**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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GLOBUS MEDICAL, INC.,
Petitioner

v.

BONUTTI SKELETAL INNOVATIONS LLC,
Patent Owner

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

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

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EX1028 Claim chart – Claim 105 vs. U.S. Patent No. 6,008,433 and U.S. Patent No. 5,298,254

## 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 8, 9, 46, 49, 105, 107, 109, and 111 of U.S. Patent No. 6,099,531, entitled "Changing Relationship Between Bones" ("the '531 patent), issued to Peter M. Bonutti and assigned to Bonutti Skeletal Innovations LLC ("Bonutti"). The '531 patent is attached as **EX1001**.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The grounds for unpatentability presented in detail, below, demonstrate how each of the challenged claims is anticipated and/or rendered obvious in view of the prior art. Evidentiary support for Petitioner's conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **EX1011.** Dr. Ochoa is an expert with over 25 years of experience in the area of design and development of orthopedic medical devices, surgical instruments and techniques, as well as biomechanics, and engineering biomaterials. Dr. Ochoa's declaration establishes that each of the challenged claims is rendered obvious in view of the prior art and confirms all of Petitioner's assertions of unpatentability. Petitioner submits that this Petition demonstrates a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. 35 U.S.C. §314(a).

Accordingly, Petitioner respectfully requests that this Petition be granted and that claims 8, 9, 46, 49, 105, 107, 109, and 111 of the '531 patent be 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)<br>HARNESS, DICKEY & PIERCE, P.L.C.<br>5445 Corporate Dr., Suite 200<br>Troy, MI 48098<br>248-641-1600 (telephone)<br>248-641-0270 (facsimile)<br>gdmoustakas@hdp.com | David P. Utykanski (Reg. No. 39,052)<br>HARNESS, DICKEY & PIERCE, P.L.C.<br>5445 Corporate Dr., Suite 200<br>Troy, MI 48098<br>248-641-1600 (telephone)<br>248-641-0270 (facsimile)<br>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 '531 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 '531 patent. *See* **EX1002.**

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 '531 patent through continuation practice. Also concurrently with this Petition, Petitioner is filing a Petition for *inter partes* review of U.S. Patent No. 6,423,063 ("the '063 patent"). The '063 patent is also related to the '531 patent through continuation practice. Petitioner understands that the '531 patent, the '385 patent, and the '063 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 '531 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 '531 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. 6,099,531 ("THE '531 PATENT") (EX1001)

The '531 patent issued on August 8, 2000, on an application filed on August 20, 1998. The earliest priority date for the '531 patent is its filing date.

### A. The '531 Patent Specification and Claims

The '531 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 '531 Patent issued with 129 claims, of which only claims 8, 9,

46, 49, 105, 107, 109, and 111 are at issue in this Petition. Claims 8, 46, 105, and 107 are independent, and each of claims 9, 49, 109, and 111 is dependent either directly or indirectly from one of claims 8, 46, 105, and 107.

The written description and drawings of the '531 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. Claims 8, 9, 46, 49, 107, 109, and 11 of the '531 Patent are directed to a method for inserting the wedge member 44 into the joint 34 by applying force to the upper and lower bones 30,32 to expand the joint 34. The wedge member 44 is used to apply force to the bones 30, 32 and pivot the upper bone 30 about an axis extending through the joint 34 such that the wedge member 44 can be inserted between the bones 30, 32 with a thin end portion 52 of the wedge member 44 leading and a thick end portion 50 of the wedge member 44 trailing. An upper surface 54 on the wedge member 44 slides along an outer surface 88 of the upper bone 30 and a lower surface 56 on the wedge member 44 slides along an outer surface 90 of the lower bone 32 while the wedge member 44 moves into the joint 34. The wedge member 44 is not rotated relative to the joint 34. A fastener member 70, 72 may be used to fix the wedge member 44 to at least one of the bones 30, 32. The force between the wedge member 44 and each of the bones 30, 32 maintains the joint 34 in the expanded condition.

Claim 105 is directed to the wedge member 44 used in the method recited in Claims 8, 9, 46, 49, 107, 109, and 11 of the '531 Patent. The wedge member 44a includes a thin end portion 52a and a thick end portion 50a. A first major side surface (or upper surface) 54a and a second major side surface (or lower surface) 56a each extend from the thin end portion 52a to the thick end portion 50a. A minor surface (or outer surface) 60a extends between the first and second major side surfaces 54a, 56a. The wedge member 44a tapers from the minor surface 60a and thick end portion 50a to the thin end portion 52a. The wedge member 44a is porous so that bone can grow through the wedge member 44a. The porous construction is provided by having passages that extend through the wedge member 44a between the first and second major side surfaces 54a, 56a.

**B. The '531 Patent Prosecution History (EX1003)**

Application No. 09/137,443, now the '531 Patent, was filed on August 20, 1998. Only a single office action issued during the prosecution history of the '531 Patent. See '531 Patent File History, Office Action mailed August 20, 1999. An Amendment was then filed responding to the Office Action on October 26, 1999. In the Amendment, Claims 1-32 and 40-51 were cancelled and no other amendments were made.

It appears that the Applicant successfully argued that Claim 8 (formerly Claim 52) was allowable over Pavlov et al. (U.S. Pat. No. 5,906,616), Michelson

(U.S. Pat. No. 5,609,635), and Salib et al. (U.S. Pat. No. 5,258,031) based on the method step of "pivoting the first bone about an axis which extends through the joint interconnecting the first and second bones." **Exhibit EX1003, '531 Patent File History, Amendment dated October 26, 1999, page 41**. It appears that the Applicant successfully argued that Claim 46 (formerly Claim 90) was allowable over the prior art based on the method step of "moving the wedge member into the joint between the first and second bones without rotating the wedge member." ***Id*., page 56**. It appears that the Applicant successfully argued that Claim 105 (formerly Claim 149) was allowable over the prior art based on the following features of the wedge member: "a wedge member having first and second major side surfaces which intersect to form an edge at a thin end portion of the wedge member" and "a minor side surface which extends between the first and second major side surfaces and extends from the thick end portion to the thin end portion of the wedge member." ***Id*., page 74**. Lastly, it appears that the Applicant successfully argued that Claim 107 (formerly Claim 151) was allowable over the prior art based on the method step of "moving a leading end portion of a wedge member through the longitudinal central axis of the first bone and through the longitudinal central axis of the second bone." ***Id*., page 75**. The Examiner accepted these arguments and issued a Notice of Allowance on February 4, 2000.

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

As established in the Declaration of Dr. Ochoa (**EX1011** at ¶ 18), a person having ordinary skill in the art (PHOSITA) of the '531 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree, in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

## V. CLAIM CONSTRUCTION

The claims of the '531 patent are to be given their broadest reasonable construction in light of the '531 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 '531 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") (EX1004)

U.S. Patent No. 5,306,309 to Wagner et al., entitled "Spinal Disk Implant and Implantation Kit," issued April 26, 1994. Wagner is prior art to the '531 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 '531 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 '531 patent.

### B. U.S. Patent No. 4,904,261 to Dove et al. ("the '261 patent" or "Dove") (EX1005)

U.S. Patent No. 4,904,261 to Dove et al., entitled "Spinal Implants," issued February 27, 1990. Dove is prior art to the '531 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 '531 patent in the United States. Dove 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 '531 patent.

### C. French Patent Application No. FR 2,747,034 to Benezech et al. ("the FR'034 application" or "Benezech") (EX1006)[1]

French Patent Application No. FR 2,747,034 to Benezech et al., entitled

[1]A certified English translation of the specification of the FR'034 application is attached as **EX1007**.

"Intersomatic Setting and Fusion System," published October 10, 1997. The FR'034 application is prior art to the '531 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 of the '531 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 '531 patent.

### D. U.S. Patent No. 5,192,327 to Brantigan ("the '327 patent" or "Brantigan") (EX1008)

U.S. Patent No. 5,192,327, entitled "Surgical Prosthetic Implant for Vertebrae," issued March 9, 1993. Brantigan is prior art to the '531 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 '531 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 '531 patent.

### E. U.S. Patent No. 6,008,433 to Stone ("the '433 patent" or "Stone") (EX1009)

U.S. Patent No. 6,008,433, entitled "Osteotomy Wedge Device, Kit and Methods for Realignment of a Varus Angulated Knee," issued December 28, 1999 from an application filed in the United States on April 23, 1998. Stone is prior art to the '531 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 ‘531 patent. Stone 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 ‘531 patent.

### F. U.S. Patent No. 5,298,254 to Prewett et al. (“the ‘254 patent or “Prewett”) (EX1010)

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 ‘531 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 ‘531 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 ‘531 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 8, 9, 46, 49, 105, 107, 109 and 11 of the ‘531 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. Of these challenged claims, claims 8, 46, 105 and 107 are independent. Claim 9 depends from claim 8; claim 49 depends from claim 46; and claims 109 and 111 depend from claim 107. In summary, and as established by the declaration of Dr. Ochoa, Wagner renders claims 8, 9, 107, 109 and 111 unpatentable as obvious under 35 U.S.C. § 103 (**EX1011 at ¶¶ 30, 32- 55, and 61-64**); Wagner in view of Dove renders claims 46 and 49 unpatentable as

obvious under 35 U.S.C. § 103 (***Id.* at ¶¶ 30- 64**); the FR'034 application in view of Brantigan renders claim 105 unpatentable as obvious under 35 U.S.C. § 103 (***Id.* at ¶¶ 65-82**); and Stone in view of Prewett renders claim 105 unpatentable as obvious under 35 U.S.C. § 103 (***Id.* at ¶¶ 83-97**).

