

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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GLOBUS MEDICAL, INC.,  
Petitioner

v.

BONUTTI SKELETAL INNOVATIONS LLC,  
Patent Owner

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Case No.: IPR2015-\_\_\_\_\_  
U.S. Patent No. 6,423,063  
Issued: July 23, 2002  
Application No: 09/569,020  
Filed: May 11, 2000

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,423,063**

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EX1010	U.S. Patent no. 5,865,847 to Kohrs
EX1011	Cameron HU, Macnab I, Pilliar RM. Evaluation of biodegradable ceramic. J Biomed Mater Res. 1977 Mar;11(2):179-86
EX1012	Chen YJ, Hsu KY, Shih HN, Huang TJ, Hsu RW. Subtalar arthrodesis for malunited os calcis fractures. J. Orthop Surg Taiwan. 1996;13:30-37
EX1013	Chen YJ, Huang TJ, Hsu KY, Hsu RW, Chen CW. Subtalar distraction realignment arthrodesis with wedge bone grafting and lateral decompression for calcaneal malunion. J Trauma. 1998 Oct;45(4):729-37
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- EX1017 Scranton PE Jr. Results of arthrodesis of the tarsus: talocalcaneal, midtarsal, and subtalar joints. *Foot Ankle.* 1991 Dec;12(3):156-64
- EX1018 Troyanovich SJ, Cailliet R, Janik TJ, Harrison DD, Harrison DE. Radiographic mensuration characteristics of the sagittal lumbar spine from a normal population with a method to synthesize prior studies of lordosis. *J Spinal Disord.* 1997 Oct;10(5):380-6
- EX1019 Uchida A, Nade SM, McCartney ER, Ching W. The use of ceramics for bone replacement. A comparative study of three different porous ceramics. *J Bone Joint Surg Br.* 1984 Mar;66(2):269-75
- EX1020 Wagner PC, Bagby GW, Brant BD, Gallina A, Ratzlaff M, Sande R. Surgical stabilization of the equine cervical spine. *Vet Surg* 1979 8:7-12
- EX1021 Claim Chart – Claims 1, 8 and 34 vs. U.S. Patent No. 5,609,635, 5,522,899 and Weiner et al., *Spine Update Lumbar Interbody Cages*, SPINE, Vol. 23, No. 5 (March 1, 1998) at 634-640
- EX1022 *Bonutti Skeletal Innovations, LLC v. Globus Medical Inc.*, U.S. District Court for the Eastern District of Pennsylvania, Civil Action no. 14-cv-6650-WY– Bonutti Skeletal’s Disclosure of Asserted Claims and Infringement Contentions

## 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. (“Globus” or “Petitioner”) hereby petitions for *inter partes* review of claims 1, 8 and 34 (“the challenged claims”) of U.S. Patent No. 6,423,063, entitled “Changing Relationship Between Bones,” issued to Peter M. Bonutti and assigned to Bonutti Skeletal Innovations LLC (“Bonutti”). The ‘063 patent is attached as **EX1001**.

The invention of the ‘063 patent is not new. Rather, the claimed invention encompasses known methods applied to implantable orthopedic devices for use in association with and affecting the spatial relationship of bones in a patient’s body. In this regard, the challenged claims of the ‘063 patent describe the method of the invention having steps that are well-known and/or inherent in the prior art relating to orthopedic implant devices.

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 claims 1, 8 and 34 of the ‘063 patent 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. **EX1006**. 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. 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. *Id.* at ¶¶1-8.

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 1, 8 and 34 of the '063 patent be reviewed and 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
George D. Moustakas (Reg. No. 44,425) HARNESS, DICKEY & PIERCE, P.L.C. 5445 Corporate Dr., Suite 200 Troy, MI 48098 248-641-1600 (telephone) 248-641-0270 (facsimile) gdmoustakas@hdp.com	David P. Utykanski (Reg. No. 39,052) HARNESS, DICKEY & PIERCE, P.L.C. 5445 Corporate Dr., Suite 200 Troy, MI 48098 248-641-1600 (telephone) 248-641-0270 (facsimile) dutykanski@hdp.com

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 ‘063 patent in the Pending Litigation. *See EX1022.*

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 6,099,531 (“the ‘531 patent”). The ‘531 patent is related to the ‘063 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 ‘063 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 ‘063 patent, they are directed to subject matter similar to that of the ‘063 patent. Petitioner understands that the ‘063 patent, the ‘531 patent, the ‘385 patent, the ‘066 patent and the ‘363 patent are all commonly owned by

Bonutti Skeletal Innovations LLC.

Further, claims 1, 8 and 34 of the '063 patent were the subject of a petition filed by Petitioner in IPR2015-01345. In IPR2015-01345, Petitioner challenged claims 1 and 8 as unpatentable over U.S. Patent no. 5,306,309 to Wagner and claim 34 as unpatentable over Wagner in view of Bradley K. Weiner & Robert D. Fraser, *Spine Update Lumbar Interbody Cages*, 23 SPINE 634 (1998) or U.S. Patent no. 5,192,327 to Brantigan. An *inter partes* review was not instituted on any ground. IPR2015-01345, Paper 9, December 16, 2015.

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

Petitioner certifies that (1) the '063 patent is available for *inter partes* review; and (2) Petitioner is not barred or estopped from requesting *inter partes* review of any claim of the '063 patent on the grounds identified in this Petition. It should be noted that, in regard to the latter, service of the Summons and Complaint issued 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.

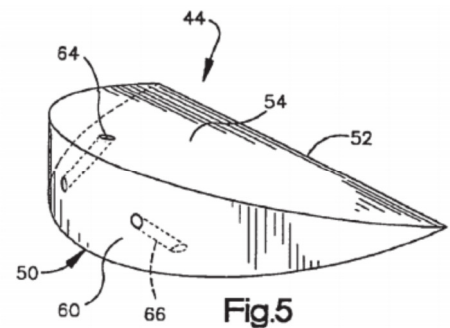
### **III. U.S. PATENT NO. 6,423,063 (“THE ‘063 PATENT”) (EX1001)**

The ‘063 patent is titled “Changing Relationship Between Bones” and issued on July 23, 2002, on an application filed on May 11, 2000. **EX1001 at [45] and [22]**. The ‘063 patent is a continuation of U.S. Application Serial No. 09/137,443, filed August 20, 1998, issued as U.S. Patent No. 6,099,531. *Id.* at [63]. The earliest priority date for the ‘063 patent is August 20, 1998.

