

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.,  
Petitioner,

v.

MARK A. BARRY,  
Patent Owner

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Case IPR2015-00783  
Patent 7,776,072 B2

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

McNAMARA, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
*Conduct of the Proceeding*  
*35 U.S.C. § 318(a) and*  
*37 C.F.R. § 42.73*

## BACKGROUND

Petitioner filed a Petition requesting an *inter partes* review of claims 1–4 of U.S. Patent No. 7,776,072 B2 (“the ’072 Patent). Paper 2 (“Pet.”) On September 9, 2015, we instituted an *inter partes* review of claims 1–4 the ’072 Patent. Paper 7 (“Dec. to Inst.”). Patent Owner filed a Patent Owner Response (Paper 23, “PO Resp.”), Petitioner filed a Petitioner Reply (Paper 38, “Pet. Reply”), and a transcript of an oral hearing held on May 17, 2016 (Paper 49, “Hr’g Tr.”)<sup>1</sup> has been entered into the record.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). We base our decision on the preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

Having reviewed the arguments of the parties and the supporting evidence, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims are unpatentable.

## PROPRIETY OF THE PETITION

As an initial matter, Patent Owner contends that we should dismiss the Petition for improperly incorporating detailed explanations into the claim charts. PO Resp. 3–6. Patent Owner cites as an example Petitioner’s claim chart entry for claim element 1[C]. *Id.* at 4. Patent Owner notes that Petitioner includes in the chart a diagram annotated to point out the elements of the reference corresponding to the claim limitations. *Id.* According to Patent Owner, the claim terms “head segment” and “threaded shank segment” do not appear in the references. *Id.* However, the figure in the

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<sup>1</sup> The oral hearing in this proceeding was consolidated with the oral hearing in related case IPR2015-00780, which involves the same parties and concerns U.S. Patent No. 7,670,358 B2 (“the ’358 Patent”).

chart is an annotated version of Figure 11 of the reference with the parts Petitioner contends correspond to the parts recited in the claim labelled and circled. Patent Owner also notes Petitioner's entry in the claim chart for claim element 3[L]. *Id.* at 5. In this chart entry, Petitioner repeats the claim limitation and quotes paragraph 55 of the '928 Appl. (Ex. 1006).

Notwithstanding Patent Owner's position that the reference does not disclose the limitation (*id.* at 5), the claim chart entry is not argumentative. Thus, we are not persuaded that, in the unique circumstances of this case, Petitioner's approach constitutes argument sufficient to warrant dismissal of the Petition.

#### THE '072 PATENT

The '072 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. 1021, col. 3, ll. 24–30. 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 overall correction. *Id.* at col. 3, ll. 39–47. The pedicle screws have a threaded shank segment and a head segment. *Id.* at col. 4, ll. 64–65. The head segment has a spinal rod conduit (or channel) that interfaces with a pre-contoured spinal rod. *Id.* at col. 4, l. 66–col. 5, l. 3. 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. 1–3; col. 5, l. 63–col. 6, l. 6.

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. 24–27. 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, ll. 60–col. 4, l. 4. 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. 7–9. 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. 10–12. 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. 13–17.

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. 52–58. 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. 59–col. 6, l. 6.

#### ILLUSTRATIVE CLAIM

1. A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising:
  - a first set of pedicle screw[s], each pedicle screw having a threaded shank segment and a head segment; and
  - 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 configured to move simultaneously each pedicle screw engagement member; wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said first set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws.

## GROUNDINGS OF INSTITUTION

In our Decision to Institute, we instituted trial on the following challenges to patentability:

Claims 1 and 2 as obvious over the combination of the Video,<sup>2</sup> the Slides,<sup>3</sup> MTOS,<sup>4</sup> and the '928 Appl.;<sup>5</sup>

Claims 3 and 4 as obvious over the combination of the Video, the Slides, MTOS, the '928 Appl., and the '291 Appl.;<sup>6</sup> and

Claims 1 and 2 as obvious over Suk.<sup>7</sup>

Dec. to Inst. 25. Collectively, the Video, the Slides, and MTOS are referred to as “the Lenke references.”

## CLAIM CONSTRUCTION

In our Decision to Institute, we adopted the following claim constructions:

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<sup>2</sup> Thoracic Pedicle Screws for Idiopathic Scoliosis Video (“the Video”) (Ex. 1002, Parts 1–7).

<sup>3</sup> Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide handout (“the Slides”) (Ex. 1003).

<sup>4</sup> 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; *see* Declaration of Dr. Lawrence Lenke, Ex. 1001 ¶ 43, asserting publication date of Nov. 13, 2003) (“MTOS”) (Ex. 1012).

<sup>5</sup> U.S. Patent Appl. No. 2005/0245928 A1, published Nov. 3, 2005 (“the '928 Appl.”) (Ex. 1006).

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

<sup>7</sup> Sang-Min Lee, Se-Il Suk, and Ewy-Ryong Chung, *Direct Vertebral Rotation: A New Technique of Three-Dimensional Deformity Correction with Segmental Pedicle Screw Fixation in Adolescent Idiopathic Scoliosis*, vol. 29:3 SPINE 343–349 (2004) (“Suk”) (Ex. 1031).

Spinal rod engagement means: This term does not appear in claim 1. The function recited in claim 2 is securing the pedicle screw and the spinal rod member extending through the spinal rod conduit in a substantially fixed relative position and orientation. The corresponding structure is *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.* Dec. to Inst. 8–9.

Claim 3 recites a different function for the recited spinal rod engagement means, i.e., “mechanically engaging with a spinal rod member,” and separately, a “spinal rod fixation means for, upon actuation, fixing the relative orientation of each pairing of said spinal rod member and said pedicle screw.” As discussed in the Decision to Institute, consistent with our analysis in *Medtronic, Inc. v. Mark A. Barry*, Case IPR2014-01212 (PTAB Feb. 10, 2015) (Decision Denying Institution, Paper 9) (“*Medtronic v. Barry III*”), for purposes of this proceeding, we observe that the spinal rod engagement means recited in claim 3 of the ’072 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. Dec. to Inst. 8–9,

Spinal rod fixation means: As we observed in *Medtronic v. Barry III*, 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. Dec. to Inst. 9–10.

Handle means: As we observed at pages 8–9 in *Medtronic v. Barry III*, in the case of the first handle means recited in claims 1–3, the function is

facilitating simultaneous application of 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, recited in claim 4, performs a similar function on a second set of pedicle screws and screw engagement members, but is not limited to three or more screw engagement 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. Dec. to Inst. 10.

Mechanically linked: We construe this term to mean joined by a physical connection. Dec. to Inst. 10.

A second group of vertebrae: Consistent with *Medtronic v. Barry III*, we construe this term to mean multiple vertebrae located at least in part at a different location on the spine than the first group of vertebrae. Dec. to Inst. 10.

Patent Owner states that it largely agrees with our constructions, although Patent Owner contends that the plain and ordinary meaning, which Patent Owner does not define, is sufficient for the term “mechanically linked.” PO Resp. 22–24.

Petitioner responds that the challenged claims are directed to a method for the “amelioration of aberrant spinal column deviation conditions” and are not limited to an “open” procedure for treating scoliosis, as argued by Patent Owner. Pet. Reply 6 (citing PO Resp. 26–27, 56). Petitioner contends that Patent Owner attempts to evade the prior art by unduly restricting the claims to exclude minimally invasive surgery. *Id.*

The claims are not limited explicitly to either open or minimally invasive procedures, nor does Patent Owner present this argument as a claim



construction issue. In this Decision, we address this issue in the context of what would have been known to one of ordinary skill in the art and obviousness of the claims at issue.

#### PRIOR ART STATUS OF THE VIDEO AND THE SLIDES

Patent Owner contends that the Video and the Slides are not applicable prior art for purposes of this proceeding. PO Resp. 6. According to Patent Owner, the Video is neither printed nor a publication. Patent Owner further contends that the Slides are not a publication. *Id.* at 6–14.

