

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

In re *Inter Partes* Review of:

U.S. Patent No. 8,623,057 B2

Inventors: Jahng et al.

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For: SPINAL STABILIZATION
DEVICE

Case No.: IPR2014-00099

Atty. Docket No. 60330-01014

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 8,623,057
UNDER TO 35 U.S.C. § 311 *ET SEQ.* AND 37 C.F.R. § 42.100 *ET SEQ.***

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LIST OF EXHIBITS

Petition Exhibit Number	Contents
1001	U.S. Patent No. 8,623,057, issued Jan. 7, 2014 to Jahng et al. (“Jahng”)
1002	U.S. Pat. No. 7,931,675 B2, issued Apr. 26, 2011 to Panjabi et al. (“Panjabi”)
1003	Originally filed patent application No. 11/072,886
1004	Annotated Figure 8 in Panjabi.
1005	U.S. Pub. No. 2004/0143264 A1, published Jul. 22, 2004 to McAfee (“McAfee”)
1006	Claim Comparison Chart
1007	Declaration of Dr. Paul C. McAfee
1008	Curriculum vitae of Dr. Paul C. McAfee
1009	Panjabi, M.M., Clinical spinal instability and low back pain, <i>Journal of Electromyography and Kinesiology</i> , 13, pp. 371-379 (2003)
1010	U.S. Pat. No. 5,733,286, issued Mar. 31, 1998 to Errico et al.
1011	U.S. Pat. No. 6,063,090, issued May 16, 2000 to Schläpfer.
1012	U.S. Pat. No. 6,280,442 B1, issued Aug. 28, 2001 to Barker et al.
1013	U.S. Pat. No. 5,474,555, issued Dec. 12, 1995 to Puno et al.
1014	U.S. Pat. No. 5,554,157, issued Sep. 10, 1996 to Errico et al.

1015	U.S. Pat. No. 5,474,551, issued Dec. 12, 1995 to Finn et al.
1016	U.S. Pat. No. 5,743,907, issued Apr. 28, 1998 to Asher et al.

I. INTRODUCTION

The Real Party in Interest, Globus Medical, Inc. (hereinafter “Petitioner”) hereby respectfully requests *Inter Partes* Review pursuant to 35 U.S.C. §§ 311 *et seq.* and 37 C.F.R. §§ 42.100 *et seq.*, of claims 23-32 and 46-55 of U.S. Patent No. 8,623,057 (the “’057 Patent”). *See* Exhibit 1001. The fee set forth in 37 C.F.R. § 42.15(a) accompanies this Petition.

As explained in detail below, claims 23-32 and 46-55 of the ’057 Patent are unpatentable under 35 U.S.C. § 103 in view of the prior art references cited herein. Accordingly, Petitioner respectfully requests that claims 23-32 and 46-55 of the ’057 Patent be canceled based on the grounds of unpatentability explained in detail herein. Petitioner meets the statutory threshold for instituting an *Inter Partes* Review because this Petition demonstrates “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

A copy of this Petition and all supporting evidence has been served on the Patent Owner (as shown by the records of the Assignments on the Web for Patents database), Depuy Acquisition LLC, at the correspondence address of record for the patent-at-issue as required by 37 C.F.R. § 42.105(a).

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

Petitioner satisfies each requirement for *Inter Partes* Review of the ’057 Patent pursuant to 37 C.F.R. § 42.8(a)(1).

A. Real Party In Interest Under 37 C.F.R. § 42.8(b)(1)

The Real Party In Interest is Globus Medical, Inc.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Petitioner states that the '057 Patent is asserted in pending litigation captioned *Depuy Synthes Products, LLC v. Globus Medical, Inc.*, U.S. Dist. Court for Dist. of Delaware, filed January 7, 2014, C.A. No. 14-11-RGA.

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner is represented by Lead Counsel, Michael W. O'Neill, Reg. No. 46,421, and Back-Up Counsel, Margaux A. Aviguetero, Reg. No. 62,940. Power of Attorney has been filed with this Petition.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is as follows:

NOVAK DRUCE CONNOLLY BOVE + QUIGG LLP
1000 Louisiana Street, 53rd Floor, Houston, TX 77002
Tel.: 713-571-3400 and Fax: 713-456-2836

Petitioner also consents to service by email: GlobusIPR@novakdruce.com

III. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '057 Patent is available for *Inter Partes* Review and that it is not barred or estopped from requesting this *Inter Partes* Review.

IV. IDENTIFICATION OF CLAIMS FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(1)

Petitioner requests *Inter Partes* Review of claims 23-32 and 46-55 of the '057 Patent.

V. THE SPECIFIC STATUTORY GROUNDS ON WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(2)

Petitioner requests that claims 23-32 and 46-55 of the '057 Patent be cancelled based on the following statutory grounds of unpatentability:

Ground 1: Claims 23-32 and 46-55 are rendered obvious under 35 U.S.C. § 103 by U.S. Pat. No. 7,931,675 B2, issued Apr. 26, 2011 to Panjabi et al. (“Panjabi,” hereinafter) and U.S. Pub. No. 2004/0143264 A1, published Jul. 22, 2004 to McAfee (“McAfee,” hereinafter). Exhibits 1002 and 1005.

Petitioner submits that Panjabi is prior art to the '057 Patent under 35 U.S.C. § 102(e). The '057 Patent issued from a series of continuation-in-part applications. Exhibit 1002, front page. The Petitioner submits that the earliest effective filing date for the claim inventions within the '057 Patent is March 3, 2005, which is the filing date of patent application No. 11/072,886. Exhibit 1003.

VI. HOW THE CHALLENGED CLAIMS ARE TO BE CONSTRUED UNDER 37 C.F.R. § 42.104(b)(3)

A. STANDARD FOR CLAIM CONSTRUCTION

Pursuant to 37 C.F.R. § 42.204(b)(3), and for purposes of this *Inter Partes* Review petition, the claims subject to this *Inter Partes* Review shall receive the

“broadest reasonable construction in light of the specification of the patent in which [they] appear[.]”

All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation in light of the patent specification including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.

B. OVERVIEW OF CLAIM CONSTRUCTION

1. Preliminary Remarks

To avoid distracting from the Board’s mission to secure just, speedy, and inexpensive resolution of every proceeding, the Petitioner proposes the following claim constructions for all independent claims and dependent claims that have been grouped together. The Petitioner understands that different claims terms are to be construed differently. Notwithstanding, given the similarity between the claim terms, the Petitioner’s proposed construction reasonably covers what each claim recites as limitations. Under the “broadest reasonable interpretation” different claim terms may have the same meaning “where the written description and prosecution history indicate that such a reading of the terms or phrases is proper.” *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009) (“Different terms or phrases in separate claims may be constructed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper.”) (quoting *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1143 (Fed.

Cir. 2005) (citing to *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987) (“[T]wo claims which read differently can cover the same subject matter.”))

2. Preamble

The preamble of each independent claim should be construed as a flexible spinal fixation device that is held into place by a pair of pedicle screws which are anchored into adjacent vertebra.

3. Specific Terms

a) Elastomeric

Elastomeric should be construed as something capable of being deformed and able to return to its original condition. The Petitioner submits for this proceeding, given the disclosure of the '057 patent, the inventors did not intend that elastomeric be understood as those skilled in the material science arts would appreciate. Rather, the inventors appear to have used the term as it would be used in its plain and ordinary meaning, *viz.* something being resilient.

b) Second rigid portion

Second rigid portion should be construed, at least, as a free end.

c) Flexible member

Flexible member should be construed as a structure capable of flexing.

d) Longitudinally compressible spacer

The longitudinally compressible spacer should be construed as a spacer capable of compressing along its length or longitudinal axis.

e) Rigid portion of the longitudinal compressible spacer

The rigid portion of the longitudinal compressible spacer should be construed as rigid spacer having at least a length.

f) Sliding

While the plain and ordinary meaning of “sliding” would denote translation only the longitudinal direction of the spinal implant, a POSITA may consider it to mean something else and rather use a more specific term such as “telescoping”. *See* Dr. McAfee Decl. ¶17. For purposes of this Petition, the Petitioner submits that “sliding,” “translation,” and “telescoping” should mean the same thing, i.e., translation or movement along the longitudinal direction of the spinal implant.

4. Claim Analysis

While the independent claims differ in presentation and slightly vary in wording, Petitioner submits that the independent claims 23 and 46 (as well as dependent claim 47) should be construed in the following manner, in order to assist in the PTAB’s mission to secure just, speedy, and inexpensive resolution of this proceeding.

