

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

STRYKER SPINE,

Plaintiff,

v.

BIEDERMANN MOTECH GMBH, *et al.*,

Defendants.

Civil Action No. 08–1827 (CKK)

MEMORANDUM OPINION

(February 16, 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 pursuant to 35 U.S.C. § 146. Pending before the Court are a series of dispositive motions. Stryker has filed a [31] Motion for Summary Judgment regarding the PTO’s refusal to redefine the interference count (“Redefinition Motion”); a [32] Motion for Summary Judgment regarding Defendants’ failure to adequately support their patent claims under 35 U.S.C. § 112 (“§ 112 Motion”); a [33] Motion for Summary Judgment regarding the unpatentability of Defendants’ claims over prior art (“Unpatentability Motion”); and a [35] Motion for Summary Judgment regarding the unconstitutionality of the appointment of an Administrative Patent Judge (“Unconstitutionality Motion”). Defendants oppose these motions and have separately filed a single [36] Motion for Summary Judgment. The United States has also intervened and filed an opposition to Stryker’s Unconstitutionality Motion. Briefing on

these motions is now complete.

For the reasons explained below, the Court shall DENY each of Stryker's motions for summary judgment and GRANT-IN-PART and DENY-IN-PART Defendants' motion for summary judgment. With respect to Stryker's Unconstitutionality Motion, the Court finds that any constitutional defect in the administrative patent judge's appointment was cured by his reappointment prior to the PTO's issuance of a final decision on rehearing. Therefore, the Court shall award judgment to Defendants on this claim. With respect to Stryker's Redefinition Motion, the Court finds that there are genuine issues of material fact that preclude the award of summary judgment to either party. Because the issues raised in the § 112 Motion and Unpatentability Motion are both contingent on Stryker's success on the Redefinition Motion, the Court shall also deny the parties' motions with respect to these issues.

I. BACKGROUND

A. The Patent Process and Interference Proceedings Generally

1. Patent Prosecution

The process of obtaining a patent is known as "prosecution" and begins with the filing of an application with the PTO. *See Intervet, Inc. v. Merial Ltd.*, 643 F. Supp. 2d 97, 99 (D.D.C. 2009); *see generally* 37 C.F.R. § 1.51. A patent application consists of a specification of the proposed patent as prescribed by 35 U.S.C. § 112, including a claim or claims, an oath or declaration, drawings as may be necessary, and the appropriate filing fee. 37 C.F.R. § 1.51(b). The specification required by 35 U.S.C. § 112 includes both a "written description of the invention" (description) and a written explanation of "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use” it (enablement).

35 U.S.C. § 112, para. 1. As Judge Henry H. Kennedy, Jr., aptly explained in a recent decision,

At the end of the written description and enablement, a proper specification should conclude with a list of “claims,” which identify the specific innovations, components or subparts of the invention, the applicant regards as hers. 35 U.S.C. § 112, para. 2. A claim is a single sentence description of what the applicant believes to be her invention, setting the boundaries of the invention the applicant wishes the PTO to examine. A single claim can be composed of multiple elements and/or limitations.^[1] Elements are the previously known physical components that make up the claimed invention. Limitations, on the other hand, usually describe the claim’s restrictions. An application may contain several claims, and each claim usually contains several restrictions. It is these claims that define the scope of patent protection.

Intervet, 643 F. Supp. 2d at 99.

A patent examiner then reviews the application to determine whether a patent should issue. “On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention.” 37 C.F.R. § 1.104(a)(1). If the patent examiner determines that the applicant is entitled to a patent under the law, a “Notice of Allowance” is issued. *Id.* § 1.311(a). If, however, the patent examiner determines that there are deficiencies or problems with the application, the examiner will issue an “Office Action” advising the applicant as to the “reasons for any adverse action or any objection or requirement.” *Id.* § 1.104(a)(2). Upon receipt of an Office Action, an applicant may amend the claims, argue as to the merits of the examiner’s findings, or both. *See id.* § 1.111. This back and forth between the applicant and the patent examiner continues until a patent is

¹ A claim may be either independent or dependent. An independent claim stands alone and does not refer to another claim, while a dependent claim makes express reference to one or more previous claims and includes all of the limitations of the earlier claims, as well as the new limitation(s) found only in the dependent claim. *See* 35 U.S.C. § 112.

issued or a final rejection occurs.

2. Patent Interference Practice

United States patent law, unlike much of the rest of the world, is premised on the principle that the first to invent—rather than the first to file a patent application—is granted the patent right. ROBERT L. HARMON, *PATENTS AND THE FEDERAL CIRCUIT*, 1151 (2009). As a consequence of this rule, there must be a mechanism for determining who among multiple patent applicants, or, as in this case, among an applicant and a patentee, was the first to invent the claimed subject matter. That mechanism is known as an interference, which is a “proceeding [] principally declared to permit a determination of priority.” *Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 674 (Fed. Cir. 1991). As is oft-repeated, “[i]nterference practice is highly arcane and specialized,” *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100 (Fed. Cir. 1994), and can be “virtually incomprehensible to the uninitiated,” *PATENTS AND THE FEDERAL CIRCUIT, supra*, at 1152.

“An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.” 37 C.F.R. § 41.203. Either the patent applicant or the patent examiner may suggest an interference. *See id.* § 41.202. If the Director of the PTO agrees that an interference is warranted— *i.e.*, that “an application is made for a patent which would interfere with any pending application, or with any unexpired patent”—he may declare an interference and provide notice of such declaration to the applicants, or applicant and patentee, as the case may be. 35

U.S.C. § 135(a); *see also* 37 C.F.R. § 41.203.² The notice declaring an interference identifies the interfering subject matter; the involved applications, patents, and claims; the accorded benefit for each count; and the claims corresponding to each count. 37 C.F.R. § 41.203(b). An administrative patent judge (APJ) may change the declaration of interference, and a party may suggest an additional interference. *Id.* § 41.203(c)-(d). The Board of Patent Appeals and Interferences (the “Board”) determines questions of priority of the inventions and may determine questions of patentability as well. 35 U.S.C. § 135(a).³

Interference proceedings are governed by the PTO’s regulations for contested cases. *See* 37 C.F.R. § 41.200(a). An interference proceeding may involve one or more counts; a count is the Board’s description of the interfering subject matter that sets the scope of admissible proofs on priority. *Id.* § 41.201. Each count must describe a patentably distinct invention. *Id.* Parties are presumed to have invented interfering subject matter in the order of the dates of their accorded benefit for each count. *Id.* § 207(a)(1). The “accorded benefit” is the Board’s recognition that a patent application provides a proper written description and enablement. *Id.* § 41.201. The party with the earlier accorded benefit is deemed the senior party, while the other party is the junior party. *Id.* Priority may be proved by a preponderance of the evidence. *Id.* § 41.207(a)(2). The parties may file substantive and responsive motions. Substantive motions

² Pursuant to the implementing regulations, an administrative patent judge declares the patent interference on the Director’s behalf. 37 C.F.R. § 41.203(b).

³ The Board is comprised of the PTO Director, the Deputy PTO Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges. *See* 37 C.F.R. § 41.2. In contested cases, such as interference proceedings, final Board actions must be taken by a panel of at least three Board members, but non-final actions may be taken by a single Board member. *Id.*

must (1) raise a threshold issue (i.e., an issue that, if resolved in favor of the movant, would deprive the opponent of standing in the interference); (2) seek to change the scope of the definition of the interfering subject matter or the correspondence of claims to the count; (3) seek to change the benefit accorded for the count; or (4) seek judgment on derivation or on priority. *See* 37 C.F.R. §§ 41.208, 41.200. “To be sufficient, a motion must provide a showing, supported with appropriate evidence, such that, if un rebutted, it would justify the relief sought.” 37 C.F.R. § 41.208(b).

B. Stryker Spine’s Patent

Stryker Spine is the assignee of U.S. Patent No. 6,974,460 (“the ’460 Patent”), which is titled “Biased Angulation Bone Fixation Assembly.” *See* Admin. Record (“AR”)⁴ 4; Defs.’ Mot. for Summ. J., Shaw Decl. Ex. 7 (the ’460 Patent) at 1. The ’460 Patent was issued on December 13, 2005, and was based on U.S. Patent Application No. 10/091,068 (“the ’068 Application”), which was filed on March 5, 2002. AR 4. The ’068 Application claimed the benefit of Provisional Application No. 60/322,042, filed on September 14, 2001. First Am. Compl. (“FAC”) ¶ 19; Answer ¶ 19. The named inventors of the ’460 Patent are John Carbone, Aaron Markworth, Michael Horan, and Yves Crozet. AR 4.

The device described by the ’460 Patent is intended for spinal fixation, i.e., securing a spinal rod to the bones of the vertebrae. The abstract of the ’460 Patent reads as follows:

A bone fixation assembly including a coupling element having an inner surface defining a first bore coaxial with a first longitudinal axis, and a second bore coaxial

⁴ 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 shall have the same effect as if originally taken and produced in this action.

with a second longitudinal axis, whereby the second longitudinal axis intersects the first longitudinal axis. The coupling element has a seat adjacent the lower end of the coupling element, the seat being defined by the inner surface of the coupling element. The assembly includes an anchoring element assembled with the coupling element, the anchoring element having a first end for insertion into bone and a head spaced from the first end, the head being in contact with the seat of the coupling element. The assembly provides sufficient angulation between adjacent anchoring elements securing a common orthopedic rod, and is particularly useful for assemblies mounted in spines having abnormal curvatures and in the cervicothoracic region of the spine.

'460 Patent at 1.

The '460 Patent contains 39 claims, five of which are independent (claims 1, 18, 24, 33, and 38). FAC ¶ 20; '460 Patent cols. 15-18. According to Stryker, claims 1 and 18 represent two distinctly patentable inventions. Claim 1, which Stryker calls the “intersecting axes” invention, is described in the '460 Patent 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 first 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.

'460 Patent col. 15:42-55.

Claim 18, which Stryker calls the “intersecting planes” invention, is described in the '460 Patent 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.

'460 Patent col. 16:50-63.

C. 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.” FAC ¶ 16; Answer ¶ 16. Defendant DePuy has been identified as the exclusive licensee of the '431 Application. Answer ¶ 18. The '431 Application was filed on January 22, 2004. FAC ¶ 23; Answer ¶ 23. 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. FAC ¶ 23; Answer ¶ 23. The named inventors of the '431 Application are Lutz Biedermann and Jurgen Harms. Defs.' Mot. for Summ. J., Shaw Decl. Ex. 6 (the '431 Application) at 1.

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 (2) 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.

