

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

MARK A. BARRY,
Patent Owner.

Case IPR2014-01211
Patent 8,361,121 B2

Before DONNA M. PRAISS, BRIAN J. McNAMARA, and
JEREMY M. PLENZLER, *Administrative Patent Judges*.

McNAMARA, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

BACKGROUND

Medtronic, Inc. (“Petitioner”) filed a petition, Paper 2 (“Pet.”), to institute an *inter partes* review of claims 1–4 (the “challenged claims”) of U.S. Patent No. 8,361,121 B2 (“the ’121 Patent”). 35 U.S.C. § 311–319. Mark A. Barry (“Patent Owner”) did not file a Preliminary Response. We conclude that Petitioner has not shown, under 35 U.S.C. § 314(a), that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

For the reasons described below, we do not institute an *inter partes* review of the ’121 Patent.

PENDING LITIGATION

Petitioner is the defendant in litigation concerning the ’121 Patent, *Mark A Barry, MD v. Medtronic, Inc.*, filed in the Eastern District of Texas as Case No. 1:14-cv-00104-RC on February 18, 2014. Petitioner was served with the complaint on February 20, 2014.

OTHER RELATED MATTERS

Two additional, related patents are the subject of concurrent petitions for *inter partes* review by Petitioner Medtronic, Inc.: Patent No. 7,670,358 (Case IPR 2014-01210) and Patent No. 7,776,072 (Case IPR 2014-01212)

THE ’121 PATENT (EXHIBIT 1022)

The ’121 Patent discloses a system for ameliorating aberrant spinal column deviation conditions, such as scoliosis, that facilitates the application of derotational forces to individual vertebra, while reducing the risk of fracture when applying such forces. Ex. 1022, col. 3, ll. 25–32. The system includes a number of bone screws that are implanted into the pedicle region(s) of individual vertebrae to be rotated, and to vertebrae to which balancing forces must be applied, as the

spinal column is manipulated en masse to achieve an overall correction. *Id.* at col. 3, ll. 42–50. The pedicle screws have a threaded shank segment and a head segment. *Id.* at col. 4, ll. 59–60. The head segment has a spinal rod conduit (or channel) that interfaces with a pre-contoured spinal rod. *Id.* at col. 5, ll. 1–4. A spinal rod engagement means is tightened, using known anti-torque techniques, to fix the pedicle screw and spinal rod in relative position and orientation, once a spinal column derotation is complete. *Id.* at col. 5, ll. 4–6; col. 5, l. 65–col. 6, l. 9.

The system also includes pedicle screw cluster derotation tools. The pedicle screw cluster derotation tool facilitates simultaneous application of manipulative forces to multiple pedicle screws implanted in a like number of vertebrae (a “cluster”). *Id.* at col. 5, ll. 29–31. The derotation tool includes shafts, extending from a common handle or linked handle array, that extend to and engage the heads of a number of implanted pedicle screws implanted in adjacent vertebrae to which derotational or balancing forces are to be applied during a spinal column derotation and alignment. *Id.* at col. 3, ll. 53–60. As manipulative forces are applied to the handle means of pedicle screw cluster derotation tool, forces are transferred and dispersed simultaneously among the engaged vertebrae so that a practitioner may, in a single motion, simultaneously and safely derotate multiple vertebrae of an affected spinal segment and apply balancing forces to other group(s) of vertebrae which are contiguous to the effected segment(s) to provide three dimensional spinal cord correction. *Id.* at col. 3, l. 62–col. 6, l. 6.

Each pedicle screw cluster derotation tool is configured from a grouping of pedicle screw wrenches joined together by pedicle screw wrench linking members to act in unison when used to effect rotation or apply a balancing force. *Id.* at col. 5, ll. 10–14. Each pedicle screw wrench includes a handle, a shaft, and a distal end that reversibly engages the head segment of a pedicle screw. *Id.* at col. 5, ll.

14–16. As the shaft is moved while the distal end is engaged with a head segment of a pedicle screw, manipulative forces are transferred to the pedicle screw and, in turn, to the vertebra in which such pedicle screw is implanted. *Id.* at col. 5, ll. 17–20.

Pre-contoured spinal rods loosely engaged with the pedicle screws are rotated from a first orientation through 90 degrees to a second orientation using hex wrenches to achieve substantial correction in the first two of three axes. *Id.* at col. 5, ll. 55–61. Manipulative forces are then applied to pedicle screw clusters relative to a third or “roll axis before tightening the pedicle screws and spinal rod in position using well-known anti-torque features of the wrenches. *Id.* at col. 5, l. 62–col. 6, l. 6.

