IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Barry
U.S. Patent No.: 8,361,121 Attorney Docket No.: 108136.00037
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

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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

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EXHIBITS

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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)

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MSD 1022 – U.S. Patent No. 8,316,121

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MSD 1026 – Declaration of Seth A. Kramer

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

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 patent") (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 Party-in-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner is the real party-in-interest for the instant 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 patent. Petitioner is the named defendant in litigation concerning the '121 patent, *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 Petitioner was served with the complaint on February 20, 2014.

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

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D. Service Information

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skramer@foxrothschild.com, and ipdocket@foxrothschild.com (referencing Attorney Docket No. 108136.00037).

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 patent 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 against Petitioner in district court litigation involving the '121 patent.

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

Petitioner requests IPR of claims 1-4 of the '121 patent on the grounds set forth in the table below and requests that each of the claims be found unpatentable. 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) in view of U.S. 2003/0065328 (the "'328 Appl."), U.S. 5,219,349 (the "'349 patent"), and U.S. 2005/0033291 (the "'291 Appl.")

2	1-4	Obvious under § 103 over the Video, the Slides, and/or MTOS Chp. 17 (alone or in combination) in view of U.S. 2005/0245928 (the "'928 Appl."), the '349 patent, and, in the '291 Appl.
3	1-4	Obvious under § 103 over the '928 Appl. in view of the Slides, MTOS Chp. 17, the '291 Appl., and the '349 patent

The Video, the Slides, the MTOS chapter (published in November 2003[1]), the '349 patent, and the '328 Appl. 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 qualifies as prior art at least under 35 U.S.C. § 102(e) because they were filed prior to Dec. 30, 2004.[2] None of these references were cited in a rejection during prosecution of the '121 patent. 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). As explained below, however, the USPTO did not take in to account the

[1] *See* Declaration of Seth A. Kramer (MSD 1026), at ¶¶ 3,4.

[2] 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.

alternative ways that one skilled in the art would understand the disclosure of the '928 Appl., such as presented herein, in view of the knowledge generally available in the art at the time of the invention to read on these claims.

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 construed or other claim terms are reasonably certain to one of ordinary skill in the art. *See generally Nautilus, Inc. v. Bioig Instruments, Inc.*, 2014 WL 2440536, __ U.S. __ (June 2, 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 are given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). 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 to this position or waiving any arguments and solely for purposes of this IPR the following alternative construction is submitted. 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 patent 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.

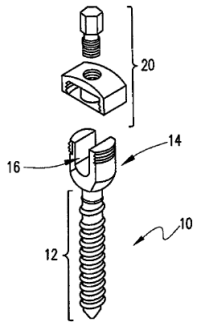


FIG. 4

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 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 to this position 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 patent 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"). 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 to this position or waiving any arguments and solely for purposes of this IPR the following construction is proposed. The claimed function is facilitating simultaneous application of manipulative forces to a first/second group of three or more pedicle screw engagement members, and simultaneously moving 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 patent 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.

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 located at least in part at a different location on the spine than the first group of vertebrae." *See, e.g.*, '121 patent 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, that is vertebra are not located side by side but rather run one on top of the other down the length of 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 patent, 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 patent at 7:41-43.

IV. SUMMARY OF THE '121 PATENT

A. Overview of the '121 Patent

The application that issued as the '121 patent 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. Patent No. 7,670,358 (the "'358 Patent") (MSD 1020).

The '121 patent describes a system and method for the alignment of vertebrae that uses 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 thereby rotate the vertebrae in which the pedicle screws are implanted. The '121 patent claims the use of two tools located across the vertebrae from each other, wherein the handles of the tools are connected by a cross-linking member.

The method also calls for the use of a pedicle screw and rod system, as 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 respect to the pedicle screw by fixation. This is essentially the same method developed by Cotrel and Dubousset in the early 1980s.

The remainder of the claims of the '121 patent 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 patent, the '072 patent, and the '358 patent, as obtained from PAIR, are submitted herewith as Exhibit MSD 1010, MSD 1009, and MSD 1008, respectively.

During prosecution of the '121 patent, United States Patent and Trademark Office ("USPTO") rejected some of the original claims under a nonstatutory obviousness-type double patenting rejection. The other claims were either allowed or objected-to as being dependent on a rejected base claim. MSD 1010 at 439.

In response, the Applicant cancelled the rejected claims and amended the objected to claims to either be in independent form or dependent on an allowable claim. MSD 1010 at 412-16. The '121 patent issued on January 29, 2013.

During prosecution of the '072 patent, to which the '121 patent claims priority, the claims were rejected numerous times by the Unites States Patent and Trademark Office ("USPTO"). In a non-final office action dated Jan. 23, 2008, the USPTO rejected claims 1 and 2 of the pending claims over U.S. 6,090,113 (the "'113 patent"), and claims 3 and 4, which both required a rotation of a spinal rod member while engaged with implanted pedicle screws, over the '113 patent in combination with U.S. 5,281,223 (the "'223 patent"). In rejecting these claims, the USPTO asserted that the '113 patent'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" as anticipating the claimed first and second sets of pedicle screws being implanted in a first and second group of vertebrae, and the presence of a 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 patent disclosed the claimed step of rotating the spinal rod member while engaged to the pedicle screws, and it would have been obvious to modify the method taught by the '113 patent to include this rod rotation step disclosed in the '223 patent "because of the benefit that the rotation of the rod has in achieving total alignment of the spinal column." *See id.* at 188.

In a reply filed on Sept. 10, 2008, the applicant first noted that that the disclosure of the '113 patent regarding the connection of pedicle screws by spinal rods was inapplicable to the patentability of the claims and was "nothing new, as pedicle screws are connected together in any number of prior art references." *See id.* at 123. In an attempt to distinguish the claims from the '113 patent, the applicant asserted that the claims were patentable because the '113 patent failed to disclose a pedicle screw cluster derotation tool that could simultaneously engage "multiple pedicle screws in clusters of selected vertebrae to effect *en masse* manipulation of that cluster is only possible through the essential system components." *See id.* at 123-24.

Unpersuaded, the USPTO issued a final office action on Jan. 13, 2009, again rejecting claims 1 and 2 over the '113 patent and claims 3 and 4 over the '113 patent and the '223 patent. The USPTO noted that the claims did not require "en masse" spinal column scoliotic correction but only required that the spinal column is corrected in the form of "clusters," which only requires more than one vertebrae

being corrected at a time. This limitation was satisfied by the '113 patent disclosing the correction of two vertebrae of the spinal column at a time. *See id.* at 84-85.