'431 Application at 1 (figure 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 ’460 Patent. *See* Pl.’s Redefinition Mot., Ex. B. Biedermann proposed two interference counts, one of which was directed to an “assembly or coupling element” as addressed in 33 claims in the ’460 Patent (which were copied by Biedermann), and the other of which was directed to a “method” as defined in four other claims in the ’460 Patent (also copied by Biedermann). Pl.’s Stmt.⁵ (Redefinition) ¶ 4. 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. Defs.’ Resp. Stmt. (Redefinition) ¶ 4; Pl.’s § 112 Mot., Exs. U-V. On April 13, 2007, the examiner in charge of the ’431 Application issued an action acknowledging Biedermann’s suggestion of interference. Pl.’s Stmt. (Redefinition) ¶ 5; Pl.’s Redefinition Mot., Ex. C (“4/13/07 PTO Commc’n”). Among other things, the PTO indicated that Biedermann had “list[ed] a variety of claims as being the proposed count” and informed Biedermann that “[r]espectfully, a count cannot consist of more than one claim.” 4/13/07 PTO Commc’n at 2. The PTO stated that Biedermann had one month to correct any deficiencies. *Id.*

⁵ The Court strictly adheres to the text of Local Civil Rule 7(h) (formerly Rule 56.1 when resolving motions for summary judgment). *See Burke v. Gould*, 286 F.3d 513, 519 (D.C. Cir. 2002) (finding district courts must invoke the local rule before applying it to the case). The Court has advised the parties that it strictly adheres to Rule 7(h) and has stated that it “assumes facts identified by the moving party in its statement of material facts are admitted, unless such a fact is controverted in the statement of genuine issues filed in opposition to the motion.” [3] Order at 1 (Oct. 29, 2008). Thus, in most instances the Court shall cite only to one party’s Statement of Material Facts (“Stmt.”) unless a statement is contradicted by the opposing party, in which case the Court may cite a party’s Response to the Statement of Material Facts (“Resp. Stmt.”). Stryker filed a separate Statement for each motion, so the Court shall refer parenthetically to substantive motion to which each corresponds. The Court shall also cite directly to evidence in the record, where appropriate.

On May 16, 2007, Biedermann filed a “Supplemental Suggestion of Interference” with the PTO. Defs.’ Resp. Stmt. (Redefinition) ¶ 6; Pl.’s Redefinition Mot., Ex. D (“Supp. Sugg. Interf.”). Biedermann explained that in its view, the PTO’s statement that a count cannot consist of more than one claim is incorrect. *See* Supp. Sugg. Interf. at 2. Biedermann explained that its proposed count was known as a “McKelvey count” and that such counts have been proposed by the Board in many interferences and are therefore acceptable.⁶ *Id.* at 2-3. Biedermann then 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.” *Id.* at 4. 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.*

D. The Interference Proceeding

On October 10, 2007, Patent Interference No. 105,578 was declared involving the ’460 Patent and the ’431 Application. Defs.’ Stmt. ¶ 1. Administrative Patent Judge (APJ) Jameson Lee was assigned to manage the interference proceeding. *Id.* ¶ 3. Biedermann and Harms, the inventors of the ’431 Application, were identified as the senior party, whereas the inventors of

⁶ An interference count that uses the alternative to describe the interfering subject matter, i.e., “Party A’s claim X *or* Party B’s claim Y,” is known as a “McKelvey count” after the APJ who first used it. *See* Pl.’s Redefinition Mot., Ex. E (Herbert D. Hart III, “An Interference: What, When, and How Much Does It Cost?”) at 4.

the '460 Patent (Carbone et al.) were identified as the junior party.⁷ *Id.* The interference was declared on the basis of a single count, which read “Carbone’s patent claim 1, 18, 24, 33, or 38 or Biedermann’s claim 6, 18, 28, 33, or 35.” AR 5.⁸ The declaration of interference scheduled an initial conference call for December 5, 2007. *Id.* ¶ 5. Under the Board’s Standing Order governing procedures in interference proceedings, each party must file a list of the substantive motions it intends to file prior to this initial conference call. AR 29 (Standing Order ¶ 104.2.1), 71 (Standing Order ¶ 204).

Stryker⁹ did not seek to contest the priority of invention *per se* in the interference proceeding. Pl.’s Unpatentability Br. at 3-4. Rather, Stryker viewed the single interference count as encompassing two distinct inventions: the first based on claims 1, 24, and 38 of the '460 Patent (the “intersecting axes” invention) and the second based on claims 18 and 33 of the '460 Patent (the “intersecting planes” invention). Stryker also thought that Biedermann’s claims lacked support and were unpatentable based on prior art. Accordingly, Stryker filed the following list of motions on November 29, 2007:

1. Carbone Miscellaneous Motion 1 (No Interference in Fact) based on Biedermann’s lack of support for the invention of the count;
2. Carbone Miscellaneous Motion 2 (to redefine the interfering subject matter)

⁷ Biedermann was accorded the benefit of the German application filed on November 10, 2000, making its claim senior to that of Carbone et al., who were accorded the benefit of a provisional application dating back to September 14, 2001.

⁸ The interference count was later redeclared to substitute Biedermann’s claim 22 for Biedermann’s claim 18. *See* AR 153-54.

⁹ Although the Board often referred to the inventors as the parties before it, the Court shall primarily utilize the names of the parties to this action (i.e., Stryker and Biedermann), with the understanding that actions were taken on their behalf in the proceedings below.

proposing a substitute count;

3. Carbone Miscellaneous Motion 3 (for judgment based on prior art) based on the unpatentability of the count;

4. Carbone Miscellaneous Motion 4 (to designate Carbone claims not corresponding to the proposed new substitute count)

Defs.' Stmt. ¶ 7. On November 30, 2007, APJ Lee issued an Order dismissing Stryker's motions as being "so vague as to be not useful for reasonable preparation of the scheduled telephone conference call on December 5, 2007." *Id.* ¶ 8; AR 148-49. APJ Lee gave Stryker until the end of the day to file a revised motions list to explain more specifically (1) why there is no interference in fact; (2) why a substitute count is needed and what substitute count is proposed; (3) which of Biedermann's claims are unpatentable and on what grounds; and (4) which of Biedermann's claims do not correspond to Stryker's proposed substitute count and why. AR 148-49. Stryker filed a revised list of motions. AR 150-52. Biedermann also filed a list of motions pertaining to priority. AR 144-45.

During the motions conference call held on December 5, 2007, Stryker's counsel discussed its revised motions list and informed APJ Lee that Stryker would not be filing a priority motion in the interference.¹⁰ Defs.' Stmt. ¶¶ 11-12. On December 6, 2007, APJ Lee issued an Order authorizing substantive motions. AR 156-61. The Order authorized Stryker to file a motion to redefine the Interference by replacing the current count with two new counts: Count 2 (consisting of Stryker's claim 1 or 24 or 38 or Biedermann's claim 6 or 28 or 35) and Count 3 (consisting of Stryker's claim 18 or 33 or Biedermann's claim 22 or 33). AR 160. The

¹⁰ In light of Stryker's concession of priority, Biedermann's proposed motions were all moot. *See* AR 160.

Order also authorized Stryker to file a contingent motion (i.e., contingent upon granting of the motion to redefine the Interference) for judgment against Biedermann's claims in proposed Count 2, for lack of written description in the specification. AR 161. However, the Order denied authorization for Stryker to file a motion attacking Biedermann's claims in proposed Count 2 for lack of enabling disclosure. AR 157-58. The Order also denied authorization for Stryker to file a motion attacking Biedermann's claims in proposed Count 3 as unpatentable over prior art. AR 159, 161.

On December 20, 2007, Stryker filed a request for rehearing of APJ Lee's ruling that Stryker was not authorized to file a motion based on lack of enabling disclosure. AR 169-187. Stryker also filed a request for rehearing of APJ Lee's ruling that Stryker was not authorized to file a motion based on unpatentability. AR 188-96. On January 22, 2008, a three-judge panel of the Board (APJs Schafer, Lee, and Moore) issued a decision denying rehearing and affirming APJ Lee's rulings. AR 202-17. The Board noted that Interference proceedings are actively managed by the APJ, and the APJ has discretion to disallow motions that will not serve the interests of achieving a speedy, just, and inexpensive resolution of the Interference. AR 204-06. The Board explained that Stryker's basis for its proposed motion as to lack of enabling disclosure was the purported lack of written description, and the Board rejected this theory as not viable because the enablement requirement is distinct from the written description requirement (i.e., an invention may be enabled even if it is not described). *See* AR 208-13. The Board also explained that although the Board may determine issues of unpatentability in interference proceedings, it is not required to do so. AR 213-16.

On February 15, 2008, Stryker filed a "Revised Substantive Motion 1" to redefine the

interference. *See* AR 307-59. Four days later, APJ Lee held a telephone conference with counsel for both parties. AR 360. APJ Lee ordered Stryker to file a revised Substantive Motion 2 to fix certain errors in its original filing. AR 364. On February 21, 2008, Stryker filed its “Revised Substantive Motion 2,” contingent upon the granting of Substantive Motion 1, for judgment that Biedermann’s claims pertaining to proposed Count 2 are unpatentable for failing to meet the “written description” requirement of 35 U.S.C. § 112. *See* AR 365-465.

On April 30, 2008, a panel of the Board (APJs Schafer, Lee, and Moore) issued a Memorandum Opinion and Order. *See* AR 468-81. The Board denied Stryker’s Revised Substantive Motion 1 to redefine the interference count. AR 469. Because Stryker’s Revised Substantive Motion 2 was contingent on the granting of Motion 1, the Board dismissed the contingent motion. AR 479. The Board then entered judgment against Stryker in the Interference, cancelling claims 1-39 of the ’460 Patent. AR 482-84. On May 30, 2008, Stryker filed a “Request for Rehearing of Judgment Based on Denial of Carbone Revised Substantive Motion 1.” AR 485-527. On August 27, 2008, a panel of the Board (APJs Schafer, Lee, and Moore) issued a written decision on Stryker’s request for rehearing. *See* AR 528-38.

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. In addition to the administrative record, which has been accepted into evidence, the parties have submitted a series of declarations and exhibits in support of their motions for summary judgment. The Court shall consider this evidence where appropriate in the context of a summary judgment motion.

