IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Barry
U.S. Patent No.: 8,361,121 Attorney Docket No.: 108136.00040
Issue Date: January 29, 2013
Appl. Ser. No.: 12/857,320
Filing Date: August 16, 2010
Title: SYSTEM AND METHOD FOR ALIGNING VERTEBRAE IN THE AMELIORATION OF ABERRANT SPINAL COLUMN DEVIATION CONDITIONS

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,361,121 PURSUANT TO 35 U.S.C. §§ 311-319, 37 C.F.R. § 42

TABLE OF CONTENTS

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8 1

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

B. Related Matters Under 37 C.F.R. § 42.8(b)(2) 1

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3) 2

D. Service Information 2

II. PAYMENT OF FEES – 37 C.F.R. § 42.103 2

III. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104 2

A. Grounds for Standing Under 37 C.F.R. § 42.104(a) 3

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested 3

C. Claim Construction under 37 C.F.R. § 42.104(b)(3) 4

1. "spinal rod engagement means" (claims 1 and 3) 5

2. "spinal rod fixation means" (claim 1) 6

3. "handle means" (claim 1) 6

4. "mechanically linked" (claims 1 and 2) 8

5. "a second group of vertebrae" (claim 1) 8

6. "a second group of vertebrae lateral to the first group of vertebrae" (claim 1) 8

IV. SUMMARY OF THE '121 PATENT 9

A. Overview of the '121 Patent 9

B. Summary of the Prosecution History of the '121 Patent 10

C. Legal Standard for Obviousness 11

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE 12

A. Ground 1 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the Video, the Slides, and/or MTOS (collectively, "Lenke References") in view of the '928 Appl., the '568 Patent, the '349 Patent and, in the alternative, the '291 Appl. 12

B. Ground 2 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the '928 Appl. in view of the '568 Patent, the Video, the Slides and/or MTOS and the '349 patent and alternatively the '219 Appl. 37

VI. CONCLUSION 60

EXHIBITS

MSD 1001 – Declaration of Lawrence G. Lenke, M.D. Regarding U.S. Patent No. 8,361,121

MSD 1002 – Thoracic Pedicle Screws for Idiopathic Scoliosis Video (2001)

MSD 1003 – Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide presentation handout (2003)

MSD 1004 – U.S. Patent Application Publication No. 2003/0065328

MSD 1005 – U.S. Patent No. 5,219,349

MSD 1006 – U.S. Patent Application Publication No. 2005/0245928

MSD 1007 – U.S. Patent Application Publication No. 2005/0033291

MSD 1008 – Prosecution History of U.S. Patent No. 7,670,358

MSD 1009 – Prosecution History of U.S. Patent No. 7,776,072

MSD 1010 – Prosecution History of U.S. Patent No. 8,361,121

MSD 1011 – *Curriculum Vitae* of Lawrence G. Lenke, M.D.

MSD 1012 – Masters Techniques in Orthopaedic Surgery: The Spine, 2nd Edition

MSD 1013 – Krag et al., *An Internal Fixator for Posterior Application to Short Segments of the Thoracic, Lumbar, or Lumbosacral Spine*, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH, 203: 75-98 (February 1986)

MSD 1014 – W. Dick, *The "fixateur interne" As a Versatile Implant for Spine Surgery*, SPINE 12:882-900 (1987)

MSD 1015 – Olerud et al., *Transpedicular Fixation of Thoracolumbar Vertebral Fractures*, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 227:44-51 (1988)

MSD 1016 – Guyer et al., *The Wiltse Pedicle Screw Fixation System*, ORTHOPAEDICS 11:1455-1460 (1988)

MSD 1017 – Ebrahim Ameri et al., *Comparison of Harrington Rod and Cotrel-Dubousset Devices in Surgical Correction of Adolescent Idiopathic Scoliosis*, 18(3) TRAUMA MON. 134: 135 (2013)

MSD 1018 – P.J. Cundy et al., *Cotrel–Dubousset instrumentation and vertebral rotation in adolescent idiopathic scoliosis*, 72-B(4) J BONE JOINT SURG [Br] 670 (1990)

MSD 1019 – J. Dubousset, *C-D Horizon: A New Cotrel-Dubousset Instrumentation*, 25(6S) SPINE 85S: 85S-97S (2000)

MSD 1020 – U.S. Patent No. 7,670,358

MSD 1021 – U.S. Patent No. 7,776,072

MSD 1022 – U.S. Patent No. 8,316,121

MSD 1023 – Declaration of David Poley

MSD 1024 – Declaration of Ashley Owens

MSD 1025 – Transcript of Thoracic Pedicle Screws for Idiopathic Scoliosis Video (2001)

MSD 1026 – Declaration of Seth A. Kramer

MSD 1027 – U.S. Patent Application Publication No. 2005/0085813

MSD 1028 – U.S. Patent No. 6,565,568

MSD 1029 – *Stryker Corp. v. Zimmer, Inc.*, 774 F.3d 1349, 1356 (Fed. Cir. 2014)

MSD 1030 – *NuVasive Inc. v. Globus Med., Inc.*, 2013 WL 3705731 (D. Del. July 12, 2013)

MSD 1031 – Suk, et al., *Direct Vertebral Rotation: A New Technique of Three-Dimensional Deformity Correction with Segmental Pedicle Screw Fixation in Adolescent Idiopathic Scoliosis,*, 29:3 SPINE 343 (2004)

MSD 1032 – Medtronic, Inc. v. Barry, Case IPR2014-01210, Paper 10 (PTAB Feb. 10, 2015)

MSD 1033 – Medtronic, Inc. v. Barry, Case IPR2014-01211, Paper 8 (PTAB Feb. 10, 2015)

MSD 1034 – Medtronic, Inc. v. Barry, Case IPR2014-01212, Paper 9 (PTAB Feb. 10, 2015)

Medtronic, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of Claims 1-4 of U.S. Patent No. 8,361,121 (the "'121 pat.") (Exhibit MSD 1022). As set forth below, Petitioner demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one of claims 1-4 identified in this petition as being unpatentable.

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

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

Petitioner and Medtronic, plc are the real parties-in-interest for the petition.

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

Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '121 pat. Petitioner is the named defendant in litigation concerning the '121 pat., *Mark A Barry, MD v. Medtronic, Inc.*, filed in the Eastern District of Texas as Case No. 1:14-cv-00104-RC on February 18, 2014. The complaint was served on February 20, 2014.

On July 27, 2014, Petitioner filed a petition for i*nter partes* review requesting review of claims 1-4 of the '121 pat., now styled *Medtronic, Inc. v. Barry*, Case No. IPR2014-01211 ("'1211 IPR") (BJM). The '1211 IPR was denied by the Patent Trial and Appeal Board ("PTAB"), which generally found that the art presented included elements of the claims at issue, with one exception – a "handle means." Petitioner submits this Petition to further explain how the art cited in the '1211 IPR petition discloses the handle means. Additionally, Petitioner adds grounds based on prior art that was not presented in the '1211 IPR petition, and that explicitly discloses the claimed feature that the PTAB did not recognize as

being taught by the previously-presented art.

While Petitioner is mindful of 35 U.S.C. § 325(d), the denial of the '1211 IPR petition does not exclude this Petition because instead of containing "the same or substantially the same . . . argument previously presented to the Office," Petitioner is responding to a noted deficiency with new argument, new prior art, and new evidence supporting these new arguments. Further, the Petition is being filed within the one year period and the Petitioner has no other avenue to present these challenges because the rules prohibit new argument in a request for rehearing.

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

LEAD COUNSEL	BACK-UP COUNSEL
Jeff E. Schwartz, Reg. No. 39,019 1030 15th Street, NW Washington, DC 20005	Seth A. Kramer, Reg. No. 67,813 2000 Market Street, 20th Floor Philadelphia, PA 19103

D. Service Information

Please address all correspondence and service to both counsel listed above. Petitioner consents to service by email at jeschwartz@foxrothschild.com, skramer@foxrothschild.com, and ipdocket@foxrothschild.com (referencing Attorney Docket No. 108136.00040).

II. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the PTO to charge Deposit Account No. 50-1943 for any fees due as a result of the filing of the present petition.

III. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

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

Petitioner certifies the '121 pat. is eligible for IPR and Petitioner is not barred or estopped from requesting IPR. This petition is filed within a year of service of a complaint in district court litigation in which the '121 pat. was asserted.

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioner requests IPR of claims 1-4 of the '121 pat. on the grounds set forth in the table below and requests that each of the claims be found unpatentable.[1] A detailed explanation of the statutory grounds for the unpatentability of each claim is provided in the form of claim charts. Additional evidence supporting each ground is provided for in the Declaration of Lawrence G. Lenke, M.D. and its appendices.

Ground	Claims	Basis for Rejection
1	1-4	Obvious under 35 U.S.C. § 103 over the Thoracic Pedicle Screws for Idiopathic Scoliosis Video (the "Video"), the Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide handout (the "Slides"), and/or the Masters Techniques in Orthopaedic Surgery: The Spine, 2nd Edition ("MTOS") Chp. 17 (alone or in combination) (collectively "Lenke References") in view of U.S. 5,219,349 (the "'349 pat."), 2005/0245928 (the "'928 Appl."), U.S. 6,565,568 (the "'568 pat."), and U.S. 2005/0033291 (the "'291 Appl.")
2	1-4	Obvious under § 103 over the '928 Appl. in view of the Slides, MTOS Chp. 17, the '291 Appl., and the '349 pat., and the '568 pat.

[1] Some of these grounds include alternative combinations, as previously approved by the PTAB, citing to specific references and providing claim charts and narrative describing portions of the references relied upon. *See, e.g.*, *Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-00506, Paper 9, at 6-7 (PTAB Feb. 13, 2014).

The Video, the Slides, MTOS (published in November 2003[2]), the '349 pat., and the '568 pat. each qualify as prior art under at least 35 U.S.C. § 102(b) because they were published more than one year prior to Dec. 30, 2004. The '928 Appl. and the '291 Appl. each qualify as prior art at least under 35 U.S.C. § 102(e) because they were filed prior to Dec. 30, 2004.[3] None of these references were cited in a rejection during prosecution of the '121 pat. The '291 Appl. was cited in the Notice of Allowance; however, the disclosure of the '291 Appl. relied on in this Petition does not appear to have been considered by the USPTO. Additionally, the '928 Appl. was cited during prosecution of a related patent, U.S. 7,776,072 (MSD 1021). The USPTO did not take in to account alternative ways that one skilled in the art would understand the disclosure of the '928 Appl. to read on these claims at the time of invention.

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

With these constructions, Petitioner does not concede that the scope of the terms

---

[2] *See* Declaration of Seth A. Kramer (MSD 1026), at ¶¶ 2, 3.

[3] Claim 1 of the '121 patent is not entitled to a Dec. 30, 2004 priority date because of new matter in this claim regarding contouring and rotating a spinal rod that was not included in the parent application. *See* Lenke Decl. at ¶ 28. This matter was added in the application filed on Aug. 10, 2005. *See id.* Therefore, the earliest priority date for claim 1 is Aug. 10, 2005. Accordingly, the '291 Appl., published on Feb. 10, 2005, is prior art under 35 U.S.C. § 102(a) with respect to claim 1.

construed or other claim terms are reasonably certain to one of ordinary skill in the art. *See generally Nautilus, Inc. v. Bioig Instruments, Inc.*, 134 S.Ct. 2120 (2014). To the contrary, Petitioner believes that many of the terms are indefinite and reserves all rights to fully argue indefiniteness in the related litigation.

In an IPR, claim terms must be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). The claims terms are understood by their plain and ordinary meanings except where otherwise construed in the specification. Means-plus-function elements, as defined by 35 U.S.C. § 112, ¶ 6, are interpreted as being the structure disclosed to accomplish the described function, and all equivalents to this structure. Consistent with this standard, a proposed interpretation for certain claim terms is provided below. Petitioner does not concede that these terms should be construed the same way in a district court proceeding.

1. "spinal rod engagement means" (claims 1 and 3)

Under the broadest reasonable construction, the plain meaning of this term is "a structure for contacting or interfacing with a spinal rod." Patent Owner has contended in co-pending litigation that this element is in means plus function form. Petitioner disagrees that the broadest reasonable interpretation is so limited. However, if the Board decides that this term is a means plus function element, without agreeing or waiving any arguments and solely for purposes of this IPR the following alternative construction is ted. The broadest reasonable construction of the claimed function is engaging a screw to a spinal rod. The corresponding structure for this function is a structure forming at least a

portion of a passageway for receiving a rod for performing the claimed function. *See, e.g.*, '121 pat. at 4:7-10; 5:1-7; 5:66 to 6:3; Figs. 3 and 4. The term, in this alternative, encompasses this structure and equivalents pursuant to 35 U.S.C. § 112, ¶ 6.

2. "spinal rod fixation means" (claim 1)

Under the broadest reasonable construction, the plain meaning of the term "spinal rod fixation means" means "a component for fixing the rod in place." Patent Owner has contended in co-pending litigation that this is a means-plus-function element. Petitioner disagrees that the broadest reasonable interpretation is so limited. If the Board decides that this term is a means plus function element, without agreeing or waiving any arguments and solely for purposes of this IPR the following alternative construction is proposed. The claimed function is upon actuation, fixing the spinal rod member relative to the pedicle screw. The corresponding structure for performing the claimed function is a fixation element. *See, e.g.*, '121 pat. at 4:7-10; 5:1-7; 5:66 to 6:3; Figs. 3 and 4. The term, in this alternative, encompasses this structure, and equivalents pursuant to 35 U.S.C. § 112, ¶ 6.

3. "handle means" (claim 1)

Under the broadest reasonable construction, the term "handle means" means "a part that is designed especially to be grasped by the hand or that may be grasped by the hand." WEBSTER'S THIRD NEW INT'L DICT. 1027 (1993) ("WEBSTER'S"). The '121 pat. and its prosecution history are devoid of any justification for narrowing or otherwise departing from the ordinary meaning of handle means by limiting the handle means to "a part that is designed especially to be grasped by the hand," while excluding the remainder

of the ordinary meaning – "or that may be grasped by hand." The broadest reasonable construction necessarily includes both aspects of this common definition reflecting the ordinary meaning of "handle means" as found in other proceedings by the District Courts and the Federal Circuit. *See, e.g., Stryker Corp. v. Zimmer, Inc.*, 774 F.3d 1349, 1356 (Fed. Cir. 2014) (affirming that barrel of pistol-shaped device that "was at least *capable* of being held" read on construction of "handle") (emphasis in original); *NuVasive Inc. v. Globus Med., Inc.*, 2013 WL 3705731, at *5 (D. Del. July 12, 2013) (construing term "handle assembly" as "an assembly that *may* be grasped by hand") (emphasis added).