In a reply filed on July 13, 2009, the applicant amended the claims to require, *inter alia*, that the first pedicle screw cluster derotation tool included "three or more" pedicle screw engagement members and that the application of manipulative force to the handle means was done in "a manner for simultaneously engaging said first group of three or more pedicle screw engagement members and said first set of multiple pedicle screws and thereby in a single motion simultaneously" rotate the vertebrae. *See id.* at 65-67. Applicant then argued that the '113 patent does not disclose such single motion to rotate the vertebrae, but instead required multiple actions. *See id.* at 71. Applicant also argued that the '113 patent did not disclose three or more pedicle screw engagement means as the disclosed tool of the '113 patent only included two arms. *See id.* at 70.

The USPTO issued a non-final office action on Sept. 30, 2009, rejecting claims 1 and 2 as anticipated by the '928 Appl. The USPTO asserted, *inter alia*, that 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.

In a reply filed on Dec. 30, 2009, the applicant amended the claims to require, *inter alia*, that 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 of the device disclosed in the '928 Appl., and therefore, the '928 Appl. did not anticipate the claims. *See id.* at 41-42. The '072 patent subsequently issued on August 17, 2010.[3]

C. Legal Standard for Obviousness

A claim is obvious, and therefore invalid, under 35 U.S.C. § 103(a) if, at the time the invention was made, "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

[3] The prosecution of the parent '358 patent was similar to that of the '072 patent, except for the amendment to the '072 claims to include three pedicle screw engagement members.

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 patent, 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 ¶ 66. As detailed in claim charts below, prior art references render obvious the challenged claims of the '121 patent.

A. Ground 1 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the Video, the Slides, and/or the MTOS chapter, in view of the '328 Appl., the '349 Patent and, in the alternative, the '291 Appl.

As shown in the claim charts below, Claims 1-4 are obvious under § 103 over the Video, the Slides and/or the MTOS chapter (alone or in combination) in view of the '328 Appl., and the '349 patent, 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 the MTOS chapter 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. As such, the Video, the Slides, and the MTOS chapter can be considered a single reference. 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 Video, the Slides, and the MTOS chapter each show a system, and its method of use, for treating and correcting deformities and injuries of the spine. Specifically, each of these references shows a surgical procedure in which the surgeon performs a derotation of the patient's vertebrae to ameliorate a scoliotic deformity. As shown in the Video, the Slides and the MTOS chapter, the surgeon performing this procedure 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 of a spinal column.

The Video, the Slides, and the MTOS chapter each also show the use of a first pedicle screw cluster derotation tool in the form of multiple apical derotators that are used simultaneously. Each apical derotator includes a handle linked to and moving a pedicle screw engagement member that engages the head segment of each pedicle screw. While only two apical derotators are shown as part of the pedicle screw cluster derotation tool 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 ¶¶ 72, 73. This is evidenced by the Slides and the MTOS chapter, 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. Moreover, the specification of the '121 patent 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 handles of each apical derotator shown in the Video, the Slides, and the MTOS chapter are grasped by the surgeon during the derotation procedure. As is evident in the Video, the Slides, and the MTOS chapter, because the spinal surgeon grasps and applies force to each of the handles of the apical derotators together and at the same time, the first handle means facilitates the simultaneous application of

manipulative forces to the first set of pedicle screws. The surgeon's hand (shown in the Video) moves the handles simultaneously en masse to form a single unit that moves each of the vertebrae together. As such, the surgeon's hand functionally links the derotators. The Slides and the MTOS chapter derotator handles are identical to those in the Video, and are similarly configured to be grabbed by a surgeon's hand and moved as a single unit en masse.

Alternatively, to the extent that the Video, the Slides, or the MTOS chapter 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 teachings of the '328 Appl. The '328 Appl. describes a system and method for the treatment of spinal column deviations, and discloses a pedicle screw cluster tool having a first handle means that includes individual handles – threaded rods 205 and 206, and threaded shank 222 of the connecting element 213 – linked to three pedicle screw engagement members and a linking member, in the form of a microschweller 204, to join the handles. The '328 Appl. provides that the linking of these handles together by the microschweller 204 facilitates simultaneous transport of the three pedicle screw engagement members in the transverse plane. *See* '328 Appl. at ¶ [0087].

It would have been obvious to one of ordinary skill at the time of invention to connect the individual handles shown in the Video, the Slides, and the MTOS chapter via a mechanical linkage, to ensure simultaneous and uniform transport of the pedicle

screw engagement members while reducing the workload on the surgeon. *See* Lenke Decl. at ¶¶ 74, 75. The Video, the Slides, and the MTOS chapter each show that the surgeon moves the handles simultaneously by hand to achieve such movement. The addition of a mechanical linking member to connect the handles and achieve the same type of movement would have been nothing more than a simple and obvious modification in view of the express teachings of the '328 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 vertebral bodies, each of which is entirely expected and common sense result. *See* Lenke Decl. at ¶¶ 74, 75. The Video, the Slides, the MTOS chapter and the '328 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 ¶ 66. Thus, a spinal derotator, and method of use thereof, 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.

The Video, the Slides, and the MTOS chapter each show a spinal rod that is coupled to the pedicle screws. The Video and the MTOS chapter each disclose that prior to this coupling, the spinal rod member is contoured with respect to the coronal plane and the sagittal plane so as to define a post-operative alignment for the spinal

column. The Video and the MTOS chapter shows 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, 77; 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, the MTOS chapter refers to the rod rotation method of Cotrel and Dubousset, noting that the apical vertebral derotation maneuver described in the MTOS chapter complements the rod rotation method, as rod rotation helped to translate the spine but did not fully derotate it. Therefore, the MTOS chapter thereby 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 the MTOS chapter, the Video, and the Slides. *See* Lenke Decl. at ¶ 77.

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 spinal column. One of these methods 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 the invention to modify the method of derotating vertebrae as shown in the Video, the Slides, and the MTOS chapter so that the spinal rod member is rotated along its length after the spinal rod member 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 ¶ 78. The Video, the Slides, the MTOS chapter 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 ¶ 66. Thus, a spinal derotator, and method of use thereof,

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.