“A motion for summary judgment in an action seeking judicial review of an interference proceeding pursuant to 35 U.S.C. § 146 is subject to the same legal standard as other proceedings unrelated to patent law issues.” *Sears Ecological Applications Co. v. MLI Assocs., LLC*, 652 F. Supp. 2d 244, 256 (N.D.N.Y. 2009). Summary judgment is proper when “the pleadings, the discovery [if any] and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of

law.” Fed. R. Civ. P. 56(c). Under the summary judgment standard, the moving party bears the “initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). In response, the non-moving party must “go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial.” *Id.* at 324 (internal quotation marks omitted). All underlying facts and inferences are analyzed in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

III. DISCUSSION

There are at least four separate issues raised by the parties’ cross-motions for summary judgment. In no particular order, those issues are: whether the PTO erred by improperly declaring and refusing to redefine the single interference count; whether the PTO erred by failing to conclude that Biedermann’s patent application lacked adequate written specification and enablement; whether the PTO erred by failing to conclude that Biedermann’s claims are unpatentable; and whether the allegedly unconstitutional appointment of one of the administrative patent judges that ruled on the interference renders the decisions made by that APJ null and void. Because a finding that one of the APJs was unconstitutionally appointed would require a remand to the Board for reconsideration of the merits of the interference proceeding, the Court considers that issue first. The Court next addresses the Redefinition Motion because Stryker’s other claims are contingent upon the redefinition of the interference count.

A. *Unconstitutional Appointment of the Administrative Patent Judge*

Stryker contends that the decisions of the Board that are under review in this action are invalid and void because Administrative Patent Judge James T. Moore, who was a member of the three-judge panel reviewing the merits of the underlying interference proceeding, received his commission in violation of the Appointments Clause of the United States Constitution, Article II, Section 2, cl. 2. Both Defendants and the United States as Intervenor contend that the Board's decisions below are valid because, among other things, APJ Moore was constitutionally reappointed before the Board issued its final decision on rehearing. Before addressing the merits of the constitutional question, however, the Court must determine whether Stryker has properly presented it to this Court.

1. Procedural Defenses

Defendants argue that Stryker has not properly presented a constitutional challenge to this Court because it did not include a request for declaratory relief in its First Amended Complaint. *See* [39] Defs.' Opp'n at 9. While that is technically true, it cannot be said that Stryker failed to plead a constitutional challenge. The First Amended Complaint contains several allegations relating to the unconstitutional appointment of the administrative patent judges, *see* First Am. Compl. ¶¶ 72, 115, 130, 146, and it specifically requests relief in the form of a remand to the PTO and an order directing the PTO to "reassign the Interference to a new APJ and a lawfully constituted panel of APJs." *Id.*, Demand for Relief ¶ 3(a). These allegations are sufficient under the notice pleading requirements of Rule 8.¹¹

¹¹ Defendants also argued that Stryker had failed to comply with Rule 5.1, which requires a litigant challenging the constitutionality of a federal statute to notify the United States so that it may intervene. [39] Defs.' Opp'n at 8-9. However, Stryker ultimately did provide a Rule 5.1

Additionally, Defendants contend that Stryker waived this argument by failing to raise it with the Board until its final May 30, 2008, request for rehearing before the Board. *See* [39] Defs.’ Opp’n at 9-11. Biedermann relies on *In re DBC*, 545 F.3d 1373 (Fed. Cir. 2008), for the proposition that an argument may be waived in federal court if it is not timely presented to the Board. The *DBC* court held that the appellant had waived his Appointments Clause challenge by failing to raise the issue before the Board and presenting for the first time on appeal in federal court. *Id.* at 1377-78. Although there is some language in *DBC* suggesting that a litigant must present a “timely” claim to the Board in order to preserve review in federal court, the rationale for that rule is to provide the agency an opportunity to correct any errors “before it is haled into federal court.” *DBC*, 545 F.3d at 1379 (quoting *Woodford v. Ngo*, 548 U.S. 81, 89 (2006)). That objective is satisfied where, as in this case, the litigant raises the issue in a motion for rehearing. Indeed, the *DBC* court approved such an approach:

[N]othing prevented DBC from taking steps while this case was before the Board to ascertain the appointment status of the administrative patent judges assigned to its case. Even if DBC did not learn of the judges assigned to its panel until oral argument or until a decision was issued, it still had an opportunity to challenge the composition of the panel in a post-argument submission or in a motion for reconsideration. If DBC had timely raised this issue before the Board, the Board could have evaluated and corrected the alleged constitutional infirmity by providing DBC with a panel of administrative patent judges appointed by the Secretary. Of course, the Board may not have corrected the problem, or even acknowledged that the problem existed. But in that case, DBC would have preserved its right to appeal the issue.

545 F.3d at 1379. Not only did Stryker raise this issue in its request for rehearing, AR 495-96, the Board actually addressed the merits of this argument and rejected it, AR 535. The Court is therefore not persuaded that Stryker waived its Appointments Clause challenge by waiting until

notice, *see* [42] Rule 5.1 Notice of Constitutional Question, and the United States did intervene.

its request for rehearing to raise it with the Board.

2. The Appointments Clause

The Appointments Clause of the United States Constitution states:

[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the Supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law; but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. CONST., art. II, § 2, cl. 2. “[A]ny appointee exercising significant authority pursuant to the laws of the United States is an ‘Officer of the United States,’ and must, therefore, be appointed in the manner prescribed by [the Appointments Clause].” *Buckley v. Valeo*, 424 U.S. 1, 126 (1976); *see also* Officers of the United States within the Meaning of the Appointments Clause, 37 Op. Off. Legal Counsel ___, 2007 OLC LEXIS 3, at *11 (2007) (describing officers as those who possess delegated sovereign authority from the federal government). The Supreme Court has held that postmasters, district court clerks, Federal Election Commissioners, and special trial judges in Tax Court are all “inferior Officers.” *See Freytag v. Comm’r*, 501 U.S. 868, 880-82 (1991); *Buckley*, 424 U.S. at 126 (citing cases). The difference between an “Officer of the United States” who must be appointed and an “employee” who may be hired is that employees are “lesser functionaries subordinate to officers of the United States.” *Buckley*, 424 U.S. at 126 n.162. In explaining why a special trial judge in Tax Court is an inferior officer subject to the Appointments Clause, the Supreme Court noted that the office of special trial judge is established by law, with the duties, salary, and means of appointment specified by statute. *Freytag*, 501 U.S. at 881. Moreover, the Court noted, they perform more than merely ministerial tasks, such as

taking testimony, conducting trials, and ruling on the admissibility of evidence, and they exercise significant discretion. *Id.*

The Appointments Clause restricts Congress’s power to vest the appointment of inferior officers to the President, the “Courts of Law,” or the “Heads of Departments.” The Supreme Court has held that “the term ‘Department’ refers only to a part or division of the executive government, as the Department of State, or of the Treasury, expressly created and given the name of a department by Congress.” *Freytag*, 501 U.S. at 868 (internal quotation marks and alterations omitted); *see also Burnap v. United States*, 252 U.S. 512, 515 (1920) (“The term ‘head of a department’ means . . . the Secretary in charge of a great division of the executive branch of the government, like the State, Treasury, and War, who is a member of the Cabinet.”) The term does not include inferior commissioners and bureau officers. *Id.* (citing *United States v. Germaine*, 99 U.S. 508, 511 (1878)). The term “Courts of Law” has been interpreted to include both Article III courts and legislative courts created pursuant to Article I of the Constitution. *Freytag*, 501 U.S. at 890.

3. Administrative Patent Judge Moore’s Appointment

The law regarding the appointment of administrative patent judges has changed several times within the last dozen years. Prior to March 29, 2000, administrative patent judges were appointed by the Secretary of Commerce. *See* 35 U.S.C.A. § 3(a) (West 1999) (“The Secretary of Commerce, upon the nomination of the Commissioner [of Patents and Trademarks], in accordance with law, shall appoint all other officers and employees.”). However, effective March 29, 2000, the law provided that administrative patent judges should be appointed by the Director of the PTO. *See* 35 U.S.C.A. § 6(a) (West 2000) (“The administrative patent judges

shall be persons of competent legal knowledge and scientific ability who are appointed by the Director.”) In 2008, the law was changed again. *See* Act of August 12, 2008, Pub. L. No. 110-313, 122 Stat. 3014 (2008). The law now provides that administrative patent judges shall be “appointed by the Secretary of Commerce, in consultation with the Director.” 35 U.S.C.A. § 6(a) (West 2009). The 2008 Act also added two additional subsections relating to appointments previously made by the PTO Director:

(c) Authority of the Secretary.—The Secretary of Commerce may, in his or her discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge.

(d) Defense to challenge of appointment.—It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge’s having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.

35 U.S.C.A. § 6 (West 2009).¹²

The parties agree that Administrative Patent Judge James T. Moore was appointed to his position on November 5, 2001. *See* Stmt. (Unconstitutionality) ¶ 13; [47] Defs.’ Corrected Resp. Stmt. (Unconstitutionality) Mot. ¶ 13. This falls within the statutory time period during which APJ appointments were being made by the PTO Director. Although Defendants do not concede that APJ Moore was appointed by the PTO Director, they do concede that Moore was not appointed by the Secretary of Commerce. *See* [47] Defs.’ Corrected Resp. Stmt. (Unconstitutionality) ¶ 13. Stryker was unable to obtain discovery from the PTO to confirm that

¹² This is the current language of 35 U.S.C. § 6, as of the date of this opinion.

Moore was appointed in this manner,¹³ but exhibits provided by the United States provide clear evidence that APJ Moore was in fact appointed by the PTO Director on November 5, 2001. *See* [53] Intervenor United States’ Mem. Supp. Constitutionality of APJ Moore, Ex. 1 (Mem. Re: Ratification of the Director’s Administrative Patent and Trademark Judge Appointments) at 2-3. On August 12, 2008—the day that the law was changed—the Secretary of Commerce reappointed APJ Moore and deemed the appointment to take effect on the date that the Director initially appointed him. *Id.*, Ex. 1 at 6; *id.*, Ex. 2, at 1.¹⁴

4. Constitutionality of APJ Moore’s Initial Appointment

The Appointments Clause provides that administrative patent judges, as inferior officers of the United States,¹⁵ may only be appointed by either the President, a “Court of Law,” or a “Head of Department.” Because APJ Moore was appointed by the PTO Director, his initial appointment would have been unconstitutional unless the Director of the PTO can be considered either a “Court of Law” or a “Head of Department.” Defendants advance theories as to why the PTO Director may belong to either of these categories. The United States, as Intervenor, while

¹³ Stryker did obtain from Defendants a letter from the PTO responding to a FOIA request in an unrelated matter that listed the APJ appointments occurring between March 29, 2000 and May 10, 2008, which included the name of APJ Moore. *See* Pl.’s Unconstitutionality Mot., Ex. DD. It appears that the PTO did not produce any documents in response to Stryker’s subpoena *duces tecum*.

¹⁴ Stryker suggests in a footnote in one of its brief that the exhibits produced by the Government lack “authentication or explanation.” *See* [55] Pl.’s Reply Mem. Resp. to United States’ Mem. at 3 n.4. However, Stryker does not actually contest the fact that APJ Moore was reappointed by the Secretary on August 12, 2008.

