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

In re *Inter Partes* Review of:	Case No.: IPR2015-00107
U.S. Patent No. 8,623,057 B2	
Inventors: Jahng et al.	Atty. Docket No. 60330-01014
Filed: Jun. 17, 2011	
Issued: Jan. 7, 2014	
For: SPINAL STABILIZATION DEVICE	

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, Journal of Electromyography and Kinesiology, 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. ("Petitioner") 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 13-19, 21, 22, and 33-45 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 below, claims 13-19, 21, 22, and 33-45 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 13-19, 21, 22, and 33-45 of the '057 Patent be canceled based on the grounds of unpatentability explained below. 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:

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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 13-19, 21, 22, and 33-45 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 13-19, 21, 22, and 33-45 of the '057 Patent be cancelled based on the following statutory grounds of unpatentability:

Ground 1: Claims 13-19, 21, 22, and 33-45 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 addressed below are 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 independent claim 13 and 33 (and dependent claim 34) 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 is held into place by a pair of pedicle screws anchored into adjacent vertebra. The 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 14, 36, and 43 limit the sliding of the rigid spacer such that it does not contact the rigid portion or free end.

Dependent claims 15, 38, and 44 circumscribe that the rigid spacer is separate from the rigid portion and free end.

Dependent claims 16 and 39 confine the free end's length to be less than both the elastomeric spacers' lengths.

Dependent claims 17 and 40 express 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 18 and 41 limit the rigid spacer to be between the elastomeric spacers.

Dependent claims 19 and 42 limit the outer surfaces of the rigid portion and rigid spacer to be cylindrical and uniform.

Dependent claims 22 and 45 limit the elastomeric spacers to be made from polycarbonate urethane (PCU).

Dependent claim 21 circumscribes the rigid spacer is longer than the free end.

Dependent claim 35 limits the rigid portion and free end to be metallic.

Dependent claim 37 limits the rigid spacer to be metallic.

The below claim charts correlate the proposed claim constructions to the respective claim elements that encompass the claimed inventions in claims 13-19, 21, 22, and 33-45.[1]

For independent claims 13, 33(d34)

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 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 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.

[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. Claim 13 further require the first rigid portion to be metallic.
[B.] a second rigid portion;	A free end. Claim 13 further require the free end to be metallic.
[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. Claim 13 limit the connection to being directly secured.
[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. Claim 13 limit the rigid spacer to be metallic.
[ii.] a first elastomeric portion located at least partially between the first rigid portion and the spacer portion, the first elastomeric portion having a length and having an inner bore extending the length	A first elastomeric spacer is located between the rigid portion and the rigid spacer having a bore for the flexible member to extend therethrough. Claim 13 identify the rigid spacer as

of the first elastomeric portion with the flexible member extending through the bore of the first elastomeric portion;	spacer metallic portion.
[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. Claim 13 identify the rigid spacer as spacer metallic portion.
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. Claim 13 identify the rigid spacer as spacer metallic portion.

For dependent claims 14, 36(d35 and d37), 43

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 15, 38, 44

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 claims 16, 39

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.	

For dependent claims 17, 40

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 18, 41

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 19, 42

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 claim 21

Claim Element	Proposed Construction
The spacer portion is longer than the second rigid portion.	The rigid spacer is longer than the free end.

For dependent claims 22, 45

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

For dependent claim 35

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

For dependent claim 37

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

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 invention was typically a person with 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.

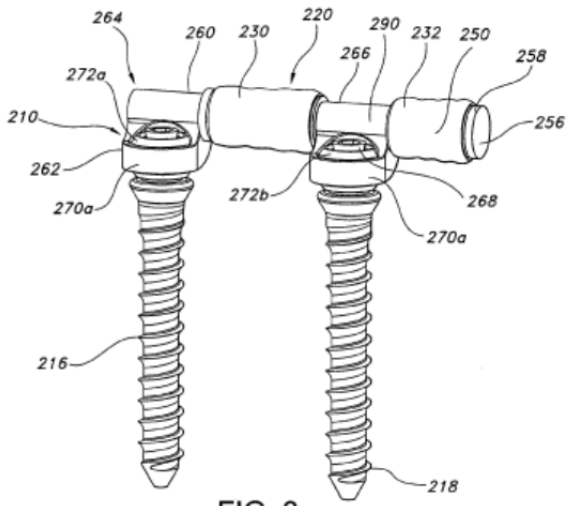
B. Specifying where each element of claim is found in the prior art

