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. 6,423,063
Issued: July 23, 2002
Application No: 09/569,020
Filed: May 11, 2000

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

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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

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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" ("the '063 patent"), 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.**[1] Dr. Ochoa is an expert

[1] Sometimes referred to herein as "Ochoa Decl."

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.

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))

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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 Matters (37 C.F.R. § 42.8(b)(2))

Petitioner states that the '063 patent is asserted in *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 ("the Pending Litigation"). Petitioner is a party to the Pending Litigation. Notably, in the Pending Litigation, Bonutti has accused certain of Globus's spinal implant devices of infringing the challenged claims of the '063 patent. *See* **EX1022.**

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 7,001,385 ("the '385 patent"). The '385 patent is related to the '063 patent through continuation practice. Also concurrently with this Petition, Petitioner is filing a Petition for *inter partes* review of U.S. Patent No. 6,099,531 ("the '531 patent"). The '531 patent is also related to the '063 patent through continuation practice. Petitioner understands that the '063 patent, the '385 patent and the '531 patent are all commonly owned by Bonutti Skeletal Innovations LLC.

Moreover, Petitioner is concurrently filing Petitions for *inter partes* review of U.S. Patent Nos. 8,486,066 ("the '066 patent") and 8,795,363 ("the '363

patent"). 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 '066 and '363 patents are likewise commonly owned by Bonutti Skeletal Innovations LLC.

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 this regard, 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 issued on July 23, 2002, on an application filed on May 11, 2000. 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. The earliest priority date for the '063 patent is August 20, 1998.

A. The '063 Patent Specification and Claims

The '063 patent is directed to changing a spatial relationship between two or more bones in a patient's body. The challenged claims, however, encompass known implantable orthopedic devices and methods for their use in association with and affecting the spatial relationship of bones in a patient's body and are unpatentable. The '063 patent issued with 35 claims, of which only claims 1, 8, and 34 are at issue in this Petition. Claims 1 and 34 are independent, and claim 8 is dependent directly from claim 1.

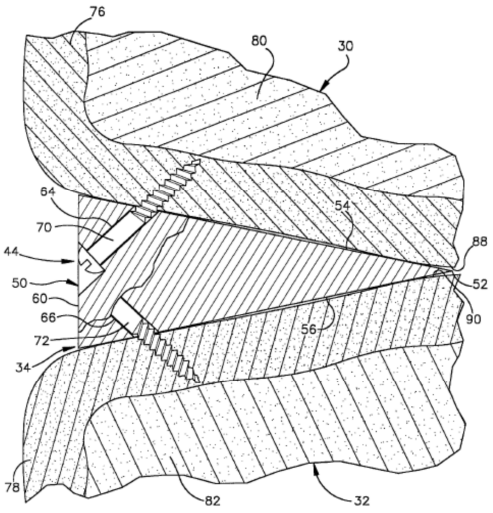
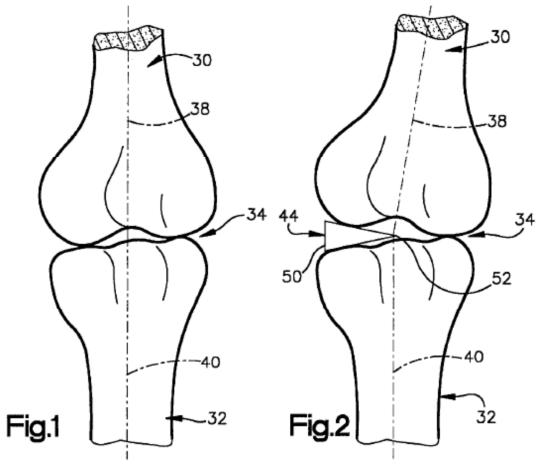


Fig.8

The written description and drawings of the '063 patent describe various embodiments of an implantable spacer device and various embodiments of methods for changing a spatial relationship between two or more bones in a patient's body using the implantable spacer device. As generally disclosed in Figure 8, an upper bone 30 may be connected to a

lower bone 32 at a joint 34. **EX1001 at 4:11-12**. The spatial relationship between the upper bone 30 and the lower bone 32 may be changed by inserting a wedge member 44 within the joint 34 between the bones 30, 32. ***Id.*** **at 4:29-36**. The wedge member 44 is then fixed within the joint by one or more fasteners 70, 72, such as screws. ***Id.*** **at 12:7-10**. Most of the specific claimed features of the alleged invention relate to the structure of the wedge member 44 which is inserted into the joint 34.



Claims 1, 8, and 34 of the '063 patent are directed to a method for changing a spatial relationship between first and second bones. The steps for changing the spatial relationship between the first and second bones includes moving a wedge member into a joint between first and second bones. The first and second bones may be abraded before moving the wedge member into the joint. The steps further include applying force against the second bone by the wedge member as the wedge member moves into the joint or engaging the abraded portions of the first and second bones with the wedge member. The wedge member is at least partially formed of biodegradable material, and once the wedge member has moved into the joint, the biodegradable material of the wedge member degrades.

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 pages 132-148.**

Upon receiving the Amendment filed February 15, 2001, the Examiner issued a Restriction Requirement and Office Action on June 18, 2001. **EX1002 at pages 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. **EX1002 at pages 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. **EX1002 at pages 189-200.** This argument was again repeated in the supplemental amendment filed October 26, 2001. **EX1002 at pages 214-225.**

An appeal brief was filed on February 12, 2002 reiterating the same arguments made in the previously filed responses. **EX1002 at pages 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. **EX1002 at pages 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

The claims of the '063 patent are to be given their broadest reasonable construction in light of the '063 patent's specification as understood by a person having ordinary skill in the art. 37 C.F.R. § 42.100(b).

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. 5,306,309 to Wagner et al. ("the '309 patent" or "Wagner") (EX1003)

U.S. Patent No. 5,306,309, entitled "Spinal Disk Implant and Implantation Kit" issued April 26, 1994. Wagner is prior art to the '063 patent 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 '063 patent in the United States. Wagner 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.

B. Weiner et al., *Spine Update Lumbar Interbody Cages*, SPINE, Vol. 23, No. 5 (March 1, 1998) at 634-640 ("Weiner" or "the SPINE article") (EX1004)

Weiner et al., *Spine Update Lumbar Interbody Cages*, SPINE, Vol. 23, No. 5 (March 1, 1998) at 634-640 **(EX1004)** published March 1, 1998. The Weiner 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 Weiner 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.

C. U.S. Patent No. 5,192,327 to Brantigan ("the '327 patent" or "Brantigan") (EX1005)

U.S. Patent No. 5,192,327, entitled "Surgical Prosthetic Implant for Vertebrae," issued March 9, 1993. Brantigan is prior art to the '063 patent 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 '063 patent in the United States. Brantigan 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, by this Petition, 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. As further discussed below, Petitioner particularly submits that claims 1, 8 and 34 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.