The Video, the Slides, and the MTOS chapter each disclose the second set of screws and the coupling of the second spinal rods to second set. To the extent that the Video does not disclose the claimed 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 the MTOS chapter. *See* Lenke Decl. at ¶¶ 82, 83. The Slides and the MTOS chapter 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 the MTOS chapter, 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 ¶ 83.

To the extent that the Video, the Slides, or the MTOS chapter 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 include such a cross-linking member in view of the express

teachings of the '349 patent. The '349 patent discloses a system and method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions, and incorporates into its disclosure the use of spinal fixation devices that utilize pedicle rod and screw systems. *See* '349 patent 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 patent at 5:4-8.

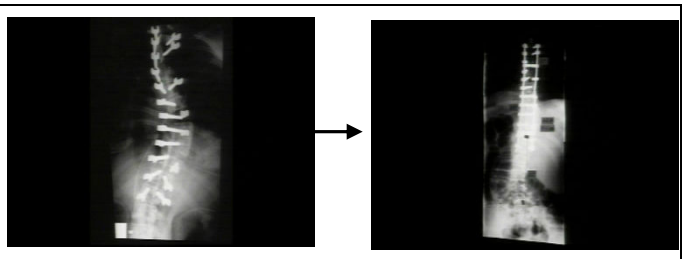
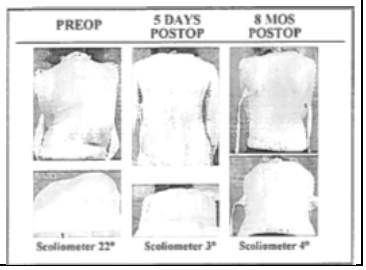
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the systems and methods shown in the Video, the Slides, and the MTOS chapter to include such a cross-linking member, in view of the express

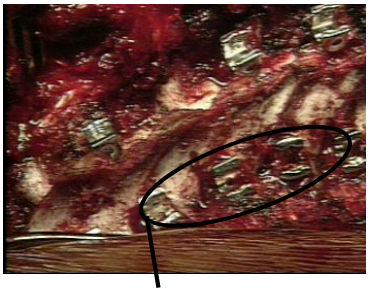
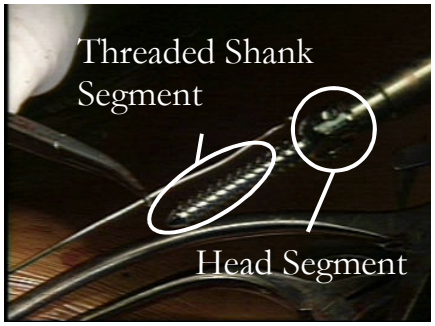
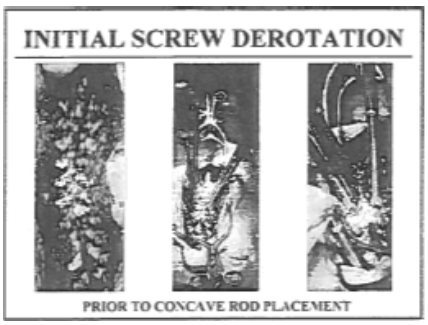
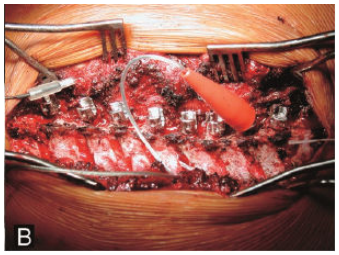
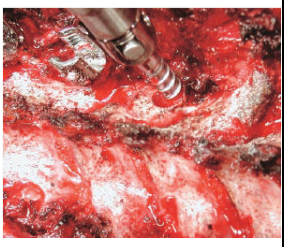
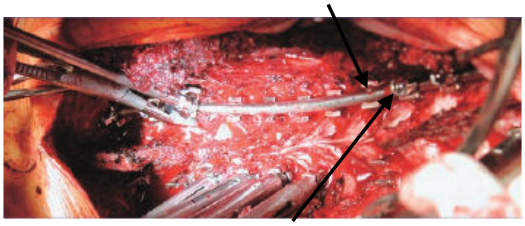
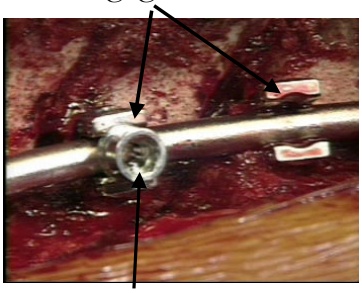
teaching of such a member in the '349 patent to "allow manipulation of the spine with even distribution of force between opposite pedicle, in order to prevent the application of excessive load to either pedicle." '349 patent at 3:36-40; *see* Lenke Decl. at ¶¶ 84, 85. The Video, the Slides, the MTOS chapter and the '349 patent 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 ¶ 66. Thus, a spinal derotator, and method of use thereof, incorporating the combined 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.

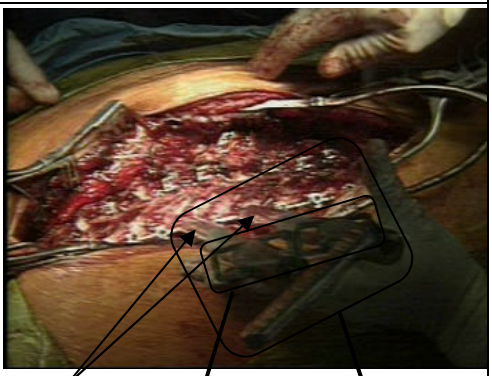
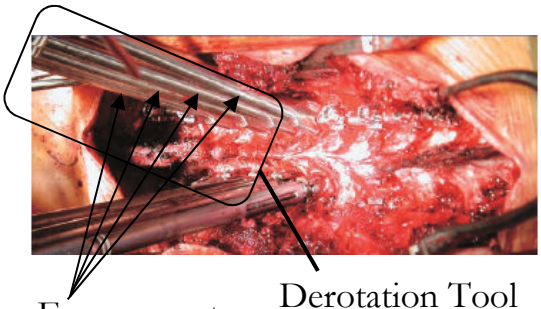
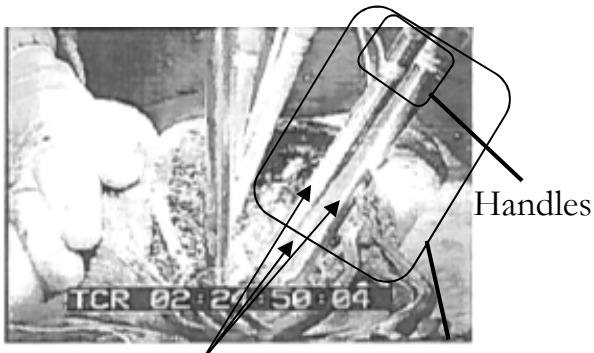
The Video, the Slides, and the MTOS chapter each show the application of manipulative force to the first group of handles to simultaneously engage the pedicle screw engagement members and the first set of pedicle screws. The spinal surgeon can thereby, in a single motion, simultaneously rotate the vertebrae 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.

