IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Barry
U.S. Patent No.: 7,670,358 Attorney Docket No.: 108136.00038
Issue Date: March 2, 2010
Appl. Ser. No.: 11/027,026
Filing Date: December 30, 2004
Title: SYSTEM AND METHOD FOR ALIGNING VERTEBRAE IN THE AMELIORATION OF ABERRANT SPINAL COLUMN DEVIATION CONDITIONS

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Patent Trial and Appeal Board
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PETITION FOR INTER PARTES REVIEW OF UNITED STATES PATENT NO. 7,670,358 PURSUANT TO 35 U.S.C. §§ 311-319, 37 C.F.R. § 42
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MSD 1001 – Declaration of Lawrence G. Lenke, M.D. Regarding U.S. Patent No. 7,670,358

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


MSD 1005 – U.S. Patent No. 5,219,349


MSD 1007 – [Reserved]

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 – [Reserved]

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


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

MSD 1017 – [Reserved]
MSD 1018 – [Reserved]
MSD 1019 – [Reserved]
MSD 1020 – U.S. Patent No. 7,670,358
MSD 1021 – U.S. Patent No. 7,776,072
MSD 1022 – [Reserved]
MSD 1023 – Declaration of David Poley
MSD 1024 – Declaration of Ashley Owens
MSD 1025 – Transcript of Thoracic Pedicle Screws for Idiopathic Scoliosis Video (2001)
MSD 1026 – Declaration of Seth A. Kramer
MSD 1028 – U.S. Patent No. 6,565,568
MSD 1029 – *Stryker Corp. v. Zimmer*, Inc., 774 F.3d 1349 (Fed. Cir. 2014)
Medtronic, Inc. ("Petitioner") petitions for Inter Partes Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-5 of U.S. Patent No. 7,670,358 (the “‘358 pat.’”) (Exhibit MSD 1020). Petitioner demonstrates below that there is a reasonable likelihood of prevailing in its challenge of at least one of claims 1-5 as being unpatentable.

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

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

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

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

Petitioner is not aware of any reexamination certificates or pending prosecution concerning the ‘358 pat. Petitioner is the named defendant in litigation concerning the ‘358 pat., Mark A Barry, MD v. Medtronic, Inc., filed in the E. D. Texas as Case No. 1:14-cv-00104-RC on Feb. 18, 2014. The complaint was served on Feb. 20, 2014.

On July 27, 2014, Petitioner filed a petition for IPR requesting review of claims 1-5 of the ‘358 pat., now styled Medtronic, Inc. v. Barry, Case No. IPR2014-01210 (“‘1210 IPR”) (BJM). The Patent Trial and Appeal Board (“PTAB”) denied the ‘1210 IPR. While the PTAB generally acknowledged that the cited art included elements of the claims at issue, the PTAB’s more narrow construction of the term “handle means” led it to find that the cited prior art did not disclose a handle means. Petitioner submits this Petition to further explain how the art cited in the ‘1210 IPR petition discloses the claimed handle means under even the PTAB’s narrow construction. Additionally, Petitioner adds grounds based on prior art not presented in the ‘1210 IPR petition that explicitly discloses the claimed feature
that the PTAB did not recognize as being taught by the previously-presented art.

While Petitioner is mindful of 35 U.S.C. § 325(d), the denial of the ‘1210 IPR peti-
tion does not exclude this Petition because instead of containing “the same or substantially
the same . . . argument previously presented to the Office,” Petitioner is responding to a
noted deficiency with new arguments and supporting evidence. Further, this Petition is
being filed within the one year time period and the Petitioner has no other avenue to pre-
sent these challenges because the rules prohibit new argument in a request for rehearing.

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

<table>
<thead>
<tr>
<th>LEAD COUNSEL</th>
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D. Service Information

Please address all correspondence and service to both counsel listed above. Peti-
tioner consents to service by email at jeschwartz@foxrothschild.com,

skramer@foxrothschild.com, and ipdocket@foxrothschild.com (referencing Attorney
Docket No. 108136.00038).

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 ‘358 pat. is eligible for IPR and Petitioner is not barred or estopped from requesting IPR. This petition is filed within one year of service of a complaint in district court litigation in which the ‘358 pat. was asserted.

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

Petitioner requests IPR of claims 1-5 of the ‘358 pat. on the grounds set forth in the table below and requests that the claims be found unpatentable.\(^1\) A detailed explanation of the statutory grounds for unpatentability is provided in claim charts. Additional supporting evidence is provided in the Declaration of Lawrence G. Lenke, M.D. and its appendices.

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<td>2</td>
<td>1</td>
<td>Invalid under § 102/103 by U.S. 2005/0245928 (the “‘928 Appl.’”)</td>
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<td>3</td>
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<td>Obvious under § 103 by the ‘928 Appl. in view of U.S. 6,565,568 (the “‘568 pat.’”)</td>
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<td>4</td>
<td>1-5</td>
<td>Obvious under § 103 by the ‘928 Appl. in view of the Thoracic Pedicle Screws for Idiopathic Scoliosis Video (the “Video”) and Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide handout (the “Slides”)Masters Techniques in Orthopaedic Surgery: The Spine, 2nd Edition (“MTOS”), Ch. 17</td>
</tr>
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<td>1-5</td>
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\(^1\) Some of these grounds include alternative combinations, as previously approved by the PTAB, citing to specific references and providing claim charts and narrative describing portions of the references relied upon. \textit{See, e.g., Medtronic, Inc. v. NuVasive, Inc., IPR2013-00506, Paper 9, at 6-7 (PTAB Feb. 13, 2014).}
The Video, the Slides, MTOS published in November 2003 (see Declaration of Seth Kramer (MSD 1026) at ¶¶ 2,3), the ‘349 pat., the ‘568 pat., and the ‘328 Appl. each qualify as prior art under §102(b) because they were published more than one year prior to December 30, 2004. The ‘928 Appl. qualifies as prior art under §102(e) because it was filed prior to December 30, 2004. None of these references was cited in a rejection during prosecution of the ‘358 pat. The ‘928 Appl. was cited during prosecution of a related patent, U.S. 7,776,072 (MSD 1021). The USPTO did not take into account alternative ways that one skilled in the art would understand the disclosure of the ‘928 Appl. to read on these claims in view of the knowledge available at the time of invention.

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

Petitioner does not concede that the scope of the terms construed or other terms in the claims are reasonably certain to one of ordinary skill in the art. See generally Nautilus, Inc. v. Bioig Instruments, Inc., 134 S.Ct. 2120 (2014). Rather, Petitioner believes that many of the terms are indefinite and reserves all rights to argue indefiniteness in the related litigation.

In an IPR, claim terms must be given their “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b). The terms are understood by their plain and ordinary meanings except where defined otherwise in the specification. Means-plus-function elements under 35 U.S.C. § 112, ¶ 6, are interpreted as the structure disclosed to accomplish the described function, and all equivalents thereto. Consistent with this standard, and without conceding that these terms should be construed the same way in a district
court proceeding, Petitioner provides proposed constructions of certain claim terms below.

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 securing 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., ‘358 pat. at 4:1-4; 4:47-59; Figs. 3 and 4. The term, in this alternative, encompasses this structure and equivalents pursuant to 35 U.S.C. § 112, ¶ 6.

2. “handle means” (claims 1 and 2)

Under the broadest reasonable construction, the term “handle means” means “a part that is designed especially to be grasped by the hand or that may be grasped by the hand.” WEBSTER’S THIRD NEW INT’L DICT. 1027 (1993) (“WEBSTER’S”). The ‘358 pat. and its prosecution history are devoid of any justification for narrowing or otherwise departing from the ordinary meaning of handle means by limiting it to “a part that is designed especially to be grasped by the hand,” while excluding the remainder of the ordinary meaning – “or that may be grasped by hand.” The broadest reasonable construction necessarily
includes both aspects of this reasonable and common definition reflecting the ordinary meaning of “handle means” as found by District Courts and the Federal Circuit. See, e.g., Stryker Corp. v. Zimmer, Inc., 774 F.3d 1349, 1356 (Fed. Cir. 2014) (affirming that barrel that “was at least capable of being held” read on construction of “handle” as a “portion of the device designed to be held by hand”) (emphasis in original); NuVasive Inc. v. Globus Med., Inc., 2013 WL 3705731, at *5 (D. Del. July 12, 2013) (construing term “handle assembly” as “an assembly that may be grasped by hand”) (emphasis added).

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

Patent Owner has contended in co-pending litigation that this element is in means plus function form. Petitioner disagrees that the broadest reasonable interpretation is so limited. However, if the Board decides that it is a means plus function element, without agreeing to this position or waiving any arguments and solely for purposes of this IPR the following construction is proposed. The claimed function is facilitating application of manipulative forces to a first/second group of pedicle screw engagement members, and 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., ‘358 pat. at 3:48-63; 5:1-35; Figs. 1, 3 and 5. The term encompasses these structures, and equivalents pursuant to 35 U.S.C. § 112, ¶ 6. Notably, in the ‘1210 IPR, the Board agreed this term was not means plus function.

3. “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 is supported by Figure 1, showing the handles 34 joined to their respective shafts 36 by a physical connection; and 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).

4. “a second group of multiple vertebrae” (claim 4)

Under the broadest reasonable construction, the term “a second group of multiple vertebrae” means “multiple vertebrae at least in part different than the first group of multiple vertebrae.” See, e.g., ‘358 pat. at Fig. 1.

IV. SUMMARY OF THE ‘358 PATENT

A. Overview of the ‘358 Patent

The ‘358 pat. is directed to methods for the amelioration of aberrant spinal column deviations. See, e.g., ‘358 pat., 3:11-17. As described and claimed, the method of the ‘358 pat. generally sets out steps for the implantation of multiple pedicle screws, the engagement of these pedicle screws by pedicle screw engagement members, and the application of
force from a handle attached to the engagement members such that the force is transmitted to the pedicle screws engagement members to rotate the vertebrae. The method also calls for the use of a pedicle screw and rod system, as was well known at the time of invention. The claims provide that this method may be performed on a second set of pedicle screws by an identical apparatus, either sequentially or simultaneously.

B. Summary of the Prosecution History of the ‘156 Patent

The application that issued as the ‘358 pat. was filed on December 30, 2004. The prosecution history of the ‘358 pat. is submitted as Exhibit MSD 1008.

