UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

STRYKER SPINE,

Plaintiff,

v.

Civil Action No. 08–1827 (CKK)

BIEDERMANN MOTECH GMBH, et al.,

Defendants.

MEMORANDUM OPINION

(November 15, 2010)

This case involves a dispute between Plaintiff Stryker Spine ("Stryker"), a French corporation, and Defendants Biedermann Motech GmbH ("Biedermann") and DePuy Spine, Inc. ("DePuy"), over a patent interference proceeding at the United States Patent and Trademark Office ("PTO"). Stryker seeks judicial review of decisions made by the PTO's Board of Patent Appeals and Interferences (the "Board") pursuant to 35 U.S.C. § 146. In a prior ruling issued on February 16, 2010, the Court denied Stryker's motions for summary judgment and granted-inpart and denied-in-part Defendants' motion for summary judgment. *See Stryker Spine v. Biedermann Motech GmbH*, 684 F. Supp. 2d 68 (D.D.C. 2010). The Court found that there were genuine issues of material fact relating to whether the Board erred by failing to redefine the interference count to account for two alleged patentably distinct inventions. Accordingly, the Court held a bench trial to hear the parties' evidence regarding this issue. This Memorandum Opinion sets forth the Court's findings of fact and conclusions of law.

The bench trial was held over two days on August 25 and 26, 2010. Stryker called one witness, Dr. Bret A. Ferree, to testify as an expert in the fields of orthopedic surgery, spinal

surgery, spinal bone fixation technology, and pedicle fixation assemblies. Defendants also called one witness, Dr. Erik K. Antonsson, to testify as an expert in the field of mechanical engineering and the application of mechanical engineering principles to orthopedic medical devices. Prior to the trial, Stryker filed a [66] Motion *in Limine* to Exclude Expert Testimony of Dr. Erik K. Antonsson. The Court took Stryker's motion *in limine* under advisement prior to and during the bench trial and allowed Dr. Antonsson to present his testimony on the record. Following the bench trial, the parties submitted proposed findings of fact and conclusions of law with citations to the record.

Having considered the evidence presented during the bench trial, the parties' proposed findings of fact and conclusions of law, the relevant authorities, and the record as a whole, the Court concludes that the Board properly declared a single interference count that does not encompass two patentably distinct inventions. Accordingly, Defendants are entitled to judgment on Stryker's claim that the Board erred by failing to redefine the interference count into two separate counts. Because the remainder of Stryker's claims are contingent upon a redefined interference count, the Court shall enter final judgment for Defendants and dismiss this action.

I. FINDINGS OF FACT¹

The following findings of fact are based on the administrative record,² the evidence

¹ Findings of fact may also be contained in the section entitled "Conclusions of Law," and vice versa. The substance of the finding or conclusion, rather than the characterization by the Court, controls.

² In a Minute Order dated March 6, 2009, the Court granted Stryker's unopposed motion to admit into evidence the administrative record of the proceedings in Interference No. 105,578. Pursuant to 35 U.S.C. § 146, the testimony and exhibits of the administrative record have the same effect as if originally taken and produced in this action. The administrative record was also admitted as Joint Exhibit 4 during the bench trial.

(testimony and exhibits) submitted by the parties during the bench trial, the parties' stipulations of undisputed facts, and the record as a whole.

A. Stryker's Patent (the '460 Patent)

Plaintiff Stryker Spine ("Stryker") is the assignee of U.S. Patent No. 6,974,460 ("the '460 Patent"), which is titled "Biased Angulation Bone Fixation Assembly." *See* Joint Ex. ("JX")³ 1 (the '460 Patent). John Carbone, Aaron Markworth, Michael Horan, and Yves Crozet are named as the inventors of the '460 Patent. *Id.*; Stip. Fact⁴ ¶ 4. The '460 Patent was issued on December 13, 2005. JX 1 at 1.

The invention described by the '460 Patent relates to spinal fixation devices, more specifically, pedicle fixation assemblies. JX 1 at col. 1, lines 12-14. Spinal fixation is a surgical technique in which surgical implants are used to fuse together and/or mechanically immobilize two or more vertebral bodies of the spinal column. *See id.* at lines 41-44. One technique for spinal fixation involves immobilizing the spine using orthopedic stabilizing rods, or spine rods, fastened with bone screws into the pedicles of vertebral bodies. *See id.* at lines 55-60. Under prior patents identified in the '460 Patent, the pedicle screw (or anchoring element) has a spherically shaped head that fits within a rod capturing assembly (which captures the spine rod) so as to permit movement of the assembly relative to the pedicle screw. *See id.* at col. 2, lines 29-40.

According to the inventors of the '460 Patent, there was a need for spinal fixation devices

³ The Court shall use the abbreviations "JX," "PX," and "DX," to refer to "Joint Exhibit," "Plaintiff's Exhibit," and "Defendants' Exhibit," respectively.

⁴ Citations to "Stip. Fact" refer to the parties' agreed stipulated facts as described in the Joint Pretrial Statement, ECF No. 64.

that provide a greater degree of angulation between the rod capturing assemblies and the

anchoring elements. Id. at lines 41-47. Therefore, one stated goal of the '460 Patent is to

provide for a bone fixation assembly that allows greater angulation so that the rod capturing

assembly can be manipulated to cover a broader range of angles for capturing an orthopedic

stabilizing rod. Id. at lines 64-67. A further goal of the '460 Patent is to provide for greater

"biased" angulation, meaning that there is greater angulation in one direction compared to

another. See id.; Tr. (8/25/10 AM) at 86:22-87:5 (Testimony of Dr. Bret Ferree).

The '460 Patent contains 39 claims, five of which are independent (claims 1, 18, 24, 33,

and 38). Stip. Fact ¶ 11. Independent claim 1 of the '460 Patent reads as follows:

1. A bone fixation assembly comprising:

- a coupling element having an inner surface defining a first bore coaxial with a first longitudinal axis and a second bore coaxial with a second longitudinal axis, wherein said first and second longitudinal axes intersect and are in communication with one another;
- said coupling element including a seat adjacent said lower end of said coupling element, said seat being defined by the inner surface of said coupling element; and
- an anchoring element assembled with said coupling element, said anchoring element having a first end for insertion into bone and a head spaced from the first end, said head being in contact with seat of said coupling element.

JX 1 at col. 15, lines 42-55; Stip. Fact ¶ 41. Claim 1 thus requires a coupling element with two

bores having intersecting longitudinal axes.

Independent claim 18 of the '460 Patent reads as follows:

18. A bone fixation assembly comprising:

a coupling element having an upper end defining a first plane, a lower end defining a second plane, and at least one bore extending from said upper end toward said lower end, wherein said first and second planes intersect one another; an anchoring element assembled with said coupling element, said anchoring element being adapted for insertion into bone; and

said coupling element having a U-shaped opening that extends from the upper end

of said coupling element toward the lower end of said coupling element, wherein said U-shaped opening is adapted to receive a stabilizing rod.

