UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC., Petitioner

v.

FLEXUSPINE, INC., Patent Owner

Case No.: IPR2015-____ U.S. Patent No. 7,204,853 Issued: April 17, 2007 Application No: 10/634,950 Filed: August 5, 2003

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,204,853

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LIST OF EXHIBITS

- EX1001 U.S. Patent no. 7,204,853
- EX1002 *Flexuspine, Inc. v. Globus Medical Inc.*, U.S. District Court for the Eastern District of Texas, Civil Action no. 15-cv-00201-JRG-KNM – Flexuspine, Inc.'s Claim Chart for P.R. 3-1 Infringement Contentions
- EX1003 Prosecution history of U.S. Patent No. 7,204,853
- EX1004 U.S. Patent no. 6,454,806 to Cohen et al.
- EX1005 U.S. Patent no. 5,782,832 to Larsen et al.
- EX1006 U.S. Patent no. 5,522,899 to Michelson
- EX1007 Declaration of Jorge A. Ochoa, P.E.
- EX1008 Curriculum Vitae of Jorge A. Ochoa, P.E.
- EX1009 U.S. Patent no. 5,665,122 to Kambin
- EX1010 U.S. Patent no. 6,045,579 to Hochshuler
- EX1011 U.S. Patent no. 6,936,071 to Marnay
- EX1012 U.S. Patent no. 7,060,100 to Ferree
- EX1013 Blumenthal SL, Ohnmeiss DD. Intervertebral cages for degenerative spinal diseases. Spine J. Jul-Aug 2003;3(4):301-309
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- EX1015 Mayer HM, Wiechert K, Korge A, Qose I. Minimally invasive total disc replacement: surgical technique and preliminary clinical results. Eur Spine J. 2002 Oct;11 Suppl 2:S124-30.
- EX1016 Foley KT, Holly LT, Schwender JD. Minimally invasive lumbar fusion. Spine (Phila Pa 1976). Aug 1 2003;28(15 Suppl):S26-35

| EX1017 | Tropiano P, Huang RC, Girardi FP, Marnay T. Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. J Spinal Disord Tech. 2003 Aug;16(4):362-8. |
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| EX1022 | U.S. Patent no. 6,159,244 to Suddaby |
| EX1023 | Claim chart: Claim 1 vs. U.S. Patent No. 6,454,806 |
| EX1024 | Claim chart: Claim 1 vs. U.S. Patent No. 5,782,832 in view of U.S. Patent No. 6,491,724 |
| EX1025 | Claim Chart: Claim 5 vs. U.S. Patent No. 5,522,899 |
| EX1026 | U.S. Patent No. 6,491,724 to Ferree |
| | |

I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, the undersigned, on behalf of and representing Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review of claims 1 and 5 of U.S. Patent No. 7,204,853, titled "Artificial Functional Spinal Unit Assemblies" ("the '853 patent"), issued to Charles Gordon and Corey Harbold and assigned to Flexuspine, Inc. ("Flexuspine"). The '853 patent is attached as **EX1001**.

The invention of the '853 patent is not new. Rather, the claimed invention encompasses known expandable artificial intervertebral implants. In this regard, the challenged claims of the '853 patent describe an invention having features that are well-known and/or inherent in the prior art.

For the reasons set forth herein, Petitioner asserts that all of the challenged claims are unpatentable. The grounds for unpatentability presented in detail below, demonstrate how each of claims 1 and 5 of the '853 patent are obvious in view of the prior art. Evidentiary support for conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. **EX1007.**¹ 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

¹ Sometimes referred to herein as "Ochoa Decl."

claims is rendered obvious in view of the prior art and confirms all of Petitioner's assertions of unpatentability.

Petitioner submits that this Petition demonstrates a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. 35 U.S.C. §314(a). Accordingly, Petitioner respectfully requests that this Petition be granted and that claims 1 and 5 of the '853 patent be reviewed and held unpatentable.

II. FORMALITIES

A. Mandatory Notices

1. <u>Real Party in Interest (37 C.F.R. § 42.8(b)(1))</u>

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

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

| Lead Counsel | Backup Counsel |
|---------------------------------------|--------------------------------------|
| George D. Moustakas (Reg. No. 44,425) | David P. Utykanski (Reg. No. 39,052) |
| HARNESS, DICKEY & PIERCE, P.L.C. | HARNESS, DICKEY & PIERCE, P.L.C. |
| 5445 Corporate Dr., Suite 200 | 5445 Corporate Dr., Suite 200 |
| Troy, MI 48098 | Troy, MI 48098 |
| 248-641-1600 (telephone) | 248-641-1600 (telephone) |
| 248-641-0270 (facsimile) | 248-641-0270 (facsimile) |
| gdmoustakas@hdp.com | dutykanski@hdp.com |

3. <u>Notice of Service (37 C.F.R. § 42.8(b)(4))</u>

Please direct all correspondence to lead counsel at the above address.