During prosecution, the USPTO rejected the claims numerous times. In an office action, the USPTO rejected all claims over U.S. Pat. No. 6,090,113 (the “‘113 pat.’”), asserting that the ‘113 pat.’s disclosure of “two systems intended to be fixed, for example, to the same vertebrae of the column, one on each side of the median axis of the spinal column” 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 1008 at 166. The applicant replied that that the disclosure of the ‘113 patent regarding the connection of pedicle screws by spinal rods was “nothing new, as pedicle screws are connected together in any number of prior art references.” See MSD 1008 at 109. The ‘358 patent subsequently issued on March 2, 2010.

C. Legal Standard for Anticipation and Obviousness

A claim is invalid as anticipated when “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Ver-
Under 35 U.S.C. § 103(a), a claim is invalid for obviousness 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, (2007). There is no requirement to find precise teachings directed to specific subject matter of a claim; common sense, inferences, and creative steps that a person of ordinary skill in the art would employ should be considered. *Id.* at 1741. The Board should apply common sense, recognizing that “familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 1742. If “a patent ‘simply arranges old elements with each performing the function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 1740.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The challenged claims recite systems and methods for spinal column derotation having features that were well known prior to the filing date of the ‘358 pat. *See e.g.*, Declaration of Lawrence G. Lenke, M.D. Regarding U.S. Patent No. 7,670,358 (the “Lenke Decl.”), attached as Exhibit MSD 1001, at ¶ 75-76. As detailed in the claim charts below, prior art references anticipate and/or render obvious the challenged claims of the ‘358 pat.
A. **Ground 1 – Claims 1-5 are Invalid Under 35 U.S.C. § 102/103 in view of the ‘349 Patent**

Claims 1-5 are anticipated and/or rendered obvious by the ‘349 pat. With respect to claim 1, as the PTAB has already found in its Decision on the ‘1210 IPR, the ‘349 pat. discloses claim elements 1[A], 1[B], and 1[D], as denoted in the claim charts below. See IPR1210 Decision, at 12-14. The ‘349 pat. 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 IPR1210 Decision, at 12; ‘349 pat. at 6:41-57 (incorporating by reference: Krag et al., *An Internal Fixator for Posterior Application to Short Segments of the Thoracic, Lumbar, or Lumbosacral Spine*, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH, 203: 75-98 (February 1986) (MSD 1013); W. Dick, *The "fixateur interne" As a Versatile Implant for Spine Surgery*, SPINE 12:882-900 (1987) (MSD 1014); Olerud et al., *Transpedicular Fixation of Thoracolumbar Vertebral Fractures*, CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 227:44-51 (1988) (MSD 1015); and Guyer et al., *The Wiltse Pedicle Screw Fixation System*, ORTHOPAEDICS 11:1455-1460 (1988) (MSD 1016). The ‘349 pat. discloses a first set of pedicle screws 12 each having a threaded shank segment and a head segment. The pedicle screws each have a spinal rod conduit (clamp 18) that is formed substantially transverse to the length of each screw, and is sized and shaped to receive a spinal rod member 22. The pedicle screws include a spinal rod engagement means (clamp bolt 20) that secures the spinal rod member to the pedicle screw in a substantially fixed relative position and orientation. The ‘349 pat.
discloses that each pedicle screw is implanted in a pedicle region of each of a first group of multiple vertebrae of a spinal column.

The ‘349 pat. also discloses a first pedicle screw cluster derotation tool. As to claim 1[C], this tool includes a first handle means in the form of hinged extensions 136, laterally extending arms 112, the lower portions of dorsally extending legs 110, and threaded rod 210 that connects the portions of dorsally extending legs 110. Regardless of whether the term “handle means” is narrowly construed (i.e., especially designed to be grasped by the hand), as opposed to a part that may be grasped by hand, the handle means of the ‘349 pat. is designed to be grasped on the laterally extending arms 112 that, as part of T-handle 100, “may be used by the surgeon simply as handles for manual manipulation of the spine.” ‘349 pat., at 5:8-12. Alternatively, the T-handle 100 itself may serve as the handle means. As the PTAB previously found, the device disclosed in ‘349 pat. “includes two T-handles 100” (1210 IPR, at 13 (citing ‘349 pat., at 4:3-16)), as well as that “each T-handle may be grasped by hand to apply forces to the spine” (id. (citing ‘349 pat., at 3:4-9)), so that “[t]he T-handles function as handles to allow manipulation of the spine with an even distribution of force between opposite pedicles, in order to prevent the application of excessive load to either pedicle.” Id. (citing ‘349 pat., at 3:37-40); see also ‘349 pat., at 2:53-56 (disclosing “device which may be used with hand application of forces”). Thus, based on the PTAB’s explicit findings, the T-handle 100 is designed to be grasped by hand and, thus, satisfies the “handle means” limitation as previously construed by the PTAB.

The tool also includes a first group of pedicle screw engagement members in the
form of shafts 14 that are mechanically linked to the above-described handle means by
shaft clamps 122. The ‘349 pat. discloses that the shafts each engage with the head seg-
ments of each pedicle screw. Because of the rigid mechanical link between the arms 112 of
the handle means and the pedicle screw shafts 14, any force placed on the handle means
would necessarily be transferred to the shafts, and subsequently transmitted to the head
segment of each pedicle screw that is engaged with the respective shaft.

The ‘349 pat. provides that the tool allows a surgeon to “execute any of the com-
mon movements of the spine (flexion, extension, distraction, compression or anteri-
or/posterior shear) with a high degree of mechanical control.” ‘349 pat. at 5:68 to 6:3. As
anterior or posterior shear is a rotational movement, the ‘349 pat. discloses that force ap-
plied to the arms 112 of the handle means simultaneously rotates the vertebrae to achieve
an amelioration of an aberrant spinal column deviation condition. Similarly, as the PTAB
found, the forces that are applied by hand allow a surgeon to “control and produce . . . axi-
al rotation, distraction/compression, anterior/posterior shear, and lateral shear.” 1210 IPR
Decision, at 12 (citing ‘349 pat., at 2:57-61).

Alternatively, the ‘349 pat. inherently discloses such simultaneous rotation of the
vertebrae as it would have been readily apparent to one of ordinary skill in the art to pro-
vide such simultaneous rotation by grasping and placing a downward force, i.e., a force in
the ventral direction, on either of the laterally extending arm 112 portions of the first han-
dle means. See Lenke Decl., at ¶¶ 62, 63, 88. Due to the rigid connection between the lat-
erally extending arms provided by the threaded rod 210, such force would necessarily be
transmitted to both shafts 14 and subsequently to the screws, thereby simultaneously pushing down the one side of vertebrae to which the screws are attached to effect simultaneous rotational vertebral movement of the attached vertebrae. See id.; ‘349 pat. at 5:8-12 (providing that T-handles 100, which include laterally extending arm 112, may be used by surgeon as handles to manually manipulate spine). Alternatively, to the extent that such disclosure is not inherent, it would have been obvious to one of ordinary skill in the art to use the device disclosed in the ‘349 pat. to simultaneously derotate the vertebrae. See id.

The ‘349 pat. also discloses that a spinal rod member 22 is extended through the spinal rod conduits, clamps 18, of one or more of the pedicle screws of the first set of pedicle screws, and after the application of manipulative force is completed, spinal rod engagement means in the form of clamp bolts 20 are actuated to lock the spinal rod member in place to maintain the desired arrangement of the vertebrae.

Claim 1[A]: A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:

The ‘349 pat. discloses a method for treating and correcting deformities and injuries of the spine. See ‘349 pat. at 2:36-40 (“It is therefore an object of the present invention to provide a device for producing realignment of vertebrae affected by various spinal disorders, including fractures and dislocations, which device employs a significant mechanical advantage.”); 2:49-52 (“It is also an object of the present invention to provide a device for alignment of a spine which distributes the applied force evenly across the screws and pedicles to which it attaches.”).

Claim 1[B]: selecting a first set of pedicle screws, said pedicle screws each having a threaded shank segment and a head segment;

The ‘349 pat. discloses the selection of a first set of pedicle screws. See ‘349 pat. at 4:36-39 (“The shaft clamps provide a positive linkage between the T-handles 100 and the shaft handles 14 attached to the pedicle screws 12.”). The ‘349 pat. discloses that the pedicle screws
have a threaded shank segment and a head segment. See ’349 pat. at FIG. 1.

Claim 1[C]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, 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 ‘349 pat. discloses a first pedicle screw cluster derotation tool having first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means. See ’349 pat. at FIGS. 2 and 3. The first handle means, which includes extending arm 112 of a T-handle 100, is designed especially to be grasped by the surgeon. See id., at 4:17-18 (“Each T-handle 100 has a dorsally extending threaded leg 110 and two laterally extending arms 112”); 5:4-12 (“The T-handles 100 of the present invention provide a positive linkage between the two pedicles to which it is attached. The linkage ensures that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle. Once the T-handles 100 have been installed as described above, they may be used by the surgeon simply as handles for manual manipulation of the spine without assembling further components of the present invention.”) (emphasis added).
Claim 1[D]: implanting a [sic] each pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;  

The ‘349 pat. discloses the implantation of each pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column that exhibits an aberrant spinal column deviation condition;  

See ‘349 pat. at 1:25-30 (“...holes are drilled in the appropriate vertebrae through the pedicle on either side of each vertebrae. After the holes are drilled, pedicle screws 12 are screwed into place using a shaft handle 14 which is attached to flats 16 provided on the top of each screw 12.”); FIG. 1; § V.A., Claim 1[A], supra (incorporated here).

Claim 1[E]: engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said first set of pedicle screws; and  

The ‘349 pat. shows the engaging of each pedicle engagement member with the head segment of a respective pedicle screw.  

See ‘349 pat. at 1:25-40 (“After the holes are drilled, pedicle screws 12 are screwed into place using a shaft handle 14 which is attached to flats 16 provided on the top of each screw 12. The shaft handles 14 are best seen in FIG. 2. Once the pedicle screws 12 are in place, each one has an articulating clamp 18 attached to it by means of a clamp bolt 20. Clamp bolt 20 is placed through clamp 18 and loosely threaded into the head of pedicle screw 12. The clamp bolts 20 are left loose until realignment of the vertebrae by the reduction frame has been completed. Shaft handles 14 remain attached to the tops of the pedicle screws 12. The shaft handles may be provided with removable grips which are not shown in FIG. 2”).

Claim 1[F]: applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.  