JX 1 at col. 16, lines 50-63; Stip. Fact \P 43. Claim 18 thus requires end surfaces defining planes, with the upper and lower planes intersecting. Claim 18 calls for "at least one bore" but does not require two bores.

B. Defendants' Patent Application & Suggestion of Interference

Defendant Biedermann is the assignee of U.S. Patent Application No. 10/763,431 ("the '431 Application"), which is titled "Bone Screw." Stip. Fact ¶ 9; JX 2 (the '431 Application) at 1. Defendant DePuy has been identified as the exclusive licensee of the '431 Application. Stip. Fact ¶ 10. The '431 Application was filed on January 22, 2004. Stip. Fact ¶ 22. The '431 Application claimed to be a continuation of Application No. 10/037,698, filed November 9, 2001, which claimed priority from German Application No. 10055888.7, filed November 10, 2000, and German Application No. 10065397.7, filed December 27, 2000. JX 2 at 1. The named inventors for the '431 Application are Lutz Biedermann and Jurgen Harms. Stip. Fact ¶ 8.

Like the '460 Patent, the '431 Application describes a device that connects a bone screw to a coupling element for the receipt of an anchoring rod. The abstract of the '431 Application reads as follows:

A bone screw having a screw member (1) possessing a threaded section (2) and a head (3) and a receiving part (5) at the head end for receiving a rod to be connected to the bone screw is provided. The receiving part (5) has on [sic] open first bore (6) and a substantially U-shaped cross-section having two free legs provided with a thread. Furthermore, the receiving part has a second bore (7) on the end opposite to the first bore (6) whose diameter is greater than that of the threaded section (20 and smaller than that of the head (3). On the bottom of the first bore a seat for the head (3) is provided. In order that the screw member can be pivoted to at least one side by an enlarged angle, the edge bounding the free end of the second bore (7) viewed relative to the axis of the first bore (6) is of asymmetric construction.

JX 2 at 1 (figures omitted).

On July 9, 2004, Beidermann filed a "Request for Declaration of Interference Under 37 CFR 1.604(a)" between the '431 Application and the application for the '460 Patent. See JX 3 ('431 Application File History) at DPS00558-69. Biedermann proposed two interference counts, one of which was directed to an "assembly or coupling element" as described by either claims 1-9, 11-13, 15-18, 20, 22-31, 34-37, 41 and 42 of the '460 Patent or claims 6-35 and 40-42 of the '431 Application, and the other of which was directed to a "method" as defined by either claims 44-47 of the '460 Patent or claims 36-39 of the '431 Application. JX 3 at DPS000559. On January 10, 2006, Biedermann filed a "Suggestion of Interference Under 37 CFR 41.202(a)" proposing only a single count of interference directed toward an assembly or coupling element. JX 3 at DPS000471-85. On May 16, 2007, Biedermann filed a "Supplemental Suggestion of Interference" with the PTO. See JX 3 at DPS000348-63. Biedermann proposed what it called a "Simplified McKelvey Count," defined as "[t]he assembly or coupling element of Carbone claims 1, 18, 24, 33, or 38, or the assembly or coupling element of Biedermann claims 6, 18, 28, 33 or 35." JX 3 at DPS000351. Biedermann explained that the simplified McKelvey count "has the advantage of combining the parties' independent claims, which are not patentably distinct from one another, while sweeping in the remaining dependent claims, which do not add features that render their subject matter as a whole each separately patentable over the parties' combined independent claims." Id.

C. The Interference Proceeding

On October 10, 2007, the Board issued a notice declaring Patent Interference No. 105,578

involving the '460 Patent and the '431 Application. Stip. Fact ¶ 12; Admin. R. ("AR") 2-7. Administrative Patent Judge (APJ) Jameson Lee was assigned to manage the interference proceeding. AR 3; Stip. Fact ¶ 29. The inventors of the '431 Application (Biedermann and Harms) were identified as the senior party, whereas the inventors of the '460 Patent (Carbone et al.) were identified as the junior party. AR 4; Stip. Fact ¶ 23. The interference was declared on the basis of a single count ("Count 1"), defined as claim 1, 18, 24, 33, or 38 of the '460 Patent or claim 6, 18, 28, 33, or 35 of the '431 Application. Stip. Fact ¶ 23; AR 5. All remaining claims of the '460 Patent and the '431 Application were said to "correspond to" the sole interference count, such that they would rise or fall with the count itself. Stip. Fact ¶ 23. The interference count was later redeclared to substitute Biedermann's claim 22 for Biedermann's claim 18. *See* AR 153-54; Stip. Fact ¶ 30.

During a motions conference held on December 5, 2007, Stryker explained its proposal to file a motion to redefine the interference by replacing Count 1 with two new counts, Count 2 and Count 3. Stip. Fact ¶ 31; AR 156-61. In an order dated December 6, 2007, APJ Lee authorized Stryker to file a motion to redefine the interference. Stip. Fact ¶ 32; AR 160. On February 15, 2008, Stryker filed its "Revised Substantive Motion 1" to redefine the interference. Stip. Fact ¶ 33; AR 307-59. Claims 1, 24, or 38 of the '460 Patent and claims 6, 28, or 35 of the '431 Application define what Stryker called proposed Count 2. Stip. Fact ¶ 37; AR 319. Claims 18 or 33 of the '460 Patent and claims 22 or 33 of the '431 Application define what Stryker called proposed Count 3. Stip. Fact ¶ 38; AR 320. In its motion, Stryker argued that Count 1 "includes two separate inventions which are patentably distinct from each other, and that it is therefore inappropriate to include these two separate inventions in a single count." AR 310. Stryker explained that the first invention, expressed by Count 2, is represented by claim 1 of the '460 Patent. AR 311. Stryker explained that the second invention, expressed by Count 3, is represented by claim 18 of the '460 Patent. AR 312. Accordingly, Stryker argued that claims 1 and 18 of the '460 Patent exemplify "entirely separate" inventions. AR 314. In support of its "Revised Substantive Motion 1," Stryker filed a declaration by Charles L. Bush, Jr. ("Bush Declaration"). *See* AR 329-51.

On April 30, 2008, a panel of the Board (APJs Schafer, Lee, and Moore) issued a Memorandum Opinion and Order which, *inter alia*, denied Stryker's Revised Substantive Motion 1. Stip. Fact ¶ 34; AR 468-81. The Board also entered judgment against Stryker in the Interference, cancelling claims 1-39 of the '460 Patent. Stip. Fact ¶ 34; AR 482-84. The Board began its written opinion by discussing the qualifications of Mr. Charles Bush as an expert, and the Board concluded that Mr. Bush was qualified to testify as to the knowledge of one skilled in the art in the field of bone fixation assemblies at the time of the invention(s). AR 471. However, the Board concluded that Mr. Bush did not offer testimony regarding what the knowledge of one skilled in the art was and did not provide evidence that his analysis of Count 1 and the two proposed Counts involved consideration of the level of ordinary skill in the art. *Id.* Therefore, the Board concluded that Stryker had failed to conduct an adequate legal analysis regarding the obviousness of proposed Count 2 over proposed Count 3, and vice versa. *See* AR 471-79. The Board explained:

When an interference involves more than one count, "each count must describe a patentably distinct invention." 37 C.F.R. § 41.201. Therefore, a party moving to redefine the interfering subject matter by dividing an existing count into two separate counts must establish that the existing count embodies two patentably distinct inventions. Two inventions are patentably distinct when the subject matter

of one invention if prior art, would not have anticipated or rendered obvious the subject of the second invention. The party filing a motion to redefine the subject matter of an interference has the burden of proof.