ILLUSTRATIVE CLAIM

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

- selecting a first set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment, each pedicle screw having a spinal rod engagement means for mechanically engaging with a spinal rod member and spinal rod fixation means for, upon actuation, fixing the relative orientation of each pairing of said spinal rod member and said pedicle screw;
- selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members and a linking member to join together the handles

linked to the pedicle screw engagement members, said first handle means moving each pedicle screw engagement member simultaneously; each pedicle screw engagement member being configured for engaging respectively with said head segment of each pedicle screw of said first set of pedicle screws, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;

implanting each pedicle screw of said first set of pedicle screws in a pedicle region of each of a first group of vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;

contouring said spinal rod member whereby, in a first plane, said spinal rod member substantially defines, in reference to two axes, a post-operative spinal column alignment for said spinal column;

engaging said spinal rod respectively with said spinal rod engagement means of each pedicle screw of said first set of pedicle screws, while said spinal rod is in a first rotational orientation;

rotating said spinal rod substantially along its length to a second rotational orientation to effect a correction of spinal column deviation in reference to two axes;

engaging each pedicle screw engagement member of said first group of pedicle screw engagement members respectively with said head segment of each pedicle screw of said first set of pedicle screws;

selecting a second set of pedicle screws;

selecting a second spinal rod member;

selecting a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitating simultaneous application of

manipulative forces to said second set of pedicle screws and a second group of pedicle screw engagement members which are mechanically linked with said second handle means, said second handle means moving each pedicle screw engagement member simultaneously, each pedicle screw engagement member being configured for engaging

respectively with said head segment of each pedicle screw of said second set of pedicle screws, and transmitting manipulative forces applied to said second handle means to said head segment of each pedicle screw of said second set of pedicle screws;

implanting each pedicle screw of said second set of pedicle screws in the pedicle region of each of a second group of vertebrae lateral to the first group of vertebrae;

contouring said second spinal rod member whereby, in a first plane, said second spinal rod member substantially defines, in reference to two axes, a post-operative spinal column alignment for said spinal column;

engaging said second spinal rod respectively with said spinal rod engagement means of each pedicle screw of said second set of pedicle screws, while said second spinal rod is in a first rotational orientation;

rotating said second spinal rod substantially along its length to a second rotational orientation to effect a correction of spinal column deviation in reference to two axes;

engaging each pedicle screw engagement member of said second group of pedicle screw engagement members respectively with said head segment of each pedicle screw of said second set of pedicle screws;

connecting with a cross-linking member the first handle means to the second handle means laterally positioned to the first handle means;

applying manipulative force to the first handle means and the second handle means in a manner for simultaneously engaging said first group of three or more pedicle screw engagement members and said first set of pedicle screws, and said second group of pedicle screw engagement members and said second set of pedicle screws laterally positioned to the first group of three or more pedicle screw engagement members and said first set of pedicle screws, thereby in a single motion simultaneously rotating said vertebrae of said first group of vertebrae and said second group of vertebrae lateral to said first group of vertebrae, in which said pedicle screws are implanted to achieve an

amelioration of an aberrant spinal column deviation condition.

BASIS OF PETITION

Petitioner asserts the following challenges to claims 1–4 of the '121 Patent. We note that several of the asserted grounds appear to be alternatives, which essentially constitute additional grounds.

Claims	Statutory Basis	References
1–4	35 U.S.C. § 103	The Video ¹ , the Slides ² , and/or MTOS ³ (alone or in combination), in view of '328 Appl. ⁴ , the '349 Patent ⁵ , the '291 Appl. ⁶
1–4	35 U.S.C. § 103	The Video, the Slides, and/or MTOS (alone or in combination), the '928 Appl., the '349 Patent, the '291 Appl.

¹ Thoracic Pedicle Screws for Idiopathic Scoliosis Video (2001). Ex. 1002 (“Video”).

² Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide presentation handout (2003). Ex. 1003 (“Slides”).

³ Anthony S. Rinella, Yongjung J. Kim, and Lawrence G. Lenke, “Posterior Spinal Instrumentation Techniques for Spinal Deformity” Chapter 17 in *Masters Techniques in Orthopaedic Surgery: The Spine*, 2nd Edition (undated, *see* Declaration of Dr. Lawrence Lenke, Ex. 1001 ¶47, asserting publication date of Nov. 13, 2003).

