

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

MARK A. BARRY,
Patent Owner.

Case IPR2015-00782
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

On February 20, 2015, 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.

REAL PARTIES IN INTEREST

Petitioner identifies the following additional real parties in interest:
Medtronic plc.

PENDING LITIGATION

Petitioner is the defendant in litigation concerning the ’121 Patent, *Barry 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

The ’121 Patent was also the subject of IPR2014-01211, filed on July 27, 2014, in which we denied institution of *inter partes* review, *Medtronic, Inc. v. Mark A. Barry*, Case IPR2014-01211 (PTAB Feb. 10, 2015) (Decision Denying Institution, Paper 8) (“Medtronic v. Barry II”). Two additional, related patents are the subject of current petitions for *inter partes* review by Petitioner: Patent No. 7,670,358 B2 (“the ’358 Patent”) is the subject of IPR 2015-00780; Patent No. 7,776,072 (“the ’072 Patent”) is the subject of IPR2015-00783. The ’358 Patent

was also the subject of IPR2014-01210, in which we declined to institute *inter partes* review. *Medtronic, Inc. v. Mark A. Barry*, Case IPR2014-01210 (PTAB Feb. 10, 2015) (Paper 10, Decision Denying Institution) (“Medtronic v. Barry I”). The ’072 Patent was also the subject of IPR2014-01212, in which we denied institution of *inter partes* review. *Medtronic, Inc. v. Mark A. Barry*, Case IPR2014-01212, (PTAB Feb. 10, 2015) (Paper 9, Decision Denying Institution) (“Medtronic v. Barry III”).

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 mass to achieve an over-all 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 [sic]

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

The following references are relied upon in Petitioner's challenges:

Reference	Designation	Exhibit No.
U.S. Patent No. 5,219,349 issued June 15, 1993	the '349 Patent	Ex. 1005
U.S. Patent Appl. No. 2005/0245928 A1, published Nov. 3, 2005	the '928 Appl.	Ex. 1006
U.S. Patent 6,565,568 B1, issued May 20, 2003	the '568 Patent	Ex. 1028
Thoracic Pedicle Screws for Idiopathic Scoliosis Video	the Video	Ex. 1002; Parts 1-7

Reference	Designation	Exhibit No.
Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide handout	the Slides	Ex. 1008
Anthony S. Rinella, Yongjung J. Kim, and Lawrence G. Lenke, “Posterior Spinal Instrumentation Techniques for Spinal Deformity in Masters Techniques,” Chapter 17 in Orthopaedic Surgery: The Spine, 2nd Edition (undated; <i>see</i> Declaration of Dr. Lawrence Lenke, Ex. 1001 ¶43, asserting publication date of Nov. 13, 2003)	MTOS	Ex. 1012
U.S. Patent Appl. No. 2005/0033291 A1, published Feb. 10, 2005	the ’291 Appl.	Ex. 1007

Petitioner asserts the following challenges to claims 1–4 of the ’121 Patent.

Claims	Statutory Basis	References
1–4	35 U.S.C. § 103	The Video, the Slides, and/or MTOS (alone or in combination; collectively, “Lenke References”), in view of the ’349 Patent, the ’928 Appl., the ’568 Patent, and the ’291 Appl. ¹
1–4	35 U.S.C. § 103	’928 Appl. in view of the Slides, MTOS, the ’291 Appl., the ’349 Patent, and the ’568 Patent ²

¹ This is the challenge as expressed on page 3 of the Petition. Elsewhere, Petitioner presents the challenge as “Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the Video, the Slides, and/or MTOS (collectively, ‘Lenke References’) in view of the ’928 Appl., the ’568 Patent, the ’349 Patent and, in the alternative, the ’291 Appl.” Pet. 12–13.

² This is the challenge as expressed on page 3 of the Petition. Elsewhere Petitioner presents that challenge as “Claims 1-4 Are Obvious Under 35 U.S.C. § 103 over the ’928 Appl. in view of the ’568 Patent, the Video, the Slides and/or MTOS and the ’349 patent and alternatively the ’219 Appl.” Pet. 37.

In the text and accompanying claim charts, Petitioner presents the challenges somewhat differently from those listed on page 3 of the Petition. We address the challenges as presented in the text and the accompanying claim charts of the Petition.