A flexible spinal fixation device that is held into place by a pair of pedicle screws which are anchored into adjacent vertebra. This fixation device includes four major components: 1) a rigid portion sized to be secured within a pedicle screw; 2) a free end opposite the rigid portion; 3) a flexible member smaller in diameter than the rigid portion and attached to the rigid portion and free end; and 4) a compressible spacer between the rigid portion and free end, and capable of being compressed along its length.

The compressible spacer includes three components: 1) a rigid spacer; 2) a first elastomeric spacer; and 3) a second elastomeric spacer. The rigid spacer separates the first and second elastomeric spacers. The rigid spacer has a bore permitting this spacer to slide along the flexible member. The rigid spacer is sized to be secured within a pedicle screw. The rigid spacer is located between the rigid portion and free end. The first elastomeric spacer has a bore for the flexible member to extend therethrough and is located between the rigid spacer and rigid portion. The second elastomeric spacer has a bore for the flexible member to extend therethrough and is located between the rigid spacer and free end. The elastomeric spacers limit the sliding of the rigid spacer along the flexible member.

Dependent claims 24 and 49 limit the sliding of the rigid spacer such that it does not contact the rigid portion or free end.

Dependent claim 25 and 55 circumscribe that the rigid spacer is separate from the rigid portion and free end.

Dependent claim 26 confines the free end's length to be less than both the elastomeric spacers' lengths.

Dependent claims 27 and 51 expresses that the compressible spacer is constructed such that the first elastomeric spacer separates the rigid portion and the rigid spacer, and the second elastomeric spacer separates the rigid spacer and free end.

Dependent claims 28 and 52 limit the rigid spacer to be between the elastomeric spacers.

Dependent claims 29 and 53 limit the outer surfaces of the rigid portion and rigid spacer to be cylindrical and uniform.

Dependent claims 30 and 48 limit the rigid portion and free end to be metallic.

Dependent claims 31 and 50 limit the rigid spacer to be metallic.

Dependent claims 32 and 54 limit the elastomeric spacers to be made from polycarbonate urethane (PCU).

The below claim charts correlate the proposed claim constructions to the respective claim elements that encompass the claimed inventions in the claims.¹

For independent claims 23 and 46(d47)

Claim Element	Proposed Construction
[PREAMBLE] A flexible, elongated connection unit for stabilizing a human spine where the flexible connection unit is configured to be surgically implanted into the human body adjacent the spine and held in place by at least a first and a	A flexible spinal fixation device which is held in place by a pair of pedicle screws that are anchored into adjacent vertebrae.

¹ Bracketed matter and paragraphing added.

second pedicle screw assembly that are configured to be anchored into a first and second, adjacent vertebra, respectively, the flexible, elongated connection unit comprising:	
[A.] a first rigid portion having an outer surface configured to be secured within the first pedicle screw assembly, the outer surface of the first rigid portion having a dimension;	A rigid portion sized to be secured within a pedicle screw.
[B.] a second rigid portion;	A free end.
[C.] a flexible member connected to the first rigid portion and to the second rigid portion, the flexible member having an outer surface;	A flexible member is smaller in diameter than the rigid portion and is connected to the rigid portion and free end.
[D.] a longitudinally compressible spacer comprising:	A compressible spacer capable of being compressed along its length.
[i.] a spacer portion having a length and having an inner bore extending the length of the spacer portion, the flexible member extending through the bore of the spacer portion, the inner bore of the spacer portion having a larger dimension than the diameter of the outer surface of the flexible member along the length of the spacer portion bore such that the spacer portion can slide along the outer surface of the flexible member, and where the spacer portion has an outer surface configured to be secured within the second pedicle screw assembly, the spacer portion being located entirely between the first rigid portion and the second rigid portion such that along the length of the connection unit no portion of the spacer portion overlaps with any portion of the first or second rigid portion;	A rigid spacer (“spacer portion”) sized to be secured to a pedicle screw, having a bore sized to permit it to slide along the flexible member, and located between the rigid portion and free end.
[ii.] a first elastomeric portion located at least partially between the first rigid portion and the spacer portion, the first	A first elastomeric spacer is located between the rigid portion and the rigid spacer having a bore for the flexible

elastomeric portion having a length and having an inner bore extending the length of the first elastomeric portion with the flexible member extending through the bore of the first elastomeric portion;	member to extend therethrough.
[iii.] a second elastomeric portion located at least partially between the second rigid portion and the spacer portion, the second elastomeric portion having a length and having an inner bore extending the length of the second elastomeric portion with the flexible member extending through the bore of the second elastomeric portion;	A second elastomeric spacer located between the free end and the rigid spacer having a bore for the flexible member to extend therethrough.
whereby the first and second elastomeric spacer portions limit the sliding of the spacer portion along the flexible member.	The elastomeric spacers limit the sliding of the rigid spacer along the flexible member.

For dependent claims 24 and 49

Claim Element	Proposed Construction
The spacer portion is physically separate from and does not physically contact the first rigid portion or the second rigid portion.	The rigid spacer does not contact the rigid portion or free end.

For dependent claims 25 and 55

Claim Element	Proposed Construction
The spacer portion is not integral with the first rigid portion or the second rigid portion.	The rigid spacer is separate from the rigid portion or free end.

For dependent claim 26

Claim Element	Proposed Construction
The second rigid portion has a longitudinal dimension that is shorter than the longitudinal dimension of both the first elastomeric portion and the	The free end's length is less than both the elastomeric spacers, individually.

second elastomeric portion individually.	
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For dependent claims 27 and 51

Claim Element	Proposed Construction
The spacer is constructed such that the first elastomeric portion physically separates the first rigid portion and the spacer portion and the second elastomeric portion physically separates the second rigid portion and the spacer metallic portion.	The compressible spacer is constructed such that the elastomeric spacers separate the rigid portion, the rigid spacer, and free end.

For dependent claims 28 and 52

Claim Element	Proposed Construction
The spacer portion physically separates the first and second elastomeric portions.	The rigid spacer separates the elastomeric spacers.

For dependent claims 29 and 53

Claim Element	Proposed Construction
The entire outer, longitudinal surface of each of the first rigid portion and the spacer portion is cylindrical and uniform.	The outer surfaces of the rigid portion and rigid spacer are cylindrical and uniform.

For dependent claims 30 and 48

Claim Element	Proposed Construction
The first and second rigid portions are metallic.	The rigid portion and free end are metallic.

For dependent claims 31 and 50

Claim Element	Proposed Construction
The spacer rigid portion is metallic.	The rigid spacer is metallic.

For dependent claims 32 and 54

Claim Element	Proposed Construction
Both the first and second spacer elastomeric portions comprise polycarbonate urethane.	The elastomeric spacers are made from polycarbonate urethane.

VII. HOW THE CONSTRUED CLAIMS ARE UNPATENTABLE UNDER 37 C.F.R. § 42.104(b)(4)

A. Person of Ordinary Skill in the Art (“POSITA”)

In view of the '057 Patent's subject matter, a POSITA at the time of the invention was typically a person who had at least a bachelor's degree in mechanical engineering, or equivalent degree, and at least two years of experience in the design, fabrication, and testing of implants or an orthopedic surgeon with experience in spinal surgery and experience in the design of implants. Exhibit 1007 (“McAfee Decl.” hereinafter), ¶4.