The ‘349 pat. discloses applying manipulative force to the first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.  

See ‘349 pat. at 2:57-61 (“A further object of the present invention is to provide a device for alignment of a spine which is capable of controlling all modes of motion, that is, flexion/extension, lateral bending, axial rotation, distraction/compression, anterior/posterior shear, and lateral shear.”); 2:62-66 (“A further object of the present invention is to provide a device for alignment of a spine which includes a
first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition; mechanical means for producing the motions of flexion/extension, distraction/compression, and anterior/posterior shear.”); 5:4-12 (“The T-handles 100 of the present invention provide a positive linkage between the two pedicles to which it is attached. The linkage ensures that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle. Once the T-handles 100 have been installed as described above, they may be used by the surgeon simply as handles for manual manipulation of the spine without assembling further components of the present invention.”) (emphasis added); 5:55 to 6:4 (“The arrangement of lower-rod assembly 200 effectively provides for rigid connection between T-handles 100 and lower-rod assembly 200, while providing five degrees of freedom for adjustment: two rotational degrees of freedom provided by clamping collars 117 around sleeves 116 and around their taper fit joints with clamping collars 220, 224; one rotational degree of freedom provided by male clamping collar 220 and sleeve 214; and two translational degrees of freedom provided by the movement of T-handle sleeves 116 or threaded leg 110 and lower-rod sleeves 214 and 215 on threaded rod 210. With the lower-rod assembly 200 installed on the T-handles 100, the surgeon may execute any of the common movements of the spine (flexion, extension, distraction, compression or anterior/posterior shear) with a high degree of mechanical control.”).

Claim 1 [G]: selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes: a spinal rod conduit formed substantially transverse

The ‘349 pat. discloses that the described device is used with a fixator device (10) implanted in vertebrae on either/both sides of the multiple vertebrae to be rigidly fixed in a corrected position, including by threading a permanent fixation rod (22) through a conduit (clamp 18) on the top of the pedicle screws. See ‘349 pat. at 6:41-57

<table>
<thead>
<tr>
<th>Spinal Rod Engagement Means</th>
<th>Spinal Rod Conduit</th>
<th>Spinal Rod Member</th>
</tr>
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</table>

Direction of rotation of vertebrae

Location where surgeon can grasp handle means and apply a downward force thereby in a single motion simultaneously rotating the vertebrae attached to the pedicle screws
of the length of said pedicle screw and sized and shaped for receiving passage of said spinal rod member therethrough; and spinal rod engagement means for securing said pedicle screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

<table>
<thead>
<tr>
<th>Claim 1 [H]: extending said first length of said spinal rod member through said spinal rod conduits of one or more of said pedicle screws of said first set of pedicle screws; and</th>
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<tr>
<td>The '349 pat. show the extension of the first length of the spinal rod member (22) through said spinal rod conduits of one or more of said pedicle screws of said first set of pedicle screws. See FIG. 1; see also § V.A., Claim 1[G], supra (incorporated here).</td>
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<tr>
<th>Claim 1 [I]: after applying said manipulative force to said first handle means, actuating said spinal rod engagement means to secure said vertebrae in their respective and relative positions and orientations as achieved through application</th>
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<tr>
<td>The '349 pat. discloses that after applying manipulative force to the first handle means (identified in element 1[C], supra), the spinal rod engagement means is actuated to secure the vertebrae in their respective and relative positions and orientations as achieved through application of force. See '349 pat. at 1:34-40 (“The clamp bolts 20 are left loose until realignment of the vertebrae by the reduction frame has been completed. Shaft handles 14 remain attached to the tops of the pedicle screws 12. The shaft handles may be provided with removable grips which are not shown in FIG. 2. As a result of various spinal disorders of the type which the fixator device 10 is intended to remedy, such as trauma, one vertebra is displaced to an abnormal position relative to an adjacent vertebra. For this reason the surgeon must manipulate the vertebrae back into normal alignment before</td>
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</table>
of said manipulative force thereto. the clamp bolts 20 are finally tightened and the spine is rigidly fixed in position.”); § V.A., Claim 1[H], supra (incorporated here).

Claim 2 depends from claim 1 and recites duplicate limitations to those in claim 1.

The ‘349 pat. discloses a second set of pedicle screws and a second pedicle screw cluster derotation tool identical to the first pedicle screw cluster derotation tool. This second pedicle screw cluster derotation tool may be used to impart manipulative forces on the second set of pedicle screws such that the vertebrae in which the pedicle screws are implanted are simultaneously rotated in a single motion. To the extent the second handle means includes components that overlap with that of the first handle means, namely the lower portions of dorsally extending legs 110 and threaded rod 210, this does not negate the ‘349 pat.’s disclosure of these two claimed handle means. See Applied Medical Resources Corp. v. U.S. Surgical Corp., 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) (“[T]he use of two terms in a claim require that they connote different meanings, not that they necessarily refer to two different structures.”) (emphases in original)). Regardless of whether the “second handle means” is given an narrow construction (i.e., especially designed to be grasped by the hand), the ‘349 patent discloses a “second handle means” in the form of the arms 112 that, as part of T-handle 100, “may be used by the surgeon simply as handles for manual manipulation of the spine.” ‘349 patent, at 5:8-12. Alternatively, the second T-handle 100 shown in Fig. 3 may be considered the second handle means.

| Claim 2[A]: The method of claim 1 further comprising the steps | The ‘349 pat. discloses a second set of pedicle screws that are implanted in the opposing pedicle region of the first set. See ‘349 pat. at 10:50-56 (claiming “installing generally dorsally extending screws in the pedicles of vertebrae adjacent to and on opposite sides of the affected loca- |
of: selecting a second set of pedicle screws;  

Claim 2[B]: selecting a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having second handle means and a second group of pedicle screw engagement members which are mechanically linked with said second handle means, each pedicle screw engagement member being configured for engaging with, 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 ‘349 pat. discloses a second pedicle screw cluster derotation tool identical to the first pedicle screw cluster derotation tool that is configured to transmit manipulative forces to the head segments of the second set of pedicle screws in the same fashion that the first pedicle screw cluster derotation tool is configured to transmit manipulative forces to the head segments of the first set of pedicle screws. This second pedicle screw cluster includes a second handle means that is designed to be grasped by the surgeon. See FIG. 3; § V.A., Claim 1[C], supra (incorporated here).  

Claim 2[C]: implanting each pedicle screw in a pedicle region of each of a second group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;  

The ‘349 pat. discloses a second set of pedicle screws that are implanted in the opposing pedicle region of the first set of pedicle screws. See § V.A., Claim 2[A], supra (incorporated here).  

Claim 2[D]: engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said second set of pedicle screws; and  

The ‘349 pat. shows the engaging of each pedicle engagement member with the head segment of a respective pedicle screw. See § V.A., Claim 1[E], supra (incorporated here); FIG. 3.
Claim 2[E]: applying manipulative force to said second handle means in a manner for simultaneously engaging said second group of pedicle screw engagement members and said second set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said second group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.

The ‘349 pat. discloses applying manipulative force to the second handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of the second group of multiple vertebrae in which the pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. See § V.A., Claim 1[F], supra (incorporated here).

Claim 3 depends from claim 2 and recites the use of a second spinal rod member in connection with the second set of pedicle screws. The ‘349 pat. also discloses the use of a second spinal rod member that is coupled to the pedicle screws through spinal rod conduits, and then fixed in place by spinal rod engagement means in the form of clamp bolts 20 after manipulative force has been applied to the second handle means.

Claim 3[A]: The method of claim 2 further comprising the steps of: selecting a second length of a spinal rod member, wherein one or more of said pedicle screws of said second set of 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

The ‘349 pat. discloses implanting a fixator device (10) in vertebrae on either/both sides of the multiple vertebrae to be rigidly fixed in a corrected position, including by threading a permanent fixation rod (22) through a conduit (clamp 18) on the top of the pedicle screws. See § V.A., Claim 1[G], supra (incorporated here); ‘349 pat. at 1:15-16 ("[T]he same components are used on the opposite side of the spine."). The ‘349 further discloses an engagement means (clamp bolt
member therethrough; and spinal rod engagement means for securing said pedicle screw and said second spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

20) for securing the pedicle screw and the spinal rod member (22), when extending through said spinal rod conduit (clamp 18), in a substantially fixed relative position and orientation.  See § V.A., Claim 1[G], supra (incorporated here).

Claim 3[B]: extending said second length of said spinal rod member through said spinal rod conduits of one or more of said pedicle screws of said second set of pedicle screws; and

The ‘349 pat. discloses implanting a fixator device (10) in vertebrae on either/both sides of the multiple vertebrae to be rigidly fixed in a corrected position, including by threading a permanent fixation rod (22) through a conduit (clamp 18) on the top of the pedicle screws.  See § V.A., Claim 1[G], 1[H], supra (incorporated here).

Claim 3[C]: after applying said manipulative force to said second handle means, actuating said spinal rod engagement means to secure said vertebrae of said second group of multiple vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.

The ‘349 pat. discloses that after applying said manipulative force to the second handle means, actuating the spinal rod engagement means to secure the vertebrae in their respective and relative positions and orientations as achieved through application of the manipulative force thereto.  See § V.A., Claim 1[I], supra (incorporated here).

Claim 4 depends from claim 3 and recites that “the steps of applying manipulative force to said first handle means and applying manipulative force to said second handle means are carried out substantially simultaneously to cooperatively achieve an amelioration of an aberrant spinal column deviation condition.”  Claim 5 depends from claim 2 and recites the same limitation.

The ‘349 patent discloses that the first handle means and the second handle means are joined together 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.  Because the first and second handle means are rigidly linked together, a force applied on either of them would necessarily cause an equal and opposite force to be simultaneously ap-
plied to the other handle means—e.g., if a downward force were applied on the first handle means, a simultaneous resultant upward force to the second handle means would occur.

B. **Ground 2 – Claim 1 is Invalid Under 35 U.S.C. § 102/103 in view of the ‘928 Application**

As shown in the claim charts below, claim 1 of the ‘358 pat. is anticipated or rendered obvious under 35 U.S.C. §§ 102/103 by the ‘928 Appl.