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

This petition presents the following Grounds of unpatentability:

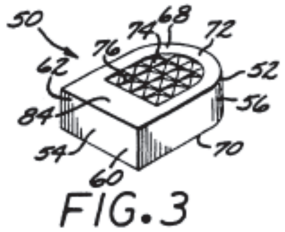
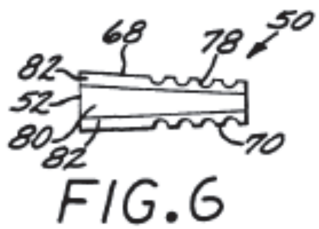
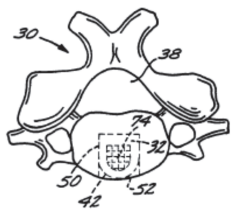
- Ground 1: Claims 8, 9, 107, 109, and 111 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (**EX1004**).
- Ground 2: Claims 46 and 49 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (**EX1004**) in view of Dove (**EX1005**).
- Ground 3: Claim 105 is unpatentable under 35 U.S.C. § 103(a) as obvious over the FR'034 application (**EX1006**) in view Brantigan (**EX1008**).
- Ground 4: Claim 105 is unpatentable under 35 U.S.C. § 103(a) as obvious over Stone (**EX1009**) in view Prewett (**EX1010**).

### A. Ground 1: Claims 8, 9, 107, 109, and 111 are unpatentable under 35 U.S.C. § 103(a) as obvious by Wagner (EX1004)

Wagner discloses a spinal implant device for use in spinal fusion surgical procedures, **EX1004 at Abstract**; **1:5-10, 2:47-52** and **FIGs. 3, 6 and 8; EX1011 at ¶30**, and a method for implanting an interbody cage during spinal fusion. **EX1011 at ¶30**. The spinal implant device ("spinal disk implant 50") of Wagner 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.***; **EX1004 at 6:63-68, FIGs. 3 and 6.** The body may be formed of a biodegradable material, preferably ceramic calcium hydroxylapatite. **EX1011 at ¶30; EX1004 at 6:13-26.** The Wagner implant is impacted into place between the vertebrae using a hammer and thereafter provides a load-bearing spacer. **EX1011 at ¶30; EX1004 at 8:57-9:2, 9:26-34.**

1. Claim 8

| **'531 patent Claim 8 vs. Wagner** |
|---|
| *A method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said method comprising the steps of* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• 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. **EX1011 at ¶30.**<br>• Wagner discloses a spinal disk implant 50 for surgically implanting between two vertebrae 30 to fuse them together. **EX1004 at Abstract**; **1:5-10** and **FIGs. 3, 6 and 8**.<br>  <br>FIG.3<br>  <br>FIG.6<br>FIG.8  <br>• 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. **EX1011 at ¶32**.

A PHOSITA would have understood that 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. **EX1011 at ¶32-33.** A PHOSITA would have also recognized that interbody cages are used to correct existing mechanical deformity of the spine. **EX1004 at Abstract**; **1:5-10, 2:47-52** and **FIGs. 3, 6 and 8; EX1011 at ¶32**. A PHOSITA, therefore, would have recognized that Wagner discloses *a method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body*, as recited in the claims. **EX1011 at ¶32**.

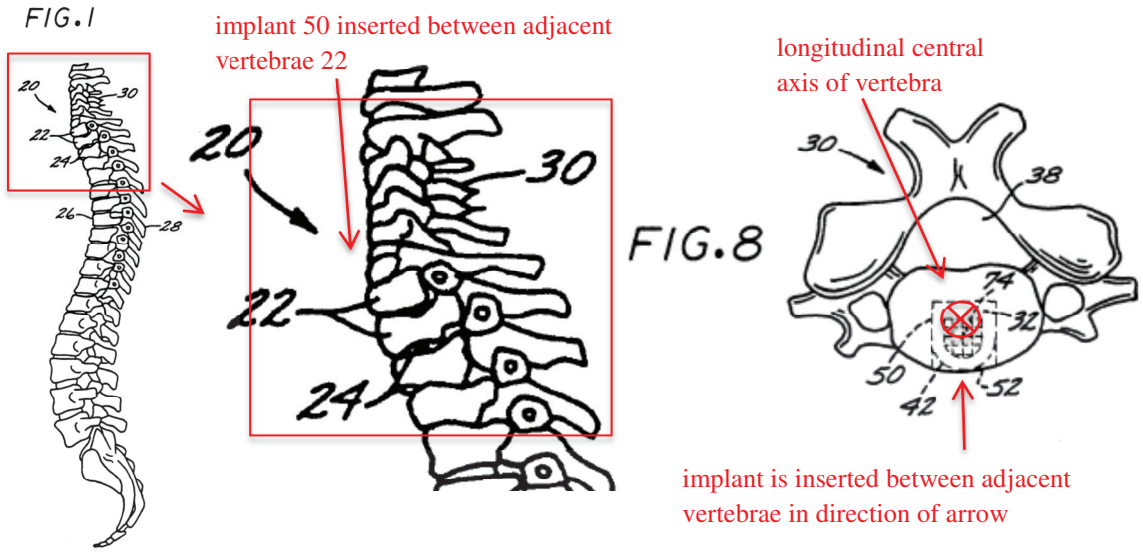
*forming an opening in a portion of the patient's body to expose the joint interconnecting the first and second bones,*

Wagner (the '309 patent) (**EX1004**) discloses:

- Wagner discloses a spinal disk implant 50 for surgically implanting between two vertebrae 30 to fuse them together. **EX1004 at Abstract**; **1:5-10** and **FIGs. 3, 6 and 8**.

A PHOSITA would have understood that implantation of the spinal implant device in the intervertebral space would require forming*, e.g.,* an abdominal surgical incision through the skin, abdominal muscles and potentially the

peritoneum to allow access to the vertebrae anteriorly. **EX1011 at ¶33**. The surgeon would use this surgical opening to access the spine and implant the device. ***Id.*** The surgical opening would then be closed at the conclusion of the procedure. ***Id.*** The step of creating a surgical access to the site of interest is fundamental to performance of an anterior fusion surgical procedure. ***Id.*** A PHOSITA would have considered the foregoing claim limitation(s) obvious and necessary in a spinal fusion surgical procedure. ***Id.***

| |
|---|
| *moving the second bone relative to the first bone, said step of moving the second bone relative to the first bone includes expanding at least a portion of the joint interconnecting the first and second bones by applying force against the first and second bones with a wedge member and pivoting the first bone about an axis which extends through the joint interconnecting the first and second bones,* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• 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. **EX1004 at 5:15-18.**<br>• The implant 50 is implanted between two vertebrae 22. ***Id.*** **at FIGs. 1** and **8,** as labeled below**.**<br>  |

- 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**.**

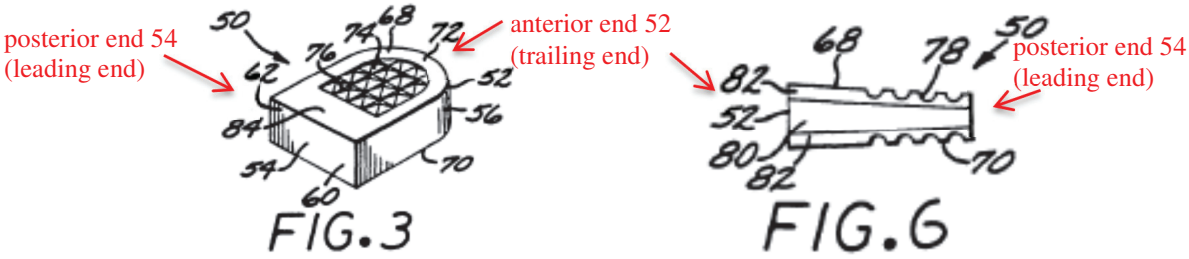
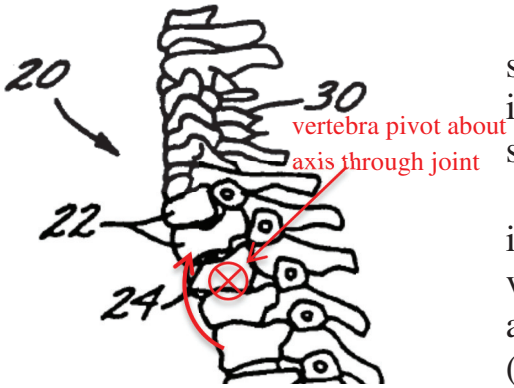



FIG.3 FIG.6

- 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**.
- 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. **EX1011 at ¶34.**




- Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae. **EX1011 at ¶35.**
- 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). **EX1011 at ¶35.**

A PHOSITA would have understood that Wagner discloses *moving the second bone* (second vertebra) *relative to the first bone* (first vertebra). **EX1011 at**