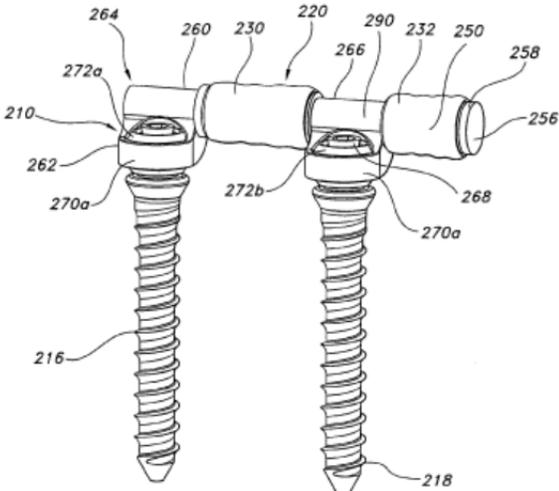
B. Specifying where each element of the claim is found in the prior art

1. Ground 1: Claims 23-32 and 46-55 are rendered obvious under 35 U.S.C. § 103 by Panjabi and McAfee.

The following claim charts, and associated analysis, demonstrate, on a limitation-by-limitation basis, how claims 23-32 and 46-55 of the '057 Patent are rendered obvious by Panjabi and McAfee.

a) Claims 23-32

(1) Claim Chart for Claim 23

Claim 23	Correspondence to the Prior Art
<p>A flexible, elongated connection unit for stabilizing a human spine where the flexible connection unit is configured to be surgically implanted into the human body adjacent the spine and held in place by at least a first and a second bone coupling assembly that are configured to be anchored into a first and second, adjacent vertebra, respectively, the flexible connection unit comprising:</p>	<p>Stabilization device 210 is held in place by bone coupling assemblies 216 and 218 respectfully. <i>See</i> Panjabi, fig. 8, reproduced below and Panjabi 11:65 to 12:19.</p> <p>Each of the pedicle screws 216, 218 includes a proximal end 274 and a distal end 276 (as the first and second pedicle screws 216, 218 are identical, similar numerals will be used in describing them). The proximal end 274 includes traditional threading 278 adapted for secure attachment along the spinal column of an individual. Panjabi, 12:9-14.</p>  <p style="text-align: center;">FIG. 8</p> <p>McAfee describes an analogous spinal rod sleeve system that allows a vertebra to slide cephalad or caudad. McAfee, [0034].</p>
<p>(a) a first rigid portion having an outer surface configured to be secured within the first bone coupling assembly;</p>	<p>First attachment member 260 with a first ball joint 262 extending from a first end 264 of housing 220. Panjabi, 12:3-5.</p> <p>The distal end 276 of the pedicle screw 216, 218 is provided with a collet 278 adapted for engagement within a receiving aperture 280a, 280b formed within the ball 272a, 272b of the first and second attachment members 260, 266 of the stabilization device 210. Panjabi, 12:14-19 and <i>see</i> Fig. 9.</p> <p>First attachment member 260 has an outer</p>

	<p>dimension as shown in Figures 8-13 of Panjabi. McAfee's rod sleeve is made from metal, which serves as a containment casing. McAfee, [0035]. As shown in Figure 3, McAfee's rod sleeve so that it vertically tracks over pedicle screw 8. McAfee, [0044], Figs. 3 and 7. Whereas McAfee's Figure 2 depicts an offset anchoring for the rod sleeve.</p>
(b) a second rigid portion;	<p>Abutment member 256 having free end 258. Panjabi, 13:9-10.</p>
(c) a flexible member connected to the first rigid portion and the second rigid portion, the flexible member having an outer surface;	<p>Alignment pin 250 (not shown in figures) extends from first attachment member 260 through a bearing aperture in 290 within the second attachment member 266. Alignment pin 250 ends with abutment member 256 having free end 258. Panjabi, 13:6-12. The alignment pin 250 is cable of functioning as both a straight guide member and as a flexible guide member. The determination as to whether the alignment pin 250 functions as a straight guide member or a flexible guide member for the springs 230, 232 is generally based upon location of the alignment pin 250 relative to the remaining stabilization device 210 components as the spine moves. This functionality is especially important during flexion. In accordance with an exemplary embodiment, the alignment pin 250 has a uniform cross sectional shape capable of performing as both a straight guide member and a flexed guide member. Panjabi, 13:43-54.</p>
(d) a longitudinally compressible spacer comprising:	<p>Portion of 210 starting with 230 and moving right and stopping at abutment member 256 as shown in figure 8 of Panjabi. <i>See also</i> Exhibit 1004 for annotated version of Panjabi's figure 8.</p>
(1) a rigid portion having a length and having an inner bore extending the length of the spacer rigid portion, the flexible member extending through the inner bore of the spacer rigid portion, the inner bore of the	<p>Second attachment member 266 with second ball joint 268. Panjabi, 12:5-7. Alignment pin 250 extends from first attachment member 260 through a bearing aperture in 290 within the second attachment member 266. Panjabi, 13:6-9. Arrangement of the alignment pin 250, first and second attachment members 260, 266 and first</p>

<p>spacer rigid portion having a larger dimension than the outer surface of the flexible member along the length of the spacer rigid portion bore such that the spacer rigid portion can slide along the outer surface of the flexible member, and</p> <p>where the spacer rigid portion has an outer surface configured to be secured within the second bone coupling assembly,</p> <p>the spacer rigid portion being located entirely between the first rigid portion and the second rigid portion such that along the length of the connection unit no portion of the spacer rigid portion overlaps with any portion of the first or second rigid portion;</p>	<p>and second springs 230, 232 allows for resistive translation of the alignment pin 250 relative to the vertebrae. Panjabi, 13:16-20.</p> <p>Second attachment member 266 with second ball joint 268 extending through a central portion of the stabilizer 220. Panjabi, 12:5-7.</p> <p>The first spring 230 is positioned to extend between the first attachment member 260 and the second attachment member 266, while the second spring 232 is positioned to extend between the second attachment member 266 and the abutment member 256 at the free end 258 of the alignment pin 250. Panjabi, 13:12-17.</p>
<p>(2) a first elastomeric portion located at least partially between the first rigid portion and the spacer rigid portion, the first elastomeric portion having a length and having an inner bore extending the length of the first elastomeric portion with the flexible member extending through the bore of the first elastomeric portion;</p>	<p>First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14.</p>
<p>(3) a second elastomeric portion located at least partially between the second rigid portion and the spacer rigid portion, the second elastomeric portion having a length and having an inner bore extending the length of the</p>	<p>Second spring 232 concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17.</p>

second elastomeric portion with the flexible member extending through the bore of the second elastomeric portion;	
whereby the first and second elastomeric spacer portions limit the sliding of the spacer rigid portion along the flexible member.	The arrangement of the alignment pin 250, first and second attachment members 260, 266 and first and second springs 230, 232 allows for resistive translation of the alignment pin 250 relative to the vertebrae. In practice, the alignment pin 250, springs 230, 232 and attachment members 260, 266 are arranged to create a compressive preload across the system. Panjabi, 13:16-23.

(a) Analysis for Claim 23

Panjabi discloses dynamic stabilization devices. Exhibit 1002, Title (“Panjabi” hereinafter). An embodiment depicted in Figures 8-13 shows the dynamic stabilization device having, what is known in the art, as an overhanging stabilizing member. *Id.*, Title, Abstract, and McAfee Decl. ¶10. The dynamic stabilization device is secured to the patient’s vertebrae by using pedicle screws 216 and 218. Each pedicle screw includes a proximal end 274 (distal portion)² and a distal end (proximal portion). The proximal end 274 includes traditional threading 278 adapted for secure attachment along the spinal column of a patient. Panjabi, 12:12-14. Since Panjabi discloses what attaches to the spine are pedicle screws, these screws are being attached to the pedicle portion of the spine. McAfee Decl. ¶20.

² Claim nomenclature will be in parenthetical when being compared to the prior art structures.

McAfee discloses spinal rod sleeve system that allows a vertebra to slide cephalad or caudad. McAfee, [0034]. Therefore, McAfee is analogous art since it is within the same field of endeavor, spinal stabilization devices and achieves the same goals. McAfee Decl. ¶21.

What Panjabi discloses as the dynamic spine stabilization device constitutes a first resilient member or spring 230 that is disposed on an elongate element, alignment pin 250 - not drawn, but labeled, that spans two attachment members 260, 266 attached to adjacent spinal vertebrae. Exhibit 1004; Panjabi's, Abstract. The elongate element, alignment pin 250, passes through at least one of the two attachment members, attachment member 266, permitting relative motion therebetween, and terminates in a free end or abutment member 256. Panjabi, 13:6-10, 17-20. Since the abutment member 256 is not held in place by another structure such as a pedicle screw, the abutment member 256 is a free end; Panjabi identifies it as such with the inclusion of free end 258. A second resilient member 232 is disposed on the elongate element, alignment pin 250, on an opposite side of the second attachment member 266, e.g., in an overhanging orientation. Panjabi, 13:14-17. The two resilient members 230 and 232 are capable of applying mutually opposing urging forces, and a compressive preload can be applied to one or both of the resilient members 230 and 232. Panjabi, 13:33-35.