Limiting "handle means" to "a part that is designed especially to be grasped by the hand" could exclude the embodiment of Fig. 1 because – although it may be grasped by hand and is capable of such use -- the patent does not explicitly show how this embodiment is designed especially to be grasped by hand. Hence, that narrow construction would improperly exclude a preferred embodiment from the scope of the claims. Such a narrow construction is incorrect under the broadest reasonable construction standard applicable in this proceeding.

Patent Owner has contended in co-pending litigation that this element is in means plus function form. Petitioner disagrees that the broadest reasonable interpretation is so limited. However, if the Board decides that it is a means plus function element, without agreeing or waiving any arguments and solely for purposes of this IPR the following construction is proposed. The claimed function is facilitating application of manipulative forces to a first/second group of three or more pedicle screw engagement members, and mov-

ing each associated pedicle screw engagement member. The corresponding structure for performing the claimed function is a handle from which shafts extend or linked handles. *See, e.g.*, '121 pat. at 3:53 to 4:2; 5:10-35; Figs. 1, 3 and 5. The term encompasses these structures, and equivalents pursuant to 35 U.S.C. § 112, ¶ 6, that may be grasped by hand or capable of being held. Although the PTAB concluded this same term was not means plus function in the '358 pat., it reached a different conclusion as to this pat. *See* IPR1210 Decision, at 10.

4. "mechanically linked" (claims 1 and 2)

Under the broadest reasonable construction, the term "mechanically linked" means "joined by a physical connection or physically joined". This proposed construction is supported by Figure 1, showing the handles 34 joined to their respective shafts 36 by way of a physical connection; and by the dictionary definitions of "mechanical" ("caused by, resulting from, or relating to a process that involves a purely physical as opposed to a chemical change") and "link" ("to couple or connect by or as if by a connecting element"). WEBSTER'S 1317 and 1400-01 (1993).

5. "a second group of vertebrae" (claim 1)

Under the broadest reasonable construction, the term "a second group of vertebrae" means "multiple vertebrae at least in part different than the first group of vertebrae." *See, e.g.*, '121 pat. at Fig. 1.

6. "a second group of vertebrae lateral to the first group of vertebrae" (claim 1)

This phrase has no reasonably certain meaning because vertebra are not lateral to

each other, i.e., vertebrae are not located side by side but rather run one on top of the other along the spinal column. Although this phrase has no reasonably certain meaning, solely for purposes of this proceeding, it is presumed to refer to portions of vertebra, i.e. one side of a group of vertebrae lateral to another side, either left to right or right to left. This is consistent with Figure 1 of the '121 pat., which depicts the cross-linking member 40 connecting the first and second handle means, which as claimed, are positioned laterally to each other. *See* '121 pat. at 7:41-43.

IV. SUMMARY OF THE '121 PATENT

A. Overview of the '121 Patent

The application that issued as the '121 pat. was filed on August 10, 2005, and is a continuation-in-part of U.S. Patent Appl. Serial No. 11/027,026, since issued as U.S. Pat. No. 7,670,358 (the "'358 pat.") (MSD 1020). The '121 pat. describes a system and method for aligning vertebrae by applying manipulative forces on pedicle screws. The method generally sets out steps for the implantation of multiple pedicle screws, the engagement of these screws by a tool that includes pedicle screw engagement members and a handle, and transmitting force on a handle means to these engagement members to rotate the vertebrae. The '121 pat. claims the use of two tools located across the vertebrae from each other, where handles of the tools may be connected by a cross-linking member. The method also calls for the use of a pedicle screw and rod system, as was well known at the time of invention. Spinal rod members are contoured to follow the shape of a post-operative spinal column, engaged with the pedicle screws, and then rotated along their length and set in

place with the pedicle screw by fixation – the same method developed by Cotrel and Dubousset in the early 1980s.

The remaining claims of the '121 pat. are directed to a system containing the components described above.

B. Summary of the Prosecution History of the '121 Patent

The prosecution history of the '121 pat., the '072 pat., and the '358 pat., as obtained from PAIR, are submitted as Exhibit MSD 1010, MSD 1009, and MSD 1008, respectively.

During prosecution of the '072 pat., the claims were rejected numerous times by the United States Patent and Trademark Office ("USPTO"). Claims 1 and 2 were rejected over U.S. 6,090,113 (the "'113 pat."); and claims 3 and 4, which both required a rotation of a spinal rod member while engaged with implanted pedicle screws, were rejectedover the '113 pat. in combination with U.S. 5,281,223 (the "'223 pat."). In its rejection, the USPTO asserted that the '113 pat.'s disclosure of "two systems intended to be fixed, for example, to the same vertebrae of the column, one on each side of the median axis of the spinal column," anticipated the claimed first and second sets of pedicle screws being implanted in a first and second group of vertebrae, as well as the claimed first and a second pedicle screw cluster derotation tool. *See* MSD 1009 at 189. In rejecting claims 3 and 4, the USPTO noted that the '223 pat. disclosed the claimed step of rotating the spinal rod member while engaged to the pedicle screws, and that it would have been obvious to modify the method of the '113 pat. to include this rod rotation step disclosed in the '223 pat. "because of the benefit that the rotation of the rod has in achieving total alignment of the spinal col-

umn." *See id.* at 188. In a reply, the applicant noted that that the disclosure of the '113 pat. regarding the connection of pedicle screws by spinal rods was "nothing new, as pedicle screws are connected together in any number of prior art references." *See id.* at 123.

The USPTO then rejected claims 1 and 2 as being anticipated by the '928 Appl. The USPTO asserted that the knob 112a of the device disclosed in the '928 Appl. was the claimed handle means, and that "[e]ach of the pedicle screw engagement members (102a, 102b, 104) are configured for engaging with and transmitting manipulative forces applied to the first handle means (112a) to the head segments of one of the pedicle screws of the first set of pedicle screws (FIG. 11)." *See id.* at 55. The Applicant replied by amending the claims to require the first and second handle means move "each pedicle screw engagement member simultaneously." *See id.* at 35-36. The applicant argued that the twisting of the knob 112a would only result in the movement of at most two of the pedicle screw engagement members, and therefore, the '928 Appl. did not anticipate the claims. *See id.* at 41-42. The '072 patent issued on August 17, 2010. At no point during prosecution of the '072 patent did the USPTO indicate an appreciation that the '928 Appl. explicitly disclosed using that device to impart a force on the vertebrae perpendicular to the direction in which distraction or compression occurs, as in a spondylolisthesis reduction, which necessarily accomplishes simultaneous movement for scoliotic correction. *See* '928 Appl. at ¶ [0055].

C. Legal Standard for Obviousness

Under 35 U.S.C. § 103(a), a claim is invalid as being obvious if, at the time of invention, "the combined teachings of the prior art, taken as a whole, would have rendered the

claimed invention obvious to one of ordinary skill in the art." *In re Napier*, 55 F. 3d 610, 613 (Fed. Cir. 1995). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416, 127 S. Ct. 1727, 1739, 167 L. Ed. 2d 705 (2007). There is no requirement to find precise teachings directed to specific subject matter of a claim; common sense, inferences, and creative steps that a person of ordinary skill in the art would employ should be considered. *Id.* at 1741. The Board should apply common sense, recognizing that "familiar items may have obvious uses beyond their primary purposes, 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." *Id.* at 1742. If "a patent 'simply arranges old elements with each performing the function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 1740.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The challenged claims recite systems and methods for spinal column derotation having features that were well known prior to the filing date of the '121 pat., and that one of ordinary skill in the art would have found obvious to combine. *See e.g.,* Declaration of Lawrence G. Lenke, M.D. Regarding U.S. Patent No. 8,361,121 (hereinafter, the "Lenke Decl."), attached hereto as Exhibit MSD 1001, at ¶¶ 82-83. As detailed in claim charts below, prior art references render obvious the challenged claims of the '121 pat.

A. Ground 1 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the Video, the Slides, and/or MTOS (collectively, "Lenke References") in view of the '928 Appl., the '568 Patent, the '349 Patent and, in the al-

ternative, the '291 Appl.

As shown in the claim charts below, Claims 1-4 are obvious under § 103 over the Video, the Slides and/or MTOS (alone or in combination) in view of the '928 Appl., the '568 pat., and the '349 pat., and, in the alternative also the '291 Appl. The Video and Slides were distributed together to interested surgeons with no restrictions on redistribution at least at the Advanced Concepts in Spinal Deformity program in Colorado Springs, CO, on May 18-19, 2003. *See* Decl. of David Poley (MSD 1023) at ¶¶ 2, 3. Similarly, the Video, the Slides, and MTOS were distributed together to interested surgeons with no restrictions on redistribution at least at the Spinal Deformity Study Group Symposium 2003 in St. Louis, MO, on November 13-15, 2003. *See* Decl. of Ashley Owens (MSD 1024) at ¶¶ 3, 4. Thus, the Video, the Slides, and MTOS can be considered a single reference (collectively, the "Lenke References"). Alternatively, such concurrent distribution to those of ordinary skill in the art prior to the time of invention evidences that the three references, at the time of invention, were an obvious combination of complementary teachings directed to overlapping subject matter.

The PTAB previously held that the Lenke References disclosed the structures of claim elements 1[A], 1[B], 1[C], 1[F], and 1[E]. *See* 1211 IPR Decision, at 13; 1210 IPR Decision, at 25. The Lenke References each show a system, and its use, for treating and correcting deformities and injuries of the spine. Each of these references shows a procedure in which the surgeon performs a derotation of the patient's vertebrae to ameliorate a scoliotic deformity. As shown in the Lenke References, the surgeon selects a first set of

pedicle screws. Each pedicle screw has a threaded shank segment and a head segment, as well as a spinal rod engagement means for mechanically engaging with a spinal rod member, and a spinal rod fixation means for securing each of the pedicle screws and the spinal rod member in a substantially fixed relative position and orientation. As shown, the pedicle screws are implanted in a pedicle region of each of a first group of vertebrae.

The Lenke References each also show the use of a first pedicle screw cluster derotation tool in the form of multiple apical derotators used simultaneously. Each apical derotator includes a handle linked to and moving a pedicle screw engagement member that engages the head segment of a pedicle screw. While only two apical derotators are shown in the Video, it would have been obvious to one of ordinary skill in the art at the time of the invention to use three or more derotators simultaneously, depending on the number of vertebrae to be derotated. *See* Lenke Decl. at ¶¶ 90, 91. This is evidenced by the Slides and MTOS, each of which shows a derotation procedure similar to that shown in the Video being performed using three to four apical derotators on first and second sets of pedicle screws. Also, the specification of the '121 pat. does not attribute any criticality, inventiveness, or other significance to the simultaneous application of manipulative forces to three or more pedicle screw engagement members. The individual handles of each apical derotator that are shown in the Lenke References are configured to and may be grasped by a hand during the derotation procedure and moved as a single unit en masse, i.e., simultaneously, as the Video shows this being done. *See* Lenke Decl. at ¶¶ 40-43, 45-46, 49-51.

To the extent the Lenke References do not disclose that the handles of the apical

derotators are interconnected via a mechanical linkage, it would have been obvious to one of ordinary skill in the art to do so in view of the '928 Appl. *See id.*, at ¶¶ 92- 96. As detailed below in Ground 2, the '928 Appl. discloses a pedicle screw cluster tool that includes a handle means in the form of multiple handles linked together such that the handles and the attached pedicle screw engagement members move in unison in response to a downward or upward force applied to one or both handles. *See* § V.B., at 38-42, *infra* (detailed discussion of '928 Appl.'s disclosure of perpendicular force and use of knobs '928 Appl. to apply this perpendicular force) (incorporated here); Lenke Decl. at ¶¶ 55-57, 92-96 . Because this force is transferred to each of the pedicle screw engagement members, the downward force is subsequently transferred to each of the pedicle screws, thereby simultaneously placing a downward or upward pressure of each of the vertebrae. *See id.* To the extent the PTAB may decide that the '928 Appl. may not explicitly disclose a handle means that is designed especially to be grasped by a hand, as explained above, in the alternative, it would have been obvious to modify the device of the '928 Appl. to include the handle means of the '568 pat. *See id*; Lenke Decl. at ¶¶ 71, 92-96.

It would have been obvious to one of ordinary skill in the art to connect the handles shown in the Lenke References via a mechanical linkage, for safety and added mechanical advantage and to help ensure simultaneous and uniform transport of the pedicle screw engagement members while reducing or easing the workload on the surgeon, freeing up a hand to use for manipulating the rod into the screw head and subsequently securing the rod in place. *See* Lenke Decl. at ¶¶ 18, 85, 92-96. One of

ordinary skill in the art would be motivated to include this common mechanical linkage to distribute the force applied more evenly across the various screws and vertebral bodies to avoid damage to either the screws or the vertebral structures. *See id.* By so distributing the forces, it is less likely such unsafe conditions will arise, and a potential mechanical advantage is gained by the connecting handle acting as a lever in some instances. *See id.* The Lenke References already show the surgeon moving the handles simultaneously by hand. The addition of a mechanical linking member to connect the handles and achieve the same type of movement, but more safely and easily, would have been a simple and obvious modification at the time of invention in view of the express teachings of the '928 Appl., and the design incentives of easing the surgeon's workload, and achieving uniformity in the movement of the pedicle screw engagement members and the attached vertebral bodies. *See id.* The Video, the Slides, MTOS the '928 Appl., and the '568 pat. are from the same field of endeavor, and each of the devices disclosed therein could be used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebral bodies. *See* Lenke Decl., at ¶ 82. Each of these references specifically teach the application of compression and distraction, as well as rotation, of multiple vertebrae; therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including the treatment of scoliosis. *See* MTOS, at 18; '568 pat., at 2:17-21; '928 Appl., at ¶ [0055]; Lenke Decl. at ¶ 82. Thus, a spinal derotator incorporating the teachings of these references is nothing more than an obvious combination of known mechanical elements arranged in their described and conventional manner in re-

sponse to a known design incentive, to achieve predictable and commonly described results. *See KSR*, 550 U.S. at 418.

