UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner

v.

BONUTTI SKELETAL INNOVATIONS LLC,
Patent Owner

Case No.: IPR2015-_____
U.S. Patent No. 6,099,531
Issued: August 8, 2000
Application No: 09/137,443
Filed: August 20, 1998

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,099,531

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I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, the undersigned, on behalf of and representing Petitioner Globus Medical, Inc. ("Petitioner") hereby petitions for *inter partes* review of claims 8, 9, 46, 49, 105, 107, 109, and 111 of U.S. Patent No. 6,099,531, entitled "Changing Relationship Between Bones" ("the '531 patent), issued to Peter M. Bonutti and assigned to Bonutti Skeletal Innovations LLC ("Bonutti"). EX1001.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The grounds for unpatentability presented in detail, below, demonstrate how each of the challenged claims is rendered obvious in view of the prior art. Evidentiary support for Petitioner's conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. EX1011**.** Dr. Ochoa is an expert with over 25 years of experience in the area of design and development of orthopedic medical devices, surgical instruments and techniques, as well as biomechanics, and engineering biomaterials. *Id.* at ¶¶1-8. Dr. Ochoa's declaration establishes that each of the challenged claims is rendered obvious in view of the prior art and confirms all of Petitioner's assertions of unpatentability.

Petitioner submits that this Petition demonstrates a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. 35 U.S.C. §314(a). Accordingly, Petitioner respectfully requests that this Petition

be granted and that claims 8, 9, 46, 49, 105, 107, 109, and 111 of the '531 patent be held unpatentable.

II. FORMALITIES

A. Mandatory Notices

1. Real Party in Interest (37 C.F.R. § 42.8(b)(1))

Globus Medical, Inc. ("Globus") is the real party-in-interest.

2. Designation of Lead and Backup Counsel (37 C.F.R.§ 42.8(b)(3))

Lead Counsel	Backup Counsel
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3. Notice of Service (37 C.F.R. § 42.8(b)(4))

Please direct all correspondence to lead counsel at the above address. Petitioner consents to email service at the above-referenced email addresses.

4. Related Proceedings (37 C.F.R. § 42.8(b)(2))

Petitioner states that the following district court litigations may affect, or be affected by, a decision in this proceeding: *Bonutti Skeletal Innovations LLC v. Globus Medical, Inc.*, Civil Action No. 2:14-cv-6650-WB (E.D. Pa.) to which Petitioner is a party ("the Pending Litigation"); and *Bonutti Skeletal Innovations*

LLC v. DePuy Synthes Sales Inc., Civil Action No. 1:14-14680-GAO (D. Mass.). Notably, Bonutti has accused certain of Globus's spinal implant devices of infringing the challenged claims of the '531 patent in the Pending Litigation. *See* EX1002**.**

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 6,423,063 ("the '063 patent"). The '063 patent is related to the '531 patent through continuation practice. In addition, *inter partes* reviews have been instituted on U.S. Patent Nos. 7,001,385 (IPR2015-01339), 8,486,066 (IPR2015-01335) and 8,795,363 (IPR2015-01333). The '385 patent is related to the '531 patent through continuation practice, and the '066 and '363 patents are related to each other through continuation practice and, although not formally related to the '531 patent, they are directed to subject matter similar to that of the '531 patent. Petitioner understands that the '531 patent, the '063 patent, the '385 patent, the '066 patent and the '363 patent are all commonly owned by Bonutti Skeletal Innovations LLC.

Further, claims 8, 9, 46, 49, 105, 107, 109, and 111 of the '531 patent were the subject of a petition filed by Petitioner in IPR2015-01346. In IPR2015-01346, Petitioner challenged claims 8, 9, 107, 109 and 111 as unpatentable over U.S. Patent no. 5,306,309 to Wagner; claims 46 and 49 as unpatentable over Wagner in view of U.S. Patent no. 4,904,261 to Dove; claim 105 as unpatentable over FR

2,747,034 A1 to Alby and Benezech in view of U.S. Patent no. 5,192,327 to Brantigan; and claim 105 as unpatentable over U.S. Patent no. 6,008,433 to Stone in view of U.S. Patent no. 5,298,254 to Prewett et al. An *inter partes* review was not instituted on any ground. IPR2015-01346, Paper 9, December 16, 2015.

B. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the '531 patent is available for *inter partes* review; and Petitioner is not barred or estopped from requesting *inter partes* review of any claim of the '531 patent on the grounds identified in this Petition. It should be noted that, in this regard, service of the Summons and Complaint in the Pending Litigation was made on Petitioner on December 30, 2014. Consequently, Petitioner is not time barred by the Pending Litigation to bring this Petition.

C. Procedural Statements

This Petition is filed in accordance with 37 C.F.R. § 42.106(a). A Power of Attorney (37 C.F.R. § 42.10(b)) and Exhibit List (37 C.F.R. § 42.63(e)) are filed concurrently with this Petition. The fee is being paid via Deposit Acct. No. 08-0750. The United States Patent and Trademark Office is authorized to charge any fee deficiency, or credit any overpayment, to Deposit Acct. No. 08-0750.

III. U.S. PATENT NO. 6,099,531 ("THE '531 PATENT") (EX1001)

The '531 patent is titled "Changing Relationship Between Bones" and issued on August 8, 2000, on an application filed on August 20, 1998. EX1001 at [45] and

[22]. The earliest priority date for the ‘531 patent is August 8, 2000.

A. The ‘531 Patent Specification and Claims

The ’531 patent relates to a method and apparatus for changing the spatial relationship between bones which are interconnected at a joint in a patient’s body. *Id.* at 1:48–50. According to the Specification, one of the bones interconnected at a joint “is moved relative to the other by expanding at least a portion of the joint with a wedge member.” *Id.* at 1:52–54.

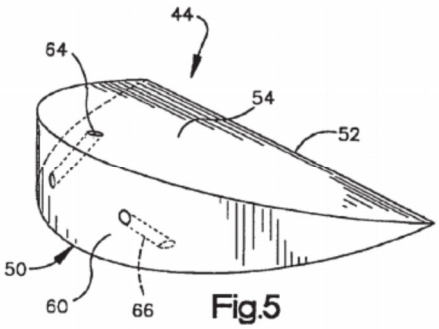


Fig.5

Figure 5 depicts a schematic view and Figure 7 depicts a side view of wedge member 44. *Id.* at 2:54–55, 58-59. Wedge member 44 tapers from thick end portion 50 to thin end portion 52 and has upper major side surface 54, lower major side surface 56, and outer side surface 60. *Id*. at 5:57–61. Wedge member 44 may be connected to one or more bones by screws passing through passages 64 and 66. *Id.* at 7:40–63.

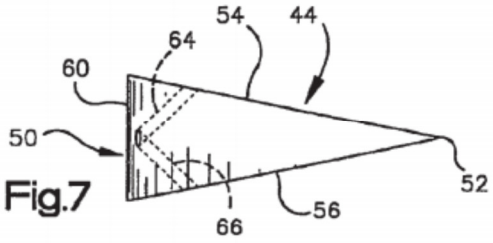


Fig.7

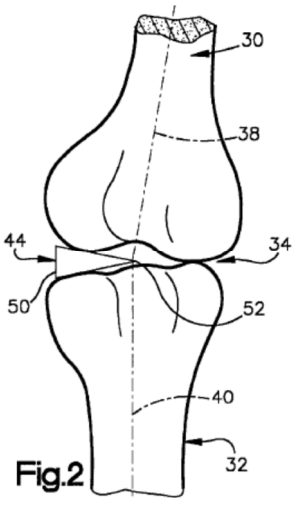


Fig.2

Figure 2 depicts wedge member 44 being inserted into a joint, causing joint expansion and changing the orientation of bones 30 and 32. *Id.* at 2:42-45; and see *id*. at 7:64–9:28 (further describing the insertion). As thin leading end portion 52 of wedge member

44 moves into joint 34, upper and lower major side surface 54 and 56 apply force against bones 30 and 32 and expand joint 34. *Id*. at 8:52–56.

Additionally, the Specification describes an embodiment wherein the wedge member is formed of a rigid porous material having an open cell construction or includes passages extending through the wedge member to enable bone to grow through the wedge member. *Id*. at 10:1–8, 33-40.

Of the '531 Patent's 129 claims, only Claims 8, 9, 46, 49, 107, 109, and 111, directed to a method for inserting the wedge member into the joint, and Claim 105, directed to the wedge member used in the method, are at issue in this Petition.

B. The '531 Patent Prosecution History (EX1003)

Application No. 09/137,443, now the '531 patent, was filed August 20, 1998 with 51 claims. A single Office Action issued during the prosecution of the '531 patent rejecting all the claims. *See* Office Action mailed August 20, 1999, EX1003 at 95-102. An Amendment in response was filed on October 26, 1999 cancelling claims 1-32 and 40-51 and adding new claims 52-173. EX1003 at 102-189. No other amendments to the claims were made.

In the Office Action mailed August 20, 1999, the Examiner applied U.S. Patent no. 5,690,635 to Michelson ("the '635 patent") in a single reference 103(a) rejection of claims 1-8, 16-20, 22-24, 33-37, 40-47, and 50. The Examiner stated that:

Michelson discloses, in figs.7A and 30, a wedge member for changing a

spatial relation between two adjacent bones interconnected at a joint, comprising a taper body with thick end portion and thin end portion, a plurality of openings including growing body tissue for promoting ingrowth. *However, Michelson does not disclose the method of using the wedge member for changing a spatial relationship between the two adjacent bones.* It would have been obvious to one having ordinary skill in [the] art to use the wedge member, as taught by Michelson, to perform the steps as claimed.

EX1003 at 97-98 (emphasis added).

In addition, the Examiner applied the '635 patent in a 103(a) combination rejecting claim 51, stating that Michelson disclosed "a wedge member comprising first and second surfaces and a plurality of passages which extend between the first and second surfaces for enabling bone to grow through said wedge member." *Id.* at 98.

In the Amendment of October 26, 1999, Applicant successfully argued that claims 33-39 (issued Claims 1-7), and new claims 52-173 (issued Claims 8-129) were allowable over the cited art, the '635 patent, Pavlov et al. (U.S. Pat. No. 5,906,616), and Salib et al. (U.S. Pat. No. 5,258,031). *Notably, none of the cited art was relied on by the Examiner to disclose the method for using a wedge to change the spatial relationship between two adjacent bones*. Specifically, applicant argued new claim 52 (issued claim 8) was allowable because the '635 patent and

the other art did not disclose the step of "pivoting the first bone about an axis which extends through the joint interconnecting the first and second bones." **EX1003 at 147**. Applicant also argued that claim 90 (issued claim 46) was allowable over the prior art because the art failed to show the step of "moving the wedge member into the joint between the first and second bones without rotating the wedge member" and the step of "fixedly connecting the wedge member to at least one of the first and second bones with a fastener member." *Id*. at 162. Additionally, Applicant argued that claim 151 (issued claim 107) was allowable over the prior art due to the step of "moving a leading end portion of a wedge member through the longitudinal central axis of the first bone and through the longitudinal central axis of the second bone." *Id*. at 181. As for claim 149 (issued claim 105), Applicant argued that claim was allowable because the art did not show the wedge member "having first and second major side surfaces which intersect to form an edge at a thin end portion of the wedge member" and "a minor side surface which extends between the first and second major side surfaces and extends from the thick end portion to the thin end portion of the wedge member." *Id*. at 180. The Examiner thereafter issued Notice of Allowance.