#### **A. The ‘063 Patent Specification and Claims**

The ‘063 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 1:53–55. 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 1:57–59.

Figure 5 depicts a schematic view and Figure 7 depicts a side view of wedge member 44. *Id.* at 2:58-59 and 62-63. 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 5:59–63. Wedge member 44 may be



connected to one or more bones by screws passing through passages 64 and 66. *Id.* at 7:45–58.

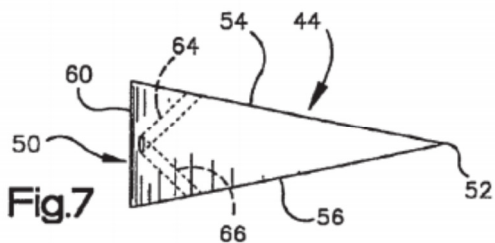
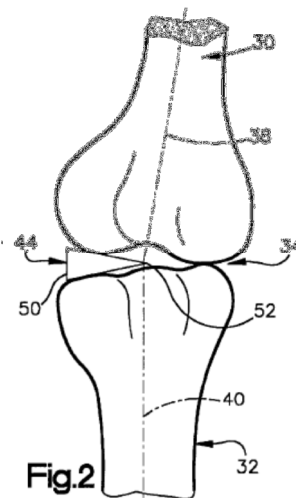


Figure 2 depicts wedge member 44 being inserted into a joint, causing joint expansion and changing the orientation of bones

30 and 32. *Id.* at 2:46-49; and see *id.* at 8:1–9:31 (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 8:55–59.



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 10:3–10, 35-42.

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 ‘063 Patent Prosecution History (EX1002)

The continuation application leading to the ‘063 patent, Serial No.

09/569,020, was filed May 11, 2000. By preliminary amendment, the original claims 2-51 were cancelled in favor of adding new claims 52-62. No bases were provided for the cancellation and addition of claims.

An Office Action issued on September 13, 2000 including a 35 U.S.C §103 rejection over Stone (U.S. Patent No. 5,116,374). In response to the Office Action, an Amendment was filed February 15, 2001 cancelling all Claims 1 and 52-62 in favor of adding new Claims 63-112 comprising the new “step of changing the spatial relationship between first and second bones as including moving a wedge member which is at least partially formed of a biodegradable material into a joint between the first and second bones,” “steps of abrading a portion of the first bone and abrading a portion of the second bone at a joint between the first and second bones,” and “step of providing a wedge member which is at least partially formed of a biodegradable material.” **EX1002 at 132-148.**

Upon receiving the Amendment filed February 15, 2001, the Examiner issued a Restriction Requirement and Office Action on June 18, 2001. ***Id.* at 180-186.** In response to the Restriction Requirement and Office Action, Claims 88, 89, and 99-110 were cancelled, Species 1, directed to Figures 5-6 and wedge member 44, was elected, and a Terminal Disclaimer as to U.S. Patent 6,099,531 was filed on September 18, 2001. ***Id.* at 188-189.** The Applicant argued that the claims were allowable over the prior art because they set forth the new steps added in the

Amendment filed February 15, 2001. ***Id.*at 189-200.** This argument was again repeated in the supplemental amendment filed October 26, 2001. ***Id.*at 214-225.**

An appeal brief was filed on February 12, 2002 reiterating the same arguments made in the previously filed responses. ***Id.*at 258-281.** It appears that Applicant successfully argued that Claims 1, 8, and 34 were allowable over the prior art based on these features. Shortly thereafter, on March 13, 2002, a Notice of Allowance was issued. ***Id.*at 354-355.**

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

As established in the Declaration of Dr. Ochoa (**EX1006 at ¶18**), a person having ordinary skill in the art (PHOSITA) of the '063 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.<sup>1</sup> 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 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. Moreover, in IPR2015-01345, the Board determined that, upon that record, no explicit construction of any claim term was needed. IPR-01346, Paper no. 9 at 6 (December 16, 2015).

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<sup>1</sup> 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.



## **VI. THE PRIOR ART RELIED UPON IN THIS PETITION**

### **A. U.S. Patent No. 5,609,635 to Michelson (“the ‘635 patent”) (EX1003)**

U.S. Patent No. 5,609,635, entitled “Lordotic Interbody Spinal Fusion Implants,” issued March 11, 1997. The ‘635 patent is prior art to the ‘063 patent 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 ‘063 patent in the United States. The ‘635 patent was cited by the Applicant in an IDS filed May 11, 2000. However, the Examiner did not discuss or rely on the ‘635 patent during the prosecution of the ‘063 patent. *See, EX1002.*

### **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 to the ‘063 patent 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 ‘063 patent in the United States. The ‘899 patent was not disclosed by the patent applicant or cited, discussed, or relied on by the Examiner during the prosecution of the ‘063 patent.

### **C. Bradley K. Weiner & Robert D. Fraser, *Spine Update Lumbar Interbody Cages*, SPINE, Vol. 23, No. 5 (March 1, 1998) at 634-640 (“the SPINE article”) (EX1004)**

The SPINE article published March 1, 1998. The SPINE article is prior art to the ‘063 patent under 35 U.S.C. § 102(a) because it is a printed publication in the

U.S. or a foreign country before the invention by the applicant of the '063 patent. The SPINE article was neither disclosed by the patent applicant nor cited, referred to, or relied on by the Examiner during the prosecution of the application leading to the '063 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 1, 8 and 34 of the '063 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of the challenged claims, claims 1 and 34 are independent; claim 8 depends from claim 1.