¹⁵ Neither Defendants nor the United States disputes that administrative patent judges are “inferior officers” subject to the Appointments Clause. Like the special trial judges of the Tax Court, which were deemed inferior officers in *Freytag*, 501 U.S. at 880-82, the office of administrative patent judge is defined by statute and is endowed with significant discretion.

not explicitly conceding the point, does not argue that APJ Moore was constitutionally appointed by the PTO Director. Rather, both Defendants and the United States argue that even if APJ Moore was unconstitutionally appointed in the first instance, his reappointment on August 12, 2008, cures any constitutional defect because (1) the Board issued its final decision on rehearing after the reappointment; (2) APJ Moore's appointment was deemed retroactive by the Secretary of Commerce; and/or (3) APJ Moore's prior actions were legitimate under the *de facto officer* doctrine.

It is well settled that courts should avoid deciding constitutional questions where it is not necessary to do so. *See generally Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 347 (1935) (Brandeis, J., concurring). Accordingly, the Court shall not decide whether APJ Moore's appointment by the PTO Director was unconstitutional unless none of the three theories above cures the alleged constitutional defect. For purposes of the analysis below, the Court shall assume *arguendo* that APJ Moore's initial appointment was unconstitutional.

5. The Board's Decision on Rehearing After APJ Moore's Reappointment

Defendants and Intervenor United States argue that APJ Moore's reappointment by the Secretary of Commerce on August 12, 2008, cured any constitutional defect in the prior Board actions because the Board did not issue its final decision denying Stryker's motion for rehearing until August 27, 2008. However, Stryker contends that the Board's decision on rehearing could not ratify the prior rulings made by an unlawfully-constituted panel because the Board's standard of review on rehearing is narrow in scope. Before examining the scope of the Board's review in the context of a motion for rehearing, the Court shall examine the legal authorities cited by each party.

In support of their argument that a lawfully appointed officer can ratify the decisions of an unlawfully appointed officer, Defendants and Intervenor cite *Andrade v. Regnery*, 824 F.2d 1253 (D.C. Cir. 1987). In *Andrade*, federal employees challenged the acts of agency officials who were implementing a reduction in force program (RIF) on the grounds that the officials had not been constitutionally appointed to their positions. See 824 F.2d at 1255. However, the court rejected the employees' challenge because the official responsible for hiring agency employees was constitutionally appointed three days before the RIF formally went into effect. *Id.* at 1256-57. The court rejected the employees' argument that the actions should be set aside because the RIF was planned and conceived before the officer was appointed, reasoning that the harm was not legally cognizable until it was formally implemented, which occurred only after an official was duly appointed. *Id.* at 1257. Defendants analogize the Board's August 2008 decision on rehearing to the *Andrade* officer's ratification of the earlier decisions. The United States also cites *Olympic Federal Savings & Loan Association v. Director, Office of Thrift Supervision*, No. 90-482, 1990 WL 134841 (D.D.C. Sept. 6, 1990). In *Olympic*, the court held that the plaintiff's Appointments Clause challenge was moot because the plaintiff: (a) did not oppose the government's mootness argument, (b) did not identify any actions it sought to have invalidated, (c) did not contest the government's representation that the properly appointed successor had ratified the prior director's acts, and (d) did not argue that the *de facto* officer doctrine was inapplicable. *Id.* at *3.

In support of its view that a ruling on rehearing is not equivalent to ratification, Stryker cites *Ryder v. United States*, 515 U.S. 177 (1995). In *Ryder*, the Supreme Court reviewed an Appointments Clause challenge brought by a Coast Guard enlistee convicted by a court-martial

whose conviction was upheld on appeal, first by the Coast Guard Court of Military Review and then by the Court of Military Appeals. 515 U.S. at 179-80. Two judges on the former court had been unconstitutionally appointed, but the Court of Military Appeals—despite realizing the constitutional violation—affirmed the judgment on the ground that the judges’ actions were valid *de facto*. *Id.* at 180. The Supreme Court rejected this application of the *de facto* officer doctrine, *id.* at 183-84, and went on to consider the government’s argument that any constitutional defect in the first court’s composition was effectively cured by the review available in the Court of Military Appeals, *id.* at 186. The Court found that after “[e]xamining the difference in function and authority between the Coast Guard Court of Military Review and the Court of Military Appeals, it is quite clear that the former had broader discretion to review claims of error, revise factual determinations, and revise sentences than did the latter.” *Id.* at 187. Thus, the Court held that the Court of Military Appeals’ review did not cure the constitutional defect because it did not “g[i]ve petitioner all the possibility for relief that review by a properly constituted Coast Guard Court of Military Review would have given him.” *Id.* at 187-88.¹⁶ Stryker analogizes the Board sitting in August 2008 to the Court of Military Appeals in *Ryder*—properly appointed but limited by a narrow standard of review.

Whether this case is governed by *Andrade* or *Ryder* depends upon the scope of the Board’s authority in the context of a motion for rehearing. If the Board had only limited authority on rehearing, then the properly constituted Board could not fully ratify its earlier

¹⁶ The *Ryder* Court did not reach the closely related question of whether the Court of Military Appeals applied some sort of harmless-error review based on the petitioner’s failure to identify any adverse consequences from the unconstitutional composition of the Coast Guard Court of Military Review. 515 U.S. at 186.

decisions, even if they were not final for purposes of judicial review until a decision had been issued on rehearing. Requests for a rehearing are governed by Board Rule 125(c), which states in pertinent part:

(3) *Burden on rehearing.* The burden of showing a decision should be modified lies with the party attacking the decision. The request must specifically identify:

- (i) All matters the party believes to have been misapprehended or overlooked, and
- (ii) The place where the matter was previously addressed in a motion, opposition, or reply.

37 C.F.R. § 125(c)(3).¹⁷ The Board's Standing Order also has a provision relating to requests for rehearings:

A request for rehearing is, in form, a miscellaneous motion, but no prior conference call is required. The argument responsive to the decision must be made with particularity in the following manner:

On page __, lines __-__, the opinion states __. The opinion is believed to have overlooked [or misapprehended] __. This point was set forth in __ Motion [or Opposition or Reply] __ at page __, lines __-__.

The request must include as an appendix an evidence list setting forth a list (in numerical order by exhibit number) of each exhibit that the party believes was overlooked or misapprehended.

AR 53 (Standing Order ¶ 125.2). As a miscellaneous motion, a request for rehearing is limited to 10 pages in length (excluding tables and appendices). AR 30 (Standing Order ¶ 121.2). The Standing Order further states that “[e]vidence not already of record at the time of the decision will not be admitted absent a showing of excusable neglect for the belated submission.” AR 53

¹⁷ The Board's rules of procedure are contained in part 41 of Title 37 of the Code of Federal Regulations. In proceedings before the Board, a party may cite “37 C.F.R. § 41.x” as “Board Rule x.” AR 2; Rules of Practice Before the Board of Patent Appeals and Interferences, 69 Fed. Reg. 49960, 49961 (Aug. 12, 2004).

(Standing Order ¶ 125.4). Stryker argues that these provisions authorize only a narrow standard of review on rehearing, limiting the Board to consideration of matters that have been “misapprehended or overlooked.” Stryker further claims, albeit without factual support, that the Board’s review on rehearing is akin to a district court’s review on a motion for reconsideration. *See* [55] Pl.’s Reply Mem. Resp. to United States’ Mem. at 4-5. Defendants and Intervenor dispute this interpretation of the Board’s regulations, construing the phrase “misapprehended or overlooked” as permitting the Board to consider on rehearing the substance of any issues that were previously before the Board.

There is admittedly some ambiguity in the Board’s regulations regarding the meaning of “misunderstood or overlooked.” However, the procedural limitations on briefing and the evidence in the record appear to be aimed at preventing an unsuccessful claimant from simply taking a second bite at the apple. And nothing in the regulations prohibits the Board from reconsidering the merits of the Board’s original decision, as long as the party properly includes the issues in its request. Here, the record shows that Stryker explicitly sought a full review on the merits in its May 30, 2008, request for rehearing of the Board’s denial of its Revised Substantive Motion 1.¹⁸ *See* AR 488 (“[Stryker] respectfully requests that the Board . . . rehear and reconsider the Board’s denial of Carbone Revised Substantive Motion 1 to Redefine the Interference by dividing Count 1 into two separate counts”) Although limited to ten pages by the rules, Stryker’s request discusses the arguments and facts raised in its Revised Substantive

¹⁸ Stryker also asked the Board to rule on the merits of Revised Substantive Motion 2. AR 488. The Board had dismissed Motion 2 because it was contingent on the granting of Motion 1, *see* AR 479, but Stryker sought a ruling on Motion 2 in the event the Board’s decision to deny Motion 1 was reversed on appeal. *See* AR 494-95. The Board declined and denied Stryker’s request for rehearing on Motion 2. AR 536.

Motion, explaining why, in Stryker's view, the inventions in proposed counts 2 and 3 are distinguishable from each other in view of prior art, discussing the level of ordinary skill in the art, and reviewing the legal authority cited by the Board in its April 30, 1998, opinion. *See* AR 488-94. Stryker also reattached the declaration of Charles L. Bush, Jr., which it had included in support of its Revised Substantive Motion 1. *See* AR 497-520.

The record indicates that the Board, sitting on rehearing as a constitutionally appointed panel, did address the merits of Stryker's request for rehearing. The Board's opinion on rehearing demonstrates that its analysis was detailed and thorough. *See* AR 532 ("Substantively, we have reviewed Carbone Revised Motion 1 anew on a page-by-page basis for a discussion of the specific elements of each count as compared to those of the other and how the differences are such that the subject matter of one count would not have been obvious over the subject matter of the other.") The decision also reveals that it specifically reconsidered the merits of the analysis it previously conducted. *See* AR 532-33 ("The Board recognizes now and recognized when it wrote the initial decision that Carbone may have a theory on why these 'inventions' are conceptually different. . . . The problem was and is that Carbone has failed to make the final, vital analysis—given the subject matter of one count why the subject matter of the other count would not have been obvious to one of ordinary skill in the art.") In doing so, the Board reaffirmed its April 30, 2008, decision that Stryker had not established that the single count of the Interference embodied two patentably distinct inventions. *See* AR 469; AR 530-34. While the Board did not have occasion to revisit the January 22, 2008, decision regarding preliminary rulings by APJ Lee, those rulings involved motions that were contingent upon the success of the

motion to redefine the Interference.¹⁹ Therefore, the denial of Revised Substantive Motion 1, upheld on rehearing, renders any constitutional defect in the January panel irrelevant.

