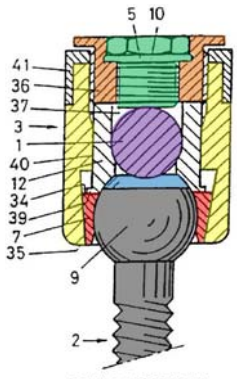
| '989 Patent Claim 2 | Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below) |
|---|---|
| The apparatus of **claim 1**, wherein | *See* claim 1 above. |
| the cap includes no further shoulders beyond the first, second, third, and fourth shoulders. | As explained *supra* for claim 1, a POSITA would have found it obvious to include a cap as taught by Schläpfer '090 and Schläpfer '262, having first and second shoulders as taught by Schläpfer '090 (opposing protrusions on 'tension screw 36'—<br>First and Second Shoulders<br>  <br><br>Schläpfer '090 FIG. 7<br>  <br><br>Schläpfer '262 FIG. 2 (excerpt)<br>Third and Fourth Shoulders |

| | |
|---|---|
| | orange) and third and fourth shoulders as taught by Schläpfer '262 ('two diametrically opposite studs 20, 21' on 'closure 7a'—orange). *See* Ex. 1009, Vito Decl. ¶¶ 64, 73-76. In addition to the first and second top shoulders being taught in the Schläpfer '090 at FIG. 7 (showing the cross-section of the cap), a POSITA would have found it obvious to utilize first and second top shoulders similar in shape to the third and fourth shoulders ('two diametrically opposite studs 20, 21') located near the bottom end of the cap disclosed in FIG. 2 of the Schläpfer '262 patent. *See* Ex. 1009, Vito Decl. ¶ 76. Such a cap would have no further shoulders beyond the first, second, third, and fourth shoulders—which imparts nothing novel to the pedicle screw system and constitutes a routine design choice. Ex. 1009, Vito Decl. ¶¶ 64, 65, 73-76. |

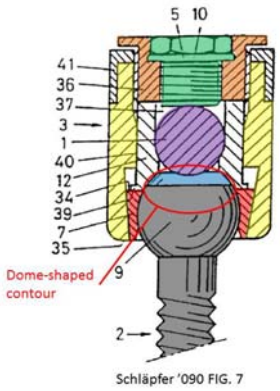
| **'989 Patent Claim 5** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 1**, further comprising | *See* claim 1 above. |
| a screw operating to thread into the bore of | **Schläpfer '090**: The apparatus for fixing a spinal column under treatment disclosed by Schläpfer '090 further |

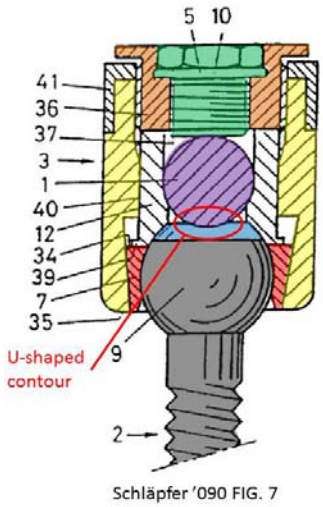
| **'989 Patent Claim 5** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| the cap, to urge the rod toward the second end of the tulip, and to tighten such that the rod, the head of the fastener, and the tulip are rigidly fixed and locked into position. | comprises a screw ('tension means 10'—green) that operates to thread into the bore of the cap, to urge the rod toward the second end of the tulip, and to tighten such that the rod, the head of the fastener, and the tulip are rigidly fixed and locked into position. Ex. 1005 at FIGS. 1 and 7; 4:35-50 ("The cavity 6 extends upwardly in the axial direction into the channel 5 so that the spring chuck 7, and the above lying insert 12, which is preferably formed as a hollow cylindrical member (e.g., in the shape of a washer), is pressable axially downwards via the longitudinal support 1 inserted in the channel 5—when the longitudinal support 1 is axially and rotationally fixed in the channel 5 by means of the tension means 10. At the same time as the downward axial displacement of the spring chuck 7 inside the cavity 6, which tapers conically downwards and is preferably shaped as a truncated cone, a spring chuck 7 compresses radially inward so that the head 9 of the pedicle screw 2, which was previously snapped into the spring chuck 7 from below, is jammed and fastened in its relative position to the retainer head 3 (and thus with the longitudinal support 1").<br><br>  <br>Schläpfer '090 FIG. 1<br><br>*See also, e.g.*, Ex. 1005 at 5:64-6:6 ("The variant of the device according to the invention shown in FIG. 7 demonstrates the application of a tension means 10 and a tensioning screw 36 in which a separate fixation of the longitudinal support 1 and the pedicle screw 2 is possible. The tensioning screw 36 is screwed<br><br>  <br>Schläpfer '090 FIG. 7 |