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); *see also In re Cuozzo Speed Techs., LLC.*, 793 F.3d 1268, 1275 (Fed. Cir. 2015). We previously construed the terms of the claims of the ’121 Patent in IPR2014-01211. *Medtronic v. Barry II* 8–12. In this proceeding, we apply the same constructions, as follows:

Spinal rod engagement means: The spinal rod engagement means recited in claim 1 of the ’121 Patent performs the function of engaging with a spinal rod member. The spinal rod conduit is the structure that performs the claimed function.

Spinal rod fixation means: The claimed function is upon actuation, fixing the spinal rod member relative to the pedicle screw and the corresponding structure is a fixation element. 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.

Handle means: 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. 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.

Mechanically linked: joined by a physical connection.

A second group of vertebrae: multiple vertebrae located at least in part at a different location on the spine than the first group of vertebrae.

A second group of vertebrae lateral to the first group of vertebrae: portions of vertebrae, one side of a group of vertebrae lateral to another side, right or left.

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 ¶ 37.

Claims 1–4 as obvious over the Video, the Slides, and/or MTOS (alone or in combination; collectively “Lenke References”), the ’928 Appl., the ’568 Patent, the ’349 Patent, and, in the alternative, the ’291 Appl.

Petitioner notes that in IPR2014-01211, we determined that the Lenke References disclose the structures in claim elements 1[A], 1[B], 1[C], 1[F], and 1[E]. Pet. 13 (citing Medtronic v. Barry II 25). Element 1[D], as designated by Petitioner, recites “selecting a first pedicle screw cluster derotation tool . . . having a first handle means for facilitating simultaneous application of manipulative force to the first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with the first handle means.” *Id.* at 24. Petitioner also designates element 1[D] as reciting “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.” *Id.* at 24–25.

Arguing that the specification of the ’121 Patent does not attribute any criticality, inventiveness, or other significance to the simultaneous application of manipulative forces to three or more pedicle screw engagement members, Petitioner contends that the Lenke References show the surgeon moving the individual handles simultaneously and that individual handles disclosed in the Lenke References could be grasped by hand during the derotation procedure to be moved as a single unit en masse, i.e., simultaneously. Pet. 14, 16. However, claim 1 recites “first handle means having a handle linked to each pedicle screw engagement member of the first group of the three or more pedicle screw engagement members and a linking member to join together the handles.” The Lenke References do not show this claimed linking member. Petitioner argues that it would have been obvious to an ordinarily skilled artisan to connect the handles of the Lenke References via a mechanical link 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 and freeing up a hand to use for manipulating the rod into the screw head and subsequently securing the rod in place. *Id.* at 15–16 (citing Lenke Decl. ¶¶ 18, 85, 92–96).

We addressed a similar argument in IPR2015-00780, where we noted that, in view of Dr. Lenke’s testimony touting the ability of the surgeon to grasp each of the handles individually and apply appropriate forces simultaneously, Petitioner’s assertion that it would have been obvious to connect the individual handles shown in the Lenke References is not persuasive. *Medtronic, Inc. v. Mark A. Barry*, Case IPR2015-00780 slip op. at 24–25 (PTAB Sept. 9, 2015)(Paper 7, Dec. to Inst.) (“*Medtronic v. Barry IV*”).

In addition, Dr. Lenke testifies that, in his opinion, to the extent that the individual handles of the Video, the Slides, and the MTOS chapter are not considered “a handle means that is functionally linked by the surgeon’s hand,” it would have been obvious to modify the device shown in the Lenke References such that the individual handles were linked together in view of the teachings of the ’928 Appl., the ’568 Patent, and/or the ’349 Patent. Lenke Decl. ¶ 96. The Lenke Declaration states that handles and linking handles, as well as the concept of linking handles using a bar, linkage, or other mechanical structure that can be grasped, whether the bar is specially designed for that purpose or not, are well known in the field as mechanical tools for imparting pushing, pulling, or rotational forces. Ex. 1001 ¶ 92. In *Medtronic v. Barry IV*, we noted that the ’349 patent describes a multiplicity of movements can alter the spine, but we were not persuaded by Petitioner’s arguments that the ’349 Patent discloses the claimed feature of applying force to the handle means in a single motion simultaneously rotating the vertebrae. *Medtronic v. Barry IV* 12–13. In this proceeding, Petitioner does not propose the same structure as disclosing the first handle means. Instead, as discussed further below, in this proceeding, in its analysis of a cross linking member between first and second handle means, Petitioner proposes that the ’349 Patent discloses that pedicle screw engagement means (shaft handles 14) are mechanically linked to first handle means in the form of hinged extensions 136 of T-handle 100. Pet. 30 (citing Ex. 1005, col. 4, ll. 35–55). Petitioner’s claim charts do not cite the ’349 Patent as disclosing claim element 1[D].