. Ex. 1012 (“MTOS”).

⁴ U.S. Patent Application Publication No. 2003/0065328 A1, published Apr. 3, 2003 . Ex. 1004 (“the '328 Appl.”).

⁵ U.S. Patent No. 5,219,349, issued June 15, 1993. Ex. 1005 (“the '349 Patent”).

⁶ U.S. Patent Application Publication No. 2005/0033291 A1, published Feb. 10, 2005. Ex. 1007 (“the '291 Appl.”).

1–4	35 U.S.C. § 103	'928 Appl. ⁷ in view of the Slides, the '291 Appl. and the '349 Patent
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CLAIM CONSTRUCTION

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes constructions for the following terms:

Spinal rod engagement means. In related IPR2014-01210, claim 1 recited a spinal rod engagement means for securing said pedicle screw and said spinal rod member. Therefore, in IPR2014-01210, we construed “spinal rod engagement means” to mean *the portion of the pedicle screw that can be tightened to secure the pedicle screw and spinal rod in a substantially fixed position and orientation*. However, claim 1 of the '121 Patent in this proceeding recites both “a spinal rod engagement means for engaging with a spinal rod member” and “a spinal rod

⁷ U.S. Patent Application Publication No. 2005/0245928 A1, published Nov. 3, 2005. Ex. 1006 (“the '928 Appl.”).

fixation means for, upon activation, fixing the relative orientation of each pairing of said spinal rod member and said pedicle screw,” as discussed further below. Referencing Figure 4, the Specification describes the pedicle screw as having a head segment configured with a spinal rod conduit or channel 16 interfacing with a spinal rod 18. Ex. 1022, col. 5, ll. 1–4. The Specification also describes the “[s]pinal rod engagement means 20 serve to fix pedicle screw 10 and spinal rod 18 in relative position and orientation, once a spinal column derotation is complete.” *Id.* at col. 5, ll. 5–7. There is no separate disclosure of a spinal rod fixation means. Thus, there is an inconsistency between the function recited in claim 1 as that performed by the ‘spinal rod engagement means’ and the description in the Specification. However, for purposes of this proceeding, we observe that the spinal rod engagement means recited in claim 1 of the ’121 Patent performs the function of engaging with a spinal rod member and that the spinal rod conduit is the structure that performs the claimed function.

Spinal rod fixation means. Petitioner contends that this term is not a “means-plus-function” term under 35 U.S.C. § 112 ¶ 6, and that the term should be given its ordinary meaning as “a component for fixing the rod in place.” Pet. 5. However, as discussed above, claim 1 recites “spinal rod fixation means for, upon actuation, fixing the relative orientation of each pairing of said spinal rod member and said pedicle screw.” Ex. 1022, col. 6, ll. 31–33. According to Petitioner, if we determine that “spinal rod fixation means” is a means-plus-function term, the claimed function is upon actuation, fixing the spinal rod member relative to the pedicle screw and the corresponding structure is a fixation element. *Id.* We agree with Petitioner’s proposal concerning the claimed function. The Specification discloses that the structure that performs the claimed function is that portion of the pedicle screw that can be tightened to perform the fixation. *Id.* at col. 6, ll. 4–9.

Handle means. In related IPR2014-01210, we construed handle means, which was not written in means-plus-function form, to mean *a part that is designed especially to be grasped by the hand*. The '121 Patent, however, recites a “first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members mechanically linked (construed below to mean *joined by a physical connection*) with said first handle means.” Ex. 1022, col. 6, ll. 35–40. Claim 1 also recites a “second handle means for applying manipulative forces to a second set of pedicle screws and a second group of pedicle screw engagement members which are mechanically linked with said second handle means.” *Id.* at col. 7, ll. 9–14. These terms are written in means-plus-function form. In the case of the first handle means, the function is simultaneously applying manipulative forces to a first set of pedicle screws and a first group of three or more pedicle screw engagement members. The second handle means performs a similar function on a second set of pedicle screws and screw engagement members, but is not limited to three screw engagement screw members. Petitioner proposes that the corresponding structure disclosed in the Specification is a handle from which the shafts extend. Pet. 6. Petitioner’s proposed structure does not address the recitation that the structure function to facilitate simultaneously applying application manipulative forces to the pedicle screws. The '121 Patent discloses that the derotation tool includes shafts extending from a common handle or linked handle array to engage the heads of a number of pedicle screws and that the engagement between the tool and the pedicle screws is such that as manipulative forces are applied to the “handle means” of the tool forces are transferred and dispersed simultaneously among engage vertebrae. Ex. 1022, col. 3, ll. 54–65. Claim 1 specifically recites a linking member to join the handles. Thus, for each of