| **'989 Patent Claim 5** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| | into the retainer head and fastens only the spherical head 9 of the pedicle screw 2. Hence, the screw can be displaced along the longitudinal support with its spherical head fastened without varying the angle between longitudinal support 1 and pedicle screw 2."). *See* Ex. 1009, Vito Decl. ¶ 78. |

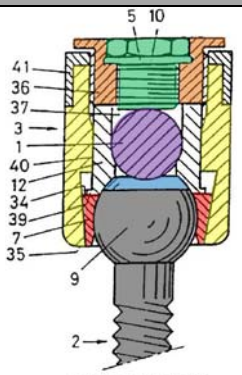
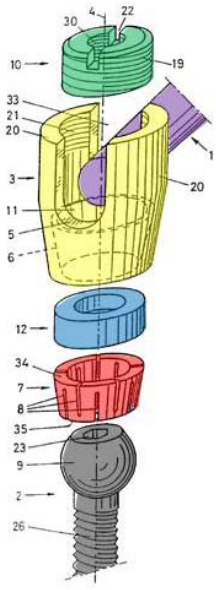
| **'989 Patent Claim 6** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 5**, further comprising | *See* claim 5 above. |
| a seat cap having first and second opposing surfaces disposed within the tulip, the first surface being oriented toward the first end of the tulip and operating to engage the rod, and the second surface being oriented toward the second end of the tulip and operating to permit sliding engagement with, and articulation of, the head when the screw is not tight. | *See also* discussion for claim 5 above in this Section V.3.d.<br><br>**Schläpfer '090**: The apparatus for fixing a spinal column under treatment disclosed by Schläpfer '090 further comprises a seat cap ('insert 12' in FIG. 1 and {not labeled} in FIG. 7—blue) which has first and second opposing surfaces disposed within the tulip. The first surface of the seat cap ('insert 12' in FIG. 1 and {not labeled} in FIG. 7—blue) is oriented toward the first end of the tulip and operates to engage the rod ('longitudinal support 1'—purple), and the second surface is oriented toward the second end of the tulip and operates to permit sliding engagement with, and articulation of, the head ('9' on 'pedicle screw 2'—gray) when the screw ('tension means 10' – green) is not tight. Ex. 1005 at FIG. 1 and 7; 4:35-50 ("The cavity 6 extends<br><br>  <br>Schläpfer '090 FIG. 1<br><br>  <br>Schläpfer '090 FIG. 7 |

| **'989 Patent Claim 6** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| | upwardly in the axial direction into the channel 5 so that the spring chuck 7, and the above lying insert 12, which is preferably formed as a hollow cylindrical member (e.g. in the shape of a washer), is pressable axially downwards via the longitudinal support 1 inserted in the channel 5—when the longitudinal support 1 is axially and rotationally fixed in the channel 5 by means of the tension means 10. At the same time as the downward axial displacement of the spring chuck 7 inside the cavity 6, which tapers conically downwards and is preferably shaped as a truncated cone, a spring chuck 7 compresses radially inward so that the head 9 of the pedicle screw 2, which was previously snapped into the spring chuck 7 from below, is jammed and fastened in its relative position to the retainer head 3 (and 50 thus with the longitudinal support 1"); *see* Ex. 1009, Vito Decl. ¶ 80-81. |