Establishing nonobviousness in a motion to redefine an interference requires the same factual inquiries required under a [sic] 35 U.S.C. § 103 to determine whether an invention is obvious, i.e., (1) the scope of and content of the prior art; (2) the differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, such as unexpected results. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

Therefore, to establish a prima facie case of nonobviousness, the movant must address not only the differences between the proposed new counts, but also the scope and content of the prior art and the level of ordinary skill in the art, to arrive at any conclusion of nonobviousness. Comparing the differences between the proposed new counts without adequately addressing the scope and content of the prior art and the level of ordinary skill in the art does not satisfy the burden of establishing prima facie nonobviousness. *See Pechiney Emballage Flexible Europe v. Cryovac, Inc.*, 73 USPQ2d 1571 (Bd. Pat. App. & Int. 2004).

Stip. Fact ¶ 39; AR 473.

On May 30, 2008, Stryker sought rehearing of the judgment and denial of its motion to redefine the interference. Stip. Fact ¶ 35; AR 485-527. On August 27, 2008, a panel of the Board (APJs Schafer, Lee, and Moore) issued a written decision denying Stryker's request for rehearing. *See* AR 528-38.

D. Stryker's § 146 Proceeding

Stryker elected to review the Board's decision and conduct further proceedings before a district court pursuant to 35 U.S.C. § 146. In its First Amended Complaint, Stryker demands, *inter alia*, a declaratory judgment that the claims at issue in the interference are directed to two separate and patentably distinct inventions corresponding to proposed Counts 2 and 3. Stip. Fact ¶ 36; First Am. Compl. at 36-37. In ruling on the parties' cross-motions for summary judgment, the Court determined that there were genuine issues of material fact with respect to this issue and

ordered that the parties present further evidence at a bench trial.

E. Evidence Presented During the Bench Trial

As Stryker's counsel explained in his opening statement, the sole issue at trial was "whether the Board of Patent Appeals and Interferences of the Patent and Trademark Office erroneously declared and adjudicated an Interference . . . as being addressed to a single count which was treated as a single invention." Tr. (8/25/10 AM) at 5:10-14. The invention described by Stryker's proposed Count 2 is also known as the "intersecting bores" or "intersecting axes" invention. Tr. (8/25/10 AM) at 48:15-20. The invention described by Stryker's proposed Count 3 is also known as the "intersecting planes" invention. *Id.* at 48:21-24. Stryker presented one witness, Dr. Bret Ferree, in support of its contention that the Board erred. Biedermann presented one witness, Dr. Erik Antonsson, to rebut Dr. Ferree's testimony.

1. Dr. Ferree

Dr. Bret A. Ferree is a board-certified orthopedic surgeon specializing in spinal surgery. Tr. (8/25/10 AM) at 20:2-4. Dr. Ferree attended college at Case Western Reserve University, where he received a degree in psychology and natural sciences. *Id.* at 20:5-13. Dr. Ferree attended medical school at the University of Cincinnati College of Medicine, graduating with an M.D. degree in 1986. *Id.* at 21:8-16. He graduated in the top five percent of his medical school class and was elected into Alpha Omega Alpha, the national medical honor society. *Id.* at 21:21-22:7. Dr. Ferree subsequently completed a five-year residency in orthopedic surgery at the University of Cincinnati. *Id.* at 23:4-24:6. During his residency, Dr. Ferree received training in spinal surgery and participated in hundreds of spinal surgeries. *Id.* at 25:7-26:2, 27:5-11. Between 1991 and 1992, Dr. Ferree completed a fellowship in the departments of orthopedic surgery and neurosurgery at Tufts University in Boston. *Id.* at 26:7-11. During his fellowship year, Dr. Ferree focused on complex spinal surgery and participated in about 350 spinal operations. *Id.* at 26:17-27:11. From 1992 to 2000, Dr. Ferree joined a practice known as Wellington Orthopedic and Sports Medicine, performing almost 400 spinal surgeries per year by the year 2000. *Id.* at 27:12-22. From 2000 to 2006, Dr. Ferree became a solo practitioner exclusively performing spinal surgery. *Id.* at 27:23-25. Since 2006, Dr. Ferree has devoted his time to the research and development of spinal devices and technologies. *Id.* at 28:1-5.

Dr. Ferree was board certified in 1995 by the American Board of Orthopedic Surgeons and is licensed to practice medicine in the state of Ohio. *Id.* at 28:6-13. He has experience as a clinical instructor, assistant professor, and research lecturer, and he has made numerous presentations at professional conferences relating to spinal surgery. *Id.* at 29:13-19, 30:5-19; PX 6 (Curriculum Vitae of Bret A. Ferree, M.D.) at 3-5. Dr. Ferree has authored or coauthored many professional publications, with a focus on spinal surgery with emphasis on fixation systems, including pedicle fixation systems and complications related to the spinal surgeries. Tr. (8/25/10 AM) at 30:20-31:7; PX 6 at 5-6. Dr. Ferree has also been involved in inventing or developing devices in the field of spinal fixation technology, and he is the named inventor on approximately 50 patents and 140 patent applications in the United States and internationally. Tr. (8/25/10 AM) at 31:23-32:5; PX at 6-7.

Dr. Ferree has extensive experience with pedicle screw systems. He led a team of engineers in designing and developing a device involving pedicle screws which has been used on approximately 30,000 or more patients in the United States and internationally. Tr. (8/25/10 AM) at 34:16-35:6. During his career as a surgeon, Dr. Ferree inserted over a thousand pedicle

screws in hundreds of patients ranging from teenagers to patients in their eighties. Id. at 35:7-25.

Without objection from Defendants, the Court qualified Dr. Ferree as an expert in the fields of orthopedic surgery, spinal surgery, spinal bone fixation technology, and pedicle fixation assemblies. *See* Tr. (8/25/10 AM) at 36:17-37:7.

Dr. Ferree explained that a pedicle screw is a metal screw generally accompanied by a coupling component of the screw or within the assembly that is screwed into the individual vertebra. Tr. (8/25/10 AM) at 37:20-25. Typically, two pedicle screws are used in each vertebra, and these pedicle screws are then connected together by a rod, which is held in place by screws within the pedicle screw. *Id.* at 37:25-38:3. The purpose of this system is to align the spine and hold it in the proper alignment during the fusion process, i.e., when two or more vertebrae are fused together. *Id.* at 38:4-10.