The PTAB held that the Lenke References disclosed a spinal rod member, and an engagement means and fixation means included in the pedicle screws for receiving and securing, respectively, the spinal rod member recited in related claims in the '358 pat. *See* 1210 IPR Decision, at 25. These references each show a spinal rod coupled to the pedicle screws. The Video and MTOS each disclose that prior to coupling, the spinal rod member is contoured with respect to the coronal and sagittal planes so as to define a post-operative alignment for the spinal column. The Video and MTOS show that the spinal rod is then placed in the spinal rod engagement means of each pedicle screw while the spinal rod member remains in this first rotational orientation.

The subsequent claimed step of rotating a rod substantially along its length to effect a correction of a spinal column deviation in reference to two axes was well-known to surgeons of ordinary skill in the art at the time of invention since Cotrel and Dubousset introduced it in the early 1980s. *See* Lenke Decl. at ¶¶ 17, 98; s*ee also* J. Dubousset, *C-D Horizon: A New Cotrel-Dubousset Instrumentation*, 25(6S) SPINE 85S: 85S-97S (2000) (MSD 1019); Ebrahim Ameri et al., *Comparison of Harrington Rod and Cotrel-Dubousset Devices in Surgical Correction of Adolescent Idiopathic Scoliosis*, 18(3) TRAUMA MON. 134: 135 (2013) (MSD 1017); P.J. Cundy et al., *Cotrel–Dubousset instrumentation and vertebral rotation in adolescent idiopathic scoliosis*, 72-B(4) J BONE JOINT SURG [Br] 670 (1990) (MSD 1018). In fact, MTOS refers to the rod rotation method of Cotrel and Dubousset, noting that the apical vertebral derotation ma-

neuver described in MTOS complements the rod rotation method, as rod rotation helped to translate the spine but did not fully derotate it. Therefore, MTOS renders obvious the combination of this well-known rod rotation maneuver and a derotation procedure using manipulative force simultaneously applied to screws as disclosed in MTOS, the Video, and the Slides. *See* Lenke Decl. at ¶¶ 98-99.

Alternatively, it would have been obvious to perform such a rod rotation step in view of the '291 Appl. The '291 Appl. provides for various systems and methods for straightening a scoliotic spine. One method involves a screw and rod system in which the rod is first contoured "in advance into a curved shape so as to follow a normal kyphosis of the thoracic spine in the spine restored to the normal state." '291 Appl. at ¶ [0146]. The '291 Appl. discloses that the rod, while in its first rotational orientation, is inserted into a notch of the head of the screw, and is then loosely tightened into place by a set screw. Once it is in this position, the rod is rotated around its length by a ratchet tool to a second rotational orientation to correct a spinal column deviation. The '291 Appl. further provides that shafts that engage with screws may be used after this rod rotation to impart more force on the screws, thereby placing the vertebrae in a final corrected position.

It would have been obvious to one of ordinary skill in the art of the time of invention to modify the method of derotating vertebrae shown in the Lenke References so that the spinal rod member is rotated along its length after it is engaged with the pedicle screws, to put the vertebrae in better alignment prior to final derotation with the derotator tool, and more specifically, to straighten the scoliotic spine while simultaneously generating a

normal kyphosis. *See* Lenke Decl. at ¶¶ 98-99. The Video, the Slides, MTOS and the '291 Appl. are from the same field of endeavor for fixing and manipulating vertebrae, and each of the devices disclosed therein could be used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebral bodies. *See* Lenke Decl., at ¶ 82. Thus, a spinal derotator incorporating the teachings of these references represents nothing more than an obvious combination of known mechanical elements arranged in their described and conventional manner in response to a known design incentive, to achieve predictable and commonly described results. *See KSR,* 550 U.S. at 418.

The Lenke References each disclose the second set of screws and the coupling of the second spinal rods to the second set of screws. To the extent the Video does not disclose the second pedicle screw cluster derotation tool having a second handle means and a second set of pedicle screw engagement members, and the application of force to this second handle means to simultaneously rotate the vertebrae, it would have been obvious to include such duplication in view of the Slides and MTOS. *See* Lenke Decl. at ¶¶ 103, 104. The Slides and MTOS each disclose a derotation procedure similar to that shown in the Video, and explicitly show the use of two pedicle screw cluster derotation tools. It would have been obvious to combine the teachings of the Video with those of the Slides and MTOS, because these references all show a similar derotation procedure in which force is applied simultaneously to multiple levels of vertebrae to solve an identical problem, namely a scoliotic spinal column. *See* Lenke Decl. at ¶¶ 82, 104.

To the extent the Video, the Slides, or MTOS do not show that the first and second

pedicle screw cluster derotation tools are linked to each other by a cross-linking member connected to the first and second handle means, it would have been obvious to do so in view of the express teachings of the '349 pat. The '349 pat. discloses a system and method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions, and incorporates the use of spinal fixation devices that utilize pedicle rod and screw systems. *See* '349 pat. at 6:41-57 (incorporating by reference: Krag et al., *An Internal Fixator for Posterior Application to Short Segments of the Thoracic, Lumbar, or Lumbosacral Spine*, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH, 203: 75-98 (February 1986) (MSD 1013); W. Dick, *The "fixateur interne" As a Versatile Implant for Spine Surgery*, SPINE 12:882-900 (1987) (MSD 1014); Olerud et al., *Transpedicular Fixation of Thoracolumbar Vertebral Fractures*, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 227:44-51 (1988) (MSD 1015); and Guyer et al., *The Wiltse Pedicle Screw Fixation System*, ORTHOPAEDICS 11:1455-1460 (1988) (MSD 1016)). Each pedicle screw is coupled to a respective first and second pedicle screw engagement means (shaft handle 14) that are mechanically linked to a respective first and second handle means (hinged extensions 136 of T-handle 100). These first and second handle means are connected by a cross-linking member (laterally extending arms 112) to satisfy the design incentive of "ensur[ing] that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle." '349 pat. at 5:4-8.

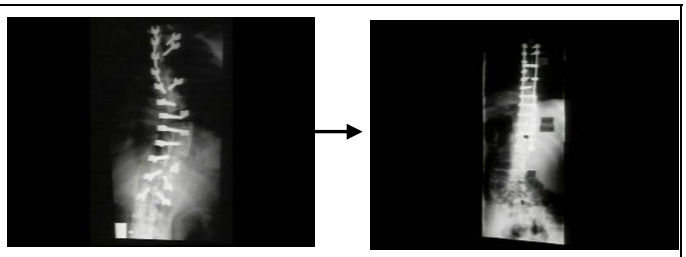
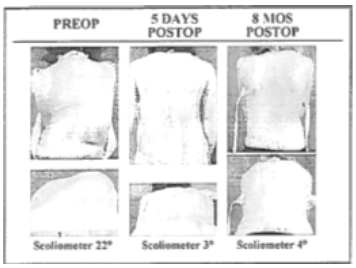
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the systems and methods shown in the Lenke References to include such a cross-linking member, in view of the express teaching of such a member in the '349

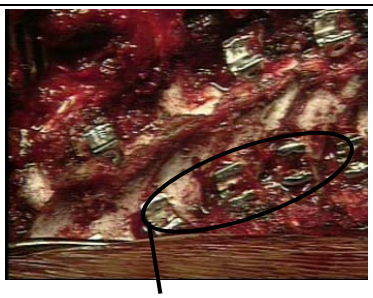
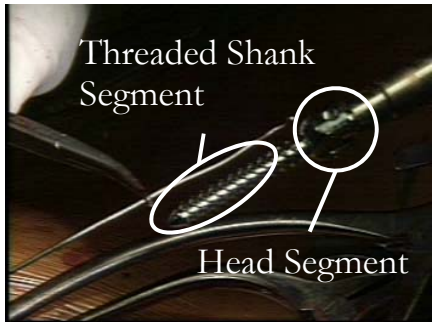
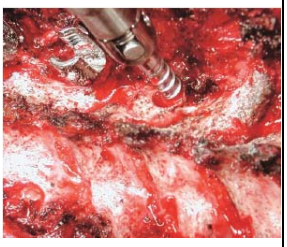
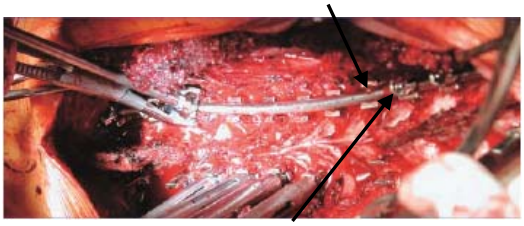
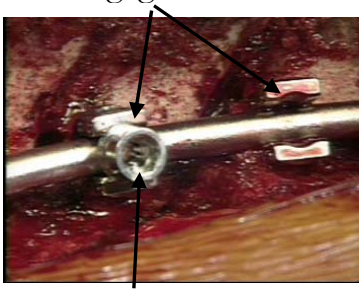
pat. to "allow manipulation of the spine with even distribution of force between opposite pedicle, in order to prevent the application of excessive load to either pedicle." '349 pat. at 3:36-40; *see* Lenke Decl. at ¶¶ 68, 105, 106. The Lenke References and the '349 pat. are from the same field of endeavor for, and each of the devices disclosed therein could be used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebral bodies. *See* Lenke Decl., at ¶ 82. The references specifically teach compression and distraction, as well as rotation, of multiple vertebrae; therefore, one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including the treatment of scoliosis. *See* MTOS, at 18; '349 pat., at 2:57-61; Lenke Decl. at ¶ 82. Thus, a spinal derotator incorporating the teachings of these references represents an obvious combination of known mechanical elements arranged in their described and conventional manner in response to a known design incentive, to achieve predictable and commonly described results. *See KSR,* 550 U.S. at 418.

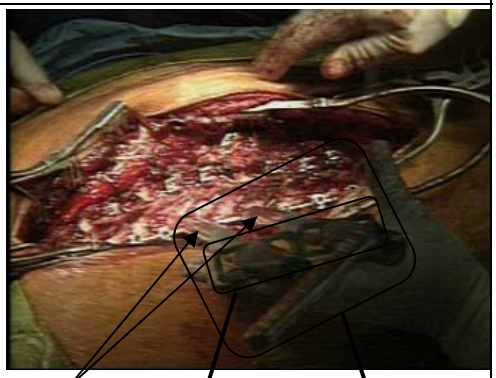
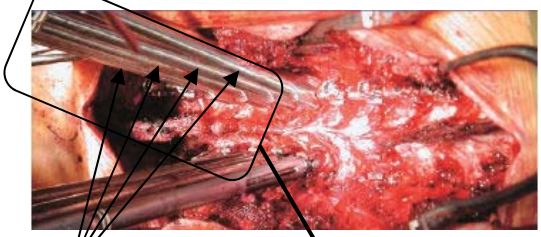
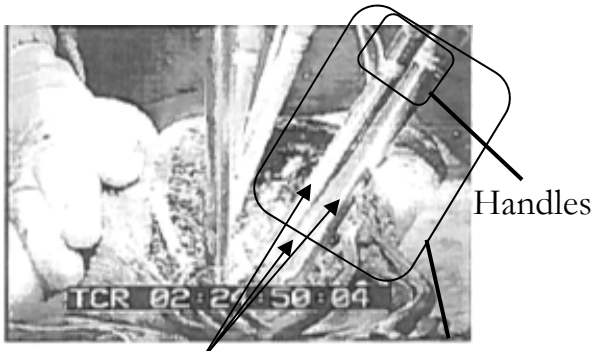
The Lenke References show the application of manipulative force to the first group of handles to simultaneously engage the pedicle screw engagement members and first set of pedicle screws. The surgeon can thereby, in a single motion, simultaneously rotate the the first group of vertebrae in which the pedicle screws are implanted to achieve an amelioration of the aberrant spinal column deviation condition in reference to a third axis.

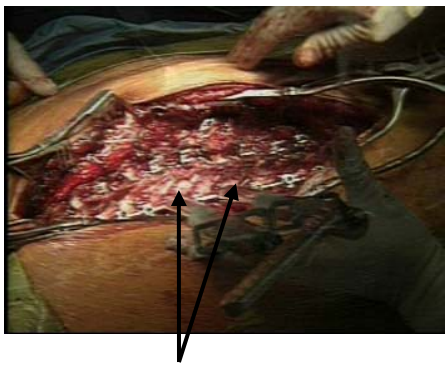
Additionally, the Slides and MTOS each show the application of manipulative force to the first and second group of handles at the same time, thereby simultaneously engaging the first group of three or more pedicle screw engagement members and the first set of

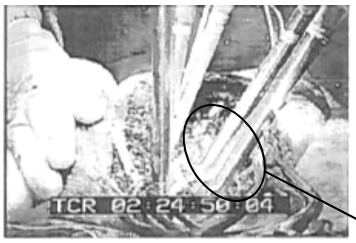
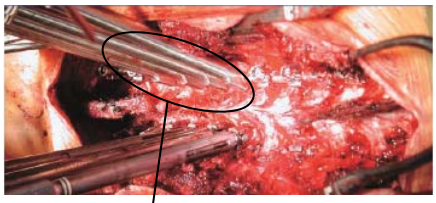
pedicle screws, and the second group of pedicle screw engagement members and the second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws. This allows for, in a single motion, the simultaneous rotation of the vertebrae of the first group of vertebrae and the second group of vertebrae lateral to the first group of vertebrae, in which the pedicle screws are implanted, to achieve the amelioration of an aberrant spinal column deviation condition. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the procedure shown in the Video to apply manipulative force to the first and second handle means simultaneously as explicitly taught in the Slides and MTOS, to decrease the surgeon's workload, to make the surgery more efficient, and to ensure that even force is placed on opposing pedicle regions of the individual vertebra in which a pedicle screw is implanted. *See* Lenke Decl. at ¶¶ 110, 111.

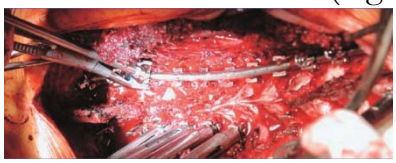
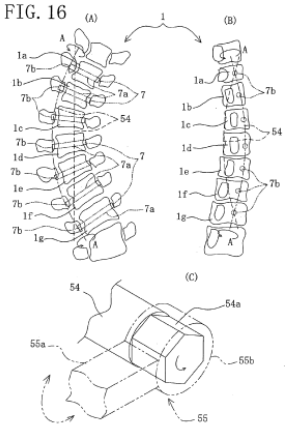
Claim 1[A]: A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:	The Video, the Slides, and MTOS each disclose a method for treating and correcting deformities and injuries of the spine. *See* Slides at 21; MTOS at 245-46 ("Thoracic and lumbar pedicle screw instrumentation allows maximum correction and minimizes complications . . . . The tremendous three-dimensional correcting power of such instrumentation is redefining how scoliosis is operatively managed at our institution."); Video, at 00:13 – 07:12.  

