

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

MARK A. BARRY,
Patent Owner

Case IPR2015-00780
Patent 7,670,358 B2

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

On September 9, 2015 we instituted an *inter partes* review of claims 1–5 of U. S. Patent No. 7,670,358 B2 (“the ’358 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, “Hrg. Tr.”)¹ 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[B]. *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 chart does not cite to or quote from the reference. *Id.* However, the figure in the chart is an annotated version of Figure 9 of the reference with the parts Petitioner contends correspond to the parts

¹ The oral hearing in this proceeding was consolidated with the oral hearing in related case IPR2015-00783, which involves the same parties and concerns U.S. Patent No. 7,776,072 B2.

recited in the claim labelled and circled. Patent Owner also notes Petitioner's entry in the claim chart for claim element 1[F]. *Id.* at 5. In this chart entry, Petitioner repeats the claim limitation to indicate it is disclosed by the reference and refers the reader to a section of the Petition.

Notwithstanding Patent Owner's position that the reference does not disclose the limitation (*id.* at 5), the claim chart entry is not argumentative (indeed, it provides no information at all). Instead, the entry refers the reader to an argument in a specific section of the Petition. *Id.* 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 '358 PATENT

The '358 Patent discloses a system for ameliorating aberrant spinal column deviation conditions, such as scoliosis, that facilitates the application of derotational forces to individual vertebrae, while reducing the risk of fracture when applying such forces. Ex. 1020, col. 3, ll. 15–25. The system includes a number of bone screws that are implanted into the pedicle region(s) of individual vertebrae to be derotated, 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. 37–43. 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. 4, ll. 61–62, col. 5, ll. 47–48. 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. 4, ll. 63–65, col. 5, ll. 48–59.

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. 25–29. 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 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. 48–54. “[A]s manipulative forces are applied to the handle means of the 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 that are contiguous to the effected segment(s). *Id.* at col. 3, ll. 54–63. 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. 4, l. 66–col. 5, l. 6. 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. 12–14. 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 that pedicle screw is implanted. *Id.* at col. 5, ll. 12–18. Ordinarily, two derotation tools will be involved on either side of the spinal column, with two pedicle screws being implanted in each vertebra. *Id.* at col. 5, ll. 7–

9. Wrench cross-linking members are used to coordinate forces applied to screw clusters on either side of the spinal column. *Id.* at col. 5, ll. 9–11.

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, said pedicle screws each having threaded shank segment and a head segment;
 - selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws,
 - implanting a each [sic] pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;
 - engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said first set of pedicle screws; and
 - applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition;
 - selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes:
 - a spinal rod conduit formed substantially transverse of the length of said pedicle screw and sized an shaped for receiving passage of said spinal rod member there-through; and
 - spinal rod engagement means for securing said pedicle screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

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

GROUNDINGS OF INSTITUTION

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

Claim 1 as obvious over the '928 Appl.;² and

Claims 1–5 as obvious over the combination of the '928 Appl., the Video,³ the Slides,⁴ and MTOS.⁵

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:

² U.S. Patent Appl. No. 2005/0245928 A1, published Nov. 3, 2005 (“the '928 Appl.”) (Ex. 1006).

³ Thoracic Pedicle Screws for Idiopathic Scoliosis Video (the Video”) (Ex. 1002, Parts 1–7).

⁴ Free Hand Thoracic Screw Placement and Clinical Use in Scoliosis and Kyphosis Surgery slide handout (“the Slides”) (Ex. 1003).

⁵ 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).

Spinal rod engagement means (for securing said screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation): The function recited in the claim 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.*

Handle means: *a part that is designed especially to be grasped by the hand.*

Mechanically linked: *joined by a physical connection.*

A second group of multiple vertebrae: no construction required.

The parties do not dispute the above claim constructions. PO Resp. 22–23; Pet. Reply 6. Nevertheless, Patent Owner attempts to provide “additional context” to the constructions it accepts by discussing statements the parties made in the corresponding district court litigation. PO Resp. 22–24. Patent Owner also identifies additional claim constructions the parties sought in the district court, but applies the plain and ordinary meaning to those terms in this proceeding. *Id.* at 26–27.