As previously found by the PTAB, the ‘928 Appl. discloses claim elements 1[A], 1[B], 1[C], 1[D], 1[E], 1[G], 1[H], and 1[I]. See IPR1210 Decision, at 16-20. The ‘928 Appl. discloses a system and method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions. The ‘928 Appl. discloses a first set of pedicle screws 602b, 603, 602a, each having a threaded shank segment, a head segment, and a spinal rod conduit (assembly 500 or 700) substantially transverse the length of each screw that is sized and shaped to receive the spinal rod member. The pedicle screws also include a spinal rod engagement means, set screw 701, that secures the spinal rod member to the pedicle screw in a substantially fixed relative position and orientation. The ‘928 Appl. discloses that each pedicle screw is implanted in a pedicle region of each of a first group of multiple vertebrae.

The ‘928 Appl. also discloses a first pedicle screw cluster tool that may be used to simultaneously rotate adjacent vertebrae in a single movement. The ‘928 Appl. states that the tool disclosed therein can be used to apply forces perpendicular to the direction in which distraction or compression of the vertebra is effected, such as would occur during a spondylolisthesis reduction procedure. See ‘928 Appl., at ¶ [0055]. One of ordinary skill in
the art would have understood at the time of invention that these perpendicular forces are applied into the patient (downward) and out of the patient (upward). See Lenke Decl. at ¶¶ 50-53, 89. Because these perpendicular forces are applied to the pedicle screws, they are offset from the center of the vertebrae, which in turn produces rotation of the vertebrae. See id. When a downward force is applied, it causes rotation of the vertebrae as it pushes one side of the vertebrae down resulting in the opposite side of the vertebrae to move upward by an equal amount. See id. Similarly, if an upward force is applied, it will also cause rotation of the vertebrae as the one side of the vertebrae is lifted upward while the opposing side is moved downward by an equal amount. See id. In sum, one of ordinary skill in the art would have understood at the time of invention that applying a force perpendicular to the direction in which distraction or compression occurs, as in spondylolisthesis reduction and as explicitly disclosed in the ‘928 Appl., would impart rotation to that spinal segment either explicitly or inherently. See id. Alternatively, one of ordinary skill in the art would have understood, based on the above-referenced disclosure, that the tool disclosed in the ‘928 Appl. is structurally configured to simultaneously rotate multiple vertebrae. The skilled artisan would have found it obvious to employ this tool for precisely such a maneuver, using a handle means that is capable of facilitating simultaneous rotation of the vertebra by way of respective pedicle screws attached thereto. See id., at ¶¶ 50-53, 90.

The tool disclosed in the ‘928 Appl. includes a handle means in the form of handles (knobs 112a and 112b and threaded rods 110b) joined together by cross-action members 107a and 107b. To the extent “handle means” is construed to require a part that is de-
signed to be grasped by the hand, the knobs 112a and 112b are especially designed to be grasped by the hand. See id., at ¶¶ 50-53, 82. The tool also includes guide tubes 102a, 102b, and 104, or anchor extensions, which may be placed under the guide tubes, either of which may serve as a first group of pedicle screw engagement members. These engagement members are mechanically linked to the knob 112b and threaded rod 110b by cross-action members 106a, 106b, 107a, and 107b and threaded rod coupling 108a. The ‘928 Appl. discloses that the pedicle screw engagement members, whether guide tubes 102a, 102b, and 104 or the anchor extensions, each engage with the head segments of each pedicle screw.

The ‘928 Appl. explicitly and inherently discloses applying force “in a single motion rotating said vertebrae” as required by Claim 1[F]. As noted above, the ‘928 Appl. explicitly teaches that the disclosed device can be used to apply force in a direction perpendicular to the pedicle screws to effect compression and distraction of the vertebrae to which the pedicle screws are attached. The application of that force is inherently done by grasping the device by hand, preferably grasping at least one knob or an equivalent handle structure (such as that disclosed in the ‘568 pat.). Accordingly, the ‘928 Appl. would have explicitly (or at least implicitly) disclosed to one of ordinary skill in the art that the handle means (knobs 112a and 112b) are especially designed to be grasped to apply a perpendicular force in addition to a twisting force. See Lenke Decl. at ¶¶ 50-53. That is, the structure identified above, including the knobs, can be pushed or pulled as well as twisted, much like a door knob can be pushed, pulled, and twisted. See id., at ¶ 52. Because of the rigid mechanical link between the handle means and the pedicle screw engagement mem-
bers, a perpendicular force exerted on either or both of the knobs (112a and 112b) necessarily will be transferred simultaneously to each pedicle screw engagement member, which will transmit the force to the head segment of each pedicle screw. See id. at ¶¶ 50-53, 89.

Exemplifying this point, the ‘928 Appl. provides that when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. Where the force applied is in the disclosed perpendicular (downward) direction, this causes a derotation of the vertebrae due to the placement of the pedicle screws. See Lenke Decl. at ¶¶ 50-53, 89. Accordingly, the ‘928 Appl. provides that a downward force may be applied to the handle means of the disclosed device in a manner for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws, thereby in a single motion simultaneously rotating the vertebrae in which the pedicle screws are implanted. See Lenke Decl. at ¶¶ 50-53, 89. In other words, the laws of physics demand that the device disclosed in the ‘928 Appl. apply force “in a single motion rotating said vertebrae.”

The ‘928 Appl. further discloses that a brace is extended through the spinal rod conduits of the pedicle screws of the first set of pedicle screws, and after the application of manipulative force is completed, the set screws are actuated to lock the brace in place to maintain the desired arrangement of the vertebrae.

<table>
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<tr>
<th>Claim 1[A]: A method for aligning vertebrae in the amelioration of aberrant spinal col-</th>
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<td>lum deviation conditions. See ‘928 Appl. at ¶ [0008] (“The present invention is directed to a system and method which allow for the displacement of bony structures, such as vertebrae of the spine relative to each other.”); ¶ [0003] (“When a</td>
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</table>
umn deviation conditions comprising the steps of: patient suffers from orthopedic injuries, deformities or degenerative diseases, it is sometimes necessary to insert implants into the patient's body to stabilize an internal structure, promote healing, or relieve pain. In the area of spinal surgery, for example, a common procedure involves the use of screws or hooks joined by a connecting brace in order to secure bones.”).

Claim 1[B]: selecting a first set of pedicle screws, said pedicle screws each having a threaded shank segment and a head segment; The '928 Appl. discloses a first set of pedicle screws that each pedicle screw includes a threaded shank segment and a head segment. See '928 Appl. at FIG. 9, 11.

Claim 1[C]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means and a first pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws, The '928 Appl. discloses 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 a three or more pedicle screw engagement members, for example, guide tubes 102a, 102b, and 104, or anchor extensions, which may be placed under the guide tubes. See id. 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 a handles in the form of knobs 112a and 112b and threaded rods 110b. See ‘928 Appl. at FIG. 11. These handles are joined together by cross-action members 107a and 107b.
The '928 Appl. provides that the device may be used so when the pedicle screw engagement member is moved by a force, the engagement member transfers the force to the fixation elements, or pedicle screws. See id. at ¶ [0055] (“In order to perform displacement, guide tubes of a displacement device are inserted over anchor extensions in process 804. Although the displacement device is inserted over the anchor extensions in the example embodiment, further embodiments provide for additional devices to be inserted over the bone anchor for direct compression and/or distraction. 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 order to begin compression or distraction in process 805.”).

<table>
<thead>
<tr>
<th>Claim 1[D]: implanting a [sic] each pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;</th>
<th>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] (“Then, pedicle screw (“anchor”) 603 is inserted through cannula 502 into a pre-tapped hole in vertebrae L5.”).</th>
</tr>
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<tbody>
<tr>
<td>Claim 1[E]: engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said first set of pedicle screws; and</td>
<td>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; 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.”).</td>
</tr>
<tr>
<td>Claim 1[F]: applying manipulative force</td>
<td>The ‘928 Appl. provides that force may be ap-</td>
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</table>
to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition; applied to the handle means of the disclosed device in a manner for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws and thereby in a single motion simultaneously rotating the vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. See § V.B., Claim 1[C], supra (incorporated here).

Claim 1[G]: selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes: 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 therethrough; and spinal rod engagement means for securing said pedicle screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

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<th>Spinal Rod Conduits</th>
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<td><img src="image" alt="Spinal Rod Conduits" /></td>
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The '928 Appl. discloses that each of the pedicle screws includes a spinal rod conduit, assemblies 500 and 700, that is formed substantially transverse of the length of said pedicle screw and sized and shaped for receiving passage of said spinal rod member therethrough. 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.
The '928 Appl. discloses a spinal rod engagement means, set screw 701, that secures the spinal rod member, brace 601, to the pedicle screw in a substantially fixed relative position and orientation. See ‘928 Appl. at ¶ [0047] (“Set screws 701, or other locking devices, are introduced down cannulas 501 and 502 to lock each end of brace 601 to its respective pedicle screw 602, 603 . . .”).

Claim 1[H]: extending said first length of said spinal rod member through said spinal rod conduits of one or more of said pedicle screws of said first set of pedicle screws; and

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<tr>
<th>Spinal Rod Engagement Means</th>
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<tr>
<td><img src="image" alt="Spinal Rod Engagement Means" /></td>
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The '928 Appl. discloses the step of extending the first length of said spinal rod member through the spinal rod conduits of one or more of said pedicle screws of said first set of pedicle screws. See § V.B., Claim 1[G], supra (incorporated here).
Claim 1[1]: after applying said manipulative force to said first handle means, actuating said spinal rod engagement means to secure said vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.

The ‘928 Appl. provides that after the application of manipulative force is completed, the set screws are actuated to lock the brace in place to maintain the desired arrangement of the vertebrae. See ‘928 Appl. at ¶ [0061] (“After all angular and lateral adjustments are made, set screws 901 are introduced down the first and second cannulas to lock each end of brace 601 to its respective anchor to maintain the desired displacement in process 807.”).


As shown in the claim charts below, claim 1 of the ‘358 pat. is obvious under 35 U.S.C. § 103 over the ‘928 Appl. in view of the ‘568 pat.

With respect to elements [A], [B], [D], [E], and [G]-[I], the analysis provided in Ground 2 also applies to this ground, and the PTAB has already found these elements present in the ‘928 Appl. See § V.B. at 22, supra. Petitioner asserts that the ‘928 Appl. anticipates claim 1 of the ‘358 pat.; in the alternative (or if the ‘928 Appl. is found to not disclose the claimed handle means), it would have been obvious to modify the device disclosed in the ‘928 Appl. to include handle means in view of the ‘568 pat.