the claimed handle means, we construe the structure to be a common handle or linked handle array from which extend shafts that engage pedicle screws. *See id.* at col. 3, ll. 55–58. This construction is consistent with the description in the Specification that each wrench 32 includes a handle 34, a shaft 36, and a distal end configured to reversibly engage the head segment of a pedicle screw, such that, as the shaft is moved, manipulative forces are transferred to the pedicle screw and, in turn to the vertebra in which that screw is implanted. *Id.* at col. 5, ll. 16–20. We also note that that the '121 Patent discloses groups of multiple pedicle screw wrenches 32 linked by linking member 42 to act in unison during use. *Id.* at col. 5, ll. 10–13.⁸

Mechanically linked. We apply the same construction in this proceeding as we applied in related IPR2014-01210. As we noted in that proceeding, the term “mechanically linked” is not used in the Specification and we agreed with Petitioner that we should construe “mechanically linked” to mean *joined by a physical connection*.

A second group of vertebrae. Citing Figure 1 of the '121 Patent, Petitioner proposes that under the broadest reasonable construction, the term “a second group of vertebrae” means “multiple vertebrae located at least in part at a different location on the spine than the first group of vertebrae.” Pet. 7. We adopt Petitioner’s construction.

⁸ The '121 Patent also discloses a variation in which wrenches 32 are linked by linking members 40, which may be replaced by a single handle member from which extend the functional equivalent of multiple shafts 36 and shaft distal ends 38 for simultaneously engaging multiple pedicle screws. Ex. 1022, col. 5, ll. This feature, however appears to correspond to the cross linking member recited in claim 1 at column 7, lines 40–42, linking the claimed first and second handle means.

A second group of vertebrae lateral to the first group of vertebrae. Although Petitioner contends there is no reasonable meaning for this term because vertebrae are not lateral to each other, for purposes of this proceeding, Petitioner contends that, consistent with Figure 1 of the '121 Patent, the term should be construed to refer to portions of vertebrae, one side of a group of vertebrae lateral to another side, right or left. Pet. 7. For purposes of this decision, we apply Petitioner's proposed construction.

ANALYSIS OF PETITIONER'S PRIOR ART CHALLENGES

All of Petitioner's challenges are based on obviousness under 35 U.S.C. § 103. The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003); *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *KSR Int'l Co.*, 550 U.S. at 418. In that regard, for an obviousness analysis it can be important to identify a reason that would have prompted one of skill in the art to combine prior art

elements in the way the claimed invention does. *Id.* However, a precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, obviousness must be gauged in view of common sense and the creativity of an ordinarily skilled artisan. *Id.* Petitioner's expert, Dr. Lenke, identifies one of ordinary skill as having an undergraduate degree in Mechanical or Biomedical Engineering or the equivalent, and at least two to three years of experience with fixation implants and methods and systems for scoliosis or spinal deformity correction and the like, or a medical degree or the equivalent, and at least two to three years of experience with fixation implants and methods and systems for scoliosis or spinal deformity correction and the like, or an equivalent amount of experience in medical device design, e.g. four years design experience could replace an undergraduate degree. Ex. 1001 ¶ 32.

Claims 1–4 as obvious over the Video, the Slides and/or MTOS in view of the '328 Appl., the '349 Patent, and, in the alternative, the '291 Patent

We addressed extensively the subject matter disclosed in the Video, the Slides and the MTOS in related proceeding IPR2012-01210. We agree with Petitioner that the Video, the Slides, and MTOS disclose a method as recited in the preamble (Claim 1[A]), a pedicle screw having a threaded shank segment, as recited in Claim 1[B], and a spinal rod engagement means and spinal rod fixation means, as recited in Claim 1[C].

Turning to Claim 1[D], Petitioner contends that the Video, the Slides, and MTOS each show the application of manipulative force to the first group of handles to simultaneously engage the pedicle screw engagement members and first set of pedicle screws. Pet. 22. Specifically, Petitioner contends that the Video discloses a first pedicle screw cluster derotation tool that includes a first group of handles for facilitating simultaneous application of manipulative forces to the first

set of pedicle screws and a first group of pedicle screw engagement members mechanically linked to the this group of handles, as claimed. *Id.* at 25–26.

