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. 7,001,385
Issued: February 21, 2006
Application No: 10/755,995
Filed: January 13, 2004

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,001,385

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I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, the undersigned, on behalf of and representing Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review of claims 1, 10, 11 14, 23, 24 and 26 of U.S. Patent No. 7,001,385, titled "Joint Spacer With Compartment for Orthobiologic Material" ("the '385 patent"), issued to Peter M. Bonutti and assigned to Bonutti Skeletal Innovations LLC ("Bonutti"). The '385 patent is attached as **EX1001**.

The invention of the '385 patent is not new. Rather, the claimed invention encompasses known 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 '385 patent describe the invention having features that are well-known and/or inherent in the prior art 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, 10, 11 14, 23, 24 and 26 of the '385 patent is anticipated and/or 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. **EX1008.**[1] Dr. Ochoa is an expert with over 25 years of experience in the area

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

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 anticipated or 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, 10, 11 14, 23, 24 and 26 of the '385 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 Matters (37 C.F.R. § 42.8(b)(2))

Petitioner states that the '385 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 '385 patent. *See* **EX1023.**

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 6,423,063 ("the '063 patent"). The '063 patent is related to the '385 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 '385 patent through continuation practice. Petitioner understands that the '385 patent, the '063 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 '385 patent, they are directed to subject matter similar to that of the '385 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 '385 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 '385 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. 7,001,385 ("THE '385 PATENT") (EX1001)

The '385 patent issued on February 21, 2006, on an application filed on January 13, 2004. The '385 patent is a continuation of U.S. Application Serial No. 10/163,480, filed June 5, 2002 issued as U.S. Patent No. 7,780,670, which is a continuation of U.S. Application Serial No. 09/569,020, filed March 11, 2000 issued as U.S. Patent No. 6,423,063, which 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 '385 patent is August 20, 1998.

A. The '385 Patent Specification and Claims

The '385 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 '385 patent issued with 41 claims, of which only claims 1, 10, 11, 14, 23, 24, and 26 are at issue in this Petition. Claims 1 and 14 are independent. Claims 10 and 11 are directly and indirectly dependent from claim 1, and claims 23, 24, and 26 are directly and indirectly dependent from claim 14.

The written description and drawings of the '385 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 FIG. 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**. The specific features of the alleged invention included in the challenged claims relate to the structure of the wedge member 44 which is inserted into the joint 34.

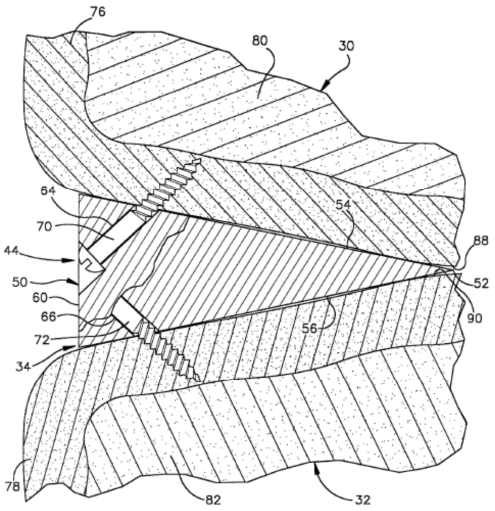
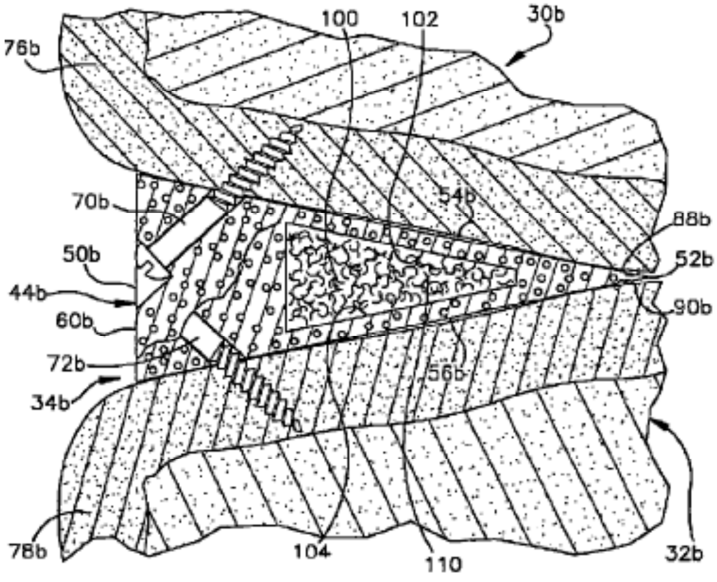


Fig.8

Claims 1, 10, 11, 14, 23, 24, and 26 of the '385 patent are directed to an apparatus that changes a spatial relationship between first and second bones and is inserted in a joint located between first and second vertebrae. The apparatus is best understood with reference to Figure 10. The apparatus is a wedge



member 44b having a thin end portion 52b, a thick end portion 50b, a first major side surface 54b, and a second major side surface 56b. ***Id.* at 11:9-16.** A minor side surface 60b extends between the first and second major side surfaces 54b, 56b and tapers from the thick end portion 50b to the thin end portion 52b. ***Id.* at 6:11-20 and 11:9-13.** The body of the wedge has a compartment 100 containing bone growth inducing material 110. ***Id.* at 11:31-38.** A fastener means 70b, 72b connects the wedge 44b to at least one of the upper bone 30b and lower bone 32b. ***Id.* at 11:2-4.**

B. The '385 Patent Prosecution History (EX1002)

The continuation application leading to the '385 patent, Serial No. 10/755,995, was filed on January 13, 2004. The prosecution of the application before the U.S. Patent and Trademark Office for the application leading to the '385 patent included a Restriction Requirement and a single substantive Office Action.

In the Response to the Restriction Requirement filed on April 13, 2005, the applicant elected to prosecute the species of the alleged invention corresponding to FIG. 10 of '385 patent. **EX1002 at page 62**.

After substantive examination, a non-final Office Action was issued rejecting all of the claims. In the responsive Amendment filed on August 24, 2005, the patent applicant amended the rejected independent claims (corresponding to challenged claims 1 and 14) to include a wedge body/member having a thin end

portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion**.** ***Id.*** **at pages 32, 33 and 38**. Thereafter, the claims were allowed.

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

As established in the Declaration of Dr. Ochoa (**EX1008 at ¶ 18**), a person having ordinary skill in the art (PHOSITA) of the '385 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 '385 patent are to be given their broadest reasonable

construction in light of the '385 patent's specification as understood by a person having ordinary skill in the art. 37 C.F.R. § 42.100(b).

Challenged claims 10 and 23 include the claim limitation "fastener means for fixedly connecting the wedge member to at least one of the first and second [bones *or* vertebrae]," and claims 11 and 24 include the limitation "wherein the fastener means includes at least one screw." Petitioner submits that, to the extent that these claim terms including the language "fastener means" are to be construed as a means-plus-function limitations as permitted under 35 U.S.C. § 112(f), the specific portions of the specification that describe the structure corresponding to the claimed function can be found in the '385 patent **EX1001 at 11:2-8** and **FIG. 10.**

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 '385 patent, as appropriate in that proceeding.

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. French Patent Application No. FR 2,747,034 to Benezech et al. ("the FR'034 application" or "Benezech") (EX1003)[2]

[2]An English translation of the specification of the FR'034 application is attached as

French Patent Application No. FR 2,747,034 to Benezech et al., entitled "Intersomatic Setting and Fusion System," published October 10, 1997. The FR'034 application is prior art to the '385 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 '385 patent. The FR'034 application 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 '385 patent.

B. International (PCT) Application Publication No. WO 1997/20526 to Bray ("the '526 publication" or "Bray") (EX1005)

International (PCT) Application Publication No. WO 1997/20526 to Bray, entitled "Anterior Stabilization Device," published June 12, 1997. Bray is prior art to the '385 patent under 35 U.S.C. § 102(b) because it is a printed publication more than one year prior to the date of the application for the '385 patent in the United States. Bray 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 '385 patent.

C. U.S. Patent No. 6,008,433 to Stone ("the '433 patent" or "Stone") (EX1006)

U.S. Patent No. 6,008,433, entitled "Osteotomy Wedge Device, Kit and Methods for Realignment of a Varus Angulated Knee," issued December 28, 1999

EX1004.

from an application filed in the United States on April 23, 1998. Stone is prior art to the '385 patent under 35 U.S.C. § 102(e)(2) because it is a patent granted on an application for patent by another filed in the United States before the invention by the applicant of the '385 patent. Stone was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '385 patent, but was not referred to or relied on by the Examiner during the prosecution.

D. U.S. Patent No. 5,298,254 to Prewett et al. ("the '254 patent or "Prewett") (EX1007)

U.S. Patent No. 5,298,254, entitled "Shaped, Swollen Demineralized Bone and Its Use in Bone Repair," issued March 29, 1994. Prewett is prior art to the '385 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 '385 patent in the United States. Prewett 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 '385 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, 10, 11, 14, 23, 24 and 26 of the '385 patent are unpatentable as anticipated pursuant to 35 U.S.C. § 102 and/or obvious pursuant to 35 U.S.C. § 103. As further discussed below, Petitioner particularly submits that claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable as anticipated pursuant to 35 U.S.C. § 102.

Alternatively, to the extent that these claims are not anticipated, claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of the challenged claims, claims 1 and 14 are independent; claims 10 and 11 ultimately depend from claim 1 and claims 23, 24 and 26 ultimately depend from claim 14.

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, the FR'034 application renders claims 1, 10, 11, 14, 23, 24 and 26 unpatentable as anticipated under 35 U.S.C. § 102 (**EX1008 at ¶¶ 31-46**); or, in the alternative, the FR'034 application in view of Bray (the '526 publication) renders claims 1, 10, 11, 14, 23, 24 and 26 unpatentable as obvious under 35 U.S.C. § 103 (***Id.* at ¶¶ 31-57**); or, in the alternative, Stone (the '433 patent) in view of Prewett (the '254 patent) renders claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable as obvious under 35 U.S.C. § 103 (***Id.* at ¶¶ 58-78**).

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

This petition presents the following Grounds of unpatentability:

- Ground 1: Claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable under 35 U.S.C. § 102(a) as anticipated by the FR'034 application (**EX1003**).
- Ground 2: Claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable under 35

U.S.C. § 103(a) as obvious over the FR'034 application (**EX1003**) in view of Bray (**EX1005**).

- Ground 3: Claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over Stone (**EX1006**) in view of Prewett (**EX1007**).

A. Ground 1: Claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable under 35 U.S.C. § 102(a) as anticipated by the FR'034 application (EX1003)

The FR'034 application discloses a system for intersomatic fusion and setting of vertebrae. **EX1004 at Abstract**. The system includes at least one open internal cage arranged for receiving spongy bone or bone substitute and is designed to be interposed between two vertebrae during diskectomy. ***Id.*** **at 1:1-9; FIGs. 1 and 2**. A cage (1, 1A) includes on its anterior face (5, 5A) an external element forming a plate (12, 12A) extending in a plane substantially perpendicular to the insertion plane of the cage, and has at each of its ends an anchor device adapted for anchoring to at least two adjacent vertebrae to be secured to each other by the cage. ***Id.*** **at 3:11-17 and FIG. 2**. The cage can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. ***Id.*** **at 3:3-5; 4:8-11**. The characteristics or features taught in the FR'034 application would have been readily identified by a PHOSITA and understood to present one of various design configurations achievable without changing the principle of operation of the implant of the FR'034 patent. **EX1008 Ochoa Decl. at ¶32.**

The systems of the invention are preferably made of titanium alloy or an equivalent material. **EX1004 at 6:3-5**. The cage is made of metal or biocompatible plastics. ***Id.*** **at 2:4-5**.