The ‘568 pat. describes an apparatus and method for the treatment of spinal column deviations and discloses the use of a handle means to apply simultaneous force to multiple adjacent vertebrae. Specifically, the ‘568 pat. discloses a levering member 20 that includes a proximally mounted handle 21 and a free end 23, with a main body 22 extending therebetween. ‘568 pat., at 5:5-26. The main body allows for the attachment of multiple outrigger members 30. The outrigger members 30 in turn engage adjacent vertebrae via spine
link members 90, such that any movement of the outrigger member caused by manipulating the handle 21 is transferred simultaneously to the adjacent vertebrae through the spine link members 90. *Id.* at 2:66 to 3:4; 5:39 to 6:8. The ‘568 pat. provides that this apparatus enables the surgeon to simultaneously rotate adjacent vertebrae during a spondylolisthesis procedure. *Id.* at 2:11-30; 4:66 to 5:4. The handle 21 and the remainder of the levering member 20 thus constitute a “handle means” even if this term is narrowly construed as “a part that is especially designed to be grasped by the hand.”

As explained above, the ‘928 Appl. teaches that the disclosed device may be used to apply force perpendicular to the direction in which distraction or compression occurs. It would have been obvious to one of ordinary skill in the art to modify the ‘928 Appl. device to include the handle means of the ‘568 patent in the form of the levering member 20 to link the pedicle screw engagement members of the ‘928 Appl. because in accordance with the express teachings of the ‘568 patent, it would “allow[] the surgeon to properly position and secure the vertebrae [] in a relatively quick and straightforward manner,” consistent with and further enabling the alternative embodiment of the ‘928 discussed above for applying this perpendicular force. *See id.* at 2:11-26; *See Lenke Decl.* at ¶¶ 66, 82-83. The obviousness of this combination is further supported by the fact that both ‘928 Appl. and the ‘568 patent are related to applying perpendicular (downward or upward) force on vertebrae to produce rotation thereof, and both disclose the use of the respective devices for spondylolisthesis procedures. *See Lenke Decl.* at ¶¶ 82-83. Adding the handle means of the ‘568 patent to the ‘928 Appl. device to achieve the type of movement disclosed in both refer-
ences would have been nothing more than a simple and obvious modification in view of
the teachings of the ‘568 patent. Doing so would accomplish: (1) easing the surgeon’s
workload, (2) achieving uniformity in the movement of the pedicle screw engagement
members and the vertebral bodies to achieve an entirely predictable result, and (3) properly
and quickly positioning and securing multiple vertebrae in a straightforward manner. See id.
The ‘928 Appl. and the ‘568 patent are from the same field of endeavor for fixing and ma-
ipulating vertebrae, and each of the devices disclosed therein could be used to achieve
spinal column derotation by the application of simultaneous force to multiple vertebral
bodies. See id. The references specifically teach the application of compression and distrac-
tion, as well as rotation of multiple vertebrae, therefore one of ordinary skill in the art
would look to the combined teachings of these references to solve similar spinal deformi-
ties, including scoliosis. See ‘568 patent, at 2:17-21; ‘928 Appl., at ¶ [0055]; Lenke Decl. at ¶
83. 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 known design incentives,
to achieve predictable results. See KSR, 550 U.S. at 418.

<table>
<thead>
<tr>
<th>Claim 1[C]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first</th>
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<tr>
<td>The ‘928 Appl. discloses a first pedicle screw cluster derotation tool that includes a first group of pedicle screw engagement members that are linked together with handles. See § V.B. Claim 1[C], supra (incorporated here). The ‘928 Appl. provides that when the pedicle screw engagement member is moved by a force, including a downward force, the engagement member transfers the force to the fixation elements, or pedicle screws. See id. The ‘568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (lev-</td>
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</table>
handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, 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, engaging member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. See ‘568 pat., at 5:5-7 (“The levering member 20 comprises an elongated main body 22 having a free distal end 23 and a proximally mounted handle 21 . . .”). Multiple outrigger members 30 may be mechanically linked to the handle means. See id., at 5:46-51 (“The main body 31 is sized to fit within the levering member slot 24 and the stabilizer member slot 42, such that the levering member 20 and the stabilizer member 40 can be positioned at various points on the outrigger members 30 by aligning the corresponding apertures 25 or 43 with the outrigger apertures 37 and fastening a pivot bolt 50.”). These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. See id., at 2:66 to 3:4 (“The ends of the outrigger members are provided with connector means for temporarily securing the outriggers to the transverse portions of the linking members in a secure manner such that any manipulation of the outrigger members is transferred to the spinal link members and thus to the vertebra or sacrum to which they are affixed.”); 6:4-5 (“[W]hereby movement by the surgeon of the outrigger member 30 in any direction is transferred directly to the spine link member 90.”).

| Claim 1[F]: applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae in which said pedicle | The ‘928 Appl. provides that a downward force may be applied to the disclosed device in a manner for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws and thereby in a single motion simultaneously rotating the vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. See § V.B., Claim 1[C], 1[F], supra (incorporated here).

The ‘568 pat. discloses that a manipulative force may be applied to a handle means (levering member 20) that is then transmitted to engagement members (outrigger members 30) that then transmit this force to pedicle screws (pedicle bolts 90) through link member 90. See ‘568 pat., at 2:66 to 3:4; 6:4-5; 6:60-64 (“[T]o affix a link member 90 between two adjacent vertebrae 110 spanning the intervertebral disks 104, pedicle bolts 98 are securely implanted in the bone using known methodology, and the link members 90 are placed onto the pedicle bolts 98 and secured using lock nuts 74.”). The ‘568 pat.
screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition; provides that the handle means may be used to rotate the vertebrae. See id. at 1:58-65 (“The reduction may require manipulation of the vertebrae and the sacrum in one or more directions, i.e., . . . rotation about the vertebral axis.”); 2:17-21 (“It is a further object to provide such an apparatus and method which enables the surgeon to . . . rotate . . . either or both the vertebrae and the sacrum as required.”).

D. Ground 4 – Claims 1-5 are Obvious Under 35 U.S.C. § 103 Over the ‘928 Appl. in view of the Video, the Slides, and MTOS (the “Lenke References”)

Claims 1-5 of the ‘358 pat. are obvious under 35 U.S.C. § 103 over the ‘928 Appl., as applied to claim 1 in Ground 2, in view of the Lenke References.

With respect to elements [A]-[E] and [G]-[I] of claim 1, all of which the PTAB previously found were disclosed in the ‘928 Appl., the analysis provided in Ground 2 also applies to this ground. See § V.B. at 22, supra. Petitioner asserts that the ‘928 anticipates claim 1 of the ‘358 patent; however, and in the alternative, despite the ‘928 Appl.’s explicit teaching of the disclosed device being capable of “applying force in a direction that is perpendicular to the direction in which distraction or compression occurs,” if the PTAB decides that the ‘928 Appl. does not disclose the step of “applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition,” it would have been obvious to do so at the time of invention in view of the teachings of Lenke References. See Lenke Decl., at ¶¶ 78, 90.
As explained in Ground 5, each of the Lenke References discloses a procedure for correcting scoliosis in which multiple vertebrae are rotated simultaneously by applying force to pedicle screws by multiple pedicle screw engagement members. See § V.E. at 42-46, infra (incorporated here). As explained above, the ‘928 Appl. explicitly teaches the use of the disclosed device, including multiple pedicle screw engagement members, to impart a downward force on each of the vertebrae attached to the device by the pedicle screws. If one of ordinary skill in the art was to use the system disclosed in the ‘928 Appl. to correct a scoliotic spinal column, it would have been obvious at the time of invention to apply manipulative force to the handle means of the device in a manner to simultaneously engage the first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotate the vertebrae in which the pedicle screws are implanted in view of the procedures shown in the Lenke References. See id. The ‘928 Appl. and the Lenke References are from the same field of endeavor of fixing vertebrae by applying an upward or downward pressure on the spine, 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 id. Each reference teaches the application of both compression and distraction, as well as rotation, of multiple vertebrae, therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including scoliosis. See MTOS, at 18; ‘928 Appl., at ¶[0055]; Lenke Decl. at ¶90. Thus, a spinal derotator, and a method of using this 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[F]: applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition; | The Video, Slides, and MTOS discloses the application of manipulative force to a group of handles that are grasped by the surgeon in a manner for simultaneously engaging a first group of pedicle screw engagement members and a first set of pedicle screws and thereby in a single motion simultaneously rotating the vertebrae of the first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. See § V.E., Claim 1[C], 1[F], infra (incorporated here). |

Claim 2 depends from claim 1 and merely recites limitations duplicative of claim 1.

The ‘928 Appl. discloses the claimed second set of pedicle screws by incorporating by reference U.S. 2005/0085813 (the “‘813 Appl.”). See ‘928 Appl. at ¶ [0001] (incorporating by reference U.S. Pat. Appl. Ser. No. 10/690,211, which published as the ‘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, through the incorporated ‘813 Appl., the ‘928 Appl. inherently discloses or makes obvious the use of a second tool on the other side. Further, the use of a second pedicle screw derotation tool would have been obvious to use as this is a mere duplication of parts without any new or unexpected result occurring due this 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 MTOS and/or the Slides, both of which disclose the derotation procedure being performed on two sets of pedicle screws on opposing sides of the spinal column using two pedicle screw cluster derotation tools. MTOS provides that the use of the two tools allows for a 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 in patients with scoliosis. Further, like the ‘349 patent, the use of two tools as disclosed ensures that equal force is applied to both pedicle regions of the vertebrae being derotated. See Lenke Decl. at ¶¶ 94–98. By performing the derotation on both sides of the vertebrae at the same time, more pedicle screws are engaged, thereby allowing for a further distribution of the forces placed on the vertebrae. This also allows for a more efficient and effective derotation procedure because it the surgeon can apply a downward force on one side of the vertebrae while simultaneously applying an upward force on the other side of the vertebrae, both which motions fall under the ‘928 Application’s explicit teaching of using the device to apply a perpendicular force on the vertebrae. See id. One of ordinary skill in the art, having knowledge of the Lenke References and performing a derotation procedure using the tool disclosed in the ‘928 Appl. would have found it obvious to use the tool on both sides of the spinal column to obtain the desired result of derotating multiple vertebrae to eliminate the scoliotic condition while ensuring that equal force being applied to the pedicle regions of the vertebrae, thereby making the procedure safer. See id. The ‘928 Appl. and the Lenke References are from the same field of endeavor for fixing and manip-
ulating 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 and the simultaneous application of a downward force to these vertebral bodies. See id. Each of the references specifically teach the application of both compression and distraction, as well as rotation, of multiple vertebrae, therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including the treatment of scoliosis. See MTOS, at 18; ‘928 Appl., at ¶ [0055]; Lenke Decl. at ¶ 97. 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.