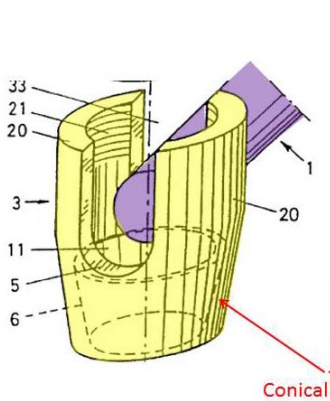
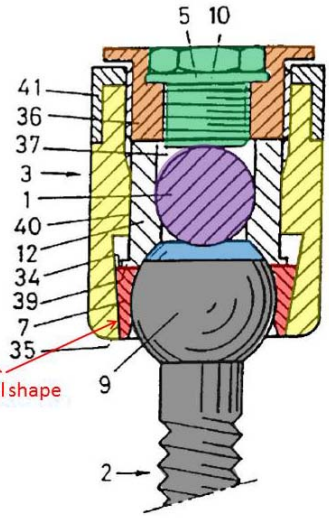
| **'989 Patent Claim 7** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 6**, wherein | *See* claim 6 above. |
| a surface of the head that engages the second surface of the seat cap includes a generally dome-shaped contour, and the second surface of the seat cap includes a complementary contour in a manner permitting sliding articulation of the head within the tulip when the screw is not tight. | *See also* discussion for claim 5 above in this Section V.3.d.<br><br>**Schläpfer '090** teaches that a surface of head ('9' of 'pedicle screw 2'—gray) that engages the second surface of the seat cap (blue) includes a generally dome-shaped contour, and the second surface of the seat cap includes a complementary contour in a manner permitting sliding articulation of the head within the tulip when the screw is not tight. Ex. 1005 at FIG. 7; *see* Ex. 1009, Vito Decl. ¶ 80-81.<br>  <br><br>Schläpfer '090 FIG. 7 |

| **'989 Patent Claim 8** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 7**, further comprising | *See* claim 7 above. |
| the first surface of the seat cap includes a U-shaped contour that complements and engages a contour of the rod in a manner permitting sliding and rotational articulation of the rod within the tulip when the screw is not tight. | *See also* discussion for claim 5 above in this Section V.3.d.<br><br>**Schläpfer '090**: The seat cap (blue) of Schläpfer '090 has a U-shaped first (top) surface that complements and engages a contour of the rod ('longitudinal support 1'—purple) in a manner permitting sliding and rotational articulation of the rod within the tulip ('retainer head 3'—yellow) when the screw ('tension means 10'—green) is not tight. Ex. 1005 at FIG. 7; *See* Ex. 1009, Vito Decl. ¶ 81.<br><br>  <br>Schläpfer '090 FIG. 7 |

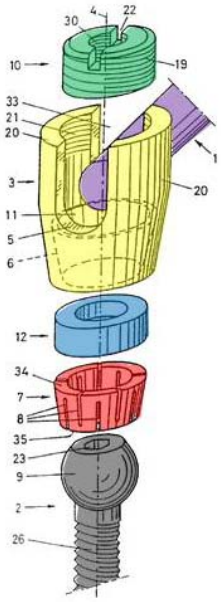
| **'989 Patent Claim 9** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 8**, further comprising | *See* claim 8 above. |
| a seat ring having an annular configuration defined by inside and outside surfaces and opposing first and second open ends,<br><br>the inside surface being sized and shaped to receive and permit articulation of the head | *See also* discussion for claim 5 above in this Section V.3.d.<br><br>**Schläpfer '090** further discloses a seat ring ('spring chuck 7'—red) having an annular configuration defined by inside and outside surfaces and opposing first and second open ends. Ex. 1005 at FIG. 7.<br><br>The inside surface of the seat ring of Schläpfer '090 is sized and shaped to received and permit articulation of the head ('9' of 'pedicle screw 2'—gray) when the screw ('tension means 10'—green) is not tight. *Id.* |

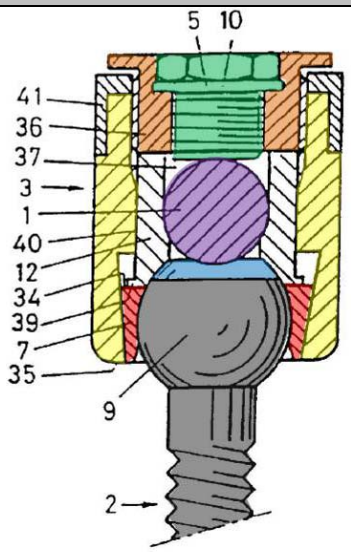
| **'989 Patent Claim 9** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| when the screw is not tight,<br><br>the second open end having a diameter sufficiently large to permit the threaded shaft to extend therethrough but not sufficiently large to permit the head to pass therethrough, and<br><br>an outside surface being sized and shaped to engage the inner wall of, and prevent the head from extending through, the second open end of the tulip. | Further, the second open end of the seat ring of Schläpfer '090 has a diameter that is sufficiently large to permit the threaded shaft to extend therethrough but not sufficiently large to permit the head to pass therethrough. *See* Ex. 1009, Vito Decl. ¶ 82.<br><br>An outside surface of the seat ring is sized and shaped to engage the inner wall of, and prevent the head ('9' of 'pedicle screw 2'—gray) from extending through, the second open end of the tulip. Ex. 1005 at 4:42-49 ("At the same time as the downward axial displacement of the spring chuck 7 inside the cavity 6, which tapers conically downwards and is preferably shaped as a truncated cone, a spring chuck 7 compresses radially inward so that the head 9 of the pedicle screw 2, which was previously snapped into the spring chuck 7 from below, is jammed and fastened in its relative position to the retainer head 3 (and thus with the longitudinal support 1)."<br><br>  <br>Schläpfer '090 FIG. 7<br><br>  <br>Schläpfer '090 FIG. 1 |