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.

In summary, and as established by the declaration of Dr. Ochoa, Wagner renders claims 1 and 8 unpatentable as obvious under 35 U.S.C. § 103 (**EX1006 at ¶¶ 30-46**); and Wagner in view of the Weiner article or Brantigan renders claim 34 unpatentable as obvious under 35 U.S.C. § 103 (***Id.* at ¶¶ 30-46**).

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

This petition presents the following Grounds of unpatentability:

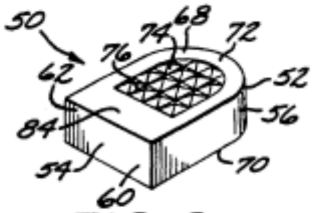
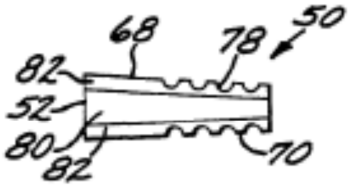
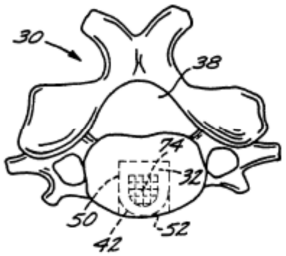
- Ground 1: Claims 1 and 8 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (**EX1003**).
- Ground 2: Claim 34 is unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (**EX1003**) in view of the Weiner article (**EX1004**).
- Ground 3: Claim 34 is unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (**EX1003**) in view of Brantigan **(EX1005**).

A. Ground 1: Claims 1 and 8 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (the '309 patent) (EX1003)

1. Claim 1

Claim 1 is directed to a method of implanting an orthopedic device affecting

the special relationship between bones interconnected at a joint. Claim 1 is rendered obvious by Wagner, as follows:

'063 patent Claim 1 vs. Wagner
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,*
Wagner (the '309 patent) (**EX1003**) discloses: • Wagner 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 in a patient's body. **EX1006 Ochoa Decl. at ¶30.** • Wagner discloses a spinal disk implant 50 for surgically implanting between two vertebrae 30 to fuse them together. **EX1003 at Abstract**; **1:5-10** and **FIGs. 3, 6 and 8**.  FIG.3  FIG.6 FIG.8  • The spinal disk implant is configured to engage the cortical bone region of the vertebrae after implantation, so that the majority of the loading transmitted through the implant is carried by the cortical bone. ***Id.*** **at 2:47-52.** • Wagner discloses a method for changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body. **EX1006 Ochoa Decl. at ¶33**.

Wagner (the '309 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 Ochoa Decl. at ¶30.** The spinal implant device ("spinal disk implant 50") of the '309 patent is configured for insertion from the anterior approach, with a substantially wedge-shaped body having transverse faces (68, 70) that are tapered from the thick anterior end (52) toward the thin posterior end (54). ***Id.***; **EX1003 at 6:63-68, FIGs. 3 and 6.** The body may be formed of a biodegradable material, preferably ceramic calcium hydroxylapatite. **EX1006 Ochoa Decl. at ¶30; EX1003 at 6:13-26.**

The '309 patent describes a method for implanting an interbody cage for use during spinal fusion. **EX1006 Ochoa Decl. at ¶33.** The body of the '309 patent is impacted into place between the vertebrae using a hammer and thereafter provides a load-bearing spacer. **EX1006 Ochoa Decl. at ¶30; EX1003 at 8:57-9:2, 9:26-34.** A PHOSITA would have also recognized that interbody cages are used to correct existing mechanical deformity of the spine. **EX1003 at Abstract**; **1:5-10, 2:47-52** and **FIGs. 3, 6 and 8; EX1006 Ochoa Decl. at ¶33**.

A PHOSITA would have recognized that the '309 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 Ochoa Decl. at ¶33**.

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 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,

Wagner (the '309 patent) (**EX1003**) discloses:

- A spinal disk implant 50, shown in FIGS. 3-7 in several variations, has a structure designed for implantation between the vertebral body regions of two adjacent vertebrae 22. **EX1003 at 5:15-18.**
- The implant 50 is implanted between two vertebrae 22. ***Id.*** **at FIGs. 1** and **8,** as labeled below**.**

FIG.1

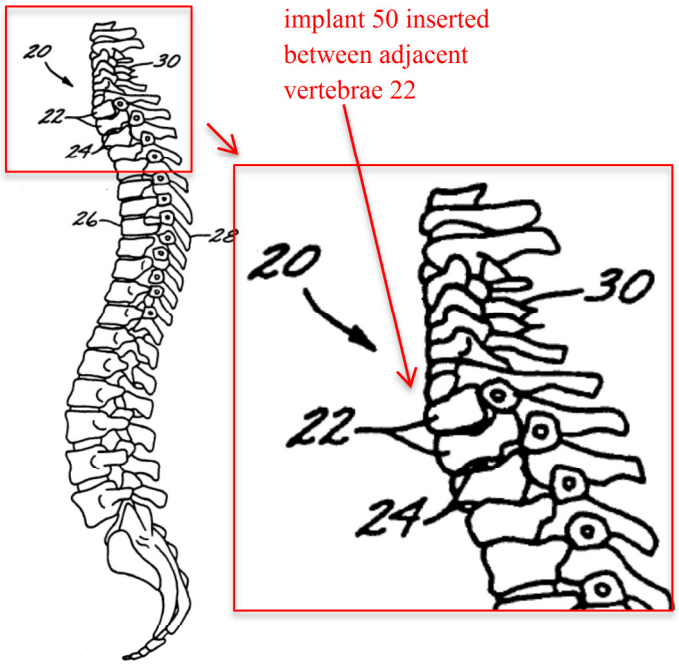
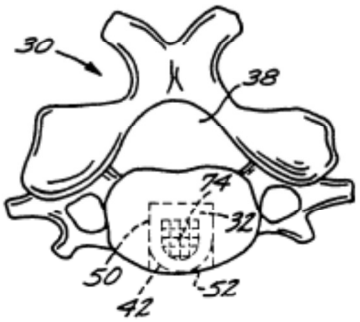


FIG.8



- The implant 50 has transverse faces 68, 70 that are not parallel to each other, but rather are tapered from the anterior end toward the more closely spaced posterior end. ***Id.*** **at 6:63-68** and **FIGs. 3** and **6,** as labeled below**.**