Thus, Panjabi substantially discloses claim 23. However, Panjabi does not expressly disclose: the first attachment member 260 (first rigid portion) having an

outer surface configured to be secured within the pedicle screw assembly (first bone coupling assembly); the alignment pin 250 (flexible member) expressly disclosed as being connected to the first attachment member 260 (first rigid portion) and the abutment member 256 (second rigid portion); the second attachment member 266 (spacer rigid portion) having an inner bore of larger diameter than the outer surface of the alignment pin 250 (flexible member), and an outer surface configured to be secured in a pedicle screw assembly (second bone coupling assembly); the second attachment member 266 (spacer rigid portion) being located entirely between the first attachment member first 266 and the abutment member 256 (first and second rigid portions) such that along the length of the stabilization device 210 no portion of the second attachment member 266 (spacer metallic portion) overlaps with any portion of the first attachment member 260 or the abutment member 256 (first or second rigid portions); and the springs 230 and 232, also disclosed as resilient members, corresponding to the first and second elastomeric portions of the compressible spacer, being made from elastomeric materials.

Panjabi uses an offset system of anchoring its flexible spinal fixation device to adjacent vertebrae for the embodiment disclosed in Figures 8-11. McAfee discloses using both an offset system and an in-line system of anchoring to a vertebra. McAfee, Figs. 2 and 3. Dr. McAfee discusses the differences between the two styles of implants. McAfee Decl. ¶14.

McAfee prefers the in-line system of anchoring because that system minimizes torque and binding friction between the components, thereby giving a greater range of motion to the patient. McAfee, [0037] and [0044]. Therefore, it would have been obvious to modify Panjabi's first and second attachment members 260 and 266 (first rigid portion and spacer rigid portion) with McAfee's in-line anchoring teaching for the benefit disclosed in McAfee. Dr. McAfee confirms McAfee's disclosure of less force on the components. McAfee Decl. ¶14.

Connecting a spinal stabilization device, such as those disclosed in the '057 patent, Panjabi, and McAfee, to the spine via polyaxial pedicle screw systems are well known in the art. Such screw systems can be classified as either in-line or offset. In-line screw systems typically include a bone screw and a tulip connector, the tulip connector designed to receive the head of the bone screw and a portion of the spinal stabilization member. Examples of in-line screw systems are shown in Exhibits 1010-1014. The '057 patent utilizes this well-known system for connecting the disclosed dynamic stabilization device. The aforementioned in-line screw systems include a ball and socket joint for a polyaxial connection of the spinal stabilization device to the spine. Offset systems, such as Panjabi and Exhibits 1015-1016, provide the same ball and socket joint as the in-line screw system that is depicted in the '057 patent and Exhibits 1010-1014, but include a slightly different connector; the difference being solely the location of the ball and socket joint relative to the spinal stabilization device. For in-line the spinal device is a top the joint; for offset the device is aside the

joint. A POSITA would have known at the time of the invention that an offset screw system can be replaced with an in-line screw system. Advantages exists using one system over the other, albeit with simultaneous disadvantages. McAfee Decl. ¶14. As the Federal Circuit has recognized that a given course of action has simultaneous advantages and disadvantages does not nullify modifying the teachings of one reference over another. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n. 8 (Fed. Cir. 2000).

While, Panjabi does not expressly disclose the alignment pin 250 (flexible member) being connected to the first attachment member 260 (first rigid portion) and the free end 258 and abutment member 256 (second rigid portion), Panjabi does disclose the alignment pin 250 extends from first attachment member 260 and ends at the abutment member 256 with free end 258. Given this disclosure, a POSITA would conclude that the alignment pin 250 is directly secured to the attachment member 260 and abutment member 256.

While Panjabi does not expressly disclose the alignment pin 250 (flexible member) as having an outer surface, Panjabi discloses that the alignment pin 250 has certain characteristics to infer its shape and size. Panjabi discloses that the alignment pin is preferably a cable, has a uniform cross-section shape, and extends through a bearing aperture 290 within the second attachment member 266 (spacer rigid portion). Panjabi 13:6-12 and 43-54. Given this description, person of ordinary skill in the art would understand a cable having an outer surface of twisted and woven materials.

McAfee Decl. ¶22. Therefore, Panjabi satisfies the requirement that the flexible member having an outer surface.

Panjabi discloses the second attachment member 266 (spacer metallic portion) having an aperture 290 (inner bore) that alignment pin 250 (flexible member) passes therethrough. Panjabi does not expressly disclose the aperture 290 having a larger dimension than the outer surface of the alignment pin 250 such that the second attachment member 266 can slide along the outer surface of the alignment pin 250. However, Dr. McAfee understands given Panjabi express disclosure of alignment pin 250 passing through the aperture 290, Panjabi satisfies the claim feature. *See* McAfee Decl. ¶23.

Turning to the requirement that the second attachment member 266 (spacer rigid portion) has an outer surface configured to be secured within the second pedicle screw assembly (second bone coupling assembly), Panjabi uses an offset system of anchoring its flexible spinal fixation device to adjacent vertebrae for the embodiment disclosed in Figures 8-11. McAfee discloses using both an offset system and an in-line system of anchoring to a vertebra. McAfee, Figs. 2 and 3. Dr. McAfee discusses the differences and functionalities between in-line and offset implants. McAfee Decl. ¶14. McAfee prefers the in-line system of anchoring because that system minimizes torque and binding friction between the components, thereby giving a greater range of motion to the patient. McAfee, [0037] and [0044]. Therefore, it would have been

obvious to modify Panjabi's first and second attachment members 260 and 266 (first rigid portion and spacer rigid portion) with McAfee's in-line anchoring teaching for the benefit disclosed in McAfee. Dr. McAfee's confirms McAfee's disclosure of less force on the components. McAfee Decl. ¶14. Thus, it would be obvious to modify Panjabi to be an in-line implant so as to achieve less rotational force or torque on the screws. *See id.* at ¶14.

Turning to the requirement that the spacer rigid portion being located entirely between the first rigid portion and the second rigid portion such that along the length of the connection unit no portion of the spacer rigid portion overlaps with any portion of the first or second rigid portion, in addition to the spatial relation disclose in Panjabi 13:12-17, Panjabi depicts in Figures 8 and 9 and discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), and the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion). The disclosed and depicted relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), and the

spring 230 is between the first attachment member 260 and the second attachment member 266 while the spring 232 is between the second attachment member and the abutment member 256, the second attachment member 256 (spacer rigid portion) is located entirely between the (first and second rigid portions) and no portion of the second attachment member 266 (spacer rigid portion) overlaps with any portion of the first attachment member 260 or the abutment member 256 (first or second rigid portions, respectfully) along the length of the connection unit. Given this disclosure, Dr. McAfee states that the claimed feature would be satisfied by Panjabi. McAfee Decl. ¶18.

For the embodiment depicted in Figures 8-13, Panjabi discloses the springs 230 and 232 as the structures to assist in resistive translation of the alignment pin 250. Panjabi, 13:16-22. In other sections of Panjabi, these structures that assist in limiting movement relative to the spine are also disclosed as resilient members. Panjabi, Abstract and 3:55-60. In addition, while springs are disclosed as being preferred in both the first and second major embodiments, Panjabi discloses that “other elastic members may be employed without departing from the spirit and scope of the present disclosure.” Panjabi, 8:35-37. Dr. McAfee provides a listing of elastic materials that would be used as the spacers. McAfee Decl. ¶19. Dr. McAfee listing includes both metal springs (as disclosed by Panjabi) and elastic materials such as PCU, UHMWPE, Dacron, and silicone. *Id.* Therefore, a POSITA would find it obvious to substitute one material for another.

(2) Claim Chart for Claim 24

Claim 24	Correspondence to the Prior Art
The flexible connection unit of claim 23, wherein the spacer rigid portion is physically separate from and does not physically contact the first rigid portion or the second rigid portion.	First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).

(a) Analysis for Claim 24

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and

232 (first and second elastomeric portions). Since the first spring 230 (first elastomeric portion) extends between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), the first spring 230 (first elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer rigid portions, respectfully). Since the second spring 232 (second elastomeric portion) extends between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), the second spring 232 (second elastomeric portion) physically separates the second attachment member 266 and the abutment member 256 (spacer rigid portion and second rigid portion, respectfully). Since second attachment member 266 is between the two springs 230 and 232 and the first spring 230 is between the first attachment portion 260 and the second attachment portion 266 and the second spring 232 is between the second attachment member portion 266 and the abutment member 256, the second attachment member 266 (spacer rigid portion) is physically separate from and does not physically contact the first attachment member 260 (first rigid portion) or abutment member 256 (second rigid portion). Given this disclosure, Dr. McAfee states that the claimed feature would be satisfied by Panjabi. McAfee Decl. ¶18.