IV. THE PERSON HAVING ORDINARY SKILL IN THE ART AND THE STATE OF THE ART

As established in the Declaration of Dr. Ochoa (EX1011 at ¶ 18), a person having ordinary skill in the art (PHOSITA) of the '531 patent would have a

Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree, in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

V. CLAIM CONSTRUCTION

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear.[1] 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015). Under that standard, and absent any special definitions, the claim terms are given their

[1] The standard for claim construction in the United States Patent and Trademark Office is different than the standard used in litigation in the U.S. District Courts. *In re Am Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004); M.P.E.P. § 2111. Petitioner, therefore, expressly reserves the right to argue a different claim construction in a different forum for any term in the '063 patent, as appropriate in that proceeding.

ordinary and customary meaning, as they would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner does not offer any explicit claim construction. However, in IPR-01346, the Board adopted the meaning of the term "tapers" as "to become progressively smaller toward one end." IPR-01346, Paper no. 9 at 7 (December 16, 2015). "Claim 105, thus, requires a minor side surface that becomes progressively smaller from said thick end portion to said thin end portion." *Id.*

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. U.S. Patent No. 5,609,635 to Michelson ("the '635 patent") (EX1004)

U.S. Patent No. 5,609,635, entitled "Lordotic Interbody Spinal Fusion Implants," issued March 11, 1997. The '635 patent is prior art under 35 U.S.C. § 102(b) because it is a patent issued more than one year prior to the date of the application for the '531 patent in the United States. Although cited in an Office Action, the Examiner did not rely on the '635 patent to reject any challenged claim. In fact, the Examiner specifically remarked that "*Michelson does not disclose the method of using the wedge member for changing a spatial relationship between the two adjacent bones*." EX1003 at 97-98.

B. U.S. Patent No. 5,522,899 to Michelson ("the '899 patent") (EX1005)

U.S. Patent No. 5,522,899, entitled "Artificial Spinal Fusion Implants," issued June 4, 1996. The '899 patent is prior art under 35 U.S.C. § 102(b) because it is a patent issued more than one year prior to the date of the application for the '531 patent in the United States. The '899 patent was not disclosed by the Applicant or cited or relied on by the Examiner during prosecution of the '531 patent.

C. U.S. Patent No. 4,904,261 to Dove ("the '261 patent") (EX1006)

U.S. Patent No. 4,904,261 to Dove et al., entitled "Spinal Implants," issued February 27, 1990. The '261 patent is prior art under 35 U.S.C. § 102(b) because it is a patent more than one year prior to the date of the application for the '531 patent in the United States. The '261 patent was not disclosed by the Applicant or cited or relied on by the Examiner during prosecution of the '531 patent.

D. U.S. Patent No. 6,008,433 to Stone ("the '433 patent") (EX1007)

U.S. Patent No. 6,008,433, entitled "Osteotomy Wedge Device, Kit and Methods for Realignment of a Varus Angulated Knee," issued December 28, 1999 from an application filed in the United States on April 23, 1998. The '433 patent is prior art under 35 U.S.C. § 102(e)(2) because it is a patent granted on an application for patent by another filed in the United States before the invention by the applicant of the '531 patent. The '433 patent was not disclosed by the

Applicant or cited or relied on by the Examiner during the prosecution of the '531 patent.

E. U.S. Patent No. 5,298,254 to Prewett et al. ("the '254 patent") (EX1008)

U.S. Patent No. 5,298,254, entitled "Shaped, Swollen Demineralized Bone and Its Use in Bone Repair," issued March 29, 1994. The '254 patent is prior art under 35 U.S.C. § 102(b) because it is a patent issued more than one year prior to the date of the application for the '531 patent in the United States. The '254 patent was not disclosed by the Applicant or cited or relied on by the Examiner during the prosecution of the '531 patent.

VII. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. §42.22(a))

Petitioner seeks a final, written decision that challenged claims 8, 9, 46, 49, 105, 107, 109 and 11 of the '531 patent are unpatentable as obvious pursuant to 35 U.S.C. §103. Of these challenged claims, claims 8, 46, 105 and 107 are independent; claim 9 depends from claim 8; claim 49 depends from claim 46; and claims 109 and 111 depend from claim 107.

In summary, and as established by the declaration of Dr. Ochoa, the '635 patent in view of the '899 patent render claims 8, 9, 107, 109 and 111 unpatentable as obvious under 35 U.S.C. §103; the '635 patent in view of the '899 patent and the '261 patent render claims 46 and 49 unpatentable as obvious under 35 U.S.C.

§103; and the ‘433 patent in view of the ‘254 patent and the ‘635 patent renders claim 105 unpatentable as obvious under 35 U.S.C. §103. **EX1011 at ¶¶ 32-93**.

VIII. IDENTIFICATION OF GROUNDS FOR UNPATENTABILITY (37C.F.R. § 42.104(b))

This petition presents the following Grounds of unpatentability:

- Ground 1: Claims 8, 9, 107, 109, and 111 are unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘635 patent (EX1004) in view the ‘899 patent (EX1005).
- Ground 2: Claims 46 and 49 are unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘635 patent (EX1004) in view the ‘899 patent (EX1005) and the ‘261 patent (EX1006).
- Ground 3: Claim 105 is unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘433 patent (EX1007) in view of the ‘254 patent (EX1008) and the ‘635 patent (EX1004).

A. Ground 1: Claims 8, 9, 107, 109, and 111 are unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘635 patent in view of the ‘899 patent

As discussed further below, Dr. Ochoa states that the ‘635 patent discloses a spinal implant device for use in spinal fusion surgical procedures that changes the spatial relationship (e.g., restores a desired anatomical relationship from a degenerative condition) between first and second bones (i.e., vertebrae) at an intervertebral joint. EX1011 at ¶33. The spinal implant device (“implant 100”) is

configured for insertion from the anterior approach, with a substantially wedge-shaped body having upper and lower surfaces (112, 114) disposed in a converging angular relationship toward each other. EX1004 at 6:19-26, 8:8-15, FIGs. 3 and 7A. The implant of the '635 patent is impacted and driven into place between the vertebrae using a hammer to cause the wedge-shaped implant to force the end plates of the adjacent vertebrae apart as the implant is advanced forward into the disc space. Thereafter the upper and lower surfaces of the implant form a support structure for bearing against the endplates of the adjacent vertebrae, maintaining the vertebrae adjacent to those surfaces in an angular relationship, creating and maintaining the desired lordosis of the spine. EX1004 at 7:54-56, 1:65-2:1, 6:30-4.

Also according to Dr. Ochoa, the '899 patent is similar to the '635 patent and discloses a spinal implant device for use in spinal fusion surgical procedures, capable of being placed between adjacent vertebrae to change the spatial relationship between first and second bones at an intervertebral joint. EX1011 at ¶34. The '899 patent further discloses an insertion method, including insertion instrumentation for implantation of the device. *Id.* at 54. The threaded end (46) of a driving member (30) is coupled to a threaded opening (26) in the implant (10). EX1005 at 8:12-25, FIGs. 4, 5, 7 and 7A. The implant (10) is configured for insertion from the anterior approach by tapping the driving member with a hammer sufficiently hard enough to drive the implant into the disc space. EX1011 at ¶54.

The insertion device does not interact with the vertebrae during insertion of the implant, and functions only to provide a removable rigid coupling to facilitate impaction of the implant. *Id.*

Dr. Ochoa opines that a PHOSITA would have been motivated to look to the combined teachings of the '635 patent and the '899 patent because they relate to substantially the same subject matter and address common issues, *i.e.*, implantable orthopedic devices for use in a spinal fusion surgical procedures that change changing a spatial relationship between bones in a patient's body.[2] EX1011 at ¶¶34, 54. According to Dr. Ochoa, a PHOSITA would have looked to this combined body of art.[3] EX1011 at ¶21. In addition, as discussed further below, the '635 patent and the '899 patent each disclose multiple features of the claimed invention and share the same inventor making the combination of their teachings obvious.[4] A PHOSITA would have been motivated, in view of the combined

[2] *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007) (if a PHOSITA would recognize that a technique would improve similar devices in the same way, using the technique is obvious).

[3] *KSR at* 420-21 (a person of ordinary creativity is not an automaton and in many cases will be able to fit the teachings of multiple patents together like pieces of a puzzle).

[4] *Black v. CE Soir Lingerie Co., Inc.*, no. 2:06-cv-522, 2008 WL 3852722 (E.D.

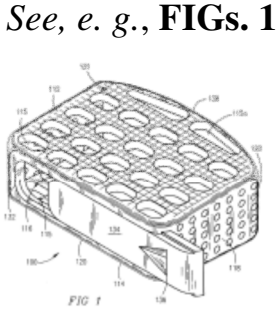
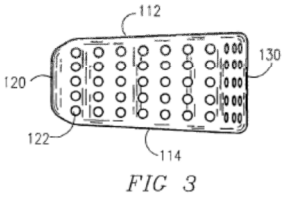
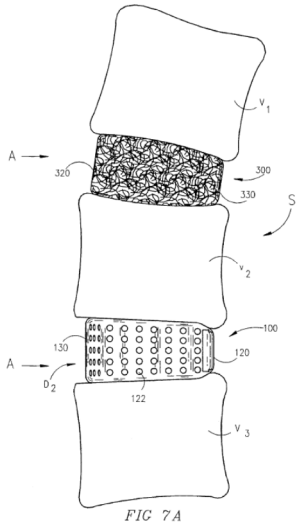
teachings of the '635 patent, and/or the '899 patent, to utilize the insertion instrument disclosed in the related '899 patent with the implant of the '635 patent, *Id.* at ¶54, which would have been considered an obvious choice that would have yielded a predictable effect in the resulting method.[5] *Id*. Any such modification would not have changed the principle of operation of the spinal implant of the '635 patent.[6] *Id.*

Tex. Aug. 15, 2008) *aff'd*, 319 F. App'x 901 (Fed. Cir. 2009) (finding motivation to combine prior art patents that dealt with substantially similar subject matter, each disclosed multiple features of the claimed invention, cited to one another, and two shared the same inventor); *Ex Parte James v. Candy & David H. Chambers*, 2010-003518, 2011 WL 3754625 (BPAI Aug. 19, 2011) (affirming the Examiner's finding of motivation to combine multiple references where each reflects the work of the same inventor and addresses the same problem with the same approach).

[5] *KSR*, 550 U.S. at 416 (the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results).

[6] *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008) (a claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined).

1. Claim 8

'531 patent Claim 8 vs. the '635 patent and the '899 patent	
A method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said method comprising the steps of	The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.** • The spinal fusion implants of the present invention are sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly or in part to the disc space created. ***Id*.** • *See, e. g.*, **FIGs. 1, 3 and 7A**.  FIG 1  FIG 3  FIG 7A • The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. **EX1004 at Abstract.** • The angular relationship of the upper and lower surfaces 112 and 114 places and maintains the vertebrae adjacent to those surfaces in an angular relationship, creating and maintaining the desired lordosis of the spine. **EX1004 at 6:30-34**.