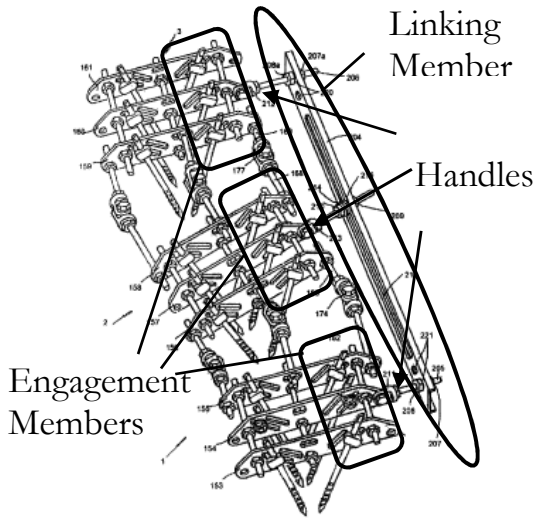
Additionally, the Slides, and the MTOS chapter each show the application of manipulative force to the first group of handles and the second group of handles at the same time, thereby simultaneously engaging the first group of three or more pedicle screw engagement members and the first set of pedicle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

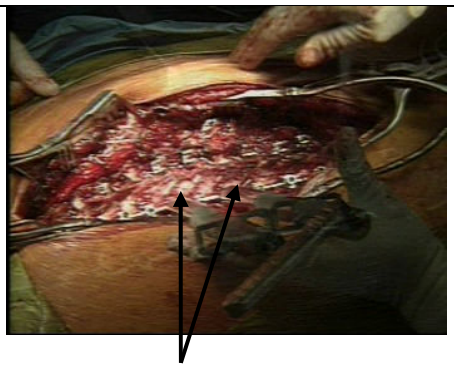
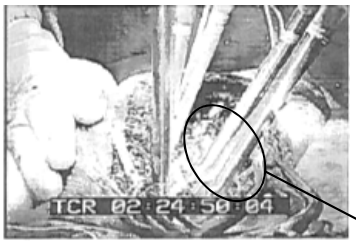
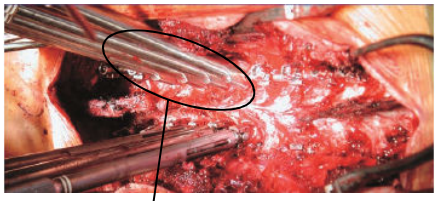
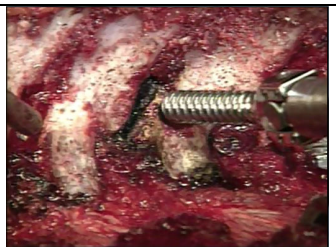
group of pedicle screw engagement members and the second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws. This allows for, in a single motion, the simultaneous rotation of the vertebrae of the first group of vertebrae and the second group of vertebrae lateral to the first group of vertebrae, in which the pedicle screws are implanted, to achieve an 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 the MTOS chapter, 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 ¶ 89, 90.

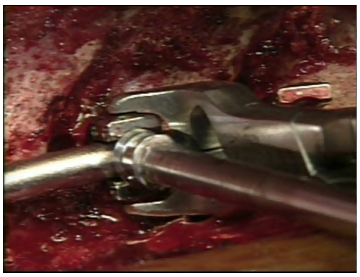
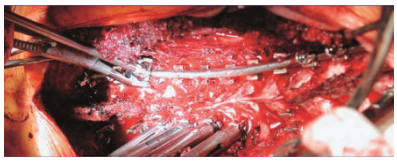
Claim 1[A]: A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:	The Video, the Slides, and MTOS each disclose a method for treating and correcting deformities and injuries of the spine. *See* Slides at 21. *See* MTOS at 245-46 ("Thoracic 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.").  

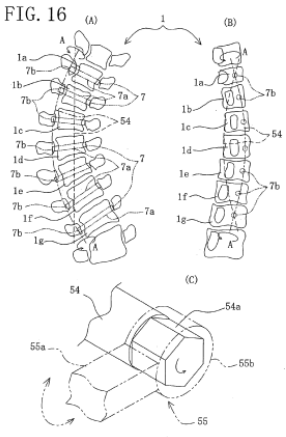
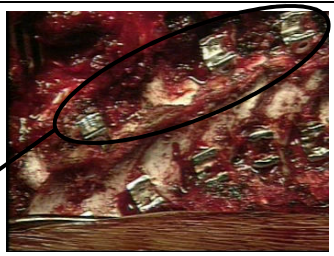
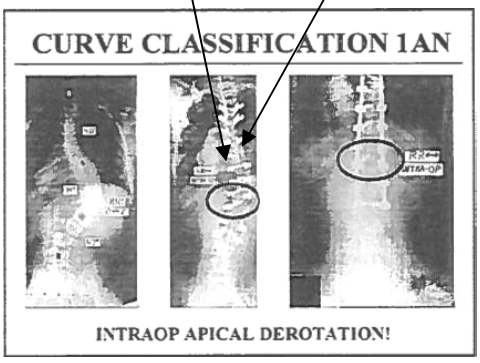
Claim 1 [B]: selecting a first set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment,	The Video shows multiple pedicle screws, any combination of which could be considered a first set, and each having threaded shank segment and a head segment.  First Set of Pedicle 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	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 Engagement Means  Fixation Means Engagement Means  Fixation Means orientation of each pairing of the spinal rod member and the pedicle screw. *See* Video at 5:38-43; MTOS at FIG. 17-