(3) Claim Chart for Claim 25

Claim 25	Correspondence to the Prior Art
The flexible connection unit of claim 23, wherein the spacer rigid	First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend

<p>portion is not integral with the first rigid portion or the second rigid portion.</p>	<p>between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).</p>
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(a) Analysis for Claim 25

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since the first spring 230 (first elastomeric portion) extends between the first attachment member 260 (first rigid portion) and

the second attachment member 266 (spacer rigid portion), the first spring 230 (first elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer rigid portions, respectfully). Since the second spring 232 (second elastomeric portion) extends between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), the second spring 232 (second elastomeric portion) physically separates the second attachment member 266 and the abutment member 256 (spacer rigid portion and second rigid portion, respectfully). Since second attachment member 266 is between the two springs 230 and 232 and the spring 230 is between the first attachment portion 260 and the second attachment portion 266 and the spring 232 is between the second attachment member portion 266 and the abutment member 256, the second attachment member 266 (spacer rigid portion) is not integral with the first attachment member 260 (first rigid portion) or abutment member 256 (second rigid portion). Given this disclosure, Dr. McAfee states that the claimed feature would be satisfied by Panjabi. McAfee Decl. ¶18.

(4) Claim Chart for Claim 26

Claim 26	Correspondence to the Prior Art
The flexible connection unit of claim 23, wherein the second rigid portion has a longitudinal dimension that is shorter than the longitudinal dimension of both the first elastomeric portion and the second elastomeric portion individually.	As shown in Panjabi figure 8, abutment member 256 having free end 258 is shorter in length than first and second springs 230, 232.

(a) Analysis for Claim 26

Description via drawings and pictures can be relied upon alone as well as by words to anticipate claimed subject matter if they clearly show the structure claimed. *In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972). Patent drawings not designated as being drawn to scale cannot be relied upon to define precise proportions of elements if the specification is completely silent on the issue. *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000). That does not mean, however, “that things patent drawings show clearly are to be *disregarded*.” *Mraz*, 455 F.2d at 1072. In this case, Panjabi’s figure 8 depicts that the abutment member 256 having free end 258 (second rigid portion) is shorter than each spring 230, 232 (elastomeric portions). Dr. McAfee states the reasons that the overhang has to be shorter than the springs. McAfee Decl. ¶24.

(5) Claim Chart for Claim 27

Claim 27	Correspondence to the Prior Art
The flexible connection unit of claim 23, wherein the spacer is constructed such that the first elastomeric portion physically separates the first rigid portion and the spacer rigid portion and the second elastomeric portion physically separates the second rigid portion and the spacer rigid portion.	First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed

second rigid portion).

(a) Analysis for Claim 27

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since the first spring 230 (first elastomeric portion) extends between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), the first spring 230 (first elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer rigid portions, respectfully). Since the second spring 232 (second elastomeric portion) extends between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), the second spring 232 (second elastomeric portion) physically separates the

second attachment member 266 and the abutment member 256 (spacer rigid portion and second rigid portion, respectfully).

(6) Claim Chart for Claim 28

Claim 28	Correspondence to the Prior Art
<p>The flexible connection unit of claim 27, wherein the spacer rigid portion physically separates the first and second elastomeric portions.</p>	<p>First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).</p>

(a) Analysis for Claim 28

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between

the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions).

(7) Claim Chart for Claim 29

Claim 29	Correspondence to the Prior Art
The flexible connection unit of claim 27, wherein the entire outer, longitudinal surface of each of the first rigid portion and the spacer rigid portion is cylindrical and uniform.	As shown in figure 8, first attachment member 260 and second attachment member 266 have a cylindrical portion surrounding the alignment pin 250. McAfee discloses the rod sleeve is cylindrical in shape. McAfee, [0041].

(a) Analysis for Claim 29

McAfee discloses that the rod sleeve which the spinal rod 3 fits into through bearing surface 2 is cylindrical in shape. By definition a cylinder is uniform. Therefore, McAfee disclosure satisfies the claimed features associate with claim 29. McAfee teachings would be used to modify the teachings of Panjabi concerning the matter of anchoring. Therefore, the combination of Panjabi and McAfee render claim 29 as obvious.

(8) Claim Chart for Claim 30

Claim 30	Correspondence to the Prior Art
The flexible connection unit of claim 27, wherein the first and second rigid portions are metallic.	First attachment member 260 and abutment member 256.

(a) Analysis for Claim 30

Panjabi's does not expressly as to the materials of the first attachment member 260 and the abutment member 256. However, a person of ordinary skill in the art understands that there are a finite number of materials acceptable for use in the body, and material chosen to make a part to be inserted into the body would select the material based on the functionality of the part and what would be acceptable in the body. McAfee Decl. ¶¶11-13 and 19. As an example in the prior art, McAfee discloses having the rod sleeve have a metal casing and this casing is encircled by the pedicle assembly. McAfee, [0036]-[0037]. In this case, the functionality of the first attachment member is to secure the stabilization device 210 to a vertebra via a pedicle screw. Panjabi, 12:2-19. Titanium is a metal that will allow this technology achieve the needed functionality. See McAfee Decl. ¶11. Thus, a person of ordinary skill in the art would find it obvious to make the first attachment member 260 (first rigid portion) out of a metallic material, in order to achieve the needed flexibility and durability. Turning to the free end 258 and abutment member 256 (second rigid portion), the likely preferred material would be titanium. *Id.* Thus, a person of ordinary skill in the art would find it obvious to make the free end 258 and abutment member 256 (second rigid portion), in order to achieve the needed flexibility and durability. It should be noted that Dr. McAfee states that for this type of technology "there is no perfect material – it depends what part of the balance or compromise that one wants to make." McAfee Decl. ¶11. For obviousness, the Federal Circuit has recognized that a given course of action often has simultaneous advantages and

disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n. 8 (Fed. Cir. 2000) (“The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.”).

(9) Claim Chart for Claim 31

Claim 31	Correspondence to the Prior Art
The flexible connection unit of claim 30, wherein the spacer rigid portion is metallic.	Panjabi speaks to springs, nuts, bolts, ball and socket joints that may have inferences drawn to the materials used to construct such structures.

(a) Analysis for Claim 31

Panjabi does not expressly disclose the second attachment member 266 (rigid spacer portion) being made from a metallic material. However, a person of ordinary skill in the art understands that there are a finite number of materials acceptable for use in the body, and material chosen to make a part to be inserted into the body would select the material based on the functionality of the part and what would be acceptable in the body. *See McAfee Decl.* ¶11. In this case, the functionality of the second attachment member 266 (rigid spacer portion, claim nomenclature is to secure the implant to the pedicle screw. Thus, a person of ordinary skill in the art would find it obvious to make the second attachment member 266 (spacer rigid portion) out of a metallic material, such as titanium, in order to have a material that is close to the

modulus of the spine. *See* McAfee Decl. ¶11. Further for obviousness, the Federal Circuit has recognized that a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d at 1349 n. 8 (Fed. Cir. 2000).

(10) Claim Chart for Claim 32

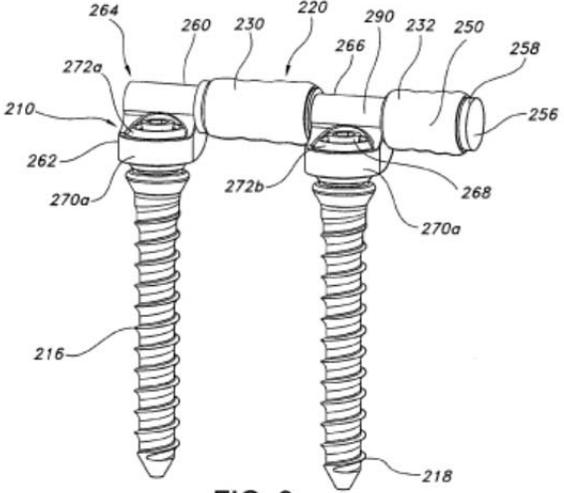
Claim 32	Correspondence to the Prior Art
The flexible connection unit of claim 31, wherein both the first and second spacer elastomeric portions comprise polycarbonate urethane.	Panjabi discloses using resilient members in a compressive preload. Abstract and col. 3, ll. 55-65.