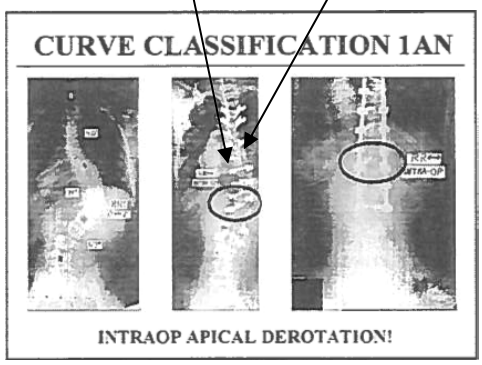
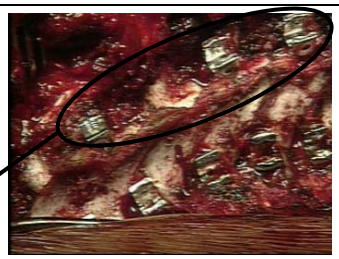
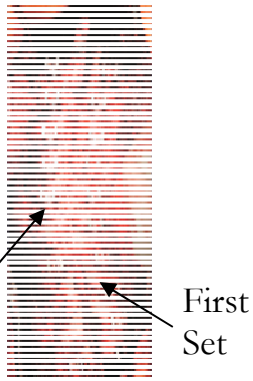
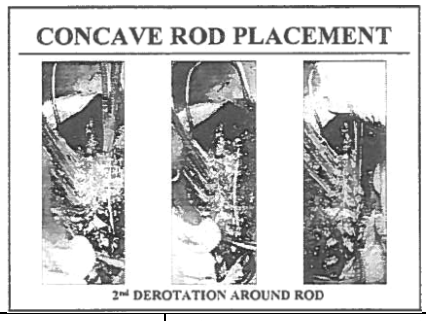
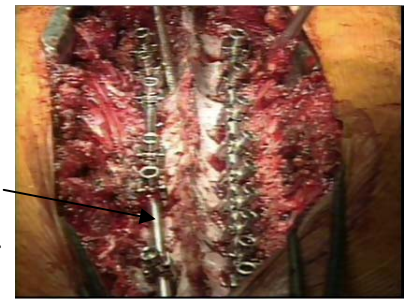
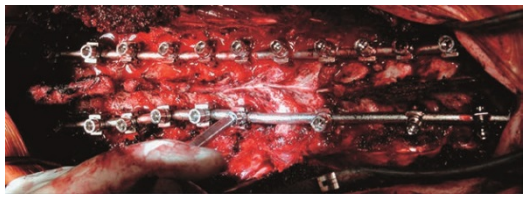
Claim 1 [B]: selecting a first set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment,	The Video shows multiple pedicle screws, any combination of which could be considered a first set, and each having threaded shank segment and a head segment.  First Set of Pedicle Screws   The Slides also show multiple pedicle screws, any combination of which could be considered a first set. *See* Slides at 19.   MTOS also discloses the selection of a first set of pedicle screws, and that each of these pedicle screws has a threaded shank segment and head segment. *See* MTOS, at 240-41; FIGS. 17-6 and 17-7.
Claim 1 [C]: each pedicle screw having a spinal rod engagement means for mechanically engaging with a spinal rod member and spinal rod fixation means for, upon actuation, fixing the relative orientation of each pairing of said spinal rod member and said pedi-	The Video, the Slides, and MTOS show the use of a spinal rod member and pedicle screws having an engagement means for mechanically engaging with a spinal rod member and spinal rod fixation means for, upon actuation, fixing the relative orientation of each pairing Engagement Means  Fixation Means Engagement Means  Fixation Means of the spinal rod member and the pedicle screw. *See* Video at 5:38-43; MTOS at FIG. 17-12; Slides at 19 (depicting placement of spinal rod and subsequent

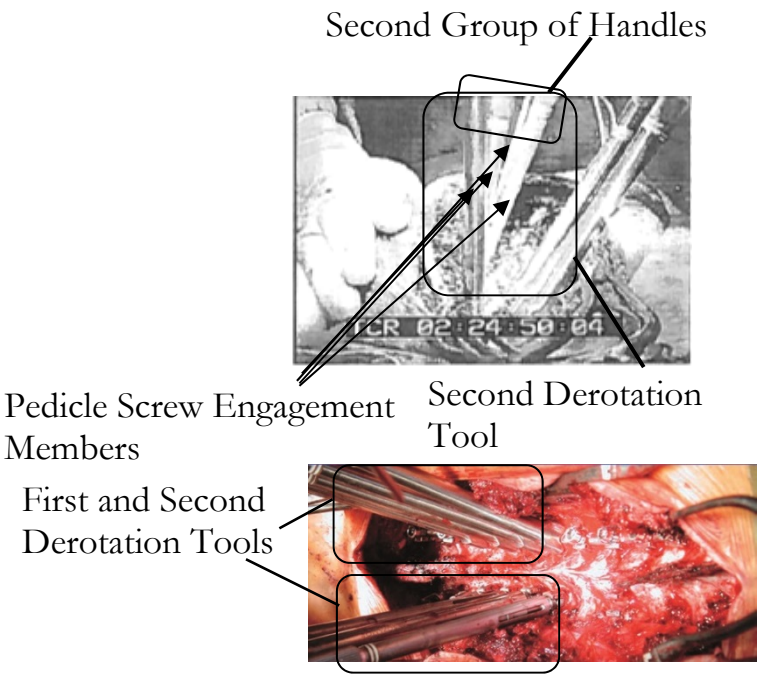
cle screw;	rotation of vertebrae around spinal rod).
Claim 1 [D]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members and a linking member to join together the handles linked to the pedicle screw engagement members, said first	The Video discloses a first pedicle screw cluster derotation tool. *See* Video at 5:59 to 6:05. The Video shows that this tool includes a first group of multiple handles for facilitating simultaneous application of manipulative forces to the first set of pedicle screws and a first group of pedicle screw engagement members that are mechanically linked with this group of handles.  Pedicle Screw Engagement Members Han- Derotation Tool The Slides and MTOS also show a first pedicle screw cluster derotation tool. *See* Slides at 19; MTOS at FIG. 17-13. These derotation tools each include a first group of handles for facilitating simultaneous application of manipulative forces to the first pedicle screws and a first group of three (the Slides) or four (MTOS) pedicle screw engagement members that are mechanically linked with the first handle means. The handles are each linked to a pedicle screw engagement member to move them.  Engagement Members Derotation Tool  Handles Pedicle Screw Engagement Members Pedicle Screw Cluster Derotation Tool The '928 Appl. discloses a first pedicle screw cluster derotation tool.

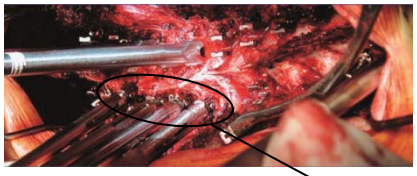
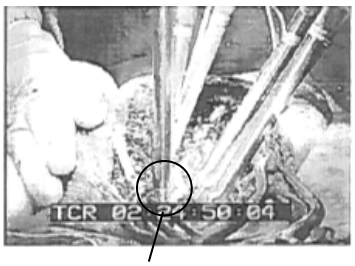
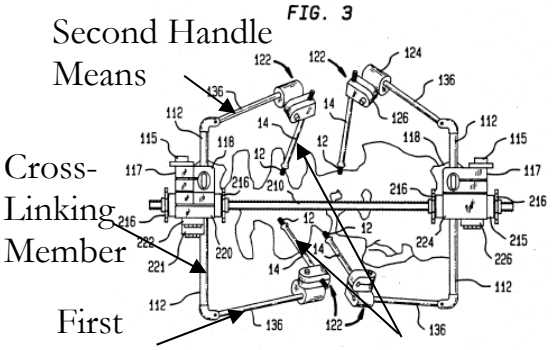
handle means moving each pedicle screw engagement member simultaneously;	*See* § V.B., Claim 1[D], *infra* (incorporated here). The pedicle screw cluster derotation tool includes a handle means in the form of knobs 112a and 112b and threaded rods 110b. *See id.* The '928 Appl. also discloses a first group of a three or more pedicle screw engagement members, for example, guide tubes 102a, 102b, and 104, or anchor extensions, which may be placed under the guide tubes. *See id.* These pedicle screw engagement members are mechanically linked to the knob 112b and threaded rod 110b by cross-action members 106a, 106b, 107a, and 107b and threaded rod coupling 108a. *See id.* The first handle means of the '928 Appl. includes a handles in the form of knobs 112a and 112b and threaded rods 110b. *See id.* The '928 Appl. provides that the device may be used to when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. *See* § V.B., Claim 1[E], *infra* (incorporated here). The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. *See* § V.B., Claim 1[D], *supra* (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.* These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.*
Claim 1[E]: each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said first set of pedicle screws, and transmitting manipulative forces applied to said first handle means to said head seg-	The Video, the Slides and MTOS show the engaging of each pedicle engagement member with the head segment of a respective pedicle screw. *See* Video at 5:59; Slides at 19; MTOS, at FIG. 17-13.  Engagement of head segments

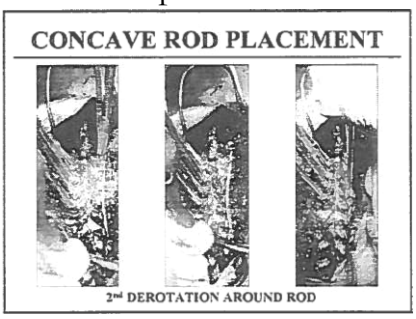
ment of each pedicle screw of said first set of pedicle screws;	  Engagement of head segments of pedicle screws
Claim 1 [F]: implanting each pedicle screw of said first set of pedicle screws in a pedicle region of each of a first group of vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;	The Video, the Slides, and MTOS disclose the implantation of each pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column. *See* Video at 2:25-4:35; Slides at 18; MTOS, at 235-41 (describing implantation of pedicle screws).  
Claim 1 [G]: contouring said spinal rod member whereby, in a first plane, said spinal rod member substantially defines, in reference to two axes, a post-operative spinal column alignment for said spinal column;	The Video and MTOS disclose that the spinal rod member is contoured with respect to two axes (along the sagittal plane and the coronal plane) so as to define a post-operative spinal column alignment for the spinal column. *See* Video at 5:13-27("A bi-planar bend in the rod is placed conforming to the position of the spine. The coronal plane is done first; the sagittal plane is bent second."); MTOS at 241 ("After the insertion of the pedicle screws, the rods are measured and contoured in the sagittal and coronal planes"). 
Claim 1 [H]: engaging said spinal rod respectively with said spinal rod engagement means of each pedicle screw of	The Video and MTOS disclose that the spinal rod is engaged with the spinal rod engagement means for securing each said pedicle screw and said spinal rod, while the spinal rod member is in a first rotational orientation. *See* Video at 5:30-44 ("The rod is then placed in the left-sided set of screws. . . . Set bolts 

said first set of pedicle screws, while said spinal rod is in a first rotational orientation;	are then fastened loosely."); MTOS at 245 ("The surgeon places the previously contoured rod and inserts the set screws at each level (Fig. 17-12). Then the surgeon tightens all screws except those at the apical six vertebrae (the four derotation vertebrae and one additional level proximally and distally)."); Fig. 17-12. 
Claim 1 [I]: rotating said spinal rod substantially along its length to a second rotational orientation to effect a correction of spinal column deviation in reference to two axes;	MTOS discloses that the claimed rod rotation maneuver may be used to treat scoliosis. *See* MTOS at 242 (referencing how rod rotation maneuver introduced by Cotrel-Dubousset translates the spine and do not provide enough derotation); *see also* MSD 1019 at 855). The '291 Appl. provides that the spinal rod member is rotated around its length by a ratchet tool to a second rotational orientation to effect a correction of spinal column deviation. *See* '291 Appl. at paras. [0157] – [0158] ("(6) The ratchet tool 55 serving as rotating means is inserted through the port 2 or the small incision into the body, and the engagement portion 55 *b* is fitted into a socket-head portion 54 *a* of the rod 54. A lever 55 *a* is caused to make a reciprocal angular motion at a small angle outside the body to cause the rod 54 to slowly rotate in the arrow A direction (back side). (7) The rod 54 is loosely tacked to the head 7 *b* of the built-in screw 7 by the setscrew 14. A relative sliding is therefore caused between the rod 54 and the setscrew 14 or the notch 9 along with rotation of the rod 54. The vertebrae . . . displace while being simultaneously subjected to twisting and compressing actions. Finally, as shown in FIG. 19(A), the vertebrae . . . form an orderly line in the up-down direction of the body as viewed in the front-back direction of the body, thus eliminating the scoliosis. As shown in FIG. 19(B), . . . the vertebrae . . . form an orderly line along the normal kyphosis line of the thoracic spine 1 as viewed in the right-left direction of the body. As a result, a three-dimensional deformity in the thoracic spine 1 is corrected."); FIG. 16(A)-(C). 
Claim 1 [J]: engaging each pedicle screw engagement member of said first group of pedicle screw engagement members respectively with said head segment of each pedicle screw of said first set of ped-	The Video, the Slides, and MTOS each show the engaging of each pedicle engagement member with the head segment of a respective pedicle screw of the first set of pedicle screws. *See* § V.A., Claim 1[E], *infra* (incorporated

icle screws;	here).
Claim 1 [K]: selecting a second set of pedicle screws;	The Video, Slides, and MTOS each disclose a second set of pedicle screws. *See* Slides at 18; MTOS at FIG. 17-9.   
Claim 1 [L]: selecting a second spinal rod member;	The Video, Slides, and MTOS each show use of second spinal rod member. *See* Video at 6:31; *See* Slides at 19; MTOS at FIG. 17-14.   
Claim 1 [M]: selecting a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitating simultaneous application of manipulative forces to said second set of pedicle screws and a second group of pedicle screw engagement members which are	The Slides and MTOS each show a second pedicle screw cluster derotation tool virtually identical to the first and engaging a second set of pedicle screws to manipulate them, except it includes four pedicle screw engagement members. This second pedicle screw cluster derotation tool functions in the same manner as the first pedicle screw cluster derotation tool in transmitting forces placed on the handle to the head segments of the pedicle screws of the second set of pedicle screws. *See* § V.A., Claim 1[E], *supra* (incorporated here).