Petitioner consents to email service at the above-referenced email addresses.

4. <u>Related Matters (37 C.F.R. § 42.8(b)(2))</u>

Petitioner states that the '853 patent is asserted in *Flexuspine, Inc. v. Globus Medical Inc.*, U.S. District Court for the Eastern District of Texas, Civil Action no. 15-cv-00201-JRG-KNM ("the Pending Litigation"). Petitioner is a party to the Pending Litigation. Notably, in the Pending Litigation, Flexuspine has accused certain of Globus's spinal implant devices of infringing the challenged claims of the '853 patent. *See* **EX1002.**

Concurrently with this Petition, Petitioner is also filing a Petition for *inter partes* review of U.S. Patent No. 7,316,714 ("the '714 patent"), U.S. Patent No. 7,909,869 ("the '869 patent"), U.S. Patent No. 8,123,810 ("the '810 patent"), and U.S. Patent No. 8,647,386 ("the '386 patent"). The '714 patent, '869 patent, '810 patent and '386 patent are each related to the '853 patent through continuation practice. Petitioner understands that the '853 patent, the '714 patent, the '869 patent, the '810 patent and the '386 patent are all commonly owned by Flexuspine.

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

Petitioner certifies that (1) the '853 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 '853 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 March 13, 2015.

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Consequently, Petitioner is not time barred by the Pending Litigation to bring this Petition.

C. Procedural Statements

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

III. U.S. PATENT NO. 7,204,853 ("THE '853 PATENT") (EX1001)

The '853 patent issued on April 17, 2007, on an application filed on August 5, 2003. The earliest priority date for the '853 patent is August 5, 2003.

A. The '853 Patent Specification and Claims

The '853 patent is generally directed to an expandable intervertebral implant. The challenged claims, however, are directed to a known implantable device for achieving the objective of restoration and maintenance of disc space height. The '853 patent issued with 53 claims, of which only claims 1 and 5 are at issue in this Petition. Claims 1 and 5 are independent.

The written description and drawings of the '853 patent describe various embodiments of an expandable intervertebral implant for restoration and maintenance of disc space height. As more particularly disclosed in FIG. 6d, an

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upper body 83 and a lower body 84 are in contact with each other, the upper body 83 having recesses through which retaining pegs 91 project upward from the superior surface of the lower



body 84. **EX1001, Col. 9, lines 41-46.** Pegs 91 are retained in the recess and prohibit dislocation of upper body 83 from lower body 84. An insert 87 resides between upper body 83 and lower body 84. *Id.* at Col. 9, lines 46-54. An expansion plate 82 is inserted between the upper body 83 and lower body 84 and is configured to elevate insert 87. *Id.* at Col. 9, lines 37-40. A locking lip 88 is employed to minimize the potential for dislocating expansion plate 82. *Id.* at Col. 9, lines 37-40.

Claims 1 and 5 of the '853 patent are directed to an expandable intervertebral implant, as best shown with reference to Figures 6a-d.

B. The '853 Patent Prosecution History (EX1003)

The application leading to the '853 patent, Serial No. 10/634,950, was filed on August 5, 2003. On February 12, 2004, the Applicant filed a Preliminary Amendment. **EX1003, pages 472-497.** On February 8, 2005, a Restriction Requirement issued. *Id.* at pages 457-463. On May 9, 2005, the Applicant responded by electing the species of a banana-shaped lower body, an expansion plate, and pegs for securing. *Id.* at pages 98-115. On August 10, 2005 the Examiner acknowledged the election and noted certain deficiencies. *Id.* at pages 75-78. On September 6, 2005, the Applicant responded by outlining the correspondence between the pending claims and the elected species. *Id.* at pages 49-73.

On December 1, 2005, a Non-Final Office Action issued. Id. at pages 34-41.

The Examiner allowed certain claims and rejected others. On December 21, 2005,

the Applicant responded to the Office Action. Id. at pages 16-32. On February 2,

2007, a Notice of Allowance issued. Id. at pages 7-12. The Reasons for

Allowance were noted as follows:

the prior art fails to disclose or teach an intervertebral implant comprising the combination of an upper body, lower body, an insert configured to be positioned between the surfaces of the upper and lower body including an expansion member configured to elevate the insert to increase a separation distance between the upper and lower body after insertion wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant.

Id. at page 11.

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

As established in the Declaration of Dr. Ochoa, a person having ordinary skill in the art (PHOSITA) of the '853 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. **EX1007, Ochoa Decl. at ¶ 18.**

V. CLAIM CONSTRUCTION

The claims of the '853 patent are to be given their broadest reasonable construction in light of the '853 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 '853 patent, as appropriate in that proceeding.