| **'989 Patent Claim 10** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| The apparatus of **claim 9**, wherein: | See claim 9 above. |
| the inner wall of the tulip includes a conical surface | See also discussion for claim 5 above in this Section V.3.d. |

| | |
|---|---|
| formed annularly about the open second end thereof; and<br><br>the outside surface of the seat ring is sized and shaped to slidingly engage the conical surface and permit articulation of the head of the fastener when the screw is not tight. | **Schläpfer '090** discloses that the inner wall of the tulip ('retainer head 3'—yellow) includes a conical surface formed annularly about the open second end thereof, and the outside surface of the seat ring ('spring chuck 7'—red) is sized and shaped to slidingly engage the conical surface and permit articulation of the head of the fastener when the screw ('tension means 10'—green) is not tight. Ex. 1005 at FIGS. 1 and 7; 4:42-49 ("At the same time as the downward axial displacement of the spring chuck 7 inside the cavity 6, which tapers conically downwards and is preferably shaped as a truncated cone, a spring chuck 7 compresses radially inward so that the head 9 of the pedicle screw 2, which was previously snapped into the spring chuck 7 from below, is jammed and fastened in its relative position to the retainer head 3 (and thus with the longitudinal support 1"). *See* Ex. 1009, Vito Decl. ¶ 83.<br><br>  <br><br>Schläpfer '090 FIG. 1 (excerpt)<br><br>  <br><br>Schläpfer '090 FIG. 7 |

| '989 Patent Claim 11 | Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below) |
|---|---|
| The apparatus of **claim 10**, wherein | See claim 10 above. |
| tightening the screw into the bore of the cap | See also discussion for claim 5 above in this Section V.3.d. |

| **'989 Patent Claim 11** | **Rendered Obvious by Schläpfer '090 and Schläpfer '262 (exemplary excerpts below)** |
|---|---|
| causes:<br><br>(i) a distal end of the screw to engage and urge the rod against the first surface of the seat cap;<br><br>(ii) the second surface of the seat cap to engage and urge the head of the fastener toward and engage the inside surface of the seat ring; and<br><br>(iii) the outside surface of the seat ring to engage the conical surface of the tulip, such that the cap, the rod, the seat cap, the head of the fastener, and the tulip are rigidly fixed and locked into position. | **Schläpfer '090**: In the apparatus disclosed, tightening the screw ('tension means 10'—green) into the bore of the cap causes (i) the distal end of the screw to engage and urge the rod ('longitudinal support 1'—purple) against the first surface of the seat cap ('insert 12'—blue); and (ii) the second surface of the seat cap to engage and urge the head ('9') of the fastener ('pedicle screw 2'—gray) toward and engage the inside surface of the seat ring ('spring chuck 7'—red); and (iii) the outside surface of the seat ring ('spring chuck 7'—red) to engage the conical surface of the tulip ('retainer head 3—yellow), such that the cap, the rod, the seat cap, the head of the fastener, and the tulip are rigidly fixed and locked into position. Ex. 1005 at FIG. 1; 4:35-50 ("The cavity 6 extends upwardly in the axial direction into the channel 5 so that the spring chuck 7, and the above lying insert 12, which is preferably formed as a hollow cylindrical member (e.g. in the shape of a washer), is pressable axially downwards via the longitudinal support 1 inserted in the channel 5—when the longitudinal support 1 is axially and rotationally fixed in the channel 5 by means of the tension means 10. At the same time as the downward axial displacement of the spring chuck 7 inside the cavity 6, which tapers conically downwards and is preferably shaped as a truncated cone, a spring chuck 7 compresses radially inward so that the head 9 of the pedicle screw 2, which was previously snapped into the spring chuck 7 from below, is jammed and fastened in its relative position to the retainer head 3 (and thus with the longitudinal support 1"). *See* Ex. 1009, Vito Decl. ¶¶ 84-85.<br><br>  <br>Schläpfer '090 FIG. 1 |