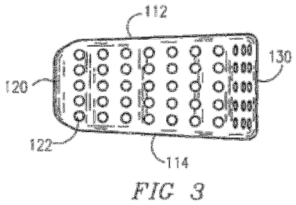
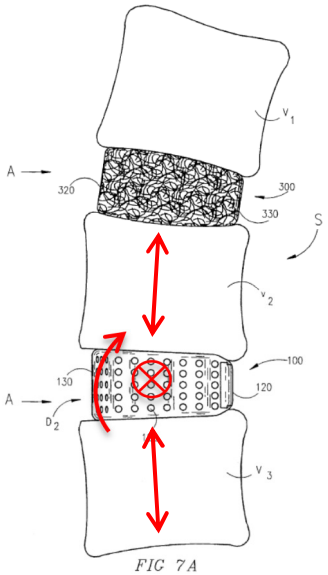
The '635 patent discloses a spinal implant device for use in spinal fusion surgical procedures that change the spatial relationship (i.e., restores a desired anatomical relationship from a degenerated condition) between first and second

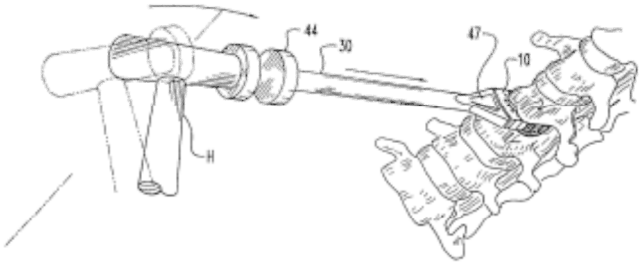
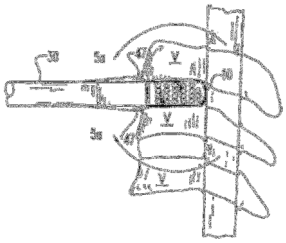
bones (i.e., vertebrae) at an intervertebral joint. EX1011 at ¶33. A PHOSITA would have recognized that the '635 patent discloses *a method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body*, as recited in the claims. EX1011 at ¶36.

forming an opening in a portion of the patient's body to expose the joint interconnecting the first and second bones,	The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.** The '899 patent (**EX1005**) discloses: • The '899 patent is a continuation of Serial no. 08/263,952. **EX1005 at 1:3-4.** • Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.** • For an anterior cervical device implantation, a short transverse incision is made across the front of the neck and to the right of the midline directly over the diseased disc… exposing the anterior aspect of the cervical spine… The adjacent vertebral endplates are gently scraped free of any remaining cartilage until diffuse fine punctuate decortication is achieved… The safety driver is then utilized to insert the implant behind the anterior lips of the vertebrae. The wound is then closed in the routine manner. **EX1005 at 5:59-6:10.**

A PHOSITA would have understood that the '635 patent describes a method for implanting a device for use during spinal fusion. EX1011 at ¶37. As Dr. Ochoa states, "[t]he steps of creating a surgical access to the site of interest and closing

said access at the conclusion of the surgery are fundamental to performance of an anterior fusion surgical procedure." *Id.* Moreover, an exemplary procedure is also described in the '899 patent and making an incision to expose the spine where implantation takes place is expressly disclosed. *Id.* and EX1005 at 5:59-6:10.

moving the second bone relative to the first bone, *said step of moving the second bone relative to the first bone includes* *expanding at least a portion of the joint interconnecting the first and second bones by applying force against the first and second bones with a wedge member and* *pivoting the first bone about an axis which extends through the joint interconnecting the first and second bones,*	The '635 patent (**EX1004**) discloses: • The upper and lower surfaces are disposed in a converging angular relationship to each other such that the implants of the present invention have an overall "wedged-shape" in an elevational side view. **EX1003 at Abstract and FIG. 3.**  FIG 3 • The implant 100 has an insertion end 120 and a trailing end 130. **EX1004 at 7:4-5 and, *e.g.*, FIG. 3.** • The modular implants may have a reduced size at their insertion end,… such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. **EX1004 at 2:64-3:7.** • The method of inserting the implant 100 is set forth in detail in application Ser. No. 08/263,952, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening 126 in the trailing end 120 [sic] of the implant 100 and the fitting of the driving instrument into the depressed portion 124 prevents movement of the implant 100 in relationship to the driving instrument. The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space. ***Id.* at 7:46-56.**  FIG 7A

	• Referring to FIG. 7A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant 100 inserted in the disc space D_2 between two adjacent vertebrae V_2 and V_3. The implant 100 is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. ***Id.*** **at 8:8-15 and FIG. 7A.** The '899 patent (**EX1005**) discloses: • Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.** • Referring to FIGS. 4, 4a, 5 and 5a, the method of inserting the implant is shown. The threaded end 46 of the internal rod 42 of the driving member 30 is attached to the threaded opening 26 of the implant 10 by turning of the knob 44. ***Id.*** **at 8:12-15.**  ***Fig. 4*** • FIG. 4 is a front perspective view showing the implant being driven into the disc space. ***Id.*** **at 6:64-65 and FIG. 4.**  ***Fig. 5*** • The implant is then placed at the entrance to the disc space between the two adjacent vertebrae V. The knob 44 is then tapped with hammer H sufficiently hard enough to drive the implant 10 into the disc space. The restriction members 47 and 49 which are wider than the disc space, prevent over penetration of the implant. ***Id.*** **at 8:20-25 and FIG. 5.**

Dr. Ochoa states that a PHOSITA would have recognized that the '635 patent discloses a method of changing a spatial relationship between first and

second vertebrae, and as such, also discloses moving a second bone (second vertebra) relative to a first bone (first vertebra), as recited in the claims. EX1011 at ¶36. Moreover, the upper (112) and lower (114) surfaces of the implant (100) of the '635 patent are disposed in a converging angular relationship to each other such that the implant has an overall "wedged-shape" in an elevational side view. EX1004 at Abstract, FIG. 3. A PHOSITA would, therefore, have understood that the '635 patent describes a *wedge member*, as recited in the claims. EX1011 at ¶38. During implantation, the implant (100) is mounted on a driving instrument or insertion tool and placed at the entrance to the disc space D_2 between the two adjacent vertebrae V_2 and V_3 in the spinal column S. EX1004 at 7:46-56, 8:8-15 and FIG. 7A. The driving instrument is tapped with a hammer sufficiently hard enough to drive the implant into the disc space in the direction of arrow A. *Id.* Thus, the '635 patent describes the step of driving the implant into the disc space under force, which causes the wedge-shaped upper and lower surfaces of the implant to force the end plates of the adjacent vertebrae V_2 and V_3 apart as the implant is advanced forward into the disc space D_2. According to Dr. Ochoa, "a PHOSITA would have understood that as the intervertebral space is wedged open, the vertebrae comprising the spinal motion segment pivot about the posterior elements of the FSU [functional spinal unit] (intact soft tissues and facet joints) which are located posterior to the intervertebral disc space." EX1011 at ¶39. "As

such," states Dr. Ochoa, "the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae at which the device is implanted, forcing the adjacent vertebrae to ramp up (*i.e. expanding at least a portion of the joint*) thus opening the intervertebral space and moving the vertebrae apart." *Id.* at ¶40.

Moreover, in view of the combined teachings of the '635 patent and the '899 patent, it would have been obvious for a PHOSITA to utilize the insertion method and insertion instrument disclosed in the '899 patent for the implant of the '635. EX1011 at ¶54; EX10057:45-8:19. The insertion device of the '899 patent does <u>*not*</u> interact with the vertebrae during insertion of the implant, and functions only to provide a removable rigid coupling to facilitate impaction of the implant. EX1011 at ¶54

Dr. Ochoa states that "[a] PHOSITA would have understood that forcing the intervertebral space open with a wedge shaped device results in a combination of translation and rotation of the first vertebral body relative to the second vertebral body." EX1011 at ¶41. Also, "[a] PHOSITA would have understood that as the spinal implant device disclosed in the '635 patent is implanted between adjacent

vertebrae, it forces one vertebra to move from a first orientation relative to the other vertebra (*e.g.,* a degenerative relationship) to a second orientation relative to the other vertebra (*i.e.,* a restored relationship), pivoting about an axis which extends through the joint that connects the vertebrae." *Id.*

A PHOSITA, therefore, would have understood that the step of *moving the second bone relative to the first bone, said step of moving the second bone relative to the first bone includes expanding at least a portion of the joint interconnecting the first and second bones by applying force against the first and second bones with a wedge member and pivoting the first bone about an axis which extends through the joint interconnecting the first and second bones,* as recited in the claims, would have occurred when implanting the device of the '635 patent. *Id.*

closing the opening in the patient's body with at least a portion of the wedge member disposed between the first and second bones at the joint interconnecting the first and second bones, and,	The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.** The '899 patent (**EX1005**) discloses: • Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.** • For an anterior cervical device implantation, a short transverse incision is made across the front of the neck and to the right of the midline directly over the diseased disc… exposing the anterior aspect of the cervical spine… The safety driver is then utilized to insert the implant behind the anterior lips of the vertebrae. The wound is then closed in the routine manner. ***Id.*** **at 5:59-6:10.**

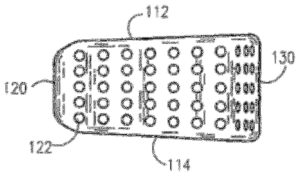
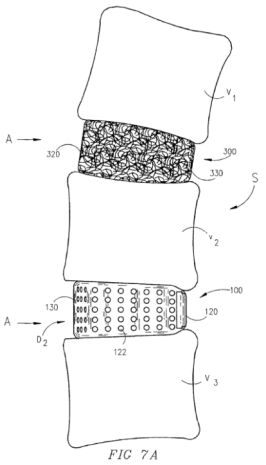
As already discussed, a PHOSITA would have understood that "[t]he steps of creating a surgical access to the site of interest and closing said access at the conclusion of the surgery are fundamental to performance of an anterior fusion surgical procedure." EX1011 at ¶42. Moreover, an exemplary procedure described in the '899 patent provides for closing the wound at the conclusion of the procedure "in the routine manner." *Id.* and EX1005 at 5:59-6:10.

thereafter, transmitting force between the first and second bones through the wedge member to maintain the joint in the expanded condition.	The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.** • The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. ***Id.*** • The angular relationship of the upper and lower surfaces places and maintains the vertebrae adjacent to those surfaces in an angular relationship to each other, creating and maintaining the desired lordosis. ***Id.*** • The fusion enhancing material that is packed within the chamber 116 of the implant 10 serves to promote bone ingrowth between the implant 100 and the adjacent vertebrae. Once the bone ingrowth occurs, the implant 100 will be a permanent fixture preventing dislodgement of the implant as well as preventing any movement between the adjacent vertebrae. **EX1004 at 7:32-38.**

Dr. Ochoa states that "[a] PHOSITA would have understood that the spinal fusion implant that is inserted during a fusion procedure becomes permanent fixture as a load-bearing member in the intervertebral space, maintaining the surgical correction and preventing movement between the adjacent vertebrae. As

such, the forces encountered along the spinal column at the vertebrae are transmitted through the implant which maintains the restored condition of the implant at the intervertebral joint." EX1011 at ¶43. Therefore, a PHOSITA would have understood that the '635 patent discloses, *transmitting force between the first and second bones through the wedge member to maintain the joint in the expanded condition*, as recited in the claims.