**¶37**. A PHOSITA would have also understood that Wagner describes an interbody cage with a generally wedge-shaped body from a thick end at its anterior or trailing end toward a thin end at its posterior or leading end. **EX1004 at 5:15-18; 6:63-68** and **FIGs. 3** and **6; EX1011 at ¶34.** A PHOSITA would have understood that Wagner discloses *a wedge member*, as recited in the claims. **EX1011 at ¶34.** A PHOSITA would have understood that the wedge-shaped spinal disk implant is implanted between first and second vertebrae (i.e. bones) using an anterior approach. **EX1004 at 5:15-18; FIGs. 1 and 8; EX1011 at ¶35.** 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. **EX1004 at 8:57-9:2; 9:26-34; EX1011 at ¶35.** Therefore a PHOSITA would have understood that Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae under force. **EX1011 at ¶35.** A PHOSITA would have also 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. ***Id.;*** **EX1004 at 8:57-9:2; 9:26-34.** A PHOSITA would have further understood that

during impaction, the tapered transverse faces (68, 70) would act as the first surface and second surface of an inclined plane (i.e. a wedge). **EX1011 at ¶36.** As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open (*i.e. expanding at least a portion of the joint*) 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. ***Id.;*** **EX1004 at 2:47-59.**

A PHOSITA would have understood that forcing the intervertebral space open with a wedge shaped device results in a combination of translational and rotational movement of the first vertebral body relative to the second vertebral body. **EX1011 at ¶37. 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 within the motion segment (i.e. the joint), posterior to the intervertebral space. ***Id.*** A PHOSITA would have understood that as the spinal implant device disclosed in Wagner 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), pivoting about an access which extends through the joint that connects the vertebrae. ***Id.*** Therefore, a PHOSITA would have understood that the foregoing claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

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| *closing the opening in the patient's body with at least a portion of the wedge member disposed between the first and second bones at the joint interconnecting the first and second bones, and,* |

A PHOSITA would have understood that the surgical opening would be closed at the conclusion of the spinal fusion procedure. ***Id.*** **at ¶38.** The step of closing the surgically created access at the conclusion of the surgery is fundamental to performance of an anterior fusion surgical procedure. ***Id.*** A PHOSITA would have considered the foregoing claim limitation(s) obvious and necessary in a spinal fusion surgical procedure. ***Id.***

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| *thereafter, transmitting force between the first and second bones through the wedge member to maintain the joint in the expanded condition.* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• The spinal disk implant is configured to engage the cortical bone region of |

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| the vertebrae after implantation, so that the majority of the loading transmitted through the implant is carried by the cortical bone. **EX1004 at 2:47-52.**<br>• 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.** |

A PHOSITA would have understood that the spinal disk implant that is inserted during a fusion procedure becomes a load bearing member in the intervertebral space, maintain the surgical correction and replacing the function of disk tissue removed during the procedure. **EX1004 at 1:66-2:4, 2:47-52, 5:15-23; EX1011 at ¶39**. As such, the forces encountered along the spinal column at the vertebrae are transmitted through the implant which maintains the restored condition of the implant at the intervertebral joint. **EX1011 at ¶39**. Therefore, a PHOSITA would have understood that Wagner discloses the foregoing step. ***Id.***

2. Claim 9

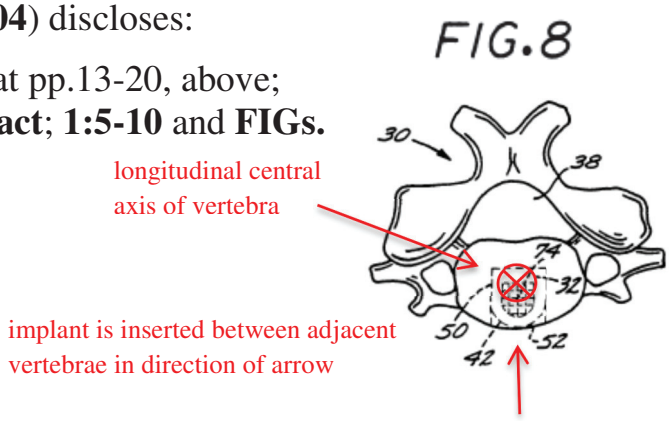
| **'531 patent Claim 9 vs. Wagner** |
|---|
| *A method as set forth in claim 8 wherein said step of applying force against the first and second bones with the wedge member includes sliding a first surface on the wedge member along an outer side surface on the first bone and sliding a second surface on the wedge member along an outer side surface on the second bone while moving the wedge member into the joint without rotating the wedge member relative to the joint.* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* claim 8, above; and *see* **EX1004 at 8:57-9:2, 9:26-34.** |

A PHOSITA would have understood that Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first

and second vertebrae under force. **EX1004 at 5:15-18, 8:57-9:2; 9:26-34, FIGs. 1 and 8; EX1011 at ¶40.** The insertion of the implant 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. **EX1011 at ¶40*;* EX1004 at 8:57-9:2; 9:26-34.** A PHOSITA would have further understood that during impaction, the tapered transverse faces (68, 70) would act as the first surface and second surface of an inclined plane (i.e. a wedge). **EX1011 at ¶41.** As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open and moving the vertebrae apart. ***Id.*** A PHOSITA would have understood that insertion of the spinal disk implant of Wagner would not require rotation of the implant. ***Id.*** Thus, a PHOSITA would have understood from the disclosure of Wagner that the wedge-shaped implant inserted between the adjacent vertebrae forces the vertebrae apart and expands a portion of the intervertebral joint by sliding the transverse faces 68, 70 of the implant 50 along outer side surfaces of the adjacent vertebrae 22 while moving the implant 50 into the joint without rotating the implant 50 relative to the joint. ***Id.*** **at**

**¶42.** A PHOSITA, then, would have understood that the foregoing claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

3. Claim 107

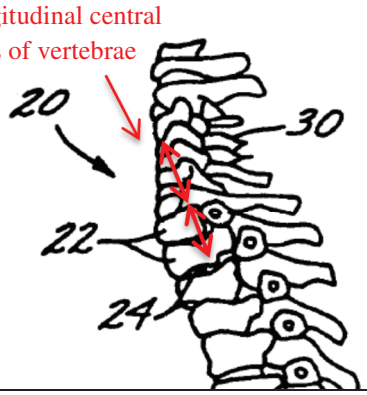
| **'531 patent Claim 107 vs. Wagner** |
|---|
| *A method of changing a spatial relationship between first and second bones having longitudinal axes which extend through a joint in a patient's body, said method comprising the steps of* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* discussion re. claim 8 at pp.13-20, above; and see, **EX1004 at Abstract**; **1:5-10** and **FIGs. 3, 6 and 8, 2:47-52.**<br>  <br> |

As already discussed at pp.17, a PHOSITA would have understood that the substantially wedge-shaped spinal disk implant of Wagner is implanted between the first and second vertebrae (i.e. bones) using an anterior approach. **EX1004 at Abstract**; **5:15-18** and **FIGs. 1 and 8; EX1011 at ¶43**. Further, a PHOSITA would have understood that the longitudinal axis of a vertebral body would run through the center of the vertebral body in a cephalad-caudal (superior-inferior) direction. **EX1011 at ¶43**. Therefore, a PHOSITA would have understood that Wagner discloses *a method of changing a spatial relationship between first and second bones having longitudinal axes which extend through a joint in a patient's body,* as recited in the claims. ***Id.***

*moving a wedge member into the joint, said step of moving the wedge member into the joint includes moving a leading end portion of the wedge member through the longitudinal central axis of the first bone and through the longitudinal central axis of the second bone, and*

Wagner (the '309 patent) (**EX1004**) discloses:

- *See* discussion re. claim 8 at pp.13-20, above; and see, **EX1004 at 5:15-18, FIGs. 1** and **8, 6:63-68** and **FIGs. 3** and **6.**
- Wagner discloses that implanting the spinal disk implant 50 between the adjacent vertebrae 22 in the spinal column 20 involves moving the posterior side 54 (*i.e.,* the leading end portion) of the implant 50 through the longitudinal central axis of the adjacent vertebra.**EX1011 at ¶44.**




A PHOSITA would have understood that the spinal disk implant (50) of Wagner is configured for insertion from the anterior approach, with a substantially wedge-shaped body having transverse faces (68, 70) that are tapered from the thin, leading posterior end (54) toward the thick, trailing anterior end (52). **EX1004 at 6:63-68** and **FIGs. 3** and **6; EX1011 at ¶44.** A PHOSITA would have understood that Wagner discloses implanting the spinal disk implant 50 between the adjacent vertebrae 22 in the spinal column 20 and involves moving the posterior side 54 (i.e., the leading end portion) of the implant 50 through the longitudinal central axes of the adjacent vertebra. **EX1011 at ¶44.** A PHOSITA, thus, would have understood that Wagner discloses the above claim limitation(s). ***Id.***

*moving the second bone relative to the first bone under the influence of force transmitted from the wedge member as the wedge member moves into the joint to change an angular relationship between the longitudinal central axes of the first and second bones from a first angular relationship in which the longitudinal*

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| *central axes of the first and second bones extend through the joint and are spaced from the wedge member to a second angular relationship in which the longitudinal central axes of the first and second bones extend through both the joint and the wedge member,* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* discussion re. claim 8 at pp.13-20, above; and see, **EX1004 at 8:57-9:2, 9:26-34, FIGs. 1, 8 and 14.** |

A PHOSITA would have understood that 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. **EX1004 at 8:57-9:2, 9:26-34; EX1011 at ¶45**. Therefore a PHOSITA would have understood that Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae under force. **EX1011 at ¶45**. 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. ***Id.;*** **EX1004 at 8:57-9:2, 9:26-34.** A PHOSITA would have further understood that during impaction, the tapered transverse faces (68, 70) would act as the first surface and second surface of an inclined plane (i.e. a wedge). **EX1011 at ¶46**. As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be

resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open (*i.e. expanding at least a portion of the joint*) and moving the vertebrae apart. ***Id.***