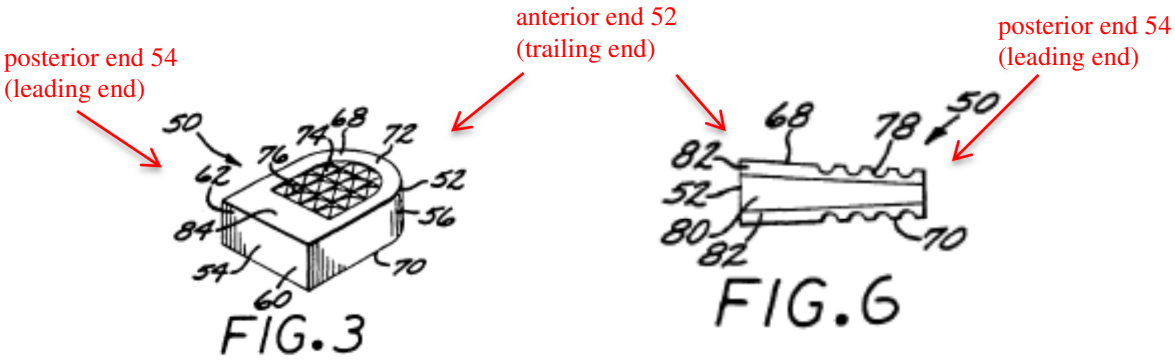


FIG. 3 FIG. 6

- The implant is made of a ceramic, a metal, a polymer, or a composite material. The implant 50 is desirably made from a material that, after surgical implantation, bonds to the natural bone of the adjacent vertebrae to form a rigid structure. The implant is preferably made from a ceramic, most preferably the ceramic calcium hydroxylapatite, having a chemical formula Ca10-(P04)6(0H)2. The use of such materials in implants is known, see for example U.S. Pat. No. 4,863,476, whose disclosure is incorporated by reference. The implant 50 may also be made from a composite material such as the carbon-fiber reinforced plastics disclosed in U.S. Pat. No. 4,904,261[*i.e.*, Dove, which provides that an implant may be made from a biodegradable fiber-reinforced composite. Dove, 1:46-49], whose disclosure is incorporated by reference. ***Id.*** **at 6:13-26.**

- FIG. 14 depicts a reusable handle 114 that can be used to place the implant 50 in the desired location during a surgical procedure…A butt end 122 of the handle 114 is rounded so that the surgeon may strike it with a surgical hammer if necessary to urge the implant 50 into place between two vertebrae that have been slightly spread apart from their normal spacing during the surgical procedure. ***Id.*** **at 8:57-9:2**.

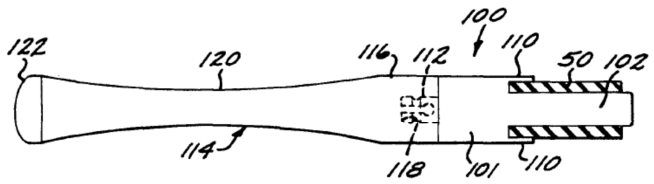


FIG. 14

- During the surgical procedure, the surgeon selects the required implant, and affixes the delivery tool 100 to the handle 114 using the engagement tip 112. The surgeon then uses the handle 114 to manipulate the implant 50 into the proper intervertebral position, tapping the butt end 122 if necessary. When the implant 50 is properly positioned, the vertebrae are allowed to relax

slightly back to their normal positions, capturing the implant 50 therebetween. ***Id.*** **at 9:26-34**.

- Wagner discloses that the spinal implant device is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1006 Ochoa Decl. at ¶37.**
- Wagner discloses that the spinal implant device is at least partially formed of a biodegradable material. **EX1006 Ochoa Decl. at ¶34.**
- Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae. **EX1006 Ochoa Decl. at ¶36.**
- Wagner discloses that as the spinal implant device is implanted between adjacent vertebrae, it forces one vertebra to move from a first orientation relative to the other vertebra (*e.g.,* a degenerated condition) to a second orientation relative to the other vertebra (*i.e.,* a restored condition). **EX1006 Ochoa Decl. at ¶¶ 30, 36.**

A PHOSITA would have understood that the '309 patent describes an interbody cage with a substantially wedge-shaped body. **EX1003 at 5:15-18, 6:63-68, FIG. 6, EX1006 Ochoa Decl. at ¶34**. The body is made from a ceramic, most preferably the ceramic calcium hydroxylapatite, which is a biodegradable material. **EX1003 at 6:13-26; EX1006 Ochoa Decl. at ¶34.** Other material options for the device of the '309 patent are incorporated by reference to U.S. Patent no. 4,904,261 to Dove, which discloses the use of biodegradable fiber-reinforced composite materials. ***Id.*** A PHOSITA would have understood that the '309 patent discloses *a wedge member which is at least partially formed of biodegradable material*, as recited in the claims. **EX1006 Ochoa Decl. at ¶34.**

A PHOSITA would have understood that the substantially wedge-shaped biodegradable spinal disk implant of the '309 patent is implanted between two

vertebrae (i.e. bones) using an anterior approach. **EX1003 at 5:15-18, FIGs. 1 and 8; EX1006 Ochoa Decl. at ¶36.** During implantation, the device is retained by an insertion tool, and is urged into place in the intervertebral space between the first and second vertebrae by impaction with a hammer. **EX1003 at 8:57-9:2, 9:26-34; EX1006 Ochoa Decl. at ¶36.** Therefore a PHOSITA would have understood that the '309 patent discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae under force. **EX1006 Ochoa Decl. at ¶36.** As stated above, a PHOSITA would have recognized that the '309 patent discloses a method comprising *changing the spatial relationship between first and second bones* and that the '309 discloses the use of *a wedge member which is at least partially formed of biodegradable material*. ***Id.*** A PHOSITA would have understood that the affected bones (i.e. vertebrae) form links in a kinematic chain (i.e. a hinge). ***Id.*** Realignment requires the insertion of a body to correct for malalignment, and in the process change the spatial relationship between bones. ***Id.*** The insertion of the body is facilitated by being in the shape of a wedge, requiring the application of axial anteroposterior force to advance the device into the intervertebral space. **EX1003 at 8:57-9:2, 9:26-34; EX1006 Ochoa Decl. at ¶36.** A PHOSITA would have further understood that during impaction, the tapered transverse faces (68, 70) would act as an inclined plane (*i.e.* a wedge). **EX1003 at 6:63-68; EX1006 Ochoa Decl. at ¶36.** 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. **EX1006 Ochoa Decl. at ¶36.** 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 intervertebral space open and moving the vertebrae apart. ***Id.*** In the final position, porous face regions (82) on the body of the implant are captured in contact by the tension in the remaining soft tissues (and ultimately the forces due to musculature and body weight) on the adjacent surfaces or end plates of the vertebrae, thereby engaging the adjacent vertebrae, minimizing the likelihood of post-operative slippage of the implant from its proper intervertebral position. **EX1003 at 2:47-59, 7:9-14; EX1006 Ochoa Decl. at ¶36.**