mechanically linked with said second handle means, said second handle means moving each pedicle screw engagement member simultaneously, each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said second set of pedicle screws, and transmitting manipulative forces applied to said second handle means to said head segment of each pedicle screw of said second set of pedicle screws;	
Claim 1 [N]: implanting each pedicle screw of said second set of pedicle screws in the pedicle region of each of a second group of vertebrae lateral to the first group of vertebrae;	The Video, Slides and MTOS disclose the implantation of the second set of pedicle screws in a region of vertebrae lateral to that of the first set of pedicle screws. *See* § V.A., Claim 1[F], [K], *supra* (incorporated here).
Claim 1 [O]: contouring said second spinal rod member whereby, in a first plane, said second spinal rod member substantially defines, in reference to two axes, a post-operative spinal column alignment for said spinal column;	The Video, the Slides, and MTOS each disclose a second spinal rod member. *See* § V.A., Claim 1[L], *supra* (incorporated here). The Video and MTOS each shows the spinal rod member is contoured with respect to two axes (along the sagittal plane and the coronal plane) so as to define a post-operative spinal column alignment for the spinal column. *See* § V.A., Claim 1[G], *supra* (incorporated here).
Claim 1 [P] engaging said second spinal rod respectively with said spinal rod engagement means of each pedicle screw of said second set of pedicle screws, while said second spinal rod is in a first rota-	The Video, the Slides, and MTOS each disclose a second spinal rod member. *See* § V.A., Claim 1[L], *supra* (incorporated here). The Video and MTOS shows that the spinal rod is engaged with the spinal rod engagement means for securing each said pedicle screw and said spinal rod, while the spi-

tional orientation;	nal rod member is in a first rotational orientation. *See* § V.A., Claim 1[H], *supra* (incorporated here).
Claim 1[Q]: rotating said second spinal rod substantially along its length to a second rotational orientation to effect a correction of spinal column deviation in reference to two axes;	The Video, the Slides, and MTOS each disclose a second spinal rod member. *See* § V.A., Claim 1[L], *supra* (incorporated here). MTOS and the '291 Appl. each provides that the spinal rod member may be rotated around its length to a second rotational orientation to effect a correction of spinal column deviation. *See* § V.A., Claim 1[I], *supra* (incorporated here).
Claim 1[R]: engaging each pedicle screw engagement member of said second group of pedicle screw engagement members respectively with said head segment of each pedicle screw of said second set of pedicle screws;	The Slides and MTOS show the second set of pedicle screw engagement member is configured to engage the head segment of each pedicle screw of the second set of pedicle screws to transmit manipulative forces. Slides at 19; MTOS at FIG. 17-11.   Engagement of head segments
Claim 1[S]: connecting with a cross-linking member the first handle means to the second handle means laterally positioned to the first handle means;	U.S. Patent No. 5,219,349 discloses a system and method for realignment of vertebrae by applying manipulative forces to pedicle screws. *See generally* '349 pat. at 3:33-36 ("The reduction frame according to the present invention allows for the controlled application of forces to produce motion of one vertebra relative to another, by means of attachment of the device to the pedicles."). The '349 pat. discloses pedicle screws on both sides of a vertebrae, with each pedicle screw attached to a pedicle screw engagement means (shaft handle 14) that itself is mechanically linked to a handle means (hinged extensions 136 of T-handle 100). *See* '349 pat. at 4:35-55 ("Disposed adjacent the outer extremity of each laterally extending arm 112 is a shaft clamp 122. The shaft clamps provide a positive linkage between the T- 

	handles 100 and the shaft handles 14 attached to the pedicle screws 12. . . . In order to allow for further flexibility in positioning the T-handles 100 and, in particular, to provide greater access to the surgical area after the reduction frame has been installed on the spine, the laterally extending arms 112 of the T-handles 100 have hinged extensions 136. Thus, in a preferred embodiment of the present invention, the shaft clamps 122 are disposed at the end of the hinged extensions 136 of the laterally extending arms 112."); Figs. 3 and 5. The first and second handle means are connected by a cross-linking member (laterally extending arms 112) to "ensure[] that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle." '349 pat. at 5:4-8.
Claim 1[T]: applying manipulative force to the first handle means and the second handle means in a manner for simultaneously engaging said first group of three or more pedicle screw engagement members and said first set of pedicle screws, and said second group of pedicle screw engagement members and said second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws, thereby in	The Video shows the application of manipulative force to the first handle means for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws and thereby in a single motion simultaneously rotating the vertebrae of the first group of vertebrae in which the pedicle screws are implanted to achieve an amelioration of the aberrant spinal column deviation condition in reference to a third axis. *See* Video at 5:59 to 6:06.  The Slides and MTOS show the application of manipulative force to the first handle means and the second handle means in a manner for simultaneously engaging the first group of three or more pedicle screw engagement members and the first set of pedicle screws, and the second group of pedicle screw engagement members and the second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws, thereby in a single motion simultane-   **Figure 17-11.** First apical vertebral derotation maneuver. Most of the derotation and downward pressure is accomplished by the convex-side screws. Additional ventral pressure is placed on the convex rib prominence.

a single motion simultaneously rotating said vertebrae of said first group of vertebrae and said second group of vertebrae lateral to said first group of vertebrae, in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.	ously rotating said vertebrae of the first group of vertebrae and the second group of vertebrae lateral to the first group of vertebrae, in which the pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. *See* Slides at 19; MTOS, at 242-43 ("With the four apical vertebrae secured on both sides, the AVD maneuver is performed (Fig. 17-11). Most of the derotation and downward pressure is accomplished by the convex-sided screws. The degree of correction depends on the flexibility of the curve on preoperative assessments and on the grip of the apical screws in the vertebrae. It is also helpful to apply ventral pressure to the convex rib prominence simultaneously with the AVD of the screws."); FIG. 17-11.

Claim 2 is directed to a system that can carry out the method of claim 1. As noted above, the Lenke References each disclose first and second sets of pedicle screws. Each pedicle screw has a threaded shank segment and a head segment. The Lenke References also each disclose the use of a first pedicle screw cluster derotation tool in the form of multiple apical derotators that are used simultaneously. As noted above, the Slides and MTOS each disclose that the pedicle screw cluster derotation tools may include three or four apical derotators on each side of the spine. Each derotator includes a handle linked to a pedicle screw engagement member, which is configured to engage the head segment of a pedicle screw to transmit manipulative forces. As the Lenke References each disclose that the surgeon applies force to each of the handles of the apical derotators at the same time, these handles facilitate simultaneous application of manipulative forces to the first set of pedicle screws. This transmission of manipulative force to the head segments of the pedicle

screws is due to the rigid connections between the handles and the pedicle screw engagement members, such that any force placed on the first handle means is necessarily transferred to the pedicle screw engagement member.

To the extent the Lenke References do not disclose that the handles of the apical derotators are each linked together, as explained in detail above, it would have been obvious to one of ordinary skill in the art to do so in view of the '928 Appl. and/or the '568 pat., which also disclose and further enable the simultaneous application of a downward (i.e., rotational) force on a group of vertebrae by means of a handle, motivated to more safely distribute the forces across the screws and vertebra and free up a hand to manipulate the rod and secure it, or for other purposes. *See* § V.A. at 16, Claim 1, *supra*; *see also* Lenke Decl. at ¶¶ 113-116.

As noted above with respect to claim 1, both the Slides and MTOS disclose the use a second pedicle screw cluster derotation tool having the same structural components as the first pedicle screw cluster tool. For the above reasons, it would have been obvious to modify the system disclosed in the Video in view of the disclosure of the Slides and MTOS. *See id.* Similarly, to the extent that the Lenke References do not show that the these first and second pedicle screw cluster derotation tools are linked to each other by a cross-linking member connected to the first and second handle means, it would have been obvious to do so in view of the '349 pat. *See id.*

Claim 2[A]: A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions	The Video, the Slides, and MTOS each disclose a method for treating and correcting deformities and injuries of the spine. *See* § V.A., Claim 1[A],

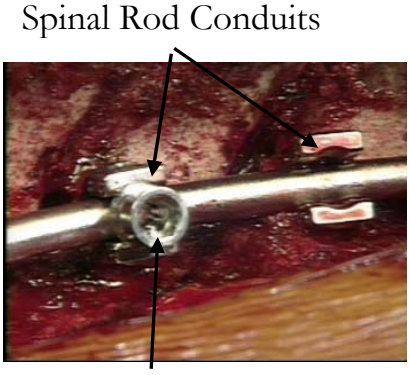
comprising:	*supra* (incorporated here).
Claim 2[B]: a first set of pedicle screws,	The Video, the Slides, and MTOS each include multiple pedicle screws, any combination of which could be considered a first set. *See* § V.A., Claim 1[B], *supra* (incorporated here).
Claim 2[C]: each pedicle screw having a threaded shank segment and a head segment; and	The Video, the Slides, and MTOS each disclose that the pedicle screws have a threaded shank segment and a head segment. *See* § V.A., Claim 1[B], *supra* (incorporated here).
Claim 2[D]: a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members and a linking member to join together the handles linked to the pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member;	The derotation tools shown in the Video, the Slides and MTOS each includes multiple handles each linked to and moving a pedicle screw engagement member. *See* § V.A., Claim 1[D], *supra* (incorporated here). The first handle means of the '928 Appl. includes handles linked together by cross-action members 107a and 107b. *See* § V.B., Claim 1[D], *supra* (incorporated here). The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. *See* § V.B., claim 1[D], *supra* (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.* These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.*
Claim 2[E]: wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said first set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;	The Video, the Slides, and MTOS each disclose that the pedicle screw engagement member is configured to engage the head segment of each pedicle screw to transmit manipulative forces. *See* § V.A., Claim 1[F], *supra* (incorporated here).
Claim 2[F]: a second set of pedicle	The Video, the Slides, and MTOS each disclose a

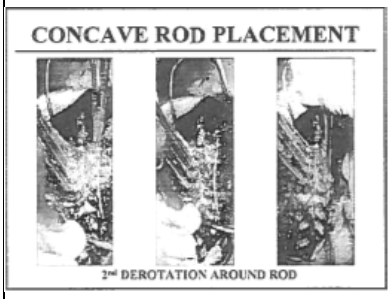
screws, each pedicle screw having a threaded shank segment and a head segment;	second set of pedicle screws. *See* § V.A., Claim 1[L], *supra* (incorporated here). The Video, the Slides, and MTOS each disclose that the pedicle screws have a threaded shank segment and a head segment. *See* § V.A., Claim 1[B], *supra* (incorporated here).
Claim 2[G]: a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitating simultaneous application of manipulative forces to said second set of pedicle screws and a second group of three or more pedicle screw engagement members which are mechanically linked with said second handle means, said second handle means having a handle linked to each pedicle screw engagement member of the second group of three or more pedicle screw engagement members and a handle linking member to join together the handles linked to the pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member;	The Slides and MTOS show a second pedicle screw cluster derotation tool virtually identical to the first, and accordingly includes a second handle means. *See* § V.A., Claim 1[M], *supra* (incorporated here). The first handle means of the '928 Appl. includes handles linked together by cross-action members 107a and 107b. *See* § V.B., Claim 1[D], *infra* (incorporated here). The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. *See* § V.B., Claim 1[D], infra (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.* These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.*
Claim 2[H]: wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said second set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said	The Slides show the pedicle screw engagement member is configured to engage the head segment of each pedicle screw of the second set of pedicle screws to transmit manipulative forces. *See* § V.A., Claim 1[R], *supra* (incorporated here). The first handle means of the '928 Appl. includes handles linked together by cross-action members 107a and 107b. *See* § V.B., Claim 1[D], *infra* (incorporated here). The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be

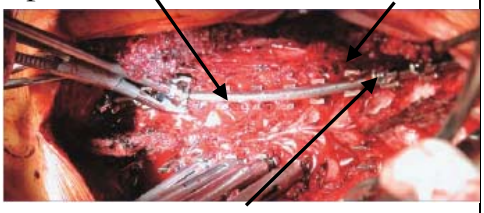
second handle means to said head segment of each pedicle screw of said second set of pedicle screws;	grasped by the hand. *See* § V.B., claim 1[D], *infra* (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.* These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.*
Claim 2[I]: a cross-linking member that links the first handle means to the second handle means.	The '349 pat. discloses a system and method for realignment of vertebrae by applying manipulative forces to pedicle screws, in which a cross-linking member links first and second handle means. *See* § V.A., Claim 1[S], *supra* (incorporated here).

Claim 3, which depends from Claim 2, adds limitations directed to a spinal rod member, and a conduit and engagement means included in the pedicle screws for receiving and securing, respectively, the spinal rod member.

The Lenke References each disclose the claimed spinal rod member. The Lenke References also disclose pedicle screws a spinal rod conduit formed substantially transverse the length of each screw on the saddle assembly of the pedicle screw, and sized and shaped to receive the spinal rod member. The Lenke References further depict the claimed spinal rod engagement means for securing each pedicle screw and the spinal rod member in a substantially fixed relative position and orientation when the pedicle screw is extending through the spinal rod conduit. Additionally, one of ordinary skill in the art would understand that such screw features are inherently disclosed due to the Slides depicting the placement and securement of a spinal rod to the pedicle screws of the disclosed system. *See* Lenke Decl. at ¶¶ 118-119

<table>
<tr>
<td>Claim 3: The system of claim 2 further comprising a spinal rod member, wherein one or more of said pedicle screws each includes: a spinal rod conduit formed substantially transverse of the length of each said pedicle screw and sized and shaped for receiving passage of said spinal rod member therethrough; and spinal rod engagement means for securing each said pedicle screw and said spinal rod, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation.</td>
<td>The Video, the Slides, and MTOS show a spinal rod member and pedicle screws having a spinal rod conduit formed substantially transverse of the length of said pedicle screw and sized and shaped for receiving passage of said spinal rod member; and a spinal rod engagement means for securing each said pedicle screw and said spinal rod in a substantially fixed relative position and orientation. See Video at 5:38-43; MTOS at FIG. 17-12; Slides at 19 (depicting placement of spinal rod and subsequent rotation of vertebrae around spinal rod).
 