Petitioner contends that the ’928 Appl. discloses a pedicle screw cluster tool that includes a handle means in the form of multiple handles linked together, e.g., links 106b, such that the handles and the attached pedicle screw engagement members move in unison to response to a downward or upward force applied to

one or both handles. *Id.* at 15 (citing arguments in Petitioner’s second challenge and Lenke Decl. ¶¶ 55–57, 92–96). In that context, Petitioner cites paragraph 55 of the ’928 Appl. concerning the application of perpendicular forces that Petitioner contends produce rotation of the vertebrae. *Id.* at 38–39. Petitioner argues that to the extent that “handle means” is construed to require a part that is designed to be grasped by the hand, knobs 112a and 112b satisfy that requirement. *Id.* at 39. We addressed a similar argument at pages 17–18 in *Medtronic v. Barry IV*. There we noted that, although the ’928 Appl. provides no disclosure concerning the application of perpendicular forces to rotate the spine, on the current record there is no evidence that disputes Dr. Lenke’s testimony that grasping the knobs or a knob and the physical linkage in the device disclosed in the 928 Appl. would achieve such rotation and that the ’928 Appl. therefore discloses the claimed handle means. We also note that the device in the 928 Appl. is shown as engaging three pedicle screws. Ex. 1006, Fig. 11. Thus, we are persuaded by Petitioner’s reliance on the ’928 Appl. to support disclosure of the claimed first handle means with the requisite linking member is sufficient for purposes of this Decision to Institute.³

Petitioner also argues that to the extent the ’928 Appl. is found not to disclose explicitly a handle means designed to be grasped by hand, it would have been obvious to modify the device of the ’928 Appl. to include the handle means of the ’568 Patent. *Id.* at 15 (citing Lenke Decl. ¶¶ 71, 92–96). We addressed a similar argument advanced by Petitioner at pages 18–20 of *Medtronic v. Barry IV*, where we determined that Petitioner had not demonstrated how the handle in the

³ As Petitioner’s claim charts demonstrate, this challenge is based on the Lenke References disclosing the handle means, while Petitioner’s other challenge in this Petition is based on the ’928 Appl. disclosing the handle means. Pet. 22–25, 48–50.

'568 Patent would be employed in combination with the device described in the '928 Appl. *Medtronic v. Barry IV* 18–20.

The Video, the Slides, MTOS, and the '928 Appl. each shows implanting pedicle screws, as recited in step 1[F]. Turning to steps 1[G] and 1[H], in *Medtronic v. Barry I*, we noted that the Video shows the surgeon inserting a spinal rod into a conduit of one or more pedicle screws and, after applying manipulative force, and actuating the spinal rod engagement means by locking the set bolts in position and tightening set screws. *Medtronic v. Barry I* 25. Petitioner contends that the subsequent step of rotating a rod substantially along its length to effect a correction of a spinal column deviation in reference to two axes, as recited in step 1[I], was well known to those of ordinary skill at the time of the invention. *Pet.* 17. Petitioner also contends that MTOS discloses that the claimed rod rotation maneuver may be used to treat scoliosis. *Pet.* 27 (citing *Ex. 1012* at 242). Figure 17-8 of MTOS illustrates performing coronal and sagittal contouring of the rod and compression and distraction of screws in the coronal plane performed after a pre-contoured rod is secured with loose set screws. *Ex. 1012*, 242.

Alternatively, Petitioner argues that it would have been obvious to perform such rod rotation in view of the '291 Appl., which discloses a system using screws and a contoured rod. *Id.* at 18. Petitioner explains that

[t]he '291 Appl. discloses that the rod, while in its first rotational orientation, is inserted into a notch of the head of the screw, and is then loosely tightened into place by a set screw. Once it is in this position, the rod is rotated around its length by a ratchet tool to a second rotational orientation to correct a spinal column deviation. The '291 Appl. further provides that shafts that engage with screws may be used after this rod rotation to impart more force on the screws, thereby placing the vertebrae in a final corrected position.