Petitioner responds that the challenged claims are directed to a “method for aligning vertebrae in 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. 18–19, 43). 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.” Pet. Reply 2.

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. Hrg. Tr. 59:1–19. Under *In re 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. *In re 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; 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 42. Although there is some dispute concerning the contents of slides distributed to attendees at other programs, the parties agree that the Slides in Ex. 1003 were distributed in a loose leaf binder at the Colorado Springs program. PO

Resp. 9–10, Pet. Reply 5.⁶ About 20 surgeons who attended the Colorado Springs program received the Slides in Ex. 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 (citing *In re Bayer*, 568 F.2d 1357, 1359 (C.C.P.A. 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 10–11 (citing Ex. 2010 (“Poley Cross-examination”), 24:26–24:6, 30:7–13).

Petitioner argues its 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

⁶ Noting that Ms. Owens testified that the exact materials she reviewed and offered as evidence by Petitioner were not distributed to any surgeons, 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.

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 publication). Petitioner argues that Patent Owner’s citation of *In re 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 *In re 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, 1351 (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 filed.” Ex. 1001, Declaration of Dr. Lawrence Lenke (“Lenke Decl.”) ¶ 34. 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. ¶ 33. 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[,] . . . for example, approximately four years of medical device design experience in place of 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. Ex. 2010, 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 sufficiently 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 1351. Thus, we agree with Patent Owner that Petitioner has not provided sufficient evidence to support its contention that the Video and Slides are publically 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 '358 Patent was filed on December 30, 2004. Ex. 1020. Patent Owner cites the Declaration of Patent Owner/inventor Dr. Mark A. Barry (Ex. 2019 (“Barry Decl.”))⁷ as evidence that he conceived of, worked diligently to reduce to practice, and had actually reduced to practice the inventions claimed in the '358 Patent before February 1, 2004. PO Resp. 29–30. Patent Owner cites Exhibits 2021 and 2031 and the testimony of Robert Pfefferkorn (Ex. 2027 (“Pfefferkorn Decl.”)) as corroborating evidence. PO Resp. 30. Thus, Patent Owner contends that the '928 Appl. cannot be applied as prior art to the '358 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. Ex.

⁷ The Patent Owner Response incorrectly identifies the Barry Decl. as Ex. 2013. Ex. 2013 is the Declaration of Dr. Walid Yassir (“Yassir Decl.”).

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 ’358 Patent as of February 1, 2004. Barry Decl. ¶¶ 5, 6. 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.⁸ 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). 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

⁸ The Barry Declaration makes similar arguments concerning the correspondence of the claims of U.S. Patent No. 7,776,072 (“the ’072 patent”), without using claim charts. The ’072 Patent is the subject of *Medtronic Inc. v. Mark A. Barry*, Case IPR2015-00783. The Barry Decl. was submitted in that proceeding as well.

distinguished from reduction to practice, and that Mr. Pfefferkorn's 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 9 (citing Pferrerkorn 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." *Id.*; see Ex. 1045 at 2. In addition, referring to the IMAST Abstract, Dr. Barry 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; the *abstract itself* discloses conception of those limitations." Ex. 1046 at 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 States*, 816 F.2d 647, 652 (Fed. Cir. 1987) (emphasis added). "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) (emphasis added). 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 ’358 Patent.

Patent Owner also asserts, without arguing, that Dr. Barry was reasonably diligent in reducing the invention to practice. PO Resp. 30. “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. Kanamaru*, 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. *McIntosh*, 230 F.2d at 619; *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 C.C.P.A. 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*, 754 F.2d at 360. 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 Pefferkorn 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. Pefferkorn 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. Pefferkorn Decl. ¶ 7. However, Mr. Pefferkorn 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 modification Dr. Barry facilitated, and the general goals of his work.” *Id.*

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, 3, 17–18 (1966).

Claim 1 as Obvious Over the '928 Appl.