In summary, and as established by the declaration of Dr. Ochoa, the '635 patent in view of the '899 patent render claims 1 and 8 unpatentable as obvious under 35 U.S.C. § 103; and the '635 patent in view of the '899 patent and the SPINE article renders claim 34 unpatentable as obvious under 35 U.S.C. § 103. (**EX1006 at ¶¶ 33-51**). A specific listing of Petitioner's asserted grounds for unpatentability, a comparison of the prior art to the challenged claims, and the supporting testimony from Petitioner's technical expert, Dr. Ochoa, follows below.

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

This petition presents the following Grounds of unpatentability:

- Ground 1: Claims 1 and 8 are unpatentable under 35 U.S.C. § 103(a) as obvious over the '635 patent (**EX1003**) in view of the '899 patent (**EX1005**).

- Ground 2: Claim 34 is unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘635 patent in view of the ‘899 patent and the SPINE article (**EX1004**).

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. **EX1006 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. **EX1003 at 6:19-26, 8:8-15, FIGs. 3 and 7A**. The implant (100) is at least partially formed of biodegradable material such as hydroxyapatite or hydroxyapatite tricalcium phosphate. *Id.* at **7:25-31**. As confirmed by Dr. Ochoa, biodegradable ceramics composed from calcium phosphates are well-known and have long been recognized as materials for use in orthopedic surgery that facilitate bone ingrowth, particularly when placed in apposition to roughened bleeding bone surfaces. **EX1006 at ¶33**. 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. **EX1003 at 7:54-6, 1:65-2: 1, 6:30-4.**

Also according to Dr. Ochoa, the '899 patent is similar to the '635 patent and discloses the method of use of artificial fusion implants that are capable of being placed between adjacent vertebrae to change the spatial relationship (*e.g.*, restore the intervertebral space to its premorbid dimensions) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1006 at ¶34.** The implant (*e.g.* 10) of the '899 patent is configured for insertion from the anterior approach by tapping with hammer sufficiently hard enough to drive the implant into the disc space. **EX1005 at 8:20-5, FIGs. 4, 5, 7 and 7A.** The '899 patent describes preparation of the vertebral endplates, gently abrading (*i.e.* scraping) the surface to remove cartilaginous material and achieve punctuate decortication. ***Id.* at 5:67-6:4.**

Further, according to Dr. Ochoa, the SPINE article describes, *inter alia*, several factors for providing an optimal environment for arthrodesis (*i.e.*, the surgical fixation of a joint to promote bony union (fusion) across the joint), including excision of the cartilaginous endplate down to healthy bleeding bone. **EX1006 at ¶¶29, 35.**

A PHOSITA would have been motivated to look to the combined teachings

of the ‘635 patent, the ‘899 patent and the SPINE article 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. **EX1006 at ¶46.** According to Dr. Ochoa, a PHOSITA would have looked to this combined body of art. **EX1006 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.<sup>2</sup>

**A. Ground 1: Claims 1 and 8 are unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘635 patent (EX1003) in view of the ‘899 patent (EX1005)**

1. Claim 1

Claim 1 is directed to a method of implanting a device affecting the special

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<sup>2</sup> *Black v. CE Soir Lingerie Co., Inc.*, no. 2:06-cv-522, 2008 WL 3852722 (E.D. 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).

relationship between bones interconnected at a joint. Claim 1 is rendered obvious by the '635 patent in view of the '899 patent, as follows:

<b>'063 patent Claim 1 vs. the '635 patent and the '899 patent</b>	
<p><i>A method comprising the steps of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body,</i></p>	<p>The '635 patent (<b>EX1003</b>) discloses:</p> <ul style="list-style-type: none"> <li>• 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. <b>EX1003 at Abstract.</b></li> <li>• 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. <b>Id.</b></li> <li>• See, e.g., <b>FIGs. 1, 3 and 7A.</b></li> <li>• 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. <b>EX1003 at Abstract and 1:65-2-1.</b></li> <li>• 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. <b>EX1003 at 6:30-34.</b></li> </ul> <div data-bbox="1071 735 1364 1008"> <p>FIG 1</p> </div> <div data-bbox="1071 1008 1396 1239"> <p>FIG 3</p> </div> <div data-bbox="1006 1239 1396 1890"> <p>FIG 7A</p> </div>

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 degenerated condition (e.g., a collapsed disc)) between first and second bones (i.e., vertebrae) at an intervertebral joint. **EX1006 at ¶33.** The spinal implant device ("implant 100") of the '635 patent is configured for insertion between adjacent vertebrae and thereafter forms a support structure for bearing against the endplates of the vertebrae, maintaining the vertebrae adjacent to the implant in an angular relationship, creating and maintaining the desired lordosis of the spine. **Id.** A PHOSITA would have recognized that the '635 patent discloses a method comprising *changing the spatial relationship between first and second bones* as well as the step of *changing the spatial relationship between first and second bones which are interconnected at a joint in a patient's body*, as recited in the claims. **EX1006 at ¶36.**

<p><i>said step of changing a spatial relationship between the first and second bones includes moving a wedge member which is at least partially formed of biodegradable material into the</i></p>	<p>The '635 patent (<b>EX1003</b>) discloses:</p> <ul style="list-style-type: none"> <li>• 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. <b>EX1003 at Abstract and FIG. 3.</b></li> <li>• 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. <b>Id.</b></li> </ul> <div data-bbox="1052 1413 1396 1652" data-label="Image"> </div>
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<i>joint between the first and second bones,</i>	<ul style="list-style-type: none"> <li>• The implant 100 itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. <b>EX1003 at 7:25-31.</b></li> </ul>
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The upper (112) and lower (114) surfaces of the implant (100) disclosed in 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. **EX1003 at Abstract, FIG. 3.** A PHOSITA would, therefore, have understood that the '635 patent describes an interbody cage with a wedge-shaped body. **EX1006 at ¶37.** The implant (100) is made of material appropriate for human implantation, and may be made of hydroxyapatite or hydroxyapatite tricalcium phosphate. Biodegradable ceramics composed from calcium phosphates have long been recognized as materials for use in orthopedic surgery that facilitate bone ingrowth, particularly when placed in apposition to roughened bleeding bone surfaces. *Id.* A PHOSITA would have understood that materials such as calcium hydroxylapatite are biodegradable materials when used as structural components, coatings or bone graft substitutes. *Id.* A PHOSITA would have understood that the '635 patent discloses *a wedge member which is at least partially formed of biodegradable material*, as recited in the claims.