| Claim 2[A]: The method of claim 1 further comprising the steps of: selecting a second set of pedicle screws; 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 ‘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.”). The Video, the Slides, and MTOS also disclose the selection of a second set of pedicle screws. See § V.E. Claim 2[A], infra (incorporated here). |
| Claim 2[B]: selecting a second pedicle cluster derotation tool, said second pedicle screw cluster derotation tool having second handle means and a second group of pedicle screw engagement members which are mechanically linked with said second handle means, each pedicle The ‘928 Appl. discloses a first pedicle screw cluster derotation tool having a first handle means in the form of knobs 112a and 112b and threaded rods 110b. 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.B., Claim 1[C], supra (incorporated here). |
screw engagement member being configured for engaging with, 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 Slides and MTOS each disclose a second pedicle screw cluster derotation tool identical to the first pedicle screw cluster derotation tool that is configured to transmit manipulative forces to the head segments of the second set of pedicle screws in the same fashion that the first pedicle screw cluster derotation tool is configured to transmit manipulative forces to the head segments of the first set of pedicle screws. See § V.E., Claim 2[B], infra (incorporated here).

Claim 2[C]: implanting each pedicle screw in a pedicle region of each of a second group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;
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 implantation of the second set of pedicle screws lateral to the first set. See § V.D., Claim 2[A], supra (incorporated here).
The Video, the Slides, and MTOS also disclose the implantation of the second set of pedicle screws. See § V.E. Claim 2[A], infra (incorporated here).

Claim 2[D]: engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said second set of pedicle screws; and
The '928 pat. discloses the engaging of each pedicle screw engagement member with the head segment of a respective pedicle screw. See § V.B., Claim 1[E], supra (incorporated here).
The Slides and MTOS each disclose engaging each pedicle screw engagement member with the head segment of a respective pedicle screw of the second set. See § V.E., Claim 2[D], infra (incorporated here).

Claim 2[E]: applying manipulative force to said second handle means in a manner for simultaneously engaging said second group of pedicle screw engagement members and said second set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said second group of multiple vertebrae in which said pedicle screws
The '928 Appl. provides that force may be applied to the handle means of the disclosed device in a manner for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws and thereby in a single motion simultaneously rotating the vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. See § V.B., Claim 1[C], [F], supra (incorporated here).
The Slides and MTOS discloses applying manipulative force to the second group of handles in a manner for simultaneously engaging the second group of pedicle screw engagement members and second set of pedicle screws and thereby in a single motion simultaneously rotating the vertebrae of the second group of multiple vertebrae in which the pedicle
are implanted to achieve an amelioration of an aberrant spinal column deviation condition. screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition. See § V.E., Claim 1[F], *infra* (incorporated here).

Claim 3 depends from claim 2 and recites the use of a second spinal rod member in connection with the second set of pedicle screws. The ‘928 Appl. discloses the claimed second spinal rod member by incorporation of the ‘813 Appl. The ‘813 Appl. discloses the pedicle screw and spinal rod member assembly is placed on both sides of the vertebrae, thus requiring a second set of pedicle screws and a second spinal rod member coupled together in the same way as the first set of pedicle screws and the first spinal rod member.

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<tr>
<th>Claim 3[A]: The method of claim 2 further comprising the steps of: selecting a second length of a spinal rod member, wherein one or more of said pedicle screws of said second set of 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 said pedicle screw and said second spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;</th>
<th>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 spinal rod member. See § V.D., Claim 2[A], <em>supra</em> (incorporated here). The ‘928 Appl. discloses pedicle screws having a spinal rod conduit formed substantially transverse of the length of each pedicle screw and sized and shaped for receiving passage of said spinal rod member therethrough, and spinal rod engagement means for securing the pedicle screw and the spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation. See § V.B., Claim 1[H], <em>supra</em> (incorporated here). MTOS also discloses the use of a second spinal rod member. See § V.E., Claim 3[A], <em>supra</em> (incorporated here).</th>
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<tr>
<td>Claim 3[B]: extending said second length of said spinal rod member through said spinal rod conduits of</td>
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Claim 3(C): after applying said manipulative force to said second handle means, actuating said spinal rod engagement means to secure said vertebrae of said second group of multiple vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.

The ‘928 Appl. provides that after the application of manipulative force is completed, the set screws are actuated to lock the brace in place to maintain the desired arrangement of the vertebrae. See §§ V.B., Claim 1[I], supra (incorporated here).

The Slides and MTOS also disclose that after applying manipulative force to the second group of handles, the spinal rod engagement means are actuated to secure the vertebrae of the second group of multiple vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto. See §§ V.E., Claim 3[D], supra (incorporated here).

Claim 4 depends from claim 3 and recites that “the steps of applying manipulative force to said first handle means and applying manipulative force to said second handle means are carried out substantially simultaneously to cooperatively achieve an amelioration of an aberrant spinal column deviation condition.” Claim 5, which depends from claim 2, recites the same limitation.

MTOS discloses that the first and second handle means may be used simultaneously because “[i]t is also helpful to apply ventral pressure to the convex rib prominence simultaneously with the [apical vertebral derotation] of the screws.” MTOS, at 245. Similarly, the Slides show the application of manipulative force to the first and second group of handles at the same time, allowing for, in a single motion, the simultaneous rotation of the vertebrae of the first and second groups of vertebrae in which the pedicle screws are implanted to ameliorate of an aberrant spinal column deviation condition. See Slides at 19. One of
ordinary skill in the art, with knowledge of the teachings of MTOS, 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 of the spinal column to obtain the desired result of derotating multiple vertebrae to eliminate the scoliotic condition while simultaneously correcting the rib hump prevalent in patients with scoliotic spinal deformities. See Lenke Decl. at ¶¶ 96, 97, 103, 104. The readily apparent benefit of such simultaneous rotation is that allows for the force applied to the engaged vertebrae to be distributed more evenly, thereby making the procedure safer. See id. Additionally, this allows for the simultaneous application of a downward force on one side of the vertebrae and an upward force on the other side of the vertebrae to fully derotate the vertebrae, and achieve an amelioration of the aberrant spinal column deviation condition. See id. The ‘928 Appl., the Slides and MTOS are from the same field of endeavor for fixing and manipulating vertebrae, and each of the devices disclosed therein is used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebral bodies. See Lenke Decl., at ¶ 75. The references specifically teach the application of compression and distraction, as well as rotation, of multiple vertebrae, therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including scoliosis. See MTOS, at 18; ‘928 Appl., at ¶ [0055]; Lenke Decl. at ¶ 97. Thus, a spinal derotator, and method of use thereof, incorporating the teachings of these references represents an obvious combination of known mechanical elements arranged in a conventional manner in response to known design incentives, to achieve predictable results. See KSR, 550 U.S. at 418.
E. Ground 5 – Claims 1-5 are Obvious Under 35 U.S.C. § 103 Over the Video, the Slides, and/or MTOS (collectively, the “Lenke References”) in view of the ‘928 Appl. and the ‘568 Patent

Claims 1-5 are obvious under § 103 over the Video, the Slides and/or MTOS (alone or in combination) in view of the ‘928 Appl. and the ‘568 pat. 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. The Video, the Slides, and MTOS were distributed together to interested surgeons with no restrictions on redistribution at least at the Spinal Deformity Study Group Symposium 2003: Emerging Trends & Advanced Surgical Techniques 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 MTOS can be considered a single reference (collectively, the “Lenke References”). Alternatively, such concurrent distribution to those of ordinary skill in the art prior to the time of invention evidences that the three references, at the time of invention, were an obvious combination of complimentary teachings directed to overlapping subject matter.

With respect to claim 1, the PTAB has already found that the Lenke References disclose claim elements 1[A], 1[B], 1[D], 1[G], 1[H], and 1[I], as well as the step of applying force to a group of handles and in a single motion simultaneous rotating the vertebrae as recited in element 1[F]. See ‘1210 IPR Decision, at 25. The Lenke References each show a system, and its use, for treating and correcting spinal deformities and injuries. Specifically, each reference 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 Lenke Refer-
ences, the surgeon selects a first set of pedicle screws, each of which has a threaded shank
segment and a head segment, as well as a spinal rod conduit formed substantially transverse
the length of each screw that is sized and shaped to receive the spinal rod member. The
pedicle screws also include a spinal rod engagement means for securing each of the pedicle
screws and a spinal rod in a substantially fixed relative position and orientation. The pedi-
cle screws are implanted in a pedicle region of each of a first group of vertebrae.

The Lenke References also show the use of a first pedicle screw cluster derotation
tool in the form of multiple apical derotators that are grasped and used simultaneously,
moving each of the connected multiple vertebra at the same time. Each apical derotator
includes a handle linked to a pedicle screw engagement member that is configured to en-
gage the head segment of each pedicle screw. The individual handles of each apical dero-
tator that are shown in the Lenke References are configured to and may be grasped by a
surgeon’s hand during the derotation procedure and moved as a single unit en masse, i.e.,
simultaneously, as shown in the Video. See Lenke Decl. at ¶¶ 36, 37, 42, 45, 46, 81, 85 and
87. To the extent that the Lenke References do not disclose that the handles of the apical
derotators are interconnected via a mechanical linkage, it would have been obvious to one
of ordinary skill in the art to do so in view of the teachings of the ‘928 Appl. See id., at ¶ 84.
As detailed above, the ‘928 Appl. discloses a pedicle screw cluster tool that includes a han-
dle means in the form of multiple handles linked together such that the handles and the
attached pedicle screw engagement members move in unison in response to a downward
or upward force applied to one or both handles. Because this force is transferred to each of the pedicle screw engagement members, the downward force is subsequently transferred to each of the pedicle screws, thereby simultaneously placing a downward or upward pressure of each of the vertebrae. See § V.B. at 24-25, supra. If the PTAB decides that the ‘928 Appl. does not explicitly disclose a handle means designed especially to be grasped by the hand, in the alternative, it would have been obvious to modify the device of the ‘928 Appl. to include the handle means disclosed in the ‘568 patent. See § V.C. at 30-31, supra.