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, ¶ 8, Abstract. The exemplary embodiment in Figure 11 of the '928 Appl. is reproduced below:

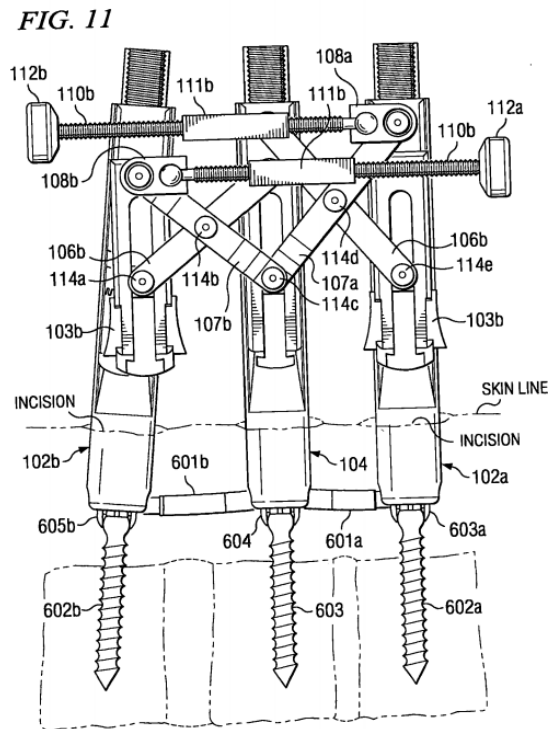


Figure 11 of the '928 Appl.

Ex. 1006, Fig. 11.

In our Decision to Institute, we noted our determination in *Medtronic, Inc. v. Barry*, Case IPR2014-01210 (PTAB Feb. 10, 2015) (Paper 10, Decision Denying Institution) (“*Medtronic v. Barry I*”) that the '928 Appl.

discloses the elements of claim 1 identified in the Petition as 1[A], 1[B], 1[C], 1[D], 1[E], 1[G], 1[H], and 1[I]. Dec. to Inst. 15. In this proceeding, the parties do not dispute these conclusions.

The primary focus of the parties' contentions in this proceeding concerns whether the '928 Appl. discloses the following limitation of claim 1 of the '358 Patent (designated in the Petition as claim limitation 1[F]):

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

Petitioner contends that limitation 1F 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. 22–24, 27–28. 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, but does not disclose applying manipulative force to a first handle means engaged with pedicle screws in such a manner as to, in a single motion, simultaneously rotate the vertebrae, as recited in claim 1 of the '358 Patent. PO Resp. 30.

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 '358 Patent. *Id.* at 7. 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, 2105)). However, Petitioner cites the '928 Appl. because claim element 1[F] recites applying force to a first handle means to simultaneously rotate the vertebrae, a feature that is not disclosed by the Cotrel-Dubousset method and system or by the Lenke References.

In our Decision to Institute, we noted that when knob 112b of the tool disclosed in the '928 App. 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. Dec. to Inst. 16 (citing *Medtronic v. Barry I*, 19). We also noted that adjusting knob 104a causes the same action relative to guide tubes 102a and 104. *Id.* Thus, unlike claim 1[F], which recites a single motion to rotate simultaneously a group of vertebrae, the '928 Appl. requires multiple motions and results in compression or distraction of the vertebrae. *Id.* at 16. Our Decision to Institute also noted Petitioner's argument 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. *Id.* at 16–17 (citing Pet. 24–25).

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. ¶ 52. 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 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 to distract or compress the vertebrae." Lenke Decl. ¶ 52. 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 application of force on one side of the spine would necessarily cause a rotation of the vertebrae.

Id.

Noting that the '928 Appl. provides no specific disclosure concerning the application of perpendicular forces to rotate the spine in spondylolisthesis reduction, we declined to institute on the basis that the '928 Appl. anticipates the '358 Patent. Dec. to Inst. 17–18. However, we instituted under 35 U.S.C. § 103 in view of Dr. Lenke's unrebutted testimony⁹ 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 rotation of the vertebrae. *Id.* at 18; Lenke Decl. ¶ 53.

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. Hrg. Tr. 32:22–25. Noting that paragraph 55 of the '928 Appl. refers to spondylolistheses reductions, Patent

⁹ Patent Owner did not file a Preliminary Response.