said step of moving the wedge member into the joint between the first and second bones includes moving the second bone from a first orientation relative to the first bone to a second orientation relative to the first bone under the influence of force applied against the second bone by the wedge member as the wedge member moves into the joint between the first and second bones,

The '635 patent (**EX1003**) discloses:

- The implant 100 has an insertion end 120 and a trailing end 130. **EX1003 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. **EX1003 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.**
- Referring to FIG. 7A, a side elevational view of a segment of the spinal column S is shown with the implant 100 inserted in the disc space D<sub>2</sub> between two adjacent vertebrae V<sub>2</sub> and V<sub>3</sub>. The implant 100 is inserted in the direction of arrow A into the disc space D<sub>2</sub> and maintains the two vertebrae V<sub>2</sub> and V<sub>3</sub> 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**

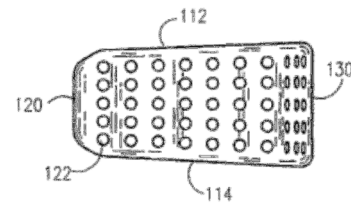


FIG. 3

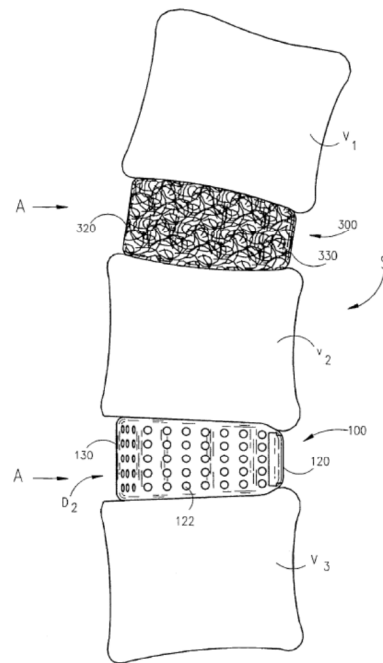
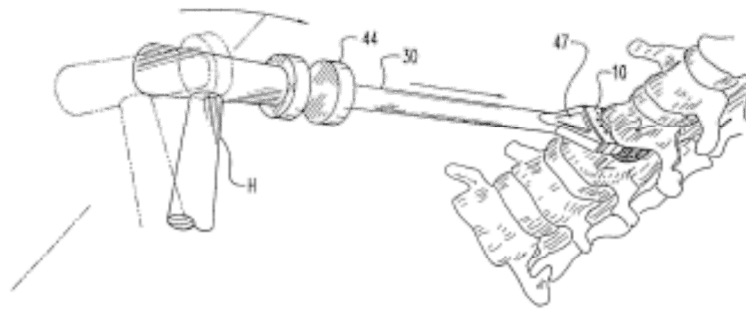


FIG. 7A

The '899 patent (**EX1005**) discloses:

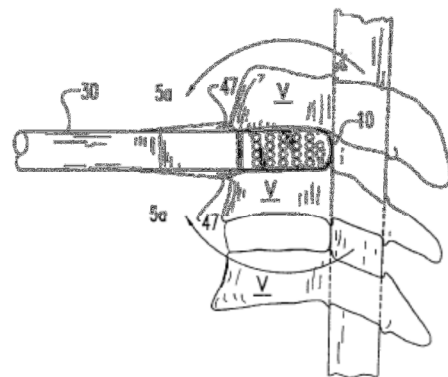
- The '899 patent is a continuation of Serial no. 08/263,952. **EX1005 at 1:3-4.**
- Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.**
- Referring to FIGS. 4, 4a, 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**

A PHOSITA would have understood that the wedge-shaped implant of the '635 patent is implanted between two vertebrae (i.e. bones) using an anterior

approach. **EX1006 at ¶39.** During implantation, the implant (100) is mounted on a driver instrument and placed at the entrance to the disc space between the two adjacent vertebrae. **EX1003 at 7:46-56.** The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant into the disc space. *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 apart as the implant is advanced forward into the disc space.

Moreover, an insertion method and instrumentation for implantation of a spinal fusion device is more specifically disclosed in the '899 patent. The threaded end (46) of the insertion device is coupled to the implant (10) through threaded opening (26), allowing the implant to be driven into the disc space using a hammer. **EX1005 at 8:12-15, 20-25 and FIGs. 4 and 5.** As clearly shown in FIGs. 3, 4, and 5a, the insertion device attaches to the implant (10) at its trailing end and does not engage the adjacent vertebrae except at the restriction members 47, 49 which prevent over penetration of the implant. *Id.* A PHOSITA would have understood that the insertion device would not have interacted directly with the vertebrae during insertion, and functions to provide a removable rigid coupling to facilitate impaction of the implant. *Id.*; **EX1006 at ¶41.**

According to Dr. Ochoa, a PHOSITA would have understood that a similar

impaction instrument could be coupled to implant (100) of the ‘635 patent using threaded opening (126) in the trailing end (120) of the implant. *Id.*; **EX1003 at 7:46-56**. A PHOSITA would have considered any modification to do so an obvious choice that would have yielded a predictable effect in the resulting method. **EX1006 at ¶41**. Such modification, if any, would not have changed the principle of operation of the spinal implant of the ‘635 patent. *Id.* A PHOSITA, therefore, would have been motivated, in view of the combined teachings of the ‘635 patent and the ‘899 patent, to use the insertion device disclosed in the ‘899 patent with the implant (100) of the ‘635 patent. *Id.*