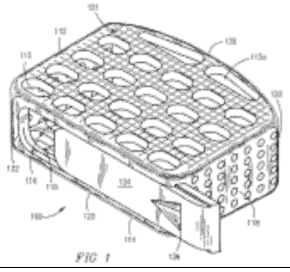
2. Claim 9

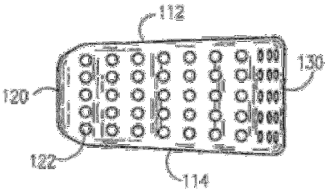
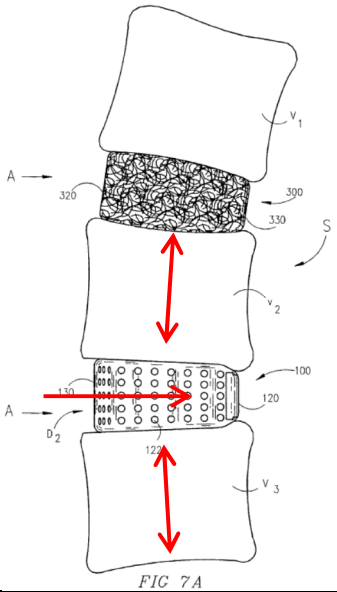
'531 patent Claim 9 vs. the '635 patent and the '899 patent	
A method as set forth in claim 8 wherein said step of applying force against the first and second bones with the wedge member includes *sliding a first surface on the wedge member along an outer side surface on the first bone and* *sliding a second surface on the wedge member along an outer side surface on the second bone while* *moving the wedge member into the joint without rotating the wedge member relative to the joint.*	The '635 patent (**EX1004**) discloses: • *See* discussion re. claim 8, above. • The modular implants may have a reduced size at their insertion end,… such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. **EX1004 at 2:64-3:7.** • The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space. ***Id.*** **at 7:46-56.**  FIG 3  FIG 7A

As already described, *e.g.*, at 13-16 and 20-23, a PHOSITA would have understood that as the implant of the '635 patent is inserted between the adjacent

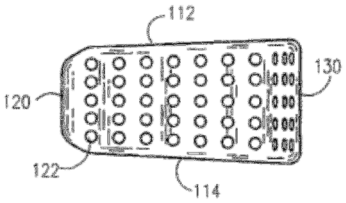
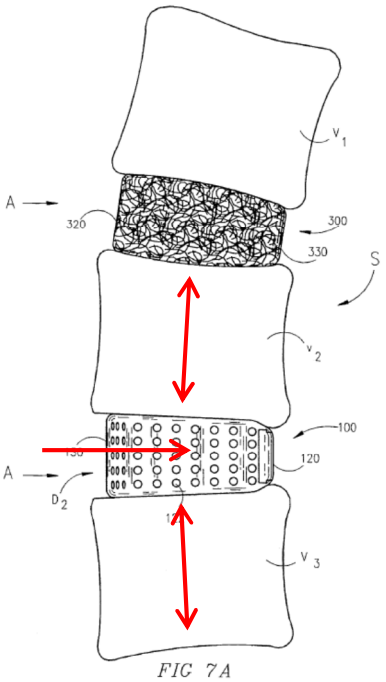
vertebrae it forces the vertebrae apart and expands a portion of the intervertebral joint by sliding the upper and lower surfaces (112, 114) of the implant (100) along outer side surfaces of the adjacent vertebrae (V_2, V_3), while moving the implant (100) into the joint without rotating the implant (100) relative to the joint. EX1011 at ¶45. Therefore, a PHOSITA would have understood that the step *wherein said step of applying force against the first and second bones with the wedge member includes sliding a first surface on the wedge member along an outer side surface on the first bone and sliding a second surface on the wedge member along an outer side surface on the second bone while moving the wedge member into the joint without rotating the wedge member relative to the joint,* as recited in the claims, would have occurred when implanting the device of the '635 patent. *Id.*

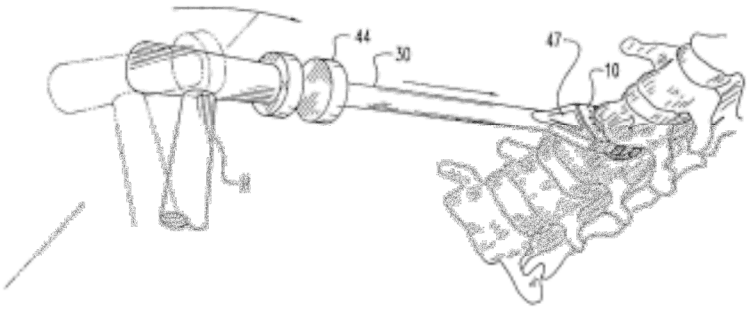
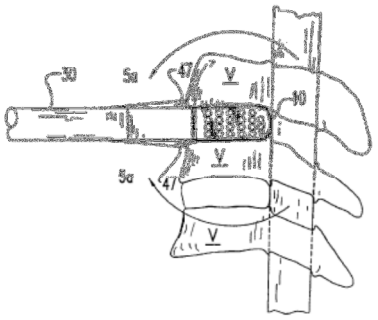
3. Claim 107

'531 patent Claim 107 vs. the '635 patent and the '899 patent	
A method of changing a spatial relationship between first and second bones having longitudinal axes which extend through a joint in a patient's body, said method comprising the	The '635 patent (**EX1004**) discloses: • *See* discussion re. claim 8, above. • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.** • The spinal fusion implants of the present invention are sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly or in part to the disc space created. ***Id*.** 

steps of	• *See, e.g.*, **FIGs. 1, 3 and 7A**.  FIG 3 • The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. **EX1004 at Abstract.** • The angular relationship of the upper and lower surfaces 112 and 114 places and maintains the vertebrae adjacent to those surfaces in an angular relationship, creating and maintaining the desired lordosis of the spine. **EX1004 at 6:30-34**.  FIG 7A

As already discussed with respect to claim 8 at 17-25, a PHOSITA would have understood that the '635 patent discloses a method of changing a spatial relationship between bones interconnected at a joint in a patient's body. Moreover, as stated by Dr. Ochoa, EX1011 at ¶46, "[a] PHOSITA would have understood that the longitudinal axis of a vertebral body would run through the center of the vertebral body in a cephalad-caudal (superior-inferior) direction," (as shown in the claim chart above) and therefore, "would have understood that the '635 patent discloses *a method of changing a spatial relationship between first and second bones having longitudinal axes which extend through a joint in a patient's body,* as recited in the claims." *Id.*

moving a wedge member into the joint, *said step of moving the wedge member into the joint includes moving a leading end portion of the wedge member through the longitudinal central axis of the first bone and through the longitudinal central axis of the second bone, and* *moving the second bone relative to the first bone under the influence of force transmitted from the wedge member as the wedge member moves into the joint to change an angular relationship between the longitudinal central axes of the first and second bones from a first angular relationship in which the longitudinal*	The '635 patent (**EX1004**) discloses: • The implant 100 has an insertion end 120 and a trailing end 130. **EX1004 at 7:4-5 and, *e.g.*, FIG. 3.**  *FIG 3* • The modular implants may have a reduced size at their insertion end,… such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. **EX1004 at 2:64-3:7.** • The method of inserting the implant 100 is set forth in detail in application Ser. No. 08/263,952, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening 126 in the trailing end 120 [sic] of the implant 100 and the fitting of the driving instrument into the depressed portion 124 prevents movement of the implant 100 in relationship to the driving instrument. The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space. ***Id.* at 7:46-56.**  *FIG 7A* • Referring to FIG. 7A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant 100 inserted in the disc space D_2 between two adjacent vertebrae V_2 and V_3. The implant 100 is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. ***Id.* at 8:8-15 and FIG. 7A**

central axes of the first and second bones extend through the joint and are spaced from the wedge member to a second angular relationship in which the longitudinal central axes of the first and second bones extend through both the joint and the wedge member, *said step of moving the second bone relative to the first bone includes applying force against a surface area on the first bone and against a surface area on the second bone with the wedge member as the wedge member moves into the joint.*	The '899 patent (**EX1005**) discloses: • The '899 patent is a continuation of Serial no. 08/263,952. **EX1005 at 1:3-4.** • Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.** • Referring to FIGS. 4, 4a, 5 and 5a, the method of inserting the implant is shown. The threaded end 46 of the internal rod 42 of the driving member 30 is attached to the threaded opening 26 of the implant 10 by turning of the knob 44. ***Id.*** **at 8:12-15 and FIG. 4.**  ***Fig. 4*** • FIG. 4 is a front perspective view showing the implant being driven into the disc space. ***Id.*** **at 6:64-65.** • The implant is then placed at the entrance to the disc space between the two adjacent vertebrae V. The knob 44 is then tapped with hammer H sufficiently hard enough to drive the implant 10 into the disc space. The restriction members 47 and 49 which are wider than the disc space, prevent over penetration of the implant. ***Id.*** **at 8:20-25 and FIG. 5.**  ***Fig. 5***

As described, *e.g.*, at 13-16 and 20-23, the spinal fusion implant (100) of the '635 patent is implanted between the adjacent vertebrae (V_2, V_3) in the spinal

column (S) in the direction of arrow A (FIG. 7A). EX1004 at 8:8-15 and FIG. 7A. This requires moving the insertion end 120 of the implant (100) through the longitudinal central axis of the adjacent vertebra (as shown in the claim chart above). EX1011 at ¶47. Therefore, according to Dr. Ochoa, a PHOSITA would have understood that the '635 patent discloses *moving a wedge member into the joint, said step of moving the wedge member into the joint includes moving a leading end portion of the wedge member through the longitudinal central axis of the first bone and through the longitudinal central axis of the second bone*, as recited in the claims. *Id.*

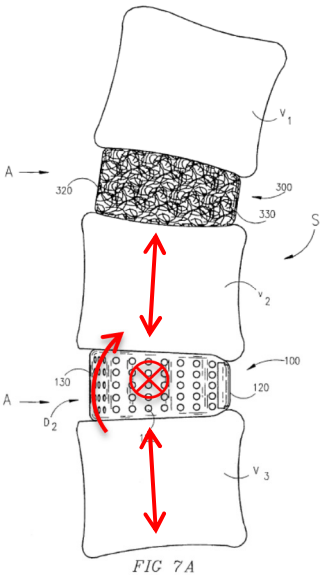
Also as described above, a PHOSITA would have understood that as the implant of the '635 patent is inserted between the adjacent vertebrae the wedge shaped body forces the adjacent vertebrae apart by sliding the upper and lower surfaces (112, 114) of the implant (100) along the surfaces of the adjacent vertebrae (V_2, V_3), while moving the implant (100) into the joint. EX1011 at ¶51. As the implant forces the vertebrae apart it causes a second vertebra to move relative to a first vertebra and change the angular relationship between the longitudinal central axes of the first and second vertebrae from a first angular relationship, in which the longitudinal central axes of the first and second vertebrae extend through the joint and are spaced from the wedge member to a second angular relationship in which the longitudinal central axes of the first and second

bones extend through both the joint and the wedge member. EX1011 at ¶51. Thus, Dr. Ochoa states that "a PHOSITA would have understood that the step of *moving the second bone relative to the first bone under the influence of force transmitted from the wedge member as the wedge member moves into the joint to change an angular relationship between the longitudinal central axes of the first and second bones from a first angular relationship in which the longitudinal central axes of the first and second bones extend through the joint and are spaced from the wedge member to a second angular relationship in which the longitudinal central axes of the first and second bones extend through both the joint and the wedge member,* as recited in the claims, would have occurred when implanting the interbody cage disclosed in the '635 patent." *Id.*