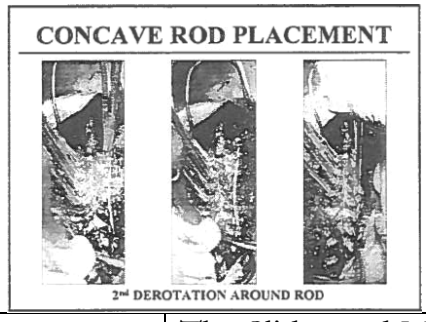
each pairing of said spinal rod member and said pedicle screw;	12; Slides at 19 (depicting placement of spinal rod and subsequent rotation of vertebrae around spinal rod).
Claim 1 [D]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first 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	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 Handle 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  Engagement Members Derotation Tool  Handles Pedicle Screw Engagement Members Pedicle Screw Cluster Derotation Tool

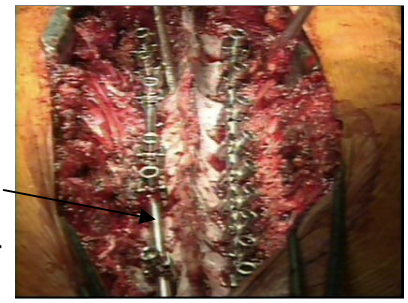
to join together the handles linked to the pedicle screw engagement members, said first handle means moving each pedicle screw engagement member simultaneously;	member to move them. The '328 Appl. discloses that the first handle means includes a handle linked to each pedicle screw engagement member of 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. Threaded rod 205 is the handle linked to the first pedicle screw engagement member (support unit 1); threaded shank 22 of the connecting element 213 is the handle linked to the second pedicle screw engagement member (support unit 2); and threaded rod 206 is the handle linked to third pedicle screw engagement member (support unit 3). A microschweller 204 serves as a linking member that joins together each of these handles. *See* '328 Appl. at ¶ [0070] ("The microschweller 204 is connected through posts 211, 212, set on the fixation junctions 154, 160 of outer support units 1 and 3, respectively, with the possibility of transport using threaded rods 205, 206 and two pairs of load-bearing nuts 207, 208, and 209, 210, respectively. Moreover, the fixation junction 157 of the intermediate support unit 2 is connected with the microschweller 204 by a connecting element 213, a pair of load-bearing nuts 209, 210 and two pairs of conical 214 and spherical 215 washers, respectively (FIG. 12). . . . In this case the connecting element 213 (FIG. 13) is made as a lug with threaded shank 222 and a through hole 223, and the axis of the lug is a perpendicular to the axis of the threaded shank 222."). 

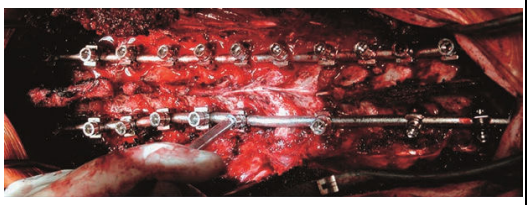
Claim 1[E]: each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said first set of pedicle screws, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;	The 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   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 discloses the implantation of each pedicle screw in a pedicle region of 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).	 each 

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 said first set of pedicle screws, while said spinal rod is in a first rotational orientation;	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 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	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

axes;	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 pedicle screws;	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[F].
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.   

<table>
<tr>
<td>Claim 1 [L]: selecting a second spinal rod member;</td>
<td>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.
 

Second Spinal Rod Member
 

  </td>
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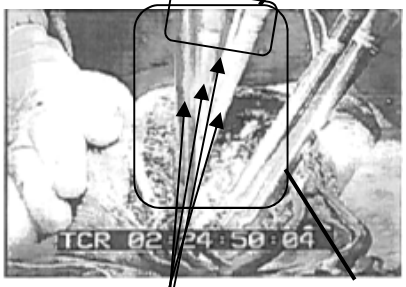
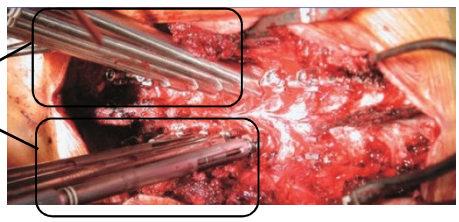
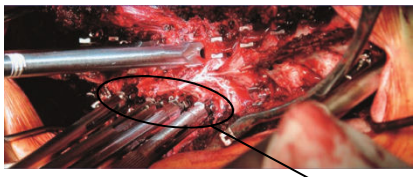
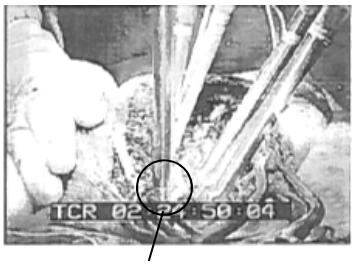
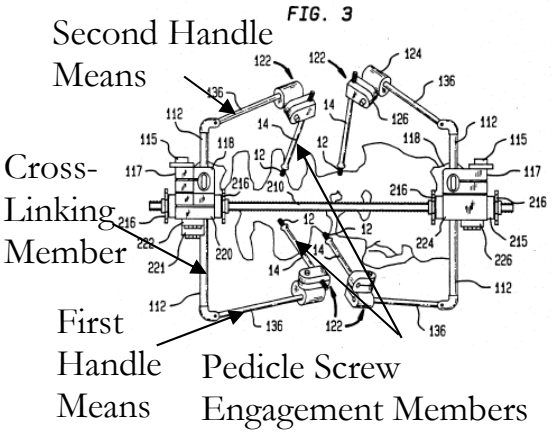
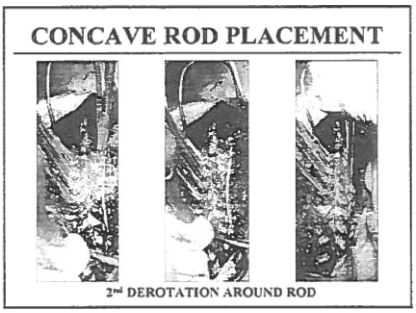
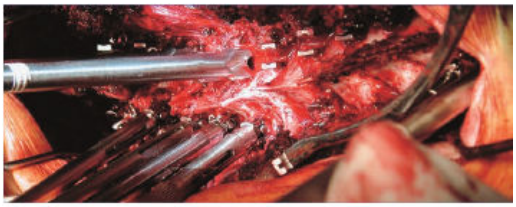
<tr>
<td>Claim 1 [M]: selecting a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitating simultaneous application of manipulative forces to said second set of pedicle screws and a second group of pedicle screw engagement 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</td>
<td>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).
Second Group of Handles
 

Pedicle Screw Engagement Members
Second Derotation Tool
First and Second Derotation Tools
  </td>
</tr>
</table>

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[G], *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[H], *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[I], *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 Video, the Slides, and MTOS each disclose a second spinal rod member. *See* § V.A., Claim 1[H], *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 spinal rod member is in a first rotational orientation. *See* § V.A., Claim 1[J], *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[H], *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[K], *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 patent 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 patent 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 patent 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 patent 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 a single motion simultaneously rotating said	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 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* Slides at 19; MTOS, at 242-43 ("With the four apical vertebrae secured on both sides, the AVD maneuver is performed (Fig. 17-11).   **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.