A PHOSITA would have understood that forcing the intervertebral space open with a wedge shaped device results in a combination of translational and rotational movement of the first vertebral body relative to the second vertebral body. ***Id.*** **at ¶47**. 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 within the motion segment (i.e. the joint), posterior to the intervertebral space. ***Id.*** A PHOSITA would have understood that as the spinal implant device disclosed in Wagner is implanted between adjacent vertebrae, it forces one vertebra to move from a first angular relationship relative to the other vertebra (*e.g.,* a degenerated condition) to a second angular relationship relative to the other vertebra (*i.e.,* a restored condition). ***Id.*** A PHOSITA would have understood from the disclosure of Wagner that as the implant 50 is inserted between the adjacent vertebrae in the spinal column 20, the implant 50 forces the vertebrae apart and causes a second vertebra

to move relative to a first vertebra and change the angular relationship (lordosis/kyphosis) between the longitudinal central axes of the first and second vertebrae from a first angular relationship, in which the longitudinal central axes of the first and second vertebrae extend through the joint and are spaced from the wedge member to a second angular relationship in which the longitudinal central axes of the first and second bones extend through both the joint and the wedge member. ***Id.*** **at ¶48**. Thus, a PHOSITA would have understood that the above claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

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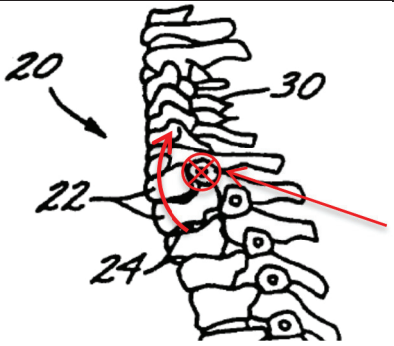
| *said step of moving the second bone relative to the first bone includes applying force against a surface area on the first bone and against a surface area on the second bone with the wedge member as the wedge member moves into the joint.* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* discussion re. claim 8 at pp.13-20, above; and see, **EX1004 at 8:57-9:2, 9:26-34.** |

A PHOSITA would have understood that during implantation, the tapered transverse faces (68, 70) would act as the first surface and second surface of an inclined plane (i.e. a wedge). **EX1011 at ¶49**. As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the surface area of the faces of the first and second vertebrae at which the

device is implanted, forcing the intervertebral space open (*i.e. expanding at least a portion of the joint*) and moving the vertebrae apart. ***Id.*** A PHOSITA would have understood from the disclosure of Wagner that the wedge-shaped implant 50 inserted between the adjacent vertebrae applies force against a surface area on the first vertebra and against a surface area on the adjacent vertebra as the implant 50 moves into the joint between the vertebrae. ***Id.*** Therefore, a PHOSITA would have understood that the above claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

4. Claim 109

| **'531 patent Claim 109 vs. Wagner** |
|---|
| *A method as set forth in claim 107 wherein the step of moving the second bone relative to the first bone includes pivoting the second bone about an axis which extends through the joint in a direction transverse to the longitudinal central axes of the first and second bones.* |
|  <br>vertebra pivot about axis through joint<br><br>Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* claim 107, above and see, **EX1004 at 5:15-18, 6:63-68, FIGs. 1, 3, 6, 8, 14.** |

A PHOSITA would have understood that during implantation, the wedge-shaped spinal disk implant of Wagner would force the intervertebral space open resulting in a combination of translational and rotational movement of the first vertebral body relative to the second vertebral body. **EX1004 at ¶50.** 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 within the motion segment (i.e. the joint), posterior to the intervertebral space. ***Id.*** A PHOSITA would have understood that the resulting rotation occurs about the axis of spinal flexion. ***Id.*** This axis extends in the medial to lateral direction and as such, is transverse to the longitudinal axes running in the cephalad-caudal (superior-inferior) direction through the vertebral bodies. ***Id.*** Therefore, a PHOSITA would have understood that the foregoing claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

5. Claim 111

| **'531 patent Claim 111 vs. Wagner** |
|---|
| *A method as set forth in claim 107 wherein said step of applying force against the surface areas on the first and second bones with the wedge member includes sliding the wedge member along the surface on the first bone and sliding the wedge member along the surface on the second bone without rotating the wedge member relative to the joint.* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* claim 107, above and see, **EX1004 at 8:57-9:2, 9:26-34, FIG. 14.** |

A PHOSITA would have understood that during implantation, the wedge-shaped spinal disk implant of Wagner is moved into the intervertebral joint between the first and second vertebrae under force. **EX1011 at ¶51.** A PHOSITA would have further understood that during impaction, the tapered transverse faces (68, 70) would act as the first surface and second surface of an inclined plane (i.e. a

wedge). ***Id.*** **at ¶52.** As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the surface area of the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open (*i.e. expanding at least a portion of the joint*) and moving the vertebrae apart. ***Id.*** A PHOSITA would have understood based on the anatomic relationship between the vertebrae, the insertion tool design and the use of an anterior surgical approach, that insertion of the spinal disk implant of Wagner would not require rotation of the implant. ***Id.*** Therefore, PHOSITA would have understood from the disclosure of Wagner that the wedge-shaped spinal disk implant 50 inserted between the adjacent vertebrae forces the vertebrae apart and expands a portion of the intervertebral joint by sliding the transverse faces 68, 70 of the implant 50 along outer side surfaces of the adjacent vertebrae 22 while moving the implant 50 into the joint without rotating the implant 50 relative to the joint. ***Id.*** Therefore, a PHOSITA would have understood that the foregoing claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

### B. Ground 2: Claims 46 and 49 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wagner (the '309 patent) (EX1004) in view of Dove (the '261 patent) (EX1005)

1. Claim 46

| **‘531 patent Claim 46 vs. Wagner and Dove** |
|---|
| *A method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said method comprising the steps of* |
| Wagner (the ‘309 patent) (**EX1004**) discloses:<br>• *See* discussion re. claim 8 at pp. 13-14, above; and see, **EX1004 at Abstract**; **1:5-10** and **FIGs. 3, 6 and 8, 2:47-52.** |

As already discussed at pp. 13-14, a PHOSITA would have understood that Wagner discloses *a method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body*. **EX1011 at** ¶32.

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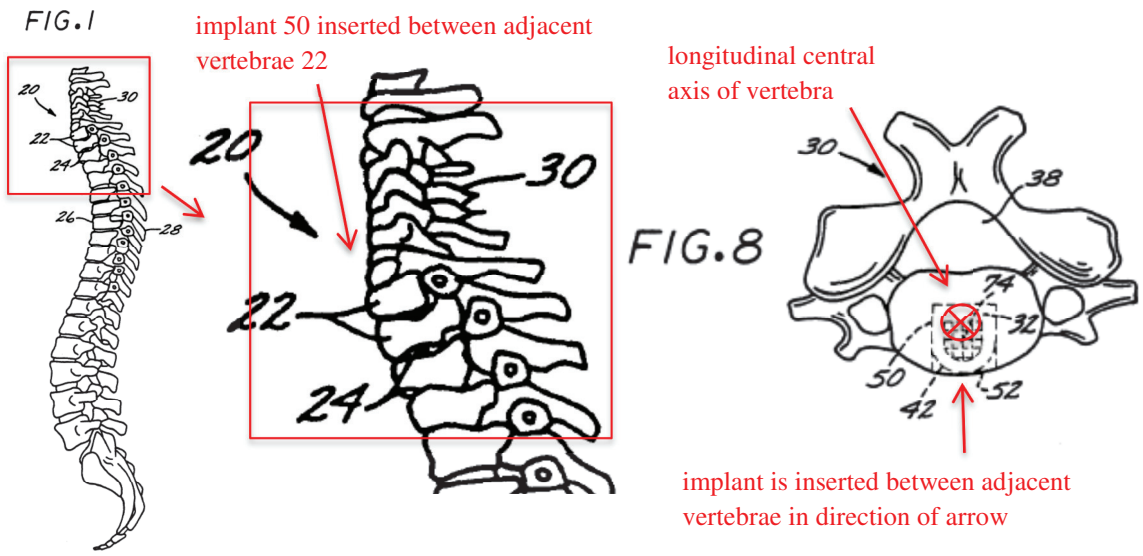
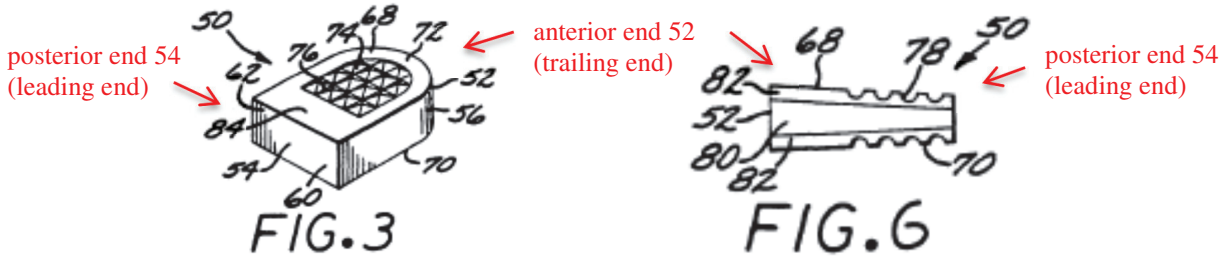
|---|
| *moving a wedge member into the joint between the first and second bones without rotating the wedge member and with a thin end portion of the wedge member leading and a thick end portion of the wedge member trailing,* |
| Wagner (the ‘309 patent) (**EX1004**) discloses:<br>• A spinal disk implant 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. **EX1004 at 5:15-18.**<br>• The implant 50 is implanted between two vertebrae 22. ***Id.*** **at FIGs. 1** and **8,** as labeled below**.** |