VI. THE PRIOR ART RELIED UPON IN THIS PETITION

A. U.S. Patent No. 6,454,806 to Cohen et al. ("the '806 patent" or "Cohen") (EX1004)

U.S. Patent No. 6,454,806 to Cohen et al., entitled "Spinal Surgical Prosthesis," issued September 24, 2002. Cohen is prior art to the '853 patent under 35 U.S.C. § 102(a) because it is a printed publication in the U.S. or a foreign country before the invention by the applicant of the '853 patent. Cohen was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '853 patent, but was not referred to or relied on by the Examiner during the prosecution.

B. U.S. Patent No. 5,782,832 to Larsen et al. ("the '832 patent" or "Larsen") (EX1005)

U.S. Patent No. 5,782,832, entitled "Spinal Fusion Implant and Method of Insertion Thereof," issued July 21, 1998. Larsen is prior art to the '853 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 '853 patent in the United States. Larsen was disclosed by the applicant to the Patent Office during the prosecution of the application leading to the '853 patent, but was not referred to or relied on by the Examiner during the prosecution.

C. U.S. Patent No. 5,522,899 to Michelson ("the '899 patent" or "Michelson") (EX1006)

U.S. Patent No. 5,522,899 to Michelson, entitled "Artificial Spinal Fusion

Implants," issued June 4, 1996. Michelson is prior art to the '853 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 '853 patent in the United States. Michelson 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 '853 patent.

D. U.S. Patent No. 6,491,724 to Ferree ("the '724 patent" or "Ferree") (EX1026)

U.S. Patent No. 6,491,724 to Ferree, entitled "Spinal Fusion Cage With Lordosis Correction," issued December 10, 2002. Ferree is prior art to the '853 patent under 35 U.S.C. § 102(a) because it is a patent issued more than one year prior to the date of the application for the '853 patent in the United States. Ferree was neither disclosed by the patent applicant nor cited, referred to, or relied on by the Examiner during prosecution of the application leading to the '853 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 independent claims 1 and 5 of the '853 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. As further discussed below, Petitioner submits that challenged independent claims 1 and 5 are obvious pursuant to 35 U.S.C. § 103.

A specific listing of Petitioner's asserted grounds for unpatentability, a comparison of the prior art to the challenged claims, and the supporting testimony

from Petitioner's technical expert, Dr. Ochoa, follows below.

In summary, and as established by the declaration of Dr. Ochoa, (i) the '806 patent in view of the knowledge of one of ordinary skill in the art renders claim 1 unpatentable as obvious under 35 U.S.C. § 103 (**EX1007, Ochoa Decl. at ¶ 50-58**); (ii) the '832 patent in view of the '724 patent renders claim 1 unpatentable as obvious under 35 U.S.C. § 103 (**EX1007, Ochoa Decl. at ¶ 41-49**); and (iii) the '899 patent in view of the knowledge of one of ordinary skill in the art renders claim 5 unpatentable as obvious under 35 U.S.C. § 103 (**EX1007, Ochoa Decl. at ¶ 41-49**); and (iii) the '899 patent in view of the knowledge of one of ordinary skill in the art renders claim 5 unpatentable as obvious under 35 U.S.C. § 103 (**EX1007, Ochoa Decl. at ¶ 32-40**).²

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

This petition presents the following Grounds of Unpatentability:

• Ground 1: Claim 1 is unpatentable under 35 U.S.C. § 103 as obvious over the '806 patent (**EX1004**) in view of the knowledge of one of ordinary skill in the art.

• Ground 2: Claim 1 is unpatentable under 35 U.S.C. § 103 as obvious over the '832 patent (**EX1005**) in view of the '724 patent (**EX1004**).

• Ground 3: Claim 5 is unpatentable under 35 U.S.C. § 103 as obvious over the '899 patent (**EX1006**) in view of the knowledge of one of ordinary skill in the art.

²KSR Int'l. Co. v. Teleflex, Inc., 550 U.S. 398 (2007).

A. Ground 1: Claim 1 is unpatentable under 35 U.S.C. § 103 as obvious over the '806 patent (EX1004) in view of the knowledge of one of ordinary skill in the art

The'806 patent discloses an intervertebral implant for use in spinal fusion surgical procedures. **EX1004, Field of the Invention.** The disclosed implants include upper and lower bodies in the form of elongated bearing surfaces for engaging the neighboring endplates after preparing the bony surfaces. Id. at Col. 4, lines 12-14; Col. 4, lines 34-38; Col. 5, lines 33-37. One disclosed embodiment includes an intervertebral implant for use in spinal fusion procedures comprising upper and lower bodies ("elongated bearing surfaces" 110) which are textured, designed or otherwise treated by known technologies to enhance the stability of the implant and to expedite fusion. Id. at Col. 3, lines 36-53; FIG. **15A.** Cam shaped inserts (112) abut the upper and lower bodies such that when an expansion member ("rod" 111) is rotated the cams rotate, engaging and striking the interior surfaces of the two bearing surfaces (110) thus increasing the separation distance between the upper and lower bodies. Id. at Col. 10, lines 42-55, FIGS.