##### *Is the Video “Printed?”*

35 U.S.C. § 311(b) limits the basis for *inter partes* review to patents and printed publications. Patent Owner contends that the Video fails to satisfy this requirement because it is not a printed document. PO Resp. 6–7 (citing *Diomed, Inc. v. AngioDynamics, Inc.*, 450 F. Supp. 2d 130, 141–42 (D. Mass. 2006)). Petitioner responds that *Diomed* is distinguished, because in *Diomed* the subject matter was shown only to conference attendees without any indication it was fixed in a tangible medium or distributed to the attendees. Pet. Reply 2 (citing *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed. Cir. 2004) for the proposition that an entirely oral presentation at a scientific conference is not a printed publication). Petitioner argues that, in this case, the Video is printed because it is fixed in a tangible medium of expression, i.e., a CD. *Id.* Petitioner cites *In re Wyer*, 655 F.2d 221, 227 (CCPA 1981) for the principle that “art can be ‘printed, handwritten or on a magnetic disc or tape, etc.’” *Id.*

Patent Owner acknowledges that a video on a CD may be available as prior art for purposes of district court litigation, but contends that, in the absence of a “printed component to the video,” a video is not a patent or

printed publication that will support *inter partes* review. Hr’g Tr. 59:1–19. Under *Wyer*, a microfiche or copy of a printed document stored in a tangible medium, such as a database, would have the “printed component” urged by Patent Owner and would comply with the “printed” requirement of the statute. *Wyer*, 655 F.2d at 227. A narrated demonstration recorded on CD, as in the Video, satisfies the “printed” requirement of the statute because the CD includes indicia stored on it that defines the content to be displayed, i.e., the “printed component” urged by Patent Owner is found in the indicia stored on the CD or other electronic medium. Thus, the Video is not excluded from the scope of 35 U.S.C. § 311(b) on the sole basis that the Video is not “printed.”

*Are the Video and the Slides Publications?*

Petitioner states that the Video and the Slides were distributed together to interested surgeons with no restriction on redistribution in 2003 at least at the following programs: Advanced Concepts in Spinal Deformity program in Colorado Springs, CO, on May 18–19, 2003 (citing Ex. 1023, Declaration of David Poley (“Poley Decl.”) ¶¶ 2, 3); and Spinal Deformity Study Group Symposium 2003: Emerging Trends & Advanced Surgical Techniques in St. Louis, MO, on November 13–15, 2003 (citing Ex. 1024, Declaration of Ashley Owens (“Owens Decl.”) ¶¶ 3, 4). Pet 12–13. Although there is some dispute concerning the contents of slides distributed to attendees at other programs, the parties agree that the Slides in Exhibit 1003 were distributed in a loose-leaf binder at the Colorado Springs program. PO Resp. 9–10; Pet. Reply 3.<sup>8</sup> About 20 surgeons who attended

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<sup>8</sup> Noting that Ms. Owens testified that the exact materials she reviewed and offered as evidence by Petitioner were not distributed to any surgeons,

the Colorado Springs program received the Slides in Exhibit 1003. PO Resp. 10 (citing Ex. 2012 (“Owens Tr.”), 23:14–24:21).

Patent Owner contends that the Video and the Slides are not publicly accessible publications for prior art purposes because Petitioner failed to demonstrate that the Video and Slides were disseminated or made available to persons of ordinary skill in a manner that such persons could locate the Video and the Slides through the exercise of reasonable diligence. PO Resp. 8–9 (citing *In re Bayer*, 568 F.2d 1357, 1359 (CCPA 1978) and *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1333 (Fed. Cir. 2009)). Patent Owner further contends that the Slides and the Video were made available not to persons of ordinary skill, but only to selected surgeons who qualified through a nine month application and approval process and were considered leaders within their field based on demonstrated excellence in their research and publications. *Id.* at 11 (citing Ex. 2010, Transcript of Deposition of David Poley (“Poley Tr.”), 24:26–24:6, 30:7–13).

Petitioner argues the distribution of the Video and the Slides without restrictions satisfies the requirements of a publication. Pet. Reply 4. *See Massachusetts Institute of Technology v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985) (finding that unrestricted distribution of six copies of paper orally presented to “between 50 and 500 persons interested and of ordinary skill in the subject matter [who] were actually told of the existence of the paper and informed of its contents” sufficient to show paper was printed

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Patent Owner argues “there is no credible evidence that the binder produced by Petitioner is identical to what was allegedly distributed to the small group of surgeons actually at the conference.” PO Resp. 12. Notwithstanding this apparent challenge to the authenticity of Ex. 1003, Patent Owner has not moved to exclude it.

publication). Petitioner argues that Patent Owner's citation of *Bayer* is misplaced because that case concerned a single thesis kept at a university library and accessible only to faculty members. Pet. Reply 4 (citing *Bayer*, 568 F.2d at 1361).

A reference is publicly accessible “upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.” *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (quoting *SRI Int'l Inc. v. Internet Sec. Sys. Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008)).

Petitioner's expert, Dr. Lenke, testifies to being “keenly aware of how one of ordinary skill would understand and interpret the art because I routinely teach, provide presentations to, and otherwise interact with surgeons of ordinary skill in this field.” Ex. 1001, Declaration of Dr. Lawrence Lenke (“Lenke Decl.”) ¶ 38. According to Dr. Lenke, in the context of this proceeding, a person of ordinary skill would have had 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. Lenke Decl. ¶ 37. Dr. Lenke further testifies that “a person of ordinary skill in the relevant art need not necessarily have formal education if they have an equivalent amount of experience in medical device design. So, for example,

approximately four years of medical device design experience could replace an undergraduate degree in that field.” *Id.*

Mr. Poley testifies that the members of the Spinal Deformity Study Group were “experts within the field of spinal deformity,” including early onset scoliosis and spondylolisthesis. Poley Tr. 24:16–23. There were guidelines governing membership and membership was determined by the vote of an executive board, based on curriculum vitae submitted by persons who wanted to be considered. *Id.* at 26:7–16. Those selected for membership were required to obtain approval from hospitals to perform research and collect data, participate in conference calls, and share manuscripts. *Id.* at 27:18–28:11. Those members who met their obligations were invited to attend meetings (and receive the materials distributed at the meetings). *Id.* at 28:13–14.

Thus, Petitioner contends that the distribution of the Video and the Slides to admittedly “experts within the field of spinal deformity” selected to participate in a study group to exchange information and share experiences with other members of the group, constitutes making the Video and Slides publicly accessible, because there was no restriction on the ability of the group’s members to share the Video and Slides with others. Petitioner’s position is not supported by precedent. First, the members of the Spinal Deformity Study Group, who received the Video and the Slides, were experts voted into membership by an executive board based on their qualifications and ability to conduct research. Petitioner has not provided sufficient evidence of any other distribution of the Video and Slides. In addition, Petitioner has not shown adequately how the Video and the Slides would have been made available outside the Spinal Deformity Study Group

to persons of ordinary skill, as defined by Dr. Lenke, or how persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, could locate the Video and the Slides. *See Kyocera Wireless*, 545 F.3d at 1350. Thus, we agree with Patent Owner that Petitioner has not provided sufficient evidence to support its contention that the Video and Slides were publicly accessible for purposes of prior art.

*Antedating of '928 Appl.*

The '928 Appl. was filed on May 3, 2004, and published on November 3, 2005. The application that led to issuance of the '072 Patent is a continuation-in-part of Application. No. 11/027,026 (“parent application”) filed on December 30, 2004. Ex. 1021. Patent Owner contends that challenged claims 1–4 are entitled to priority based on the parent application. PO Resp. 27. Patent Owner cites the Declaration of Patent Owner/inventor Dr. Mark A. Barry (Ex. 2019 (“Barry Decl.”)) as evidence that he conceived of, worked diligently to reduce to practice, and had actually reduced to practice the inventions claimed in the '072 Patent before February 1, 2004. PO Resp. 27–28. Patent Owner cites Exhibits 2021, 2031, and the testimony of Robert Pfefferkorn (Ex. 2027 (“Pfefferkorn Decl.”)) as corroborating evidence. PO Resp. 28. Thus, Patent Owner contends that the '928 Appl. cannot be applied as prior art to the '072 Patent. *Id.*

Petitioner argues that Patent Owner’s attempt to incorporate the entirety of the Barry and Pfefferkorn Declarations into the Patent Owner Response is an improper evasion of its page limitations. Pet. Reply 8. Exhibit 2021 is an abstract of a presentation Dr. Barry proposed to deliver at the 11th International Meeting on Advanced Spinal Techniques (IMAST) in

July 2004 (“the IMAST Abstract”). In his declaration, Dr. Barry contends that the IMAST Abstract demonstrates his conception of the invention claimed in the ’072 Patent as of February 1, 2004. Barry Decl. ¶ 5. The Barry Decl. includes a claim chart purporting to show the correspondence between the claims of the ’358 Patent and the contents of the IMAST Abstract.<sup>9</sup> The Barry Decl. makes similar arguments concerning the correspondence of the claims of the ’072 Patent without using claim charts. Barry Decl. ¶ 10. To the extent that the contents of the Barry Decl. attempt to demonstrate such contentions, we agree with Petitioner that such argument should have been included in the Patent Owner Response and that its omission from the Patent Owner Response and placement in the Barry Decl. is deficient procedurally.