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.	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 described and claimed in claim 1. As noted above with respect to claim 1, the Video, the Slides, and the MTOS chapter each disclose first and second sets of pedicle screws. Each of the pedicle screws of these sets has a threaded shank segment and a head segment.

The Video, the Slides, and the MTOS chapter 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 the MTOS chapter each disclose that the pedicle screw cluster derotation tools may include three apical derotators or four apical derotators on each side of the spine. Each apical derotator includes a handle linked to a pedicle screw engagement member, which are configured to engage the head segment of each pedicle screw to transmit manipulative forces. As the Video, the Slides, and the MTOS chapter each disclose that the surgeon

applies force to each of the handles of the apical derotators at the same time, this first handle means is shown as facilitating 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 handle means 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 that the Video or Slides 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 '328 Appl. *See* § V.A., Claim 1, *supra.*

As noted above with respect to claim 1, both the Slides and the MTOS chapter disclose the use a second pedicle screw cluster derotation tool having the same structural components as the first pedicle screw cluster tool. For the reasons provided above, it would have been obvious to modify the system disclosed in the Video in view of the disclosure of the Slides and the MTOS chapter. *See* § V.A., Claim 1, *supra.* Similarly, to the extent that the Video, the Slides, or the MTOS chapter 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 include such cross-linking member in view of the '349 patent. *See* § V.A., Claim 1, *supra.*

Claim 2[A]: A system for aligning	The Video, the Slides, and MTOS each

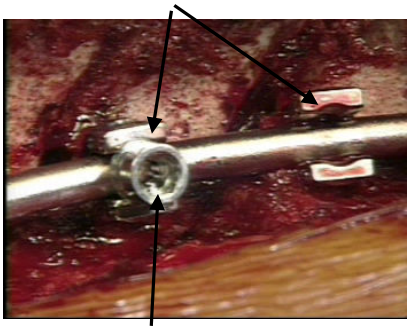
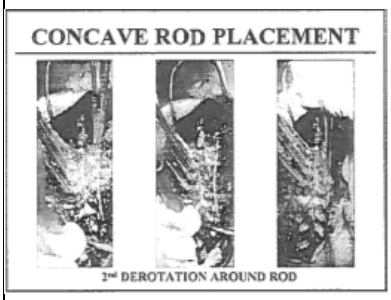
vertebrae in the amelioration of aberrant spinal column deviation conditions comprising:	disclose a method for treating and correcting deformities and injuries of the spine. *See* § V.A., Claim 1[A], *supra* (incorporated here).
Claim 2[B]: a first set of pedicle screws,	The Video, the Slides, and MTOS 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[C], *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 Video, the Slides, and MTOS each disclose a first pedicle screw cluster derotation tool. The Each reference shows that this tool includes a first group of 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 said first handle means. The handles of the first group of handles each linked to a pedicle screw engagement member that are gasped simultaneously by the surgeon. Both the Slides and MTOS disclose that the tool includes 3 or more pedicle screw engagement members. *See* § V.A., Claim 1[E], *supra* (incorporated here). The '328 Appl. discloses a first handle means that includes 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. *See* § V.A., Claim 1[E], *supra* (incorporated here).
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	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],

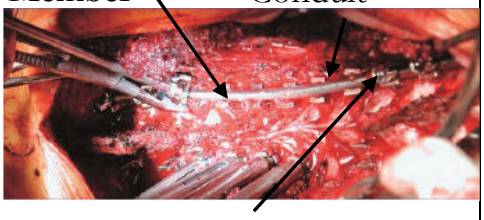
pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;	*supra* (incorporated here).
Claim 2[F]: a second set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment;	The Video, the Slides, and MTOS each disclose a second set of pedicle screws. *See* § V.A., Claim 1[L], *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 each disclose a second pedicle screw cluster derotation tool virtually identical to the first, and accordingly includes a second handle means, which like the first handle means, includes individual hands that are grasped at the same time. *See* § V.A., Claim 1[N], *supra* (incorporated here). The '328 Appl. also discloses that the first handle means includes 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. *See* § V.A., Claim 1[E], *supra* (incorporated here).
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 second handle means to said head segment of each pedicle screw of said second set of pedicle screws;	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[T], *supra* (incorporated here).

Claim 2[I]: a cross-linking member that links the first handle means to the second handle means.	The '349 patent 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[U], *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 Video, the Slides, and the MTOS chapter each disclose the claimed spinal rod member. The Video, the Slides, and the MTOS chapter also disclose pedicle screws having the claimed 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 Video, the Slides, and the MTOS chapter 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,. To the extent that these claimed features of the pedicle screws are not clearly shown in the Slides, one of ordinary skill in the art would understand that such 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.

<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).
Spinal Rod Conduits

Engagement Means


Spinal Rod Member
Spinal Rod Conduit

Spinal Rod Engagement</td>
</tr>
</table>

Claim 4, which depends from claim 3, recites the additional limitation that "the spinal rod is precontoured." The Video and the MTOS chapter 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").

B. Ground 2 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the Video, the Slides, and/or the MTOS chapter in view of the '928 Appl., the '349 Patent and, in the alternative, the '291 Appl.

As shown in the claim charts below, Claims 1-4 are obvious pursuant to § 103 over the Video, the Slides and/or the MTOS chapter (alone or in combination) in view of the '928 Appl., and the '349 patent, and, in the alternative also the '291 Appl.

With respect to elements [A]-[D] and [F]-[U] of claim 1, elements [A]-[C], [E]-[F], and [H]-[I] of claim 2, as well as claims 3 and 4, the same analysis for the invalidity of these claims and claim elements over the Video and Slides in combination with the '349 patent as discussed in Ground 1 is applicable for this ground. *See* § V.A., *supra*.