Pet. 18; *see id.* at 27 (citing Ex. 1007 ¶¶ 157–158). In view of these disclosures, we are persuaded that, for purposes of this Decision, Petitioner has demonstrated sufficiently that the MTOS and '121 references disclose the claimed step of rotating the spinal rod substantially along its length to a second rotational orientation to effect a correction of the spinal column deviation in two axes. Claim element 1[J] requires engaging the pedicle screw engagement members with a head segment of a pedicle screw. Petitioner has demonstrated that this feature is disclosed by the Video, the Slides, and MTOS. Pet. 19, 27–28.

Steps 1[K]–1[Q] recite substantially the same steps recited in steps 1[B]–1[J] on a second set of pedicle screws using a second derotation tool. The analysis we applied to steps 1[B]–1[I] applies to corresponding claim elements 1[K]–1[R].

Claim element 1[S] recites connecting with a cross linking member the first handle means to the second handle means laterally positioned to the first handle means. Petitioner contends that this feature is disclosed by the '349 Patent. Pet. 19–20, 30–31. As noted above, Petitioner's claim chart does not cite the '349 Patent as disclosing the first handle means, nor were we persuaded that the structure from the '349 Patent cited by Petitioner in *Medtronic v. Barry IV* discloses the claimed handle means. The structure Petitioner cites in the '349 Patent in this proceeding is a single T-handle in which the outer extremity of each laterally extending arm 112 is a shaft clamp 122 that provides a positive linkage between T-handle 100 and shaft handles 14 attached to pedicle screws 12. Ex. 1005, col. 4, ll. 35–39. Shaft clamps 122 are disposed at the end of hinged extensions 136 of laterally extending arms 112 to allow further flexibility in positioning T-handles 100 and to provide greater access to the surgical area after installation of the reduction frame on the spine. *Id.* at col. 4, ll. 47–55.

According to Petitioner, in the '349 Patent,

[e]ach pedicle screw is coupled to a respective first and second pedicle screw engagement means (shaft handle 14) that are mechanically linked to a respective first and second handle means (hinged extensions 136 of T-handle 100). These first and second handle means are connected by a cross-linking member (laterally extending arms 112) to satisfy the design incentive of “ensur[ing] that force applied is evenly distributed to the two pedicles, thereby decreasing the likelihood of damage to any one pedicle.”

Pet. 20 (quoting Ex. 1005, col. 5, ll. 4–8).

Petitioner argues that it would have been obvious to one of ordinary skill to modify the Lenke References to include a cross linking member in view of the express teaching in the '349 Patent to allow manipulation of the spine with even distribution of force between opposite pedicles, in order to prevent the application of excessive load to either pedicle. Pet. 20–21 (citing Ex. 1005, col. 3, ll. 36–40; Lenke Decl. ¶¶ 68, 105, 106). However, as we indicated above, in view of Dr. Lenke's other testimony touting the ability of a surgeon to grasp each of the handles simultaneously and apply force appropriately, we are not persuaded by Petitioner's argument concerning the combination of the '349 Patent with the Lenke References.

Petitioner does not address the combination of the '349 Patent with the '928 Appl. other than to say the combination would have been obvious because both references are from the same field of endeavor. Lenke Decl. ¶ 106. In the absence of articulated reasoning to support such a conclusion, we are not persuaded by Petitioner's argument. In consideration of the above, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to claim 1 of the '121 Patent.

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 2. Thus, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in its challenge to claims 1–4 as obvious over the Video, the Slides, and/or MTOS (alone or in combination) (collectively, “the Lenke References”), the ’928 Appl., the ’568 Patent, the ’349 Patent, and, in the alternative the ’291 Appl.

Claims 1–4 as Obvious Over the ’928 Appl. in view of the Slides, MTOS, the ’291 Appl., the ’349 Patent, and the ’568 Patent.

As previously discussed, Petitioner’s claim charts demonstrate that, in this challenge, Petitioner asserts that the ’928 Appl. discloses the handle means, as opposed to the previous challenge, in which Petitioner contends that the Lenke References disclose the handle means. Pet. 22–25, 48–50. We addressed that aspect of this challenge above. Petitioner incorporates by reference its arguments from the previous challenge concerning the purported disclosure of the claimed linking member in the ’349 Patent. We apply the same analysis to this challenge and exercise our discretion to decline to institute *inter partes* review based on this duplicative challenge.

SUMMARY

Petitioner has not demonstrated a reasonable likelihood of prevailing in any of the challenges presented in the Petition. Therefore, we decline to institute *inter partes* review of any of the challenged claims.

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ORDER

In consideration of the foregoing, we do not institute *inter partes* review of any of the claims of the '121 Patent.

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