1. Ground 1: Claims 13-19, 21, 22, and 33-45 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 13-19, 21, 22, and 33-45 of the '057 Patent are rendered obvious by Panjabi and McAfee.

a) Claims 13-19, 21, 22, and 33-45

(1) Claim Chart for Claim 13

Claim 13	Correspondence to the Prior Art
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:	Panjabi - Stabilization device 210 is held in place by bone coupling (pedicle screws) assemblies 216 and 218 respectfully. *See* Panjabi, fig. 8, reproduced below, and Panjabi 11:65 to 12:19. 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.  FIG. 8 McAfee describes an analogous spinal rod sleeve system that allows a vertebra to slide cephalad or caudad. McAfee, [0034].
(a) a first, metallic rigid portion having an outer surface configured to be secured within the first bone coupling assembly;	First attachment member 260 with a first ball joint 262 extending from a first end 264 of housing 220. Panjabi 12:3-5. 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 *see* Fig. 9. 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.
(b) a second, metallic rigid portion;	Abutment member 256 having free end 258. Panjabi, 13:9-10.
(c) a flexible member connected with 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 290 within 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 flexible and provides flexible guidance for springs 230, 232 without debris causing bearing surfaces, provides tensile for the preload, provides low friction, straight bearing surface as it moves through second attachment member 266 and functions at times as a straight member and at other times as a flexible guide for springs 230, 232. Panjabi, 13:35-42. 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.
(d) 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. *See also* Exhibit 1004 for annotated version of Panjabi's figure 8.
(1) a metallic, rigid portion having a length and having an inner bore extending the length of the spacer metallic portion, the flexible member extending through the inner bore of the spacer metallic portion, the inner bore of the spacer metallic portion having a larger dimension than the outer surface of the flexible member along the length of the spacer metallic portion bore such that the spacer metallic portion can slide along the outer surface of the flexible member, and	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 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.
where the spacer metallic portion has an outer surface configured to be secured within the second bone coupling assembly, the spacer metallic 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 metallic portion overlaps with any portion of the first or second rigid portion;	Second attachment member 266 with second ball joint 268 extending through a central portion of the stabilizer 220. Panjabi, 12:5-7. The first spring 230 is positioned to extend between first attachment member 260 and second attachment member 266, while the second spring 232 is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of the alignment pin 250. Panjabi, 13:12-17.
(2) a first elastomeric portion located at least partially between the first rigid portion and the spacer metallic portion, the first elastomeric portion having a	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.

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;	
(3) a second elastomeric portion located at least partially between the second rigid portion and the spacer metallic 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;	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. Panjabi, 13:10-14.
whereby the first and second elastomeric spacer portions limit the sliding of the spacer metallic 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 13

Panjabi discloses dynamic stabilization devices. Exhibit 1002, Title ("Panjabi"). 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.

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

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

the elongate element, alignment pin 250, on an opposite side of 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 13, but does not expressly disclose: first attachment members 260 and abutment member 256 (first and second rigid portions) being metallic; first attachment member 260 (first rigid portion) having an outer surface configured to be secured within the pedicle screw assembly (first bone coupling assembly); alignment pin 250 (flexible member) expressly disclosed as being connected to first attachment member 260 (first rigid portion) and abutment member 256 (second rigid portion); second attachment member 266 (spacer rigid portion) having an inner bore of larger diameter than the outer surface of alignment pin 250 (flexible member), and an outer surface configured to be secured in a pedicle screw assembly (second bone coupling assembly); second attachment member 266 (spacer metallic portion) being metallic and located entirely between first attachment member 260 and abutment member 256 (first and second rigid portions) such that along the length of stabilization device 210 no portion of second attachment member 266 (spacer metallic portion) overlaps with any portion of first attachment member 260 or abutment member 256 (first or second rigid portions); and springs 230 and 232, also

disclosed as resilient members, corresponding to first and second elastomeric portions of the compressible spacer, being made from elastomeric materials.