(a) Analysis for Claim 32

It should be noted that Dr. McAfee states that for this type of technology “there is no perfect material – it depends what part of the balance or compromise that one wants to make.” McAfee Decl. ¶11. Moreover, Dr. McAfee provides a listing of elastic materials that would be used as the spacers. McAfee Decl. ¶19. Dr. McAfee listing includes both metal springs (as disclosed by Panjabi) and elastic materials such as PCU, UHMWPE, Dacron, and silicone. *Id.* For obviousness, the Federal Circuit has recognized that a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d at 1349 n. 8 (Fed. Cir. 2000). Therefore, a POSITA would find it obvious to substitute one material for another.

b) Claims 46-55

(1) Claim Chart for Claim 46

Claim 46	Correspondence to the Prior Art
<p>A kit for stabilizing a human spine, comprising:</p>	<p>Stabilization device 210 is held in place by bone coupling assemblies, pedicle screws 216 and 218 respectfully. <i>See</i> Panjabi, fig. 8, reproduced below and Panjabi 11:65 to 12:19.</p>  <p style="text-align: center;">FIG. 8</p> <p>McAfee describes an analogous spinal rod sleeve system that allows a vertebra to slide cephalad or caudad. McAfee, [0034].</p>
<p>(a) a first bone coupling assembly and a second bone coupling assembly, each having a distal portion configured to be secured to a vertebra and a proximal portion; and</p>	<p>Each of the pedicle screws 216, 218 includes a proximal end 274 and a distal end 276 (as the first and second pedicle screws 216, 218 are identical, similar numerals will be used in describing them). The proximal end 274 includes traditional threading 278 adapted for secure attachment along the spinal column of an individual. The distal end 276 of the pedicle screw 216, 218 is provided with a collet 278 adapted for engagement within a receiving aperture 280a, 280b formed within the ball 272a, 272b of the first and second attachment members 260, 266 of the stabilization device 210. Panjabi, 12:9-19.</p>
<p>(b) a flexible, connection unit comprising:</p>	<p>Stabilization device 210 is held in place by bone coupling assemblies 216 and 218 respectfully. <i>See</i></p>

	Panjabi, fig. 8, reproduced below and Panjabi 11:65 to 12:19.
(1) a first rigid portion having an outer surface configured to be secured within the proximal portion of the first bone coupling assembly;	<p>First attachment member 260 with a first ball joint 262 extending from a first end 264 of housing 220. Panjabi, 12:3-5.</p> <p>The distal end 276 of the pedicle screw 216, 218 is provided with a collet 278 adapted for engagement within a receiving aperture 280a, 280b formed within the ball 272a, 272b of the first and second attachment members 260, 266 of the stabilization device 210. Panjabi, 12:14-19 and <i>see</i> Fig. 9.</p> <p>First attachment member 260 has an outer dimension as shown in Figures 8-13 of Panjabi. McAfee's rod sleeve is made from metal, which serves as a containment casing. McAfee, [0035]. As shown in Figure 3, McAfee's rod sleeve so that it vertically tracks over pedicle screw 8. McAfee, [0044], Figs. 3 and 7. Whereas McAfee's Figure 2 depicts an offset anchoring for the rod sleeve.</p>
(2) a second rigid portion;	Abutment member 256 having free end 258. Panjabi, 13:9-10.
(3) a flexible member connected to the first rigid portion and the second rigid portion, the flexible member having an outer surface;	Alignment pin 250 (not shown in figures) extends from first attachment member 260 through a bearing aperture in 290 within the second attachment member 266. Alignment pin 250 ends with abutment member 256 having free end 258. Panjabi, 13:6-12. The alignment pin 250 is cable of functioning as both a straight guide member and as a flexible guide member. The determination as to whether the alignment pin 250 functions as a straight guide member or a flexible guide member for the springs 230, 232 is generally based upon location of the alignment pin 250 relative to the remaining stabilization device 210 components as the spine moves. This functionality is especially important during flexion. In accordance with an exemplary embodiment, the alignment pin 250 has a uniform cross sectional shape capable of performing as

	both a straight guide member and a flexed guide member. Panjabi, 13:43-54.
(4) a longitudinally compressible spacer comprising:	Portion of 210 starting with 230 and moving right and stopping at abutment member 256 as shown in figure 8 of Panjabi. <i>See also</i> Exhibit 1004 for annotated version of Panjabi's figure 8.
(i) a rigid portion having a length and having an inner bore extending the length of the spacer rigid portion, the flexible member extending through the inner bore of the spacer rigid portion, the inner bore of the spacer rigid portion having a larger dimension than the outer surface of the flexible member along the length of the spacer rigid portion bore such that the spacer rigid portion can slide along the outer surface of the flexible member, and where the spacer rigid portion has an outer surface configured to be secured within the proximal portion of the second bone coupling assembly;	Second attachment member 266 with second ball joint 268. Panjabi, 12:5-7. Alignment pin 250 extends from first attachment member 260 through a bearing aperture in 290 within the second attachment member 266. Panjabi, 13:6-9. Arrangement of the alignment pin 250, first and second attachment members 260, 266 and first and second springs 230, 232 allows for resistive translation of the alignment pin 250 relative to the vertebrae. Panjabi, 13:16-20. Second attachment member 266 with second ball joint 268 extending through a central portion of the stabilizer 220. Panjabi, 12:5-7.
(ii) a first elastomeric portion located at least partially between the first rigid portion and the spacer rigid portion, the first elastomeric portion having a length and having an inner bore extending the length of the first elastomeric portion with the flexible member extending through the bore of the first elastomeric portion;	First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14.
(iii) a second elastomeric portion located at least partially between	Second spring 232 concentrically positioned about alignment pin 250 and is positioned to

<p>the second rigid portion and the spacer rigid portion, the second elastomeric portion having a length and having an inner bore extending the length of the second elastomeric portion with the flexible member extending through the bore of the second elastomeric portion;</p>	<p>extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17.</p>
<p>whereby the first and second elastomeric spacer portions limit the sliding of the spacer rigid portion along the flexible member.</p>	<p>The arrangement of the alignment pin 250, first and second attachment members 260, 266 and first and second springs 230, 232 allows for resistive translation of the alignment pin 250 relative to the vertebrae. In practice, the alignment pin 250, springs 230, 232 and attachment members 260, 266 are arranged to create a compressive preload across the system. Panjabi, 13:16-23.</p>

(a) Analysis for Claim 46

Panjabi discloses dynamic stabilization devices. Exhibit 1002, Title (“Panjabi” hereinafter”). An embodiment depicted in Figures 8-13 shows the dynamic stabilization device having, what is known in the art, as an overhanging stabilizing member. *Id.*, Title, Abstract, and McAfee Decl. ¶10. The dynamic stabilization device is secured to the patient’s vertebrae by using pedicle screws 216 and 218. Each pedicle screw includes a proximal end 274 (distal portion) and a distal end (proximal portion). The proximal end 274 includes traditional threading 278 adapted for secure attachment along the spinal column of a patient. Panjabi, 12:12-14. Since Panjabi discloses what attaches to the spine are pedicle screws, these screws are being attached to the pedicle portion of the spine. McAfee Decl. ¶20.

McAfee discloses spinal rod sleeve system that allows a vertebra to slide cephalad or caudad. McAfee, [0034]. Therefore, McAfee is analogous art since it is within the same field of endeavor, spinal stabilization devices and achieves the same goals. McAfee Decl. ¶21.

What Panjabi discloses as the dynamic spine stabilization device constitutes a first resilient member or spring 230 that is disposed on an elongate element, alignment pin 250 - not drawn, but labeled, that spans two attachment members 260, 266 attached to adjacent spinal vertebrae. Exhibit 1004; Panjabi's, Abstract. The elongate element, alignment pin 250, passes through at least one of the two attachment members, attachment member 266, permitting relative motion therebetween, and terminates in a free end or abutment member 256. Panjabi, 13:6-10, 17-20. Since the abutment member 256 is not held in place by another structure such as a pedicle screw, the abutment member 256 is a free end; Panjabi identifies it as such with the inclusion of free end 258. A second resilient member 232 is disposed on the elongate element, alignment pin 250, on an opposite side of the second attachment member 266, e.g., in an overhanging orientation. Panjabi, 13:14-17. The two resilient members 230 and 232 are capable of applying mutually opposing urging forces, and a compressive preload can be applied to one or both of the resilient members 230 and 232. Panjabi, 13:33-35.