We also agree with Petitioner that Patent Owner has not antedated the ’928 Application. An inventor “may date his patentable invention back to the time of its conception, if he connects the conception with its reduction to practice by reasonable diligence on his part, so that they are substantially one continuous act.” *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (citation omitted). Constructive reduction to practice occurs when a patent application on the claimed invention is filed. *Weil v. Fritz*, 572 F.2d 856, 865 n.16 (CCPA 1978).

Petitioner argues that both the Barry and Pfefferkorn Declarations do not support Patent Owner’s position. Pet. Reply 8–11. Petitioner contends that Patent Owner cites the IMAST Abstract to support conception, as distinguished from reduction to practice, and that Mr. Pfefferkorn’s

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<sup>9</sup> The ’358 Patent is the subject of *Medtronic Inc. v. Mark A. Barry*, Case IPR2015-00780. The Barry Decl. was submitted in that proceeding as well.

testimony fails to corroborate Dr. Barry's assertions because Mr. Pfefferkorn acknowledges that he had not seen a completed prototype of the finished method when he stopped working with Dr. Barry in June 2004. *Id.* at 8 (citing Pfefferkorn Decl. ¶ 12).

In corresponding district court litigation, Dr. Barry defended against allegations of inequitable conduct for failing to disclose 21 surgeries alleged to be prior art, by arguing that "the record is devoid of evidence showing that any of these surgeries practiced every limitation of any claim of the asserted patents." Ex. 1045, 2. In addition, referring to the IMAST Abstract, Patent Owner argued "Nowhere does Dr. Barry's PTO declaration state that any one or all of the experimental surgeries discussed in the abstract practiced all of the '358 claim limitations<sup>10</sup>; . . . *the abstract itself* discloses his conception of those limitations." Ex. 1046, 3. Thus, in the district court, Dr. Barry acknowledged that the abstract establishes conception only.

In order to establish an actual reduction to practice, the inventor must establish that: (1) the inventor constructed an embodiment or performed a process that met all of the claim limitations; and (2) the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). The inventor's testimony must be corroborated by independent evidence. *Id.* at 1330. It is well settled that "[t]here cannot be a reduction to practice of the invention . . . without a physical embodiment which includes all limitations of the claim." *UMC Elecs. Co. v. United*

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<sup>10</sup> In the context of antedating the '928 Appl., Patent Owner's statements concerning reduction to practice of the invention claimed in the '358 Patent, which issued from the parent application, apply to the '072 Patent as well.



*States*, 816 F.2d 647, 652 (Fed. Cir. 1987). “It is equally well established that every limitation of the [claim] must exist in the embodiment and be shown to have performed as intended.” *Newkirk v. Lulejian*, 825 F.2d 1581, 1582 (Fed. Cir. 1987). Patent Owner’s arguments in the district court contradict any assertion in this proceeding that Patent Owner had achieved an actual reduction to practice prior to the filing date of the application that led to issuance of the ’072 Patent.

Patent Owner also asserts, without arguing, that Dr. Barry was reasonably diligent in reducing the invention to practice. PO Resp. 28. “The reasonable diligence standard balances the interest in rewarding and encouraging invention with the public’s interest in the earliest possible disclosure of innovation.” *Griffith v. Kanamuru*, 816 F.2d 624, 626 (Fed. Cir. 1987). During the period in which reasonable diligence must be shown, there must be continuous exercise of reasonable diligence. *In re McIntosh*, 230 F.2d 615, 619 (CCPA 1956); *see also Burns v. Curtis*, 172 F.2d 588, 591 (CCPA 1949) (referring to “reasonably continuous activity”). A party alleging diligence must account for the entire critical period. *Griffith*, 816 F.2d at 626. Even a short period of unexplained inactivity is sufficient to defeat a claim of diligence. *Morway v. Bondi*, 203 F.2d 742, 749 (CCPA 1953). The work done directed to the generic invention cannot be relied upon as evidence of diligence for the specific claimed invention. *In re Nelson*, 420 F.2d 1079, 1081 (CCPA 1970) (“[W]e must consider the evidence only as it relates to the specific invention claimed.”). A party alleging diligence must provide corroboration with evidence that is specific both as to facts and dates. *Gould v. Schawlow*, 363 F.2d 908, 920 (CCPA 1966); *Kendall v. Searles*, 173 F.2d 986, 993 (CCPA 1949). The rule of

reason does not dispense with the need for corroboration of diligence that is specific as to dates and facts. *Gould*, 363 F.2d at 920; *Kendall*, 173 F.2d at 993; *Coleman v. Dines*, 754 F.2d 353, 360 (Fed. Cir. 1985). The Patent Owner Response contains no argument specifically directed to establishing these elements of diligence to reduce the invention to practice.

Even if we consider the Barry and Pfefferkorn Declarations, these documents do not provide sufficient dates and facts to establish the requisite diligence. For example, although the Barry Decl. mentions general time frames during which he contends he was pursuing his invention, Dr. Barry does not provide specific documentary evidence to support his development of the claimed features. Mr. Pfefferkorn states that he arranged for a local machine shop to modify certain components of instruments delivered to Dr. Barry and that Dr. Barry had 3 slots in the handles of derotation tools. Pfefferkorn Decl. ¶ 7. However, Mr. Pfefferkorn acknowledges that he “was not given details of the overall system or associated methods of use” and that he “did not have any detailed information beyond my knowledge of the pre-existing, unmodified instruments, the specific modifications Dr. Barry facilitated, and the general goals of his work.” *Id.* ¶ 6.

In view of the above, we are not persuaded that Patent Owner has antedated the '928 Application as a prior art reference.

## ANALYSIS OF PRIOR ART CHALLENGES

### *Introduction*

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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.” We resolve the question of obviousness 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. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

*Claim 1 and 2; Obviousness over the Combination of the Video, the Slides and MTOS (the Lenke References) and the '928 Appl.*

The parties do not dispute that the '928 Appl. discloses the elements of claim 1 identified in the Petition as 1[A], 1[B], and 1[C]. The primary focus of the parties' contentions in this proceeding concerns whether the combination of the disclosures in the Lenke References and the '928 Appl. discloses the following limitation of claim 1 of the '072 Patent (designated in the Petition as claim limitation 1[D]):

a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means configured to move simultaneously each pedicle screw engagement member.

In related case *Medtronic, Inc. v. Mark A. Barry*, Case IPR2015-00780 (“*Medtronic v. Barry IV*”) claim 1 recites “applying manipulative force to said first handle means in a manner for simultaneously engaging” a group of pedicle screws members and pedicle screws and “thereby in a single motion simultaneously rotating said vertebrae.” In this case, although claim 1 recites a derotation tool, independent apparatus claim 1 and method claim 3 do not include the limitation “in a single motion simultaneously

rotating vertebrae.” As discussed below, many of the parties’ arguments are similar to those advanced in *Medtronic v. Barry IV* because the remaining Lenke Reference, i.e., MTOS, concerns rotating the vertebrae using individual pedicle screw engagement members, and the ’928 Appl. concerns a tool for compression and distraction of the spine in which pedicle screw engagement members are linked. In this case, a fundamental issue is the disputed contention that it would have been obvious to a person of ordinary skill to combine the features of these tools to arrive at a tool with a handle means that facilitates simultaneous application of forces to pedicle screws mechanically linked through engagement members to the handle means.