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. Ex. 2013, Declaration of Dr. Walid Yassir (“Yassir Decl.”) ¶¶ 96.

As noted above, paragraph 55 of the ’928 Appl. discusses the application of perpendicular force in the context of spondylolisthesis. Ex. 1006 ¶¶ 55. Patent Owner describes spondylolisthesis as the slippage of one vertebrae forward in relation to an adjacent vertebrae in the sagittal (front to back) plane. 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. Ex. 1043, Deposition Transcript of Dr. Walid Yassir (“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 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 “the 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 vertebra at the apex of the scoliotic curve are rotated about a much longer construct which is fixed above and below the vertebra being rotated.” *Id.* Dr. Yassir continues “[t]hose 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 we noted in our Decision to Institute, the ’928 Appl. does not mention spinal rotation. Dec. to Inst. 17–18. The 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 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.” Lenke Decl. ¶ 52. 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 18 (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 12–14. Petitioner calls 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. 37). 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 '358 Patent, which concerns surgeries involving long incisions and exposure of underlying tissue. PO Resp. 41–43 (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 16. Petitioner argues that Dr. Lenke “consistently testified that the '928 device is usable in the procedures described in the '358 Patent and is physically identical to instruments he personally used for such procedures, including those described in the Lenke References.” *Id.* (citing Lenke Decl. ¶¶ 49–53; 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 Appl." (Lenke Decl. ¶ 53), there is no testimony supporting Petitioner's assertion that 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.* at ¶¶ 5–6. Therefore, the '928 Appl. seeks to provide a "system and method for displacing, such as by compression and distraction, bony structures using a single device." *Id.* at ¶ 8.

The Summary of the Invention in the '928 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.* at ¶ 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 ’358 Patent that is the subject of this proceeding refers to “scoliosis” and associated “scoliosis curvature” and “severe twisting of the spine.” Ex. 1020, col. 1, ll. 15–20. 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 on the curvature of the spine.

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. Ex. 1006 ¶ 4. 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 (“As you grab it [the knob of the device disclosed in the '928 Appl.] and just move it up and down.”).

Petitioner contends that the application of force in a direction perpendicular to the pedicle screws is inherently done by grasping the handle of the at least one knob or an equivalent structure. Pet. 24. 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 moving upward (or downward) by an equal amount. *Id.* at 23. Although Dr. Lenke testifies rotation of the vertebrae would “naturally occur,” Dr. Lenke does not state explicitly whether such rotation is intended or incidental. Lenke Decl. ¶ 52. 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 attempting to rotate vertebrae, much less rotate them simultaneously using a single motion.

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 “applying manipulative force” to the first handle means “in a manner for simultaneously engaging” the first group of pedicle screw engagement members and pedicle screws “and thereby in a single motion simultaneously rotating” the vertebrae in which the pedicle screws

are implanted to ameliorate an aberrant spinal column deviation. 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 in which 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" that 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 rotation 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 simultaneously rotate in a single motion the vertebrae in which the pedicle screws are inserted.

In consideration of the above, Petitioner has not demonstrated by a preponderance of the evidence that claim 1 of the '358 Patent is obvious over the '928 Appl.

Claims 1–5 as Obvious Over the Combination of the '928 Appl. and the Lenke References

As there appears to be no dispute that the '928 Appl. discloses the features of claim 1, other than element 1[F], our analysis of this challenge again focuses on claim element 1[F]. We concluded above that Petitioner has not demonstrated by a preponderance of the evidence that claim element 1[F] would have been obvious to one of ordinary skill based on the disclosure in the '928 Appl. Petitioner contends that claim element 1[F] is also disclosed by the Video, the Slides, and MTOS. Pet. 35 (referencing claim charts at Pet. 47, 49). As previously discussed, Petitioner has not demonstrated by a preponderance of the evidence that the Video and the Slides are prior art that can be applied against the '928 Appl. Among the Lenke References, MTOS remains an applicable reference.