Thus, Panjabi substantially discloses claim 46. However, Panjabi does not expressly disclose: the first attachment member 260 (first rigid portion) having an

outer surface configured to be secured within the pedicle screw assembly (first bone coupling assembly); the alignment pin 250 (flexible member) expressly disclosed as being connected to the first attachment member 260 (first rigid portion) and the abutment member 256 (second rigid portion); the second attachment member 266 (spacer rigid portion) having an inner bore of larger diameter than the outer surface of the alignment pin 250 (flexible member), and an outer surface configured to be secured in a pedicle screw assembly (second bone coupling assembly); and the springs 230 and 232, also disclosed as resilient members, corresponding to the first and second elastomeric portions of the compressible spacer, being made from elastomeric materials.

Panjabi uses an offset system of anchoring its flexible spinal fixation device to adjacent vertebrae for the embodiment disclosed in Figures 8-11. McAfee discloses using both an offset system and an in-line system of anchoring to a vertebra. McAfee, Figs. 2 and 3. Dr. McAfee discusses the differences between the two styles of implants. McAfee Decl. ¶14.

McAfee prefers the in-line system of anchoring because that system minimizes torque and binding friction between the components, thereby giving a greater range of motion to the patient. McAfee, [0037] and [0044]. Therefore, it would have been obvious to modify Panjabi's first and second attachment members 260 and 266 (first rigid portion and spacer rigid portion) with McAfee's in-line anchoring teaching for the benefit disclosed in McAfee.

Connecting a spinal stabilization device, such as those disclosed in the '057 patent, Panjabi, and McAfee, to the spine via polyaxial pedicle screw systems are well known in the art. Such screw systems can be classified as either in-line or offset. In-line screw systems typically include a bone screw and a tulip connector, the tulip connector designed to receive the head of the bone screw and a portion of the spinal stabilization member. Examples of in-line screw systems are shown in Exhibits 1010-1014. The '057 patent utilizes this well-known system for connecting the disclosed dynamic stabilization device. The aforementioned in-line screw systems include a ball and socket joint for a polyaxial connection of the spinal stabilization device to the spine. Offset systems, such as Panjabi and Exhibits 1015-1016, provide the same ball and socket joint as the in-line screw system that is depicted in the '057 patent and Exhibits 1010-1014, but include a slightly different connector; the difference being solely the location of the ball and socket joint relative to the spinal stabilization device. For in-line the spinal device is a top the joint; for offset the device is aside the joint. A POSITA would have known at the time of the invention that an offset screw system can be replaced with an in-line screw system. Advantages exists using one system over the other, albeit with simultaneous disadvantages. McAfee Decl. ¶14. As the Federal Circuit has recognized that a given course of action has simultaneous advantages and disadvantages does not nullify modifying the teachings of one reference over another. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n. 8 (Fed. Cir. 2000).

While, Panjabi does not expressly disclose the alignment pin 250 (flexible member) being connected to the first attachment member 260 (first rigid portion) and the free end 258 and abutment member 256 (second rigid portion), Panjabi does disclose the alignment pin 250 extends from first attachment member 260 and ends at the abutment member 256 with free end 258. Given this disclosure, a POSITA would conclude that the alignment pin 250 is directly secured to the attachment member 260 and abutment member 256.

While Panjabi does not expressly disclose the alignment pin 250 (flexible member) as having an outer surface, Panjabi discloses that the alignment pin 250 has certain characteristics to infer its shape and size. Panjabi discloses that the alignment pin is preferably a cable, has a uniform cross-section shape, and extends through a bearing aperture 290 within the second attachment member 266 (spacer rigid portion). Panjabi 13:6-12 and 43-54. Given this description, person of ordinary skill in the art would understand a cable having an outer surface of twisted and woven materials. McAfee Decl. ¶22. Therefore, Panjabi satisfies the requirement that the flexible member having an outer surface.

Panjabi discloses the second attachment member 266 (spacer metallic portion) having an aperture 290 (inner bore) that alignment pin 250 (flexible member) passes therethrough. Panjabi does not expressly disclose the aperture 290 having a larger dimension than the outer surface of the alignment pin 250 such that the second attachment member 266 can slide along the outer surface of the alignment pin 250.

However, Dr. McAfee understands given Panjabi express disclosure of alignment pin 250 passing through the aperture 290, Panjabi satisfies the claim feature. *See* McAfee Decl. ¶23.

Turning to the requirement that the second attachment member 266 (spacer rigid portion) has an outer surface configured to be secured within the second pedicle screw assembly (second bone coupling assembly), Panjabi uses an offset system of anchoring its flexible spinal fixation device to adjacent vertebrae for the embodiment disclosed in Figures 8-11. McAfee discloses using both an offset system and an in-line system of anchoring to a vertebra. McAfee, Figs. 2 and 3. Dr. McAfee discusses the differences and functionalities between in-line and offset implants. McAfee Decl. ¶14. McAfee prefers the in-line system of anchoring because that system minimizes torque and binding friction between the components, thereby giving a greater range of motion to the patient. McAfee, [0037] and [0044]. Therefore, it would have been obvious to modify Panjabi's first and second attachment members 260 and 266 (first rigid portion and spacer rigid portion) with McAfee's in-line anchoring teaching for the benefit disclosed in McAfee. Dr. McAfee's confirms McAfee's disclosure of less force on the components. McAfee Decl. ¶14. Thus, it would be obvious to modify Panjabi to be an in-line implant so as to achieve less rotational force or torque on the screws. *See id.* at ¶14.

For the embodiment depicted in Figures 8-13, Panjabi discloses the springs 230 and 232 as the structures to assist in resistive translation of the alignment pin 250. Panjabi, 13:16-22. In other sections of Panjabi, these structures that assist in limiting movement relative to the spine are also disclosed as resilient members. Panjabi, Abstract and 3:55-60. In addition, while springs are disclosed as being preferred in both the first and second major embodiments, Panjabi discloses that “other elastic members may be employed without departing from the spirit and scope of the present disclosure.” Panjabi, 8:35-37. Dr. McAfee provides a listing of elastic materials that would be used as the spacers. McAfee Decl. ¶19. Dr. McAfee listing includes both metal springs (as disclosed by Panjabi) and elastic materials such as PCU, UHMWPE, Dacron, and silicone. *Id.* Therefore, a POSITA would find it obvious to substitute one material for another.

(2) Claim Chart for Claim 47

Claim 47	Correspondence to the Prior Art
<p>The kit of claim 46, wherein the spacer rigid portion is located entirely between the first rigid portion and the second rigid portion such that along the length of the connection unit no portion of the spacer rigid portion overlaps with any portion of the first or second rigid portion.</p>	<p>First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14.</p> <p>Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17.</p> <p>As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).</p>

(a) Analysis for Claim 47

Turning to the requirement that the spacer rigid portion being located entirely between the first rigid portion and the second rigid portion such that along the length of the connection unit no portion of the spacer rigid portion overlaps with any portion of the first or second rigid portion, in addition to the spatial relation disclose in Panjabi 13:12-17, Panjabi depicts in Figures 8 and 9 and discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), and the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion). The disclosed and depicted relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), and the spring 230 is between the first attachment member 260 and the second attachment member 266 while the spring 232 is between the second attachment member and the abutment member 256, the second attachment member 256 (spacer rigid portion) is located entirely between the (first and second rigid portions) and no portion of the second attachment member 266 (spacer rigid portion) overlaps with any portion of

the first attachment member 260 or the abutment member 256 (first or second rigid portions, respectfully) along the length of the connection unit. Given this disclosure, Dr. McAfee states that the claimed feature would be satisfied by Panjabi. McAfee Decl. ¶18.

(3) Claim Chart for Claim 48

Claim 48	Correspondence to the Prior Art
48. The kit of claim 47, wherein the first rigid portion and the second rigid portion are metallic.	First attachment member 260 and abutment member 256

(a) Analysis for Claim 48

Panjabi's does not expressly as to the materials of the first attachment member 260 and the abutment member 256. However, a person of ordinary skill in the art understands that there are a finite number of materials acceptable for use in the body, and material chosen to make a part to be inserted into the body would select the material based on the functionality of the part and what would be acceptable in the body. McAfee Decl. ¶¶11-13 and 19. As an example in the prior art, McAfee discloses having the rod sleeve have a metal casing and this casing is encircled by the pedicle assembly. McAfee, [0036]-[0037]. In this case, the functionality of the first attachment member is to secure the stabilization device 210 to a vertebra via a pedicle screw. Panjabi, 12:2-19. Titanium is a metal that will allow this technology achieve the needed functionality. *See* McAfee Decl. ¶11. Thus, a person of ordinary skill in the art would find it obvious to make the first attachment member 260 (first rigid portion)

out of a metallic material, in order to achieve the needed flexibility and durability. Turning to the free end 258 and abutment member 256 (second rigid portion, claim nomenclature the likely preferred material would be titanium. *Id.* Thus, a person of ordinary skill in the art would find it obvious to make the free end 258 and abutment member 256 (second rigid portion) out of titanium, in order to achieve the needed flexibility and durability. Of note for obviousness, the Federal Circuit has recognized that a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d at 1349 n. 8 (Fed. Cir. 2000).