Petitioner makes similar assertions concerning the Slides and MTOS. *Id.*

Petitioner contends that the Video, the Slides, and MTOS each show the surgeon moves the handles simultaneously by hand. Pet. 17. We have construed the first and second handle means to be a common handle or linked handle array from which extend shafts that engage pedicle screws. Petitioner does not identify such a structure in the Video, Slides, or MTOS. Petitioner also does not demonstrate such a structure in the '328 Appl.

As we discussed in our construction of “handle means,” Claim 1[D] of the '121 Patent recites a linking member that joins together the handles linked to the pedicle screw engagement members, said first handle means moving each pedicle screw engagement member simultaneously. Citing paragraph 70 of the '328 Appl., Petitioner contends that microschweller 204 serves as the linking member that joins together each of the handles. *Id.* at 26. According to Petitioner, the '328 Appl. discloses threaded rod 205 as the handle linked to the first pedicle screw engagement member (support unit 1), threaded shank 222 of connecting element 213 as the handle linked to the second pedicle engagement member (support unit 2) and threaded rod 206 as the handle linked to the third pedicle screw engagement member (support unit 3) and that microschweller 204 links each of these handles. *Id.* However, Petitioner does not explain how the rods and threaded shank function as handles, nor do the structures Petitioner cites constitute shafts extending from a common handle or linked handle array.

The “handle means” recited in the '121 Patent Claim 1[D] is part of a derotation tool, selected as a step in carrying out the claimed method. The '328 Appl. does not disclose a tool. The '328 Appl. discloses a device with up to nine

fixing units connected to each other in groups of 3 with the aid of threaded ties, thereby forming support units (2 side units and 1 intermediate unit, the intermediate unit being connected to the side support units so that it can move with the aid of connecting hinge junctions). *Id.* at Abstract. Paragraphs 83–85 of the '328 Patent explain the manipulation of distraction rods in the support units to correct the spine. Referring to Figures 11–13, paragraphs 86–87 of the '328 Patent explain that adjustments can be achieved using a microschweller 204 in which connecting post 213, fastened with the help of load bearing nuts 209 and 210, is set in the longitudinal slot of the microschweller and connected to the fixation junction 157 of an intermediate support unit. By graduated turning of the load bearing nut 210, transport of the microschweller in the transverse plane is performed. Load bearing nuts 207, 207a, 208, and 208a are then fixed.

Noting that the '328 Appl. is from the same field of endeavor, Petitioner contends that the addition of a mechanical linking member to the Video, the Slides, and MTOS would have been nothing more than a simple and obvious modification in view of the express teachings of the '328 Appl., as well as the design incentives of easing the surgeon's workload, and achieving uniformity in the movement of the pedicle screw engagement members and the vertebral bodies, each of which is an entirely expected and common sense result. Pet. 17 (citing the declaration of Dr. Lawrence Lenke ("Lenke Decl.") Ex. 1001 ¶¶ 66, 74, 75.) Although Paragraph 66 of the Lenke Decl. mentions the Video, the Slides, MTOS, and the '928 Appl., Paragraph 75 of the Lenke Decl. concerns only the combination of the '928 Appl. and the '328 Appl. Paragraph 76 of the Lenke Decl. appears to be relevant to Petitioner's assertions as well. In any case, Dr. Lenke states that the linking of these handles has an obvious benefit in that it allows the surgeon to grasp this

connecting member when simultaneously moving the engagement members, instead of having to grasp each handle member individually. Ex. 1001 ¶ 75.