Panjabi does not expressly disclose the materials of first attachment member 260 and the abutment member 256. However, a POSITA understands that there are a finite number of materials acceptable for use in the body, and material chosen would be based on the functionality of the implant 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 POSITA would find it obvious to make first attachment member 260 (first rigid portion) out of a metallic material, in order to achieve the needed flexibility and durability. Turning to the abutment member 256 (second rigid portion), the likely preferred material would be titanium. *Id.*. Thus, a POSITA would find it obvious to make the abutment member 256 (second rigid portion) out of metallic material, 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.").

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 metallic 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 alignment pin 250 (flexible member) being connected to first attachment member 260 (first rigid portion) and 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 second attachment member 266 (spacer metallic portion). Panjabi 13:6-12 and 43-54. Given this description, a POSITA 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 does not expressly disclose second attachment member 266 (spacer metallic portion) being made from a metallic material. However, a POSITA 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 second attachment member 266 (spacer metallic portion) is to secure the implant to the pedicle screw.

Thus, a POSITA would find it obvious to make second attachment member 266 (spacer metallic portion) out of a metallic material, in order to such as titanium, in order to have a material that is close to the modulus of the spine. *See* McAfee Decl. ¶11.

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 second attachment member 266 (spacer metallic 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 metallic 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 metallic 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 metallic 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 first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer metallic portion), and second spring 232 (second elastomeric portion) is positioned to extend between second attachment member 266 (spacer metallic portion) and the abutment member 256 (second rigid portion). The disclosed and depicted relationship places second attachment member 266 (spacer metallic portion) between first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since second attachment member 266 (spacer metallic portion) is between springs 230 and 232 (first and second elastomeric portions), and spring 230 is between first attachment

member 260 and second attachment member 266 while spring 232 is between the second attachment member and the abutment member 256, the second attachment member 256 (spacer metallic portion) is located entirely between the (first and second rigid portions) and no portion of second attachment member 266 (spacer metallic portion) overlaps with any portion of first attachment member 260 or abutment member 256 (first or second rigid portions) 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 of Figures 8-13, Panjabi discloses springs 230 and 232 as the structures to assist in resistive translation of 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. The 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 14

Claim 14	Correspondence to the Prior Art

The flexible connection unit of claim 13, wherein the spacer metallic 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 14

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

between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer metallic portion), first spring 230 (first elastomeric portion) physically separates the first and second attachment members 260 and 266 (first rigid and spacer metallic portions, respectfully). Since second spring 232 (second elastomeric portion) extends between second attachment member 266 (spacer metallic portion) and the abutment member 256 (second rigid portion), second spring 232 (second elastomeric portion) physically separates second attachment member 266 and the abutment member 256 (spacer metallic 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, second attachment member 266 (spacer metallic portion) is physically separate from and does not physically contact 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 15

Claim 15	Correspondence to the Prior Art
The flexible connection unit of claim 13, wherein the spacer metallic portion is not integral with 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 15

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

and spacer metallic portions, respectfully). Since second spring 232 (second elastomeric portion) extends between second attachment member 266 (spacer metallic portion) and abutment member 256 (second rigid portion), second spring 232 (second elastomeric portion) physically separates second attachment member 266 and the abutment member 256 (spacer metallic portion and second rigid portion, respectfully). Since second attachment member 266 is between the two springs 230 and 232 and spring 230 is between first attachment portion 260 and second attachment portion 266 and spring 232 is between second attachment member portion 266 and abutment member 256, second attachment member 266 (spacer metallic portion) is not integral to 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 16

Claim 16	Correspondence to the Prior Art
The flexible connection unit of claim 13, 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 16

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 17

Claim 17	Correspondence to the Prior Art
The flexible connection unit of claim 13, wherein the spacer is constructed such that the first elastomeric portion physically separates the first rigid portion and the spacer metallic portion and the second elastomeric portion physically separates the second rigid portion and the spacer metallic 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 17

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

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

(6) Claim Chart for Claim 18

Claim 18	Correspondence to the Prior Art
The flexible connection unit of claim 17, wherein the spacer	The first spring 230 is positioned to extend between first attachment member 260 and second

metallic portion physically separates the first and second elastomeric portions.	attachment member 266, while the second spring 232 is positioned to extend between second attachment member 266 and the abutment member 256 at the free end 258 of the alignment pin 250. Panjabi, 13:12-17. 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 18

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

metallic portion) physically separates springs 230 and 232 (first and second elastomeric portions).