A PHOSITA would have understood that the spinal implant for use during spinal fusion including a cage (*i.e.,* a body) having an internal opening that can be packed with bone graft and a plate that is used to secure fixation of the cage to the adjacent vertebral bodies taught in the FR'034 application anticipates claims 1, 10, 11, 14, 23, 24 and 26 of the '385 patent. The claim charts and accompanying analysis, below, evidence this conclusion.

1. Claims 1and 14

Claims 1 and 14 are each directed to an implant device and differ in immaterial respects in syntax, but are substantively the same. Claims 1 and 14 are anticipated by the FR'034 application, as follows:

'385 patent Claims 1 and 14 vs. FR'034 Application
Claim 1: *An implantable device for changing the spatial relationship between first and second bones, the device comprising* *Claim 14:* *A spinal implant for insertion in a joint located between first and second vertebrae, the implant comprising*
The FR'034 application (**EX1003**) discloses: • The FR'034 application 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. **EX1008**

Ochoa Decl. at ¶31.

- The system includes at least one open internal cage arranged for receiving spongy bone or bone substitute and is designed to be interposed between two vertebrae during a diskectomy. **EX1004 at 1:1-9** and, *see, e.g.*, **FIGs. 2** and **3**.
- The system is made either in the form of an internal cage and an external plate including devices for assembling the plate to the cage (e.g., FIG. 2) or in the form of a single piece cage-and-plate unit (e.g., FIG. 3). ***Id.*** **at 2:9-12.**
- The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1008 Ochoa Decl. at ¶31.**
- *See*, *e.g.,* **EX1004 at FIGs. 2 and 3**, below.

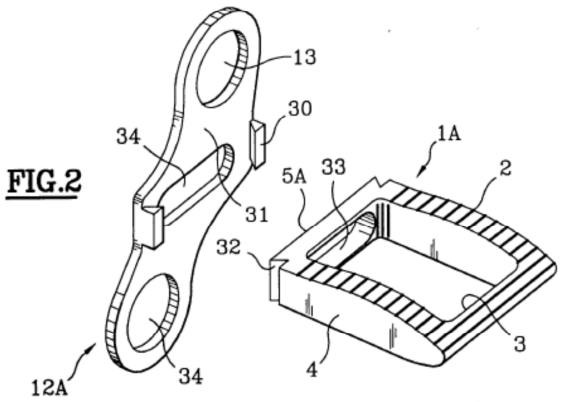


FIG.2

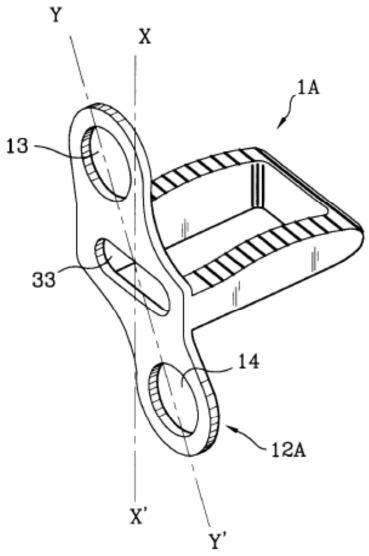


FIG.3

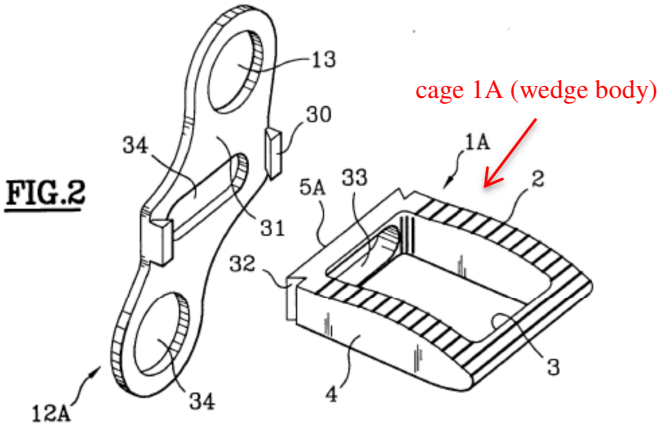
- The FR'034 application discloses an implantable device (the spinal implant) for changing the spatial relationship between first and second bones (vertebrae) in a patient's body. **EX1008 Ochoa Decl. at ¶35.**

The preamble of claims 1 and 14 merely state the intended use of the invention and do not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[3]

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

To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of the FR'034 application is for use in spinal fusion surgical procedures in association with vertebrae in a patient's spine. **EX1004 at 1:1-9** and **EX1008 Ochoa Decl. at ¶35**. Therefore, a PHOSITA would have recognized that the FR'034 application discloses an *implantable device for changing the spatial relationship between first and second bones* (vertebrae), as recited in claim 1, **EX1008 Ochoa Decl. at ¶35**, and moreover that the FR'034 application discloses *a spinal implant for insertion in a joint located between first and second vertebrae*, as recited in claim 14. ***Id.* at ¶36**.

Claims 1 and [14]: *a wedge body [member] configured and dimensioned for insertion into [the joint] a joint located between the first and second bones,*
The FR'034 application (**EX1003**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The anterior face and posterior face of the cage are of heights that are determined so as to conserve an appropriate intervertebral space. ***Id.* at 3:3-5**. • The profile and shape of the cage 1A of FIG. 2 enable the overall device to fit perfectly in the intervertebral space. ***Id.* at 5:1-3.** • The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae. **EX1008 Ochoa Decl. at ¶33.** • The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. ***Id*.** • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. ***Id*. at ¶32.** • *See*, *e.g.,* **EX1004 at FIG. 2**, as labeled below.



- The FR'034 application discloses that the spinal implant has a wedge body configured and dimensioned for insertion into a joint located between the first and second bones. **EX1008 Ochoa Decl. at ¶37.**

The phrases in claims 1 and 14 that the wedge body (claim 1) and wedge member (claim 14) are *"configured and dimensioned for insertion into [the joint] a joint located between the first and second bones,"* are recitations of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and, therefore, is not material to patentability. As such, this language carries no patentable weight.[4] Moreover, a PHOSITA would not understand the limitation, *configured and dimensioned for insertion into a joint,* to disclose any intrinsic or specific structural limitation of the implant. **EX1008 Ochoa Decl. at ¶22.**

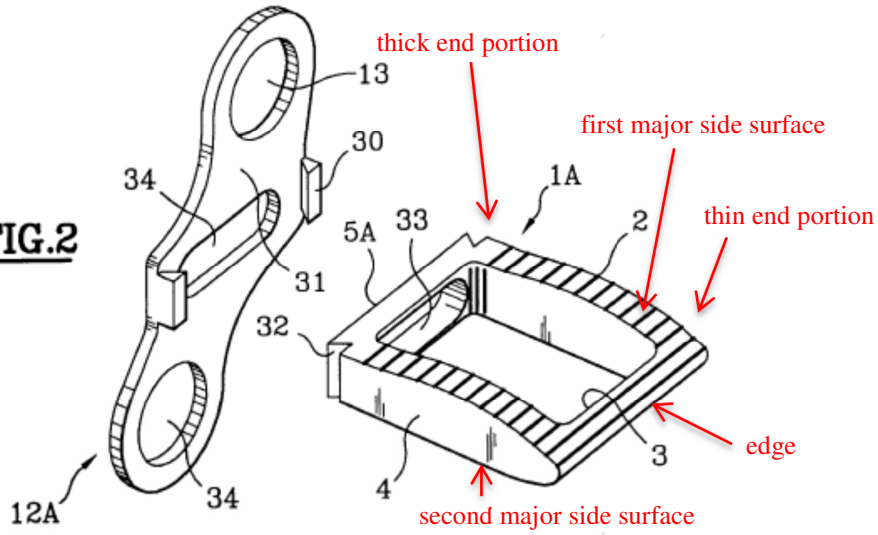
However, to the extent that this language limits the claims, the FR'034

[4] *In re Schreiber,* 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart,* 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); *and In re Danly,* 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

application discloses these limitations. A PHOSITA would have understood that the FR'034 application discloses that the body of the spinal implant is dimensioned to conserve an appropriate intervertebral space and that the body may have a profile and shape to enable it to fit perfectly in the intervertebral space. **EX1004 at 3:3-5, 4:8-11, 5:1-3; EX1008 Ochoa Decl. at ¶¶37, 38.** A PHOSITA would have understood that to achieve the desired fit while correcting for the natural lordotic angle between a first and second vertebrae of the lumbar spine would require a generally wedge shaped body of the implant with a thicker anterior or trailing portion and a thinner posterior or leading portion, as illustrated in Figure 2 of the FR'034 application. **EX1008 Ochoa Decl. at ¶¶37, 38.** It had been documented, and would have been known to a PHOSITA at the time of invention, that the average angle of the intervertebral disc space varies between approximately 5 and 15 degrees in the lumbar spine. ***Id*.**

Therefore, a PHOSITA would have understood that the FR'034 application discloses *a wedge body configured and dimensioned for insertion into a joint located between the first and second bones*, as recited in claim 1, ***Id.* at ¶37**, and that the FR'034 application discloses *a wedge member configured and dimensioned for insertion into the joint*, as recited in claim 14. ***Id.* at ¶38.**

Claims 1 and [14]: *the wedge body [member]having a thin end portion, a thick end portion,* *a first major side surface which extends from the thin end portion to the thick end*

portion, *a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and*
The FR'034 application (**EX1003**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The anterior face and posterior face of the cage are of heights that are determined so as to conserve an appropriate intervertebral space. ***Id.*** **at 3:3-5**. • The profile and shape of the cage 1A of FIG. 2 enable the overall device to fit perfectly in the intervertebral space. ***Id.*** **at 5:1-3.** • The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae. **EX1008 Ochoa Decl. at ¶33.** • The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. ***Id.*** • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. ***Id.*** **at ¶32.** • *See*, *e.g.,* **EX1004 at FIG. 2**, as labeled below. FIG.2 

A PHOSITA would have understood that the FR'034 application discloses that the body of the spinal implant is dimensioned to conserve an appropriate

intervertebral space and that the body may have a profile and shape to enable it to fit perfectly in the intervertebral space. **EX1004 at 3:3-5, 4:8-11, 5:1-3; EX1008 Ochoa Decl. at ¶40.** A PHOSITA would have understood that to achieve the desired fit in the intervertebral space of the lumbar spine would require the body of the implant to have a thicker anterior or trailing portion and a thinner posterior or leading portion in order to correct for the natural lordotic angle of the vertebral space. **EX1008 Ochoa Decl. at ¶40.** A PHOSITA would have understood that this would be achieved by tapering the profile of the body from the thick end portion to the thin end portion. ***Id*.** A PHOSITA would have understood Figure 2 to illustrate that the body has a thick end portion at the anterior or trailing end of the body, a thin end portion at the posterior or leading end of the body, and a profile tapering from the thick and portion to the thin end portion. ***Id*.** This configuration of the body would have been recognized by a PHOSITA as being consistent with a spinal implant that is intended for use to restore the natural lordosis between vertebrae of the lumbar spine. ***Id*.**