Dr. Ferree further testified that the first pedicle screws he used during the 1980s were single components with a thread on one end, to be screwed into the vertebra, and a U-shaped seat on the other end, into which rods were inserted. Tr. (8/25/10 AM) at 40:3-8. Dr. Ferree explained that the problem with these types of devices was that the spinal rods would need to be bent in order to fit into a series of pedicle screws, and bending the rods was difficult. *Id.* at 40:11-16. Dr. Ferree explained that beginning around approximately 1992, the pedicle screws were separated into two components, a coupling component and a screw component. *Id.* at 40:20-24. This enabled the coupling element to swivel relative to the screw component, making it easier to align the rods with the coupling element of the screws. *Id.* at 40:23-41:1.

Dr. Ferree explained that the inventions in the '460 Patent and the '431 Application improved upon these prior screw systems by increasing the angulation permitted between the axis of the screw and the axis of the coupling element in at least one plane, making it easier for pedicle screws to be inserted into areas of the spine with large curvatures or deformities, such as the neck. Tr. (8/25/10 AM) at 41:2-24.

Dr. Ferree opined that as of November 2000, a person of ordinary skill in the field of bone fixation relating to the spine and spinal problems would fall into one of two categories. *See* Tr. (8/25/10 AM) at 44:8-17. The first category would be persons with an engineering degree and several years' experience designing medical devices. *Id.* at 44:17-19. Dr. Ferree later explained that a mechanical engineering degree would qualify and that "several years" means three or four or more years. *Id.* at 106:3-9. The second category would be surgeons who have used a variety of these spinal devices and who have been involved in designing medical devices and medical technologies. *Id.* at 44:20-23. Dr. Ferree testified that as of November 2000, he had worked with many individuals who fell into each of these categories, and he considered himself to be a person in the second category as of November 2000. *Id.* at 44:24-45:14.

Before trial, Dr. Ferree reviewed the '460 Patent and its drawings, written specification, and claims. Tr. (8/25/10 AM) at 46:12-17. Dr. Ferree testified that in his opinion, the '460 Patent contains at least two inventions. *Id.* at 46:18-22. The first invention, described by claims 1, 24, and 38 of the '460 Patent, calls for a coupling element with two bores that have longitudinal axes that intersect. *Id.* at 46:23-47:18. Dr. Ferree explained that a "bore" means an "elongate cylindrical hollow area within the coupling component." *Id.* at 47:11-14. The second invention, described by claims 18 and 33 of the '460 Patent, calls for a coupling element having an upper and lower end defining planes that intersect. *Id.* at 47:19-48:14. Claim 18 does not make any reference to intersecting axes or intersecting bores. *Id.* at 48:5-7. Claim 1 does not make any reference to intersecting planes. Id. at 48:8-10.

Dr. Ferree testified that Figure 2 of the '460 Patent illustrates a device that incorporates the intersecting bores invention but not the intersecting planes invention. Tr. (8/25/10 AM) at 49:2-50:2; JX 1 at Fig. 2. Figure 2 is described as "a simplified view of a pair of bone fixation assemblies coupled with an orthopedic stabilizing rod, in accordance with certain preferred embodiments of the present invention." JX 1 at col. 5, lines 52-56. Figure 2 does not purport to identify prior art. See Tr. (8/25/10 AM) at 50:4-51:7. In the drawing, it appears that the upper and lower ends of the assemblies are parallel, i.e., not intersecting. See JX at Fig. 2. However, Figure 2 does not show the internal geometry of the coupling element. See id.; Tr. (8/25/10 AM) at 51:14-16. According to Dr. Ferree, a person of ordinary skill in the art of bone fixation relating to the spine and spinal problems as of November 2000 would conclude that the device shown in Figure 2 has two bores, one that enables the insertion of a screw and one that holds the rod in place, and that those bores intersect one another. Tr. (8/25/10 AM) at 51:17-53:7. Therefore, according to Dr. Ferree, a person of ordinary skill in the art of bone fixation relating to the spine and spinal problems as of November 2000 would have recognized Figure 2 as embodying only the intersecting bores invention and not the intersecting planes invention. *Id.* at 80:2-9.

Dr. Ferree opined that the intersecting bores invention and the intersecting planes invention can be used separately and independently, or they may be used together. Tr. (8/25/10 AM) at 80:18-25.

Dr. Ferree opined that a person of ordinary skill in the art as of November 2000 would not have found the intersecting planes claims obvious over the intersecting bores claims. Tr. (8/25/10 AM) at 82:22-83:1. Dr. Ferree explained that the basis for this opinion was the fact that the intersecting planes claims, such as claim 18 of the '460 Patent, focus on the external geometry of the coupling element (i.e., the top, bottom, and sides of the coupling element) and do not describe whether the coupling element has intersecting bores. *Id.* at 83:2-8, 18-21. Similarly, the intersecting bores claims, such as claim 1 of the '460 Patent, describes only the internal geometry of the coupling element (i.e., the bores and the seat) and makes no mention of intersecting planes. *Id.* at 83:9-17. For the same reasons, Dr. Ferree also opined that a person of ordinary skill in the art as of November 2000 would not have found the intersecting bores claims obvious in view of the intersecting planes claims. Tr. (8/25/10 AM) at 83:22-84:15.

Dr. Ferree explained that in his view, the intersecting bores invention is more advantageous than the intersecting planes invention because it allows for greater angulation of the screw without removing any portion of the seat, which could compromise the stability of the screw. *See* Tr. (8/25/10 AM) at 84:19-85:22. The "seat" of the coupling element is designed to capture the head of the screw so as to prevent the screw from falling or being pulled out of the coupling element. *See id.* at 63:5-18. Dr. Ferree compared the embodiment illustrated in Figure 7 of the '460 Patent (and modeled three-dimensionally by PX 11⁵), which shows increased angulation without removal of the seat, with the embodiment illustrated in Figure 3 of the '431 Application (and modeled three-dimensionally by PX 13), which shows that increased angulation is achieved by removing part of the seat. *Id.* at 85:3-22. Dr. Ferree testified that the ordinary

⁵ Prior to the trial, Dr. Ferree worked with Stryker to create three-dimensional models that fairly depict, in Dr. Ferree's view, the important features of certain figures drawn in the '460 Patent and the '431 Application. Tr. (8/25/10 AM) at 55:13-58:13. The Court admitted these models as demonstrative exhibits, designated as Plaintiff's Exhibits 10, 11, 12, and 13. *Id.* at 59:14-24.

skilled artisan would have understood this advantage of the intersecting bores invention over the intersecting planes invention. *Id.* at 94:24-95:2, 95:20-96:9.

Dr. Ferree testified that the ordinary skilled artisan would understand that the object of both the intersecting bores invention and the intersecting planes invention—as described in claims 1 and 18 of the '460 Patent—is to achieve a greater angulation in at least one direction as compared to another, i.e., biased angulation. Tr. (8/25/10 AM) at 86:22-87:5.