(7) Claim Chart for Claim 19

Claim 19	Correspondence to the Prior Art
The flexible connection unit of claim 17, wherein the entire outer, longitudinal surface of each of the first rigid portion and the spacer metallic 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 19

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 discloses the claimed features associate with claim 19. McAfee would be used to modify the teachings of Panjabi concerning the matter of anchoring. Therefore, the combination of Panjabi and McAfee render claim 19 as obvious.

(8) Claim Chart for Claim 21

Claim 21	Correspondence to the Prior Art
The flexible connection unit of claim 17, wherein the spacer metallic portion is longer than the second rigid portion.	As shown in Panjabi's Figure 8, second attachment member 266 (corresponds to the spacer metallic portion) is longer than the abutment member 256 (corresponds to the second rigid portion).

(a) Analysis for Claim 21

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 second attachment member 266 (spacer metallic portion) is longer than the abutment member 256 (second rigid portion). Dr. McAfee explains the need to accommodate anatomic confinement issues and thusly the need for appropriate sizing of the components that constitute the spinal implant. McAfee Decl. ¶¶24, 26, and 27.

(9) Claim Chart for Claim 22

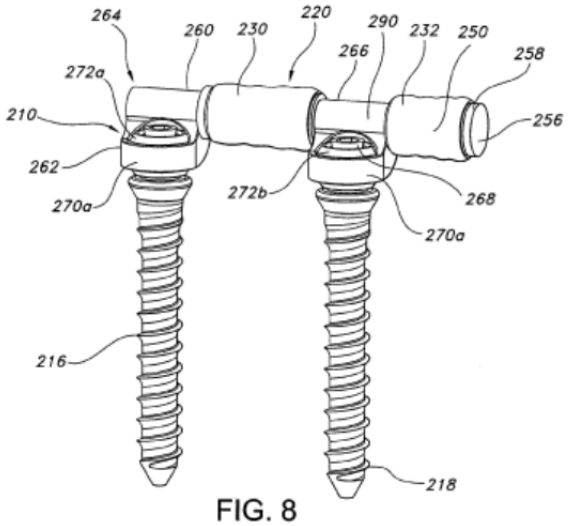
Claim 22	Correspondence to the Prior Art
The flexible connection unit of claim 17, wherein both the first and second spacer elastomeric portions comprise polycarbonate urethane.	Panjabi discloses using resilient members in a compressive preload. Abstract and col. 3, ll. 55-65.

(a) Analysis for Claim 22

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 33

Claim 33	Correspondence to the Prior Art
A flexible, spinal fixation assembly for stabilizing a human spine, comprising:	Stabilization device 210 is held in place by bone coupling assemblies 216 and 218 respectfully. *See* Panjabi, fig. 8, reproduced below and Panjabi 11:65 to 12:19.  FIG. 8 McAfee describes an analogous spinal rod sleeve system that allows a vertebra to slide cephalad or caudad. McAfee, [0034].
(a) a first bone coupling assembly having a distal portion configured to be secured to a first vertebra and a proximal portion; (b) a second bone coupling assembly having a distal portion	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

configured to be secured to a second vertebra and a proximal portion;	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.
(c) a first rigid portion having an outer surface secured within the proximal portion of the first bone coupling assembly;	First attachment member 260 with a first ball joint 262 extending from a first end 264 of housing 220. Panjabi, 12:3-5. 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 *see* Fig. 9. 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.
(d) a second rigid portion;	Abutment member 256 having free end 258. Panjabi, 13:9-10.
(e) 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 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.
(f) 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. *See also* Exhibit 1004 for annotated version of Panjabi's figure 8.
(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 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	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 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.
where the spacer rigid portion has an outer surface secured within the proximal portion of the second bone coupling assembly;	Second attachment member 266 with second ball joint 268 extending through a central portion of the stabilizer 220. Panjabi, 12:5-7.
(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	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.