- 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 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. **EX1011 at ¶53.**
- Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae. **EX1011 at ¶53.**

A PHOSITA would have understood that the substantially wedge-shaped spinal disk implant of Wagner is implanted between the first and second vertebrae (i.e. bones) using an anterior approach. **EX1004 at 5:15-18, FIGs. 1** and **8; EX1011 at ¶53.** A PHOSITA would have understood that the spinal implant device ("spinal disk implant 50") of Wagner is configured for insertion from the

anterior approach, with a substantially wedge-shaped body having transverse faces (68, 70) that are tapered from the thin leading posterior end (54) toward the thick trailing anterior end (52). **EX1004 at 6:63-68** and **FIGs. 3** and **6; EX1011 at ¶53.** A PHOSITA would have understood that insertion of the spinal disk implant of Wagner, based on the anatomic relationship between the vertebrae, the insertion tool design and the use of an anterior surgical approach, would not require rotation of the implant. **EX1011 at ¶53.** A PHOSITA would have understood from the disclosure of Wagner that implanting the spinal disk implant 50 between the adjacent vertebrae 22 in the spinal column 20 involves moving the posterior side 54 (i.e., the leading end portion) of the implant 50 first. ***Id.*** A PHOSITA would have understood that Wagner discloses the above claim limitation(s). ***Id.***

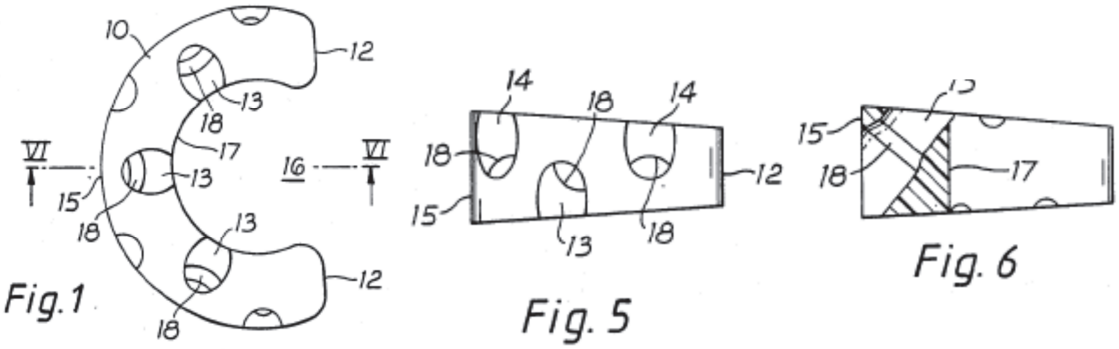
| *applying force against the first and second bones with the wedge member as the wedge member is moved into the joint to move the second bone from a first orientation relative to the first bone to a second orientation relative to the first bone,* |
|---|
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• 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. **EX1004 at 8:57-9:2**.<br>• 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**.

A PHOSITA would have understood that the substantially wedge-shaped spinal disk implant of Wagner is implanted between the first and second vertebrae (i.e. bones) using an anterior approach. **EX1004 at Abstract**; **5:15-18** and **FIGs. 1 and 8; EX1011 at ¶54**. 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. **EX1004 at 8:57-9:2, 9:26-34; EX1011 at ¶54**. Therefore a PHOSITA would have understood that Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae under force. **EX1011 at ¶54**. 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. ***Id.;*** **EX1004 at 8:57-9:2, 9:26-34.** A PHOSITA would have further understood that during impaction, the tapered transverse faces (68, 70) would act as the first and second surfaces of an inclined plane (i.e. a wedge). **EX1011 at ¶54**. As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-

frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open (*i.e. expanding at least a portion of the joint*) and moving the vertebrae apart. ***Id.*** A PHOSITA would have understood that forcing the intervertebral space open with a wedge shaped device results in a combination of translational and rotational movement of the first vertebral body relative to the second vertebral body. ***Id.*** **at ¶55**. 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 within the motion segment (i.e. the joint), posterior to the intervertebral space. ***Id.*** A PHOSITA would have therefore have understood from the disclosure of Wagner that as the spinal disk implant 50 is inserted between the adjacent vertebrae in the spinal column 20, the implant 50 forces the vertebrae apart and causes a second vertebra to move relative to a first vertebra and change the orientation between the first and second vertebrae (*e.g.,* lordosis/kyphosis) such that a vertebra (second bone) is moved from a first orientation relative to the adjacent vertebra (a first bone) to a second orientation relative to the adjacent vertebra. ***Id.*** Consequently, a PHOSITA would have understood that the foregoing claim limitation(s) would have occurred during

implantation of the Wagner device. ***Id.***

| *fixedly connecting the wedge member to at least one of the first and second bones with a fastener member, and* |
|---|
| Dove (the '261 patent) (**EX1005**), however, discloses:<br>• A spinal implant, e.g., to replace an excised disc, that comprises a rigid generally horseshoe shape of biocompatible material, such as carbon-fiber reinforced plastics, having upper and lower planar faces (10, 11) converging towards the ends (12) of the horseshoe, and at least one hole (13, 14) from each planar face (10, 11) emerging in the outer curved face (15) of the horseshoe, to enable the horseshoe to be fixed by screws inserted through one or more selected holes in each plurality (13, 14) from the ends in the outer curved face (15) into respective adjacent vertebrae. **EX1005 at Abstract** and **FIGs. 1, 5** and **6.**<br>  <br><br>Fig. 1 Fig. 5 Fig. 6<br>• The "horseshoe" spinal implant shown in the drawings is intended to be contained substantially within the confines of the anterior vertebral column and act as a spacer between adjacent vertebrae at the peripheries of the ends thereof which are structurally the strongest parts. **EX1005 at 2:3-8.**<br>• The implant has upper and lower planar faces 10, 11 respectively converging towards the ends 12 of the horseshoe, and pluralities of holes 13, 14 respectively are provided from each planar face (10, 11 respectively) emerging in the outer curved face 15 of the horseshoe, to enable the horseshoe to be fixed between adjacent vertebrae (not shown) as by fixation screws (not shown) inserted through one or more selected holes in each plurality, from the ends of the holes in the outer curved face 15 and into the respective vertebrae. **EX1005 at 2:9-19.**<br>• Each hole 13, 14 has a shoulder 18 (between portions of slightly different diameter) against which the head of a screw can bear. **EX1005 at 2:23-25.** |

- Dove discloses connecting the wedge member to at least one of the first and second bones with a fastener member. **EX1011 at ¶56.**

A PHOSITA would have understood that Dove discloses a wedge shaped anterior spinal implant for use in spinal fusion surgical procedures. **EX1005 at Abstract, 2:3-8** and **FIGs. 1, 5** and **6; EX1011 at ¶56.** A PHOSITA would have understood that the spinal implant of Dove may be fixed to the adjacent vertebrae using screws inserted through a plurality of holes (13, 14) from the curved outer face (15) into the respective vertebrae. **EX1005 at 2:9-19; EX1011 at ¶56.** Each screw head would bear upon a countersunk shoulder (18). **EX1005 at 2:23-25; EX1011 at ¶56.** A PHOSITA would have understood that Dove discloses connecting the wedge member to at least one of the first and second bones with a fastener member. **EX1011 at ¶56.** Therefore, a PHOSITA would have understood that Dove discloses, *fixedly connecting the wedge member to at least one of the first and second bones with a fastener member*, as claimed. ***Id.***

A PHOSITA would have been motivated to look to the teachings of Wagner, Dove 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] ***Id.*** **at ¶57.** A PHOSITA would have been motivated to

[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

apply the teachings of Dove to those of Wagner because both Dove and Wagner disclose an implantable orthopedic device for use in a spinal fusion surgical procedures that change the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint in a patient.[3] ***Id.*** **at ¶58.** It would have been recognized by a PHOSITA that the spine disk implants of Dove and Wagner both correct existing mechanical deformity, provide mechanical stability, and provide a suitable environment for arthrodesis through the use of an interbody spacer in conjunction with either natural or synthetic bone graft materials. ***Id.*** **at ¶59.** Therefore, the applicability and advantage of adding a plurality of holes to enable the use of fixation screws disclosed in Dove when applied to the device of Wagner would have been readily apparent to a PHOSITA. ***Id.*** A PHOSITA would have understood that Wagner teaches that dislocation of the implant leads to unsatisfactory results and further teaches the importance of providing an implant that is configured to provide a reliable and secure load path that can securely hold its position post operatively and minimize motion at the interfaces. **EX1005 at 2:55-59, 4:15-18; EX1011 at ¶59.** A PHOSITA would have understood, then, that the use of screw fixation taught in Dove would be supplemental and

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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).

complementary to the features taught in Wagner. **EX1011 at ¶59.** A PHOSITA, therefore, would have been motivated, in view of the combined teachings of Wagner, and '261 patent, to include a step of *fixedly connecting the wedge member to at least one of the first and second bones with a fastener member* in the method for implantation of the spinal implant of Wagner to provide additional fixation. ***Id.*** **at ¶60.** A PHOSITA would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting method.[4] ***Id.*** **at ¶61.** This modification would not have changed the principle of operation of the spinal implant of Wagner.[5] ***Id.***

| *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.* |
|---|
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* discussion re. claim 8 at pp.13-14 above, and see **EX1004 at 2:47-52, 5:15-23.** |

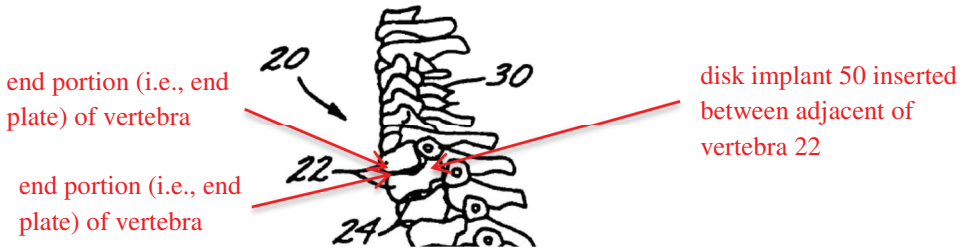
A PHOSITA would have understood that the spinal disk implant that is inserted during a fusion procedure becomes a load bearing member in the intervertebral space, maintaining the surgical correction and replacing the function of disk tissue removed during the procedure. **EX1004 at 1:66-2:4, 2:47-52, 5:15-**

[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).