As previously discussed, Petitioner has not established that the Video or the Slides are applicable prior art. However, of the Lenke References, MTOS remains applicable prior art. Petitioner contends that Figure 17-13 of MTOS discloses a “first pedicle screw cluster derotation tool” that includes “a group of handles for facilitating simultaneous application of manipulative forces to the first pedicle screws and a first group of . . . four (MTOS) pedicle screw engagement members that are mechanically linked to the handles.” Pet. 21. Figure 17-13 of MTOS appears to be reproduced as the second image in the claim chart on page 21 of the Petition, but does not illustrate a handle—only pedicle screw engagement members are shown. *Id.* The word “Handles” is also shown in the claim chart on page 21 of the Petition and appears with a line to another figure, absent an arrow. *Id.* A third figure at the bottom of this section of the claim chart appears to be taken from the Video,<sup>11</sup> and appears to identify a portion of each pedicle

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<sup>11</sup> We do not consider the Video prior art, but cite this image to identify Petitioner’s designations in MTOS.

screw engagement member that is remote from the pedicle screw as a handle. *Id.*

MTOS states that the majority of the chapter concentrates on the advantages and techniques of using pedicle screws in the thoracic and lumbar spine, with an emphasis on surgical planning and decision making. Ex. 1012, 231.<sup>12</sup> The description of the AVD maneuver in MTOS states that previous maneuvers derotate the correcting rod 90 degrees and translate the spine without much derotation. *Id.* at 242. According to Dr. Lenke, “because such a rod rotation [in the Cotrel-Dubousset technique] only translated the spine, it was beneficial to also use the disclosed apical vertebral derotation maneuver disclosed therein to fully correct the scoliotic deformity.” Lenke Decl. ¶ 52.

In the MTOS AVD maneuver, correcting posts are placed on each of four screws on the concave and convex sides of the apex of the curve. Ex. 1012, 242. In the first maneuver, most of the derotation and downward pressure is accomplished by the convex side screws, as shown in Figure 17-11. *Id.* at 242–45. The degree of correction depends upon the flexibility of the curve on preoperative assessments and on the grip of the apical screws in the vertebrae. *Id.* at 245. The surgeon then places a previously contoured rod, inserts set screws, and tightens all but the screws on the derotation vertebrae and one additional level proximally and distally. *Id.* After putting the rod in place, the surgeon performs the AVD maneuver on the concave

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<sup>12</sup> MTOS is Ex. 1012 in both *Medtronic v. Barry IV* and this proceeding. For consistency among the proceedings and the Petition, we cite the page numbers of the published MTOS chapter, rather than the page numbers of Ex. 1012.

side and tightens the set screws. *Id.* At the lower left, Figure 17-11 shows at least four pedicle screw engagement members, but does not show a first handle that is manipulated in a manner to simultaneously engage the first group of pedicle screws and thereby in a single motion rotate the vertebrae.

Patent Owner contends that MTOS does not describe manipulating multiple posts simultaneously, nor does it show mechanically linked posts. PO Resp. 47 (citing Ex. 2013, Declaration of Dr. Walid Yassir (“Yassir Decl.”) ¶ 106). Dr. Lenke states that “[a]s shown in this MTOS chapter, the individual handles of each apical derotator are grasped simultaneously by the surgeon during the derotation procedure.” Lenke Decl. ¶ 50. However, in his declaration, Dr. Lenke does not point a specific passage or figure in MTOS that shows the surgeon grasping each of the handles simultaneously. *Id.* Dr. Lenke asserts that the MTOS chapter “explicitly discloses the simultaneous application of manipulative force to the handles of the first and second groups of apical derotators located on opposite sides of the spinal column.” *Id.* ¶ 51. Again, Dr. Lenke’s declaration does not cite to a figure or text in MTOS to support this assertion. *Id.*

Although MTOS discloses the use of pedicle screws and individual engagement members that allow a surgeon to manipulate one or more of the vertebrae in which the pedicle screws are implanted, Petitioner has not demonstrated by a preponderance of the evidence that a person of ordinary skill would have modified MTOS to connect the ends of the extensions (or handles) together or modified MTOS in some other way that would result in “a first handle means for facilitating simultaneous application of manipulative forces” to pedicle screws and pedicle screw engagement members “which are mechanically linked with said first handle means . . .

configured to move simultaneously each pedicle screw engagement member,” as recited in claim element 1[D]. In addition, as previously discussed, the parties do not dispute our construction of “handle means,” in which we have found the corresponding structure to be a common handle or linked handle array from which extend shafts that engage pedicle screws. MTOS does not show a common handle or linked handle array.

Petitioner contends that to the extent the individual handles in the Lenke References (i.e., MTOS) do not disclose that they are interconnected by a mechanical linkage to form a handle means, connecting handles is an old and well known design choice and that the ’928 Appl. discloses this feature. Pet. 13–14 (citing Lenke Decl. ¶¶ 85, 89–93). Dr. Lenke asserts that the device in the ’928 Appl. “is interchangeable with” and “is very similar in structure” to the devices depicted in the Lenke References, i.e., MTOS “with the exception that the handles of the device disclosed in the ’928 Application are linked together.” Lenke Decl. ¶ 57.

The ’928 Appl. discloses systems and methods for displacement of bony structures, such as vertebrae of the spine, relative to each other using a single device. Ex. 1006, Abstract, ¶ 8. The exemplary embodiment in Figure 11 of the ’928 Appl. is reproduced below:

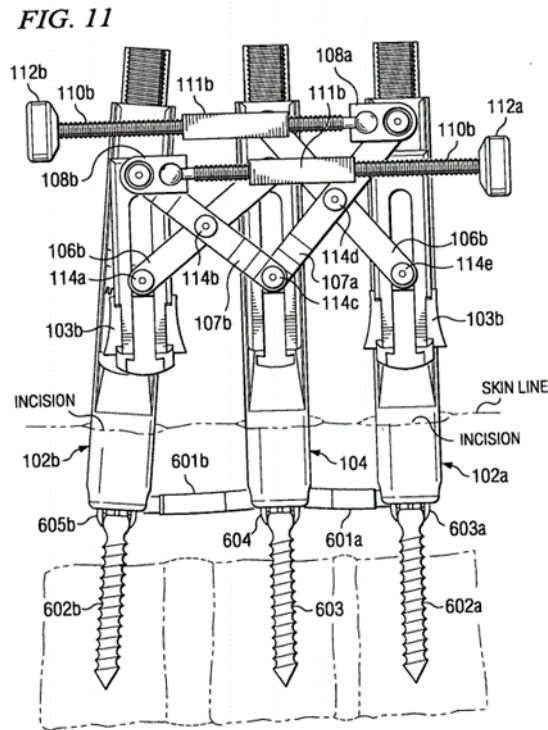


Figure 11 of the '928 Appl.

Ex. 1006, Fig. 11.

Petitioner notes that the device disclosed in the '928 Appl. "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." Pet. 22. As to the simultaneous movement, Petitioner further contends that limitation 1[D] is taught by the disclosure in paragraph 55 of the '928 Appl. of applying forces perpendicular to the direction in which distraction or compression of the vertebrae is affected, i.e., Petitioner contends that the application of force perpendicular to the direction of distraction and compression results in simultaneously rotating the vertebrae. Pet. 15–16. According to Petitioner, the tool disclosed in the '928 Appl. is configured structurally to rotate multiple vertebrae simultaneously and a skilled artisan would have found it obvious to employ this tool using a



handle means that is capable of facilitating simultaneous rotation of the vertebrae via the pedicle screws to which it is attached. *Id.* at 16, 21.

Patent Owner contends that the '928 Appl. discloses a displacement device that is intended to compress or distract adjacent vertebrae along the vertical axis of the spine. PO Resp. 29. Patent Owner notes that our Decision to Institute in *Medtronic v. Barry IV* recognizes that the '928 Appl. provides no explicit disclosure concerning the application of perpendicular forces to rotate the spine. *Id.* (citing *Medtronic v. Barry IV*, Dec. to Inst. (Paper 7) at 17 (PTAB Sept. 9, 2015)).