Dr. Ferree testified, and the Court agrees, that Figure 7 of the '460 Patent is an embodiment of both claim 1 and claim 18.⁶ Tr. (8/25/10 AM) at 96:10-14, 20-24. Dr. Ferree also testified that Figure 7 would have been an obvious embodiment of claims 1 and 18 to an ordinary skilled artisan reading the '460 Patent in November 2000. *Id.* at 96:16-19, 96:25-97:3.

Dr. Ferree testified that an ordinary skilled artisan as of November 2000 would have understood that the most common way to end a bore is in a plane perpendicular to the axis of the bore, and that this would have been obvious to the skilled artisan. Tr. (8/25/10 AM) at 103:3-17. The bores shown in Figure 7 each end in planes that are perpendicular to their axes. *See id.* at 103:18-104:3; JX 1 at Fig. 7.

Plaintiff's Exhibit 10 is a model created by Dr. Ferree representing the embodiment described in Figure 2 of the '460 Patent. *Id.* at 60:2-6. The angle between the first bore and second bore in Plaintiff's Exhibit 10 is less than the angle shown in Figure 2, however. *Id.* at 107:19-24. Dr. Ferree also testified that the U-shaped opening in Plaintiff's Exhibit 10 extends below the intersection of the bores, which is lower than what is illustrated in Figure 2. *Id.* at

⁶ Except where stated otherwise, all references to claims and figures are to the '460 Patent.

107:25-108:13. Dr. Ferree explained that he believed, based on the written specification and other embodiments in the '460 Patent, that the rod should go low enough to articulate with the head of the screw that goes into the coupling device, to help immobilize the screw. *Id.* at 108:4-109:19. Dr. Ferree also admitted that the other figures on which he relied all had intersecting planes and not just intersecting bores. *Id.* at 109:12-19. Dr. Ferree testified that in Plaintiff's Exhibit 10, the screw does not substantially angulate more to the left than to the right, with any difference being a matter of a few degrees. *Id.* at 114:5-16. Dr. Ferree thus testified that it is possible that the embodiment in Figure 2 would not achieve the object of the invention in allowing greater biased angulation. *Id.* at 119:23-120:4.

Plaintiff's Exhibit 13 is a model created by Dr. Ferree representing the embodiment described in Figure 3 of the '431 Application. Tr. (8/25/10 AM) at 74:16-23. Plaintiff's Exhibit 13 represents the intersecting planes invention but not the intersecting bores invention. *Id.* at 76:14-20; 114:22-25. Dr. Ferree testified that the screw in Plaintiff's Exhibit 13 clearly angulated more to the right than to the left. *Id.* at 115:1-5. Dr. Ferree conceded that his model of the intersecting planes invention in Plaintiff's Exhibit 13 allows greater favored angulation than his model of the bores invention in Plaintiff's Exhibit 10. *Id.* at 115:6-10. Dr. Ferree agreed that if the seat in the coupling element is sufficient to hold the screw in position, the intersecting planes invention in Figure 3 of the '431 Application would be better than the intersecting bores invention alone. *Id.* at 115:11-16.

Dr. Ferree testified that it would obvious to the skilled artisan in November 2000 reading claim 18 to make a bone fixation assembly comprising a coupling element and an anchoring element, such as a screw with a round head. Tr. (8/25/10 PM) at 4:9-23. He further testified that

it would obvious that the top end of the coupling element defines a first plane and the bottom end defines a second plane, with one or more bores going from the top plane to the bottom plane. *Id.* at 5:8-13. However, Dr. Ferree testified that he was not convinced that it would be obvious to the skilled artisan in November 2000 to seek a solution that has two bores. *Id.* at 6:17-7:24. Dr. Ferree confirmed that during his deposition, he had testified that it would be obvious to use one bore and also obvious that two bores could be used. *Id.* at 9:15-24. Dr. Ferree also testified that in his opinion, the most obvious solution using two bores would involve colinear bores of different sizes, not bores with intersecting axes. *Id.* at 10:4-20. However, he conceded that such an arrangement would actually constitute a single bore as defined in the '460 Patent, not multiple bores. *Id.* at 10:21-11:2.

During Dr. Ferree's cross-examination, counsel for Defendants drew a diagram that was admitted into evidence as Defendants' Exhibit 10. *See* Tr. (8/25/10 PM) at 12:21-24. Dr. Ferree conceded that the diagram in Defendants' Exhibit 10 was drawn based on the information in claim 18. *Id.* at 13:20-22. Dr. Ferree testified that Defendants' Exhibit 10 depicts a coupling element that has a top end that defines a plane and a bottom end that defines a plane, and those planes intersect. *Id.* at 13:2-8. Dr. Ferree explained that the ordinary skilled artisan would understand that there needs to be a seat to hold the screw in place, and the ordinary way to form that seat would be with an axis perpendicular to the bottom surface of the coupling element. *Id.* at 12:6-16. Dr. Ferree also testified that the ordinary way to machine a seat would have been to cut an angled bore into the bottom end. *Id.* at 12:17-19. Dr. Ferree testified that the seat may be considered to be a part of the bore. *See* Tr. (8/25/10 AM) at 72:22-73:4, 92:1-93:21. Therefore, Dr. Ferree agreed that Defendants' Exhibit 10 shows two intersecting bores, with intersecting

axes. Tr. (8/25/10 PM) at 13:9-12. Dr. Ferree testified that the diagram in Defendants' Exhibit 10 meets all the limitations of claim 1 of the '460 Patent. *Id.* at 13:16-19.

Defendants' Exhibit 9 is a CAD drawing that represented one version of Figure 2 of the '460 Patent, with intersecting bores but parallel planes. Tr. (8/25/10 PM) at 13:23-14:8. In Defendants' Exhibit 9, the screw head is touching the seat of the coupling member at a lower part on the left of the drawing than on the right. *Id.* at 14:17-22. Dr. Ferree testified that the ordinary skilled artisan would understand, if he tried to fabricate Figure 2 using physical or CAD models, that there was excess metal on the right side that could be machined off without having any impact on the screw. *Id.* at 14:25-15:15. In fact, Dr. Ferree explained that there would be motivation to remove this excess material because it would allow for greater angulation of the screw, thereby achieving the object of the invention. *Id.* at 15:25-16:14. Therefore, Dr. Ferree testified that it would be obvious for the ordinary skilled artisan doing work on a parallel planes embodiment with intersecting bores to remove excess material from one side of the lower end of the coupling element. *Id.* The result of removing that material would be an embodiment that has both intersecting bores and intersecting planes.