 
</td>
</tr>
</table>

Claim 4 depends from claim 3, and additionally recites "the spinal rod is precontoured." The Video and MTOS disclose that the spinal rod member is contoured with respect to two axes (along the sagittal plane and the coronal plane) to define a post-operative spinal column alignment for the spinal column. *See* Video at 5:13-27 ("A bi-planar bend in the rod is placed conforming to the position of the spine. The coronal plane is done first; the sagittal plane is bent second."); MTOS at 241 ("After the insertion of the pedicle screws, the rods are measured and contoured in the sagittal and coronal planes").

B. Ground 2 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the '928 Appl. in view of the '568 Patent, the Video, the Slides and/or MTOS and the '349 patent and alternatively the '219 Appl.

As shown in the claim chart below, Claims 1-4 are obvious under § 103 by the '928 Appl. in view of the '568 pat., the Lenke References (alone or in combination) and the '349 pat., and alternatively the '219 pat.

With respect to claim 1, as previously found by the PTAB, the '928 Appl. discloses the structures found in claim elements 1[A], 1[B], 1[C], 1[F], and 1[J], and 1[I]. *See* IPR1210 Decision, at 16-20. The '928 Appl. discloses a system and method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions. The '928 Appl. discloses a first set of pedicle screws 602b, 603, 602a, each having a threaded shank segment and a head segment, as well as a spinal rod engagement means, assembly 500 or 700, that is able to mechanically couple the pedicle screw with a spinal rod member. The pedicle screws also include a spinal rod fixation means, set screw 701, that secures the spinal rod member to the pedicle screw in a substantially fixed relative position and orientation. Each pedicle screw is implanted in a pedicle region of each of a first group of multiple vertebrae.

The '928 Appl. also discloses a first pedicle screw cluster tool that may be used to simultaneously rotate adjacent vertebrae in a single movement. The '928 Appl. states that the tool can be used to apply forces perpendicular to the direction in which distraction or compression of the vertebra is effected, such as would occur during a spondylolisthesis reduction procedure. *See* '928 Appl., at ¶ [0055]. One of ordinary skill in the art would have understood at the time of invention that these perpendicular forces are applied into the patient (downward) and out of the patient (upward). *See* Lenke Decl. at ¶¶ 55-57, 108. Because these perpendicular forces are applied to the pedicle screws, the forces are offset

from the center of the vertebrae, **which in turn produces rotation of the vertebrae**. *See id.* Where this force is applied in a downward direction, it will cause rotation of the vertebrae as it pushes one side of the vertebrae down resulting in the opposite side of the vertebrae moving upward in an equal amount. *See id.* Similarly, if the device is used to apply an upward force, it will also cause rotation of the vertebrae as the one side of the vertebrae is lifted upward while the opposing side is moved downward in an equal amount. *See id.* In sum, one of ordinary skill in the art would have understood at the time of invention that applying a force perpendicular to the direction in which distraction or compression occurs, as in spondylolisthesis reduction and as explicitly disclosed in the '928 Appl., would impart rotation to that spinal segment. *See id.* Alternatively, one of ordinary skill in the art would have understood, based on the above-referenced disclosure, that the tool disclosed in the '928 Appl. is structurally configured to simultaneously rotate multiple vertebrae. The skilled artisan would have found it obvious to employ this tool for precisely such a maneuver, using a handle means that is capable of facilitating simultaneous rotation of the vertebra by way of respective pedicle screws attached thereto. *See id.*, at ¶ 109.

The tool disclosed in the '928 Appl. includes a handle means in the form of handles (knobs 112a and 112b and threaded rods 110b) joined together by cross-action members 107a and 107b. To the extent "handle means" is construed to require a part that is designed to be grasped by the hand, the knobs 112a and 112b are especially designed to be grasped by the hand, and they also may be grasped by hand. *See id.*, at ¶¶ 55-57, 92. The tool also includes guide tubes 102a, 102b, and 104, or anchor extensions, which may be

placed under the guide tubes, either of which may serve as a first group of pedicle screw engagement members. These pedicle screw engagement members are mechanically linked to the knob 112b and threaded rod 110b by cross-action members 106a, 106b, 107a, and 107b and threaded rod coupling 108a. The '928 Appl. discloses that the pedicle screw engagement members, whether guide tubes 102a, 102b, and 104 or the anchor extensions, each engage with the head segments of each pedicle screw.

Alternatively, to the extent that the '928 Appl. is found not to disclose the claimed handle means, it would have been obvious to modify the device disclosed in the '928 Appl. to include a handle means in view of the teachings of the '568 pat., for example to accomplish the common goal of applying a simultaneous rotational force to multiple vertebrae. The '568 pat. describes an apparatus and method for the treatment of spinal column deviations and discloses the use of a handle means to apply simultaneous force to multiple adjacent vertebrae (as the '928 Appl. does). Specifically, the '568 pat. discloses a levering member 20 that includes a proximally mounted handle 21 and a free end 23, with a main body 22 extending therebetween. '568 pat., at 5:5-26. The main body allows for the attachment of multiple outrigger members 30. The outrigger members 30 in turn engage adjacent vertebrae via spine link members 90, such that any movement of the outrigger member caused by manipulating the handle 21 is transferred simultaneously to the adjacent vertebrae through the spine link members 90. *Id.* at 2:66 to 3:4; 5:39 to 6:8. The '568 pat. provides that this apparatus enables the surgeon to simultaneously rotate adjacent vertebrae during a spondylolisthesis procedure, similar to that of the disclosure of the '928

Appl. *Id.* at 2:11-30; 4:66 to 5:4. The handle 21 and the remainder of the levering member 20 thus constitute a "handle means" regardless of whether this term is construed narrowly and limited to "a part that is especially designed to be grasped by the hand."

As explained above, the '928 Appl. teaches that the disclosed device may be used to apply force perpendicular to the direction in which distraction or compression occurs as in spondylolisthesis reduction. It would have been obvious to one of ordinary skill in the art to modify the device disclosed in the '928 Appl. to include the handle means of the '568 pat. in the form of the levering member 20 to link together the pedicle screw engagement members of the '928 Appl. because, in accordance with the express teachings of the '568 pat., it would "allow[] the surgeon to properly position and secure the vertebrae . . . in a relatively quick and straightforward manner," consistent with and further enabling the alternative embodiment of the '928 Appl. discussed above for applying this perpendicular force for the same purposes. *See id.* at 2:11-26; *See* Lenke Decl. at ¶ 93. The obviousness of this combination is further supported by the fact that both the '928 Appl. and the '568 pat. are related to applying perpendicular (downward or upward) force on vertebrae to produce rotation thereof, and both specifically disclose the use of the respective devices for spondylolisthesis procedures. *See* Lenke Decl. at ¶¶ 82, 93. The addition of the handle means of the '568 pat. to the device of the '928 Appl. to help achieve the type of movement disclosed in both references would have been nothing more than a simple and obvious modification in view of the teachings of the '568 pat., and the design incentives of

easing the surgeon's workload, and achieving uniformity in the movement of the pedicle screw engagement members and the vertebral bodies to achieve an entirely predictable result; and properly positioning and securing multiple vertebrae in a relatively quick and straightforward manner. *See id.*, at ¶¶ 71, 93. Similarly, this well known mechanical manner of linking extension arms to facilitate distribution of the loads across the screws and vertebral bodies reduces the likelihood of damage to the screws or vertebrae. *See id.* The '928 Appl. and the '568 pat. are from the same field of endeavor, and each of the devices disclosed therein teach and explicitly disclose use to achieve spinal column derotation by the application of simultaneous force to multiple vertebral bodies. *See id.*, at ¶ 82. Both references specifically teach compression and distraction, as well as rotation, of multiple vertebrae; therefore, one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including the treatment of scoliosis. *See* '568 pat., at 2:17-21; '928 Appl., at ¶ [0055]; Lenke Decl. at ¶ 82. Thus, a spinal derotator incorporating the teachings of these references represents nothing more than an obvious combination of known mechanical elements arranged in their described and conventional manner in response to a known design incentive, to achieve predictable and commonly described results. *See KSR,* 550 U.S. at 418.

The '928 Appl. explicitly and inherently discloses applying force "in a single motion simultaneously rotating said vertebrae" as required by claim element 1[T]. As noted above, the '928 Appl. explicitly teaches that the disclosed device can be used to apply force to the

pedicle screws in a direction perpendicular to compression and distraction. The application of that force is inherently done by grasping the device by hand, preferably grasping at least one knob or an equivalent handle structure (like in the '568 pat.). Accordingly, the '928 Appl. would have explicitly, or implicitly, disclosed to one of ordinary skill in the art that the handle means (knobs 112a and 112b) are especially designed to be grasped to apply a perpendicular force **in addition to** a twisting force. *See* Lenke Decl. at ¶¶ 55-57. That is, the structure identified above, including the knobs, can be pushed or pulled as well as being twisted, much like a door knob handle can be pushed or pulled as well as twisted. *See id.* Because of the rigid mechanical link between the handle means and the pedicle screw engagement members, a perpendicular force exerted on the knobs (112a and 112b) individually or collectively necessarily will be transferred simultaneously to each of the pedicle screw engagement members, which in turn will transmit the force to the head segment of each pedicle screw. *See id.*

Exemplifying this point, the '928 Appl. provides that when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. Where the force applied is in the disclosed perpendicular, i.e., downward, direction, because of the placement of the pedicle screws this causes, as explained above, a derotation of the vertebrae. *See id.* Accordingly, the '928 Appl. provides that a downward force may be applied to the handle means of the disclosed device in a manner for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws, and thereby in a single motion simultaneously

rotate the vertebrae in which the pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. *See id.* In other words, the laws of physics demand that the device disclosed in the '928 Appl. apply force "in a single motion rotating said vertebrae." Thus, the '928 Appl. at least inherently, if not explicitly, discloses the application of force "in a single motion simultaneously rotating said vertebrae" as required by claim element 1[T].

While the '928 Appl. discloses the coupling of a spinal rod to each of the pedicle screws and the contouring of the spinal rod in two axes to track the curvature of the spine, and coupling of a spinal rod to each of the pedicle screws, to the extent that it does not disclose the rotation of the spinal rod member around its length to a second rotational orientation, it would have been obvious to do so in view of MTOS and/or the '291 Appl., both of which disclose the well-known Cotrel and Dubousset rod rotation maneuver. *See* Lenke Decl. at ¶¶ 98-99; *see also* § V.A. at 17-18, Claim 1, *supra* (incorporated here).

It would have been obvious to one of ordinary skill in the art of the time of invention to modify the method of derotating a scoliotic spinal column disclosed by the '928 Appl. to include the step of rotating the spinal rod along its length to put the vertebrae in better alignment prior to derotation, using the derotator tool taught by MTOS and the '291 Appl. *See* Lenke Decl. at ¶¶ 98-99. The '928 Appl., the '568 pat., the Slides, MTOS and the '291 Appl. are from the same field of endeavor for fixing and manipulating vertebrae, and each of the devices disclosed therein could be used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebral bodies. *See* Lenke Decl., at ¶ 82.

Thus, a method of correcting scoliosis incorporating the teachings of these references represents nothing more than an obvious combination of known mechanical elements arranged in a conventional manner in response to a known design incentive, to achieve predictable results. *See KSR,* 550 U.S. at 418. Additionally, it would have been obvious to include such a step because this method of rod contouring and rotation to correct a scoliotic spinal column had been known and performed since being introduced by Cotrel and Dubousset in the 1980s, and was well within the common knowledge of those of ordinary skill in the art at the time of invention. *See* Lenke Decl. at ¶ 17.

The '928 Appl. also discloses the claimed second set of pedicle screws and the second spinal rod member by its incorporation by reference of U.S. 2005/0085813 (the "'813 Appl."). *See* '928 Appl. at ¶ [0001] (noting incorporation by reference of U.S. Pat. Appl. Ser. No. 10/690,211, published as '813 Appl.). The '813 Appl. discloses that the pedicle screw and spinal rod member assembly is placed on both sides of the vertebrae, thus necessitating a second set of pedicle screws and a second spinal rod member. Due to the disclosure of the incorporated '813 Appl., the '928 Appl. inherently discloses the use of a second tool, or alternatively makes obvious the use of a second tool on the other side. Further, the use of a second pedicle screw cluster derotation tool would have been obvious as this is a mere duplication of parts or a simple design choice without any new or unexpected result occurring due the duplication. *See In re Harza*, 274 F.2d 669 (CCPA 1960).