Petitioner argues that simultaneous rotation of vertebrae using pedicle screws was known in the art. Pet. Reply 7–9. Petitioner contends that the Cotrel-Dubousset method uses pedicle screws and was well known long before the filing date of the '072 Patent. *Id.* at 6. According to Petitioner, the Lenke References and Suk<sup>13</sup> also demonstrate that simultaneous rotation was known in the prior art. *Id.* Petitioner further argues that Patent Owner's expert, Dr. Walid Yassir, acknowledged that derotation of vertebrae using lever arm derotators and pedicle screws was well known in the art, and that he had used such techniques as early as 2003. *Id.* (citing Ex. 1043, Transcript of Deposition of Dr. Walid Yassir ("Yassir Tr.") 21:3–22). According to Petitioner, Patent Owner concedes that "one can grasp multiple unlinked derotators and rotate multiple vertebrae at the same time." *Id.* at 7–8 (citing Ex. 1044, *Mark A. Barry v. Medtronic, Inc.*, 1:14-cv-104 (E.D. Tex.), Claim Construction Hearing Transcript (Nov. 10, 2015)). However, Petitioner cites the '928 Appl. because claim element 1[D] requires a first

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<sup>13</sup> Suk is discussed in detail later in this Decision.

handle means for facilitating simultaneous application of manipulative forces” with the “first handle means configured to move simultaneously each pedicle screw engagement member.” We look to the ’928 Appl. because Petitioner has not demonstrated that this feature is disclosed by the Cotrel-Dubousset method and system or by the Lenke References.

When knob 112b of the tool disclosed in the ’928 Appl. 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. Ex. 1006 ¶ 66. Adjusting knob 104a causes the same action relative to guide tubes 102a and 104. *Id.* Thus, unlike claims 1 and 3, which recite a derotation tool, the ’928 Appl. requires multiple motions and results in compression or distraction of the vertebrae. Petitioner argues that to achieve rotation, the tool can be pushed or pulled to apply upward or downward force, as well as twisted, much like a doorknob can be pushed, pulled, or twisted. Pet. 16–17 (citing Lenke Decl. ¶¶ 55–57).

Petitioner’s expert, Dr. Lenke, acknowledges that “the ’928 Application indicates that this tool may be used for displacement (distraction and compression) of adjacent vertebrae.” Lenke Decl. ¶ 56. However, Dr. Lenke also points out language in the ’928 Appl. that states the tool may be used to “apply force in a direction that is perpendicular to the direction in which distraction or compression occurs, as in a spondylolisthesis reduction.” *Id.* (citing Ex. 1006 ¶ 55). Dr. Lenke identifies this direction as “along the dorsal-ventral axis.” *Id.*

Paragraph 55 of the ’928 Appl. states as follows:

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**. Alternatively, force is transmitted directly to the rod cages in order to begin compression or distraction. The surgeon may engage the displacement mechanism by turning knob **112**, as discussed above with respect to **FIG. 1**.

Ex. 1006 ¶ 55. In Figure 8 of the '928 Appl., process step 805 is labelled “TRANSMITTING FORCE TO ANCHOR EXTENSIONS TO DISPLACE BONY STRUCTURES.”

In his Declaration, Dr. Lenke contends that the explicit disclosure of applying

a perpendicular force in addition to a displacement force, explicitly and implicitly discloses to one of ordinary skill that the handles are designed to be grasped to apply this perpendicular force, and not just twisted<sup>14</sup> to distract or compress the vertebrae.

Lenke Decl. ¶ 56. Dr. Lenke further states:

If a surgeon was to use the tool disclosed in the '928 Application to apply this perpendicular force in a downward direction, it would naturally cause a derotation of the vertebrae as it would cause the engaged side of the vertebrae to go down, with the opposite side of the vertebrae moving upward in an equal amount. . . . The surgeon would know that they need not rotate the knobs to impart this force, but rather could simply grasp the knob, or the knob and physical linkage and apply the force he desired in the direction and in the manner desired. This is analogous to how a person may twist a door knob handle to unlatch a door, but may also apply any force on that knob, including, but not limited to, pushing, pulling, or lifting in various directions to open, close, lift or lower a door. . . . Such

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<sup>14</sup> In this context “twisted” appears to refer to turning the adjusting knobs to compress or distract the vertebrae.

application of force on one side of the spine would necessarily cause a rotation of the vertebrae.

*Id.*

Claim element 1[D] recites “a first pedicle screw cluster derotation tool.” As we noted in *Medtronic v. Barry IV*, the ’928 Appl. provides no specific disclosure concerning the application of perpendicular forces to rotate the spine in spondylolisthesis reduction. Dec. to Inst. 13–14 (citing *Medtronic v. Barry IV*, Dec. to Inst. 16–18). However, we instituted under 35 U.S.C. § 103 in view of Dr. Lenke’s unrebutted testimony<sup>15</sup> that one of ordinary skill would have recognized the tool disclosed in the ’928 Appl. could be used mechanically for derotation of the vertebrae, because the tool provides multiple rigid connections to individual pedicle screws, thereby facilitating derotation of the vertebrae. *Id.*; Lenke Decl. ¶ 57.

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to use the tool disclosed in the ’928 Appl. for derotation of vertebrae because one would not push, pull, grab, or twist the tool, as he or she would a doorknob. Hr’g Tr. 32:22–25. Noting that paragraph 55 of the ’928 Appl. refers to spondylolistheses reductions, Patent Owner supports this argument with the testimony of its expert, Dr. Walid Yassir, that correction of spondylolisthesis does not include meaningful or significant rotation of the vertebrae. Yassir Decl. ¶ 96.

As noted above, paragraph 55 of the ’928 Appl. discusses the application of perpendicular force in the context of spondylolisthesis. Patent Owner describes spondylolisthesis as the slippage of one vertebrae forward in relation to an adjacent vertebrae in the sagittal (front to back) plane.

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<sup>15</sup> Patent Owner did not file a Preliminary Response.

Yassir Decl. ¶ 75. Dr. Yassir provides the following illustration where the fifth lumbar vertebra (L5) has slipped forward over the S1 vertebra:



*Id.* To correct the condition, the slipped vertebra is drawn toward the patient’s back, restoring its alignment with other vertebrae. PO Resp. 36. As in the example shown, Dr. Yassir states that surgical reduction of the slippage sometimes requires that the L5 vertebra be drawn back over the S1 vertebra, requiring that force be applied in the sagittal plane running from front to back. Yassir Decl. ¶ 75. In his deposition testimony, Dr. Yassir acknowledges that some references disclose that in some cases, e.g., in some patients that have scoliosis, there can be a rotational component to spondylolisthesis. Yassir Tr. 86:14–87:7, 88:6–22. In the only discussion of the degree of such rotation during his deposition, Dr. Yassir noted that the amount of rotation was minimal. *Id.* at 91:13–92:17. According to Dr. Yassir, the ’928 Appl. does not disclose a tool that could be used for rotation because “correction of spondylolisthesis does not include meaningful or significant rotation of the vertebrae” and “one of ordinary skill in the art would understand that attempting to rotate the vertebrae using

the displacement device of the '928 Appl. would create, rather than correct, a spinal deformity.” Yassir Decl. ¶ 96.

Dr. Yassir notes that another reason it would not have been obvious from the displacement tool in the '928 Appl. to apply manipulative force to the handle in a manner that would result in simultaneous rotation of the vertebrae lies in the difference between the forces needed to address scoliosis and spondylolisthesis. Yassir Decl. ¶ 97. Referring to the tool in the '928 Appl., Dr. Yassir points out that “[t]he lever arm described by the device is much smaller than that used in the rotation of vertebrae during apical vertebral rotation maneuvers” and that after rotating two or three vertebrae connected by rods 601, they would simply rotate back to their original positions. *Id.* According to Dr. Yassir, “in the correction of apical rotation of scoliosis, a cluster of vertebrae at the apex of the scoliotic curve are rotated about a much longer construct which is fixed above and below the vertebrae being rotated.” *Id.* Dr. Yassir continues, “Those vertebrae above and below the rotated vertebrae anchor the rod in position to hold the apical vertebrae in their derotated position.” *Id.* Petitioner cites testimony in Dr. Yassir’s cross examination that the vertebrae are held in place by locking down the screws. Pet. Reply 17 (citing Yassir Tr. 80:21–81:13). However, the context of the cited testimony is distraction and compression disclosed in the '928 Appl. Petitioner further contends Dr. Yassir’s argument that the tool in the '928 Appl. could only apply a small amount of rotational force due to the length of the tubes is without basis because the '928 Appl. does not limit the length of the tubes. *Id.* at 17–18.

As in *Medtronic v. Barry IV*, although the '928 Appl. does not mention spinal rotation, our basis for instituting under 35 U.S.C. § 103(a) is

Dr. Lenke's testimony that applying a perpendicular force as stated in paragraph 55 of the '928 Appl. "would naturally cause a derotation of the vertebrae as it would cause the engaged side of the vertebrae to go down, with the opposite side of the vertebrae moving upward in an equal amount." See Dec. to Inst. 13–14; Lenke Decl. ¶ 56. Petitioner contends that because the basis of this proceeding is 35 U.S.C. § 103(a), to establish obviousness Petitioner need not demonstrate that the tool disclosed in the '928 Appl. works; instead, we must consider the modifications one skilled in the art would make to a device borrowed from the prior art. Pet. Reply 17 (citing *In re Icon Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed. Cir. 2007)).