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. **EX1006 Ochoa Decl. at ¶36.** A PHOSITA would have understood that as the intervertebral space is wedged open, the vertebrae comprising the spinal motion segment pivot about the intact soft tissues and facet joints, which are located posterior to the intervertebral space. ***Id.*** A PHOSITA, therefore, would have understood that *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, would have occurred during implantation of the spinal disk implant of Wagner. ***Id.***

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,
Wagner (the '309 patent) (**EX1003**) discloses: • The spinal disk implant is configured to engage the cortical bone region of the vertebrae after implantation, so that the majority of the loading transmitted through the implant is carried by the cortical bone. **EX1003 at 2:47-52.** • The spinal disk implant is readily inserted between the vertebrae during a surgical procedure, produces a load-bearing joint in which the majority of the load on the spine is borne through the cortical bone, and is highly resistant to dislocation away from its proper position between the vertebrae. ***Id.*** **at 5:15-23.** • Wagner discloses that, after implanting the spinal implant device between the adjacent vertebrae in a spinal fusion surgical procedure, the forces encountered along the spinal column at the vertebrae are transmitted through the implant, which maintains the restored condition of the vertebrae at the intervertebral joint. **EX1006 Ochoa Decl. at ¶38.**

A PHOSITA would have understood that the spinal disk implant of the '309 patent remains in in place after the procedure and engages the vertebral bone such

that the majority of the loading transmitted through the implant is carried by the cortical bone. **EX1003 at 2:47-52; EX1006 Ochoa Decl. at ¶38.** Because of the load bearing nature of the '309 spinal disk implant, a PHOSITA would have understood that the implant would be resistant to dislocation and would therefore maintain the mechanical correction achieved during surgery. **EX1003 at 5:15-23; EX1006 Ochoa Decl. at ¶38.**

A PHOSITA would have recognized that the method disclosed in the '309 patent discloses *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,* as recited in the claims. **EX1006 Ochoa Decl. at ¶38.**

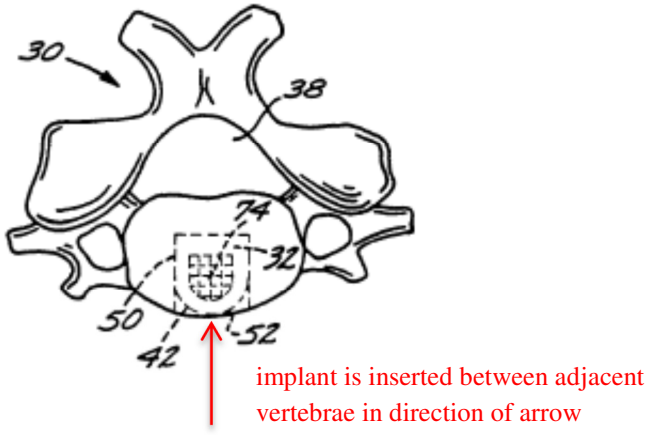
thereafter, degrading biodegradable material of the wedge member.
Wagner (the '309 patent) (**EX1003**) discloses: • The spinal disk implant may be made from a composite material such as disclosed in U.S. Pat. No. 4,904,261 [*i.e.*, Dove, which provides that an implant may be made from a biodegradable fiber-reinforced composite. Dove, 1:46-49]. **EX1003 at 6:22-26.** • The spinal implant device made from a biodegradable material degrades after it has been implanted. **EX1006 Ochoa Decl. at ¶35.**

A PHOSITA would have understood that biodegradable materials, such as the materials described in the '309 patent, degrade over time in the human body following surgery. **EX1006 Ochoa Decl. at ¶35.** Therefore, a PHOSITA would have understood that the '309 patent discloses *degrading [of the] biodegradable material of the wedge member*. ***Id.***

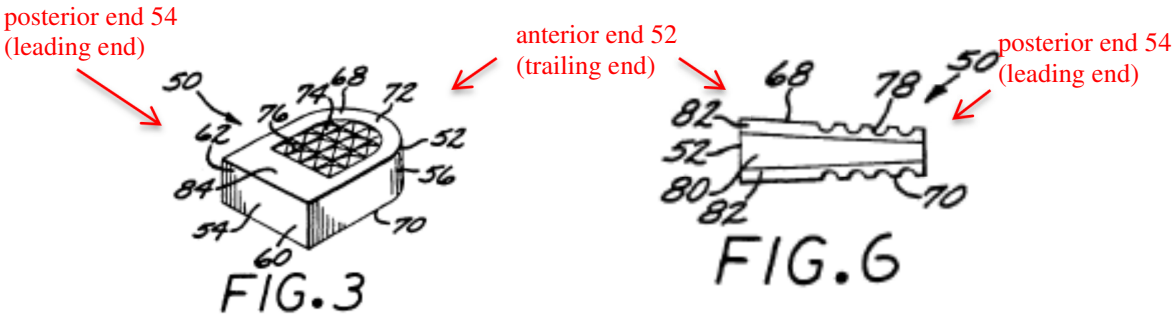
Consequently, in view of the foregoing and as supported by Dr. Ochoa, Wagner (the '309 patent) renders claim 1 unpatentable as obvious under 35 U.S.C. § 103.

2. Claim 8

Claim 8 depends from claim 1 and further defines the method of implanting an orthopedic device affecting the special relationship between bones interconnected at a joint, calling for the thin end of the device to lead as the device is moved into the joint trailed by the thick end of the device. Claim 8 is obvious over Wagner (the '309 patent), as follows:

'063 patent Claim 8 vs. Wagner
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.*
Wagner (the '309 patent) (**EX1003**) discloses: • *See* claim 1, above. • The implant 50 is implanted between two vertebrae 22. **EX1003 at *e.g.*, FIG. 8,** as labeled below**.** FIG.8 

- The implant 50 has transverse faces 68, 70 that are not parallel to each other, but rather are tapered from the anterior end toward the more closely spaced posterior end. ***Id.*** **at 6:63-68** and **FIGs. 3** and **6,** as labeled below**.**



- Wagner discloses that the spinal disk implant device is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1006 Ochoa Decl. at ¶37.**
- Wagner discloses that the spinal disk implant device is implanted with a thin end portion of the wedge member leading and a thick end portion of the wedge member trailing. **EX1006 Ochoa Decl. at ¶37.**