through the bore of the first elastomeric portion;	
(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 second elastomeric portion with the flexible member extending through the bore of the second elastomeric portion;	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.
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 33

Panjabi discloses dynamic stabilization devices. Exhibit 1002, Title ("Panjabi"). 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 a 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, Abstract. 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 abutment member 256 is not held in place by another structure such as a pedicle screw, 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 second attachment member 266, e.g., in overhanging orientation. Panjabi, 13:14-17. Resilient members 230, 232 are capable of applying mutually opposing urging forces, and a compressive preload can be applied to one or both of resilient members 230, 232. Panjabi, 13:33-35.

Thus, Panjabi substantially discloses claim 33, but does not expressly disclose: 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 first attachment member 260 (first rigid portion) and the abutment member 256 (second rigid portion); 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. 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 alignment pin 250 (flexible member) being connected to first attachment member 260 (first rigid portion) and free end 258 and abutment member 256 (second rigid portion), Panjabi does disclose that alignment pin 250 extends from first attachment member 260 and ends at abutment member 256 with free end 258. Given this disclosure, a POSITA would conclude that alignment pin 250 is directly secured to attachment member 260 and abutment member 256.

While Panjabi does not expressly disclose alignment pin 250 (flexible member) as having an outer surface, Panjabi discloses that 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 second attachment member 266 (spacer rigid portion). Panjabi 13:6-12 and 43-54. Given this description, a POSITA 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 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], [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. 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 springs 230 and 232 as the structures to assist in resistive translation of 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 lists elastic materials that would be used as spacers. McAfee Decl. ¶19. Dr. McAfee's list 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.

(11) Claim Chart for Claim 34

Claim 34	Correspondence to the Prior Art
The spinal fixation assembly of claim 33, 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 fixation assembly no portion of the spacer rigid portion overlaps with any portion of the first or 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 34

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 first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), and second spring 232 (second elastomeric portion) is positioned to extend between second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion). The disclosed and depicted relationship places second attachment member 266 (spacer rigid portion) between first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since 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 first attachment member 260 and 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 second attachment member 266 (spacer

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

(12) Claim Chart for Claim 35

Claim 35	Correspondence to the Prior Art
The spinal fixation assembly of claim 34, wherein the first rigid portion and the second rigid portion are metallic.	First attachment member 260 and abutment member 256

(a) Analysis for Claim 35

Panjabi's does not expressly as to the materials of first attachment member 260 and the abutment member 256. However, a POSITA understands that there are a finite number of materials acceptable for use in the body. Material chosen for a part to be inserted into the body would be selected based on the functionality of the part and what would be acceptable in the body. McAfee Decl. ¶¶11-13, 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 POSITA would find it obvious to make 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 POSITA 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 at 1349 at n. 8 (Fed. Cir. 2000).

(13) Claim Chart for Claim 36

Claim 36	Correspondence to the Prior Art
The spinal fixation assembly of claim 35, 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 36

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

attachment portion 266, and second spring 232 is between second attachment member portion 266 and abutment member 256, second attachment member 266 (spacer rigid portion) is physically separate from and does not physically contact 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.

(14) Claim Chart for Claim 37

Claim 37	Correspondence to the Prior Art
The spinal fixation assembly of claim 36, 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 37

Panjabi does not expressly disclose second attachment member 266 (rigid spacer portion) being made from a metallic material. However, a POSITA 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 second attachment member 266 (rigid spacer portion) is to secure the implant to the pedicle screw. Thus, a POSITA would find it obvious to make 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).