Alternatively, it would have been obvious to one of ordinary skill in the art at the time of invention to include a second pedicle screw cluster derotation tool in view of the

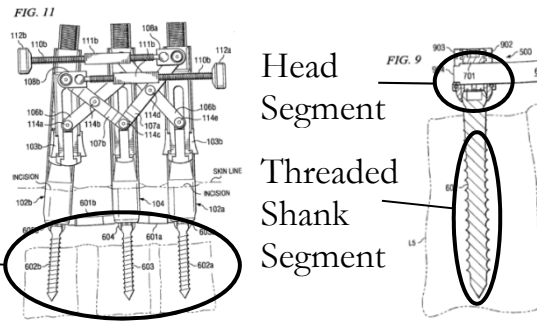
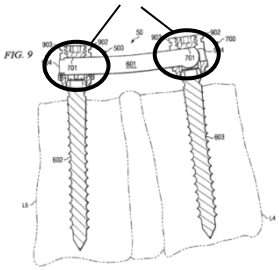
Slides and MTOS, each of which disclose the derotation procedure being simultaneously performed on two sets of pedicle screws on opposing sides of the spinal column, using two pedicle screw cluster derotation tools. *See* Lenke Decl. at ¶¶ 103, 104. MTOS provides that the use of two tools allows downward force to be placed on the vertebrae to derotate it, while allowing the simultaneous application of ventral pressure to the convex rib prominence to correct the rib hump evident in patients with scoliotic spine deformities. *See id.* at ¶ 103. Further, like the '349 pat., the use of two tools ensures that equal force is applied to both pedicle regions of the vertebrae being derotated. *See* Lenke Decl. at ¶¶ 105, 110-111. By performing the derotation on both sides of the vertebrae at the same time, more pedicle screws are engaged by the surgeon, thereby allowing for a further distribution of the forces being placed on the vertebrae. This also allows for a more efficient and effective derotation procedure because the surgeon can apply a downward force on one side of the vertebrae while simultaneously applying an upward force on the other side of the vertebrae, both of which motions fall under the '928 Application's explicit teaching of using the device to apply a perpendicular force on the vertebrae. *See* Lenke Decl. at ¶¶ 110-111. One of ordinary skill in the art, having knowledge of the Lenke References and performing a derotation procedure using the tool disclosed in the '928 Appl., would have found it obvious to use the tool on both sides on the spinal column to obtain the desired result of derotating multiple vertebrae to eliminate the scoliotic condition, while ensuring that equal force is applied to the pedicle regions of the vertebrae thereby making the procedure safer. *See id.*. The '928 Appl., the '568 pat., the Slides, and MTOS are from the same field of en-

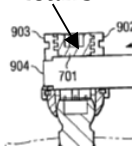
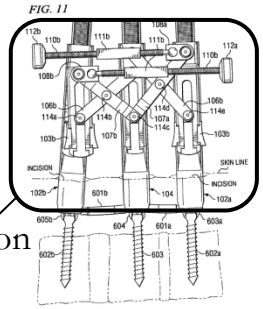
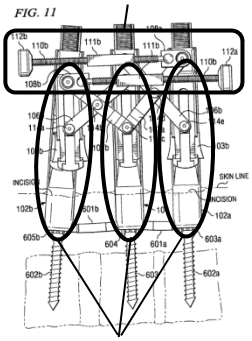
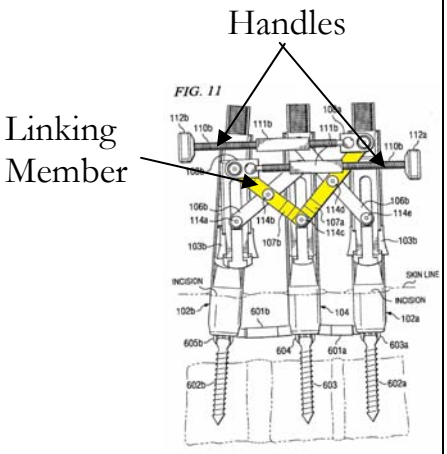
deavor, and each of the devices disclosed therein could be used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebral bodies. *See* Lenke Decl., at ¶¶ 82, 111. The references teach compression and distraction, as well as rotation, of multiple vertebrae; therefore, one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including the treatment of scoliosis. *See* MTOS, at 18; '928 Appl., at ¶ [0055]; Lenke Decl. at ¶ 82. Thus, a spinal derotator incorporating the teachings of these references represents nothing more than an obvious combination of known mechanical elements arranged in their described and conventional manner in response to a known design incentive, to achieve predictable and commonly described results. *See KSR,* 550 U.S. at 418.

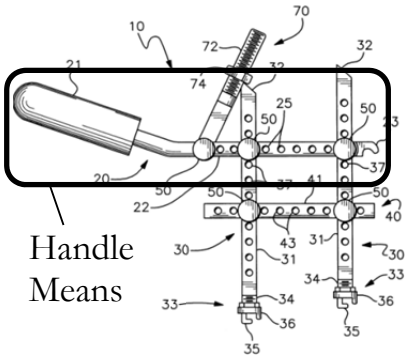
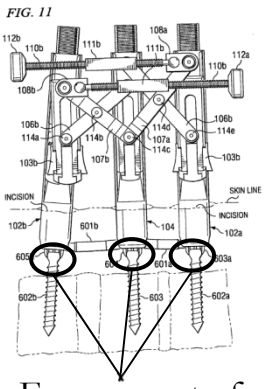
Further, as noted above in Ground 1, it would have been obvious to modify the method of derotating a scoliotic spinal column shown in the combination of the '928 Appl., the Slides and MTOS to include a cross-linking member to connect the handle means of the of the first and second pedicle screw cluster derotation tools in view of the '349 pat., to "ensure[] that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle." '349 pat. at 5:4-8.

Finally, as described above, the Slides and MTOS each show the application of manipulative force to the first group of handles and the second group of handles at the same time to provide simultaneous application of rotational force in a single motion. *See* § V.A. at 21-22, Claim 1, *supra* (incorporated here). It would have been obvious to one of ordinary skill in the art to modify the procedure shown in the '928 Application to apply manip-

ulative force to the first and second handle means simultaneously, as explicitly taught in the Slides and MTOS, to decrease the surgeon's workload, to make the surgery more efficient, and to ensure that even force is being placed on opposing pedicle regions of the individual vertebra in which a pedicle screw is implanted. *See* Lenke Decl. at ¶ 110, 111.

Claim 1 [A]: A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:	The '928 Appl. discloses a system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions. *See* '928 Appl. at ¶ [0008] ("The present invention is directed to a system and method . . . for the displacement of . . . vertebrae of the spine relative to each other."); ¶ [0003] ("When a patient suffers from . . . deformities or degenerative diseases, it is sometimes necessary to insert implants into the patient's body to stabilize . . . promote healing, or relieve pain. In . . . spinal surgery . . . a common procedure involves the use of screws . . . joined by a connecting brace in order to secure bones.").
Claim 1 [B]: selecting a first set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment,	The '928 Appl. discloses a first set of three pedicle screws 602b, 603, and 602a. *See* '928 Appl. at FIG. 11. The '928 Appl. discloses that each pedicle screw includes a threaded shank segment and a head segment. *See* '928 Appl. at FIG. 11 
Claim 1 [C]: each pedicle screw having a spinal rod engagement means for mechanically engaging with a spinal rod member and spinal rod fixation means for, upon actuation, fixing the relative orientation of	The '928 Appl. discloses that each of the pedicle screws includes a spinal rod engagement means, assemblies 500 and 700, that is able to mechanically engage with a spinal rod member. *See* '928 Appl. at ¶ 0048 ("Assemblies 500 and 700 (FIG. 9) are coupled to pedicle screws 602 and 603, respectively in process 801. . . . Generally, such receiving member formed by assemblies 500 and 700 is a noncontiguous (e.g., open-back member) having at least two walls, such as walls 902 and 903, that are separated by slots. . . . In process 803, brace 601 is extended from assembly 500 to assembly 700; *id.* at ¶ [0052] ("Assembly 700 is adapted to receive the proximal end 904 of brace 601 . . . ."); *id.* at FIG. 

each pairing of said spinal rod member and said pedicle screw;	9. The '928 Appl. discloses a spinal rod fixation means, set screw 701, that secures the spinal rod member, brace 601, to the pedicle screw in a substantially fixed relative position and orientation. *See* '928 Appl. at ¶ [0047] ("Set screws 701, or other locking devices, are introduced down cannulas 501 and 502 to lock each end of brace 601 to its respective pedicle screw 602, 603 . . . ."). 
Claim 1 [D]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means having a handle linked to each pedicle screw engagement member of the first group of	The '928 Appl. discloses a first pedicle screw cluster derotation tool. *See* FIG. 11.  The '928 Appl. discloses that the pedicle screw cluster derotation tool includes a handle means in the form of knobs 112a and 112b and threaded rods 110b. *See* '928 Appl. at FIG. 11. The '928 Appl. also discloses a first group of three or more pedicle screw engagement members, for example, guide tubes 102a, 102b, and 104, or anchor extensions, which may be placed under the guide tubes. *See id.* at FIG. 11; *id.* at ¶ [0043] ("The guide tubes 102 and 104 of displacement device 10 are placed over anchor extensions 606 and 607. Anchor extensions 606 and 607 are removably attached to rod cages 605 and 604 respectively."). These pedicle screw engagement members are mechanically linked to the knob 112b and threaded rod 110b by cross-action members 106a, 106b, 107a, and 107b and threaded rod coupling 108a. *See id.*  The handle means facilitates simultaneous application of manipulative forces to the first set of pedicle screws. *See* § V.B., Claim 1[E], *infra* (jncorporated here).  The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering

three or more pedicle screw engagement members and a linking member to join together the handles linked to the pedicle screw engagement members, said first handle means moving each pedicle screw engagement member simultaneously	member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. *See* '568 pat., at 5:5-7 ("The levering member 20 comprises an elongated main body 22 having a free distal end 23 and a proximally mounted handle 21 . . . ."). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.*, at 5:46-51("The main body 31 is sized to fit within the levering member slot 24 and the stabilizer member slot 42, such that the levering member 20 and the stabilizer member 40 can be positioned at various points on the outrigger members 30 by aligning the corresponding apertures 25 or 43 with the outrigger apertures 37 and fastening a pivot bolt 50."). These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.*, at 2:66 to 3:4 ("The ends of the outrigger members are provided with connector means for temporarily securing the outriggers to the transverse portions of the linking members in a secure manner such that any manipulation of the outrigger members is transferred to the spinal link members and thus to the vertebra or sacrum to which they are affixed."); 6:4-5 ("[W]hereby movement by the surgeon of the outrigger member 30 in any direction is transferred directly to the spine link member 90.").  Handle Means *Fig. 1*
Claim 1 [E]: each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said first set of pedicle screws, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;	The '928 Appl. discloses that the guide tubes 102a, 102b, and 104 each engage with the head segments, labeled assemblies 500 and 700, which include rod cages 603a, 604, and 605b, of each pedicle screw. *See* '928 Appl. at FIG. 11; Section V.B., Claim 1[D], *supra* (incorporated here). The '928 Appl. further provides that when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. *See id.* at ¶ [0055] ("In order to perform displacement, guide tubes of a displacement device are inserted over anchor extensions in process 804. . . ., further embodiments provide for additional devices to be inserted over the bone anchor . . . Another embodiment has the displacement device placed over extensions or bone anchors, such as a device for applying force in a direction that is perpendicular to the direction in which distraction or compression  Engagement of head segments

	occurs, as in a spondylolisthesis reduction. Force is then transmitted to the anchor extensions . . . in process 805.”).
Claim 1 [F]: implanting each pedicle screw of said first set of pedicle screws in a pedicle region of each of a first group of vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;	The ‘928 Appl. discloses the implantation of each pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column. *See* ‘928 Appl. at ¶ [0041] (“A small incision may be made through the skin and a device is used to pinpoint where a pedicle screw, such as pedicle screw 602, is to be placed. Dilators, such as dilators 503 and 504, are introduced until a diameter suitable for passing the pedicle screw and its extensions is achieved. . . . [B]race (or “rod”) 601 is attached to pedicle screw (“anchor”) 602 to form a brace-screw assembly. The assembly is placed at the distal end of cannula 501, inserting pedicle screw 602 into . . . vertebrae L4. . . . pedicle screw (“anchor”) 603 is inserted through cannula 502 into . . .vertebrae L5.”).
Claim 1 [G]: contouring said spinal rod member whereby, in a first plane, said spinal rod member substantially defines, in reference to two axes, a post-operative spinal column alignment for said spinal column;	The ‘928 Appl. discloses that the spinal rod member may be contoured with respect to two axes so as to define a post-operative spinal column alignment for the spinal column. *See* ‘928 Appl. at ¶ [0039] (providing that spinal rod may be “curved to match the curvature of the patient’s spine”).
Claim 1 [H]: engaging said spinal rod respectively with said spinal rod engagement means of each pedicle screw of said first set of pedicle screws, while said spinal rod is in a first rotational orientation;	The ‘928 Appl. discloses that each of the pedicle screws includes a spinal rod engagement means, assemblies 500 and 700, that is able to mechanically engage with a spinal rod member. *See* § V.B., Claim 1[D]-[E], *supra* (incorporated here).
Claim 1[I]: rotating said spinal rod substantially along its length to a second rotational orientation to effect a correction of spinal column deviation in reference to two axes;	MTOS and/or the ‘291 Appl. provides that the spinal rod member is rotated around its length by a ratchet tool to a second rotational orientation to effect a correction of spinal column deviation. *See* § V.A., Claim 1[I], *supra* (incorporated here).
Claim 1[J]: engaging each pedicle screw engagement member of said first group of pedicle screw engagement members respectively with said head segment of each pedicle screw of said first set of pedicle screws;	The ‘928 Appl. discloses that the guide tubes 102a, 102b, and 104 each engage with the head segments, labeled assemblies 500 and 700, which include rod cages 603a, 604, and 605b, of each pedicle screw. *See* § V.B., Claim 1[E], *supra* (incorporated here).
Claim 1[K]: selecting a	The ‘928 Appl., through incorporation of the ‘813 Appl., discloses that the pedicle screw and spinal rod member assembly is placed on both sides of

second set of pedicle screws;	the vertebrae, thus necessitating the selection of a second set of pedicle screws. *See* '813 Appl. at ¶ [0039] ("For a single level the above procedure is typically performed first on one side of both vertebral levels and then on the other side. When finished, four pedicle screws are inserted, holding two braces positioned laterally with respect to the center of the spine.").
Claim 1[L]: selecting a second spinal rod member;	The '928 Appl., through incorporation of the '813 Appl., discloses that the pedicle screw and spinal rod member assembly is placed on both sides of the vertebrae, thus necessitating the selection of a second spinal rod member. *See* § V.B., Claim 1[K], *supra* (incorporated here).
Claim 1[M]: selecting a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitating simultaneous application of manipulative forces to said second set of pedicle screws and a second group of pedicle screw engagement members which are mechanically linked with said second handle means, said second handle means moving each pedicle screw engagement member simultaneously, each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said second set of pedicle screws, and transmitting manipulative forces applied to said second handle means to said head seg-	The '928 Appl. discloses the use of a first handle means for moving each pedicle screw engagement member simultaneously, with each pedicle screw engagement member being configured for engaging respectively with the head segment of each pedicle screw of the first set of pedicle screws, and transmitting manipulative forces applied to the first handle means to the head segment of each pedicle screw of the first set of pedicle screws. *See* § V.B., Claim 1[D],[E], *supra* (incorporated here). The Slides and MTOS each show a second pedicle screw cluster derotation tool virtually identical to the first and engaging a second set of pedicle screws to manipulate them, except it includes four pedicle screw engagement members. This second pedicle screw cluster derotation tool functions in the same manner as the first pedicle screw cluster derotation tool in transmitting forces placed on the handle to the head segments of the pedicle screws of the second set of pedicle screws. *See* § V.A., Claim 1[D], [M], *supra* (incorporated here). The '568 pat. discloses that a manipulative force may be applied to a handle means (levering member 20) that is then transmitted to engagement members (outrigger members 30) that then transmit this force to pedicle screws (pedicle bolts 90) through link member 90. *See* '568 pat., at 2:66 to 3:4; 6:4-5; 6:60-64 ("[T]o affix a link member 90 between two adjacent vertebrae 110 spanning the intervertebral disks 104, pedicle bolts 98 are securely implanted in the bone using known methodology, and the link members 90 are placed onto the pedicle bolts 98 and secured using lock nuts 74."). The '568 pat. provides that the handle means may be used to rotate the vertebrae. *See id.* at 1:58-65 ("The reduction may require manipulation of the vertebrae and the sacrum in one or more directions, i.e., . . . rota-