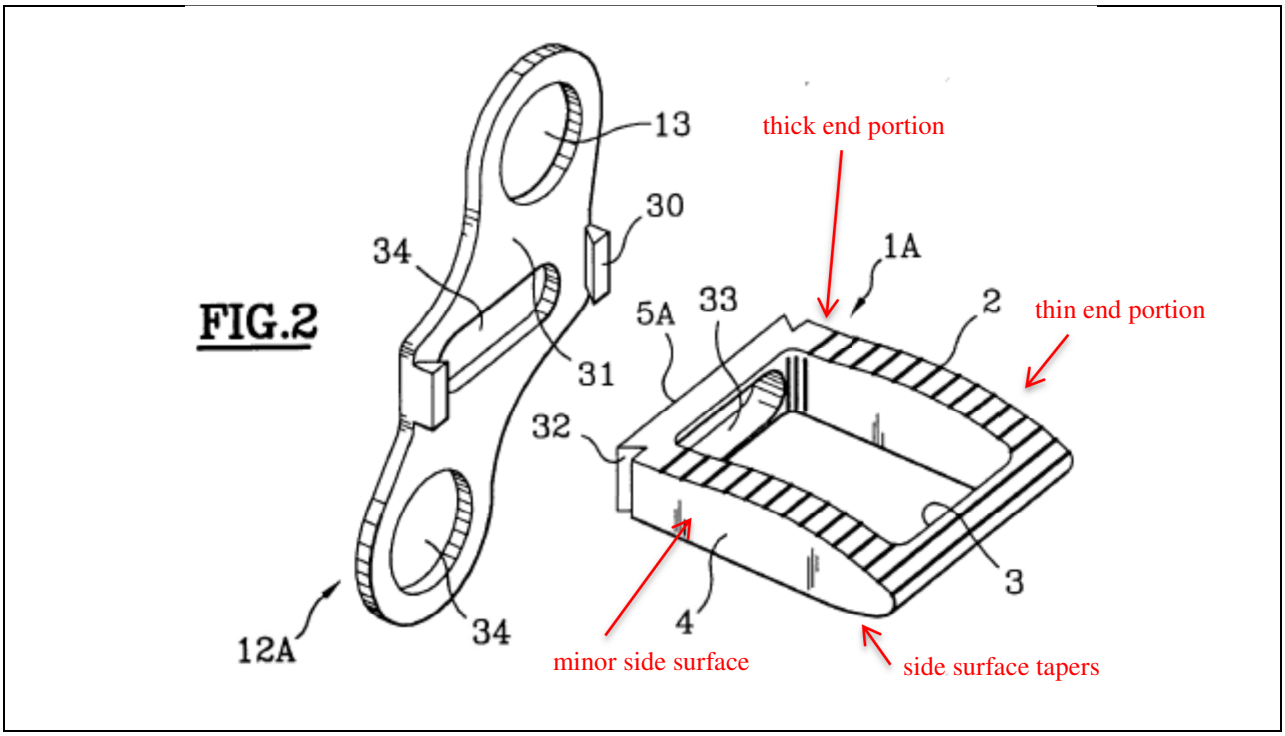
A PHOSITA, therefore, would have understood that the FR'034 application discloses *the wedge body (or member) having a thin end portion, a thick end portion*, as recited in the claims. ***Id.*** **at ¶39.**

In addition, a PHOSITA would have understood that the body ("cage 1A") of the FR'034 application spinal implant includes top and bottom faces ("faces 8

and 9"), each of which extends from the anterior thick end portion of the body to the posterior thin end portion. **EX1004 at 2:27-3:2; EX1008 Ochoa Decl. at ¶41.** The top and bottom faces provide the supporting surfaces for the adjacent bone when the body is inserted between two vertebrae. ***Id.*** A PHOSITA would have recognized that top and bottom surfaces of the body ("faces 8 and 9") intersect to form an edge at the leading posterior end of the body. **EX1008 Ochoa Decl. at ¶41*;* EX1004 at FIG. 2.**

A PHOSITA, therefore, would have recognized that the FR'034 application discloses *a first major side surface which extends from the thin end portion to the thick end portion,* and *a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion,* as recited in the claims. **EX1008 Ochoa Decl. at ¶41.**

Claims 1 and 14: *a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion,*
The FR'034 application (**EX1003**) discloses: • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1008 Ochoa Decl. at ¶32.** • *See*, *e.g.,* **EX1004 at FIG. 2,** as labeled below.

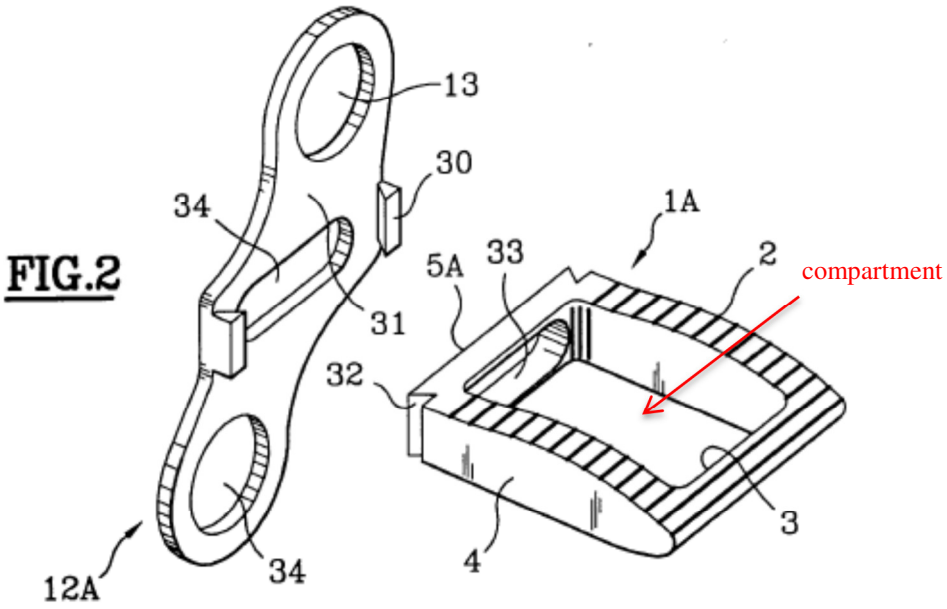


A PHOSITA would have understood that the body ("cage 1A") of the FR'034 application spinal implant also includes opposite side walls ("side walls 2 and 4") each including a side surface. **EX1008 Ochoa Decl. at ¶42.** The dimensions of the side walls vary along the profile of the body, tapering from the anterior thick end portion of the body to the posterior thin end portion. ***Id.;* EX1004 at 3:3-5, 4:8-11, FIG. 2.** A PHOSITA would have recognized that the FR'034 application discloses *a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion*, as recited in the claims. **EX1008 Ochoa Decl. at ¶42.**

Claims 1 and [14]: *the wedge body [member] having a compartment containing a bone growth inducing material.*

The FR'034 application (**EX1003**) discloses:

- The system includes at least one open internal cage arranged for receiving spongy bone or bone substitute and is designed to be interposed between two vertebrae during a diskectomy. The system is capable of installing a bone graft or material encouraging fusion between the two vertebrae concerned. **EX1004 at 1:1-9** and, *see, e.g.*, **FIG. 2**, as labeled below.



- The cage is designed to receive spongy bone or bone substitute material via its top and bottom open faces and/or via a front opening. ***Id.*** **at 2:7-8** and **2:26-32**.
- The spongy bone or other bone substitute can be put into place either before or after the cage has been positioned between the vertebrae. ***Id.*** **at 4:12-14.**
- The anterior face 5A of the cage-and-plate unit has an oblong slot 33 so as to enable spongy bone to be inserted frontally into the cage portion after the cage-and-plate unit has been put into place. ***Id.*** **at 4:25-30**.
- The "cage" (body) of the device has a compartment for containing bone growth inducing material for promoting bone growth. **EX1008 Ochoa Decl. at ¶43.**

A PHOSITA would have understood that the FR'034 application discloses an open internal body ("cage 1A") that is designed to receive graft materials such as spongy bone or bone substitute. **EX1004 at 1:3-9, 2:4-8, FIG. 2; EX1008**

Ochoa Decl. at ¶43. A PHOSITA would have understood that the open internal body provides a compartment to contain the graft materials. **EX1008 Ochoa Decl. at ¶43.** The graft materials could be put in place either before or after the cage has been positioned between the vertebrae to encourage fusion between the two vertebrae. **EX1004 at 4:12-14; EX1008 Ochoa Decl. at ¶43.** This would create an area of contact between the endplate and graft, thus providing an excellent milieu for arthrodesis. **EX1008 Ochoa Decl. at ¶43.** Therefore, a PHOSITA would have understood that the FR'034 application discloses *the wedge body (or member) having a compartment containing a bone growth inducing material*, as recited in the claims. ***Id*.**

Consequently, and as supported by Dr. Ochoa, the FR'034 application anticipates and renders claims 1 and 14 unpatentable under 35 U.S.C. § 102.

2. Claims 10 and 23

Claims 10 and 23 depend, respectively, from claims 1 and 14 and are substantively identical. Claims 10 and 23 further describe device as including fastener means for connecting the body to at least one of the bones. Claims 10 and 23 are anticipated by the FR'034 application, as follows:

'385 patent Claims 10 and 23 vs. FR'034 Application
Claims 10 and [23]: *The device [implant] of claim 1 [14] further including fastener means for fixedly connecting the wedge body [member] to at least one of the first and second bones [vertebrae].*

The FR'034 application (**EX1003**) discloses:

- *See* claim 1, above.
- The spinal implant device includes two primary components: a "cage" (body) and a "plate" (mounting strip). **EX1008 Ochoa Decl. at ¶31.**
- The cage carries on its anterior face an external strap-forming element ("plate") extending in a plane that is substantially perpendicular to the insertion plane of the cage, on either side thereof, and having at each of its ends anchor devices for anchoring to at least two adjacent vertebrae in order to connect them together via the cage. **EX1004 at 3:11-17**.
- The anchor device for anchoring the plate 12A on the vertebrae, after the cage 1A has been fixed make use of pedicular screws passing through corresponding holes 13 and 14 formed through the ends of the strap 12A. ***Id.* at 5:10-15.**
- *See*, *e.g.*, ***Id.* at FIGs. 2 and 3**, as labeled below.