As stated by Dr. Ochoa, **EX1006 at ¶40**, “a PHOSITA would have understood that the affected bones (i.e. vertebrae) form links in a kinematic chain (i.e. a hinge). Realignment requires the insertion of a body to correct for malalignment, and in the process change the spatial relationship between bones. A PHOSITA would also have understood that insertion of the body is facilitated by being in the shape of a wedge, allowing the leading end of the insert to be inserted between the vertebrae and then allowing for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space. This would require the application of axial anteroposterior force applied through an insertion device by tapping with a hammer to drive the device into the intervertebral space. A PHOSITA would have understood that during impaction,

the tapered transverse faces (112, 144) would act as an inclined plane (i.e. a wedge). As such, the axial anteroposterior impaction forces applied to the anterior 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 posteriorly in the intervertebral space, the wedge shaped body engages the faces of the vertebrae at which the device is implanted (end plates), forcing the adjacent vertebrae to ramp up, opening the intervertebral space and moving the vertebrae apart.” Further, 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. 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 [functional spinal unit] (intact soft tissues and facet joints) which are located posterior to the intervertebral disc space.” *Id.*

Therefore, a PHOSITA would have understood that the cited art discloses a method wherein *a step of changing a spatial relationship between the first and second bones includes moving a wedge member which is at least partially formed of biodegradable material into the joint between the first and second bones, said step of moving the wedge member into the joint between the first and second bones*

*includes moving the second bone from a first orientation relative to the first bone to a second orientation relative to the first bone under the influence of force applied against the second bone by the wedge member as the wedge member moves into the joint between the first and second bones, as recited in the claims. Id.*

<p><i>thereafter, 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, and,</i></p>	<p>The ‘635 patent (<b>EX1003</b>) discloses:</p> <ul style="list-style-type: none"> <li>• 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. <b>EX1003 at Abstract.</b></li> <li>• 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. <b>EX1003 at Abstract and 1:65-2-1.</b></li> <li>• 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. <b>Id.</b></li> </ul>
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The spinal fusion implant (100) of the ‘635 patent has upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. **EX1003 at Abstract, 1:65-2-1.** As Dr. Ochoa states, “a PHOSITA would have recognized that providing stability and supporting adjacent vertebrae in an angular relationship would require the transmission of force between the vertebral endplates and the spinal fusion implant.” **EX1006 at ¶43.** A PHOSITA would have, therefore, recognized 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.*

<i>thereafter, degrading biodegradable material of the wedge member.</i>	<p>The ‘635 patent (<b>EX1003</b>) discloses:</p> <ul style="list-style-type: none"> <li>• The implant 100 itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. <b>EX1003 at 7:25-31.</b></li> </ul>
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A PHOSITA would have understood that the biodegradable materials for the implant (100) that are described in the ‘635 patent degrade over time in the human body following surgery. **EX1006 at ¶38.** Therefore, a PHOSITA would have understood that the ‘635 patent discloses degrading biodegradable material of the wedge member. *Id.*

Consequently, in view of the foregoing and as supported by Dr. Ochoa, the ‘635 patent in view of the ‘899 patent renders claim 1 unpatentable as obvious under 35 U.S.C. § 103.

## 2. Claim 8

Claim 8 depends from claim 1 and further defines the method of implanting a device affecting the special relationship between bones interconnected at a joint. Claim 8 is obvious over the ‘635 patent in view of the ‘899 patent, as follows:

**‘063 patent Claim 8 vs. the ‘635 patent and the ‘899 patent**

*A method as set forth in claim 1 wherein said step of moving a wedge member into the joint between the first and second bones is performed with a thin end portion of the wedge member leading and a thick end portion of the wedge member trailing.*

The ‘635 patent (EX1003) discloses:

- See claim 1, above.
- The implant 100 has an insertion end 120 and a trailing end 130. **EX1003 at 7:4-5 and, e.g., FIG. 3.**

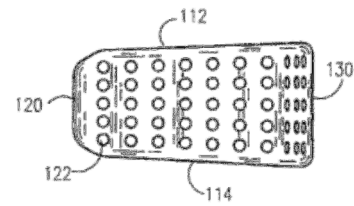


FIG. 3

- 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. **EX1003 at 2:64-3:7.**
- 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<sub>2</sub> between two adjacent vertebrae V<sub>2</sub> and V<sub>3</sub>. The implant 100 is inserted in the direction of arrow A into the disc space D<sub>2</sub> and maintains the two vertebrae V<sub>2</sub> and V<sub>3</sub> 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**

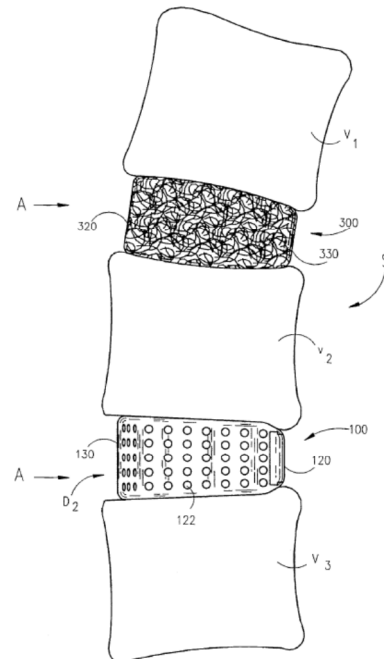


FIG. 7A

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. **EX1003 at**



**Abstract, FIG. 3.** Further, the implant 100 is configured with a thinner insertion end (120) and a thicker trailing end (130). *Id. at 7:4-5.* A PHOSITA would have recognized that the ‘635 patent discloses the step of *moving a wedge member into the joint between the first and second bones is performed 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. **EX1006 at ¶42.**

As set forth above, and supported by Dr. Ochoa, claims 1 and 8 are obvious over the ‘635 patent in view of the ‘899 patent pursuant to 35 U.S.C. § 103 and unpatentable.

**B. Ground 2: Claim 34 is unpatentable under 35 U.S.C. § 103(a) as obvious over the ‘635 patent (EX1003) in view of the ‘899 patent (EX1005) and the SPINE article (EX1004)**

1. Claim 34

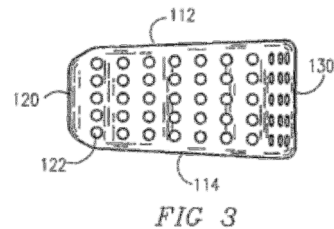
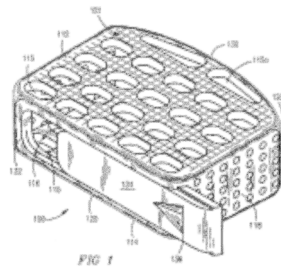
Claim 34 is also directed to a method of implanting a device affecting the special relationship between bones interconnected at a joint and includes limitations similar to those of Claim 1. Claim 34 also includes the step of abrading portions of the bone where the device is implanted. Claim 34 is rendered obvious over the ‘635 patent in view of the ‘899 patent and the SPINE article, as follows.