ment of each pedicle screw of said second set of pedicle screws;	tion about the vertebral axis."); 2:17-21 ("It is a further object to provide such an apparatus and method which enables the surgeon to . . . rotate . . . either or both the vertebrae and the sacrum as required.").
Claim 1[N]: implanting each pedicle screw of said second set of pedicle screws in the pedicle region of each of a second group of vertebrae lateral to the first group of vertebrae;	The '928 Appl., through incorporation of the '813 Appl., discloses that the pedicle screw and spinal rod member assembly is placed on both sides of the vertebrae, thus necessitating the implantation of the second set of pedicle screws lateral to the first set. *See* § V.B., Claim 1[K], *supra* (incorporated here).
Claim 1[O]: contouring said second spinal rod member whereby, in a first plane, said second spinal rod member substantially defines, in reference to two axes, a post-operative spinal column alignment for said spinal column;	The '928 Appl., through incorporation of the '813 Appl., discloses that the pedicle screw and spinal rod member assembly is placed on both sides of the vertebrae, thus necessitating the selection of a second spinal rod member. *See* § V.B., Claim 1[K], *supra* (incorporated here). The '928 Appl. discloses that the spinal rod member may be contoured with respect to two axes so as to define a post-operative spinal column alignment for the spinal column. *See* § V.B., Claim 1[G], *supra* (incorporated here).
Claim 1[P]: engaging said second spinal rod respectively with said spinal rod engagement means of each pedicle screw of said second set of pedicle screws, while said second spinal rod is in a first rotational orientation;	The '928 Appl. discloses that each of the pedicle screws includes a spinal rod engagement means, assemblies 500 and 700, that is able to mechanically engage with a spinal rod member. *See* § V.B., Claim 1[C], *supra* (incorporated here).
Claim 1[Q]: rotating said second spinal rod substantially along its length to a second rotational orientation to effect a correction of spinal column deviation in reference to two axes;	MTOS and/or the '291 Appl. provides that the spinal rod member is rotated around its length by a ratchet tool to a second rotational orientation to effect a correction of spinal column deviation. *See* § V.A., Claim 1[I], *supra* (incorporated here).
Claim 1[R]: engaging each pedicle screw engagement member of said second group of pedicle screw engagement members respectively with said head segment of each pedicle screw of said second set of pedicle screws;	The Slides and MTOS each show the pedicle screw engagement member is configured to engage the head segment of each pedicle screw of the second set of pedicle screws to transmit manipulative forces. *See* § V.A., Claim 1[R], *supra* (incorporated here). The '928 Appl. discloses pedicle screw engagement members configured to engage the head segment of each pedicle screw of to transmit manipulative forc-

	es. *See* § V.B., Claim 1[E], *supra* (incorporated here).
Claim 1[S]: connecting with a cross-linking member the first handle means to the second handle means laterally positioned to the first handle means;	The '349 pat. discloses a system and method for realignment of vertebrae by applying manipulative forces to pedicle screws, in which a cross-linking member links first and second handle means. *See* § V.A., Claim 1[S], *supra* (incorporated here).
Claim 1[T]: applying manipulative force to the first handle means and the second handle means in a manner for simultaneously engaging said first group of three or more pedicle screw engagement members and said first set of pedicle screws, and said second group of pedicle screw engagement members and said second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws, thereby in a single motion simultaneously rotating said vertebrae of said first group of vertebrae and said second group of vertebrae lateral to said first group of vertebrae, in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.	The Slides and MTOS each show the application of manipulative force to the first handle means and the second handle means for simultaneously engaging the first group of three or more pedicle screw engagement members and the first set of pedicle screws, and the second group of pedicle screw engagement members and the second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws, thereby in a single motion simultaneously rotating said vertebrae of the first group of vertebrae and the second group of vertebrae lateral to the first group of vertebrae, in which the pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. *See* § V.A., Claim 1[T], *supra* (incorporated here).

Claim 2 is directed to a system that can carry out the method of claim 1. As noted above, the '928 Appl. discloses a first set of pedicle screws each having a threaded shank segment and a head segment. Additionally, the '928 Appl. discloses the first pedicle screw cluster derotation tool having a handle means in the form of knobs 112a and 112b and threaded rods 110b joined together by cross-action members 107a and 107b. *See* § V.B at 39-40, Claim 1, *supra* (incorporated here). Alternatively, as discussed above, it would have been obvious to modify the '928 Appl. to include the handle means disclosed by the '568

pat. to further facilitate the identical spinal rotation technique taught in both references. *See id.* The tool also includes guide tubes 102a, 102b, and 104, or anchor extensions, which may be placed under the guide tubes, either of which serves as a first group of three or more pedicle screw engagement members. These engagement members are mechanically linked to the knob 112b and threaded rod 110b by cross-action members 106a, 106b, 107a, and 107b and threaded rod coupling 108a, and each engage the head segments of the pedicle screws. Because of the rigid mechanical link between the handle means and the pedicle screw engagement members, any force placed on the handle means would necessarily be transferred to the pedicle screw engagement members, and subsequently transmitted to the head segment of each pedicle screw that is engaged with the respective pedicle screw engagement member.

As noted above, the '928 Appl. also discloses the claimed second set of pedicle screws and the second spinal rod member through its incorporation of the '813 Appl. To the extent the '928 Appl. does not disclose the inclusion of an identical second pedicle screw cluster derotation tool, it would have been obvious to do so because such inclusion is a mere duplication of parts or design choice without any new or unexpected results occurring due the duplication. *See In re Harza*, 274 F.2d 669 (CCPA 1960). Alternatively, it would have been obvious in view of the common knowledge among those of ordinary skill in the art at the time of invention that such a derotation procedure should be carried out on both sides of the vertebrae to obtain the desired effect. *See* Lenke Decl., at ¶ 103, 104, 110, 111. As another alternative, for the same reasons as explained above, it would

have been obvious to include this duplicative tool in view of the Slides and MTOS, each of which show the use of a second pedicle screw cluster derotation tool on a second set of pedicle screws. *See* § V.B. at 45-46, Claim 1, *supra* (incorporated here).

To the extent that the '928 Appl., the Slides, or MTOS do not show that the these first and second pedicle screw cluster derotation tools are linked to each other by a cross-linking member connected to the first and second handle means, as detailed above, it would have been obvious to do so in view of the '349 pat. *See* § V.B., Claim 1, *supra*.

Claim 2 [A]: A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising:	The '928 Appl. discloses a system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions. *See* § V.B., Claim 1[A], *supra* (incorporated here).
Claim 2 [B]: a first set of pedicle screws,	The '928 Appl. discloses a first set of pedicle screws 602b, 603, and 602a. *See* § V.B., Claim 1[B], *supra* (incorporated here).
Claim 2 [C]: each pedicle screw having a threaded shank segment and a head segment; and	The '928 Appl. discloses that each pedicle screw includes a threaded shank segment and a head segment. *See* § V.B., Claim 1[B], *supra* (incorporated here).
Claim 2 [D]: a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means having a handle linked to each pedicle screw	The '928 Appl. discloses a first pedicle screw cluster derotation tool. *See* § V.B., Claim 1[D], *supra* (incorporated here). The '928 Appl. discloses that the pedicle screw cluster derotation tool includes a handle means in the form of knobs 112a and 112b and threaded rods 110b. *See id.* The '928 Appl. also discloses a first group of a three or more pedicle screw engagement members, for example, guide tubes 102a, 102b, and 104, or anchor extensions, which may be placed under the guide tubes. *See id.* The first handle means of the '928 Appl. in the form of knobs 112a and 112b and threaded rods 110b. These handles are joined together by cross-action members 107a and 107b. *See id.* The handle means of the '928 Appl. facilitates simultane-

engagement member of the first group of three or more pedicle screw engagement members and a linking member to join together the handles linked to the pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member;	ous application of manipulative forces to the first set of pedicle screws. *See* § V.B., Claim 1[E], *supra* (incorporated here). The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. *See* § V.B., claim 1[D], *supra* (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.* These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.*
Claim 2 [E]: wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said first set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;	The '928 Appl. discloses that the guide tubes 102a, 102b, and 104 each engage with the head segments, labeled assemblies 500 and 700, which include rod cages 603a, 604, and 605b, of each pedicle screw. *See* § V.B., Claim 1[E], *supra* (incorporated here). The '928 Appl. provides that when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. *See id.*
Claim 2 [F]: a second set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment;	The '813 Appl., incorporated by reference into the disclosure of the '928 Appl., discloses that the pedicle screw and spinal rod member assembly is placed on both sides of the vertebrae, thus necessitating the selection of a second set of pedicle screws. *See* § V.B. Claim 1[K], *supra* (incorporated here).
Claim 2 [G]: a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitat-	The '928 Appl. discloses the use of a first handle means for moving each pedicle screw engagement member simultaneously, with each pedicle screw engagement member being configured for engaging respectively with the head segment of each pedicle screw of the first set of pedicle screws, and transmitting manipulative forces applied to the first handle means to the head segment of each pedicle screw of the first set of pedicle screws. *See* § V.B.,

ing simultaneous application of manipulative forces to said second set of pedicle screws and a second group of three or more pedicle screw engagement members which are mechanically linked with said second handle means,	Claim 1[D], *supra* (incorporated here). The '568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. *See* § V.B., claim 1[D], *supra* (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. *See id.* These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. *See id.* The Slides and MTOS each show a second pedicle screw cluster derotation tool virtually identical to the first. *See* § V.A, Claim 1[M], *supra* (incorporated here).
Claim 2 [H]: said second handle means having a handle linked to each pedicle screw engagement member of the second group of three or more pedicle screw engagement members and a handle linking member to join together the handles linked to the pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member;	The first handle means of the '928 Appl. includes a handles in the form of knobs 112a and 112b and threaded rods 110b. These handles are joined together by cross-action members 107a and 107b. *See* § V.B., Claim 1[D], *supra* (incorporated here). This handle means is configured to move simultaneously each pedicle screw engagement member. *See id.* The Slides and MTOS each show a second pedicle screw cluster derotation tool virtually identical to the first. *See* § V.A, Claim 1[M], *supra* (incorporated here).
Claim 2 [I]: wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said second set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said second handle means to said head segment of each pedicle screw of said second set of pedicle screws;	The '928 Appl. discloses that the guide tubes 102a, 102b, and 104 each engage with the head segments, labeled assemblies 500 and 700, which include rod cages 603a, 604, and 605b, of each pedicle screw. *See* § V.B., Claim 1 [E], *supra* (incorporated here). The '928 Appl. provides that when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. *See* § V.B., Claim 1[F], *supra* (incorporated here). The Slides and MTOS each show the pedicle screw engagement member is configured to engage the head segment of each pedicle screw of the second set of pedicle screws to transmit manipulative forces from the second handle means to the pedicle screws. *See* § V.A., Claim 1[R], *supra* (incorporated here).

Claim 2 [J]: a cross-linking member that links the first handle means to the second handle means.	The '349 pat. discloses a system and method for realignment of vertebrae by applying manipulative forces to pedicle screws, in which a cross-linking member links first and second handle means. *See* § V.A., Claim 1[S], *supra* (incorporated here).

Claim 3 depends from Claim 2 and adds limitations directed to a spinal rod member, and a conduit and engagement means included in the pedicle screws for receiving and securing, respectively, the spinal rod member.

The '928 Appl. discloses a spinal rod member; and pedicle screws having a spinal rod conduit formed substantially transverse the length of each screw on the saddle assembly of the pedicle screw, and sized and shaped to receive the spinal rod member. The '928 Appl. further discloses a spinal rod engagement means for securing each of the pedicle screws and the spinal rod in a substantially fixed relative position and orientation.

Claim 3 [A]: The system of claim 2 further comprising a spinal rod member, wherein one or more of said pedicle screws each includes: a spinal rod conduit formed substantially transverse of the length of each said pedicle screw and sized and shaped for receiving passage of said spinal rod member therethrough; and	The '928 Appl. discloses that the system may include a spinal rod member and that each of the pedicle screws may include a spinal rod conduit, assemblies 500 and 700, that is formed substantially transverse of the length of each pedicle screw and sized and shaped for receiving passage of the spinal rod member. *See* § V.B., Claim 1[C], *supra* (incorporated here).
Claim 3[B]: spinal rod engagement means for securing each said pedicle screw and said spinal rod, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation.	The '928 Appl. discloses a spinal rod fixation means, set screw 701, that secures the spinal rod member, brace 601, to the pedicle screw in a substantially fixed relative position and orientation. *See* § V.B., Claim 1[C], *supra* (incorporated here).

Claim 4, which depends from claim 3, recites the additional limitation that "the spinal rod is precontoured." The '928 Appl. discloses that the spinal rod may be contoured

with respect to two axes so as to define a post-operative spinal column alignment for the spinal column. *See* '928 Appl. at ¶ [0039] (providing that spinal rod may be "curved to match the curvature of the patient's spine").

VI. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for Claims 1-4 of the '121 patent.

Respectfully submitted,

Dated: _February 20, 2015__

_/Jeff E. Schwartz/_____
Jeff E. Schwartz, Reg. No. 39,019
Fox Rothschild LLP
1030 15th Street, NW
Washington, DC 20005
Tele: 202-696-1470
Fax: 202-461-3102

Attorneys for Petitioner

CERTIFICATE OF SERVICE ON PATENT OWNER

UNDER 37 C.F.R. § 42.105(a)

Pursuant to 37 C.F.R. §§ 42.8(e) and 42.105(b), the undersigned certifies that on the 20th day of February 2015 a complete and entire copy of this Petition for Inter Partes Review and all supporting exhibits was provided via FedEx to the Patent Owner by serving the address:

David G. Henry
GRAY REED & McGRAW, P.C.
1601 ELM STREET
Suite 4600
Dallas TX 75021

Dated: _February 20, 2015_

/Jeff E. Schwartz/
Jeff E. Schwartz, Reg. No. 39,019
Fox Rothschild LLP
1030 15th Street, NW
Washington, DC 20005
Tele: 202-696-1470
Fax: 202-461-3102

Attorneys for Petitioner