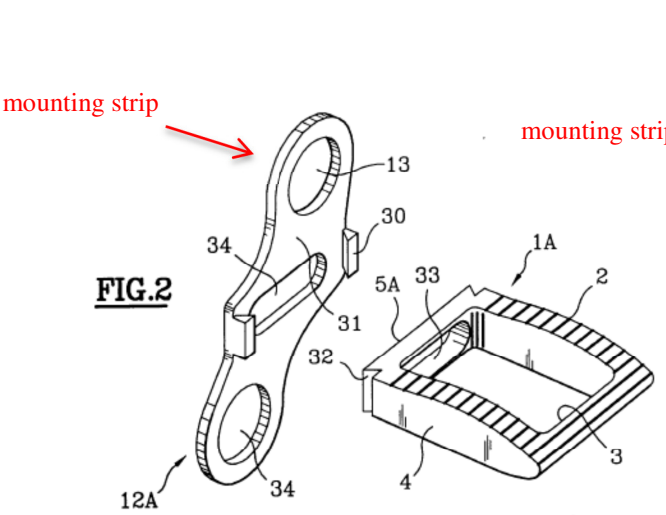


FIG.2

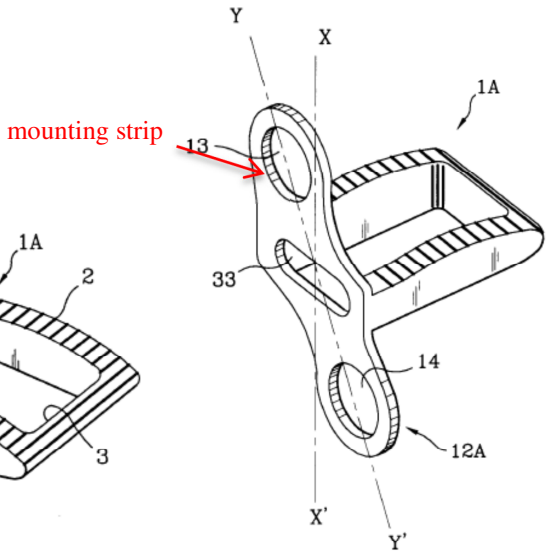


FIG.3

- The spinal implant is anchored to the vertebrae by pedicular screws passing through holes in the "plate" (mounting strip). **EX1008 Ochoa Decl. at ¶44.**
- The device includes fastener means for fixedly connecting the wedge body to at least one of the first and second bones. ***Id.***

A PHOSITA would have understood that the spinal implant disclosed in the FR'034 application comprises an assembly including both the body ("cage 1A")

and an external metallic strap or plate ("plate 12") configured to include screw holes ("fixing holes 13 and 14"). **EX1004 at 3:11-17, 3:21-24, 5:10-15, 6:3-5, FIG. 2; EX1008 Ochoa Decl. at ¶44.** A PHOSITA would have understood that the FR'034 application discloses fixation of the cage to the vertebrae using pedicular screws passing through the corresponding holes in the plate. **EX1004 at 5:10-15; EX1008 Ochoa Decl. at ¶44.** A PHOSITA would have also understood that when used in the spine, the threads of the screws would engage the neighboring vertebrae. **EX1008 Ochoa Decl. at ¶44.** Therefore, a PHOSITA would have understood that the FR'034 application discloses inclusion of *fastener means for fixedly connecting the wedge body (or member) to at least one of the first and second bones*, as recited in the claims. ***Id.***

In summary, and as confirmed by Dr. Ochoa, the FR'034 application anticipates and renders claims 10 and 23 unpatentable under 35 U.S.C. § 102.

3. Claims 11 and 24

Claims 11 and 24 depend, respectively, from claims 1 and 14 and are substantively identical. Claims 11 and 24 further describe the fastener means of the device as including a screw. Claims 11 and 24 are anticipated by the FR'034 application, as follows:

'385 patent Claims 11 and 24 vs. FR'034 Application
Claims 11 and [24]: *The device of claim 10 [23] wherein the fastener means includes at least one*

screw.

The FR'034 application (**EX1003**) discloses:

- *See* claim 10, above.
- *See*, *e.g.*, **EX1004 at FIGs. 2 and 3**, as labeled below.

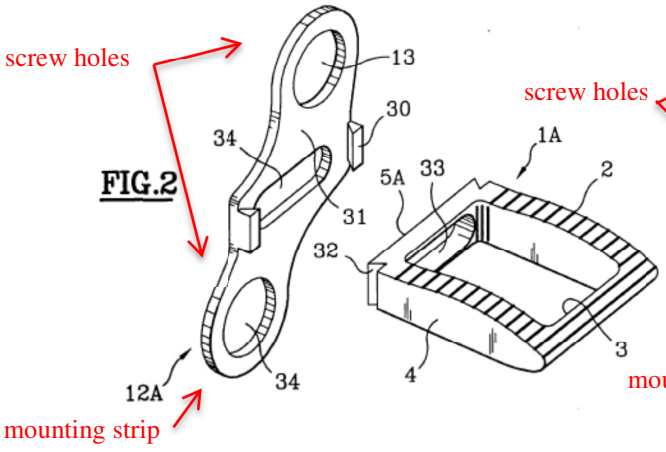


FIG.2

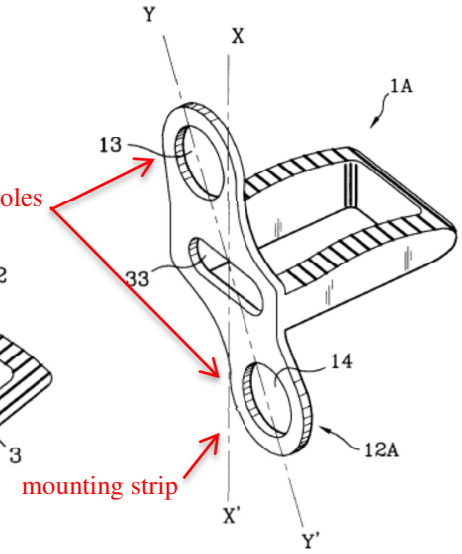


FIG.3

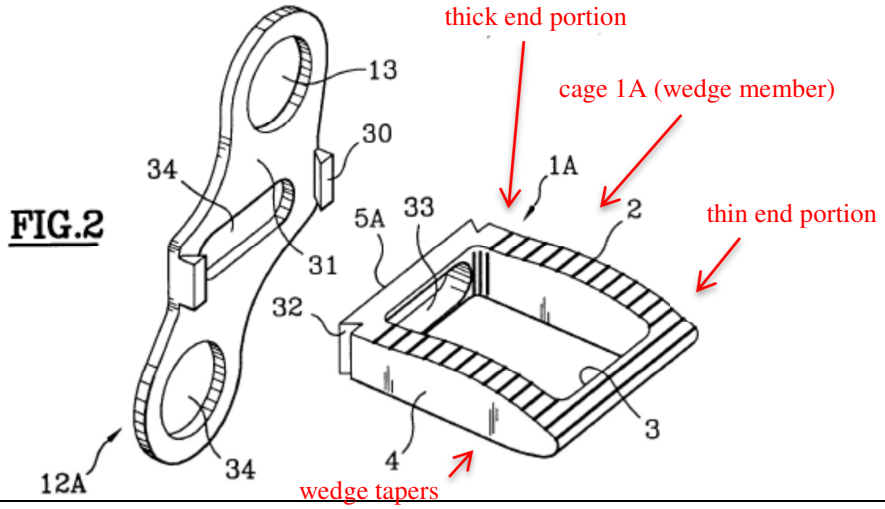
- The spinal implant is anchored to the vertebrae by pedicular screws passing through holes in the "plate" (mounting strip). **EX1008 Ochoa Decl. at ¶45.**
- The fastener means of the device includes at least one screw. ***Id.***

A PHOSITA would have understood that the FR'034 application discloses fixation of the cage to the vertebrae using pedicular screws passing through the corresponding holes in the plate. **EX1004 at 3:11-17, 3:21-24, 5:10-15, 6:3-5, FIG. 2; EX1008 Ochoa Decl. at ¶45.** Therefore, a PHOSITA would have understood that the FR'034 application discloses a *fastener means* that *includes at least one screw*, as recited in the claims. **EX1008 Ochoa Decl. at ¶45.**

Consequently, and as supported by Dr. Ochoa, the FR'034 application anticipates and renders claims 11 and 24 unpatentable under 35 U.S.C. § 102.

4. Claim 26

Claim 26 depends from claim 14 and further describes geometric feature of the wedge member. Claim 26 is anticipated by the FR'034 application, as follows:

'385 patent Claim 26 vs. FR'034 Application
The implant of claim 14 wherein the wedge member tapers from the thick end portion to the thin end portion.
The FR'034 application (**EX1003**) discloses: • *See* claim 14, above. • The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1004 at 4:8-11**. • The anterior face and posterior face of the cage are of heights that are determined so as to conserve an appropriate intervertebral space. ***Id.*** **at 3:3-5**. • The profile and shape of the cage 1A of FIG. 2 enable the overall device to fit perfectly in the intervertebral space. ***Id.*** **at 5:1-3.** • The shape and profile of the device are adapted to fit into the intervertebral space between two adjacent vertebrae. **EX1008 Ochoa Decl. at ¶33.** • The "cage" (body) is generally wedged-shaped from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. ***Id.*** • The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. ***Id.*** **at ¶32.** • *See*, *e.g.,* **EX1004 at FIG. 2**, as labeled below.    FIG.2

A PHOSITA would have understood that the FR'034 application discloses that the body of the spinal implant is dimensioned to conserve an appropriate intervertebral space and that the body may have a profile and shape to enable it to fit perfectly in the intervertebral space. **EX1004 at 3:3-5, 4:8-11, 5:1-3; EX1008 Ochoa Decl. at ¶40.** A PHOSITA would have understood that to achieve the desired fit in the intervertebral space of the lumbar spine would require the body of the implant to have a thicker anterior or trailing portion and a thinner posterior or leading portion in order to correct for the natural lordotic angle of the vertebral space. **EX1008 Ochoa Decl. at ¶40.** A PHOSITA would have understood that this would be achieved by tapering the profile of the body from the thick and portion to the thin end portion. ***Id*.** A PHOSITA would have understood Figure 2 to illustrate that the body has a thick end portion at the anterior or trailing end of the body, a thin end portion at the posterior or leading end of the body, and a profile tapering from the thick and portion to the thin end portion. ***Id*.** This configuration of the body would have been recognized by a PHOSITA as being consistent with a spinal implant that is intended for use to restore the natural lordosis between vertebrae of the lumbar spine. ***Id*.**

Therefore, a PHOSITA would have understood that the FR'034 application discloses that *the wedge member tapers from the thick end portion to the thin end portion*, as recited in the claims. ***Id.* at ¶42.**

Thus, as confirmed by Dr. Ochoa, the FR'034 application renders claim 26 unpatentable as anticipated under 35 U.S.C. § 102.

B. Ground 2: Claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (EX1003) in view of Bray (EX1005)

To the extent that the spinal implant device of the FR'034 application does not disclose the wedge body [member] to include *"a compartment containing a bone growth inducing material,"* of independent claims 1 and 14, the FR'034 application (**EX1003**) in view of Bray (the '526 publication) (**EX1005**) renders claims 1 and 14, and the claims which depend therefrom, obvious and unpatentable under 35 U.S.C. § 103(a).

The '526 publication discloses an interbody fusion device (e.g. a spinal implant device) for use in a spinal fusion surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint. **EX1008 Ochoa Decl. at ¶47.** A PHOSITA, therefore, would have recognized that the '526 publication discloses an *implantable device for changing the spatial relationship between first and second bones* (vertebrae), as recited in claim 1, ***Id*. at ¶ 49**, and moreover that the FR'034 application discloses *a spinal implant for insertion in a joint located between first and second vertebrae*, as recited in claim 14. ***Id.***

An important feature of the '526 publication is the hollow interior that is filled with graft material. **EX1005 at 6:21-24, 9:21-29, 11:3-8, FIGs. 3** and **16; EX1008 Ochoa Decl. at ¶48.**

A PHOSITA would have been motivated to look to the teachings of the FR'034 application, the '526 publication, 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. **EX1008 Ochoa Decl. at ¶51.**[5] Further, a PHOSITA would have been motivated to apply the teachings of the '526 publication to those of the FR'034 application because both the FR'034 application and the '526 publication discloses 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 ¶52.**[6]

'385 patent Claims 1 and 14 vs. FR'034 Application and '526 publication
• *See*, claims 1 and 14, above. Both claims 1 and 14 include the limitation that:
the wedge body having a compartment containing a bone growth inducing material.

[5] *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).

[6] *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).

To the extent that the FR'034 application (**EX1003)** does not disclose *the wedge body having a compartment containing a bone growth inducing material*:

The '526 publication (Bray) (**EX1005**) discloses:

- Bray discloses an implant (e.g., 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. **EX1008 Ochoa Decl. at ¶47.**
- Bray discloses an implantable device (the spinal implant) for changing the spatial relationship between first and second bones (vertebrae) in a patient's body. ***Id*. at ¶49.**
- The spacer (spinal implant) is placed on the anterior surface and in the intervertebral space of two adjacent vertebral bodies to thereby fix the spatial relationship of the vertebral bodies to achieve stabilization and/or bone fusion. **EX1005 at 1:5-10**.
- *See, e.g.,* ***Id.*** **at FIGs. 1a, 1c**.