<b>‘063 patent Claim 34 vs. the ‘635 patent, the ‘899 patent, the SPINE article</b>	
<i>A method comprising the steps of changing a</i>	<p>The ‘635 patent (EX1003) discloses:</p> <ul style="list-style-type: none"> <li>• 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</li> </ul>

*spatial relationship between first and second bones which are interconnected at a joint in a patient's body,*

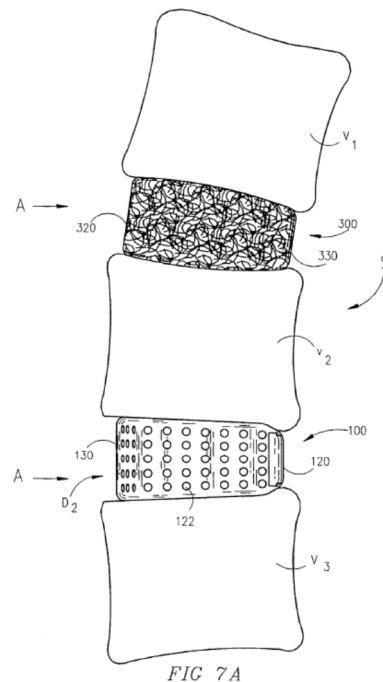
relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. **EX1003 at Abstract.**

- 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.**



- 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. **EX1003 at Abstract and 1:65-2-1.**

- 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. **EX1003 at 6:30-34.**



As previously discussed with respect to Claim 1, 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

degenerated condition) between first and second bones (i.e., vertebrae) at an intervertebral joint. **EX1006 at ¶33.** The spinal implant device (“implant 100”) of the ‘635 patent is configured for insertion between adjacent vertebrae and thereafter forms a support structure for bearing against the endplates of the vertebrae, maintaining the vertebrae adjacent to the implant in an angular relationship, creating and maintaining the desired lordosis of the spine. *Id.* A PHOSITA, therefore, would have recognized that the ‘635 patent discloses a method comprising *changing the spatial relationship between first and second bones* as well as the step of *changing the spatial relationship between first and second bones which are interconnected at a joint in a patient’s body*, as recited in the claims. **EX1006 at ¶36.**

<p><i>said step of changing a spatial relationship between the first and second bones includes abrading a portion of the first bone at the joint between the first and second bones, abrading a portion of the second bone at</i></p>	<p>The ‘899 patent (<b>EX1005</b>) discloses:</p> <ul style="list-style-type: none"> <li>• 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. <b>EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.</b></li> <li>• To use the implant of the present invention a, conventional discectomy is performed and, the vertebral endplates scraped, but not perforated. <i>Id.</i> <b>at 5:54-56.</b></li> <li>• The adjacent vertebral endplates are gently scraped free of any remaining cartilage until diffuse fine punctuate decortication is achieved. <i>Id.</i> <b>at 6:1-4.</b></li> </ul> <p>The SPINE article (<b>EX1004</b>) discloses:</p> <ul style="list-style-type: none"> <li>• The SPINE article discusses interbody cage devices used to assist interbody fusion in the surgical management of chronic low back pain. <b>EX1004 at Abstract.</b></li> <li>• The SPINE article discusses the provision of optimal</li> </ul>
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<i>the joint between the first and second bones,</i>	<p>environment for arthrodesis. <b>EX1004 at 635.</b></p> <ul style="list-style-type: none"> <li>• The best environment for inter body fusion consists of 1) complete discectomy so that no intervening tissue lies between the bony fusion beds; 2) complete excision of the cartilaginous endplate down to healthy bleeding bone; 3) preservation of the bony end plate to maintain structural integrity and discourage subsidence; 4 ) use of the smallest volume of cage (as cage volume increases, graft volume decreases) that will provide for mechanical stability; 5) use of optimal grafting techniques-large amounts of graft (autogenous, cancellous) with the widest possible interface with the fusion beds (bony endplates) and maximal graft filling the inters pace; and 6) provision of compression through “distractive compression” (<i>i.e.</i>, restoration of annular tension) and return of load bearing to the anterior column. <b><i>Id.</i></b></li> </ul>
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As discussed by Dr. Ochoa, “a PHOSITA would have understood that the spinal fusion implant of the ‘635 patent is used as an interbody spacer during spinal fusion procedures. A PHOSITA would have understood that when in place, openings (115) in the upper and lower surfaces (112, 114) would provide a surface with favorable porosity and pore size for bone ingrowth. A PHOSITA would have also understood that the implant would be used with osteogenic, osteoconductive, osteoinductive or other fusion enhancing materials, including bone graft to promote bone ingrowth between the implant and the adjacent vertebrae. A PHOSITA would have understood that the fusion enhancing materials would promote ingrowth of bone into the pores in the face, but that this would require contact between the porous face and bleeding bone.” **EX1006 at ¶44.**

Although the '635 patent does not explicitly recite the abrading of the vertebral end plates, Dr. Ochoa concludes that "a PHOSITA would have understood that the related '899 patent describes gently scraping of the vertebral endplates to remove any remaining cartilage until diffuse fine punctuate decortication is achieved. A PHOSITA would have understood that the '635 implant, like that described in the '899 patent, is intended for fusion of the adjacent vertebrae. As such implantation would require appropriate preparation of the endplates to provide an optimal environment for bone ingrowth and arthrodesis."