**23; EX1011 at ¶62**. As such, the forces encountered along the spinal column at the vertebrae are transmitted through the implant which maintains the restored condition of the implant at the intervertebral joint. **EX1011 at ¶62**. A PHOSITA would have understood that Wagner discloses the above claim limitation(s). ***Id.***

2. Claim 49

| **'531 patent Claim 49 vs. Wagner and Dove** |
|---|
| *A method as set forth in claim 46 wherein said step of moving the wedge member into the joint between the first and second bones includes moving the wedge member along a path which extends between an end portion of the first bone and an end portion of the second bone and* |
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* claim 46, above and see **EX1004 at 5:15-18, FIGs. 1** and **8**.<br>  <br> |

A PHOSITA would have understood that the substantially wedge-shaped spinal disk implant of Wagner is implanted between the first and second vertebrae (i.e. bones) using an anterior approach. **EX1004 at 5:15-18, FIGs. 1** and **8; EX1011 at ¶63.** 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. **EX1004 at 8:57-9:2, 9:26-34; EX1011 at ¶63.** As the implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces (end portions)

of the first and second vertebrae at which the device is implanted along a path between the endplates of the first and second adjacent vertebrae. **EX1011 at ¶63.** Therefore, a PHOSITA would have understood that Wagner discloses the above claim limitation(s). ***Id.***

| *increasing a distance between a surface area on the end portion of the first bone and a surface area on the second bone under the influence of force transmitted from the wedge member to the end portions of the first and second bones.* |
|---|
| Wagner (the '309 patent) (**EX1004**) discloses:<br>• *See* claim 46, above and see **EX1004 at 9:26-34.** |

A PHOSITA would have understood that during implantation, the substantially wedge-shaped spinal disk implant of Wagner 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. **EX1004 at 8:57-9:2, 9:26-34; EX1011 at ¶64.** Therefore a PHOSITA would have understood that Wagner discloses moving the wedge-shaped spinal implant device into the intervertebral joint between the first and second vertebrae under force. **EX1011 at ¶64.** A PHOSITA would have further understood that during impaction, the tapered transverse faces (68, 70) would act as the first surface and second surface of an inclined plane (i.e. a wedge). ***Id.*** As such, the axial anteroposterior impaction forces applied to the anterior end of the device would be resisted by a combination of tangential-frictional and normal forces at the interface between the device and bone. ***Id.*** As the implant advances, sliding posteriorly in the intervertebral space,

the first and second surfaces of the wedge shaped body engage the surface area of the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open (*i.e. expanding at least a portion of the joint*) and moving the vertebrae apart. ***Id.*** A PHOSITA would have understood from the disclosure of Wagner that the tapered (*i.e.,* wedge-shaped) spinal disk implant 50 inserted between the adjacent vertebrae applies force against a surface area on the first vertebra and against a surface area on the adjacent vertebra as the implant 50 moves into the joint between the vertebrae during implantation. ***Id.*** Therefore, a PHOSITA would have understood that the above claim limitation(s) would have occurred during implantation of the Wagner device. ***Id.***

### C. Ground 3: Claim 105 is unpatentable under 35 U.S.C. § 103(a) as obvious over FR 2,747,034 (the FR'034 application) (EX1006) in view Brantigan (the '327 patent ) (EX1008)

The FR'034 application discloses a system for intersomatic fusion and setting of vertebrae. **EX1007 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**. 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. **EX1011 at ¶¶66.** 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. ***Id*. at ¶65.**

Brantigan (the ‘327 patent) discloses a spinal implant device (e.g. 11) having a substantially wedge-shaped body (40). **EX1008 at 2:55-59, 5:50-57, claim 14, and FIGs. 7 and 11**. A central aperture is provided to receive bone graft material to expedite fusion of the prosthesis device in the spinal column. **EX1008 at 4:50-56.** The hollow interior (23) is bisected by an integral partition (32) forming a pair of side-by-side apertures which are configured to receive bone graft material. **EX1008 at 4:50-56, 5:36-43, FIGs. 4 and 6.** Brantigan 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. **EX1011 at ¶70.**

| **‘531 patent Claim 105 vs. the FR’034 application and Brantigan** |
|---|
| *An apparatus for use in changing the spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said apparatus comprising* |
| The FR’034 application (**EX1006**) discloses:<br>• 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. **EX1011 at ¶65.**

- 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. **EX1007 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). **EX1011 at ¶65.**
- 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. **EX1011 at ¶69.**

The preamble of claim 105 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction.[6] To the extent that the preamble limits the claim, a PHOSITA would have understood that a PHOSITA would have recognized that the FR'034 application discloses *for use in changing the spatial relationship between first and second bones which are interconnected at a joint in a patient's body*, as recited in the claims. **EX1011 at ¶69.**

*a wedge member which is movable into the joint between the first and second bones,*

The FR'034 application (**EX1006**) discloses:

- The "cage" (body) can have various dimensions in height, in width, and in depth and may also be given a preferred anatomical shape. **EX1007 at 4:8-11**.

[6] *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.

- 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. **EX1011 at ¶71.**
- 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. **EX1011 at ¶71.**

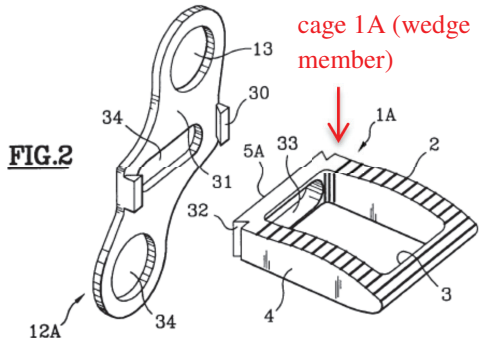


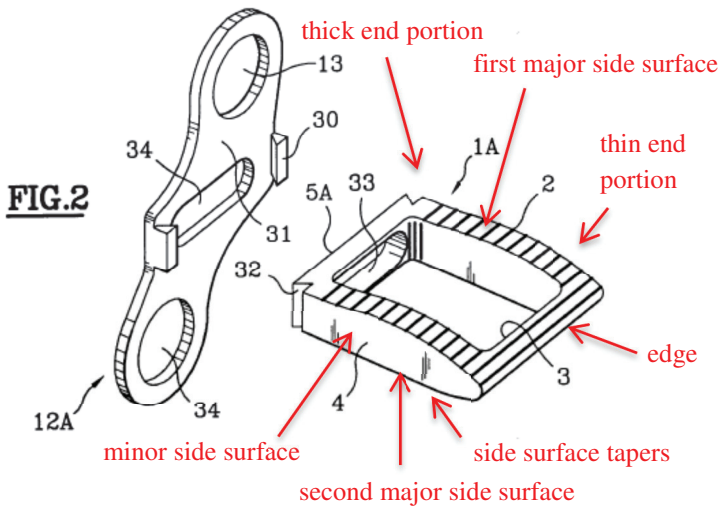
FIG.2

- The "cage" (body) possesses various characteristics or features that are intrinsic to the geometric configuration of the device as clearly illustrated in the figures. **EX1011 at ¶66.**
  - *See*, *e.g.,* **EX1007 at FIG. 2**, as labeled.
  - 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. **EX1011 at ¶71.**

The claim language "*which is movable into the joint between the first and second bones*" is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and, therefore, is not material to patentability. As such, this language carries no patentable weight.[7] To the extent that this language limits the claim, 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. **EX1007 at3:3-5, 4:8-11, 5:1-3; EX1011 at ¶71.** A PHOSITA would have understood that to

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

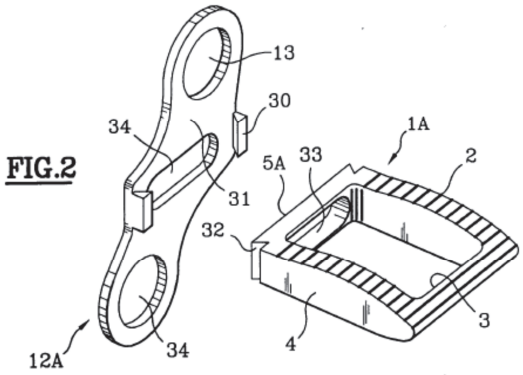
achieve the desired fit while correcting for the natural lordotic angle between a first and second vertebrae of the lumbar spine would require a generally wedge shaped body of the implant with a thicker anterior or trailing portion and a thinner posterior or leading portion, as illustrated in FIG. 2. **EX1011 at ¶71.** Therefore, a PHOSITA would have understood that the FR'034 application discloses the above claim limitation(s). ***Id.***

| |
|---|
| *said wedge member having a thin end portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and* |
| *a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion,* |
| The FR'034 application (**EX1006**) discloses:<br>• *See*, *e.g.,* **EX1007 at FIG. 2**, as labeled.<br>  <br> |