A PHOSITA would have understood that the spinal disk implant of the '309 patent is implanted between two vertebrae using an anterior approach. **EX1003 at FIG. 8; EX1006 Ochoa Decl. at ¶37.** A PHOSITA would have also understood that the spinal implant device ("spinal disk implant 50") of the '309 patent is configured with a substantially wedge-shaped body having transverse faces (68, 70) that are tapered from the thick (trailing) anterior end (52) toward the thin (leading) posterior end (54). **EX1003 at 6:63-68** and **FIGs. 3** and **6; EX1006 Ochoa Decl. at ¶37.** A PHOSITA would have recognized that the method disclosed in the '309 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 Ochoa Decl. at ¶37.**

As set forth above, and supported by Dr. Ochoa, claims 1 and 8 are obvious over Wagner 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 Wagner (EX1003) in view of Weiner (the SPINE article) (EX1004)

1. Claim 34

Claim 34 is directed to a method of implanting an orthopedic device affecting the special relationship between bones interconnected at a joint and includes similar limitations 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 Wagner in view of Weiner, as follows:

'063 patent Claim 34 vs. Wagner and Weiner
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,*
Wagner (the '309 patent) (**EX1003**) discloses: • Wagner discloses a spinal disk 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 in a patient's body. **EX1006 Ochoa Decl. at ¶30**. • Wagner discloses a spinal disk implant 50 for surgically implanting between two vertebrae 30 to fuse them together. **EX1003 at Abstract**; **1:5-10** and **FIGs. 3, 6 and 8**.

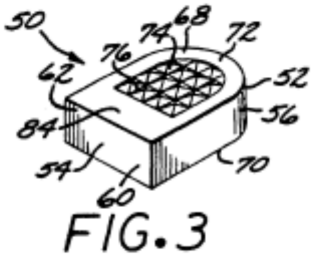


FIG.3

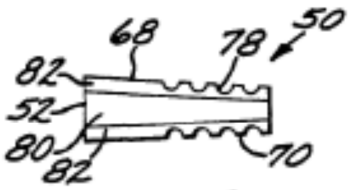
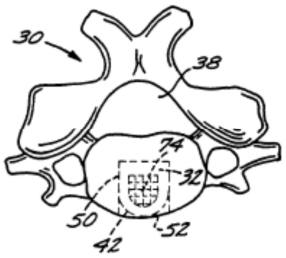


FIG.6

FIG.8



- The spinal disk implant is configured to engage the cortical bone region of the vertebrae after implantation, so that the majority of the loading transmitted through the implant is carried by the cortical bone. ***Id.*** **at 2:47-52.**
- Wagner discloses a method for changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body. **EX1006 Ochoa Decl. at ¶33**.

Wagner 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 Ochoa Decl. at ¶30.** The spinal implant device ("spinal disk implant 50") of the '309 patent is configured for insertion from the anterior approach, with a substantially wedge-shaped body having transverse faces (68, 70) that are tapered from the thick anterior end (52) toward the thin posterior end (54). ***Id.***; **EX1003 at 6:63-68, FIGs. 3 and 6.** The body maybe formed of a biodegradable material, preferably ceramic calcium hydroxylapatite. **EX1006 Ochoa Decl. at ¶30; EX1003 at 6:13-26.**

The '309 patent describes a method for implanting an interbody cage for use during spinal fusion. **EX1006 Ochoa Decl. at ¶33.** The body of the '309 patent is

impacted into place between the vertebrae using a hammer and thereafter provides a load-bearing spacer. **EX1006 Ochoa Decl. at ¶30; EX1003 at 8:57-9:2, 9:26-34.** A PHOSITA would have also recognized that interbody cages are used to correct existing mechanical deformity of the spine. **EX1003 at Abstract**; **1:5-10, 2:47-52** and **FIGs. 3, 6 and 8; EX1006 Ochoa Decl. at ¶33**.

A PHOSITA would have recognized that the '309 patent discloses a method comprising a step of *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 [inter]connected at a joint in a patient's body*, as recited in the claims. **EX1006 Ochoa Decl. at ¶33**.

The SPINE article provides a review of available spinal interbody cages and the state of the art at the time of its authorship. **EX1006 Ochoa Decl. at ¶32.** A structural classification system is provided for commonly used devices which are assessed against surgical goals including the ability to correct existing deformity (e.g. restore a desired anatomical relationship from a degenerated condition), provide mechanical stability, provide a suitable environment for arthrodesis, and limit morbidity. ***Id.*** Cage types are classified as horizontal cylinders, vertical rings, or open boxes. ***Id.*** The discussion of wedge shaped cages, including the Brantigan ALIF cage, and the ability to restore lordosis is addressed. ***Id.***

A PHOSITA would have understood that the spinal interbody cages

discussed in the SPINE article are used to 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. ***Id*.**

A PHOSITA would have been motivated to look to the teachings of the '309 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 improvements to the design of such devices.[2] **EX1006 Ochoa Decl. at ¶40.** A PHOSITA would have been motivated to apply the teachings of the SPINE article to those of the '309 patent because each of the '309 patent and the SPINE article 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.[3] ***Id.*****at ¶41.**

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 the joint between the first and second bones,

[2] *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).
[3] *KSR*, 550 U.S. at 417 (if a PHOSITA would recognize that a technique would improve similar devices in the same way, using the technique is obvious).

Wagner (the '309 patent) (**EX1003**) discloses:

- Wagner discloses the spinal implant used as an interbody spacer during spinal fusion procedures is made from ceramic calcium hydroxylapatite. **EX1003 at 6:13-26.**
- Partly porous face regions (82) on the implant provide a surface with favorable porosity and pore size for bone ingrowth. **EX1003 at 7:9-23; EX1006 Ochoa Decl. at ¶39**.

Weiner (the SPINE publication) (**EX1004**) discloses:

- Weiner discusses interbody cage devices used to assist interbody fusion in the surgical management of chronic low back pain. Weiner provides a structural classification of commonly used devices and assesses them against a set of clearly defined surgical goals, including ability to correct the existing mechanical deformation, ability to provide mechanical stability, ability to provide a suitable environment for arthrodesis, and ability to limit "builtin" morbidity. In addition, the materials used in the devices are examined regarding their biomechanical, biologic, and radiographic characteristics. **EX1004 at Abstract**.
- Weiner discusses the Provision of Optimal Environment for Arthrodesis. **EX1004 at 635.**
- 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. ***Id.***
- Weiner discloses that portions of the adjacent vertebral faces of the vertebrae at which the spinal implant device is to be implanted are abraded. **EX1006 Ochoa Decl. at ¶39**.