Further, as the implant advances into the joint, the wedge-shaped body (and <u>not</u> the insertion tool since the insertion tool only engages the trailing end of the implant) engages the surfaces of the adjacent vertebrae to drive them apart. Thus, a PHOSITA would have understood that the "spinal fusion implant (100) inserted between the adjacent vertebrae applies force against a surface area on the first vertebra and against a surface area on the adjacent vertebra as the implant (100) moves into the joint between the vertebrae," EX1011 at ¶53. Therefore, "a PHOSITA would have understood that the *step of moving the second bone relative to the first bone includes applying force against a surface area on the first bone*

and against a surface area on the second bone with the wedge member as the wedge member moves into the joint, as recited in the claims, would have occurred when implanting the interbody cage disclosed in the '635 patent." *Id.*

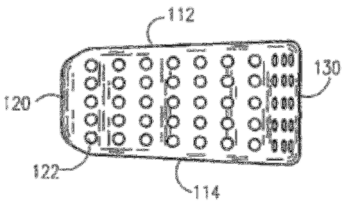
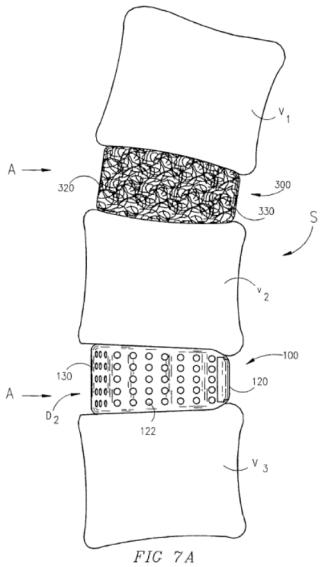
4. Claim 109

'531 patent Claim 109 vs. the '635 patent and the '899 patent	
A method as set forth in claim 107 wherein the step of moving the second bone relative to the first bone includes pivoting the second bone about an axis which extends through the joint in a direction transverse to the longitudinal central axes of the first and second bones.	The '635 patent (**EX1004**) discloses: • *See* discussion re. claims 8 and 107, above. • Referring to FIG. 7A,… [t]he implant 100 is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. **EX1004 at 8:8-15 and FIG. 7A.**  FIG 7A

"As the intervertebral space is wedged open [by the device (100)], the vertebrae comprising the spinal motion segment pivot about the intact soft tissues and facet joints, which are located within the motion segment (i.e. the joint), and posterior to the intervertebral space." EX1011 at ¶55. "A PHOSITA would have understood that the resulting rotation occurs about the axis of spinal flexion," which "extends in the medial to lateral direction and as such, is transverse to the longitudinal axis running in the cephalad-caudal (superior-inferior) direction through the vertebral bodies." *Id.* Therefore, Dr. Ochoa states that "a PHOSITA

would have understood that the steps of the method *wherein the step of moving the second bone relative to the first bone includes pivoting the second bone about an axis which extends through the joint in a direction transverse to the longitudinal central axes of the first and second bones*, as recited in the claims, would have occurred when implanting the interbody cage disclosed in the '635 patent." *Id.*

5. Claim 111

'531 patent Claim 111 vs. the '635 patent and the '899 patent	
A method as set forth in claim 107 wherein said step of applying force against the surface areas on the first and second bones with the wedge member includes sliding the wedge member along the surface on the first bone and sliding the wedge member along the surface on the second bone without rotating the wedge member relative to the joint.	The '635 patent (**EX1004**) discloses: • *See* discussion re. claims 9 and 107, above. • The modular implants may have a reduced size at their insertion end,… such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. **EX1004 at 2:64-3:7.** • The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space. ***Id.*** **at 7:46-56.**  FIG 3  FIG 7A

As discussed, *e.g.* at 13-16 and 20-23, a PHOSITA would have understood that as the implant of the '635 patent is inserted between the adjacent vertebrae it forces the vertebrae apart and expands a portion of the intervertebral joint by

sliding the upper and lower surfaces (112, 114) of the implant (100) along outer side surfaces of the adjacent vertebrae (V_2, V_3), while moving the implant (100) into the joint without rotating the implant (100) relative to the joint. EX1011 at ¶57. Dr. Ochoa states, therefore, that "a PHOSITA would have understood that the step *wherein said step of applying force against the first and second bones with the wedge member includes sliding a first surface on the wedge member along an outer side surface on the first bone and sliding a second surface on the wedge member along an outer side surface on the second bone while moving the wedge member into the joint without rotating the wedge member relative to the joint,* as recited in the claims, would have occurred when implanting the device of the '635 patent." *Id.*

B. Ground 2: Claims 46 and 49 are unpatentable under 35 U.S.C. § 103(a) as obvious over the '635 patent (EX1004) in view of the '899 patent (EX1005) and the '261 patent (EX1006)

Dr. Ochoa also describes the '261 patent as disclosing a spinal implant device for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerative condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. EX1011 at ¶35. The spinal implant disclosed in the '261 patent is horseshoe-shaped interbody spacer for use to supplement anterior spinal fusions. EX1006 at Abstract, 2:3-8. The device has a wedge-shaped profile with upper and lower

planar faces (10, 11) converging from the anterior (15), towards the posterior (12) ends of the horseshoe. *Id.* The device has a plurality of holes (13, 14) provided from each planar face (10, 11) to the outer curved surface (15) of the horseshoe to allow for insertion of fixation pins or screws to enable the device to be fixed between adjacent vertebrae. *Id.* at 1:29-32, 54-59, 2:8-24, FIGs. 4 and 5.

Dr. Ochoa opines that a PHOSITA would have been motivated to look to the combined teachings of the '635 patent and the '899 patent and the '261 patent because they all relate to substantially the same subject matter and address common issues, *i.e.*, implantable orthopedic devices for use in a spinal fusion surgical procedures that change changing a spatial relationship between bones in a patient's body. EX1011 at, e.g., ¶¶34, 54, 64. According to Dr. Ochoa, a PHOSITA would have looked to this combined body of art. EX1011 at ¶21. In addition, as discussed further below, the '635 patent and the '899 patent each disclose multiple features of the claimed invention and share the same inventor making the combination of their teachings obvious.[7]

Dr. Ochoa opines that a PHOSITA would have been motivated to look to the teachings of the'635 patent, the '899 patent, 'the 261 patent and other prior art disclosing implantable orthopedic devices for use in association with bones in a patient's body (e.g., for changing the spatial relationship of bones in the human

[7] *See* fn. 4, *supra*.

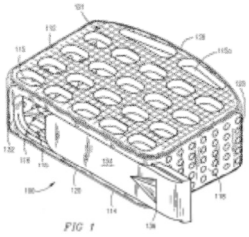
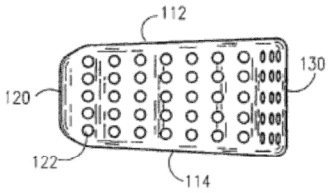
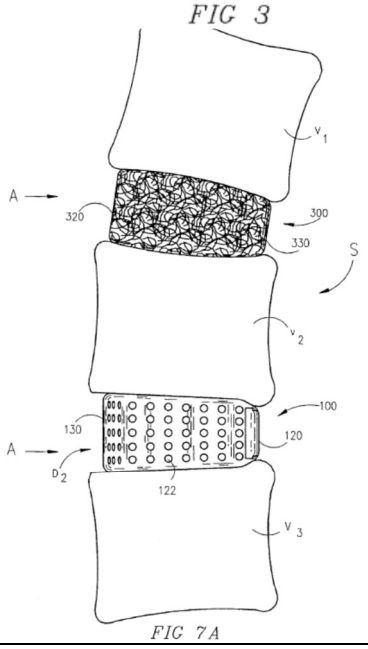
body) when considering improvements to the design of such devices.[8] *Id.* at ¶63-67. A PHOSITA would have been motivated to look to the teachings of the '261 patent to those of the '635 patent because both disclose an implantable orthopedic device for use in a spinal fusion surgical procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint in a patient.[9] *Id.* According to Dr. Ochoa, "[i]t would have been recognized by a PHOSITA that the spine disk implants of the '261 patent and the '635 patent both correct existing mechanical deformity, provide mechanical stability, and provide a suitable environment for arthrodesis through the use of an interbody spacer in conjunction with either natural or synthetic bone graft materials." *Id.* at ¶65.

1. Claim 46

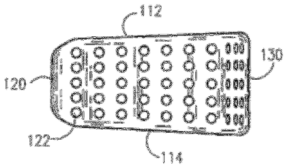
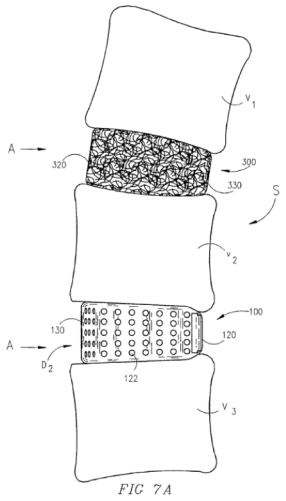
'531 patent Claim 46 vs. the '635 patent, the '899 patent, and the '261 patent	
A method of changing a spatial relationship between first and second bones which are interconnected at a joint in a	The '635 patent (**EX1004**) discloses: • *See* discussion re. claims 8 and 107 above. • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.**

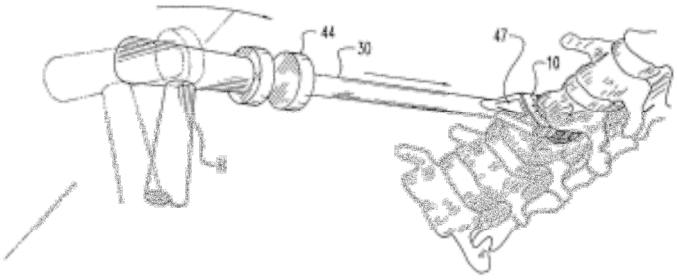
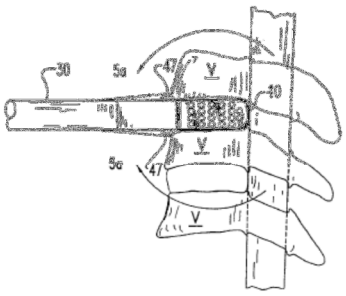
[8] *See KSR*, 550 U.S. at 417, fn. 2, *supra*.