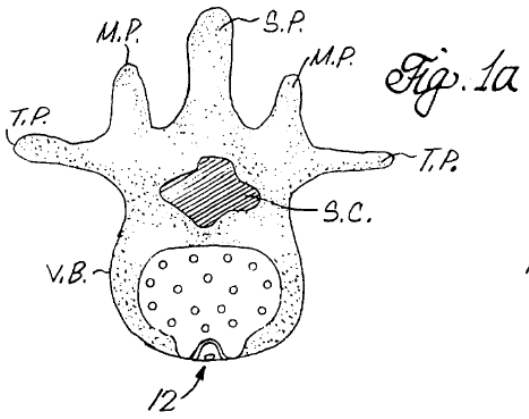


Fig. 1a

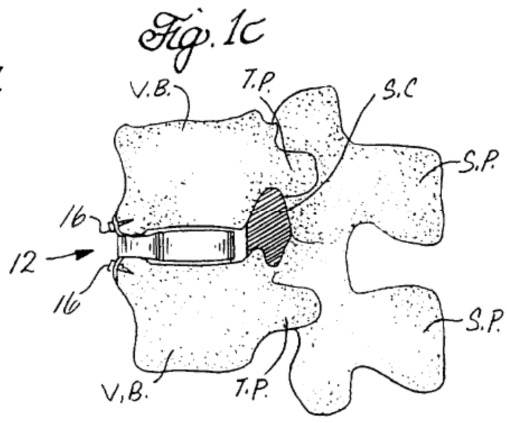
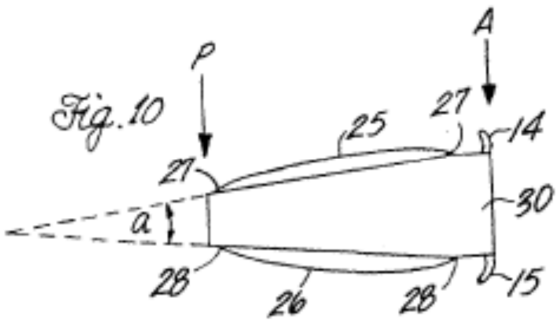
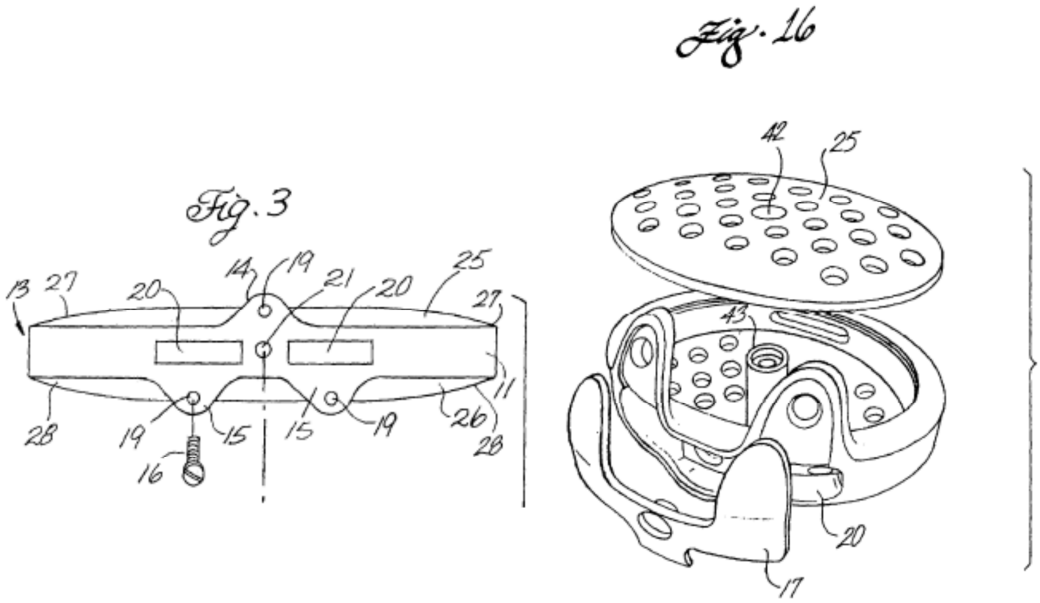


Fig. 1c

- The dimensions of the intervertebral spacer vary depending on the intended use of the spacers, having small spacers for the cervical spine, medium spacer for the thoracic spine, and large spacers for the lumbar spine. A spacer 30with a lordotic angle, a, is illustrated in FIG. 10. The lordotic angle extends from a smaller posterior surface, P, to a larger anterior surface, A. The angle, a, can range from about 1° to about 45°. ***Id.*** **at 8:19-21, 31-36** and **FIG. 10**.



- As shown in FIG. 3, the side wall of the spacer 13 has access openings 20 on both sides of a threaded set screw aperture 21. The openings 20 allow access into the interior of the hollow spacer. Alternatively, as shown in FIG. 16, the superior wall of the spacer can be removable. The interior of the spacer can be packed with bone grafts, bone morphogenic protein, or the like before or after insertion of the spacer into the intervertebral disk space. ***Id.*** **at 6:21-24, 9:21-29, 11:3-8** and **FIGs. 3** and **16.**



- The spinal implant has a wedge body and a compartment in the body for containing a bone growth inducing material. **EX1008 Ochoa Decl. at ¶50.**

A PHOSITA would have understood that the '526 publication discloses is the hollow interior that is filled with graft material. **EX1005 at 6:21-24, 9:21-29, 11:3-8, FIGs. 3** and **16; EX1008 Ochoa Decl. at ¶48.**

The spinal implant device of the '526 publication is hollow to allow for graft material to be inserted inside, facilitating bone growth through porous superior and inferior walls. **EX1005 at 6:21-24, 9:21-29, 11:3-8, FIGs. 3** and **16; EX1008 Ochoa Decl. at ¶47.** The hollow interior is contained within the sidewall ("11") and superior ("25") and inferior ("26") walls. **EX1005 at 6:21-24, 9:21-29, 11:3-8, FIGs. 3** and **16; EX1008 Ochoa Decl. at ¶48.** The sidewalls of the device may be tapered for use with kyphotic or lordotic angles. **EX1005 at 8:19-21, 8:31-36, FIG. 10; EX1008 Ochoa Decl. at ¶47.** Superior and inferior lips extending from the anterior side of the spacer allow the fixation of the device to the neighboring vertebrae using screws. **EX1008 Ochoa Decl. at ¶47.** A PHOSITA would have understood that the '526 publication discloses a spinal implant with *wedge body having a compartment containing a bone growth inducing material,* as recited in the claims. ***Id.*** **at ¶50**.

It would have been recognized by a PHOSITA that the body of the implant device of the '526 publication is analogous to the body ("cage 1A") of the FR'034 application. ***Id.*** **at ¶53**. To the extent that one may argue that the central opening of the FR'034 application is not a "compartment," a PHOSITA would have understood that the porous superior ("25") and inferior ("26") walls of the '526 publication would interact with the vertebral endplates in a similar manner to the top and bottom faces from the FR'034 application. ***Id.*** The addition of porous

surfaces as disclosed in the '526 publication would provide increased containment of the graft material prior to and during implantation. ***Id.*** Therefore, the applicability and advantages of the compartment containing a bone growth inducing material disclosed in the '526 publication to the device of the FR'034 application would have been readily apparent to a PHOSITA. ***Id.***

Therefore, a PHOSITA would have been motivated in view of the combined teachings of the FR'034 application and the '526 publication to configure the interbody cage of the FR'034 application with *a compartment containing a bone growth inducing material t*o provide increased containment of the graft material prior to and during implantation. ***Id.*** **at ¶54**. A PHOSITA would have considered such a modification an obvious design choice that would have yielded a predictable effect in the resulting design[7] and would not have changed the principle of operation of the spinal implant FR'034 application.[8] ***Id.*** **at ¶55**.

A PHOSITA would have understood that the product resulting from the combined teachings of the FR'034 application and the '526 publication would have produced a spinal implant with a *wedge body having a compartment containing a*

[7] *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).

[8] *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).

bone growth inducing material., as recited in the claims. ***Id.* at ¶56**.

In view of the foregoing discussion, and as confirmed by Dr. Ochoa, the FR'034 application in view of Bray (the '526 publication) renders claims 1, 10, 11, 14, 23, 24 and 26 unpatentable as obvious under 35 U.S.C. § 103(a).

C. Ground 3: Claims 1, 10, 11, 14, 23, 24 and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over Stone (EX1006) in view of Prewett (EX1007)

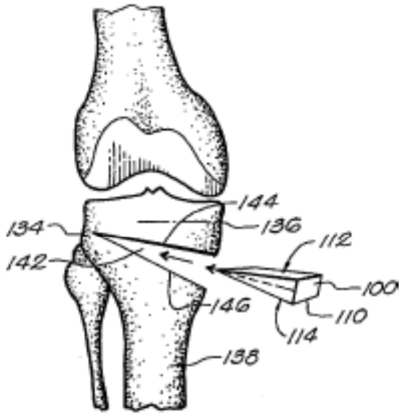
Stone (the '433 patent) (**EX1006**) discloses an implantable spacer for use in a high tibial osteotomy surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, the femur and tibia) at the knee. **EX1008 Ochoa Decl. at ¶58.** Specifically, the device is described for use as a spacer during an opening wedge osteotomy procedure, to realign varus angulated knees. ***Id.***

Prewett (the '254 patent) (**EX1007**) teaches a spinal implant including bone wedges used as intervertebral support blocks inserted between adjacent vertebrae used in place of an intervertebral disk that has been removed (i.e. during discectomy). **EX1007 at 6:65-7:13; FIGs. 5** and **6; EX1008 Ochoa Decl. at ¶61.**

A PHOSITA would have understood that the implantable spacer taught in Stone, when considered in combination with the spinal implant taught in Prewett, renders obvious claims 1, 10, 11, 14, 23, 24 and 26 of the '385 patent. The claim charts and accompanying analysis, below, evidence this conclusion.

1. Claims 1and 14

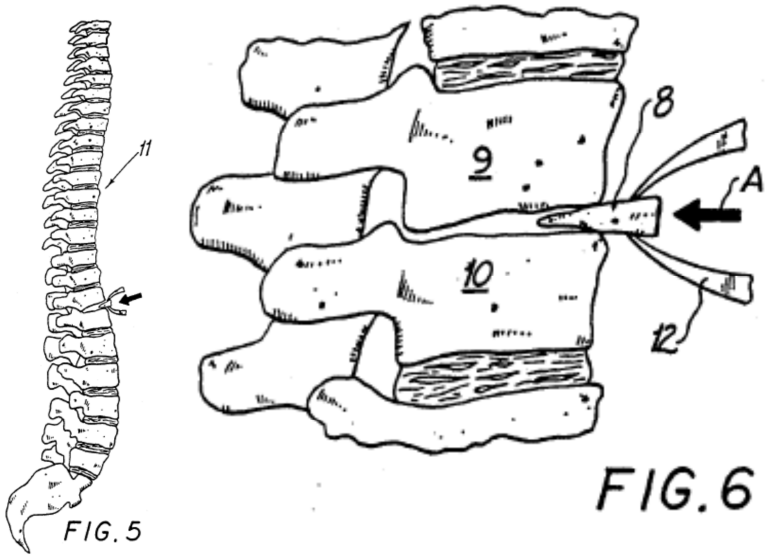
Claims 1 and 14 are each directed to an implant device and differ in immaterial respects in syntax, but are substantively the same. Claims 1 and 14 are rendered obvious over Stone (the '433 patent) (**EX1006**) in view of Prewett (the'254 patent) (**EX1007**), as follows:

'385 patent Claims 1 and 14 vs. Stone and Prewett
Claim 1: *An implantable device for changing the spatial relationship between first and second bones, the device comprising* *Claim 14:* *A spinal implant for insertion in a joint located between first and second vertebrae, the implant comprising*
Stone (the '433 patent) (**EX1006**) discloses: • Stone discloses a device, and kit and methods for realigning varus angulated knees, but also may be used for realigning any malaligned bone. **EX1006 at 2:59-61**. • Stone discloses an implantable wedge and method for surgically correcting abnormal angulations of the femoral-tibial joint, *i.e.*, the knee. **EX1008 Ochoa Decl. at ¶58**. • *See, e.g.,* **EX1006 at FIG. 3C.**    *FIG. 3C* • Stone discloses an implantable device for changing the spatial relationship

between first and second bones. **EX1008 Ochoa Decl. at ¶60**.