2. <u>Dr. Antonsson</u>

Dr. Erik K. Antonsson is the director of research for the Northrop Grumman Aerospace Corporation and a faculty associate at the California Institute of Technology. Tr. (8/25/10 PM) at 33:16-24. Dr. Antonsson earned a Ph.D. from the Massachusetts Institute of Technology ("MIT") in 1982 and served on the faculty of the California Institute of Technology for 25 years as a professor of mechanical engineering. *Id.* at 33:4-16, 39:16-40:3. During his graduate studies at MIT, Dr. Antonsson worked under the supervision of Professor Robert W. Mann in the field of engineering design applied to biomechanics. *Id.* at 34:17-23. After receiving his doctoral degree, Dr. Antonsson worked as a researcher at MIT and at Massachusetts General Hospital, focusing on biomechancial research. *Id.* at 36:23-37:10. During his academic career and continuing to the present, Dr. Antonsson consults as an expert witness in intellectual property cases, including some involving orthopedic medical devices in which he was qualified to testify about the design of spine devices. *Id.* at 40:4-17. Dr. Antonsson could recall at least three such cases within the last five years, and a fourth such case at some earlier point in time. *Id.* at 56:9-57:1, 59:5-60:20.

Defendants moved to qualify Dr. Antonsson as an expert in the field of mechanical engineering and the application of mechanical engineering principles to orthopedic medical devices. Tr. (8/25/10 PM) at 42. Stryker objected, and the Court took the objection to his expert testimony under advisement. *Id.* at 62:23-25. The Court finds that Dr. Antonsson is qualified to give expert testimony regarding the field of mechanical engineering and the application of mechanical engineering principles to orthopedic medical devices.⁷ The Court acknowledges that the most of Dr. Antonsson's experience relating to biomechanics dates back to his early academic career, and the Court considers this fact in weighing his opinions.

Dr. Antonsson testified that in preparation for his testimony, he had reviewed the expert report and deposition testimony of Dr. Ferree, the '460 Patent and the '431 Application, and the administrative record in the interference proceeding. Tr. (8/25/10 PM) at 63:18-25. Dr. Antonsson did not consider any other prior art. *Id.* at 65:3-5.

⁷ For this reason, the Court DENIES Stryker's [66] Motion *in Limine* to Exclude Expert Testimony of Dr. Erik K. Antonsson.

Dr. Antonsson opined that a person of ordinary skill in the art relating to the inventions at issue in this case would be a person who, as of November 2000, holds a four-year bachelor's degree from an accredited institution in mechanical engineering or biomechanics, or a surgeon with some experience in designing spinal implant devices. *Id.* at 66:18-22, 67:12-19. Dr. Antonsson testified that he qualifies as a person of ordinary skill in the art under his definition. *Id.* at 67:9-11.

Dr. Antonsson testified that in his opinion, claim 18 would be obvious to a person of ordinary skill in the art as of November 2000 based on claim 1. Tr. (8/25/10 PM) at 68:10-16. Dr. Antonsson explained that although claim 1 does not specifically address the ends of the coupling element or the planes defined by them, a person of ordinary skill in the art would understand that bores have ends, i.e., they are not of infinite length, and that those ends are defined by planes. *Id.* at 69:22-71:16. Dr. Antonsson further testified that the conventional way to make a bore is to create a hole with an axis perpendicular to the plane that bounds it, as this enables the bore to be fabricated in a precise and controlled manner. Id. at 75:12-76:5. Dr. Antonsson explained that it is harder to fabricate an oblique bore opening because, in such a circumstance, the cutting tool is only cutting material for a portion of its revolution, producing a less precise cut and possibly damaging tools or leaving tool marks. *Id.* at 76:8-17. Dr. Antonsson opined that a person of ordinary skill in the art would understand that the standard and most obvious configuration of a bore is for its axis to be perpendicular to the plane that ends it. Id. at 76:19-77:3. Dr. Antonsson testified that Figure 7 of the '460 Patent is an example of this conventional configuration. Id. at 77:18-78:23. Dr. Antonsson also testified that Figure 7 captures every element of claim 18. Id. at 80:4-6.

Dr. Antonsson testified that in his opinion, a person of ordinary skill in the art would not, based on claim 1, create a device with the configuration shown in Defendants' Exhibit 9. Tr. (8/25/10 PM) at 83:8-16. Dr. Antonsson explained that the configuration is Defendants' Exhibit 9 is not an obvious configuration because (a) it deviates from the convention of having bores with axes perpendicular to their end planes and (b) it has a seat with excess, i.e., unnecessary material on one side that, if removed, would facilitate greater angulation of the screw in accordance with the object of the invention. *Id.* at 83:17-85:15.

Dr. Antonsson also testified that in his opinion, claim 1 would be obvious to a person of ordinary skill in the art based on claim 18. Tr. (8/25/10 AM) at 86:21-87:6. Dr. Antonsson opined that it would be obvious to use two bores based on the language "at least one bore" in claim 18. *Id.* at 87:13-24. Dr. Antonsson further opined that it would be obvious to a skilled artisan to make a two-bored device such that the axes of the bores intersect. *Id.* at 87:25-88:11. Dr. Antonsson explained that the bases for this opinion are the conventional arrangement of bores having axes perpendicular to the surfaces from which they extend and the desire to achieve increased angulation. *Id.* at 90:15-91:3.

F. Finding Regarding the Level of Skill in the Relevant Art

The Court finds that as of November 2000, a person with the ordinary level of skill in the art of spinal bone fixation devices would be a person who understands both the medical need for such devices and the mechanical operation of such devices, developed through a combination of professional training and experience. The Court finds that the definitions of an ordinary skilled artisan proffered by Drs. Ferree and Antonsson and substantially the same. Therefore, the Court finds that both Dr. Ferree and Dr. Antonsson are persons of at least ordinary skill in the relevant

art as of November 2000.

II. LEGAL STANDARD

This action is brought pursuant to 35 U.S.C. § 146, which states in pertinent part that "[a]ny party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action" Judicial review under section 146 is "described as a hybrid of an appeal and a trial *de novo*." *Estee Lauder Inc. v.* L'Oreal, S.A., 129 F.3d 588, 592 (Fed. Cir. 1997). "Questions of law are reviewed de novo, but the underlying factual determinations made by the Board are reviewed for clear error." Abbott *GMBH & Co. KG v. Yeda Research & Dev. Co, Ltd.*, 576 F. Supp. 2d 44, 49 (D.D.C. 2008) (citing Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000)). An action brought under § 146 is essentially a proceeding to review the action of the Board. Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994). "A party may not . . . advance new legal theories at the trial court level, even if the overarching legal issue was presented below." Boston Sci. Scimed, Inc. v. Medtronic Vascular, Inc., 497 F.3d 1293, 1298 (Fed. Cir. 2007). The record below may be admitted by either party, but the parties may also "take further testimony." See 35 U.S.C. § 145; see also Agilent Tech., Inc. v. Affymetrix, Inc., 567 F.3d 1366, 1379 (Fed. Cir. 2009). However, the parties' right to offer new evidence is limited to issues raised by the parties during the proceedings below or by the Board's decision. Widmayer, 21 F.3d at 1102. If the district court accepts new evidence not previously before the Board, the Court must make de novo factual findings for issues on which the court accepts new evidence. Yeda Research & *Dev.*, 576 F. Supp. 2d at 49.