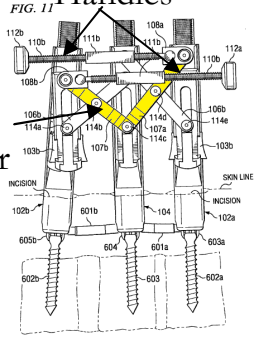
While it would have been obvious to link the handles of the handles of the pedicle screw cluster derotation tool shown in the Video, the Slides, and the MTOS chapter alone, or alternatively in view of the '928 Appl., as another alternative grounds, it would have been obvious to do so in view of the '928 Appl.

The '928 Appl. discloses a system and method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions. As noted in the below claim chart, the system comprises a device that imparts forces on pedicle screws using pedicle screw engagement members in the form of guide tubes (102, 104). The device incorporates two handles, in the form of knobs (112a, 112b) and threaded rods (110b), that each allow a practitioner to simultaneously apply forces to two of the

pedicle screw engagement members. The handles are interconnected by a linkage in the form of cross-action members (107a, 107b), so that the handles and the attached pedicle screw engagement members move in unison in response to a force, or forces, applied to one or both handles.

As noted above in Ground 1, the Video, the Slides, and the MTOS chapter already show that the surgeon moves the handles simultaneously by hand to achieve such movement. The addition of a mechanical linking member to connect the handles and achieve the same type of movement 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* Lenke Decl. at ¶¶ 74, 75. The Video, the Slides, the MTOS chapter and the '928 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 ¶ 66. Thus, a spinal derotator 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.

Claim 1 [E]: said first handle means having a handle linked to each pedicle screw	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.

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 handle means moving each pedicle screw engagement member simultaneously;	*See* § V.A., Claim 1[E], *supra* (incorporated here). The first handle means of the '928 Appl. includes a handles in the form of knobs 112a and 112b and threaded rods 110b. *See* '928 Appl. at FIG. 11. These handles are linked together by cross-action members 107a and 107b. Handles Linking Member  FIG. 11

Similarly, with respect to the linking of the handles of the first and second handle means recited in claim 2, it would have been obvious to modify the system shown in the Video and Slides to include such linking in view of the '928 Appl. for the same reasons as provided above.

Claim 2[D]: 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[E], *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[E], *supra* (incorporated here).
Claim 2[G]: 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 2[G], *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[E], *supra* (incorporated here).

C. Ground 3 – Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the '928 Appl. in view of the Slides and/or the MTOS chapter 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 Slides and/or the MTOS chapter (alone or incombination) and the '349 patent, and alternatively the '219 patent.

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 of a spinal column.

The '928 Appl. also discloses a first pedicle screw cluster derotation tool. The '928 Appl. indicates that this tool may be used for displacing adjacent vertebrae, including applying force perpendicular to the direction in which distraction or compression occurs, as in spondylolisthesis reduction. One of ordinary skill in the art would have understood that applying a force perpendicular to the direction in which distraction or compression occurs, as in spondylolisthesis reduction would impart a derotation to that spinal segment either explicitly or inherently. *See* Lenke Decl. at

¶¶ 54, 87. In the alternative, one of ordinary skill in the art would have understood that the tool could mechanically be used for derotation of the vertebrae, and would have found it obvious to do so because the tool provides multiple rigid connections to individual pedicle screws via a handle means that facilitates simultaneous rotation of the vertebra by way of their respective pedicle screws. *See* Lenke Decl. at ¶ 88. This point is underscored by the fact that the tool disclosed in the '928 Appl. contains mechanical components similar to the structures disclosed in the drawings and specification of the '121 patent.

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. The tool also includes guide tubes 102a, 102b, and 104, or anchor extensions that may be placed under the guide tubes, either of which serve as the claimed first group of three or more pedicle screw engagement members. These three 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 pedicle screw engagement members, whether the guide tubes 102a, 102b, and 104 or alternatively the anchor extensions, each engage the head segments of each pedicle screw. 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 three 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. 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. *See* '928 Appl. at ¶ [0055].

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 the MTOS chapter and/or the '291 Appl., both of which, as detailed above, disclose the well-known rod rotation maneuver first introduced by Cotrel and Dubousset. *See* Lenke Decl. at ¶¶ 17, 77; *see also* § V.A., 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 the MTOS chapter and the '291 Appl. *See* Lenke Decl. at ¶ 78. The '928 Appl., the Slides, the MTOS chapter 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 ¶ 66. 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 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, 77.

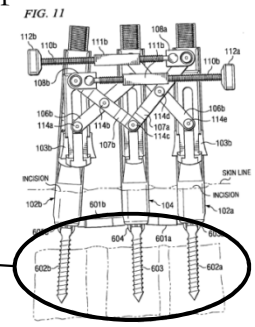
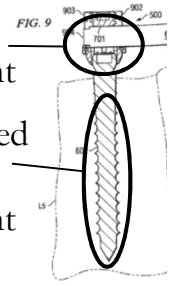
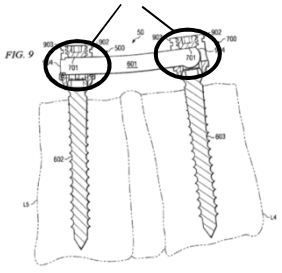
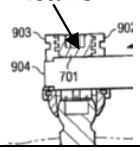
The '928 Appl. also discloses the claimed second set of pedicle screws and the second spinal rod member by its incorporation by reference of U.S. 2005/0085813 (the "'813 Appl."). *See* '928 Appl. at ¶ [0001] (noting incorporation by reference of U.S. Pat. Appl. Ser. No. 10/690,211, published as '813 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. Additionally, 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 for use 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 without any new or unexpected result occurring due the duplication. *See In re Harza*, 274 F.2d 669 (CCPA 1960).