Because the Board conducted the same analysis and reached the same conclusion on rehearing as it did in its initial decision on Stryker's Revised Substantive Motion 1 (to redefine the Interference), Stryker cannot credibly argue that it was denied the opportunity to have its substantive claims considered by a properly constituted panel. Unlike in *Ryder*, the constitutionally-appointed rehearing panel gave Stryker all the possibility of relief that a properly constituted panel would have given it initially. Therefore, any constitutional defect in APJ Moore's initial appointment was cured in this particular instance by the substantive decision on the merits on rehearing by a properly constituted panel.

In light of the substantive nature of the Board's review on rehearing, a remand to the Board for *de novo* consideration is unnecessary. Although Stryker seeks a remand to a completely new panel of APJs, it has not provided the Court with any reason—other than administrative inertia—for ordering the Board to appoint a different panel of judges to rehear Stryker's claims. *See* Pl.'s Unconstitutionality Br. at 16-17. That is inconsistent with the principle that a new judge should only be assigned on remand where there is some allegation of bias or impropriety by the prior judge. *See, e.g.*, 28 U.S.C. § 144 (requiring recusal where judge

¹⁹ Stryker's requests for rehearing of APJ Lee's rulings indicate that Stryker's proposed motions attacking Biedermann's claims based on lack of enabling disclosure and unpatentability were grounded on Proposed Counts 2 and 3, respectively. *See* AR 176 (discussing lack of disclosures with respect to "claim 1," the basis for Proposed Count 2); AR 196 ("[Stryker] requests authorization to bring the Proposed Motion attacking the claims of Biedermann set forth in Proposed Count 3.") As Defendants point out, Stryker has conceded the contingent nature of these motions, which it has essentially renewed before this Court on summary judgment. *See* Stmt. P. & A. Supp. Pl.'s § 112 Mot. at 1-2; Stmt. P. & A. Supp. Pl.'s Unpatentability Mot. 2.

has personal bias or prejudice against a party); *Armco, Inc. v. United Steelworkers of Am.*, 280 F.3d 669, 683 (6th Cir. 2002) (holding that factors to be considered before reassigning a different judge are (1) whether the original judge likely would have difficulty setting aside previously-expressed views on remand, (2) whether reassignment is advisable to preserve the appearance of justice, and (3) whether reassignment would be excessively wasteful and duplicative). Stryker fears that the same panel on remand might simply issue the same rulings that it did before. But such a result would not be unconstitutional. *See Andrade*, 824 F.2d at 1256-57 (holding that Appointments Clause is satisfied when constitutionally-appointed officer implements and ratifies the acts of prior, unappointed officers). Moreover, Stryker has not identified any reason to believe that a different panel would reach a different conclusion.

Accordingly, the Court shall deny Stryker's Unconstitutionality Motion and grant-in-part Defendants's motion for summary judgment with respect to the allegedly unconstitutional appointment of APJ Moore. Because the Court finds that the Board's decision on rehearing cures the constitutional defect in its earlier decisions, it does not reach the parties' alternative arguments regarding the 2008 statutory provisions permitting retroactive appointment and a *de facto officer* defense.

B. Redefining the Interference Count

The Court shall now address the parties' cross-motions for summary judgment on the issue of whether the Board erred by failing to redefine the interference count as two separate counts—one for the “intersecting axes” invention and another for the “intersecting planes” invention. Stryker claims that these inventions are distinctly patentable and that the Board erred as a matter of law by declaring an interference based on a single count containing both

inventions. Stryker now 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. *See* Pl.'s Redefinition Br. at 43-44. Defendants claim that, based on the record before the Board and before this Court, Stryker cannot establish that its two proposed interference counts are distinctly patentable and therefore Defendants are entitled to judgment as a matter of law.

Stryker raises three primary claims of error by the Board in its motion for summary judgment. First, Stryker claims that the Board erred as a matter of law by declaring a single interference count consisting of multiple independent claims. Second, Stryker claims that the Board's declaration of interference was arbitrary and capricious because the Board did not provide any rational explanation for declaring only a single claim. And third, Stryker claims that the Board erred by failing to redefine the interference as having two separate counts, one for each of Stryker's patentably distinct inventions. After reviewing the evidence presented to the Board and the relevant standards that apply, the Court shall address each of the parties' contentions.

1. The Significance of the Interference "Count"

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 on its motion to redefine the interference count to include two separate counts, Stryker must show that the inventions in proposed Counts 2 and 3 are patentably distinct from each other. *See* [41] Defs.' Redefinition Opp'n at 15; [31] Pl.'s Redefinition Br. at 28. In proceedings before the Board, a party filing a motion to redefine the interference has the

burden of proof to establish it is entitled to the relief requested. 37 C.F.R. § 41.121(b).

For one claim to be patentably distinct from another, the first claim must not be obvious based on the subject matter of the second claim. “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 ordinary skill in the pertinent art. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (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. *Id.* at 17-18; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007) (reaffirming *Graham*). 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).

2. Stryker’s Motion to Redefine the Interference

In Stryker’s Revised Substantive Motion 1 (“Motion 1”), Stryker sought to persuade the Board that Count 1 of the interference actually contained two patentably distinct inventions and should therefore be redefined into two counts: Count 2 (pertaining to the “intersecting axes” invention) and Count 3 (pertaining to the “intersecting planes” invention). Stryker explained in Motion 1 that the ’460 Patent is directed to spinal fixation devices for altering the alignment of adjacent vertebral bodies relative to each other, known as “pedicle screw systems.” AR 312-13.

Stryker further explained that the prior art for these systems (including U.S. Patent No. 6,537,276, the “Metz Patent”) captured a spine rod but did not work when the rod capturing assemblies needed to be rotated to extreme angles. AR 313. Stryker argued that to solve this problem, the ’460 Patent encompassed two distinct bone fixation assembly inventions, exemplified by claims 1 and 18 of the ’460 Patent. The first invention, described by claim 1,²⁰ creates greater angulation by having a pair of bores with longitudinal axes that intersect each other, thus biasing the head of a fastener to one side. AR 314. This “intersecting axes” invention also has a seat at the lower end of the coupling element and an anchoring element with a head in contact with that seat. *Id.* Stryker explained that the advantage of claim 1 over prior art is the much greater angulation of the fastener with respect to the coupling element, allowing the spinal rod to be situated closer to the bone. AR 315. Stryker uses the “intersecting axes” invention in a commercial product called the OASYS implant system. AR 314.

By contrast, Stryker explained in Motion 1 that claim 18 of the ’460 Patent was directed to a bone fixation assembly “in which the coupling element has only a single bore extending from the upper end to the lower end,” but with the upper and lower ends defining first and second planes which intersect each other. AR 316. This “intersecting planes” invention also has an anchoring element and a coupling element with a U-shaped opening to receive a stabilizing rod. *Id.* Stryker argued that the “intersecting planes” invention was exemplified by all of the embodiments in Biedermann’s ’431 Application and is also used in a commercial product sold by

²⁰ For simplicity, Stryker limited its analysis of the two inventions to claims 1 and 18 of the ’460 Patent. *See* Pl.’s Redefinition Br. at 24 n.10. However, the invention in proposed Count 2 actually includes claims 1, 24, and 38, while proposed Count 3 includes claims 18 and 13. Stryker asserts that “[a] similar analysis could be provided between any pair of claims from the two proposed counts.” *Id.*

Defendant DePuy as the MOUNTAINEER OCT spinal system. *Id.* Stryker argued that although the “intersecting planes” invention also results in greater angulation compared to the prior art, it does so in a “very different manner” from the “intersecting axes” invention. AR 317. Stryker analyzed the products shown in the ‘431 Application and the commercial MOUNTAINEER OCT system and determined that they do not create angulation by using two bores with intersecting axes, but rather “are the result of simply removing an angled portion of the lower end of the single bore coupling element.” AR 318.²¹ As Stryker wrote in its Motion:

It is thus clear that the claims in both the Carbone ’460 Patent and the Biedermann [’431] application encompass two different inventions which do not overlap each other, one of which requires two separate bores having intersecting longitudinal axes in the coupling element, and the other of which requires only a single bore but first and second ends of the coupling element which are contained in planes which intersect each other; *i.e.*, which are not parallel to each other.

AR 318. Stryker therefore proposed its two substitute interference counts, with Count 2 consisting of the claims pertaining to the “intersecting axes” invention and Count 3 consisting of the claims pertaining to the “intersecting planes” invention. AR 319-20.

Stryker appended to Motion 1 a declaration by Charles L. Bush, Jr., an engineering manager at Stryker’s Cervical Division. *See* AR 329-351 (“Bush Decl.”), ¶ 1. Mr. Bush declared that he had been a design engineer in the field of biomedical engineering for sixteen years and that he was listed as a named inventor on several patents and patent applications for

²¹ The parties have used numerous illustrations to explain and clarify their positions before the Board and this Court. Although the Court does not include any technical diagrams in this opinion to aid a layperson’s understanding, the Court can offer an oversimplified version of Stryker’s basic position regarding the difference between the two inventions. Imagine a cylinder with parallel ends, such as a typical can of soup. According to Stryker, the “intersecting planes” invention is created by cutting one end of the cylinder at an angled edge, such that the ends are no longer parallel. By contrast, the “intersecting axes” invention would be created by joining two cylinders at an angle.

medical devices, including devices for spinal use. Bush Decl., ¶¶ 3-4 (AR 330). Mr. Bush stated that “[h]aving worked with many biomedical engineers and orthopedic and neuro [sic] surgeons prior to and up to 2001, I am familiar with the level [sic] a person of ordinary skill had in the field of medical devices in 2000 and 2001.” *Id.*, ¶ 4 (AR 330-31). Stryker relied heavily on the Bush declaration in Motion 1.

In the legal argument section of Motion 1, Stryker argued that the Board should apply a “two-way test” to determine that Count 2 and Count 3 contain patentably distinct inventions, citing *Eli Lilly & Co. v. Board of Regents of the University of Washington*, 334 F.3d 1264 (Fed. Cir. 2003). AR 321. Under the two-way test, the invention in Count 2 must be patentable over the invention in Count 3 as prior art, and vice versa. *Eli Lilly*, 334 F.3d at 1268.²² Stryker then explained why, in its view, the “intersecting axes” invention (Count 2) was nonobvious over the “intersecting planes” invention (Count 3) as prior art. *See* AR 323-24.²³ Stryker claimed that with separate bores of intersecting axes, one could achieve greater angulation of the screw vis-a-vis the coupling element and obtain a lower profile, whether or not the ends of the device are parallel to each other. AR 323. Stryker also emphasized that the invention in Count 2 allows for greater strength than the invention in Count 3 because the fastener is coaxial (i.e., aligned) with the lower bore and thus is not subjected to torsion when forces pull the fastener away from the coupling element. AR 324. Stryker also explained why, in its view, the “intersecting planes”

²² As explained below, the *Eli Lilly* court’s application of a two-way test is based on PTO regulations that have since been amended. *See* Rules of Practice Before the Board of Patent Appeals and Interferences, 69 Fed. Reg. 49960 (Aug. 12, 2004).