Petitioner notes the arguments in the Patent Owner Response that to apply perpendicular force in the context of the '928 Appl. one of ordinary skill would use reduction screws. *Id.* at 12–13. Petitioner call this argument speculative. *Id.* at 13. Although Dr. Yassir testifies that the use of reduction screws in spondylolistheses reduction was common at the time of the '928 Appl. (PO Resp. 40 (citing Yassir Decl. ¶ 85; Ex. 2023)), Patent Owner acknowledges that the '928 Appl. provides no disclosure of how spondylolistheses reduction would be performed (PO Resp. 36). Therefore, we agree that Patent Owner's arguments concerning the use of reduction screws are speculative. However, as we have repeatedly noted, although the '928 Appl. mentions the application of perpendicular force, the '928 Appl. never mentions rotating the vertebrae, even in the context of spondylolisthesis reduction. Ex. 1006 ¶ 55. Thus, Dr. Lenke's testimony concerning how the perpendicular force would be applied in such a manner as to rotate the vertebrae is equally speculative.

In view of the clearly conflicting testimony of the parties' experts, we weigh the evidence in the context of the disclosure in the '928 Appl. Patent Owner contends that the '928 Appl., which concerns minimally-invasive surgeries, as evidenced by its disclosure of transmitting force percutaneously (through the skin) to bony structures, is irrelevant to the problems solved by the '072 Patent, which concerns surgeries involving long incisions and exposure of underlying tissue. PO Resp. 40–42 (citing Yassir Decl. ¶¶ 99–100; Ex. 2009, Deposition Transcript of Dr. Lawrence Lenke (“Lenke Tr.”) 55:3–10, 222:24–223:22). Petitioner responds that it is “intuitively obvious” that an instrument used through small incisions can also by be used in larger incisions. Pet. Reply 15. Petitioner argues that Dr. Lenke “consistently testified that the '928 device is usable in the procedures claimed in the '072 Patent and is physically identical to instruments he has used for such procedures, including those described in the Lenke References.” *Id.* at 16 (citing Lenke Decl. ¶¶ 53–58; Lenke Tr. 158–172). The cited portions of Dr. Lenke’s testimony do not support Petitioner’s argument. The cited portions of Dr. Lenke’s deposition transcript concern the subject matter in paragraph 55 of the '928 Appl. Although Dr. Lenke’s Declaration states he “performed derotation procedures using devices very similar to the device disclosed in the '928 Application” (Lenke Decl. ¶ 57), there is no testimony supporting Petitioner’s assertion the device in the '928 Appl. is “physically identical” to any instrument used by Dr. Lenke. In any case, even Dr. Lenke acknowledges that the word “rotation” is not used in paragraph 55 of the '928 Appl. Lenke Tr. 166:21–22. Thus, we analyze the '928 Appl. for what it actually discloses to one of ordinary skill.



The Background of the Invention in the '928 Appl. states that when performing surgery, the surgeon often needs to distract bone by pulling it away from the work site or compress bone to pull it together, for example, when the bone is broken. Ex. 1006 ¶ 4. The '928 Appl. also discusses applying force to move spinal implants along a rod, or before insertion of a rod, in order to distract or compress bone or implants into the most favorable position. *Id.* The '928 Appl. notes that in such procedures, surgeons often have to switch devices or parts of devices, such as handles, depending on whether compression or distraction is desired, resulting in the use of large top-heavy devices that must be held steady, and a more invasive procedure. *Id.* ¶¶ 5–6. Therefore, the '928 Appl. seeks to provide a “system and method for displacing, such as by compression or distraction, bony structures using a single device.” *Id.* ¶ 7.

The Summary of the Invention in the '928 Appl. states: “Displacement may include at least one of compression and distraction, and embodiments of the present invention provide for a device that may perform compression and distraction interchangeably without the need for having separate compression and distraction devices.” *Id.* ¶ 8. The '928 Appl. further states that “embodiments of the present invention provide for an integrated device that allows for compression and distraction to be selectively performed with a single device.” *Id.* The introductory paragraph in the Description of the Invention of the '928 Appl. states:

Certain embodiments of the present invention provide a system and method which allow for both the compression and distraction of bony structures, such as a spine, during a surgical procedure. According to certain embodiments, a displacement device comprises at least two guide members connected by cross members wherein the guide members are displaced relative to

each other responsive to manipulation of a user interface. The guide members provide for the transmission of distraction or compression force percutaneously to bony structures, thus allowing compression or distraction of these bony structures. Although various embodiments are described with reference to a displacement device that compresses or distracts, certain embodiments provide for a displacement device that performs at least one of compression and distraction without the need for a large incision, thereby performing compression or distraction in a minimally invasive manner.

Ex. 1006 ¶ 24. There is no mention of rotating the spine or any other bony structure in the '928 Appl.

The '072 Patent that is the subject of this proceeding refers to “scoliosis” and associated “scoliosis curvature” and “severe twisting of the spine.” Ex. 1021, col. 1, ll. 16–27. The '928 Appl. makes no mention of scoliosis, scoliosis curvature, or twisting of the spine, but speaks only of compression and distraction of bony structures. The '928 Appl. discusses providing an angular adjustment with a thumb slide 103 to adjust the angular positioning of guide tube 102, when the anchors are not positioned perfectly parallel to each other and when the connecting brace positioned between the anchors is not entirely straight (e.g., is curved to match the curvature of the spine). Ex. 1006 ¶¶ 38–39. However, the '928 Appl. provides only for distraction and compression—there is no discussion of rotating the vertebrae to have an effect of the curvature of the spine, nor does the '928 Appl. mention a handle means for facilitating simultaneous application of manipulative forces configured to move simultaneously each pedicle screw engagement member engaged respectively with a pedicle screw head segment.

Paragraph 55 of the '928 Appl. does not mention pushing, pulling, or twisting the disclosed tool. In the context of spondylolistheses reduction, paragraph 55 of the '928 Appl. refers to a displacement device placed over extensions (referenced with respect to Figure 6 as elements 606 and 607, but not shown in Figure 6) or bone anchors (i.e., pedicle screws 602, 603; *see* Ex. 1006 ¶¶ 24, 38) and applying force in a direction that is perpendicular to the direction in which distraction or compression occurs. Ex. 1006 ¶ 55. Force is then transmitted to the anchor extensions or bone anchors (pedicle screws) in order to begin compression or distraction, i.e., by engaging the displacement mechanism by turning knob 112. *Id.* Paragraph 4 of the '928 Appl. states that in the context of spinal surgery, a surgeon may approach the patient from a posterior position. Thus, paragraph 55 of the '928 Appl. appears to disclose pressing downward or upward from the posterior of the patient and then applying distraction by turning the knobs of the tool. *See* Lenke Tr. 158:20–21 (“[A]s you grab it [the device disclosed in the '928 Appl.] and just move it up and down.”).

Petitioner contends that to the extent the derotation tools of the Lenke References (MTOS) do not disclose the handles of the apical derotators linked, it would have been obvious to do so in order to distribute the mechanical load and free up one of the surgeons hands, in view of the disclosures in the '928 Appl. of the mechanical linkage between the pedicle screw engagement members and the application of force in a direction perpendicular to compression and distraction. Pet. 14–16; Lenke Decl. ¶ 56. Petitioner argues that, because 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, i.e., when a downward (or upward) force

is applied, it causes rotation of the vertebrae as it pushes one side of the vertebrae down (or up) resulting in the opposite side of the vertebrae to move upward (or downward) by an equal amount. Pet. 15. Petitioner further argues that “the ’928 Appl. would have explicitly (or at the very 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.” *Id.* at 16–17 (citing Lenke Decl. ¶¶ 55–57). Although Dr. Lenke testifies that the application of perpendicular force would “naturally cause a derotation of the vertebrae” the ’928 Appl. does not mention rotation and Dr. Lenke does not state explicitly whether, in the context of spondylolisthesis reduction mentioned in the ’928 Appl., such rotation is intended or incidental. Lenke Decl. ¶ 56. There is no evidence in the ’928 Appl. that such rotation is possible or desirable. As noted above, Dr. Yassir testifies that using the tool disclosed in the ’928 Appl. to rotate vertebrae would likely introduce, rather than correct spinal deformities. Yassir Decl. ¶ 96. In any case, rotation of vertebrae certainly is not stated to be an objective of the tool disclosed in the ’928 Appl. As previously noted, the ’928 Appl. provides an extensive discussion of displacing bony structures, such as vertebrae, by compression and distraction, but does not discuss a pedicle screw derotation tool. .