Prewett (the '254 patent) (**EX1007**) discloses:

- Prewett teaches a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae. **EX1007 at 6:65-7:13; FIGs. 5** and **6**.
- A wedge 8 is inserted between adjacent vertebrae 9 and 10 in a spinal column 11 in place of an intervertebral disk that has been removed. More specifically, FIG. 6 illustrates insertion of the wedge 8 in the direction of arrow A. ***Id***.
- *See, e.g.,* **EX1007 at FIG. 6**, below.



- Prewett discloses a spinal implant for insertion in a joint located between first and second vertebrae. **EX1008 Ochoa Decl. at ¶61**.

The preamble of claims 1 and 14 merely state the intended use of the invention and do not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[9]

To the extent that the preamble limits the claim, a PHOSITA would have understood that Stone describes a wedge shaped implantable spacer for use in, *e.g.*

[9] *See* footnote 3, supra.

high tibial osteotomy, that may be used for realigning any malaligned bone. **EX1006 at 2:59-61; EX1008 Ochoa Decl. at ¶60**. A PHOSITA would have also recognized that osteotomy spacers are implantable devices. A PHOSITA would have recognized that the '433 patent discloses an *implantable device for changing the spatial relationship between first and second bones*, as recited in claim 1. **EX1008 Ochoa Decl. at ¶60**.

Prewett discloses the use of swollen demineralized bone for use as an osteoconductive and/or osteoinductive material. **EX1007 at 1:44-47; EX1008 Ochoa Decl. at ¶61**. The described material may be formed in a in a variety of desired shapes for use as surgical implants. **EX1007 at 1:37-39; EX1008 Ochoa Decl. at ¶61**. The mechanical properties of the material can be modified by processing and such that the resulting device can be pressed into a surgical implant site. **EX1007 at 5:20-36; EX1008 Ochoa Decl. at ¶61**. The '254 patent discloses the use of wedges of material for use as intervertebral support blocks, used in place of an intervertebral disk that has been removed (i.e. during discectomy). **EX1007 at 6:65-7:13; FIGs. 5** and **6; EX1008 Ochoa Decl. at ¶61**. A PHOSITA, therefore, would have recognized that Prewett discloses a device for use during spinal fusion, and as such discloses a *wedge member* for use as an *implantable device for changing the spatial relationship between first and second bones*, as recited in claim 1, **EX1008 Ochoa Decl. at ¶61**, and moreover that Prewett

discloses *a spinal implant for insertion in a joint located between first and second vertebrae*, as recited in claim 14. ***Id.***

A PHOSITA would have been motivated to look to the teachings of Stone, Prewett, and other prior art disclosing implantable orthopedic devices for use in association with bones in a patient's body (*e.g.,* for changing the spatial relationship of bones in the human body) when considering improvements to the design of such devices. ***Id.*** **at ¶62**.

A PHOSITA would have understood that the devices of both the Stone and Prewett disclose implantable spacers with a substantially wedge-shaped body. ***Id.*** **at ¶63**. The function of the wedge shaped body is analogous between the two references regardless of the anatomic location of use. ***Id.*** The objective for either device is to *change the spatial relationship between first and second bones*. ***Id.*** The affected bones form links in a kinematic chain (i.e. a hinge) whether the hinge into which the wedge is inserted is created through an osteotomy, or by surgical removal of disk material in the spine. ***Id.*** In both cases the realignment function 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, in each case requiring the application of axial force to advance the device into the space. ***Id.;*** **EX1006 at 7:3-32; 36; EX1007 at 6:32-36, 7:7-8.**

It would have been recognized by a PHOSITA that the principal surfaces (112, 114) of the body of the Stone spacer is analogous to the cephalad and caudal surfaces of the wedges (8) disclosed in Prewett. **EX1008 Ochoa Decl. at ¶64.** In this respect, in each device the surfaces would mechanically engage the prepared bone surfaces while filling the interspace with graft material, thereby promoting contiguous bone formation. ***Id.;*** **EX1006 at 2:64-67; EX1007 at 1:44-48.**

A PHOSITA would have been motivated to apply the teachings of Prewett to those of Stone because both Stone and Prewett disclose substantially wedge-shaped implantable orthopedic devices for use in procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*e.g.* vertebrae) at an intervertebral joint in a patient. **EX1008 Ochoa Decl. at ¶65.** Further, both Stone and Prewett teach the use of bone growth inducing materials to promote bony union at the treated site. ***Id.***

A PHOSITA, therefore, would have been motivated in view of the combined teachings of Stone and Prewett to insert the *wedge body* (spacer) disclosed in Stone *into a joint located between first and second bones*. ***Id.*** **at ¶66**. Moreover, a PHOSITA would not understand the limitation, *configured and dimensioned for insertion into a joint,* to disclose any intrinsic or specific structural limitation of the implant. ***Id.*** Therefore, a PHOSITA would have understood that the combined

teachings of Stone and Prewett disclose *a wedge body configured and dimensioned for insertion into a joint located between the first and second bones*, as recited in claim 1, ***Id.,*** and more specifically, a PHOSITA would have understood from the teachings of Prewett that the spacer disclosed in Stone could similarly be employed as a *spinal implant for insertion in a joint located between first and second vertebrae*, as recited in the claims. ***Id.***

A PHOSITA would have considered using the wedge-shaped spacer of Stone in an intervertebral space as taught by Prewett an obvious use for the device that would have yielded a predictable effect.[10] This use would not have changed the principle of operation of the spacer of the '433 patent.[11]

Claims 1 and [14]: *a wedge body [member] configured and dimensioned for insertion into [the joint] a joint located between the first and second bones,*
Stone (the '433 patent) (**EX1006**) discloses: • The implantable device has a substantially wedge-shaped body 110 having two angularly offset intersecting principal surfaces 112, 114. The principal surfaces 112,114 intersect at a vertex 121 at insertion end 120 and extend about a principal plane 122 extending midway between surfaces 112, 114 from the vertex 121 at the insertion end 120 to a drive surface 126 at a drive end 118. The principal plane 122 contains a drive axis 116. The drive surface 126 extends, at least in part, in a direction transverse to the principal plane 122. The drive surface 126 is adapted to receive a force in the direction of the drive axis 116 towards the insertion end 120. **EX1006 at 5:27-40; FIGs. 1A** and **2B**, as labeled below.

[10] See footnote 7, supra.
[11] See footnote 8, supra.

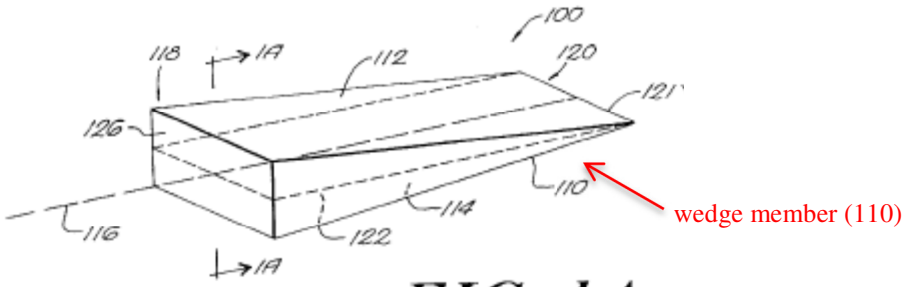


FIG. 1A

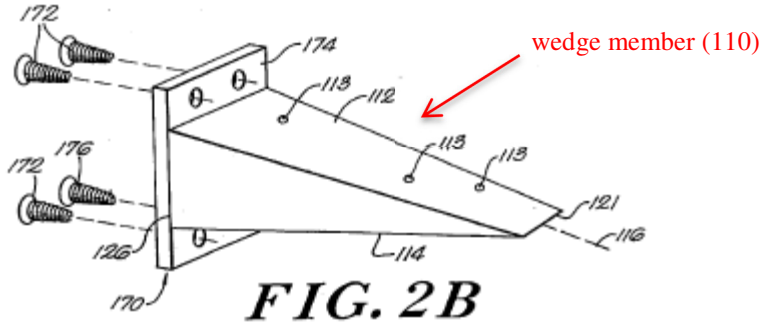


FIG. 2B

- The wedge body is configured and dimensioned for insertion between upper and lower portions of a bone joined at a lateral portion. **EX1006 at 7:14-31.**
- *See*, *e.g.,* **EX1006 at FIG. 3C**, as labeled below.

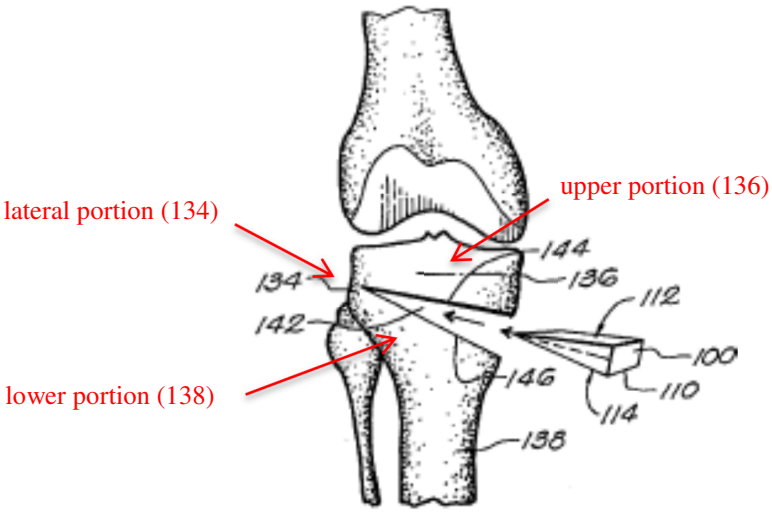


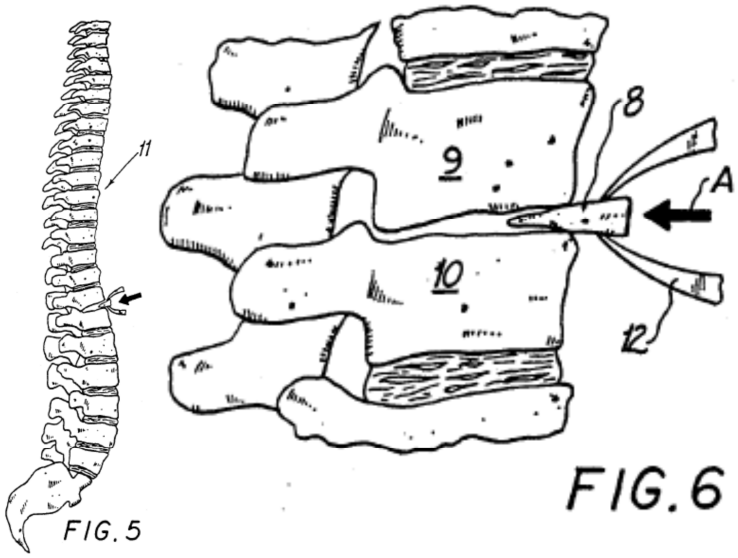
FIG. 3C

Prewett (the '254 patent) (**EX1007**) discloses:

- Prewett teaches a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae. **EX1007 at 6:65-7:13; FIGs. 5** and **6**.
- A wedge 8 is inserted between adjacent vertebrae 9 and 10 in a spinal

column 11 in place of an intervertebral disk that has been removed. More specifically, FIG. 6 illustrates insertion of the wedge 8 in the direction of arrow A. ***Id***.