A PHOSITA would have understood that the ceramic calcium hydroxylapatite spinal implant of the '309 patent is used as an interbody spacer

during spinal fusion procedures. **EX1006 Ochoa Decl. at ¶39.** A PHOSITA would have understood that when in place, partly porous face regions (82) would provide a surface with favorable porosity and pore size for bone ingrowth. **EX1003 at 7:9-23; EX1006 Ochoa Decl. at ¶39**. A PHOSITA would have understood that the porous ceramic surface would act as a synthetic graft material to promote ingrowth of bone into the pores in the face, but that this would require contact between the porous face and bleeding bone. **EX1006 Ochoa Decl. at ¶39**. Although the '309 patent does not explicitly recite abrading the endplates, a PHOSITA would have understood that the '309 device is intended for fusion of the adjacent vertebrae, **EX1003 at 9:45-48**, and as such would intrinsically require appropriate preparation of the endplates to provide an optimal environment for bone ingrowth and arthrodesis. **EX1006 Ochoa Decl. at ¶39**.

The SPINE article discloses factors for provision of 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.*

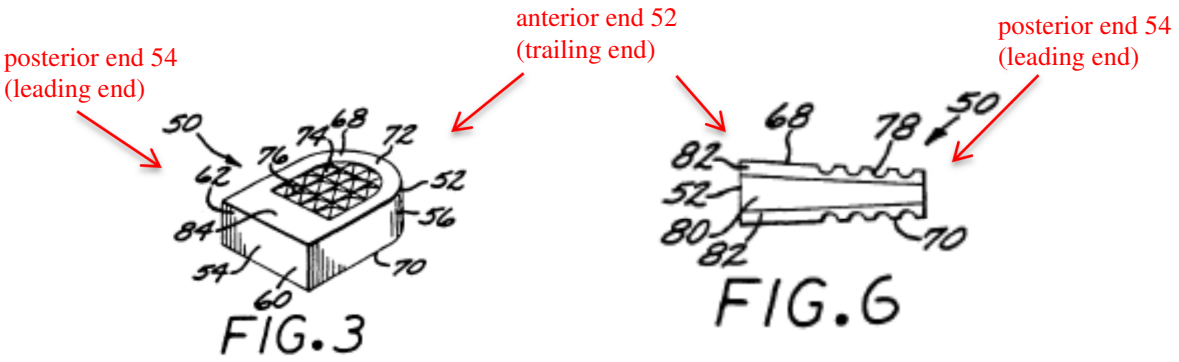
***Id.;* EX1004 at ¶35.**

It 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. **EX1006 Ochoa Decl. at ¶39**. 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*.** A PHOSITA would have further understood that abrasion and preparation of the endplate could be achieved using a number of instruments and methods. ***Id*.**

A PHOSITA would have recognized that the spine disk implants of the '309 patent and the SPINE article 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. ***Id*. at ¶42**. Therefore, the applicability and advantages of the preparing the vertebral endplates as disclosed in the SPINE article when applied to the device of the '309 patent would have been readily apparent to a PHOSITA. ***Id*.**

A PHOSITA, therefore, would have been motivated, in view of the combined teachings of the '309 patent and the SPINE article to include a step of *abrading a portion of the first and second bone at the joint between the first and*

second bones in the method for implantation of the spinal implant of the '309 patent to provide and optimal environment for arthrodesis. ***Id*. at ¶43**. A PHOSITA would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting method.[4] This modification would not have changed the principle of operation of the spinal implant of the '309 patent.[5] ***Id*. at ¶44**.

providing a wedge member which is at least partially formed of biodegradable material, and
Wagner (the '309 patent) (**EX1003**) discloses: • The implant 50 has transverse faces 68, 70 that are not parallel to each other, but rather are tapered from the anterior end toward the more closely spaced posterior end. **EX1003 at 6:63-68** and **FIGs. 3** and **6,** as labeled below**.** 

[4] *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).

[5] *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).

- The implant is made of a ceramic, a metal, a polymer, or a composite material. The implant 50 is desirably made from a material that, after surgical implantation, bonds to the natural bone of the adjacent vertebrae to form a rigid structure. The implant is preferably made from a ceramic, most preferably the ceramic calcium hydroxylapatite, having a chemical formula Ca10-(P04)6(0H)2. The use of such materials in implants is known, see for example U.S. Pat. No. 4,863,476, whose disclosure is incorporated by reference. The implant 50 may also be made from a composite material such as the carbon-fiber reinforced plastics disclosed in U.S. Pat. No. 4,904,261[*i.e.*, Dove, which provides that an implant may be made from a biodegradable fiber-reinforced composite. Dove, 1:46-49], whose disclosure is incorporated by reference. ***Id.* at 6:13-26.**
- Wagner discloses that the spinal implant device is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1006 Ochoa Decl. at ¶30.**
- Wagner discloses that the spinal implant device is at least partially formed of a biodegradable material. **EX1006 Ochoa Decl. at ¶30.**

A PHOSITA would have understood that the '309 patent describes an interbody cage with a substantially wedge-shaped body. **EX1003 at 5:15-18, 6:63-68, FIG. 6, EX1006 Ochoa Decl. at ¶34**. The body is made from a ceramic, most preferably the ceramic calcium hydroxylapatite, which is a biodegradable material. **EX1003 at 6:13-26; EX1006 Ochoa Decl. at ¶34.** Other material options for the device of the '309 patent are incorporated by reference to U.S. Patent no. 4,904,261 to Dove, which discloses the use of biodegradable fiber-reinforced composite materials. ***Id.***

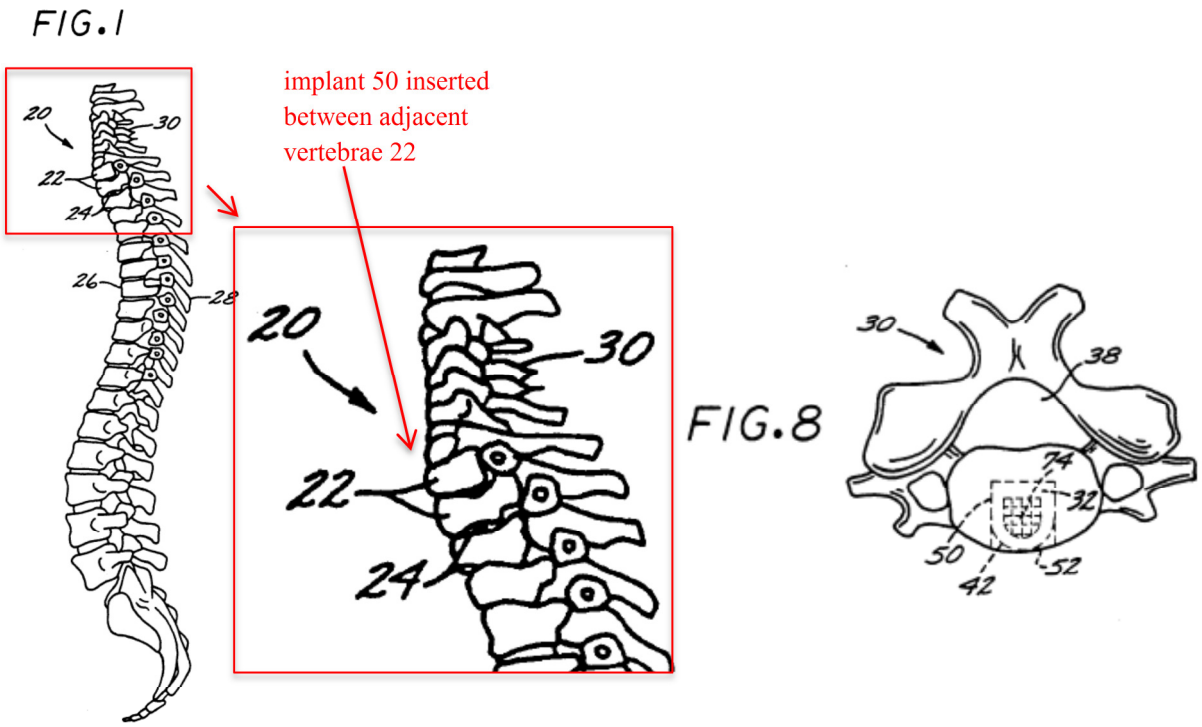
A PHOSITA would have understood that the '309 patent discloses *a wedge member which is at least partially formed of biodegradable material*, as recited in