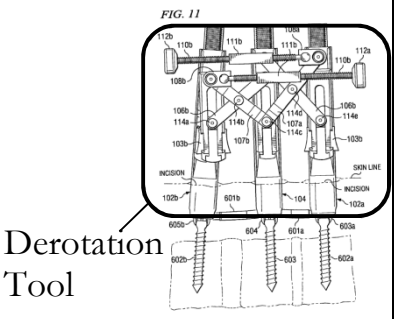
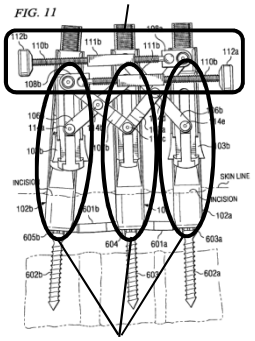
Alternatively, it would have been obvious to one of ordinary skill in the art at the time of invention to include a second pedicle screw cluster derotation tool in view of the Slides and the MTOS chapter, each of which disclose the derotation procedure being simultaneously performed on two sets of pedicle screws on opposing sides of the spinal column, using two pedicle screw cluster derotation tools. *See* Lenke Decl. at ¶¶ 82, 83, 89, 90. The MTOS chapter 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 ¶ 82, 83. Further, the use of two tools as disclosed in the Slides and the MTOS chapter ensures that equal force is applied to both pedicle regions of the vertebrae being derotated. *See id.* at ¶ 82, 83. Accordingly, one of ordinary skill in the art, having knowledge of the MTOS chapter 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.* at ¶ 82, 83. The '928 Appl., the Slides, and the MTOS chapter 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 ¶ 66. Thus, a spinal derotator, and method of

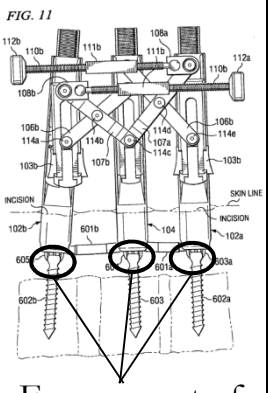
use thereof, incorporating the teachings of these references represents nothing more than an obvious combination of known mechanical elements arranged in a conventional manner in response to a known design incentive, to achieve predictable results. *See KSR,* 550 U.S. at 418.

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 the MTOS chapter 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 patent, to "ensure[] that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle." '349 patent at 5:4-8.

Finally, as described above, the Slides and the MTOS chapter 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., 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 manipulative force to the first and second handle means simultaneously, as explicitly taught in the Slides and the MTOS chapter 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 ¶ 89, 90.

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  Pedicle Screws  Head Segment Threaded Shank Segment
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 pedicle	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. 9. Spinal Rod Engagement Means  Spinal Rod Fixation Means  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

screw;	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 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	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 first handle means of the ‘928 Appl. includes handles linked together by cross-action members 107a and 107b. *See* § V.B., Claim 1[E], *supra* (incorporated here).  FIG. 11 Derotation Tool  FIG. 11 Handle Means Pedicle Screw Engagement Members
Claim 1 [E]: each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said first	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.C., Claim 1[D], *supra* (incorporated here). The ‘928 Appl. further provides that when the pedicle screw engagement member is moved by a force,

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 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 occurs, as in a spondylolisthesis reduction. Force is then transmitted to the anchor extensions . . . in process 805.").  Engagement of head segments
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	The '928 Appl. discloses that each of the pedicle screws

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;	includes a spinal rod engagement means, assemblies 500 and 700, that is able to mechanically engage with a spinal rod member. *See* § V.C., Claim 1[D]; *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[J], *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.C., Claim 1[F], *supra* (incorporated here).
Claim 1[K]: selecting a second set of pedicle screws;	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 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.C., Claim 1[L], *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 segment of each pedicle screw of said second set of pedicle screws;	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* Claim 1[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[E] and [N], *supra* (incorporated here).
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.C., Claim 1[L], *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	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.C., Claim 1[L], *supra* (incorporated here). The '928 Appl. discloses that the spinal rod

spinal column;	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.C., Claim 1[H], *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.C., Claim 1[D], *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[J], *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[S], *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 patent 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[T], *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 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

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.	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[U], *supra* (incorporated here).

Claim 2 is directed to a system that can carry out the method described in 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.

The '928 Appl. also discloses the first pedicle screw cluster derotation tool having a handle means in the form of knobs 112a and 112b and threaded rods 110b that are joined together by cross-action members 107a and 107b. 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 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, 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 by reference 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. *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 because one of ordinary skill would have known that such a derotation procedure should be carried out on both sides of the vertebrae to obtain the desired effect. 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 the MTOS Chapter, each of which show the use of a second pedicle screw cluster derotation tool on a second set of pedicle screws. *See* § V.C., Claim 1, *supra* (incorporated here).

To the extent that the '928 Appl. or the Slides 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 include such cross-linking member in view of the '349 patent. *See* § V.C., Claim 1, *supra*.

Claim 2 [A]: A system for aligning	The '928 Appl. discloses a system for aligning

vertebrae in the amelioration of aberrant spinal column deviation conditions comprising:	vertebrae in the amelioration of aberrant spinal column deviation conditions. *See* § V.C., 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.C., 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.C. Claim 1[C], *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 '928 Appl. discloses a first pedicle screw cluster derotation tool. *See* § V.C. Claim 1[E], *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* '928 Appl. at FIG. 11. 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* § V.C., Claim 1[E], *supra* (incorporated here). 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.C., Claim 1 [E], *supra* (incorporated here).
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	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.C., Claim 1[F], *supra* (incorporated here). The '928 Appl. provides that when the pedicle screw engagement member is moved by a

forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;	force, the engagement member transfers the force to the fixation elements, or pedicle screws. *See* § V.C., Claim 1[F], *supra* (incorporated here).
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.C. Claim 1[L], *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,	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.C., Claim 1[E], *supra* (incorporated here). The Slides and MTOS each show a second pedicle screw cluster derotation tool virtually identical to the first. *See* § V.C, Claim 1[N], *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.C. Claim 1[E], *supra* (incorporated here). The Slides and MTOS each show a second pedicle screw cluster derotation tool virtually identical to the first. *See* § V.C, Claim 1[N], *supra* (incorporated here).
Claim 2 [I]: wherein each pedicle screw engagement member is configured to	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

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;	cages 603a, 604, and 605b, of each pedicle screw. *See* § V.C., Claim 1 [F], *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.C., 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.C., Claim 1[S], *supra* (incorporated here).
Claim 2 [J]: a cross-linking member that links the first handle means to the second handle means.	The '349 patent 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[U], *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 '928 Appl. discloses the claimed spinal rod member; and pedicle screws having the claimed 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 the claimed 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	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

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	formed substantially transverse of the length of each pedicle screw and sized and shaped for receiving passage of the spinal rod member. *See* § V.C., Claim 1[D], *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.C., Claim 1[D], *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: July 27, 2014

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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 27th day of July 2014 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:

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