Petitioner does not provide articulated reasoning to support the combination of the Video, the Slides, and MTOS with the '328 Appl. as disclosing the first handle means recited in claim 1. As previously mentioned, the '328 Appl. does not concern a tool, but a device that appears to be an implanted device. One purpose of the microschweller is to increase the design rigidity of the outer fixation junctions 154 and 160 of the outer support units 1 and 3 and intermediate support unit 3. Ex. 1004 ¶¶ 30, 80. The microschweller is connected through posts 211 and 212, set on fixation junctions 154, 160 of outer support units 1, 3 with the possibility of transport using threaded rods 205, 206 and load bearing nuts 207, 208, 209, and 210. Ex. 1004 ¶¶ 30, 70. The '328 Appl. discloses a number of distraction rods connected by hinge junctions parallel to the sagittal plane between the intermediate and side support units, the rods being set in connecting holes of respective plates with the possibility of transport. This is different from the claimed structure in which a fixation means is that portion of the pedicle screw that can be tightened to perform the fixation. Petitioner cites rods 205 and 206 and threaded rod 222 in the '328 Appl. as handles, but does not explain how they function as handles. Petitioner does not explain how the surgeon grasps the microschweller as a connecting member linking handles. Pet. 26. Petitioner also does not provide articulated reasoning why one of ordinary skill would look to the graduated transverse motion of the microschweller, achieved by adding a component to the support units of the device in the '328 Appl., as constituting a first handle means of a derotation tool, as recited in the claims. In view of the structural differences between the device disclosed in the '328 Appl. and those described in the Video, the Slides, MTOS, and the other references cited in this

challenge, Petitioner also does not describe sufficiently why one of ordinary skill would be motivated to combine the disclosures of the '328 Appl. with the teachings in those references.

Independent claim 2 recites a first pedicle screw cluster derotation tool limitation similar to that recited in claim 1, instead using “wherein” language concerning the configuration of the tool to move the pedicle screw engagement members simultaneously and transmit manipulative forces applied to the handle means to the head segment of each pedicle screw. Thus, our analysis of claim 1 applies equally to claim 2. Claims 3 and 4 depend directly or indirectly from claim 1.

Therefore, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in demonstrating that claims 1–4 are unpatentable as obvious over the Video, the Slides, and/or MTOS in view of the '328 Appl., the '349 Patent, and, in the alternative, the '291 Appl. references cited and we do not institute a trial on this challenge.

Claims 1–4 as Obvious Over The Video, the Slides, and/or MTOS (alone or in combination), the '928 Appl., the '349 Patent, the '291 Appl.

We addressed Video, the Slides, and MTOS respect to Claim 1 [A], [B], and [C] in our previous discussion of another of Petitioner’s challenges. Turning to Claim 1[D], in this challenge, again citing paragraphs 74 and 75 of the Lenke Decl., Petitioner asserts that it would be obvious to link the handles of the pedicle screw derotation tool shown in the Video, the Slides and MTOS in view of the '928 Appl. Pet. 40–41.

We note that Petitioner identifies the elements of claim 1 differently in this challenge from those of the previous challenge. In the challenge previously discussed herein, Petitioner identifies Claim 1 [D], which is drawn to the selecting

a first pedicle screw cluster derotation tool, as including the language “said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members and a linking member to join together the handles linked to the pedicle screw engagement members, said first handle moving each pedicle screw engagement member simultaneously.” *Id.* at 25–26. However, in this challenge, Petitioner breaks this language out separately as Claim 1[E]. *Id.* at 41–42. Claim 1[E], as identified by Petitioner in the previous ground, concerns the pedicle screw engagement member being configured for engaging the head of each pedicle screw. *Id.* at 27. Petitioner states that its analysis for claim 1 elements [A]–[D] and [F]–[U] for the Video and the Slides in combination with the ’349 Patent (the previous challenge) is applicable for this ground. *Id.* at 40. In its explanation of Claim 1[E] in this challenge, Petitioner’s table refers to its discussion of Claim 1[E] in the previous challenge. *Id.* at 42.

FIG. 11

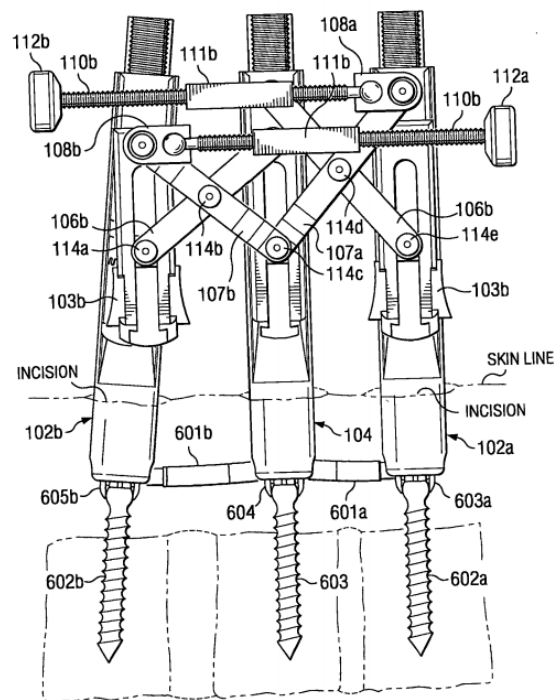


Figure 11 of the '928 Appl.