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 set of pedicle screws by engaging with the heads of the pedicle screws and a group of pedicle screw engagement members that are linked to the handles. Pet. 47. Figure 17-13 of MTOS appears to be reproduced as the middle image of three images in the claim chart on page 47 of the Petition, but does not illustrate a handle, only pedicle screw engagement members. *Id.* The word “Handles” is shown in the claim chart on page 47 of the Petition and with a line pointing to the image above the middle image (“the top image”). *Id.* The top image does not appear to be taken from MTOS. A third figure at the bottom of this section of the claim chart appears to be taken from the

Slides,¹⁰ and appears to identify a portion of each pedicle screw engagement member that is remote from the pedicle screw as a handle. *Id.* Petitioner cites the Apical Vertebral Derotation (AVD) maneuver in MTOS Figure 17-11 as disclosing the application of manipulative force to the group of handles that simultaneously engage the pedicle screws and thereby in a single motion simultaneously rotate the vertebrae in in which the pedicle screws are implanted. *Id.* (citing Ex. 1012, 242–243).

In *Medtronic v. Barry I*, we noted that 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. *Medtronic v. Barry I*, 22; Ex. 1012, 231.¹¹ 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.*, Ex. 1012 at 242. According to Dr. Lenke, because such 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. ¶ 48.

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

¹⁰ See, Ex. 1003 at 19. We do not consider the Slides or the Video prior art, but cite this image to identify Petitioner’s designations in MTOS.

¹¹ MTOS is Ex. 1012 in both *Medtronic v. Barry I* 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.

pressure is accomplished by the convex side screws, as shown in Figure 17-11. *Id.* at 242–245. 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 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.

Dr. Lenke asserts similarity between the device in the '928 Appl. and that disclosed in the Lenke References, “with the exception of a handle means formed from individual handles that are linked together.” Lenke Decl. ¶ 53. As our focus is on limitation 1[F], the use of the handle means to provide simultaneous engagement of pedicle screws and rotation of vertebrae in which the pedicle screws are implanted is a focus of our analysis.

Patent Owner contends that MTOS does not describe manipulating multiple posts simultaneously, nor does it show mechanically linked posts. PO Resp. 47 (citing Yasir Decl. ¶ 106). Dr. Lenke states that “[a]s shown in the MTOS chapter, the individual handles of each apical derotator are grasped simultaneously by the surgeon during the procedure.” Lenke Decl. ¶ 46. However, in his declaration, Dr. Lenke does not point to 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.* ¶ 47. 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 “applying manipulative force to [a] handle means in a manner for simultaneously engaging [a] group of pedicle screw engagement members and [a] set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted” as recited in claim element 1[F].

Patent Owner 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 the prior art because the prior art does not disclose explicitly the features recited in claim element 1[F]. *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. ¶ 53. 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 of a handle means formed from individual handles that 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 (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.

Lenke Decl. ¶ 53.

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 it would have been obvious to one of ordinary skill to use the tool disclosed in the '928 Appl. for derotation of the spine. *Id.*

Petitioner has not demonstrated a person of ordinary skill would have combined the teachings of the '928 Appl. and MTOS in a manner that would have produced the limitations of claim 1[F]. Patent Owner emphasizes the clear distinction between the open surgical procedures associated with treating scoliosis and the Lenke references, generally, and the minimally invasive procedures for which the tool in the '928 Appl. is adapted.. PO Resp. 50. 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 element 1[F]. 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 it would have been obvious to a person of ordinary skill from 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 the vertebrae would be rotated simultaneously, for example by linking the handles. 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 element 1[F]. As claim element 1[F] is common to all the claims, we conclude that Petitioner has not demonstrated that claims 1–5 would have been obvious over the combination of the '928 Appl. and MTOS.

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. 58. 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") 5–6.

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. 58. 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 '358 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 1–5 of the '358 Patent have not been 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.

IPR2015-00780
Patent 7,670,358 B2

PETITIONER

Jeff E. Schwartz
jeschwartz@foxrothschild.com
Seth A. Kramer
skramer@foxrothschild.com

PATENT OWNER

John Alemanni
jalemanni@kilpatricktownsend.com
Clay D. Holloway
cholloway@kilpatricktownsend.com