*Id.*

Further, according to Dr. Ochoa, "[i]t would have been common knowledge to a PHOSITA that appropriate endplate preparation includes removal of the disc tissue and complete excision of the cartilaginous endplate down to healthy bleeding bone, as discussed in the SPINE article. Thus, a PHOSITA would have understood that the SPINE article discloses that portions of the adjacent vertebral faces of the vertebrae at which the spinal implant device is to be implanted are abraded." *Id.* Specifically, the SPINE article discloses providing an optimal environment for arthrodesis as follows:

*The best environment for inter body fusion consists of 1) complete discectomy so that no intervening tissue lies between the bony fusion beds; 2) complete excision of the cartilaginous endplate down to healthy bleeding*

*bone; 3) preservation of the bony end plate to maintain structural integrity and discourage subsidence; 4 ) use of the smallest volume of cage (as cage volume increases, graft volume decreases) that will provide for mechanical stability; 5) use of optimal grafting techniques-large amounts of graft (autogenous, cancellous) with the widest possible interface with the fusion beds (bony endplates) and maximal graft filling the inters pace; and 6) provision of compression through “distractive compression” (i.e., restoration of anular tension) and return of load bearing to the anterior column.*

**EX1004 at 635.**

As stated by Dr. Ochoa, a PHOSITA would have been motivated to look to the teachings of the ‘899 patent, the SPINE article, 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 the method of use for such devices.<sup>3</sup> **EX1006 at ¶45.** As Dr. Ochoa states, “a PHOSITA would have been motivated to apply the teachings of the SPINE article or the ‘899 patent to those of the ‘635 patent because each of the

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<sup>3</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420-21 (2007) (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).

‘635 patent, the SPINE article and the ‘899 patent disclose implantable orthopedic devices 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.” *Id.* at ¶46. “[I]t would have been recognized by a PHOSITA that the spine disk implants of the ‘635 patent, the SPINE article and/or the ‘899 patent each correct existing mechanical deformation, provide mechanical stability, and provide a suitable environment for arthrodesis through the use of interbody spacer in conjunction with either natural or synthetic bone graft materials. Therefore, the applicability and advantages of the preparing the vertebral endplates as disclosed in the ‘899 patent and the SPINE article when applied to the device of the ‘635 patent would have been readily apparent to a PHOSITA.” *Id.* at ¶47. “A PHOSITA, therefore, would have been motivated, in view of the combined teachings of the ‘635 patent, the SPINE article and/or the ‘899 patent, to include a step of *abrading a portion of the first bone at the joint between the first and second bones, abrading a portion of the second bone at the joint between the first and second bones* in the method for implantation of the spinal implant of the ‘635 patent to provide and optimal environment for arthrodesis.” *Id.* at ¶48.

Still further, a PHOSITA would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting

method.<sup>4</sup> *Id.* at ¶49. This modification would not have changed the principle of operation of the spinal implant of the '635 patent.<sup>5</sup> *Id.*

<p><i>providing a wedge member which is at least partially formed of biodegradable material, and</i></p>	<p>The '635 patent (<b>EX1003</b>) discloses:</p> <ul style="list-style-type: none"> <li>• 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. <b>EX1003 at Abstract and FIG. 3.</b></li> <li>• 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. <i>Id.</i></li> <li>• The implant 100 itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. <b>EX1003 at 7:25-31.</b></li> </ul> <div data-bbox="1052 468 1401 703" data-label="Image"> </div>
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As already discussed with respect to Claim 1, the upper (112) and lower

<sup>4</sup> *KSR* 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).

<sup>5</sup> *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).



(114) surfaces of the implant (100) disclosed in 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. **EX1003 at Abstract, FIG. 3.** A PHOSITA would, therefore, have understood that the '635 patent describes an interbody cage with a wedge-shaped body. **EX1006 at ¶37.** In addition, the implant (100) is made of material appropriate for human implantation, and may be made of a biodegradable ceramic (i.e., hydroxyapatite or hydroxyapatite tricalcium phosphate, **EX1003 at 7:25-31**), which have been recognized as materials for use in orthopedic surgery that facilitate bone ingrowth, particularly when placed in apposition to roughened bleeding bone surfaces. **EX1006 at ¶37.** A PHOSITA would have understood that materials such as calcium hydroxylapatite are biodegradable materials when used as structural components, coatings or bone graft substitutes. *Id.* A PHOSITA would have understood that the '635 patent discloses *a wedge member which is at least partially formed of biodegradable material*, as recited in the claims.

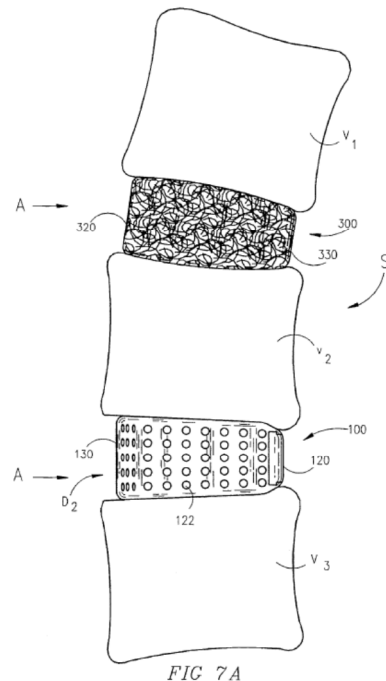
<p><i>moving the wedge member which is at least partially formed of biodegradable material into the joint between the first and second bones, said step of</i></p>	<p>The '635 patent (<b>EX1003</b>) discloses:</p> <ul style="list-style-type: none"> <li>• The implant 100 has an insertion end 120 and a trailing end 130. <b>EX1003 at 7:4-5 and, e.g., FIG. 3.</b></li> <li>• 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</li> </ul> <div data-bbox="1032 1545 1385 1785" data-label="Image"> <p style="text-align: center;"><b>FIG 3</b></p> </div>
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*moving the wedge member which is at least partially formed of biodegradable material into the joint between the first and second bones includes engaging the abraded portion of the first bone with the wedge member and engaging the abraded portion of the second bone with the wedge member.*

advanced forward into the disc space. **EX1003 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.**