It would have been obvious to one of ordinary skill in the art to connect the individual handles shown in the Lenke References via a mechanical linkage, for safety and added mechanical advantage and to help ensure simultaneous and uniform transport of the pedicle screw engagement members while reducing the surgeon’s workload. See Lenke Decl. at ¶ 18, 84. The Lenke References show the surgeon moving the handles simultaneously by hand. Adding a mechanical linking member to connect the handles and achieve the same type of movement would have been a simple and obvious modification in view of the express teachings of the ‘928 Appl. by itself or as modified by the ‘568 pat. to have linked handles to apply a simultaneous downward pressure on adjacent vertebrae. See id. at ¶ 87. Further, 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 would motivate one to combine these references. See id. Moreover, one would be motivated to physically connect or link the individual handles of the Lenke References to more safely perform this maneuver by distributing the force applied to multiple
screws and multiple vertebrae to avoid damaging or breaking either the individual screws or portions of the vertebrae, any of which individually would be more likely to deform or break. See id. The ‘928 Application and/or the ‘568 application individually or in combination provide the means for this mechanical connection of the Lenke References to achieve this distributed load across the individual vertebrae and screws and to free the surgeon’s hand to manipulate the connecting rod and secure it while holding the vertebrae in place with one hand on one handle means. See id. The Lenke References, ‘928 Appl., and ‘568 pat. 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 id. The references specifically teach the application of compression and distraction, as well as rotation, of multiple vertebrae, therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including scoliosis. See MTOS, at 18; ‘568 pat., at 2:17-21; ‘928 Appl., at ¶ [0055]; Lenke Decl. at ¶ 75. Thus, a spinal derotator incorporating the teachings of these references represents 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.

As the Lenke References show that the surgeon applies force to each of the handles of the apical derotators at the same time, this first handle means, as modified in view of the ‘928 Appl. and ‘568 pat., 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 mechanical connections between
the handle means, as modified in view of the ‘928 Appl. and ‘568 pat., and the pedicle
screw engagement members, such that any force placed on the first handle means is neces-
sarily transferred to the pedicle screw engagement member. As shown, the application of
this manipulative force rotates the vertebrae to correct the scoliotic spinal column.

The Lenke References each show the use of a spinal rod that is coupled to the pedi-
cle screws. The spinal rod is fixed in place by set bolts after the vertebrae have been dero-
tated following an application of manipulative force to the pedicle screws.

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<tr>
<th>Claim 1 [A]: A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:</th>
<th>The Video, the Slides and MTOS disclose a method for treating and correcting deformities and injuries of the spine. See Video, at 00:13 – 07:12; Slides at 21. MTOS at 245-46 (“Thoracic and lumbar pedicle screw instrumentation allows maximum correction . . . . The tremendous three-dimensional correcting power of such instrumentation is redefining how scoliosis is operatively managed at our institution.”).</th>
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<tr>
<td>Claim 1 [B]: selecting a first set of pedicle screws, said pedicle screws each having a threaded shank segment and a head segment.</td>
<td>The Video, Slides, and MTOS each show multiple pedicle screws, any combination of which could be considered a first set, and each having threaded shank segment and a head segment. See Slides at 19; MTOS, at 240-41; FIGS. 17-6 and 17-7.</td>
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Claim 1 [C]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first handle means; and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first handle means.

The Video and MTOS discloses a first pedicle screw cluster derotation tool. See Video at 5:59 to 6:05; MTOS, at FIG. 17-13. The Video and MTOS shows that this tool includes a group of handles for facilitating simultaneous application of manipulative forces to the first set of pedicle screws by engaging with the heads of the pedicle screws, and a first group of pedicle screw engagement members that are mechanically linked to these handles. The first group of handles is shown transmitting forces to the head segment of the pedicle screws.

The Slides show a first pedicle screw cluster derotation tool. See Slides at 19. This derotation tool includes a first group of handles for facilitating simultaneous application of manipulative forces to the first pedicle screws and a first group pedicle screw engagement members that are mechanically linked with the handles. The first group of handles is shown transmitting forces to the head segment of the pedicle screws.

The ‘928 Appl. discloses a first pedicle screw cluster derotation tool that includes a first group of pedicle screw engagement mem-

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<th>Handles</th>
<th>Derotation Tool</th>
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<td>Pedicle Screw Engagement Members</td>
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handle means to said head segment of each pedicle screw of said first set of pedicle screws,

bers that are linked together with handles. See § V.B. Claim 1[C], supra (incorporated here). The ‘928 Appl. provides that when the pedicle screw engagement member is moved by a force, including a downward force, the engagement member transfers the force to the fixation elements, or pedicle screws. See id.

The ‘568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. See § V.C., claim 1[C], supra (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. See id. These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. See id.

Claim 1 [D]: implanting a [sic] each pedicle screw in a pedicle region of each of a first group of multiple 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 each of a first group of multiple vertebrae of a spinal column. See Video at 2:25-4:35; Slides at 18; MTOS, at 235-41 (describing implantation of pedicle screws).

Claim 1 [E]: engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said first set of pedicle screws; and

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.
Claim 1 [F]: applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition;

The Video, Slides, and MTOS show the application of manipulative force to a first group of handles in a manner for simultaneously engaging the first group of pedicle screw engagement members and the first set of pedicle screws and thereby in a single motion simultaneously 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. See Video at 5:59 to 6:06; Slides at 19; See MTOS, at 242-43 (“With the four apical vertebrae secured on both sides, the AVD maneuver is performed (Fig. 17-11). Most of the derotation and downward pressure is accomplished by the convex-sided screws. The degree of correction depends on the flexibility of the curve on preoperative assessments and on the grip of the apical screws in the vertebrae. It is also helpful to apply ventral pressure to the convex rib prominence simultaneously with the AVD of the screws.”); FIG. 17-11.

Claim 1 [G]: selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes: 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 therethrough; and spinal rod engagement means for securing

The Video, the Slides, and MTOS each show the use of 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. The Video, the Slides, and MTOS also disclose a spinal rod engagement means for securing
engagement means for securing said pedicle screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

| Claim 1 [H]: extending said first length of said spinal rod member through said spinal rod conduits of one or more of said pedicle screws of said first set of pedicle screws; and |
| Claim 1 [I]: after applying said manipulative force to said first handle means, actuating said spinal rod engagement means to secure said vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto. |

The Video, the Slides and MTOS show the extending of the first length of the spinal rod member throw the spinal rod conduit of the pedicle screws. See Video at 5:27 (“The rod is then placed in the left-sided set of screws.”); 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.”); § V.E., Claim 1[G], supra (incorporated here).

The Video and MTOS provide that after the application of manipulative force, set bolts are locked in place to secure the vertebrae in the derotated position. See Video at 6:17-6:22 (“Set bolts are then locked in to the derotated position.”); MTOS at 245 (“With the rod in place and all set screws except those at the apical six levels tightened, the surgeon replaces the concavity-sided posts and reperforms the AVD maneuver (Fig. 17-14). The apical set screws are tightened through the posts on the concavity.”).

Claim 2 depends from claim 1 and recites duplicate limitations of claim 1.

The Lenke References each show the first and second sets of pedicle screws and the coupling of the first and second spinal rods to each set, respectively. To the extent that the Video does not disclose a second pedicle screw cluster derotation tool having a second handle means and a second set of pedicle screw engagement members, and the application...
of force to this second handle means to simultaneously rotate the vertebrae, it would have been obvious to include such duplication in view of the Slides and MTOS. The Slides and MTOS each disclose a derotation procedure similar to that shown in the Video, and show the use of two pedicle screw cluster derotation tools. It would have been obvious to combine the teachings of the Lenke References because they all show a similar derotation procedure in which force is applied simultaneously to multiple vertebrae to ameliorate scoliosis. See Lenke Decl. ¶¶ 94-98.

<table>
<thead>
<tr>
<th>Claim 2 [A]: The method of claim 1 further comprising the steps of: selecting a second set of pedicle screws;</th>
<th>The Video, Slides, and MTOS each disclose a second set of pedicle screws. See Slides at 18; MTOS at FIG. 17-9.</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Set</td>
<td>Second Set</td>
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<tr>
<th>Claim 2 [B]: selecting a second pedicle cluster derotation tool, said second pedicle screw cluster derotation tool having second handle means and a second group of pedicle screw engagement members which are mechanically linked with said second handle means,</th>
<th>The Slides and MTOS each show a second pedicle screw cluster dero-</th>
</tr>
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<tbody>
<tr>
<td>First and Second Pedicle Screw Cluster Derotation Tools</td>
<td></td>
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</tbody>
</table>

First Set Second Set
<table>
<thead>
<tr>
<th>Claim 2 [C]: implanting each pedicle screw in a pedicle region of each of a second group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;</th>
<th>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.E., Claim 2[A], supra (incorporated here).</th>
</tr>
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<tbody>
<tr>
<td>Claim 2 [D]: engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said second set of pedicle screws; and</td>
<td>The Slides 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.</td>
</tr>
<tr>
<td>Claim 2 [E]: applying manipulative force to said second handle means in a manner for simultaneously engaging said second group of pedicle screw engagement members and said second set of pedicle screws and thereby in a single motion simultaneously rotating said</td>
<td>The Slides and MTOS each show the application of manipulative force to the second group of handles in a manner for simultaneously engaging the second group of pedicle screw engagement members and the second set of pedicle screws and thereby in a single motion simultane-</td>
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</tbody>
</table>

| each pedicle screw engagement member being configured for engaging with, 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, | Engagement tool virtually identical to the first and engaging a second set of pedicle screws to manipulate them. See Slides at 19; MTOS at FIG. 17-13. |
vertebrae of said second group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.

Claim 3 depends from claim 2 and recites the use of a second spinal rod member in connection with the second set of pedicle screws. The Lenke References each disclose a second spinal rod member coupled to the second set of pedicle screws. Even if the Video does not explicitly disclose spinal rod fixation means actuated to fix the spinal rod in place after force is applied, it would have been obvious to do so in view of the disclosure of MTOS, which provides for securing the second spinal rod member to the second set of pedicle screws after applying force to the second set. See Lenke Decl. at ¶¶ 100, 101.