(4) Claim Chart for Claim 49

Claim 49	Correspondence to the Prior Art
<p>The kit of claim 48, wherein the spacer rigid portion is physically separate from and does not physically contact the first rigid portion or the second rigid portion.</p>	<p>First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).</p>

(a) Analysis for Claim 49

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion)

and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since the first spring 230 (first elastomeric portion) extends between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), the first spring 230 (first elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer rigid portions, respectfully). Since the second spring 232 (second elastomeric portion) extends between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), the second spring 232 (second elastomeric portion) physically separates the second attachment member 266 and the abutment member 256 (spacer rigid portion and second rigid portion, respectfully). Since second attachment member 266 is between the two springs 230 and 232 and the first spring 230 is between the first attachment portion 260 and the second attachment portion 266 and the second spring

232 is between the second attachment member portion 266 and the abutment member 256, the second attachment member 266 (spacer rigid portion) is physically separate from and does not physically contact the first attachment member 260 (first rigid portion) or abutment member 256 (second rigid portion). Given this disclosure, Dr. McAfee states that the claimed feature would be satisfied by Panjabi. McAfee Decl. ¶18

(5) Claim Chart for Claim 50

Claim 50	Correspondence to the Prior Art
The kit of claim 49, wherein the spacer rigid portion is metallic.	Panjabi speaks to springs, nuts, bolts, ball and socket joints that may have inferences drawn to the materials used to construct such structures.

(a) Analysis for Claim 50

Panjabi does not expressly disclose the second attachment member 266 (rigid spacer portion) being made from a metallic material. However, a person of ordinary skill in the art understands that there are a finite number of materials acceptable for use in the body, and material chosen to make a part to be inserted into the body would select the material based on the functionality of the part and what would be acceptable in the body. McAfee Decl. ¶¶11-13 and 19. In this case, the functionality of the second attachment member 266 (rigid spacer portion) is to secure the spinal implant to the pedicle screw. Thus, a person of ordinary skill in the art would find it obvious to make the second attachment member 266 (spacer rigid portion) out of a

metallic material, such as titanium, in order to achieve the needed flexibility and durability.

(6) Claim Chart for Claim 51

Claim 51	Correspondence to the Prior Art
<p>The kit of claim 50, wherein the spacer is constructed such that the first elastomeric portion physically separates the first rigid portion and the spacer rigid portion and the second elastomeric portion physically separates the second rigid portion and the spacer rigid portion.</p>	<p>First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).</p>

(a) Analysis for Claim 51

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between

the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since the first spring 230 (first elastomeric portion) extends between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), the first spring 230 (first elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer rigid portions, respectfully). Since the second spring 232 (second elastomeric portion) extends between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), the second spring 232 (second elastomeric portion) physically separates the second attachment member 266 and the abutment member 256 (spacer rigid portion and second rigid portion, respectfully).

(7) Claim Chart for Claim 52

Claim 52	Correspondence to the Prior Art
The kit of claim 51, wherein the spacer rigid portion physically separates the first and second elastomeric portions.	The first spring 230 is positioned to extend between the first attachment member 260 and the second attachment member 266, while the second spring 232 is positioned to extend between the second attachment member 266 and the abutment member 256 at the free end 258 of the alignment pin 250. Panjabi, 13:12-17.

(a) Analysis for Claim 52

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion)

and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions).

(8) Claim Chart for Claim 53

Claim 53	Correspondence to the Prior Art
The kit of claim 52, wherein the entire, longitudinal outer surface of each of the first rigid portion and the spacer rigid portion is cylindrical and uniform.	As shown in figure 8, first attachment member 260 and second attachment member 266 have a cylindrical portion surrounding the alignment pin 250. McAfee discloses the rod sleeve is cylindrical in shape. McAfee, [0041].

(a) Analysis for Claim 53

McAfee discloses that the rod sleeve which the spinal rod 3 fits into through bearing surface 2 is cylindrical in shape. By definition a cylinder is uniform.

Therefore, McAfee disclosure satisfies the claimed features associate with claim 53.

McAfee teachings would be used to modify the teachings of Panjabi concerning the

matter of anchoring. Therefore, the combination of Panjabi and McAfee render claim 53 as obvious.

(9) Claim Chart for Claim 54

Claim 54	Correspondence to the Prior Art
The kit of claim 53, wherein both the first and second spacer elastomeric portions comprise polycarbonate urethane.	Panjabi discloses using resilient members in a compressive preload. Abstract and col. 3, ll. 55-65.

(a) Analysis for Claim 54

It should be noted that Dr. McAfee states that for this type of technology “there is no perfect material – it depends what part of the balance or compromise that one wants to make.” McAfee Decl. ¶11. Moreover, Dr. McAfee provides a listing of elastic materials that would be used as the spacers. McAfee Decl. ¶19. Dr. McAfee listing includes both metal springs (as disclosed by Panjabi) and elastic materials such as PCU, UHMWPE, Dacron, and silicone. *Id.* For obviousness, the Federal Circuit has recognized that a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int’l Royalty Corp. v. Wang*, 202 F.3d at 1349 n. 8 (Fed. Cir. 2000). Therefore, a POSITA would find it obvious to substitute one material for another.

(10) Claim Chart for Claim 55

Claim 55	Correspondence to the Prior Art
The kit of claim 47, wherein the spacer rigid portion is not integral with the first rigid portion or the	First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend between first attachment member 260 and second

second rigid portion.	attachment member 266. Panjabi, 13:10-14. Second spring 232 is concentrically positioned about alignment pin 250 and is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of alignment pin 250. Panjabi, 13:11,14-17. As shown in Panjabi figure 8, second attachment member 266 does not overlap, contact, nor integral with first attachment member 260 or abutment member 256 (correlating to the claimed second rigid portion).
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(a) Analysis for Claim 55

Panjabi discloses that the first spring 230 (first elastomeric portion) is positioned to extend between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), while the second spring 232 (second elastomeric portion) is positioned to extend between the second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid portion). Panjabi, 13:12-17 and Fig. 8. This relationship places the second attachment member 266 (spacer rigid portion) between the first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since the second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), the second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since the first spring 230 (first elastomeric portion) extends between the first attachment member 260 (first rigid portion) and the second attachment member 266 (spacer rigid portion), the first spring 230 (first

elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer rigid portions, respectfully). Since the second spring 232 (second elastomeric portion) extends between the second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), the second spring 232 (second elastomeric portion) physically separates the second attachment member 266 and the abutment member 256 (spacer rigid portion and second rigid portion, respectfully). Since second attachment member 266 is between the two springs 230 and 232 and the spring 230 is between the first attachment portion 260 and the second attachment portion 266 and the spring 232 is between the second attachment member portion 266 and the abutment member 256, the second attachment member 266 (spacer rigid portion) is not integral with the first attachment member 260 (first rigid portion) or abutment member 256 (second rigid portion). Given this disclosure, Dr. McAfee states that the claimed feature would be satisfied by Panjabi. McAfee Decl. ¶18.

VIII. CONCLUSION

In view of the foregoing, claims 23-32 and 46-55 of the '057 Patent are not patentable over the prior art documents cited herein. The prior art documents teach the subject matter of the '057 Patent in a manner establishing a reasonable likelihood that the Petitioner will prevail with respect to at least one of the claims challenged in this Petition as required by 35 U.S.C. § 314(a). Accordingly, Petitioner respectfully requests that Trial be instituted and that claims 23-32 and 46-55 of the '057 Patent be canceled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this **PETITION FOR INTER PARTES REVIEW OF 8,623,057 UNDER TO 35 U.S.C. § 311 ET SEQ. AND 37 C.F.R. § 42.100 ET SEQ.** has been served via Priority mail on

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