Although Petitioner’s evidence indicates that there is room for debate about whether spondylolistheses reduction requires rotating the vertebrae, Dr. Yassir contends that any such rotational component is minimal. Yassir Tr. 86:18–92:17. More relevant is that neither Dr. Lenke’s testimony nor Dr. Yassir’s acknowledgement of the possibility that spondylolistheses may have a rotational component sufficiently demonstrates that there is any

suggestion in the '928 Appl. that one of ordinary skill in that art would consider using the tool in the '928 Appl. as a surgical approach to rotating vertebrae, given that the subject is not even mentioned in the '928 Appl.

Claim 1 recites “a first handle means for facilitating simultaneous application of manipulative force” to pedicle screws. The handle means is “configured to move simultaneously each pedicle screw engagement member.” Petitioner disputes Dr. Yassir’s testimony that one of ordinary skill would not use the device in the '928 Appl. to achieve this result because, in the context the application of perpendicular force is disclosed, i.e., spondylolisthesis reduction, the amount of rotation associated with spondylolisthesis is minimal, the device would be ineffective to achieve sufficient rotation to correct spinal curvature and the result could be counterproductive. Petitioner argues that it is “intuitively obvious” that the device in the '928 Appl. could be used in more invasive surgeries than that disclosed in the '928 Appl., and that it is “inherent” rotation would result from the application of the perpendicular force discussed in paragraph 55 as associated with spondylolisthesis treatment. Dr. Lenke does not discuss how much perpendicular force would be necessary to achieve intended rotation of the vertebrae, and it is not clear from the evidence presented whether the rotation Dr. Lenke contends would result from applying perpendicular force as discussed in paragraph 55 of the '928 Appl. is incidental or desired. Most important is that the '928 Appl. does not mention derotation of spinal vertebrae at all. Thus, the evidence does not support a conclusion that one of ordinary skill would have been motivated to apply the teachings of the '928 Appl. to the teaching of MTOS to arrive at the claimed handle means, as we have construed that term, i.e., Petitioner has not provided sufficient

evidence to show that a person of ordinary skill would have been motivated by the disclosure in the '928 Appl. to modify the individual handles in MTOS to form a structure with a common handle or linked handle array from which extend shafts that engage pedicle screws to move simultaneously each pedicle screw engagement member thereby facilitating simultaneous application of manipulative forces to a 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.

Patent Owner also contests the objectivity of Dr. Lenke because Dr. Lenke, who is an author of the Lenke References, and MTOS in particular, has a reputational interest and a measurable pecuniary interest in the outcome of this proceeding. PO Resp. 14–16. Patent Owner emphasizes that Dr. Lenke's testimony is used to fill in gaps missing in prior art that does not disclose explicitly the features recited in claim element 1[D]. *Id.* at 15–16. Petitioner does not deny Dr. Lenke's financial interest, but responds that there is no authority holding that receipt of royalties by an expert who is not himself a party makes that expert biased. Pet. Reply 5–6. Petitioner asserts that it engaged Dr. Lenke because of his work at the forefront of the development of spinal derotation procedures. *Id.* at 6.

We do not doubt Dr. Lenke's expertise. As we discussed earlier in this Decision, Dr. Lenke testified that one of ordinary skill would have understood that the tool in the '928 Appl. could be used for derotation of the vertebrae because it provides multiple rigid connections to individual pedicle screws via a handle that facilitates simultaneous rotation of the vertebrae by way of the implanted pedicle screws. Lenke Decl. ¶57. However, Dr. Lenke supports this assertion with his own experience stating:

The device disclosed in the '928 Application is very similar in structure to the devices depicted in the Video, the Slides, and the MTOS chapter with the exception that the handles of the device disclosed in the '928 Application are linked together, and is interchangeable with those devices for use in the surgery depicted in the Video, the Slides, and the MTOS chapter. Indeed, I would have been, and actually was, motivated to do so long before the alleged invention by Dr. Barry, to obtain a safe, reproducible, and uniform way to manipulate multiple derotators at the same time, more evenly distributing the force applied in a perpendicular direction (as taught by the '928 and demonstrated by the Video, Slides and MTOS chapter as well as the '568 patent and Suk) to, for example, achieve spondylolisthesis reduction (a goal discussed in the '928 and the purpose of the Video, Slides, and MTOS chapter, Suk, and the '568 patent) across multiple screws and vertebrae, to reduce the likelihood of any one screw or vertebrae being damaged and to free up one of the surgeon's hands to allow further manipulation and securing of the connecting rod into the screw heads.

*Id.*

Regardless of any personal interest he may have in the outcome of this proceeding, Dr. Lenke's testimony as to whether he, as an expert, would have been motivated to use the tool in the '928 Appl. for derotation does not support his assertion that one of ordinary skill would have the requisite motivation to use the tool disclosed in the '928 Appl. for derotation of the spine.

Petitioner has not demonstrated a person of ordinary skill would have combined the teachings of '928 Appl. and MTOS in a manner that would have produced the limitations of claim 1[D]. Patent Owner emphasizes the clear distinction between the open surgical procedures associated with treating scoliosis and the Lenke references, generally and the tool in the '928 Appl. that is adapted for minimally invasive procedures. PO Resp. 26–27,

40–41, 46, 48–55. In addition, as discussed above, although both the '928 Appl. and MTOS disclose a tool in which pedicle screws implanted in the spine are manipulated through extensions to move vertebrae, neither the '928 Appl. nor MTOS discloses claim elements 1[D] and. The '928 Appl. discloses a tool with linked members and knobs that are turned to achieve controlled distraction and compression of bony structures.

As discussed extensively above, Petitioner has not demonstrated by a preponderance of the evidence that a person of ordinary skill would have been motivated by the disclosure in paragraph 55 of the '928 Appl. to use the tool to rotate vertebrae. MTOS discloses individual handles linked to pedicle screw engagement members that can be used to execute a derotation maneuver, but Petitioner has not shown that MTOS discloses linking the handles or the claimed handle means. Notwithstanding Dr. Lenke's testimony that the tools in MTOS and the '928 Appl. are similar, they appear to have different uses in different surgical environments. Petitioner has not demonstrated that a person of ordinary skill would have modified either the tool disclosed in the '928 Appl. or the pedicle screw engagement members disclosed in MTOS in a manner that would have achieved claim elements 1[D].

In consideration of the above, Petitioner has not demonstrated by a preponderance of the evidence that claim 1 or claim 2, which depends from claim 1, of the '072 Patent would have been obvious over the combination of the Video, the Slides, MTOS and the '928 Appl.



*Claims 3 and 4; Obviousness Over the Combination of the Video, the Slides, and MTOS (the Lenke References), the '928 Appl. and the '291 Appl.*

Independent claim 3 and claim 4, which depends from claim 3, recite as claim element 3[E] the first handle means recited in claim 1 as element 1[D]. As discussed above, Petitioner has not demonstrated that this element is obvious over the combination of MTOS (the remaining Lenke Reference) and the '928 Appl. Petitioner cites the '291 Appl. as an alternative to MTOS in disclosing systems and methods for straightening a scoliotic spinal column. Pet. 28–29. Petitioner notes that the '291 Appl. discloses that once a rod is contoured and in its first derotational position, it is loosely tightened into place by a set screw and rotated around its length by a ratchet tool to a second rotational orientation. *Id.* at 28. Petitioner notes that a pedicle screw engagement means in the form of a shaft may be used after the rod rotation to impart more force on the screws. *Id.* However, Petitioner relies on the '928 Appl., rather than the '291 Appl. as disclosing element 3[E]. Pet. 30. Therefore, consistent with our analysis of claim element 1[D], we conclude that Petitioner has not demonstrated by a preponderance of the evidence that independent claim 3 or dependent claim 4 is unpatentable over the combination of the Video, the Slides, MTOS, the '928 Appl., and the '291 Appl.