[9] *See KSR*, 550 U.S. at 421-21, fn. 3, *supra*.

patient's body, said method comprising the steps of	• The spinal fusion implants of the present invention are sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly or in part to the disc space created. ***Id.*** • *See, **Id.*** **at FIGs. 1, 3 and 7A**. • The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. **EX1004 at Abstract.** • The angular relationship of the upper and lower surfaces 112 and 114 places and maintains the vertebrae adjacent to those surfaces in an angular relationship, creating and maintaining the desired lordosis of the spine. **EX1004 at 6:30-34**.   FIG 3  FIG 7A

As already discussed above at 13-17, a PHOSITA would have understood that the '635 patent discloses *a method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body*. EX1011 at ¶¶33, 36.

moving a wedge member into the joint between the first and second bones without rotating the wedge member and *with a thin end portion of the wedge member leading and a thick end portion of the wedge member trailing,* *applying force against the first and second bones with the wedge member as the wedge member is moved into the joint to move the second bone from a first orientation relative to the first bone to a second orientation relative to the first bone,*	The '635 patent (**EX1004**) discloses:  FIG 3 • The implant 100 has an insertion end 120 and a trailing end 130. **EX1004 at 7:4-5 and, *e.g.*, FIG. 3.** • The modular implants may have a reduced size at their insertion end,… such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. **EX1004 at 2:64-3:7.**  FIG 7A • The method of inserting the implant 100 is set forth in detail in application Ser. No. 08/263,952, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening 126 in the trailing end 120 [sic] of the implant 100 and the fitting of the driving instrument into the depressed portion 124 prevents movement of the implant 100 in relationship to the driving instrument. The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space. ***Id.* at 7:46-56.** • Referring to FIG. 7A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant 100 inserted in the disc space D_2 between two adjacent vertebrae V_2 and V_3. The implant 100 is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. ***Id.* at 8:8-15 and FIG. 7A.** • The '635 patent teaches a variety of features that may be used to provide a reliable and secure load path and securely hold the implant in position. ***Id.* at 2:9-22, 3:57- 4:7, 6:34-44.**

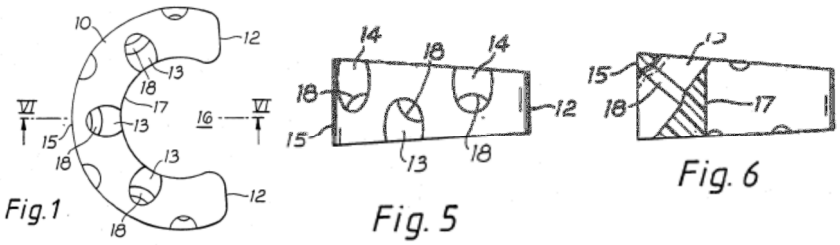
	The '899 patent (**EX1005**) discloses: • The '899 patent is a continuation of Serial no. 08/263,952. **EX1005 at 1:3-4.** • Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.** • Referring to FIGS. 4, 4a, 5 and 5a, the method of inserting the implant is shown. The threaded end 46 of the internal rod 42 of the driving member 30 is attached to the threaded opening 26 of the implant 10 by turning of the knob 44. ***Id.*** **at 8:12-15.**  ***Fig. 4*** • FIG. 4 is a front perspective view showing the implant being driven into the disc space. ***Id.*** **at 6:64-65 and FIG. 4.** • The implant is then placed at the entrance to the disc space between the two adjacent vertebrae V. The knob 44 is then tapped with hammer H sufficiently hard enough to drive the implant 10 into the disc space. ***Id.*** **at 8:20-25 and FIG. 5.**  ***Fig. 5***

As already described above, *e.g.*, at 13-16 and 20-23, the implant 100 of the '635 patent is implanted between the adjacent vertebrae V_2, V_3 in the spinal column S in the direction of arrow A. EX1004 at 8:8-15 and FIG. 7A. The wedge-shaped body of the implant has a thin leading end 120 and a thick trailing end 130.

Id. at 7:4-5, FIG. 3 and EX1011 at ¶58. And as described, the insertion tool does not interact with the vertebrae during insertion. EX1011 at ¶54. As such, the surfaces of the wedge-shaped body of the implant engage the surfaces of the adjacent vertebrae, forcing the vertebrae apart and opening the intervertebral space. "A PHOSITA would have understood that insertion of the spinal disk implant of the '635 patent, based on the anatomic relationship between the vertebrae, the insertion tool design, and the use of an anterior surgical approach, would not require rotation of the implant." EX1011 at ¶58. A PHOSITA would, therefore, have understood that the '635 patent discloses implanting the spinal fusion implant (100) between the adjacent vertebrae (V_2, V_3) in the spinal column (S) involves moving the thin leading end 120 of the implant (100) followed by the thick trailing end (130). *Id.* Thus, "a PHOSITA would have understood that the '635 patent discloses *moving a wedge member into the joint between the first and second bones without rotating the wedge member and with a thin end portion of the wedge member leading and a thick end portion of the wedge member trailing*, as recited in the claims." *Id.*

Moreover, for reasons discussed above, a PHOSITA would have understood that the '635 patent discloses *applying force against the first and second bones with the wedge member as the wedge member is moved into the joint to move the second bone from a first orientation relative to the first bone to a second*

orientation relative to the first bone, as recited in the claims. EX1011 at ¶¶60-61.

fixedly connecting the wedge member to at least one of the first and second bones with a fastener member, and	The '261 patent (**EX1006**) discloses: • A spinal implant, e.g., to replace an excised disc, that comprises a rigid generally horseshoe shape of biocompatible material, such as carbon-fiber reinforced plastics, having upper and lower planar faces (10, 11) converging towards the ends (12) of the horseshoe, and at least one hole (13, 14) from each planar face (10, 11) emerging in the outer curved face (15) of the horseshoe, to enable the horseshoe to be fixed by screws inserted through one or more selected holes in each plurality (13, 14) from the ends in the outer curved face (15) into respective adjacent vertebrae. **EX1006 at Abstract** and **FIGs. 1, 5** and **6.**  Fig.1 Fig. 5 Fig. 6 • The "horseshoe" spinal implant shown in the drawings is intended to be contained substantially within the confines of the anterior vertebral column and act as a spacer between adjacent vertebrae at the peripheries of the ends thereof which are structurally the strongest parts. **EX1006 at 2:3-8.** • The implant has upper and lower planar faces 10, 11 respectively converging towards the ends 12 of the horseshoe, and pluralities of holes 13, 14 respectively are provided from each planar face (10, 11 respectively) emerging in the outer curved face 15 of the horseshoe, to enable the horseshoe to be fixed between adjacent vertebrae (not shown) as by fixation screws (not shown) inserted through one or more selected holes in each plurality, from the ends of the holes in the outer curved face 15 and into the respective vertebrae. **EX1006 at 2:9-19.** • Each hole 13, 14 has a shoulder 18 (between portions of slightly different diameter) against which the head of a screw

	can bear. **EX1006 at 2:23-25.**

A PHOSITA would have understood that the '261 patent discloses a wedge shaped anterior spinal implant for use in spinal fusion surgical procedures. EX1006 at Abstract, 2:3-8 and FIGs. 1, 5 and 6; EX1011 at ¶62. A PHOSITA would have understood that the spinal implant of the '261 patent may be fixed to the adjacent vertebrae using screws inserted through a plurality of holes (13, 14) from the curved outer face (15) into the respective vertebrae. EX1006 at 2:9-19; EX1011 at ¶62. Each screw head would bear upon a countersunk shoulder (18). EX1006 at 2:23-25; EX1011 at ¶62. A PHOSITA would have understood that the '261 patent discloses connecting the wedge member to at least one of the first and second bones with a fastener member. EX1011 at ¶62. Therefore, a PHOSITA would have understood that the '261 patent discloses, *fixedly connecting the wedge member to at least one of the first and second bones with a fastener member*, as claimed. ***Id.***

According to Dr. Ochoa, "[t]he applicability and advantage of adding a plurality of holes to enable the use of fixation screws disclosed in the '261 patent when applied to the device of the '635 patent would have been readily apparent to a PHOSITA." EX1011 at ¶65. "A PHOSITA would have understood that the '635 patent teaches the importance of providing stability at the bone implant interface and preventing dislocation of the implant. The '635 patent further teaches a variety of features that may be used to provide a reliable and secure load path and securely

hold the implant in position post operatively, thus enhancing stability. A PHOSITA would have understood that the use of screw fixation taught in the '261 patent would be supplemental and complementary to the features taught in the '635 patent." *Id.*

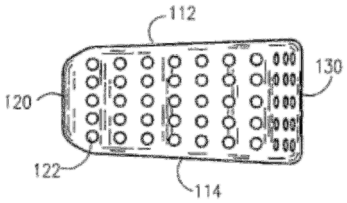
Dr. Ochoa states that "[a] PHOSITA would have been motivated, in view of the combined teachings of the '635 patent, and the '261 patent, to include a step of fixedly connecting the wedge member to at least one of the first and second bones with a fastener member in the method for implantation of the spinal implant of the '635 patent to provide additional fixation." *Id.* at 66. Moreover, a PHOSITA would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting method without changing the principle of operation of the spinal implant of the '635 patent. *Id.* at 67.

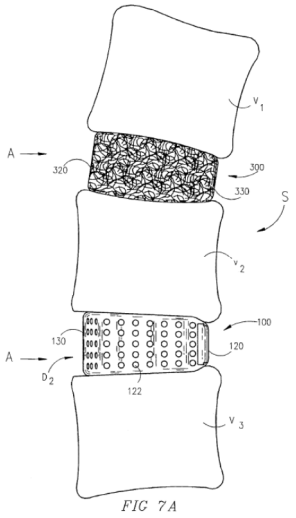
transmitting force between the first and second bones through the wedge member while the second bone is in the second orientation relative to the first bone.	The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.** • The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. ***Id.*** • The angular relationship of the upper and lower surfaces places and maintains the vertebrae adjacent to those surfaces in an angular relationship to each other, creating and maintaining the desired lordosis. ***Id.***

Similarly, as discussed above with respect to claim 8 at 24-25, Dr. Ochoa

states that "[a] PHOSITA would have understood that the spinal fusion implant that is inserted during a fusion procedure becomes permanent fixture as a load-bearing member in the intervertebral space, maintaining the surgical correction and preventing movement between the adjacent vertebrae. As such, the forces encountered along the spinal column at the vertebrae are transmitted through the implant which maintains the restored condition of the implant at the intervertebral joint." EX1011 at ¶68. Therefore, a PHOSITA would have understood that the '635 patent discloses, *transmitting force between the first and second bones through the wedge member while the second bone is in the second orientation relative to the first bone*, as recited in the claims. *Id.*

2. Claim 49

'531 patent Claim 49 vs. the '635 patent, the '899 patent and the '261 patent	
A method as set forth in claim 46 wherein said step of moving the wedge member into the joint between the first and second bones includes *moving the wedge member along a path which extends between an end portion of the first bone and an end portion of the second bone and* *increasing a distance*	The '635 patent (**EX1004**) discloses: • *See* discussion re. claim 46 above. • The implant 100 has an insertion end 120 and a trailing end 130. **EX1004 at 7:4-5 and, *e.g.*, FIG. 3.**  FIG 3 • The modular implants may have a reduced size at their insertion end,… such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. **EX1004 at 2:64-3:7.**

between a surface area on the end portion of the first bone and a surface area on the second bone under the influence of force transmitted from the wedge member to the end portions of the first and second bones.	• Referring to FIG. 7A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant 100 inserted in the disc space D_2 between two adjacent vertebrae V_2 and V_3. The implant 100 is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. ***Id.* at 8:8-15 and FIG. 7A.**  FIG 7A

As discussed above, the wedge-shaped implant of the '635 patent is implanted in the spinal column S between first and second vertebrae V_2, V_3, driven into the intervertebral space D_2 in the direction of arrow A. EX1004 at 8:8-15 and FIG. 7A; EX1011 at ¶69. Consequently, "a PHOSITA would have understood that the '635 patent discloses *said step of moving the wedge member into the joint between the first and second bones includes moving the wedge member along a path which extends between an end portion of the first bone and an end portion of the second bone*, as recited in the claims." EX1011 at ¶69.