### Claim 3[A]:
The method of claim 2 further comprising the steps of: selecting a second length of a spinal rod member, the Video, Slides, and MTOS each show use of second spinal rod member. See Video at 6:31; Slides at 19; MTOS at FIG. 17-14.

### Claim 3[B]:
wherein one or more of the pedicle screws of said second set of 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 said pedicle screw and said second spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation; The Video and MTOS both show use of second spinal rod member coupled to the second set of pedicle screws. Like the first set of pedicle screws, each of the pedicle screws of the second set includes 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 § V.E., Claim 1[G], supra (incorporated here).

### Claim 3[C]:
extending said second length of said spinal rod member through said spinal The Video and MTOS both show use of second spinal rod member coupled to the second set of pedicle screws. It is inherent that the Video discloses extension of the
Claim 3[D]: after applying said manipulative force to said second handle means, actuating said spinal rod engagement means to secure said vertebrae of said second group of multiple vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.  See § V.E., Claim 1[H], supra (incorporated here).

MTOS discloses that after applying manipulative force to the second group of handles, the spinal rod engagement means are actuated to secure the vertebrae of the second group of multiple vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.  See MTOS at 245 (listing placement of second rod after application of force); FIG. 17-14.

Claim 4 (depends from claim 3) and claim 5 (depends from claim 2) both recite “the steps of applying manipulative force to said first handle means and applying manipulative force to said second handle means are carried out substantially simultaneously to cooperatively achieve an amelioration of an aberrant spinal column deviation condition.”

The Video shows the manipulative force applied to a first group of handles to simultaneously engage a first set of pedicle screws, 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.  The Slides and MTOS each show the application of manipulative force to the first and second group of handles simultaneously to achieve an amelioration of an aberrant spinal column deviation condition for numerous beneficial reasons.  See § V.D. at 40-41, Claim 5, supra (incorporated here).  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 such that manipulative force was applied to both the first and second groups of handles at the same time in view
of this exact teaching from the Slides and/or MTOS. See Lenke Decl. at ¶ 102-104.

F. Ground 6 – Claims 1-5 are Obvious Under 35 U.S.C. § 103 Over the Video, the Slides, and/or MTOS in view of the ‘568 Patent

Claims 1-5 of the ‘358 pat. are rendered obvious under § 103 by the Lenke References (alone or in combination) in view of the ‘568 pat.

As to elements [A]-[B] and [D]-[I] of claim 1, (of which the PTAB has already found that the Lenke References disclose elements [A], [B], [D], and [G]-[I]), and claims 2-5, the same analysis as discussed in Ground 5 applies to this ground. See § V.E. at 42-54, supra. While it would have been obvious to link the handles of the pedicle screw cluster derotation tool shown in the Lenke References by common sense, or in view of the ‘928 Appl., alternatively, it would have also been obvious to do so in view of the ‘568 pat.

As explained in Ground 3, the ‘568 pat. describes an apparatus and method for the treatment of spinal column deviations and discloses the use of a handle means to apply simultaneous force to multiple adjacent vertebrae. See § V.C. at 29-30, supra. It would have been obvious to one of ordinary skill in the art to connect the individual handles shown in the Lenke References via a mechanical linkage, to help ensure simultaneous and uniform transport of the pedicle screw engagement members as taught in the ‘568 pat., while reducing the workload on the surgeon. See Lenke Decl. at ¶ 66, 82-84, 87. The Lenke References already show that the surgeon moves the handles simultaneously by hand to achieve such movement. Adding a mechanical linking member to connect the handles and achieve the same type of movement would have been a simple and obvious modification in view
of the express teachings of the ‘568 pat. to fix the position of the engaged adjacent vertebrae in a “quick and straightforward” manner. See id. at 2:11-26. Further, the design incentives of easing the surgeon’s workload (allowing one of the surgeon’s hands to be freed up to maneuver and secure the connecting rod), distributing the force uniformly across multiple pedicle screws and multiple vertebrae, and achieving uniformity in the movement of the pedicle screw engagement members and the attached vertebral bodies, as well as the Lenke References and the ‘568 pat.’s shared teaching of rotating the vertebrae, would provide one of ordinary skill in the art motivation to combine the teachings of these references. See Lenke Decl. at ¶¶ 82-84, 87. The Lenke References and the ‘568 pat. 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 id. The references specifically teach the application of compression and distraction, as well as rotation, of multiple vertebrae, therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including the treatment of scoliosis. See MTOS, at 18; ‘568 pat., at 2:17-21; Lenke Decl. at ¶ 75. Thus, a spinal derotator incorporating the teachings of these references represents an obvious combination of known mechanical elements arranged in a conventional manner in response to a known design incentive, to achieve predictable results of a safe and uniform maneuver requiring only one hand. See KSR, 550 U.S. at 418.

Claim 1 [C]: selecting a first pedicle

The Video, the Slides, and MTOS each show a first pedicle
pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, 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,

screw cluster derotation tool. These derotation tools include a first group of handles that are grasped at the same time by the surgeon to facilitate simultaneous application of manipulative forces to the first pedicle screws and a first group of three pedicle screw engagement members that are mechanically linked with the first handle means. See § V.E., Claim 1[C], supra (incorporated here).

The ‘568 pat. discloses an apparatus for transmitting simultaneous manipulative force to adjacent vertebrae that includes a handle means (levering member 20) that has a proximally mounted handle 21 that is designed to be grasped by the hand. See § V.C., claim 1[C], supra (incorporated here). Multiple outrigger members 30 may be mechanically linked to the handle means. See id. These outrigger members transfer any force applied on the handle means to the adjacent vertebrae. See id.

G. Ground 7 – Claims 1-5 are Obvious Under 35 U.S.C. § 103 Over the Video, the Slides, and/or MTOS in view of the ‘349 Patent

Claims 1-5 are rendered obvious under § 103 by the Lenke References (alone or in combination) in view of the ‘349 pat. As noted in Grounds 1 and 6, the PTAB has previously found the ‘349 pat. discloses claim elements 1[A], 1[B], and 1[D], and the Lenke References disclose claim elements 1[A], 1[B], 1[D], 1[G], 1[H], and 1[I], thus exemplifying these references compatibility and the motivation to combine their teachings.

With respect to elements 1[A]-[B] and 1[D]-[I], and claims 2-5, the same analysis of Ground 6 applies to this ground. See § V.F. at 55-57, supra. It would have been obvious to link the handles of the handle means of the pedicle screw cluster derotation tool shown in the Lenke References in view of the ‘349 pat. to more evenly distribute the forces across multiple pedicle screws and multiple vertebra to avoid deforming or breaking the screws or
vertebra and to free one hand of the surgeon to manipulate and secure the connecting rod.

As explained in Ground 1, the ‘349 pat. discloses a first pedicle screw cluster derotation tool that includes a first handle means in the form of hinged extensions 136, laterally extending arms 112, the lower portions of dorsally extending legs 110, and threaded rod 210 that connects the portions of dorsally extending legs 110. See § V.A. 10-11, supra (incorporated here). To the extent that the term handle means is construed to require a part that is especially designed to be grasped by the hand, the ‘349 pat. discloses that the laterally extending arms 112, as part of T-handle 100, “may be used by the surgeon simply as handles for manual manipulation of the spine.” ‘349 pat., at 5:8-12.

It would have been obvious to one of ordinary skill in the art at the time of invention to connect the individual handles shown in the Lenke References via a mechanical linkage to help ensure simultaneous and uniform transport of the pedicle screw engagement members while reducing the surgeon’s workload in view of the ‘349 pat. and allowing for distributing the loads across multiple screws and multiple vertebra to avoid damaging or breaking either the screws or vertebra and to free up the surgeon’s hand to, for example, manipulate the rod and secure it in the screw heads while holding the vertebra in position with the other hand. See Lenke Decl. at ¶¶ 64, 82-84, 87, 88. 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 teachings of the ‘349 pat. of this linkage providing a high degree of mechanical control, and the design incentives of easing the surgeon’s workload, achieving uniformity in the movement of
the pedicle screw engagement members and the vertebral bodies. See id; ‘349 pat., at 5:67 to 6:3 (“With the lower-rod assembly 200 installed on the T-handles 100, the surgeon may execute any of the common movements of the spine (flexion, extension, distraction, compression or anterior/posterior shear) with a high degree of mechanical control.”). The Lenke References and the ‘349 pat. are from the same field of endeavor for fixing and manipulating vertebrae, including the simultaneous rotation of multiple vertebrae, and each of the devices disclosed therein could be used to achieve spinal column derotation via fixation of pedicle screws to multiple vertebrae. See Lenke Decl., at ¶¶ 82-84, 87, 88. Each reference teach the application of both compression and distraction, as well as rotation, of multiple vertebrae, therefore one of ordinary skill in the art would look to the combined teachings of these references to solve similar spinal deformities, including scoliosis. See MTOS, at 18; ‘349 pat., at 2:57-61; Lenke Decl. at ¶ 75. Thus, a spinal derotator, and method of use thereof, incorporating the teachings of these references represents 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.

<table>
<thead>
<tr>
<th>Claim 1 [C]: selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging</th>
<th>The Video, the Slides, and MTOS each show a first pedicle screw cluster derotation tool. These derotation tools include a first group of handles that are grasped at the same time by the surgeon to facilitate simultaneous application of manipulative forces to the first pedicle screws and a first group of three pedicle screw engagement members that are mechanically linked with the first handle means. See § V.E., Claim 1[Œ], supra (incorporated here).</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ‘349 pat. discloses a first pedicle screw cluster dero-</td>
<td>The Video, the Slides, and MTOS each show a first pedicle screw cluster derotation tool. These derotation tools include a first group of handles that are grasped at the same time by the surgeon to facilitate simultaneous application of manipulative forces to the first pedicle screws and a first group of three pedicle screw engagement members that are mechanically linked with the first handle means. See § V.E., Claim 1[Œ], supra (incorporated here).</td>
</tr>
</tbody>
</table>
VI. CONCLUSION

For the reasons above, Petitioner respectfully requests institution of *inter partes* review for Claims 1-5 of the ‘358 patent.

Respectfully submitted,

Dated: February 20, 2015

/ Jeff E. Schwartz /

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Fax: 202-461-3102

*Attorneys for Petitioner*
CERTIFICATE OF SERVICE ON PATENT OWNER

UNDER 37 C.F.R. § 42.105(a)

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

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Dated: __February 20, 2015__

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