| ’989 Patent Claim 11 | Rendered Obvious by Schläpfer ’090 and Schläpfer ’262 (exemplary excerpts below) |
|---|---|
| | *See also, e.g.*, Ex. 1005 at FIG. 7; 5:64-6:6 (“The variant of the device according to the invention shown in FIG. 7 demonstrates the application of a tension means 10 and a tensioning screw 36 in which a separate fixation of the longitudinal support 1 and the pedicle screw 2 is possible. The tensioning screw 36 is screwed into the retainer head and fastens only the spherical head 9 of the pedicle screw 2. Hence, the screw can be displaced along the longitudinal support with its spherical head fastened without varying the angle between longitudinal support 1 and pedicle screw 2.”); *see* Ex. 1009, Vito Decl. ¶¶ 84-85.   Schläpfer ’090 FIG. 7 |

## VI. CONCLUSION

Petitioner respectfully submits that, for the reasons set forth above, there is, at a minimum, a reasonable likelihood that Petitioner will prevail on at least one claim of the challenged claims. Accordingly, Petitioner respectfully requests that this Petition be granted and claims 1, 2, and 5-11 of the ’989 patent be found unpatentable and canceled.

As identified in the attached Certificate of Service and in accordance with §§ 1.33(c), 42.105, and 42.100, a copy of the present Request, in its entirety, is being served on the Patent Owner at the correspondence address of record for the subject

patent as reflected in the publicly available records of the PTO as designated in the Office's Patent Application Information Retrieval system.

The Director is hereby authorized to charge any fee set in 37 C.F.R. § 42.15(a) for this Petition, and any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this proceeding by this firm) to our Deposit Account 18-1945, under Order No. 110432-0003-651.

Please direct all correspondence to the undersigned.

Date: February 11, 2014

Respectfully submitted,

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| United States Patent No.: 8,162,989 | § | Attorney Docket No.: 110432-0003-651 |
| Inventor: Farid Bruce Khalili | § | |
| Formerly Application No.: 10/693,698 | § | |
| Issue Date: Apr. 24, 2012 | § | Customer No. 28120 |
| Filing Date: Oct. 27, 2003 | § | |
| Former Group Art Unit: 3733 | § | Petitioner: Globus Medical, Inc. |
| Former Examiner: Mary C. Hoffman and Eduardo C. Robert | § | |

For: ORTHOPEDIC ROD SYSTEM

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**CERTIFICATE OF SERVICE**

It is certified that copies of the following documents have been served in their entirety on the patent owner as provided in 37 C.F.R. § 42.105:

Petition for *Inter Partes* Review of United States Patent No. 8,162,989.

| Exhibit | Description |
|---|---|
| Ex. 1001 | U.S. Patent No. 8,162,989 ("the '989 patent) |
| Ex. 1002 | U.S. Patent No. 8,162,989 File History |
| Ex. 1003 | U.S. Patent No. 6,786,903 ("Lin") |
| Ex. 1004 | U.S. Patent No. 5,669,911 ("Errico") |
| Ex. 1005 | U.S. Patent No. 6,063,090 ("Schläpfer '090") |
| Ex. 1006 | U.S. Patent No. 6,077,262 ("Schläpfer '262") |
| Ex. 1007 | International Patent Publication No. WO 01/52758 A1 to Yuan et al. ("Yuan") |
| Ex. 1008 | U.S. Patent App. Publ. No. 2006/0200128 to Mueller ("Mueller") |
| Ex. 1009 | Declaration of Raymond Vito |
| Ex. 1010 | Declaration of Marc A. Cavan |

The copy has been served on February 11, 2014 by causing the aforementioned document to be deposited in the United States Postal Service as Express Mail postage (EF 003 033 294 US and EF 003 033 317 US) pre-paid in an envelope addressed to:

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