- *See*, *e.g.,* **EX1007 at FIG. 6**, below.



- Prewett discloses a wedge member configured and dimensioned for insertion into a joint located between the first and second vertebrae. **EX1008 Ochoa Decl. at ¶61**.

The phrases in claims 1 and 14 that the wedge body (claim 1) and wedge member (claim 14) are *"configured and dimensioned for insertion into [the joint] a joint located between the first and second bones,"* are recitations of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and, therefore, is not material to patentability. As such, this language carries no patentable weight.[12] Moreover, a PHOSITA would not understand the limitation, *configured and dimensioned for insertion into a joint,* to disclose any intrinsic or specific structural limitation of the implant. **EX1008 Ochoa Decl. at**

[12] *See* footnote 4, supra.

¶66.

To the extent that this language limits the claims, it would have been recognized by a PHOSITA that the principal surfaces (112, 114) of the body of the Stone spacer is analogous to the cephalad and caudal surfaces of the wedges (8) disclosed in Prewett. ***Id*. at ¶64.** In this respect, in each device the surfaces would mechanically engage the prepared bone surfaces while filling the interspace with graft material, thereby promoting contiguous bone formation. ***Id.;* EX1006 at 2:64-67; EX1007 at 1:44-48.**

A PHOSITA would have been motivated to apply the teachings of Prewett to those of Stone because both Stone and Prewett disclose substantially wedge-shaped implantable orthopedic devices for use in procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*e.g.* vertebrae) at an intervertebral joint in a patient. **EX1008 Ochoa Decl. at ¶65.** Further, both Stone and Prewett teach the use of bone growth inducing materials to promote bony union at the treated site. ***Id.***

A PHOSITA, therefore, would have been motivated in view of the combined teachings of Stone and Prewett to insert the *wedge body* (spacer) disclosed in the Stone *into a joint located between first and second bones*. ***Id.* at ¶66**. Moreover, a PHOSITA would not understand the limitation, *configured and dimensioned for*

insertion into a joint, to disclose any intrinsic or specific structural limitation of the implant. ***Id.*** Therefore, a PHOSITA would have understood that the combined teachings of Stone and Prewett disclose *a wedge body configured and dimensioned for insertion into a joint located between the first and second bones*, as recited in claim 1, ***Id.,*** and more specifically, a PHOSITA would have understood from the teachings of Prewett that the spacer disclosed in Stone could similarly be employed as a *spinal implant for insertion in a joint located between first and second vertebrae*, as recited in the claims. ***Id.***

A PHOSITA would have considered using the wedge-shaped spacer of Stone in an intervertebral space as taught by Prewett an obvious use for the device that would have yielded a predictable effect.[13] ***Id.*** **at ¶67**. This use would not have changed the principle of operation of the spacer of the '433 patent.[14] ***Id.***

Claims 1 and [14]: *the wedge body [member]having a thin end portion, a thick end portion,* *a first major side surface which extends from the thin end portion to the thick end portion,* *a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and*
Stone (the '433 patent) (**EX1006**) discloses: • The device has a substantially wedge-shaped body 110 having two angularly offset intersecting principal surfaces 112, 114. The principal surfaces 112,114 intersect at a vertex 121 at insertion end 120 and extend about a

[13] See footnote 7, supra.
[14] See footnote 8, supra.

principal plane 122 extending midway between surfaces 112, 114 from the vertex 121 at the insertion end 120 to a drive surface 126 at a drive end 118. **EX1006 at 5:27-40.**

- *See, e.g.,* **EX1006 at FIGs. 1A** and **2B**, as labeled below.

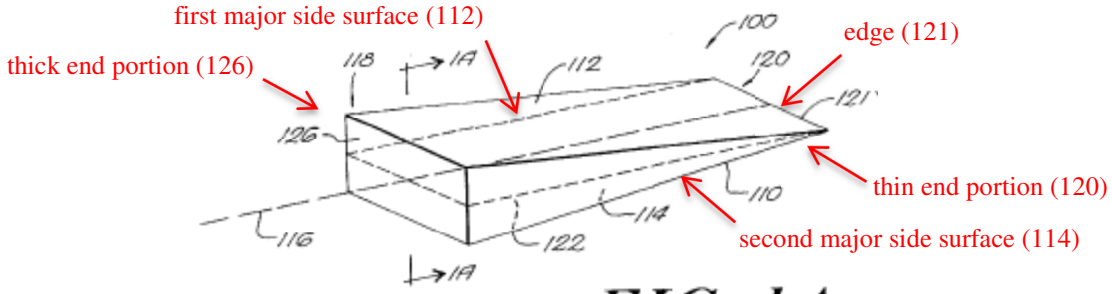


FIG. 1A

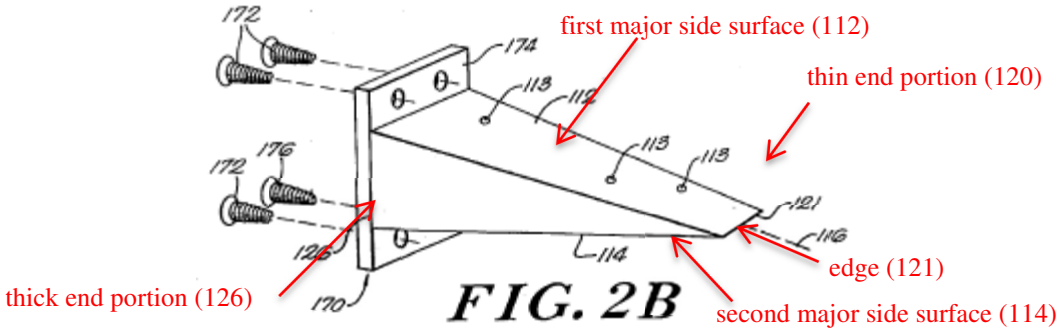


FIG. 2B

A PHOSITA would have understood that the wedge-shaped body (110) of the implantable spacer disclosed in Stone is substantially wedge shaped having two angularly offset principal surfaces (112, 114) that extend from a drive surface (126) at the thick, drive end portion of the device (118) to intersect at a thin end portion at the vertex (121). **EX1006 at 5:27-40, FIGs. 1A, 2B; EX1008 Ochoa Decl. at ¶70.** A PHOSITA would have understood the figures to illustrate that the body has a thick end portion at the trailing, drive end of the body, and a thin end portion at the leading vertex of the body. **EX1008 Ochoa Decl. at ¶70.** This

configuration of the body would have been recognized by a PHOSITA as being consistent with an implantable spacer that is intended for use to restore the natural alignment between bones at a joint. ***Id.*** A PHOSITA would have understood that Stone discloses *the wedge body (or member) having a thin end portion, a thick end portion*, as recited in the claims. ***Id.***

A PHOSITA would have understood that the two principal surfaces (112, 114) of the wedge-shaped body (110) of the implantable spacer of Stone extend from the drive surface (126) at the thick, drive end portion of the device (118) to intersect at a thin end portion at the vertex (121). **EX1006 at 5:27-40; FIGs. 1A** and **2B; EX1008 Ochoa Decl. at ¶72.** The principal surfaces provide the supporting surfaces and engage the adjacent bone when the body is inserted between bony surfaces. **EX1006 at 3:28-31; EX1008 Ochoa Decl. at ¶72**. Therefore, a PHOSITA would have recognized that the '433 patent discloses *a first major side surface which extends from the thin end portion to the thick end portion,* and *a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion,* as recited in the claims. **EX1008 Ochoa Decl. at ¶72.**

Claims 1 and 14: *a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion,*

Stone (the '433 patent) (**EX1006**) discloses:

- *See, e.g.,* **EX1006 at FIGs. 1A** and **2B**, as labeled below.

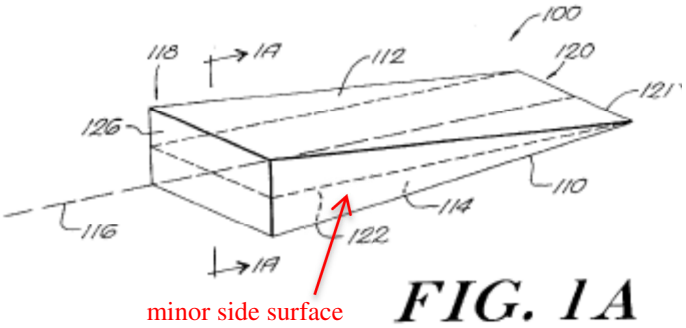


FIG. 1A

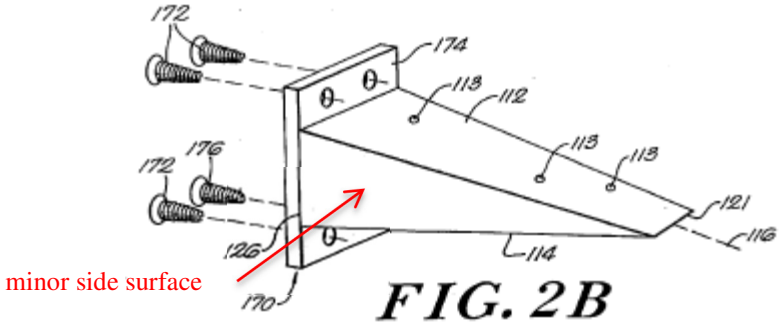
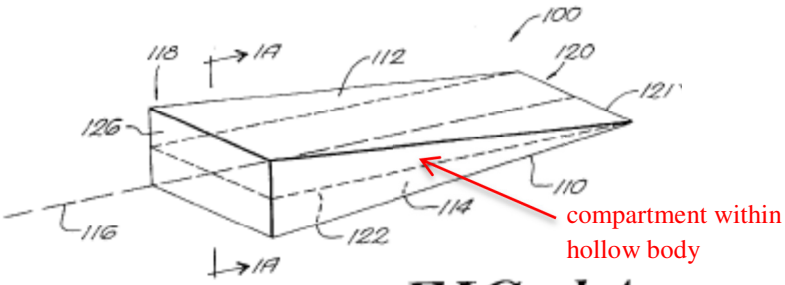
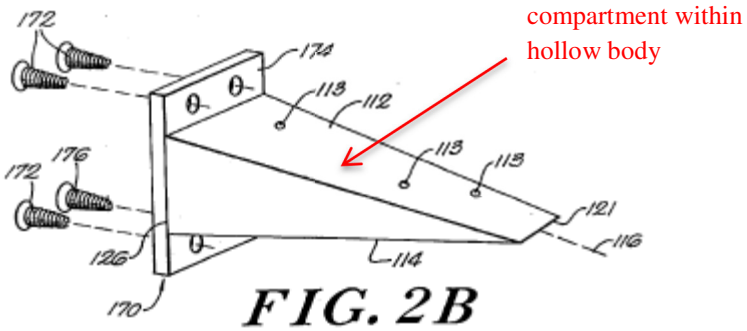