*Claims 1 and 2: Obviousness over Suk*

Suk discloses a surgical procedure in which pedicle screws are inserted at each segment on the correction sides (thoracic concave) and every second or third segment on the support side (thoracic convex) of a curve. Ex. 1031, 345, col. 1. A pre-contoured rod on the correction side is rotated counter-clockwise without any compression or distraction, and screw

derotators are inserted onto the pedicle screws. *Id.* During or after rod derotation, the screw derotators are rotated in the opposite direction of the rod derotation and the lowermost pedicle screws are rotated appropriately. *Id.*

Turning to claim 1, Petitioner contends that Suk discloses a derotation tool in which multiple handles facilitate simultaneous application of forces to a first set of pedicle screws, each having a threaded shank, and a head segment. Pet. 58. Suk discloses that in some circumstances, for example, when the preoperative compensatory lumbar curve crosses the central sacral vertical line with significant rotation (as in King Type II or Lenke Type IC), it may be necessary to rotate the two lowermost screws in a direction opposite the direction of the thoracic DVR. Ex. 1031, 347–48. Petitioner contends that because Suk discloses distributing the rotational torque among several pedicle screws to help prevent breakage, Suk discloses that the application of force to the pedicle screws is simultaneous. Pet. 58 (citing Ex. 1031, 347).

Citing Figure 2C of Suk, Petitioner argues that Suk has multiple handles that facilitate simultaneous application of manipulative forces to pedicle screws configured to move each pedicle screw engagement member simultaneously (Pet. 58) or that it would have been obvious to one of ordinary skill to modify Suk to include the handle means (*id.* at 59). Figure 2C of Suk is a photograph showing a surgeon grasping individual handles with one hand and a perpendicular member with the other hand and the direction of rotations applied in the DVR procedure.

We instituted on this challenge based on Petitioner's contention that the disclosure in Suk of distributing rotational force among a plurality of

pedicle screws would have suggested the first handle means to one of ordinary skill in the art. Dec. to Inst. 18–19. Petitioner argues that “Suk inherently provides that the derotators are linked, or provides the motivation to link the derotators to obtain, as Dr. Yassir provided, the predictable result of simultaneous derotation.” Pet. Reply 23 (citing Yassir Tr. 137:2–18; Lenke Tr. 214:7–218:24).

According to Patent Owner, Dr. Lenke’s testimony assumes there is linkage implied by the Figures, but there is no clear disclosure to establish such a linkage shown in the reference. PO Resp. 59 (citing Yassir Decl. ¶¶ 110–111). Dr. Yassir describes other features in Fig. 2C and the accompanying description in Suk that dispute Dr. Lenke’s testimony. Yassir Decl. ¶¶ 108–112. For example, referring to the handles or levers illustrated, Dr. Yassir states that Fig. 2C appears to show a surgeon grasping two pedicle screw drivers with one hand (Yassir Tr. 59:17–60:25). Commenting on Dr. Lenke’s testimony that these screw drivers are levers, Dr. Yassir states that Figure 2C appears to show the surgeon’s other hand grasps a “t-handle” for one of the two levers and that the “t-handle” is used to tighten the lock nut of a pedicle screw. Yassir Decl. ¶ 111. However, Dr. Yassir states that there is nothing linking the levers in Fig. 2C. *Id.*

Patent Owner contends that Suk teaches using unlinked long lever arm screw derotators, and that, similar to MTOS, Suk does not teach the derotators are linked to form the claimed handle means. PO Resp. 57. Patent Owner argues that nothing in Suk discloses or otherwise informs a person of ordinary skill to use a linked handle in order to impart force over multiple pedicle screws. *Id.* (citing Yassir Decl. ¶ 108). Noting that claim 1 requires simultaneous movement of three pedicle screws, Patent Owner

argues that Fig. 2C shows only two handles and does not show any linkage between them. *Id.* at 58–59. According to Patent Owner, Suk at most expresses as a goal coordinating the movement of independent levers to reduce the force on any single pedicle screw that might result in breakage, but does not inform a person of ordinary skill how this goal could be accomplished beyond the use of individual, unlinked levers. *Id.* at 58; Yassir Decl. ¶ 113. Suk states, “There is little chance of canal intrusion due to pedicle breakage during DVR when the screws are inserted correctly because the medial wall of pedicle is three times stronger than the lateral wall.” Ex. 1031, 347.

At the oral hearing Petitioner argued:

the point about Suk teaching distributing the force, is that this is a motivation, a motivation to link these tubes. If you want to distribute the force, which is known in the prior art, which Dr. Yassir said was well-known to a person of skill, in the background knowledge of a person of skill distributing the force, would motivate you to connect these tubes regardless of whether Suk himself is connecting the tubes or not.

Hr’g Tr. 82:3–10.

Petitioner points to testimony by Dr. Yassir that one way to accomplish distribution of rotational torque is to connect the tubes or derotators and that, if you connected them together, they would move at the same time. Yassir Tr. 137:2–18. Dr. Yassir’s testimony that the derotators would move at the same time after they were connected together, does not address whether one of ordinary skill would have been motivated by Suk to connect the derotators in the first place. Instead, the questions posed to Dr. Yassir presume that one of ordinary skill had already connected the derotators together.

Dr. Yassir disagrees that Suk discloses that a single manipulative force applied to a handle means would move all the engagement members simultaneously. Yassir Decl. ¶ 150. Dr. Yassir further disagrees that because Suk discloses distributing rotational torque among several pedicle screws to help prevent breakage, Suk would suggest to one of ordinary skill in the art that the application of force to the pedicle is simultaneous. Yassir Decl. ¶¶ 151–152. Dr. Lenke and Dr. Yassir disagree on what a person of ordinary skill would infer from Suk’s disclosure of distributing rotational torques and whether a person of ordinary skill would have been motivated to form a handle means with a common handle or linked handle array from which extend shafts that engage pedicle screws to move simultaneously each pedicle screw engagement member thereby facilitating simultaneous application of manipulative forces to a first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked to the handle means. Notwithstanding Dr. Lenke’s inferences concerning Suk, the fact remains that the text in Suk does not describe or mention a handle means that moves each of at least 3 derotation members simultaneously. Therefore, we conclude that Petitioner has not demonstrate by a preponderance of the evidence that claims 1 and 2 are unpatentable under 35 U.S.C. § 103(a) as obvious over Suk.

*Objective Considerations*

Patent Owner asserts objective considerations, such as evidence of long felt need and commercial success, demonstrate non-obviousness of the challenged claims. PO Resp. 59. As discussed above, Petitioner has not demonstrated by a preponderance of the evidence that the claims are

unpatentable over the cited art. Therefore, we need not address the parties' arguments concerning objective criteria.

*Patent Owner's Motion to Seal*

Patent Owner has moved to seal Exhibits 2019 and 2026 on the basis that they disclose personal financial information of Dr. Barry. Paper 22 ("Mot. To Seal"). Patent Owner has filed corresponding redacted Exhibits 2035 and 2037 respectively as substitutes for Exhibits 2019 and 2026. Petitioner opposes Patent Owner's Motion to Seal at least because Patent Owner's conduct in this proceeding indicates that the information is not truly confidential. Paper 35 ("Opp. To Mot. To Seal").

Patent Owner relied on the information it seeks to seal in support of its contentions that objective considerations demonstrate the challenged claims are not obvious. PO Resp. 59–60. However, for the reasons discussed above, we need not consider these objective criteria and we do not rely on the information Patent Owner asserts is confidential in this Decision. In view of these circumstances, Patent Owner's Motion to Seal is moot.

We remind the parties that confidential information that is subject to a protective order ordinarily becomes public 45 days after denial of a petition to institute or 45 after final judgment in a trial. Office Trial Practice Guide 77 Fed. Reg. 48756, 48761 (Aug. 14, 2012). A party seeking to maintain the confidentiality of the information may file a motion to expunge the information from the record prior to the information becoming public. 37 C.F.R. § 42.56.

## CONCLUSION

For the reasons discussed above, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims of the '072 Patent are unpatentable and that Patent Owner's Motion to Seal is moot.

## ORDER

In consideration of the above, it is

ORDERED that challenged claims 1–4 of the '072 Patent have not be shown by a preponderance of the evidence to be unpatentable:

FURTHER ORDERED, that Patent Owner's Motion to Seal is moot; and

FURTHER ORDERED, that because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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