²³ In Motion 1, Stryker referred to the invention in Count 3 as “Invention (1)” and the invention in Count 2 as “Invention (2).” *See* AR 322-26.

invention was nonobvious over the “intersecting axes” invention as prior art. AR 324-26.

Stryker explained that by removing material to create an angled end, the invention in Count 3 is easier to manufacture. AR 325. However, the design exposes more of the screw, weakening the device and subjecting the fastener to torsional forces when the fastener is placed in an angulated position. AR 325-26. Stryker thus argued that these Counts contain completely distinct inventions.

3. The Board’s Rejection of Stryker’s Motion to Redefine the Interference

In its April 30, 2008, Memorandum Opinion and Order, the Board denied Stryker’s motion to redefine the interference. The Board began its written opinion by discussing the qualifications of Mr. Bush, and the Board concluded that Mr. Bush is 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.* Thus, the Board ruled that Mr. Bush’s testimony was insufficient to prove that Count 1 encompasses two patentably distinct inventions. *Id.*

The Board began its legal analysis with a reference to the standard for patentability under 35 U.S.C. § 103 as elaborated in *Graham*. AR 473. The Board then explained that, “to establish a prima facie case of nonobviousness, [Stryker] 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.” *Id.* The Board cited *Pechiney Emballage Flexible Europe v. Cryovac Inc.*, 73 U.S.P.Q.2d 1571 (B.P.A.I. 2004), in support of

this proposition. *Id.* The Board noted that although Stryker discussed prior art cited in the '460 Patent, it “did not discuss prior art relating to coupling art in general, even though the focus of the proposed counts relates to the ‘coupling element’ recited in the corresponding claims.” AR 475. Thus, the Board asked: “Was the level of ordinary skill in the art and the scope and content of the prior art such that one of ordinary skill would not have known that either the body of the coupling element or merely the entrance or exit angle at an end of the coupling element can be responsible for the coupling element’s facing different directions at opposing ends?” AR 475.

The Board went on to note that Stryker did not even discuss the level of ordinary skill in the art in its motion, instead stating legal conclusions in its statement of material facts (the second appendix to the motion) based on statements in the Bush Declaration. AR 476. As for the contents of the Bush declaration, the Board ruled that Mr. Bush’s statements as to obviousness were conclusory and based only on a brief discussion of the differences between the two inventions. AR 476-77. “He [Mr. Bush] does not discuss the art relating to this interference beyond a few products manufactured by his company and an affiliated company. He does not discuss or mention the knowledge that a skilled artisan did or did not have during the relevant time-frame.” AR 477. Without that discussion and analysis, the Board held, Stryker failed to satisfy the burden of proving *prima facie* nonobviousness. *Id.* Moreover, the Board held that Stryker had failed to sufficiently consider another of the *Graham* factors: the differences between the claimed subject matter and the prior art. *Id.*

In addition to holding that Stryker had failed to conduct the patentability analysis required by *Graham*, the Board stated that Stryker had not even persuasively distinguished the claims of the two proposed counts, i.e., claims 1 and 18 of the '460 Patent. AR 477. Although Stryker

characterized the “intersecting planes” invention in Motion 1 as having “a single bore,” the language of claim 18 in the ’460 Patent actually refers to a coupling element with “at least one bore.” AR 477-78. The Board deemed this language significant because it suggests multiple bores, and therefore claims 1 and 18 are not distinguishable by the number of bores involved. AR 478. In addition, the Board noted that claim 1 does not preclude the upper and lower ends from having intersecting planes, as recited in claim 18. *Id.* The Board also found that claim 18 describes a “U-shaped” opening to receive the stabilizing rod, but this could also be a feature of claim 1. AR 478-79. The Board said that Stryker had not shown that the variances in the claims would not have been obvious to one of ordinary skill in the art. *Id.* Accordingly, the Board denied Motion 1.

In its request for rehearing, Stryker argued that the Board had erred in denying Motion 1. First, Stryker argued that the Board misapprehended Mr. Bush’s testimony regarding the knowledge of one skilled in the art. AR 489. Stryker claimed that Mr. Bush testified in detail regarding the differences between the inventions and the Metz Patent, which was the most relevant prior art. AR 490-91. Second, Stryker argued that the Board should not have relied on the *Pechiney* case for the evidentiary standard, and that Stryker satisfied that standard in any event. AR 491-92. Third, Stryker argued that contrary to the Board’s ruling, it did emphasize the differences between the two inventions and the prior art. AR 493-94. Stryker noted that it had repeatedly shown how the “intersecting axes” invention and the “intersecting planes” invention were distinct from and not suggested by the Metz Patent. *Id.*

In its decision on rehearing, the Board rejected Stryker’s arguments. The Board began by reiterating that when analyzing whether proposed interference counts are patentably distinct, each

proposed count is presumed to be prior art to the others, and the remaining counts are evaluated in light of that count for nonobviousness and lack of anticipation.²⁴ AR 530-31. The Board noted that although Stryker analyzed whether each proposed count was patentably distinct from the Metz Patent as prior art, it did not adequately analyze whether the proposed counts were patentably distinct from *each other*. AR 531-32. Although Stryker focused generically on the different inventions described by each proposed count, the Board stated that “[t]he problem was and is that [Stryker] has failed to make the final, vital analysis—given the subject matter of one count why the subject matter of the other count would not have been obvious to one of ordinary skill in the art.” AR 533. The Board found that Stryker had not considered and discussed the prior art relating to the features that distinguished the two proposed counts, i.e., the coupling element. AR 533. The Board also discussed Mr. Bush’s declaration, noting that it was deficient because it did not discuss the level of skill in the art as required for a full obviousness analysis under *Graham*, and it did not focus on the closest prior art that can potentially make up the differences between the two proposed counts. AR 534. Finally, the Board explained that its reliance on *Pechiney Emballage* as an example of the required patentability analysis is not improper and that Stryker had failed to show how discussion of that case was error. AR 534-35. Accordingly, the Board rejected Stryker’s arguments and denied rehearing.

4. The Form of the Single Interference Count

Stryker’s first objection in this § 146 proceeding is to the form of the interference count

²⁴ 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. The parties have not argued, and the Board did not find, that either of Stryker’s proposed counts were invalid for anticipation.

declared by the Board. *See* Pl.’s Redefinition Br. at 16-20.²⁵ Stryker contends that the Board erred by including multiple independent claims from both the ’460 Patent and the ’431 Application in a single interference count. Stryker claims that a proper interference count can contain at most *one* independent claim from each party, with each claim defining the same patentable subject matter. *See* Pl.’s Redefinition Br. at 18. Defendants counter that Stryker’s objection to the form of the count is a new legal theory that was never presented to the Board and therefore cannot be raised here. Defs.’ Redefinition Opp’n at 12 (citing *Boston Scientific*, 497 F.3d at 1298 (“A party may not . . . advance new legal theories at the trial court level, even if the overarching legal issue was presented below.”)) Rather than identify in the record where it had raised this issue with the Board, however, Stryker disputes that it is foreclosed from raising new legal theories before this Court. *See* Pl.’s Redefinition Reply at 2.²⁶

“It is well-established that a party generally may not challenge an agency decision on a basis that was not presented to the agency.” *In re DBC*, 545 F.3d at 1378 (citing *Woodford v. Ngo*, 548 U.S. 81, 90 (2006)). In the specific context of § 146 proceedings in the district court, the Federal Circuit has explained that a party may present new evidence to the trial court when appealing a board decision in an interference proceeding but it may not “advance new legal

²⁵ To a certain extent, Stryker’s objection to the form of the interference count is intertwined with its argument that the Board erred by declaring a single interference count containing two distinctly patentable inventions. The Court addresses this substantive objection below under subheading 6.

²⁶ Stryker also disputes that it is foreclosed from raising new legal theories in the context of its opposition to Defendants’ motion for summary judgment with respect to the Board’s failure to consider Stryker’s arguments regarding the unpatentability of Proposed Count 3 over prior art. *See* Pl.’s Opp’n to Defs.’ Mot. for Summ. J. at 13-22. Rather than rebrief the issue in its reply brief supporting its Redefinition Motion, Stryker incorporated the arguments from its earlier opposition. *See* Pl.’s Redefinition Reply at 2.

theories at the trial court level, even if the overarching legal issue was presented below.” *Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc.*, 497 F.3d 1293, 1298 (Fed. Cir. 2007).

Stryker asserts that *Boston Scientific* is distinguishable because the parties had stipulated that the only issue to be decided was priority and one party sought to raise theories of constructive trust and equitable assignment. *See id.* The Court does not agree that the parties’ stipulation was the reason the Federal Circuit sanctioned exclusion of evidence related to new legal theories; rather, it was the party’s failure to present its theories to the Board that justified denying their consideration in the district court. *See id.*

This principle was thoroughly explained in *Conservolite v. Widmayer*, 21 F.3d 1098 (Fed. Cir. 1994). The *Conservolite* court explained that “[w]hile the expression ‘*de novo*’ is often used to describe a § 146 action, the statute does not use this language or state that new issues can freely be raised.” 21 F.3d at 1102. “[T]he parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources.” *Id.* In order to adequately raise an issue so that it qualifies for consideration in a § 146 proceeding, “the issue should have been raised as specified in the PTO’s interference rules, for example, through preliminary motions, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or opposition to these motions.” *Id.* The *Conservolite* court also said that under appropriate circumstances, a district court may exercise its discretion and admit testimony on issues that were not raised before the Board. *Id.* Appropriate circumstances may include an intervening change in the law, the presence of a new issue, or the admission of other evidence deserving of a response or further

elaboration. *Id.* Stryker does not dispute these principles.²⁷

Stryker has failed to articulate where in the record it presented arguments to the Board regarding the allegedly improper form of the interference count, and it is not apparent from the record that the Board had occasion to address it. The record demonstrates that Stryker could have presented this argument to the Board, but did not. Moreover, Stryker failed to argue that this case presents an appropriate circumstance for the Court to exercise its discretion to consider a new legal issue. Accordingly, the Court declines to exercise its discretion to hear this new issue, and it is not proper for Stryker to present that issue to this Court for adjudication in a § 146 proceeding. Stryker's motion for summary judgment will not be granted on the basis that the form of the interference count was improper.