(15) Claim Chart for Claim 38

Claim 38[3]	Correspondence to the Prior Art
The spinal fixation assembly of claim 33, wherein the spacer rigid portion is not integral with 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 38

Panjabi discloses that first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), while second spring 232 (second elastomeric portion) is positioned to extend between second attachment member 266 (spacer rigid portion) and the abutment member 256 at the free end 258 (second rigid

[3] Claim 44 is a duplicate to claim 38.

portion). Panjabi, 13:12-17 and Fig. 8. This relationship places second attachment member 266 (spacer rigid portion) between first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since first spring 230 (first elastomeric portion) extends between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), 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 second spring 232 (second elastomeric portion) extends between second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), second spring 232 (second elastomeric portion) physically separates 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, second attachment member 266 (spacer rigid portion) is not integral to 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.

(16) Claim Chart for Claim 39

Claim 39	Correspondence to the Prior Art
The spinal fixation assembly of claim 36, 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 39

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.

(17) Claim Chart for Claim 40

Claim 40	Correspondence to the Prior Art
The spinal fixation assembly of claim 36, 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 40

Panjabi discloses that first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), while second spring 232 (second elastomeric portion) is positioned to extend between 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 second attachment member 266 (spacer rigid portion) between first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since first spring 230 (first elastomeric portion) extends between first attachment

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

(18) Claim Chart for Claim 41

Claim 41	Correspondence to the Prior Art
The spinal fixation assembly of claim 40, wherein the spacer rigid portion physically separates the first and second elastomeric portions.	The first spring 230 is positioned to extend between first attachment member 260 and second attachment member 266, while the second spring 232 is positioned to extend between 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 41

Panjabi discloses that first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), while second spring 232 (second elastomeric portion) is positioned to extend between 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 second attachment

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

(19) Claim Chart for Claim 42

Claim 42	Correspondence to the Prior Art
The spinal fixation assembly of claim 40, 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 42

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 42. 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 42 as obvious.

(20) Claim Chart for Claim 43

Claim 43	Correspondence to the Prior Art
The spinal fixation assembly of claim 33, wherein the spacer rigid	First spring 230 is concentrically positioned about alignment pin 250 and is positioned to extend

portion is physically separate from and does not physically contact the first rigid portion or the second rigid portion.	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 43

Panjabi discloses that first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), while second spring 232 (second elastomeric portion) is positioned to extend between 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 second attachment member 266 (spacer rigid portion) between first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since first spring 230 (first elastomeric portion) extends between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid

portion), 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 second spring 232 (second elastomeric portion) extends between second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), second spring 232 (second elastomeric portion) physically separates 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 first spring 230 is between the first attachment portion 260 and the second attachment portion 266 and second spring 232 is between the second attachment member portion 266 and the abutment member 256, second attachment member 266 (spacer rigid portion) is physically separate from and does not physically contact 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.

(21) Claim Chart for Claim 44

Claim 44	Correspondence to the Prior Art
The spinal fixation assembly of claim 33, wherein the spacer rigid portion is not integral with 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 44

Panjabi discloses that first spring 230 (first elastomeric portion) is positioned to extend between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), while second spring 232 (second elastomeric portion) is positioned to extend between 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 second attachment member 266 (spacer rigid portion) between first spring 230 (first elastomeric portion) and second spring 232 (second elastomeric portion). Since second attachment member 266 (spacer rigid portion) is between the springs 230 and 232 (first and second elastomeric portions), second attachment member 266 (spacer rigid portion) physically separates the springs 230 and 232 (first and second elastomeric portions). Since first spring 230 (first elastomeric portion) extends between first attachment member 260 (first rigid portion) and second attachment member 266 (spacer rigid portion), 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 second spring 232 (second elastomeric portion) extends between

second attachment member 266 (spacer rigid portion) and the abutment member 256 (second rigid portion), second spring 232 (second elastomeric portion) physically separates 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, second attachment member 266 (spacer rigid portion) is not integral with 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.

(22) Claim Chart for Claim 45

Claim 45	Correspondence to the Prior Art
The spinal fixation assembly of claim 40, 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 45

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.

VIII. CONCLUSION

In view of the foregoing, claims 13-19, 21, 22, and 33-45 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 13-19, 21, 22, and 33-45 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* REVIEWOF 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 October 21, 2014, upon the following:

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