For the reasons discussed above, a PHOSITA would have understood the FR'034 application to disclose the body has a thick end portion at the anterior or trailing end of the body, and a thin end portion at the posterior or leading end of the body.**EX1011 at ¶72.** A PHOSITA would have understood FIG. 2 to illustrate

that the body has a thick end portion at the anterior or trailing end of the body, and 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.*** **at ¶73.** A PHOSITA would have also understood that the body includes top and bottom surfaces ("faces 8 and 9"), each of which extends from the anterior thick end portion to the posterior thin end portion. **EX1007 at 2:27-3:2; EX1011 at ¶74**, and provide supporting surfaces for the adjacent bone when the body is inserted between two vertebrae. ***Id.*** A PHOSITA would have recognized that the top and bottom surfaces intersect to form an edge at the leading posterior end of the body. **EX1011 at ¶74.** A PHOSITA would have understood that the body also includes opposite side walls ("side walls 2 and 4") each including a side surface. **EX1007 at FIG. 2; EX1011 at ¶75.** 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. **EX1007 at 3:3-5, 4:8-11, FIG. 2; EX1011 at ¶75.** Therefore, a PHOSITA would have understood that the FR'034 application discloses the above claim limitation(s). ***Id.*** **at ¶¶72, 74, 75.**

| *said wedge member having a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member.* |
|---|
| The FR'034 application (**EX1006)** discloses:<br>• 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 |

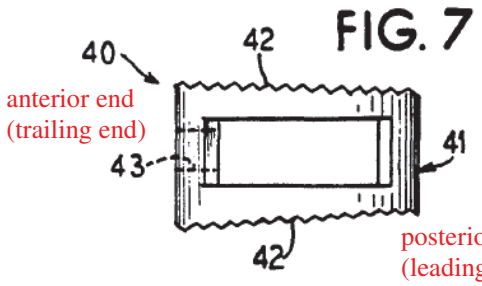



graft or material encouraging fusion between the two vertebrae concerned. **EX1007 at 1:1-9**.

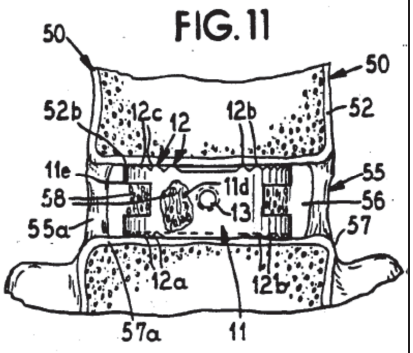
- The cage is designed to receive spongy bone or bone substitute material via its top and bottom open faces and/or via a front opening. ***Id.* at 2:7-8** and **2:26-32**.
- *See, e.g.*, **FIG. 2**, as labeled.

Brantigan (the '327 patent) (**EX1008**) discloses:

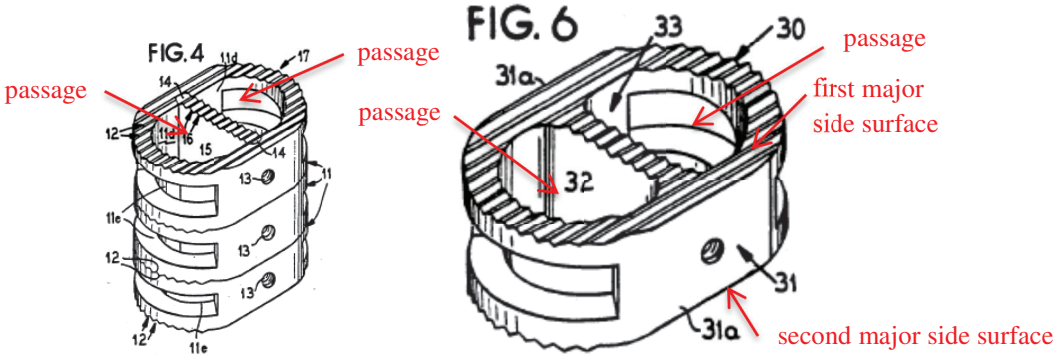
- Brantigan discloses a spinal implant device for use in spinal fusion surgical procedures that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, vertebrae) at an intervertebral joint in a patient's body. **EX1011 at ¶70.**
- Brantigan discloses changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body. **EX1011 at ¶70**.
- 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. **EX1008 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. **EX1008 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**.
- The central aperture 11d of each plug 11 is separated by the bar 15 into two side-by-side chambers which are easily packed with bone graft material to




expedite the fusion of the prosthesis device in the spinal column. In addition, the slots 11e in the ends 11b of the plugs can receive bone graft material and also provide free spaces for blood flow to speed up the fusion process. **EX1008 at 4:50-56** and **FIG. 4**.




- The hollow interior 23 of the plug 31 is bisected by an integral internal partition 32 forming a pair of side-by-side apertures through the plug adapted to receive bone graft material. **EX1008 at 5:36-43** and **FIG. 6**.




- The hollow interior 11d and the slots 11 e of the plug 11 are packed with boned graft material 58. **EX1008 at 6:37-40.**

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. **EX1007 at 1:3-9, 2:4-8, FIG. 2; EX1011 at ¶76.** A PHOSITA would have understood that the open internal body provides a compartment to contain the graft materials. **EX1011 at ¶76.** 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. **EX1007 at 4:12-14;**

**EX1011 at ¶76.** This would create an area of contact between the endplate and graft, thus providing an excellent milieu for arthrodesis. **EX1011 at ¶76.** A PHOSITA, therefore, would have understood that the FR'034 application discloses a wedge member having a passage extending between the first and second major side surfaces for enabling bone to grow through said wedge member. ***Id.***

A PHOSITA would have understood that Brantigan discloses *an apparatus for use in changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body,* as recited in the claims. **EX1011 at ¶70.** A PHOSITA would have understood that Brantigan discloses a hollow interior which can be packed with bone graft. **EX1008 at 6:37-40; EX1011 at ¶77.** A PHOSITA would have understood that the hollow interior of the device disclosed in Brantigan extends between the top and bottom faces (42) of the device. **EX1008 at FIGs. 6, 7; EX1011 at ¶77.** A PHOSITA would have understood that the graft material is used facilitate bone ingrowth and speed the fusion process. **EX1008 at 2:14-18, 4:50-56; EX1011 at ¶77.** Brantigan also teaches that the hollow interior may be bisected by a reinforcing bar (32) to form a pair of side-by side apertures (passages) through the device adapted to receive bone graft material. **EX1008 at 4:50-56, 5:36-43, FIG. 6; EX1011 at ¶77.** A PHOSITA would have understood that the reinforcing bar increases the strength of the device. **EX1011 at ¶77.**

A PHOSITA would have been motivated to look to the teachings of the FR'034 application, Brantigan, 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. **EX1011 at ¶78.** A PHOSITA would have been motivated to apply the teachings of Brantigan to those of the FR'034 application because both Brantigan, and the FR'034 application 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 ¶79.** It would have been recognized by a PHOSITA that the spine disk implants of the FR'034 application and Brantigan correct existing mechanical deformity, 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 ¶80.** The applicability and advantages of increasing the strength of the body of the device using a central reinforcing bar as disclosed in Brantigan, would have been readily apparent to a PHOSITA when applied to the device of the FR'034 application. ***Id.*** A PHOSITA, therefore, would have been motivated, in view of the combined teachings of the FR'034 patent and Brantigan, to include central reinforcing bar in

the device of the FR'034 patent and increase the strength of the device, therefore resulting in *said wedge member having a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member*, as recited in the claims. ***Id.*** **at ¶81.** A PHOSITA would have considered such a modification an obvious choice that would have yielded a predictable effect in the resulting method.[8] ***Id.*** **at ¶82.** This modification would not have changed the principle of operation of the spinal implant of the FR'034 application.[9] ***Id.***

### D. Ground 4: Claim 105 is unpatentable under 35 U.S.C. § 103(a) as obvious over Stone (EX1009) in view Prewett (EX1010)

Stone (the '433 patent) (**EX1009**) 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. **EX1011 at ¶83.** 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) (**EX1010**) teaches a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae used in place of an intervertebral disk that has been removed (i.e. during

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

discectomy). **EX1010 at 6:65-7:13; FIGs. 5** and **6; EX1011 at ¶86.**

| **'531 patent Claim 105 vs. Stone and Prewett** |
|---|
| *An apparatus for use in changing the spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said apparatus comprising* |
| Stone (the '433 patent) (**EX1009**) discloses:<br>• Stone discloses a device, and kit and methods for realigning varus angulated knees, but also may be used for realigning any malaligned bone. **EX1009 at 2:59-61**.<br>• Stone discloses an implantable device for changing the spatial relationship between first and second bones interconnected at a joint in a patient's body. **EX1011 Ochoa Decl. at ¶85**. |

To the extent that the preamble limits the claim, [10] a PHOSITA would have understood Stone (the '433 patent) (**EX1009**) discloses an osteotomy device for use in a high tibial osteotomy surgical procedure that changes the spatial relationship (*e.g.*, restores a desired anatomical relationship from a degenerated condition) between first and second bones (*i.e.*, the femur and tibia) at the knee. **EX1011 at ¶83.** Specifically, the device is described for use as a spacer during an opening wedge osteotomy procedure, to realign varus angulated knees. ***Id.;*** **EX1009 at 2:59-61.** A PHOSITA would have understood that the wedge shaped implantable spacer of Stone may be used for realigning any malaligned bone. **EX1011 at ¶85.** A PHOSITA would have recognized that Stone discloses an *implantable device for changing the spatial relationship between first and second*

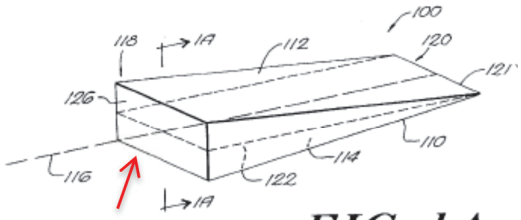
[10] The preamble of claim 105 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations and is of no significance to claim construction. *See* footnote 6, *supra*.