5. The Lack of Agency Explanation Accompanying the Declaration of Interference

Stryker next claims that the PTO acted arbitrarily and capriciously by failing to provide an explanation to accompany the declaration of interference as a single count. *See* Pl.'s Redefinition Br. 20-23. Citing numerous precedents from the field of administrative law, Stryker contends that the Board should have provided a detailed explanation for why it defined the interference as a single count so as to permit effective judicial review of its decision-making process. However, the Court is not persuaded that the APJ's declaration of interference was an arbitrary and capricious agency action. The PTO's regulations state that "[a]n interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered

²⁷ Stryker contends in its opposition brief that *Conservolite* actually supports the admission of evidence relating to the Katz references as prior art. *See* Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 15-16. But Stryker did not make a similar argument with respect to its argument regarding the form of the declaration of interference.

obvious the subject matter of a claim of the opposing party and vice versa.” 37 C.F.R.

§ 41.203(a).²⁸ By declaring an interference of a single count, the APJ defined the scope of the interfering subject matter in accordance with the regulations. *See id.* § 41.203(b) (requiring a declaration to identify (1) the interfering subject matter; (2) the involved applications, patents, and claims; (3) the accorded benefit for each count; and (4) the claims corresponding to each count). “As a prerequisite to the declaration of an interference between an application and an issued patent, the PTO must determine that the subject matter of the application claim, whether or not the language of the claim is identical to that of the patent claim, is patentable, and whether the claims are drawn to the same invention.” *Conservolite*, 21 F.3d at 1101.²⁹ Thus, the declaration of interference represented the PTO’s conclusion that the claims contained therein are drawn to the same invention.

While it is true that the notice of declaration does not elaborate on the reasons why an interference was declared, the actual declaration is just one of a series of events that shed light on the agency’s decision-making process. As Stryker itself identified in its brief, an interference was first suggested by Biedermann in its prosecution of the ‘431 Application. After the Board suggested a deficiency, Biedermann filed a supplemental suggestion of interference proposing

²⁸ This describes a “two-way unpatentability test.” *See* Rules of Practice Before the Board of Patent Appeals and Interferences, 69 Fed. Reg. 49960, 49969 (Aug. 12, 2004).

²⁹ The *Conservolite* court relied on a prior version of the PTO regulations which explained that one invention (invention A) is the “same patentable invention” as another invention (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. 21 F.3d at 1101 n.3 (citing 37 C.F.R. § 1.601(n) (1994)). Although this language is no longer in the regulations, the standard is substantively embodied in the current language of 37 C.F.R. § 41.203(a).

what it called a “Simplified McKelvey Count,” which included each of the independent claims of the ‘460 Patent and the ‘431 Application. The Board adopted Biedermann’s suggestion when it declared the interference. Thus, the Board did not act arbitrarily in declaring the interference count as it did; its decision was based on the suggestion of interference during Biedermann’s prosecution of the ‘431 Application. Stryker has not cited, and this Court has not found, any cases in which a declaration of interference was held to be arbitrary or capricious in violation of the Administrative Procedure Act, *see* 5 U.S.C. § 706. In light of the record on which the Board apparently based its decision, the Court shall deny Stryker’s motion for summary judgment on that basis.

6. The Patentable Distinctness of Stryker’s Two Proposed Interference Counts

The Court now turns to Stryker’s core argument—that the inventions described by its proposed Counts 2 and 3 are patentably distinct. If they are, then the Board erred by declaring a single interference count and rejecting Stryker’s motion to redefine the interference as two counts. *See* 37 C.F.R. 41.201 (“[E]ach count must describe a patentably distinct invention.”) The only d issue regarding patentable distinctness is obviousness—whether the “intersecting axes” invention is obvious over the “intersecting planes” invention as prior art, and vice versa.³⁰

³⁰ Stryker contends the facts support separate patentability based on a “two-way test” as described above. *See* Pl.’s Redefinition Br. at 29. The Board explained the proper test as “the inverse of a two-way obviousness test”: “If a first proposed count is shown or demonstrated as non-obvious in light of and not anticipated by a second proposed count, the test of patentable distinction is met for those two counts.” AR 531. This is consistent with a prior Board regulation that defined the standard for patentable distinctness: “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.’” *See Eli Lilly*, 334 F.3d at 1268 (quoting 37 C.F.R. § 1.601(n) (2003)).

Obviousness is a legal conclusion that is reviewed *de novo* by this Court. *In re DBC*, 545 F.3d at 1377.³¹ Accordingly, the Court shall review the evidence that Stryker presented to the Board in addition to the evidence it has presented in this § 146 proceeding and determine whether Stryker has shown that its proposed Counts 2 and 3 contain patentably distinct inventions.

a. Obviousness.

An obviousness analysis is based on several factual inquiries, and a court must examine the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009) (citing *Graham*, 383 U.S. 1 at 17-18).

The court may also consider secondary objective evidence of nonobviousness, such as commercial success, long felt but unsolved need, failure of others, and the like. *Id.*

“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

³¹ Obviousness is a legal conclusion based on underlying findings of fact, and the Board’s factual findings are reviewed for substantial evidence. *In re DBC*, 545 F.3d at 1377. However, it does not appear that the Board ever made factual findings regarding the patentable distinctness of claims 1 and 18 of the ‘460 Patent because, pursuant to its regulations, the Board presumed the single interference count to be proper and placed the burden on Stryker to establish otherwise. *See* 37 C.F.R. § 41.121(b). Accordingly, the Court must make its own factual findings based on the evidence presented in this § 146 proceeding to support its conclusion with respect to obviousness.

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 Co. v. Teleflex Inc.*, 550 U.S. 398, 407, 415, 420 (2007).³²

Defendants claim that there is an “overlap” in subject matter between the two proposed counts and that this overlap establishes a prima facie case of obviousness that Stryker has failed to rebut.³³ *See* Defs.’ Redefinition Opp’n at 17. Specifically, Defendants claim that there is an overlap because proposed Count 2 (claim 1) calls for a “pair of bores” and proposed Count 3 (claim 18) calls for “at least one bore,” which can include two bores. Thus, Defendants argue,

³² Stryker is correct in that prior art’s failure to preclude a claimed invention does not render a claim obvious. *See* Pl.’s Redefinition Br. at 31-32. This does not mean, however, that the Board “demonstrated a distressing lack of understanding of basic patent law principles” when it explained that although claim 1 of the ’460 Patent does not explicitly call for intersecting planes, it does not preclude them. *See id.* at 31. The Board was merely explaining why, in its view, Stryker had failed to meet its burden of proof with respect to nonobviousness. *See* AR 477-78.

³³ Once a prima facie case of obviousness is established with respect to an invention, the burden shifts to the invention’s proponent to come forward with evidence and/or argument to establish patentability. *See In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007). The Board never indicated that a prima facie case of obviousness had been established with respect to the two proposed counts, although its presumption that the single interference count was correct appears to have had a similar effect. *See* AR 473 (explaining Stryker’s obligation to establish nonobviousness). Because this Court reviews the determination of obviousness *de novo*, the Board’s position regarding any prima facie case of obviousness is immaterial.

the intersecting planes invention overlaps with the intersecting axes invention, rendering the latter obvious. Defendants cite two cases for the proposition that this overlap in subject matter establishes a prima facie case of obviousness. In *In re Peterson*, 315 F.3d 1325 (Fed. Cir. 2003), the Federal Circuit affirmed the Board’s conclusion that a patent claim for a metal alloy was obvious based on prior art that disclosed ranges for elemental composition that overlapped with the ranges for the claimed patent. The *Peterson* court held that in cases involving overlapping ranges, even a slight overlap in range establishes a prima facie case of obviousness. 315 F.3d at 1329. The second case cited by Defendants, *In re Malagari*, 499 F.2d 1297 (C.C.P.A. 1974), also affirmed a finding of prima facie obviousness based on prior art that disclosed the range of carbon that should be used in a certain steelmaking process.³⁴

The Court agrees with Stryker that these “range” cases are inapplicable. The range cases, which involve claims for specific compositions of materials, provide a poor analogy for the elements of the claims at issue in this case. Even though claims 1 and 18 “overlap” in the sense that they may both involve two bores, this overlap does not create prima facie obviousness because the number of bores—unlike elemental composition in a metal alloy—is not the critical feature of either claim. The critical feature of claim 1 is that it calls for two bores with intersecting axes, and the critical feature of claim 18 is that it calls for upper and lower ends with intersecting planes. It may be that claim 18’s suggestion of two bores makes it obvious to a person skilled in the art that those bores should have intersecting axes, but that is a conclusion

³⁴ In a footnote, Defendants also cite *Aelony v. Arni*, 547 F.2d 566 (C.C.P.A. 1977), apparently for the proposition that, where a plaintiff has “failed to proffer any evidence which would support their mere allegation of patentable distinction,” *id.* at 571, judgment should be entered for the defendant. *See* Defs.’ Reply Supp. Mot. for Summ. J. at 2.

that must be drawn based on a proper *Graham* analysis, not on flimsy comparisons to cases involving completely different patentable subject matter.

The Court agrees with the Board that Stryker failed to conduct an appropriate obviousness analysis utilizing the three factors identified in *Graham*: (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 ordinary skill in the pertinent art. *Graham*, 383 U.S. at 17. Although Stryker thoroughly discussed the differences between each of the two inventions and what it viewed as the “closest prior art (the Metz Patent),” AR 490, Stryker should have explained in more detail why each invention was not obvious over the other as prior art. Relying on conclusory statements of nonobviousness by one expert who is skilled in the art does not meet the standard required by *Graham*. Mr. Bush’s declaration did not explain what the level of ordinary skill in the art was (beyond stating that he possessed it) or explain in any detail why he thought, in light of the prior art and the level of skill, that one invention would not have been obvious over the other. *See* Bush Decl., ¶¶ 4, 28-29.

Stryker argues that a “full-blown *Graham* analysis” is inappropriate when deciding whether two claims from the same patent are patentably distinct from each other. *See* Pl.’s Opp’n to Defs.’ Mot. for Summ. J. at 6-7. Yet Stryker fails to explain why the Board should apply a different test to determine the patentable distinctness of separate interference counts than it does when determining whether there is an interference in the first place. *See* 37 C.F.R. § 41.203(a) (“An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.”) Stryker’s only citations in support of a different test are to a part of the PTO’s *Manual*

of Patent Examining Procedure regarding restriction and double patenting and to a Federal Circuit case involving “obviousness”-type double patenting. *See* Pl.’s Opp’n to Defs.’ Mot. for Summ. J. at 7. Those contexts are quite different from interference proceedings, where the Board has previously required a *Graham* obviousness analysis to be applied when determining patentable distinctness. *See Pechiney Emballage*, 73 U.S.P.Q.2d at 1573. The PTO’s interpretation of its own regulations is entitled to substantial deference, *see Eli Lilly*, 334 F.3d at 1266, and Stryker has not shown that the PTO’s adoption of the *Graham* analysis is plainly erroneous or inconsistent with 37 C.F.R. § 41.201. Accordingly, the Court shall apply the *Graham* analysis for obviousness that has been reaffirmed by the Supreme Court. *See Teleflex*, 550 U.S. at 406-07.