III. CONCLUSIONS OF LAW

The sole legal issue to be decided by the Court is whether the PTO erred by improperly declaring and refusing to redefine the single interference count. Stryker's position is that the Board erred by failing to redefine the interference count as two separate counts—one for the "intersecting axes" invention as described by claims 1, 24, and 38 of the '460 Patent and another for the "intersecting planes" invention described by claims 18 and 33 of the '460 Patent. Stryker claims that these inventions are patentably distinct and that the Board erred as a matter of law by declaring an interference based on a single count containing both inventions. Stryker thus asks this Court to reverse the Board's decision and either remand for further proceedings or rule on Stryker's contingent motions for summary judgment as to unpatentability and lack of written specification or enabling disclosure.⁸ Defendants claim that, based on the record before the Board and before this Court, Stryker cannot establish that its two proposed interference counts are patentably distinct and therefore Defendants are entitled to judgment.

A. The Interference Count and the Test for Patentable Distinctness

According to PTO regulations, a "count" is "the Board's description of the interfering subject matter that sets the scope of admissible proofs on priority." 37 C.F.R. § 41.201. "Where there is more than one count, each count must describe a patentably distinct invention." *Id.* The parties agree that to prevail, Stryker must show that the inventions in proposed Counts 2 and 3 are patentably distinct from each other. Two inventive claims are patentably distinct when one of

⁸ Stryker filed two such motions: [32] Motion for Summary Judgment Regarding Defendants' Failure to Comply with 35 U.S.C. § 112 and [33] Motion for Summary Judgment Regarding Unpatentability of Defendants' Claims Under 35 U.S.C. §§ 102 and 103. Because success on these motions is contingent upon the redefinition of the interference count, the Court previously denied these motions as premature. *See* 684 F. Supp. 2d at 102.

the claims anticipates or renders obvious the other claim when considered as prior art. *See Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1268 (Fed. Cir. 2003) ("Invention 'A' is the *same patentable invention* as invention 'B' when invention 'A' is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention 'B' assuming invention 'B' is prior art with respect to invention 'A.'" (citation omitted)); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 986 (Fed. Cir. 2001) ("A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim."). Accordingly, Stryker must establish that the invention in proposed Count 2 is patentable over the invention in Count 3 as prior art, and vice versa. *Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d at 1268. Whether a claim is patentably distinct from another is a question of law that is reviewed de novo. *In re DBC*, 545 F.3d 1373, 1377 (Fed. Cir. 2008).

The only disputed issue regarding patentable distinctness is obviousness—whether the "intersecting axes" invention is obvious over the "intersecting planes" invention as prior art, and vice versa.⁹ "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). There are several basic factual inquiries associated with determining whether an invention is obvious: (1) the scope and content of prior art; (2) the differences between the claimed subject matter and the prior art; and (3) the level of

⁹ The parties have not argued, and the Board did not find, that either of Stryker's proposed counts were invalid for anticipation. Anticipation defeats patentability and occurs when each and every claim limitation is disclosed in a prior art reference, either explicitly or implicitly. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1323-24 (Fed. Cir. 2008); *see* 35 U.S.C. § 102.

ordinary skill in the pertinent art. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). Where appropriate, a court should also look to secondary factors that may be relevant to the obviousness analysis, such as commercial success, long felt but unsolved needs, and failure of others. *Graham*, 383 U.S. at 17-18; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007) (reaffirming *Graham*).

"Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains." In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998). This person skilled in the art is akin to the "reasonable person" used as a reference in negligence determinations, and the person is presumed to have knowledge of all relevant prior art references. Id. Most, if not all, inventions are combinations of elements from prior art. Id. A court may not rely on hindsight in order to show that an invention is obvious; rather, it must show "reasons why the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." Id. There are at least three possible sources for a motivation to combine prior art references: (1) the teachings of prior art; (2) the knowledge of persons of ordinary skill in the art; and (3) the nature of the problem to be solved. Id. The Supreme Court has stated that this inquiry—known as the "teaching, suggestion, or motivation" test—should be made flexibly, with an appreciation for the role that common sense may play in the inventive process. See KSR Int'l, 550 U.S. at 407, 415, 420 (2007). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421. "The ultimate determination of whether an invention would have been obvious is a legal conclusion based on

underlying findings of fact." In re DBC, 545 F.3d at 1377.

B. The Obviousness of Stryker's Proposed Counts

In conducting an obviousness analysis, the Court considers all of the relevant factors described above. The Court has heard testimony from two experts whom it finds to possess at least an ordinary level of skill in the relevant art. Neither of these experts considered any prior art other than the alternative proposed interference counts, as the test for patentable distinctness requires each proposed count to be considered prior art to the other.¹⁰ The parties have also not presented any evidence of secondary factors that are relevant to the obviousness analysis. Accordingly, the Court focuses primarily on the level of ordinary skill in the art and the differences between the proposed interference counts, as defined by claims 1 and 18 of the '460 Patent.

Stryker asks the Court to agree with Dr. Ferree's opinion testimony that the intersecting bores invention as described by claim 1 would not be obvious to a person skilled in the art based on the intersecting planes invention as described by claim 18 as prior art. This testimony effectively amounts to a legal conclusion that claims 1 and 18 represent patentably distinct inventions. However, for the reasons explained below, the Court does not find Dr. Ferree's testimony on this point to be persuasive.

When asked to explain why he did not think it would be obvious for the skilled artisan to intuit that the invention described in claim 1 could have intersecting planes, Dr. Ferree simply

¹⁰ Defendants argue that Stryker's failure to present evidence regarding any other prior art is fatal to its claim. However, the Court finds that it is unnecessary to address this argument because it concludes that Stryker's proposed counts are not patentably distinct without considering other prior art.

testified that claim 1 focuses only on the "internal geometry" of the coupling element and therefore it does not say anything about intersecting planes. However, that testimony merely establishes that claim 1 does not anticipate claim 18; it does not do anything to explain how the ordinary skilled artisan would have constructed the "external geometry" of the coupling element based on claim 1. Dr. Ferree focused his testimony on Figure 2 of the '460 Patent, the only embodiment of claim 1 that has what appear to be parallel planes. But when Dr. Ferree created a three-dimensional working model based on Figure 2, he created a model that did not provide for any meaningful degree of favored angulation, one of the objects of the invention. Dr. Ferree also testified that the ordinary skilled artisan would understand from a CAD drawing based on Figure 2 that it would be advantageous to remove excess material from one side of the lower end, which would result in an invention with intersecting planes. Moreover, Dr. Ferree did not testify that Figure 2 was the only obvious embodiment of claim 1. To the contrary, he agreed that Figure 7, which contains intersecting planes and all of the other limitations of claim 18, was also an obvious embodiment of claim 1. And Dr. Ferree agreed that the ordinary skilled artisan would have understood that the most common way for a bore to end would be in a plane perpendicular to the axis of the bore. Therefore, Dr. Ferree's testimony supports the conclusion that the ordinary skilled artisan reading claim 1 would have found it obvious to create an invention with intersecting planes.