The figure above is a reproduction of Figure 11 of the '928 Appl. Ex. 1006. As shown in Figure 11, when knob 112b is turned, cross action members 106b and 107b move, causing guide tubes 102b to be displaced by compression or distraction relative to guide tube 104, which remains stationary. *Id.* at ¶ 66. Adjusting knob 112a causes the same action with respect to guide tubes 102a and 104. *Id.* Thus, the '928 Appl. describes displacing the vertebrae using separate motions.

We have construed the first handle means to be a means-plus-function claim limitation in which the function is simultaneously applying manipulative forces to a first set of pedicle screws and a first group of three or more pedicle screw engagement members. Petitioner contends that the '928 Appl. discloses two handles in the form of knobs 112a and 112b and threaded rods 110b that each allow a practitioner to apply forces to two of the pedicle screw engagement members. Pet. 40. Petitioner further notes that in the '928 Appl. the handles are interconnected by a linkage in the form of cross-action members 107a, 107b, so that the pedicle screw engagement members move in unison in response to a force applied to one or both handles. *Id.* at 41. As discussed above, in the '928 Appl. adjusting one knob causes a pedicle screw engagement member (guide tube 102a or guide tube 102b) to adjust relative to stationary pedicle screw engagement member (guide tube 104). Adjusting both knobs at the same time would cause the position of only two pedicle screw engagement members to be adjusted because guide tube 104 remains stationary. Ex. 1006 ¶ 66. Petitioner does not explain how adjusting the knobs, as disclosed in the '928 Appl., results in simultaneously applying manipulative force to a first set of pedicle screws and a first group of three or more screw engagement members, such that the first handle means moves

each pedicle screw engagement member simultaneously, as required by the claim. Petitioner also does not provide articulated reasoning why a person of ordinary skill would be motivated to combine the teachings of the '928 Appl., which achieve lateral movement of pedicle screw engagement members relative to a stationary pedicle screw engagement member using multiple cross member linkages, to the teachings of the Video, Slides, and MTOS, which describe an apical vertebral derotation (AVD) maneuver involving the application of downward pressure. *See* Ex. 1012, 241–245 (describing segmental compression and distraction of screws in straightening the curve, as distinguished from derotation in the AVD maneuver).

Independent claim 2 recites a first pedicle screw cluster derotation tool limitation similar to that recited in claim 1, instead using “wherein” language concerning the configuration of the tool to move the pedicle screw engagement members simultaneously and transmit manipulative forces applied to the handle means to the head segment of each pedicle screw. Thus, our analysis of claim 1 applies equally to claim 2. Claims 3 and 4 depend directly or indirectly from claim 1.

Therefore, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in demonstrating that claims 1–4 are unpatentable as obvious over the Video, the Slides, and/or MTOS (alone or in combination), the '928 Appl., the '349 Patent, and the '291 Appl. and we do not institute a trial on this challenge.

Claims 1–4 as Obvious Under 35 U.S.C. § 103 over the '928 Appl. in view of the Slides and/or the MTOS chapter and the '349 patent and alternatively the '219 Appl.

In this challenge, Petitioner cites the same references as those in previous challenges, but applies them differently. Pet. 43–59. For example, in this case, Petitioner cites the '928 Appl., rather than the Video, the Slides, and MTOS, as disclosing the pedicle screw limitations in Claims 1 [B] and [C]. As in the previous challenge, Petitioner cites the '928 Appl. as disclosing the features of the first pedicle screw cluster derotation tool recited in Claim 1[D] and Claim1[E], as Petitioner has defined the elements of claim 1 in this challenge. We addressed Petitioner's assertion in the previous challenge on the grounds that the claims are obvious over the Video, the Slides, and/or MTOS (alone or in combination), the '928 Appl., the '349 Patent, and the '291 Appl. As discussed above, we are not persuaded that the combination of the Video, the Slides, and the '928 Appl. discloses the first handle means. Petitioner has not persuaded us otherwise in this challenge and we decline to institute a trial on this ground.

SUMMARY

We do not authorize an *inter partes* review on any of the grounds asserted in the Petition.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is DENIED.

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