The wedge-shaped spinal fusion implant of the '635 patent device is retained by an insertion tool, and is advanced forward into the intervertebral space by impaction with a hammer. EX1004 at 2:64-3:7, 7:46-56, 8:8-15, FIG. 7A; EX1011 at ¶70. As already described, the insertion tool does not interact with the vertebrae

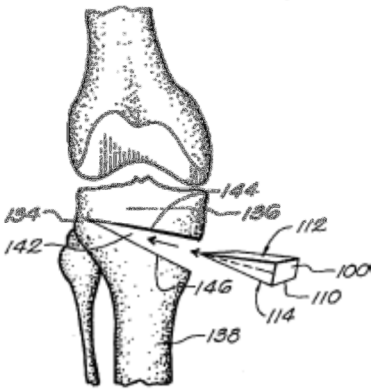
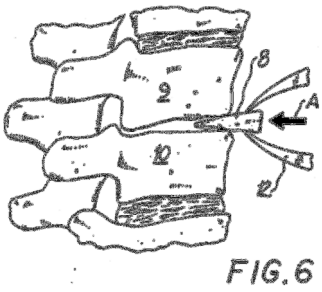
during insertion. EX1011 at ¶54. As such, the surfaces of the wedge-shaped body of the implant engage the surfaces of the adjacent vertebrae, forcing the vertebrae apart and opening the intervertebral space. *Id.* Dr. Ochoa states that "a PHOSITA would have understood from the disclosure of the '635 patent that the wedge-shaped spinal fusion implant (100) inserted between the adjacent vertebrae applies force against a surface area on the first vertebra and against a surface area on the adjacent vertebra as the implant (100) moves into the joint between the vertebrae." EX1011 at ¶70. "Therefore, a PHOSITA would have understood that the action of *increasing a distance between a surface area on the end portion of the first bone and a surface area on the second bone under the influence of force transmitted from the wedge member to the end portions of the first and second bones*, as recited in the claims, would have occurred when implanting the interbody cage disclosed in the '635 patent." *Id.*

C. Ground 3: Claim 105 is unpatentable under 35 U.S.C. § 103(a) as obvious over the '433 patent in view of the '254 patent and the '635 patent

Dr. Ochoa states that the '433 patent discloses an implantable wedge-shaped spacer for use in a high tibial osteotomy surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, the femur and tibia) at the knee. EX1011 at ¶¶71, 72. The device (120) is used as a spacer during an opening wedge

osteotomy procedure, to realign varus angulated knees, but may be used for realigning *any* malaligned bone. EX1007 at 2:59-61. The implant has two angularly offset principal surfaces (112, 114) which intersect at vertex (121) at the insertion end portion of the device and is. Abstract, 5:27:40 and FIG. 1A.

The '254 patent teaches a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae used in place of an intervertebral disk that has been removed (i.e. during discectomy). EX1008 at 6:65-7:13; FIGs. 5 and 6; EX1011 at ¶74.

'531 patent Claim 105 vs. the '433 patent, the '254 patent, the '635 patent	
An apparatus for use in changing the spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said apparatus comprising	The '433 patent (**EX1007**) discloses: • The '433 patent discloses a device, and kit and methods for realigning varus angulated knees, but also may be used for realigning any malaligned bone. **EX1007 at 2:59-61 and FIG. 3C.**  FIG. 3C The '254 patent (**EX1008**) discloses: • The '254 patent discloses a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae. **EX1008 at 6:65-7:13; FIGs. 5 and 6**.  FIG.6 • A wedge 8 is inserted between adjacent vertebrae 9 and 10 in a spinal column 11 in place of an intervertebral disk that has been removed. More specifically, FIG. 6 illustrates insertion

	of the wedge 8 in the direction of arrow A. ***Id***. The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract.**

The preamble of claim 105 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[10] To the extent that the preamble limits the claim, a PHOSITA would have understood that the '433 patent discloses implantable wedge-shaped spacer for changing the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, the femur and tibia) at the knee joint. EX1011 at ¶71. The wedge-shaped spacer of the '433 patent may be used for realigning <u>*any*</u> malaligned bone. EX1007 at 2:59-61; EX1011 at ¶73.

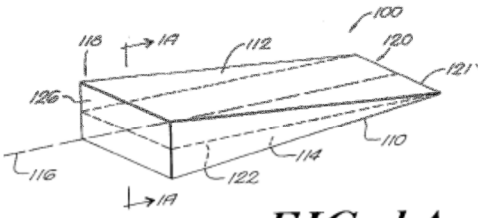
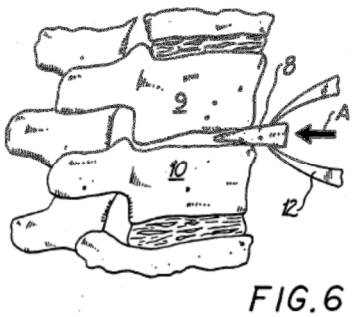
Moreover, the '254 patent discloses bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae used in place of an intervertebral disk that has been removed (i.e. during discectomy). EX1008 at 6:65-7:13; FIGs. 5 and 6. Still further, the '635 patent discloses a spinal implant device for use in spinal fusion that changes the spatial relationship (*e.g.*, restores a

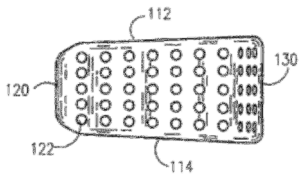
[10] *Pitney Bowes, Inc. v. Hewlett-Packard Co.,* 182 F.3d 1298, 1305, 51 U.S.P.Q.2d 1161, 1165 (Fed. Cir. 1999); M.P.E.P. § 2111.02.

desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. EX1011 at ¶75.

Dr. Ochoa states that "a PHOSITA would have been motivated to look to the teachings of the '433 patent, the '254 patent, the '635 patent, and other prior art disclosing implantable orthopedic devices for use in association with bones in a patient's body (e.g., for changing the spatial relationship of bones in the human body) when considering improvements to the design of such devices." *Id.* at ¶76. "[A] PHOSITA would have understood that the devices of the '433 patent, the '254 patent and the '635 patent disclose implantable spacers with a wedge-shaped body" whose functions are analogous "regardless of the anatomic location of use." *Id.* at ¶77. "The objective for these devices is to *change the spatial relationship between first and second bones*. The affected bones form links in a kinematic chain (i.e. a hinge) whether the hinge into which the wedge is inserted is created through an osteotomy, or by surgical removal of disk material in the spine. In each case, the realignment function requires the insertion of a body to correct for malalignment, and in the process change the spatial relationship between bones. The insertion of the body is facilitated by being in the shape of a wedge, in each case requiring the application of axial force to advance the device into the space." *Id.* A PHOSITA would have recognized that the '433 patent, the '254 patent and the '635 patent each discloses an *apparatus for use in changing the spatial*

relationship between first and second bones which are interconnected at a joint in a patient's body, as recited in the claim. EX1011 Ochoa Decl. at ¶71-77.

a wedge member which is movable into the joint between the first and second bones,	The '433 patent (**EX1007**) discloses: • The implantable device has a substantially wedge-shaped body 110 having two angularly offset intersecting principal surfaces 112, 114. The principal surfaces 112,114 intersect at a vertex 121 at insertion end 120 and extend about a principal plane 122 extending midway between surfaces 112, 114 from the vertex 121 at the insertion end 120 to a drive surface 126 at a drive end 118. The principal plane 122 contains a drive axis 116. The drive surface 126 extends, at least in part, in a direction transverse to the principal plane 122. The drive surface 126 is adapted to receive a force in the direction of the drive axis 116 towards the insertion end 120. **EX1007 at 5:27-40; FIG. 1A**.  FIG. 1A • The wedge body is configured and dimensioned for insertion between upper and lower portions of a bone joined at a lateral portion. **EX1007 at 7:14-31**. The '254 patent (**EX1008**) discloses: • The '254 patent teaches a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae. **EX1008 at 6:65-7:13; FIGs. 5** and **6**.  FIG. 6 • A wedge 8 is inserted between adjacent vertebrae 9 and 10 in a spinal column 11 in place of an intervertebral disk that has been removed. More specifically, FIG. 6 illustrates insertion of the wedge 8 in the direction of arrow A. ***Id***. The '635 patent (**EX1004**) discloses:

	• A spinal implant where the upper and lower surfaces are disposed in a converging angular relationship to each other such that the implants of the present invention have an overall "wedged-shape" in an elevational side view. **EX1004 at Abstract and FIG. 3.**  FIG 3

The '433 patent discloses an implantable spacer with a wedge-shaped body. EX1007 at 5:27-40; FIG. 1A. The wedge-shaped body has two angularly offset principal surfaces (112, 114) which intersect at vertex (121) at the thin end portion of the device (120). *Id.* The principal surfaces of the device are adapted to be placed within and engage mechanically the adjacent bony surfaces to promote contiguous bone formation. EX1011 at ¶78. Both the '254 patent and the '635 patent also disclose implantable spacers with a wedge-shaped body. EX1008 at 6:65-7:13; FIG. 6; and EX1004 at Abstract and FIG. 3.

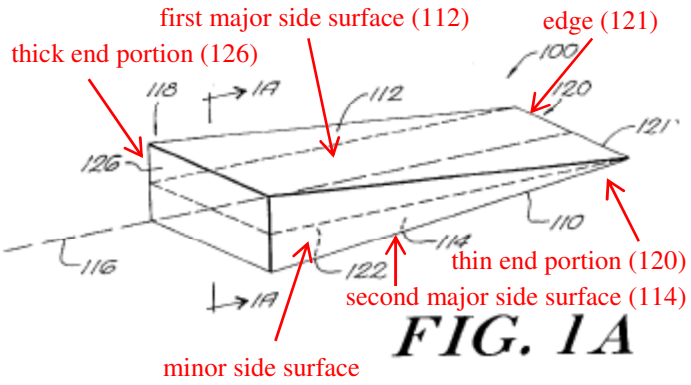
The claim language "*which is movable into the joint between the first and second bones*" is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and, therefore, is not material to patentability. As such, this language carries no patentable weight.[11] To the extent that this language limits the claim, a PHOSITA would have recognized that the '254 patent and the '635 patent each disclose *a wedge member which is movable*

[11] *In re Schreiber,* 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); M.P.E.P. § 2114.

into the joint between the first and second bones, as recited in the claims. EX1011 at ¶80. Moreover, "a PHOSITA would have [] understood from the teachings of the'254 patent and '635 patent that the spacer disclosed in the '433 patent could similarly be employed as *a wedge member which is movable into the joint between the first and second bones*, as recited in the claims." *Id.* According to Dr. Ochoa, "[i]t would have been recognized by a PHOSITA that the principal surfaces (112, 114) of the '433 [patent] body are analogous to the cephalad and caudal surfaces of the wedges (8) disclosed in the '254 patent, as well as the upper and lower (112, 114) surfaces disclosed in the '635 patent. In this respect, in each device the surfaces would mechanically engage the prepared bone surfaces while filling the interspace with graft material, thereby promoting contiguous bone formation." EX1011 at ¶78.