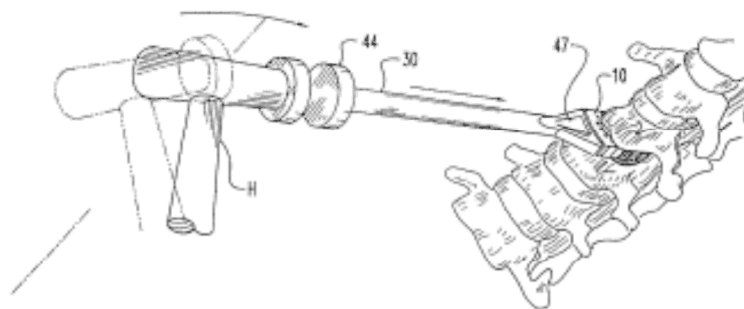
- Referring to FIG. 7A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant 100 inserted in the disc space D<sub>2</sub> between two adjacent vertebrae V<sub>2</sub> and V<sub>3</sub>. The implant 100 is inserted in the direction of arrow A into the disc space D<sub>2</sub> and maintains the two vertebrae V<sub>2</sub> and V<sub>3</sub> 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:

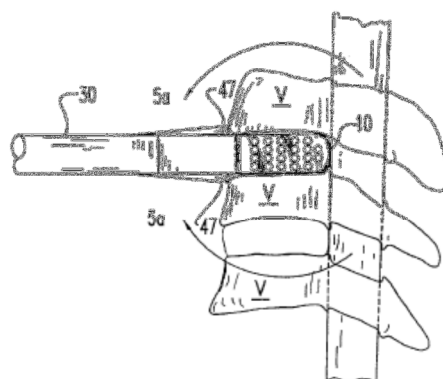
- The '899 patent is a continuation of Serial no. 08/263,952. **EX1005 at 1:3-4.**
- Referring to FIGS. 1 through 5 an implant for use in the disc space and associated apparatus used for inserting the implant 10 is shown. **EX1005 at 7:38-40 and FIGs. 3, 4, 4a, 5 and 5a.**
- Referring to FIGS. 4, 4a, 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**

Dr. Ochoa states that “a PHOSITA would have understood that the substantially wedge-shaped, at least partially biodegradable spinal fusion implant of the ‘635 patent is implanted between two vertebrae using an anterior approach. A PHOSITA would have understood that during implantation, the implant (100) is mounted on a driver instrument and placed at the entrance to the disc space between the two adjacent vertebrae. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant into the disc space.

Therefore a PHOSITA would have understood that the ‘635 patent discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae under force such that the natural angle (i.e. lordosis) of that segment of the spinal column is restored.” **EX1006 at ¶50.** Further, Dr. Ochoa states “a PHOSITA would have understood that creating and maintaining the desired lordosis of the spine is achieved by engagement between the angular upper and lower surfaces (112 and 114) and the vertebral endplates. As discussed above, a PHOSITA would have also understood that endplate preparation would have included abrasion of the surface to provide an optimal environment for bone ingrowth and arthrodesis.” *Id.* Therefore, a PHOSITA would have understood that the prior art discloses *moving the wedge member which is at least partially formed of biodegradable material into the joint between the first and second bones, said step of moving the wedge member which is at least partially formed of biodegradable material into the joint between the first and second bones includes engaging the abraded portion of the first bone with the wedge member and engaging the abraded portion of the second bone with the wedge member*, as recited in the claims. *Id.*

As discussed above, therefore, Claim 34 is rendered obvious under 35 U.S.C. § 103 over the ‘635 patent in view of the ‘899 patent and the SPINE article.

**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 based on a new combination of references that were not presented in IPR2015-01345 and were not previously considered by the Office. This Petition significantly relies on different prior art references, the '635 patent and the '899 patent (the latter of which has not previously been cited to the Office), and arguments relating to those references. 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 were known in the art. More specifically, Petitioner's new challenges find strong support in the teachings of the '899 patent 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 IPR2015-01345, Petitioner was unaware of the '899 patent and did not knowingly withhold this reference from its prior petition. Consequently, the proposed combination of the '635 patent and the '899 patent discussed herein could not have previously been made by Petitioner in the prior petition.

Additionally, the fact that the '635 patent was cited by Patent Owner during prosecution of the '063 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. Although the '635 patent was cited to the Office, it was not discussed or relied on by the Examiner during the prosecution of the '063 patent. Moreover, the '899 patent was not before the Office, so the combination now argued by Petitioner has not previously been considered.

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 1, 8 and 34 of the ‘063 patent are unpatentable. Petitioner, therefore, respectfully requests that the Board institute an *inter partes* review of the ‘063 patent.

Dated: December 29, 2015      By: / George D. Moustakas /  
George D. Moustakas, Reg. No. 44,425  
(gdmoustakas@hdp.com)  
David P. Utykanski, Reg. No. 39,052  
(dutykanski@hdp.com)  
Harness, Dickey & Pierce, PLC  
5445 Corporate Dr., Suite 200  
Troy, MI 48098  
Telephone: (248) 641-1600  
Facsimile: (248) 641-0270

Attorneys for Petitioner,  
Globus Medical, Inc.

## **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. 6,423,063 (and accompanying Exhibits EX1001-EX1022) to be served via FedEx, next day delivery, on patent owner at the following correspondence address of record for the subject patent, on this 29<sup>th</sup> day of December, 2015:

Paul D. Bianco  
Fleit Gibbons Gutman Bongini & Bianco PL  
21355 East Dixie Highway, Suite 115  
Miami, FL 33180

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 29<sup>th</sup> day of December, 2015:

John M. Desmarais  
Laurie Stempler  
Kevin K. McNish  
Desmarais LLP  
230 Park Avenue  
New York, NY 10169

By: / George D. Moustakas /  
George D. Moustakas, Reg. No. 44,425  
(gdmoustakas@hdp.com)  
David P. Utykanski, Reg. No. 39,052  
(dutykanski@hdp.com)



Harness, Dickey & Pierce, PLC  
5445 Corporate Dr., Suite 200  
Troy, MI 48098  
Telephone: (248) 641-1600  
Facsimile: (248) 641-0270

Attorneys for Petitioner,  
Globus Medical, Inc.