*bones*, as recited in the claims. ***Id.***

| *a wedge member which is movable into the joint between the first and second bones,* |
|---|

Stone (the '433 patent) (**EX1009**) 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. **EX1009 at 5:27-40; FIG. 1A**.



wedge member (110)

FIG. 1A

- The wedge body is configured and dimensioned for insertion between upper and lower portions of a bone joined at a lateral portion. **EX1009 at 7:14-31**.

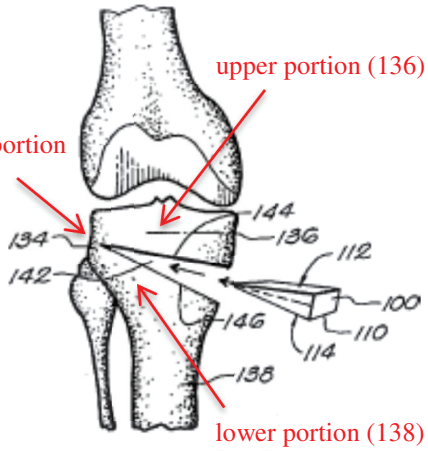


FIG. 3C

Prewett (the '254 patent) (**EX1010**) discloses:

- Prewett teaches a spinal implant including bone wedges 8 used as intervertebral support blocks inserted between adjacent vertebrae. **EX1010 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***.
- Prewett discloses an implantable wedge member movable into a joint between the first and second bones. **EX1011 at ¶86**.

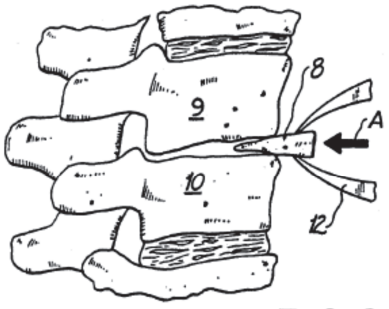


FIG. 6

To the extent that this language limits the claim,[11] Stone discloses an implantable spacer configured with a substantially wedge-shaped body having two angularly offset principal surfaces (112, 114) which intersect at vertex (121) at the thin end portion of the device (120). **EX1009 at 5:27:40, FIG. 1A; EX1011 at ¶84**. The principal surfaces of the device are adapted to engage mechanically with the bony surfaces to promote contiguous bone formation. **EX1011 at ¶84**. The hollow body ("110") of the device contains bone graft material to promote bone growth and eventual fusion of the osteotomy through holes on at least one of the principal surfaces (113). **EX1009 at 7:9-14, FIGs. 1A, 2B; EX1011 at ¶84.** Additional fixation is provided by screws (172, 176) which can be screwed through an integrated plate (174) and into the adjacent bone. **EX1009 at 6:64-7:2, FIG. 2B; EX1011 at ¶84.**

Prewett discloses the use of swollen demineralized bone for use as an osteoconductive and/or osteoinductive material. **EX1010 at 1:44-47; EX1011 at ¶86**. The described material may be formed in a in a variety of desired shapes for use as surgical implants. **EX1010 at 1:37-39; EX1011 at ¶86**. The mechanical properties of the material can be modified by processing and such that the resulting

[11] The claim language "*which is movable into the joint between the first and second bones*" is a recitation of the intended use for the claimed apparatus; does not structurally distinguish the claimed apparatus and, therefore, is not material to patentability. As such, this language carries no patentable weight. *See,* footnote 7, *supra.*

device can be pressed into a surgical implant site. **EX1010 at 5:20-36; EX1011 at ¶86**. Prewett 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). **EX1010 at 6:65-7:13; FIGs. 5** and **6; EX1011 at ¶86**. 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 which are interconnected at a joint in a patient's body*, as recited in the claims. **EX1011 at ¶86**.

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 ¶87**. 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 ¶88**. 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.;*** **EX1009 at 7:3-32; 36; EX1010 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. **EX1011 at ¶89.** 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.;*** **EX1009 at 2:64-67; EX1010 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. **EX1011 at ¶90.** 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 ¶91**. 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 the claims. ***Id.*** More specifically, a PHOSITA would have been understood from the teachings of Prewett that the spacer disclosed in Stone could similarly be employed as *a wedge member which is movable into the joint between the first and second bones*, as recited in the claims. ***Id.*** 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.[12] ***Id.*** **at ¶92**. This use would not have changed the principle of operation of the spacer of Stone.[13] ***Id.*** **at ¶92**.

| |
|---|
| *said wedge member having a thin end portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and* |
| *a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion,* |
| Stone (the '433 patent) (**EX1009**) discloses:<br>• *See* **EX1009 at 5:27-40; FIG. 1A**, as labeled below. |

[12] *See* footnote 4, *supra*.
[13] *See* footnote 5, *supra*.

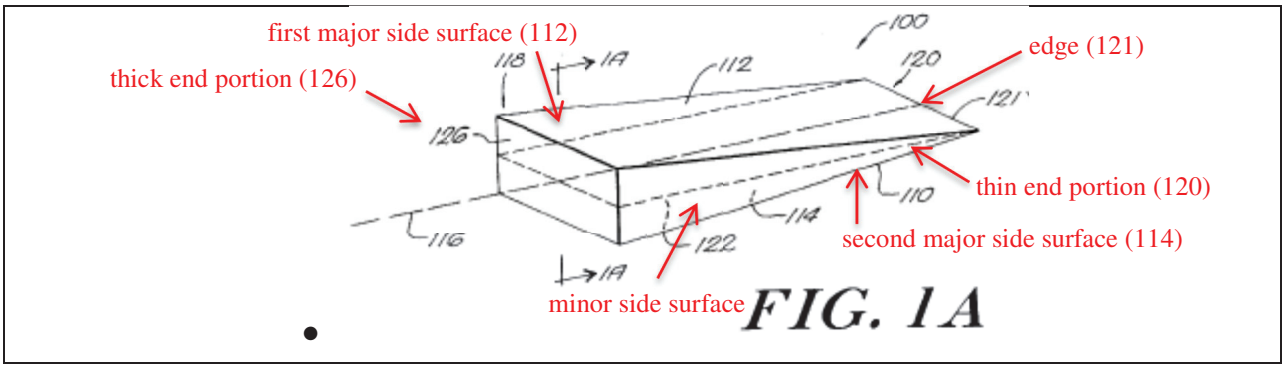


FIG. 1A

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). **EX1009 at 5:27-40, FIGs. 1A** and **2B; EX1011 at ¶94.** A PHOSITA would have understood that the wedge-shaped body (110) of implantable spacer of Stone also includes opposite side surfaces. **EX1011 at ¶96.** 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. **EX1009 at FIGs. 1A** and **2B; EX1011 at ¶96.** A PHOSITA would have recognized that Stone discloses the above claim limitation(s). **EX1011 at ¶¶94-96.**

| *said wedge member having a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member.* |
|---|
| Stone (the '433 patent) (**EX1009**) discloses:<br>• One or both of the principal surfaces 112, 114 are formed of a material selected to engage mechanically surfaces adjacent to body 110. By way of example, the principal surface 112 can be formed of a porous material which allows bone cells to grow within and throughout the pores. **EX1009 at 6:31-** |

**36**.

- The body 110 of the device can be hollow and, accordingly, materials such as ground cancellous bone can be packed inside. A plurality of holes on the principal surface can facilitate packing of material within the body 110. **EX1009 at 7:9-14.**

A PHOSITA would have understood that the principal surfaces (112, 114) of the wedge-shaped body (110) of the implantable spacer disclosed in Stone provide the supporting surfaces and engage the adjacent bone when the body is inserted between bony surfaces and may be formed of porous material. **EX1009 at 3:28-31, 6:31-36; EX1011 at ¶97.** The hollow body (110) of the device contains bone graft material to promote bone growth and eventual fusion of the osteotomy through holes on at least one of the principal surfaces (113). **EX1009 at 7:9-14, FIGs. 1A, 2B; EX1011 at ¶97.** A PHOSITA would have understood from the disclosure of Stone that the wedge 110 formed of a porous material and is hollow provides a plurality of passages which extend between the first and second major side surfaces for enabling bone to grow through said wedge member. **EX1011 at ¶97.**[14] A PHOSITA would have recognized that Stone discloses the above claim limitation(s). ***Id.***

## IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 8, 9, 46, 49, 105, 107,

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

109 and 111 of the '531 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '531 patent.

Dated: June 5, 2015

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## CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, this is to certify that I caused a true and correct copy of the PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,099,531 (and accompanying Exhibits **EX1001-EX1028**) 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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& Bianco PL
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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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