the claims. **EX1006 Ochoa Decl. at ¶34.**

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.*

Wagner (the '309 patent) (**EX1003**) discloses:

- A spinal disk implant 50, shown in FIGS. 3-7 in several variations, has a structure designed for implantation between the vertebral body regions of two adjacent vertebrae 22. **EX1003 at 5:15-18.**
- The implant 50 is implanted between two vertebrae 22. ***Id.*** **at FIGs. 1** and **8,** as labeled below**.**



- FIG. 14 depicts a reusable handle 114 that can be used to place the implant 50 in the desired location during a surgical procedure…A butt end 122 of the handle 114 is rounded so that the surgeon may strike it with a surgical hammer if necessary to urge the implant 50 into place between two vertebrae that have been slightly spread apart from their normal spacing during the surgical procedure. ***Id.*** **at 8:57-9:2**.

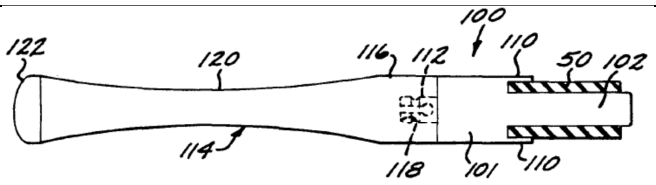


FIG. 14

- During the surgical procedure, the surgeon selects the required implant, and affixes the delivery tool 100 to the handle 114 using the engagement tip 112. The surgeon then uses the handle 114 to manipulate the implant 50 into the proper intervertebral position, tapping the butt end 122 if necessary. When the implant 50 is properly positioned, the vertebrae are allowed to relax slightly back to their normal positions, capturing the implant 50 therebetween. ***Id.*** **at 9:26-34**.
- Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae. **EX1006 Ochoa Decl. at ¶36.**
- Wagner discloses that the wedge-shaped spinal implant device engages the abraded portions of the adjacent vertebral faces of the vertebrae at which the device is implanted. **EX1006 Ochoa Decl. at ¶45.**

A PHOSITA would have understood that the substantially wedge-shaped biodegradable spinal disk implant of the '309 patent is implanted between two vertebrae using an anterior approach. **EX1003 at 5:15-18, FIGs. 1 and 8; EX1006 Ochoa Decl. at ¶45.** During implantation, the device is urged into place in the interbody space between the first and second vertebrae by impaction with a hammer. **EX1003 at 8:57-9:2, 9:26-34; EX1006 Ochoa Decl. at ¶45.** Therefore a PHOSITA would have understood that the '309 patent discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae. **EX1006 Ochoa Decl. at ¶45.**

A PHOSITA would have further understood that during impaction, the

tapered transverse faces (68, 70) would act as an inclined plane. **EX1003 at 6:63-68; EX1006 Ochoa Decl. at ¶45.** As such the axial 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. **EX1006 Ochoa Decl. at ¶45.** As the body advances posteriorly in the intervertebral space, the wedge shaped body engages the abraded portions of the vertebral faces (end plates) of the vertebrae at which the device is implanted, forcing the intervertebral space open. ***Id.*** In the final position, porous face regions (82) are captured in contact by the tension in the remaining soft tissues (and ultimately the forces due to musculature and body weight), thereby engaging the adjacent vertebrae, minimizing the likelihood of post-operative slippage of the implant from its proper intervertebral position. **EX1003 at 2:47-49; EX1006 Ochoa Decl. at ¶45.**

A PHOSITA, therefore, would have understood that *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, would have occurred during implantation of the spinal disk implant of Wagner. **EX1006 Ochoa Decl. at ¶45.**

Consequently, the foregoing has established that claim 34 is obvious pursuant to 35 U.S.C. § 103 over Wagner (the '309 patent) in view of the SPINE article.

C. Ground 3: Claim 34 is unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (the '309 patent) (EX1003) in view of Brantigan (the '327 patent) (EX1005)

Alternatively, Claim 34 is rendered unpatentable and obvious over Wagner (the '309 patent) in view of Brantigan (the '327 patent) under 35 U.S.C. § 103, as follows:

The '327 patent discloses a spinal implant device for use in spinal fusion 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 Ochoa Decl. at ¶31.** The spinal implant device (*e.g.,* 10) of the '327 patent is configured for insertion from the anterior approach, and may include a substantially wedge-shaped body (40). **EX1005 at FIG. 7; EX1006 Ochoa Decl. at ¶31.** A central aperture is provided to receive bone graft material to expedite fusion of the prosthesis device in the spinal column. **EX1005 at 4:50-54; EX1006 Ochoa Decl. at ¶31.** The '327 patent describes preparation of the vertebral endplates, using a burr drill to flatten the surfaces and removing cartilaginous material. **EX1005 at 2:59-66; EX1006 Ochoa Decl. at ¶31.**

A PHOSITA would have understood that the spinal interbody cages

discussed in the '327 patent are used to 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. **EX1006 Ochoa Decl. at ¶ 31.** A PHOSITA, therefore, would have been motivated to look to the teachings of the '309 patent, the '327 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. **EX1006 Ochoa Decl. at ¶40.** A PHOSITA would have been motivated to apply the teachings of the '327 patent to those of the '309 patent because each of the '309 patent and the '327 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 ¶41.**[6]