In attempt to cure the defects in Mr. Bush’s declaration, Stryker proffers the testimony of Dr. Bret Ferree, an expert in spinal fixation technology. *See* Pl.’s Redefinition Br., Decl. of Dr. Bret Ferree (“Ferree Decl.”). Dr. Ferree declares that he is an orthopedic surgeon specializing in spinal surgery and that he has authored research papers on spinal fixation technology, specifically pedicle screw fixation. Ferree Decl. ¶ 1. Dr. Ferree states that in his opinion, as of November 2000, a person of ordinary skill in the field of spinal bone fixation technology would have been either a person with an engineering degree and at least several years of experience in the design of medical devices or a surgeon who had performed surgery on spinal disorders using a variety of existing devices and who had design experience. Ferree Decl. ¶ 5. Dr. Ferree further declares that nothing in claims 1, 24, and 38 of the ‘460 Patent (defining the “intersecting axes” invention) would suggest to a person of ordinary skill in the art that the upper and lower planes of the coupling element should intersect. *Id.* ¶ 19. Similarly, Dr. Ferree opines that nothing in

claims 18 and 33 of the '460 Patent (defining the “intersecting planes” invention) would suggest to a person of ordinary skill in the art that a coupling element should have two internal bores with intersecting axes. *Id.* ¶ 20.

Dr. Ferree’s testimony is rebutted by Defendants’ expert, Erik K. Antonsson, Ph.D., P.E. Dr. Antonsson is the Director of Research at Northrop Grumman Aerospace Systems, and he is a Board Certified Registered Professional Engineer with experience in biomechanics. *See* Defs.’ Redefinition Opp’n, Ex. A (Expert Report of Erik K. Antonsson, Ph.D., P.E.) (“Antonsson Report”) at 1. Dr. Antonsson opines that, as of November 2000, the level of skill in the art of spinal fixation devices was a person with a Bachelor of Science degree in mechanical engineering (or equivalent) from a four-year accredited university, with a year or two of experience in orthopedic biomechanics, or equivalent experience, or a surgeon who had performed surgery on spinal disorders using a variety of existing devices and treatment regimens and having experience designing spinal implants. *Id.* at 3. Dr. Antonsson’s Dr. Ferree’s conclusions regarding the obviousness of the “intersecting axes” invention with respect to the “intersecting planes” invention, and vice versa. *Id.* at 7-14. Dr. Antonsson explains that, in his view, a skilled artisan would understand that it would be conventional for the axis of a bore to extend perpendicularly from the plane defined by the end from which the bore extends. *Id.* at 7. Therefore, a skilled artisan would understand that claim 1, with its pair of bores with intersecting axes, would include ends with intersecting planes. *Id.* Similarly, the skilled artisan would understand that claim 18, with at least one bore and ends having intersecting planes, would include a coupling element with bores of intersecting planes. *Id.* Thus, Dr. Antonsson disagrees with Dr. Ferree’s opinion that claims 1 and 18 represent patentably distinct inventions. *Id.* at 8.

The parties have thus produced conflicting expert testimony regarding the facts that must be considered in the obviousness analysis. Specifically, the parties' experts disagree about the level of knowledge of one skilled in the art and whether it would have been obvious to one skilled in the art that, given a coupling element with ends defining planes that intersect, there should be a pair of bores with intersecting axes. However, in order to create a genuine issue of material fact that precludes summary judgment, the parties' expert testimony must be admissible under the principles in Federal Rules of Evidence. *See* Fed. R. Civ. P. 56(e)(1) (holding that supporting affidavits must set out facts that would be admissible in evidence); *Merit Motors, Inc. v. Chrysler Corp.*, 569 F.2d 666, 673 (D.C. Cir. 1977) ("To hold that [Federal Rule of Evidence] 703 prevents a court from granting summary judgment against a party who relies solely on an expert's opinion that has no more basis in or out of the record than [the expert's] theoretical speculations would seriously undermine the principles of Rule 56.") Unsurprisingly, the parties object to each other's expert testimony as inadmissible. The Court shall therefore consider whether either Dr. Ferree's or Dr. Antonsson's testimony must be excluded under the Federal Rules of Evidence.

b. Expert testimony.

Federal Rule of Evidence 702 governs the use of expert testimony in federal courts. Rule 702 provides: "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and

methods reliably to the facts of the case.” The Supreme Court’s decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), established a gatekeeping role for trial court judges in determining the admissibility of expert testimony on scientific evidence. *See also Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999) (extending gatekeeping requirements to non-scientific expert testimony). The judge must make “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” 509 U.S. at 592-93. The *Daubert* Court established a list of factors a court should consider when assessing the reliability of expert testimony: (1) whether a theory or technique can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) the known or potential rate of error and the existence of control standards; and (4) the level of general acceptance in the relevant scientific community. *Id.* at 593-94. In cases involving technical rather than scientific expertise, a court may apply any of these factors to the extent they are relevant. *Kumho Tire*, 526 U.S. at 150. “The inquiry envisioned by Rule 702 is . . . a flexible one.” *Daubert*, 509 U.S. at 594.³⁵

i. Dr. Ferree.

Defendants contend that Dr. Ferree’s opinions do not meet the minimum standards for reliability under Rule 702. Defendants note that Dr. Ferree did not consider several relevant materials, such as the papers in the Interference proceedings, the prior art referred to by Mr. Bush

³⁵ The concerns underlying the court’s role as gatekeeper under *Daubert* are of lesser import in a bench trial, where no screening of the factfinder can take place, but the standards of relevance and reliability must still be met. *Seaboard Lumber Co. v. United States*, 308 F.3d 1283 (Fed. Cir. 2002). Stryker did not demand a jury trial for contested issues of fact, and it not clear in any event that it is entitled to a jury determination in a proceeding under 35 U.S.C. § 146.

in his report, and the file histories of the ‘460 Patent and the ‘431 Application. *See* Pl.’s Resp. Stmt. ¶ 62. Defendants also contend that Dr. Ferree’s deposition testimony indicated that his conclusions regarding the patentable distinctness of claims 1 and 18 are unsupported. For example, Dr. Ferree said he had heard of the *Graham v. John Deere* test for obviousness but did not know what the elements of the test were. Defs.’ Stmt. ¶ 65. Dr. Ferree also stated that in deciding that claims 1 and 18 were patentably distinct, he did not consider the prior art. Pl.’s Resp. Stmt. ¶ 66. He also did not consider what the ‘460 Patent or the ‘431 Application disclosed. Pl.’s Stmt. ¶¶ 67-68. He also agreed that the phrase “at least one” bore suggested that a person skilled in the art could use more than one bore. Pl.’s Stmt. ¶ 69.

Defendants contend that the above statements show that Dr. Ferree’s opinions are too conclusory to be reliable. However, the Court finds that these objections go to the weight of Dr. Ferree’s testimony rather than its admissibility. Dr. Ferree’s failure to understand the purely legal analysis of *Graham* or review the entire record of the Interference proceeding does not render his opinion unreliable. Dr. Ferree’s opinion regarding the level of skill in the art and the teachings of claims 1 and 18 are based on his expertise in the relevant field and therefore may be considered by this Court at trial.

ii. Dr. Antonsson.

Stryker contends that Dr. Antonsson is not qualified to give expert testimony regarding the knowledge of one skilled in the art of bone fixation assemblies because his experience is in general mechanical engineering with little or no expertise in orthopedic biomechanics, a species of biomedical engineering. *See* Pl.’s Redefinition Reply at 10-20. Stryker argues that Dr. Antonsson’s only work related to biomedical engineering occurred long before November 2000,

the relevant time in question for this patent . Indeed, Dr. Antonsson’s primary experience relating to biomechanics appears to date back to his time as an undergraduate and graduate student, when he worked on hip prosthetics. *See* Antonsson Report at 1-2. In 1984, Dr. Antonsson also held the position of Assistant Professor of Orthopedics (Bioengineering) at the Harvard University Medical School. *Id.* at 2. However, Dr. Antonsson’s more recent work has not involved biomechanics and has focused on other aspects of mechanical engineering. *See id.* at 2. He has, however, recently given expert testimony pertaining to biomechanics and orthopedic spine implants specifically. *See id.* at 15.

Stryker cites several cases in support of its argument that Dr. Antonsson’s expertise is insufficiently specific to be reliable in this case. In *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378 (D. Md. 2001), that court explained that “an expert who is a mechanical engineer is not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering. Unless he is to testify only to general engineering principles that any mechanical engineer would know, the engineer must possess ‘some special skill, knowledge, or experience’ concerning the particular issue before the Court.” *Id.* at 392 (internal citation omitted). The *Shreve* court excluded the testimony of a mechanical engineering expert on the ground that he had no professional experience relating to the safe design and operation of “snow throwers,” which were at issue in that case. Stryker also cites *Oglesby v. General Motors Corp.*, 190 F.3d 244 (4th Cir. 1999), in which the court similarly held that testimony by a mechanical engineer could be excluded because the engineer lacked specialized knowledge of the manufacturing process to which his testimony was directed. *Id.* at 247.

Unlike the experts whose testimony was rejected in these and other cases cited by Stryker,

however, Dr. Antonsson does have some experience in orthopedic biomechanics—it is just that it was very early in his career. His recent expert testimony regarding orthopedic spine implants, while not adequate on its own to establish specialized knowledge, strongly suggests that Dr. Antonsson has continuing expertise in the specific field. In addition, the cases cited by Stryker mostly involve expert testimony on design defects, in which the need for specialized knowledge is paramount. By contrast, Dr. Antonsson explains in his expert report that “the technology at issue concerns the application of principles of mechanical engineering to the design of orthopedic devices.” Antonsson Report at 3. Thus, the level of specialized expertise to which Dr. Antonsson is testifying is closer to that of a generalized mechanical engineer than to an expert in spinal fixation. The Court therefore finds that his testimony is sufficiently reliable under Rule 702 not to be excluded. Stryker’s objections to the bases for Dr. Antonsson’s conclusions go to their weight rather than their admissibility.

Therefore, based on the present record, the Court finds that neither party has shown that there are no genuine issues of material fact and that either party is entitled to judgment as a matter of law with respect to the redefinition of the interference count. The Court shall proceed toward a hearing of the experts and any other factual issues to be resolved.

C. The Parties’ Remaining Motions

The Court shall now address the remaining issues raised by the parties’ dispositive motions. The relief sought by Stryker in its Unpatentability Motion and § 112 Motion are contingent upon the Court’s granting its Redefinition Motion. Therefore, because the Court denies Stryker’s Redefinition Motion, it shall also deny Stryker’s Unpatentability Motion and § 112 Motion. Similarly, Defendants seek summary judgment with respect to the Board’s