Similarly, when asked to explain why it would not be obvious for the skilled artisan to intuit that the invention described in claim 18 could have bores with intersecting axes, Dr. Ferree's answer was that claim 18 does not say anything about the internal structure of the bores. As noted above, however, this testimony merely establishes that claim 18 does not anticipate claim 1; it does not explain how the ordinary skilled artisan would go about constructing the invention in claim 18 without intersecting bores. Dr. Ferree testified that he was not convinced that it would be obvious to the skilled artisan reading claim 18 to use two intersecting bores, despite having previously testified at his deposition that it *would* be obvious and despite the fact that the language of claim 18 calls for "at least one" bore. Dr. Ferree further opined that if two bores were used, it would be most obvious to use two colinear bores of different sizes, but he later conceded that such an arrangement would actually qualify as a single bore for purposes of the '460 Patent. Therefore, the Court does not find this testimony persuasive. Dr. Ferree also explained that the seat is part of the bore and that the ordinary skilled artisan would understand that the normal way to arrange the seat would be to have its axis perpendicular to the plane that ends it. And Dr. Ferree testified that Figure 7 is an obvious embodiment of both claim 1 and claim 18. Therefore, Dr. Ferree's testimony supports the conclusion that it would be obvious for the ordinary skilled artisan reading claim 18 to create an invention with two bores with intersecting axes.

Based on Dr. Ferree's testimony alone, then, the Court concludes that as of November 2000, it would have been obvious for a person of ordinary skill in the art reading claim 1 to create an invention with all of the limitations of claim 18. Similarly, the Court concludes that as of November 2000, it would have been obvious for a person of ordinary skill in the art reading claim 18 to create an invention with all of the limitations of claim 1. Therefore, the Court concludes that claim 1 is obvious in view of claim 18, and claim 18 is obvious in view of claim 1. Accordingly, the Court concludes that Stryker's proposed interference Counts 2 and 3 do not represent patentably distinct inventions, and therefore the Board did not err by declaring a single

interference count or refusing to redefine the interference count.

The Court is able to reach these conclusions without relying on the expert testimony of Dr. Antonsson. However, in the alternative, the Court finds that Dr. Antonsson's testimony supports the conclusion that claims 1 and 18 do not describe patentably distinct inventions. Dr. Antonsson testified that the "conventional way" for a bore to be drilled is perpendicular to the face from which it extends and that the ordinary skilled artisan would understand to this to be the case. Therefore, an ordinary skilled artisan reading claim 1 would understand that the normal way to end each of the intersecting bores would be to create intersecting planes. Similarly, an ordinary skilled artisan reading claim 18 would understand the bores would extend perpendicularly from the intersecting planes to create intersecting axes. Dr. Antonsson also explained that the ordinary skilled artisan would understand that the embodiment in Figure 2-the only embodiment with intersecting bores but not intersecting axes-does not achieve the object of the invention because it contains excess material on the lower end that inhibits greater angulation of the screw, meaning that the artisan would have motivation to makes the end planes nonparallel, i.e., intersecting. And like Dr. Ferree, Dr. Antonsson also testified that Figure 7 is an obvious embodiment of both claim 1 and claim 18. Therefore, the Court concludes that Dr. Antonsson's testimony provides an alternative basis for holding that claims 1 and 18 do not describe patentably distinct inventions.

Stryker relies primarily on Figure 2 in asserting that the intersecting axes invention and the intersecting planes invention are patentably distinct. However, the test for patentable distinctness is not whether there exists *some* embodiment of the first invention that does not cover the second invention. Rather, the test is whether there is an *obvious* embodiment of the

first invention that also covers the second invention. See Comcast Cable Commc'ns Corp. v. Finistar Corp., 571 F. Supp. 2d 1137, 1145 (N.D. Cal. 2008) ("A single obvious embodiment of a claim is sufficient to invalidate the entire claim even if the claim would also cover not-soobvious embodiments.").¹¹ Here, both experts testified that Figure 7 of the '460 Patent was an obvious embodiment of both the intersecting axes invention and the intersecting planes invention. Stryker argues that this an improper test because the focus must be on the *claims* and not on the embodiments of those claims. To illustrate its position, Stryker proposes two hypothetical claims, one describing "[a] clock with a digital readout" and the other describing "[a] radio which receives AM and FM stations," such that a digital AM-FM clock radio would be an embodiment of both of these claims. See Pl.'s Response to Defs.' Proposed Findings of Fact & Conclusions of Law at 3. Stryker argues that under the approach favored by Defendants, the digital clock and the radio are not patentably distinct inventions because there is a single embodiment that encompasses both. See id. However, Stryker misconstrues Defendants' argument because it omits the most critical element of the analysis: obviousness. If it would be *obvious* to the ordinary skilled artisan to create a digital clock radio based solely on either a digital clock or a radio (a highly suspect proposition), then the two inventions would not be patentably distinct. See Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1328 n.4 ("[C]laims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter." (citation omitted)). The case of Gould v.

¹¹ Stryker argues that *Comcast Cable* is inapplicable because it involved an infringement dispute in which the asserted patent claim was alleged to be invalid for obviousness under 35 U.S.C. § 103. However, this is the same standard of obviousness that is applied when determining whether two inventions are patentably distinct. *See Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d at 1268.

Mossinghoff, 711 F.2d 396 (D.C. Cir. 1983), cited by Stryker, is distinguishable because it focused on the issue of collateral estoppel and did not involve questions of obviousness.

Stryker also argues that the Court's conclusion improperly relies on hindsight because there is nothing in claim 1 that teaches or suggests that there would be intersecting planes, and there is nothing in claim 18 that teaches or suggests that there would be intersecting bores. However, Stryker's reliance on the "teaching or suggestion" test is overly mechanical. Common sense dictates that the ordinary skilled artisan would have had to make at least an educated guess about how to compose the exterior of the coupling element based only on claim 1 and the interior of the coupling element based only on claim 18; the artisan would not have been at a complete loss as to how to do these things. The testimony in the record showed that it would have been obvious to the artisan to try to use intersecting planes and intersecting axes in the same invention and that he would have had motivation to do so in order to achieve the object of the invention. Therefore, the Court's determination that the inventions are not patentably distinct is not based on hindsight, but rather on the record evidence regarding the level of ordinary skill in the art.

C. Summary of Conclusions and Judgment

As explained above, the Court concludes that based on the evidence in the record of this § 146 proceeding, the "intersecting axes" invention and the "intersecting planes" invention described in Stryker's proposed Counts 2 and 3 are not patentably distinct. Therefore, the Board did not err by declaring a single interference count encompassing both inventions or denying Stryker's motion to redefine the interference as two separate counts. Because all of Stryker's remaining claims in this action are contingent upon a redefined interference, the Court shall enter judgment for Defendants and dismiss this action. An appropriate Order accompanies this Memorandum Opinion.

Date: November 15, 2010

/s/

COLLEEN KOLLAR-KOTELLY United States District Judge