As discussed above in Section VIII. B., the '309 patent discloses or renders obvious all the limitations of the method of claim 34, although it does not explicitly recite abrading the endplates of the adjacent vertebrae where the device is implanted. A PHOSITA would have understood, however, that the '309 device is intended for fusion of the adjacent vertebrae, **EX1003 at 9:45-48**, and that the

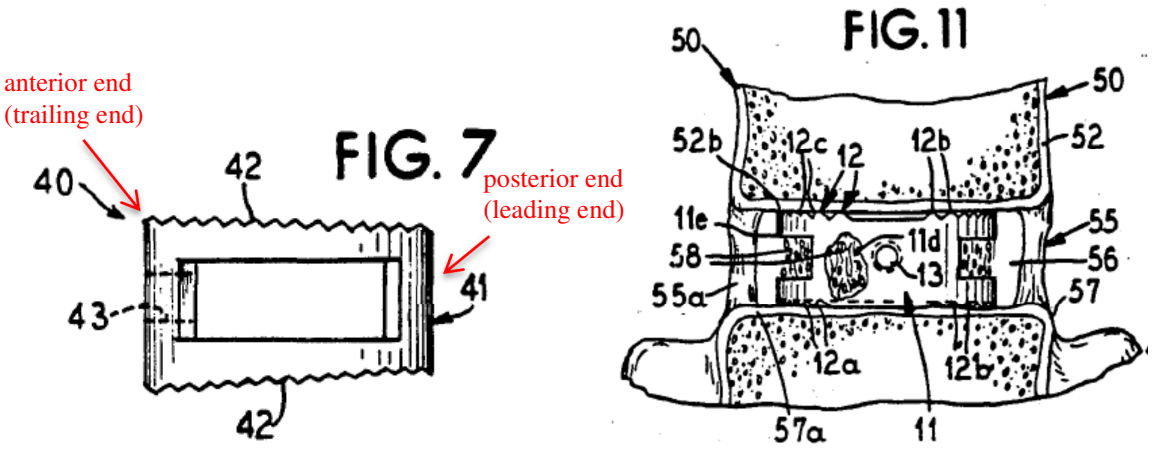
[6] *See* footnote 2, *supra.*

porous ceramic surface of the device would act as a synthetic graft material to promote ingrowth of bone into the pores in the face, but that this would require contact between the porous face and bleeding bone. **EX1006 Ochoa Decl. at ¶39**. As such, a PHOSITA would have understood implantation of the device would intrinsically require appropriate preparation of the endplates to provide an optimal environment for bone ingrowth and arthrodesis. ***Id***.

'063 patent Claim 34 vs. Wagner and Brantigan
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 the joint between the first and second bones,*
Wagner (the '309 patent) (**EX1003**) discloses: • *See* discussion above re. Wagner and Weiner (the SPINE article). • Wagner discloses the spinal implant used as an interbody spacer during spinal fusion procedures is made from ceramic calcium hydroxylapatite. **EX1003 at 6:13-26.** • Partly porous face regions (82) on the implant provide a surface with favorable porosity and pore size for bone ingrowth. **EX1003 at 7:9-23; EX1006 Ochoa Decl. at ¶39**. Brantigan (the '327 patent) (**EX1005**) discloses: • Brantigan 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 in a patient's body. **EX1006 Ochoa Decl. at ¶31.** • Brantigan discloses a method for changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body. **EX1006 Ochoa Decl. at ¶¶ 31, 39**. • Brantigan provides vertebral prosthetic implant devices (a spinal disk

implant) suitable for anterior, posterior or lateral placement in any area of the spine requiring replacement of disk or vertebral body. **EX1005 at 2:55-59.**

- Brantigan discloses a prosthetic device seating on hard end plates of vertebrae in a vertebral column…comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated,… having … a central aperture therethrough … adapted to be packed with bone graft material and … having an anterior portion higher than the posterior portion to provide a wedging effect when inserted into position between the hard end plate faces of the vertebrae. **EX1005 at 9:1-10:9, claim 14.**
- Brantigan discloses that in the implant device 40 shown in FIG. 7, the plug 41 is tapered to be higher or thicker at its anterior end than at its posterior end. … By way of an example, the trailing end could be 12 mm in height while the leading end reduced to 9 mm in height. ***Id.*** **at 5:50-57**
- *See, e.g.,* **FIGs. 7** and **11**, as labeled below.



- Since the implants are intended to bottom out on adjacent vertebral faces, which preferably have been prepared by flattening with a burr drill, removing cartilaginous material and stretching the annular fibrosis so that the vertebrae can tightly grip the plug, the plugs can be inserted either anteriorly, posteriorly or laterally into the vertebral column while mounted on the end of an insertion tool. **EX1005 at 2:59-66.**
- Brantigan discloses that portions of the adjacent vertebral faces of the vertebrae at which the spinal implant device is to be implanted are abraded. **EX1006 Ochoa Decl. at ¶39**.

A PHOSITA would have understood that Brantigan (the '327 patent)

discloses abrasion and preparation of the endplates. **EX1005 at 2:59-66; EX1006 Ochoa Decl. at ¶¶31, 39.** A PHOSITA would have understood that abrasion and preparation of the endplate could be achieved using a number of instruments and methods. **EX1006 Ochoa Decl. at ¶39.** Such methods would include using a burr drill to abrade portions of the adjacent vertebral faces, as disclosed for the method of implantation of the spinal implant device in the '327 patent. **EX1005 at 2:59-66; EX1006 Ochoa Decl. at ¶39**.

A PHOSITA would have recognized that the spine disk implants of the '309 patent and the '327 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. **EX1006 Ochoa Decl. at ¶42**. Therefore, the applicability and advantages of the preparing the vertebral endplates as disclosed in the '327 patent when applied to the device of the '309 patent would have been readily apparent to a PHOSITA. ***Id*.**

A PHOSITA, therefore, would have been motivated, in view of the combined teachings of the '309 patent and the '327 patent to include a step of *abrading a portion of the first and second bone at the joint between the first and second bones* in the method for implantation of the spinal implant of the '309 patent to provide and optimal environment for arthrodesis. ***Id*. at ¶43**. A PHOSITA

would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting method.[7] . ***Id*. at ¶44.** This modification would not have changed the principle of operation of the spinal implant of the '309 patent.[8] ***Id*.**

In summary, Wagner (the '309 patent) in view of Brantigan (the '327 patent) renders claim 34 obvious and unpatentable under 35 U.S.C. § 103.

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1, 8 and 34 of the '063 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '063 patent.

Dated: June 5, 2015

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[7] *See* footnote 4, *supra.*
[8] *See* footnote 5, *supra.*

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 5th day of June, 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 5th day of June, 2015:

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