FIG. 2B

A PHOSITA would have understood that the wedge-shaped body (110) of the implantable spacer of Stone also includes opposite side surfaces. **EX1008 Ochoa Decl. at ¶73.**The height of the side walls vary along the profile of the body, tapering from the anterior thick end portion of the body to the posterior thin end portion. **EX1006 at FIGs. 1A** and **2B; EX1008 Ochoa Decl. at ¶73.** A PHOSITA would have recognized that Stone discloses *a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion*, as recited in the claims. **EX1008 Ochoa Decl. at ¶73.**

Claims 1 and [14]:

the wedge body [member] having a compartment containing a bone growth inducing material.
Stone (the '433 patent) (**EX1006**) discloses: • The body 110 of the device can be hollow and, accordingly, materials such as ground cancellous bone can be packed inside. A plurality of holes on the principal surface can facilitate packing of material within the body 110. **EX1006 at 7:9-14.** • *See, e.g.,* **EX1006 at FIGs. 1A** and **2B**, as labeled below.    FIG. 1A    FIG. 2B • The implant includes a wedge member having a compartment containing a bone growth inducing material. **EX1008 Ochoa Decl. at ¶74.**

A PHOSITA would have understood that Stone discloses an open hollow body that is designed to receive graft materials such as cancellous bone through a plurality of holes in the principal surface. **EX1006 at7:9-14, 47-54, FIGs. 1A** and **2B; EX1008 Ochoa Decl. at ¶74.** A PHOSITA would have understood that the cancellous bone in this would be used as a graft material to promote growth of bone through the holes on the principal surface. **EX1008 Ochoa Decl. at ¶74.** This

would create an area of contact between the surrounding bone and graft, thus providing an excellent milieu for arthrodesis. ***Id*.** Therefore, a PHOSITA would have understood that Stone discloses *the wedge body (or member) having a compartment containing a bone growth inducing material*, as recited in the claims. ***Id*.**

Thus, as set forth above and confirmed by Dr. Ochoa, Stone in view of Prewett renders claims 1 and 14unpatentable as obvious under 35 U.S.C. § 103(a).

2. Claims 10 and 23

Claims 10 and 23 depend, respectively, from claims 1 and 14 and are substantively identical. Claims 10 and 23 further describe device as including fastener means for connecting the body to at least one of the bones. Claims 10 and 23 are rendered obvious over Stone in view of Prewett, as follows:

'385 patent Claims 10 and 23 vs. Stone and Prewett
Claims 10 and [23]: *The device [implant] of claim 1 [14] further including fastener means for fixedly connecting the wedge body [member] to at least one of the first and second bones.*
Stone (the '433 patent) (**EX1006**) discloses: • *See* claim 14, above. • The device can be secured with a screw and plate system 170, as illustrated in FIG. 2B. Screws 172 can be screwed through plate 174 and into the body 110. Additional screws 176 can be screwed through the plate 174 and through the cortical bone into the cancellous bone. **EX1006 at 6:64-7:2; FIG. 2B.** • *See*, *e.g.,* **EX1006 at FIG. 2B**, below.

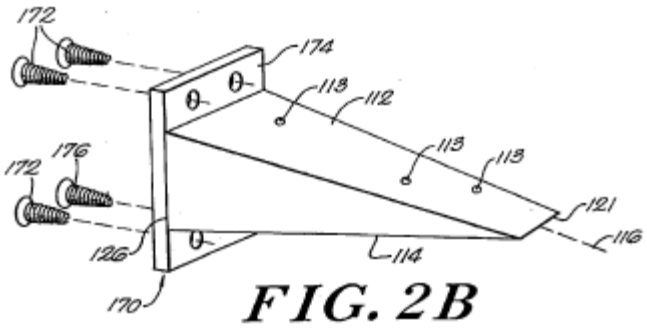


FIG. 2B

- The implant includes fastener means for fixedly connecting the wedge body to at least one of the first and second bones. **EX1008 Ochoa Decl. at ¶75.**

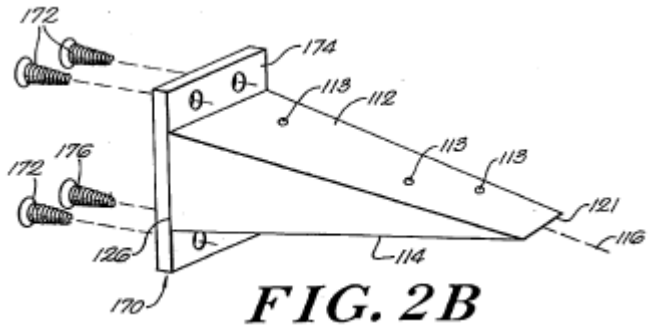
A PHOSITA would have understood that the implantable spacer disclosed in Stone can be secured to the neighboring bone using a plate and screw system (170, 172, 174, 176). **EX1006 at 6:64-7:2; FIG. 2B; EX1008 Ochoa Decl. at ¶75.** Screws 172 can be screwed through plate 174 and into the body 110. **EX1006 at 6:64-7:2; FIG. 2B.** Additional screws 176 can be screwed through the plate 174 and through the cortical bone into the cancellous bone. ***Id.*** A PHOSITA would have also understood a screw is a fastener and that the use of screw and plate systems would provide fixation to the neighboring bone to reduce micromotion and facilitate healing. **EX1008 Ochoa Decl. at ¶75.**

Therefore, a PHOSITA would have understood that Stone discloses a *fastener means for fixedly connecting the wedge body(or member) to at least one of the first and second bones*, as recited in the claims. ***Id.***

In summary, and as confirmed by Dr. Ochoa, Stone in view of Prewett renders claims 10 and 23 unpatentable as obvious under 35 U.S.C. § 103(a).

3. Claims 11 and 24

Claims 11 and 24 depend, respectively, from claims 1 and 14 and are substantively identical. Claims 11 and 24 further describe the fastener means of the device as including a screw. Claims 11 and 24 are rendered obvious over Stone in view of Prewett, as follows:

'385 patent Claims 11 and 24 vs. Stone and Prewtt
Claims 11 and [24]: *The device of claim 10 [23] wherein the fastener means includes at least one screw.*
Stone (the '433 patent) (**EX1006**) discloses: • *See* claim 23, above. • The device can be secured with a screw and plate system 170, as illustrated in FIG. 2B. Screws 172 can be screwed through plate 174 and into the body 110. Additional screws 176 can be screwed through the plate 174 and through the cortical bone into the cancellous bone. **EX1006 at 6:64-7:2; FIG. 2B.** • *See*, *e.g.,* **EX1006 at FIG. 2B**, below.    FIG. 2B • The fastener means of the implant includes at least one screw. **EX1008 Ochoa Decl. at ¶76.**

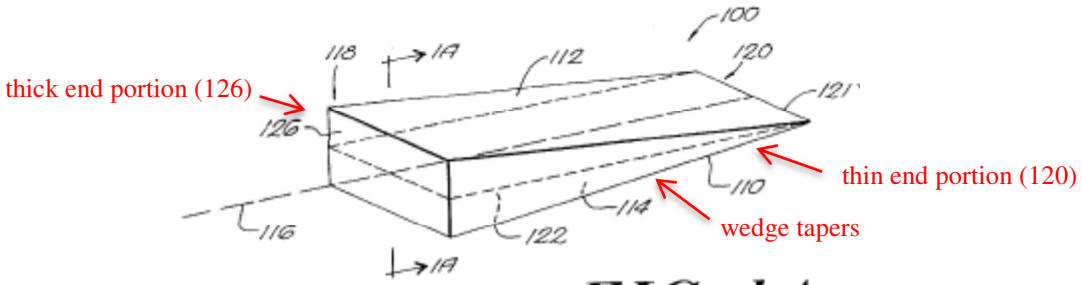
As discussed above, a PHOSITA would have understood that the implantable spacer disclosed in Stone can be secured to the neighboring bone using

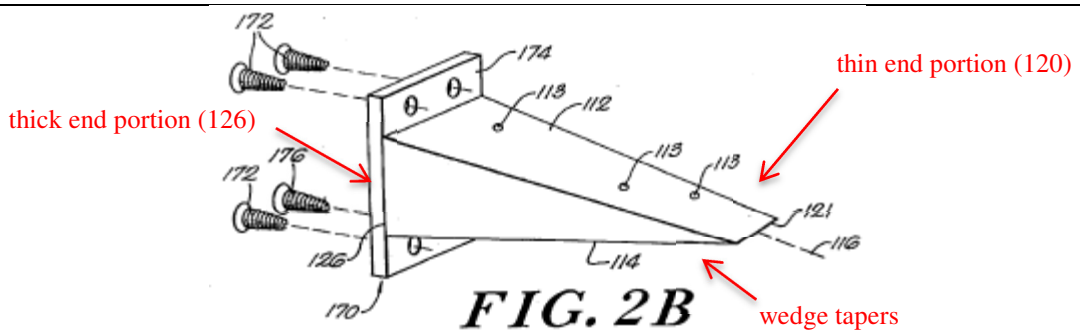
a plate and screw system (170, 172, 174, 176). **EX1006 at 6:64-7:2; FIG. 2B; EX1008 Ochoa Decl. at ¶76,** and that screws 176 can be screwed through the plate 174 and through the cortical bone into the cancellous bone. **EX1006 at 6:64-7:2; FIG. 2B.**

Therefore, a PHOSITA would have understood that Stone discloses a *fastener means* that *includes at least one screw*, as recited in the claims. **EX1008 Ochoa Decl. at ¶76.**

4. Claim 26

Claim 26 depends from claim 14 and further describes geometric feature of the wedge member. Claim 26 is rendered obvious over Stone in view of Prewett, as follows:

'385 patent Claim 26 vs. Stone and Prewett
The implant of claim 14 wherein the wedge member tapers from the thick end portion to the thin end portion.
Stone (the '433 patent) (**EX1006**) discloses: • *See* claim 14, above. • *See, e.g.,* **EX1006 at FIGs. 1A** and **2B**, as labeled below.    *FIG. 1A*



- The implant includes a wedge member that tapers from the thick end portion to the thin end portion. **EX1008 Ochoa Decl. at ¶71.**

A PHOSITA would have understood that Stone discloses an implantable spacer having a wedge-shaped body (110). **EX1008 Ochoa Decl. at ¶71.** A PHOSITA would have understood that the wedge-shaped body (110) of the implantable spacer has two angularly offset principal surfaces (112, 114) that extend from a drive surface (126) at the thick, drive end portion of the device (118) to intersect at a thin end portion at the vertex (121). **EX1006 at 5:27-40, FIGs. 1A, 2B; EX1008 Ochoa Decl. at ¶70.** A PHOSITA would have understood the figures to illustrate that the wedge-shaped body tapers from the thick end portion (126) to the thin end portion (120). **EX1008 Ochoa Decl. at ¶71.** A PHOSITA, therefore, would have understood that Stone discloses that *the wedge member tapers from the thick end portion to the thin end portion*, as recited in the claims. ***Id.***

In summary, as confirmed by Dr. Ochoa, Stone in view of Prewett renders claims 1, 10, 11, 14, 23, 24 and 26 unpatentable as obvious under 35 U.S.C. § 103(a).

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1, 10, 11, 14, 23, 24 and 26 of the '385 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '385 patent.

Dated: June 4, 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. 7,001,385 (and accompanying Exhibits **EX1001-EX1023**) to be served via FedEx, next day delivery, on patent owner at the following correspondence address of record for the subject patent, on this 4th day of June, 2015:

Paul D. Bianco
Fleit Gibbons Gubman 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 4th day of June, 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.