"A PHOSITA would have been motivated to apply the teachings of the '254 patent and '635 patent to those of the '433 patent because [they] disclose wedge-shaped implantable orthopedic devices for use in procedures that change the spatial relationship… between first and second bones..." *Id.* at ¶79**.** "Further, each of the '254, '635 and '433 patents teaches the use of bone growth inducing materials to promote bony union at the treated site." *Id.* A PHOSITA, therefore, would have been motivated in view of the combined teachings of the '433 patent, the '254 patent and the '635 patent to insert the *wedge body* disclosed in the '433 patent *into*

a joint located between first and second bones. *Id.* at ¶80. A PHOSITA would have considered using the spacer of the '433 patent in an intervertebral space as taught by the '254 patent and the '635 patent an obvious use for the device that would have yielded a predictable effect.[12] *Id.* at ¶81. This use would not have changed the principle of operation of the '433 patent spacer.[13] *Id.*

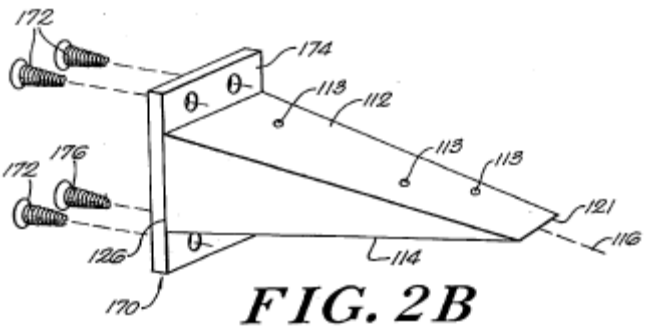
said wedge member having a thin end portion, *a thick end portion,* *a first major side surface which extends from the thin end portion to the thick end portion,* *a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and* *a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion,*	The '433 patent (**EX1007**) discloses: • *See* **EX1007 at 5:27-40; FIG. 1A**, as shown below.  FIG. 1A

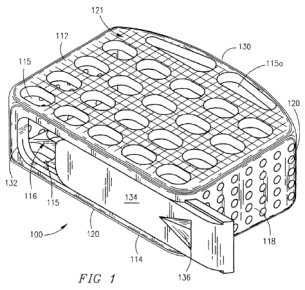
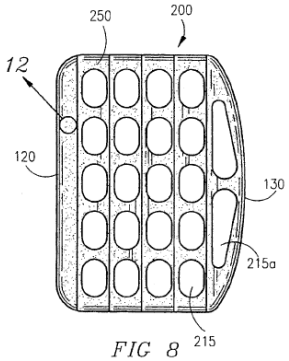
A PHOSITA would have understood that the spacer of the '433 patent has a wedge-shaped body (110) with two angularly offset principal surfaces (112, 114)

[12] *See* footnote 4, *supra*.

[13] *See* footnote 5, *supra*.

that extend from a drive surface (126) at the thick end portion (118) of the device to intersect at an edge (121) at a thin end portion. EX1007 at 5:27-40, FIGs. 1A; EX1011 at ¶83. A PHOSITA would have understood that spacer of the '433 patent also includes opposite side surfaces. EX1011 at ¶85. The side surfaces vary along the profile of the body, tapering from the thick end portion of the body to the thin end portion. EX1007 at FIG. 1A. A PHOSITA would have recognized that the '433 patent discloses the above claim limitation(s). EX1011 at ¶¶83-85.

said wedge member having a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member.	The '433 patent (**EX1007**) discloses: • By way of example, the principal surface 112 can be formed of a porous material which allows bone cells to grow within and throughout the pores. **EX1007 at 6:31-36**. • The body 110 of the device can be hollow and, accordingly, materials such as ground cancellous bone can be packed inside. **EX1007 at 7:9-14 and FIG. 2B.**  FIG. 2B • A plurality of holes on the principal surface can facilitate packing of material within the body 110. ***Id.*** The '635 patent (**EX1004**) discloses: • The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1004 at Abstract and FIG. 1.** • The upper and lower surfaces are disposed in a converging angular relationship to each other such that the implants of the

	present invention have an overall "wedged-shape" in an elevational side view. **EX1004 at Abstract.** • The implant 100 is hollow and comprises a plurality of openings 115 passing through the upper and lower surfaces 112 and 114 and into a central hollow chamber 116. The openings 115 provide for bone growth to occur from the vertebrae through the openings 115 to the internal chamber 116. **EX1004 at 6:56-61 and FIGs. 1, 2 and 8.**  FIG 1 • The fusion enhancing material that is packed within the chamber 116 of the implant 10 serves to promote bone ingrowth between the implant 100 and the adjacent vertebrae. Once the bone ingrowth occurs, the implant 100 will be a permanent fixture preventing dislodgement of the implant as well as preventing any movement between the adjacent vertebrae. ***Id.*** **at 7:32-38.** • Referring to FIGS. 8-12, an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention, generally referred to by the numeral 200, is shown. The implant 200 has a similar overall configuration as the implant 100 described above. In the preferred embodiment, the implant 200 is solid and comprises a plurality of channels 215 passing from the upper surface 212 to the lower surface 214 through the implant 200. The channels 215 provide for bone ingrowth and facilitate the incorporation of the implant 200 into the spinal fusion mass. ***Id.*** **at 8:20-29.**  FIG 8

The hollow body (110) of the spacer of the '433 patent contains bone graft material to promote bone growth and eventual fusion to adjacent bone through holes (113) on at least one of the principal surfaces (112, 114). EX1007 at 6:31-36, 7:9-14 and FIG. 2B. The wedge 110 can be formed of a porous material and be

hollow for enabling bone to grow through said wedge member.[14] *Id.*

The implant (100) of the '635 patent is hollow and includes a plurality of openings (115) passing through the upper and lower surfaces (112, 114) and into a central hollow chamber (116). EX1004 at 6:56-61 and FIGs. 1 and 2.The openings (115) provide for bone growth to occur from the vertebrae through the openings (115) to the internal chamber (116). *Id.* Fusion enhancing material is packed within the chamber (116) of the implant (10) to promote bone ingrowth between the implant 100 and the adjacent vertebrae. *Id.* at 7:32-38. In addition, the '635 patent discloses implant 200 that is solid and comprises a plurality of channels 215 passing from the upper surface 212 to the lower surface 214 through the implant 200. *Id.* at 8:20-29 and FIG. 8. The channels 215 provide for bone ingrowth and facilitate the incorporation of the implant 200 into the spinal fusion mass. *Id.*

Dr. Ochoa states that "[a] PHOSITA would have recognized that the '635 patent discloses *said wedge member having a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member,* as recited in the claims." EX1011 at ¶87. A PHOSITA would have recognized that the implants of the '433 patent and the '635

[14] It should be noted also that the '531 patent states that "the wedge member 44*a* is porous so that bone can grow through the wedge member." EX1001 at 10:2-3.

patent "each correct existing mechanical deformity, provide mechanical stability, and provide a suitable environment for arthrodesis through the use of an interbody spacer in conjunction with either natural or synthetic bone graft materials." *Id.* at ¶90. "A PHOSITA would have understood that the '433 and '635 patents each disclose implants with a hollow body that can be packed with graft material," and that "each disclose the use of holes in the surfaces of the device to allow bone ingrowth into the hollow structure." *Id.* "Therefore, the applicability and advantage of adding a plurality of channels (i.e. passages) disclosed in the '635 patent when applied to the device of the '433 patent would have been readily apparent to a PHOSITA." *Id.*

A PHOSITA would have been motivated, in view of the combined teachings of the '433 patent and the '635 patent, to modify the implant of the '433 patent with *a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member*, as recited in the claims. A PHOSITA would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting implant and its intended use.[15] *Id.* at ¶92. This modification would not have changed the principle of operation of the implant of the '433 patent.[16] *Id.*

[15] *See,* footnote 5, *supra.*

[16] *See,* footnote 6, *supra.*

IX. THE BOARD SHOULD EXERCISE ITS DISCRETION UNDER 35 U.S.C. § 325(d) TO GRANT THE PETITION

Petitioner's previous challenge to the '063 patent (based on *different* prior art), and the '635 patent's appearance in the art of record, are factors which the Board "may take into account" according to 35 U.S.C. § 325(d). *Praxair Distribution, Inc. v. INO Therapeutics, LLC,* IPR2015-00893, Paper 14, p. 8 (September 22, 2015). Petitioner submits, however, that these circumstances should *not* prevent the Board from exercising its discretion under 35 U.S.C. § 325(d) to grant the Petition in this proceeding, just as it did not reject the petition on similar grounds in *Praxair*.

This Petition raises *new* challenges to the claims that were not presented in IPR2015-01346 and, significantly, relies on *different* combinations of prior art references and arguments relating to those references not previously considered by the Office. In particular, as described in detail above, Petitioner's *new* challenges primarily rely on the combined teachings of the '635 patent *and the '899 patent* to show that the steps in the challenged method claims and structural features of the claimed apparatus were known in the art. More specifically, Petitioner's *new* challenges find strong support in the teachings of the '899 patent (which has not previously been cited to the Office) for the method of implanting a spinal fusion implant, in combination with the structure of the spinal fusion implant disclosed in the '635 patent.

Further, at the time of filing the prior petition in IPR2015-01346, Petitioner was *unaware* of the '899 patent and did not knowingly withhold this reference from its prior petition. Consequently, the proposed combination of Michelson '635 and Michelson '899 discussed herein could *not* have previously been made by Petitioner in the prior petition.

Additionally, the fact that the '635 patent was cited by the Examiner during prosecution of the '531 patent does not support denial of the Petition on grounds, *e.g.*, that it relies on substantially the same prior art and arguments that Patent Owner encountered during prosecution. In this regard, although cited in an Office Action against other claims, the Examiner did *not* apply the '635 patent to reject any *challenged claim*. Moreover, the '899 patent was *not* before the Office, so the combination now argued by Petitioner, which specifically addresses the '635 patent's shortcomings noted by the Examiner of lacking disclosure relating to a method of using the wedge member, has not previously been considered. **EX1003 at 97-98.**

Lastly, Petitioner's timing in bringing this Petition so soon after the Board denying institution of *inter partes* review in IPR2015-01345 is not for any improper purpose or gamesmanship. Rather, Petitioner must act now to avoid a time bar pursuant to 37 C.F.R. § 42.101(b) for seeking the requested relief from the Board brought about the Pending Litigation.

For the foregoing reasons, Petitioner, therefore, respectfully requests that the Board exercise its discretion under 35 U.S.C. § 325(d) and grant this Petition. *Praxair; and see, Microsoft Corporation v. Parallel Networks Licensing, LLC*, IPR2015-00483, Paper 10, p. 8 (July 15, 2015) and *Cepheid v. Roche Molecular Systems, Inc. et al.*, IPR2015-00881, Paper No. 9, pp. 5-6 (September 17, 2015).

X. CONCLUSION

Petitioner has demonstrated in this Petition that claims 8, 9, 46, 49, 105, 107, 109 and 111 of the '531 patent are unpatentable. Petitioner, therefore, respectfully requests that the Board institute an *inter partes* review of the '531 patent.

Dated: December 30, 2015 By: / George D. Moustakas /

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CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, this is to certify that I caused a true and correct copy of the PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,099,531 (and accompanying Exhibits EX1001-EX1025) to be served via FedEx, next day delivery, on patent owner at the following correspondence address of record for the subject patent, on this 30th day of December, 2015:

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A copy of this Petition and the associated Exhibits was also served via FedEx, next day delivery, on lead counsel of record in the related action in the United States District Court for the Eastern District of Pennsylvania, on this 30th day of December, 2015:

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