15A and 15C; EX1007, Ochoa Decl. ¶ 50.

A PHOSITA would have understood that the spinal implant taught in the Cohen patent renders claim 1 of the '853 obvious. The claim charts and accompanying analysis below evidence this conclusion. 1. <u>Claim 1</u>

Claim 1 is directed to an implant device. Claim 1 is obvious in view of Cohen. This is demonstrated with reference to the chart below and accompanying text.

| '853 patent Claim 1 vs. '806 patent | | |
|---|---|--|
| 1. An intervertebral implant for a human spine, comprising: | *853 patent Claim 1 vs. *806 patent Cohen (the '806 patent) (EX1004) discloses: The present invention relates to an improved spinal surgical prosthesis and more particularly to apparatus and methods for achieving stability of adjacent vertebrae and preserving the inter-disc space following disectomy by internal fixation or fusion. EX1004, Field of the | |
| | Invention It will thus be seen that the present invention provides improved means for achieving fusion of the inter-vertebral space and stabilization as a single procedure in a manner consistent with the conventional methods of disectomy and re-establishing the ideal an dnormal pre-existing disc interspace which is easier, quicker, safer, and entails less blood loss than other known means. EX1004, Col. 11, lines 50-56 Cohen discloses an intervertebral implant for a human spine. EX1007, Ochoa Decl. at ¶ 51. | |

The preamble of claim 1 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations.³

To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of Cohen is for use for implantation in a human

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

spine. **EX1004 at Col. 11, lines 50-56**. A PHOSITA would have understood that the spinal implant described in the '806 patent is an interbody spacer for use in spinal fusion procedures. *Id.* **at Field of the Invention; Col. 11, lines 50-56; EX1007, Ochoa Decl. ¶ at 51.**

A PHOSITA would have recognized that the '806 patent application discloses an intervertebral implant for a human spine, as recited in the claims.

EX1007, Ochoa Decl. at ¶ 51.

| '853 patent Claim 1 vs. the '806 patent | | |
|--|--|--|
| an upper body | Cohen (the '806 patent) (EX1004) discloses: | |
| comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the | The present invention is an inter-space implant utilized to replace a damaged disc. The present invention is clearly an improvement over the prior art providing an implant prosthesis intrinsically participating in this fusion process, self-stabilizing to the spinal segments, consistent with conventional methods of disectomy and uniquely and novel consistent with the preservation of the integrity of the adjacent vertebrae. EX1004, Col. 3, lines 36-53 A conventional disectomy is performed and the vertebral end plates are roughened in preparation for use of the implant | |
| human spine; AND | prosthesis of the present invention. EX1004, Col. 4, lines 11-13 | |
| a lower body comprising a superior surface and an inferior | • The disc involved is identified and removed by known, acceptable and conventional surgical methods. The adjacent vertebral end plates are gently scraped free of any remaining cartilage until diffuse fine punctuate decortication is achieved. The dimensions of the inter-space are then | |
| surface, wherein the inferior surface of the lower body is configured to | measured in mild distraction and compared with the stereo- tactic pre-surgical x-ray diagnostic procedures and video imaging devices which helps to determine the exact intra- discal space to be restored relative to the vertebrae involved | |
| engage a second | and the undamaged disc space that exists inferiorly and | |



| the human spine and a lower body comprising a superior surface and an inferior surface, wherein the inferior surface |
|---|
| of the lower body is configured to engage a second vertebra of the human spine. EX1007, Ochoa Decl. at ¶ 52. |

The phrase "an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine," and "a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine," 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.⁴ Moreover, a PHOSITA would not understand the limitation, "configured to engage," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Cohen reference discloses these limitations. A PHOSITA would have understood that the cam type expandable cage described in the '806 patent comprises an upper body and a lower body ("elongated bearing surfaces" 110). **EX1004, Col. 10, lines 42-55; FIG. 15A.** Surfaces included on the inferior surface of the upper body and

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

the superior surface of the lower body may be textured, designed or otherwise treated by known technologies to enhance the stability of the implant and to expedite fusion. Id. at Col. 3, lines 36-53; FIG. 15A. Each body also includes an interior surface, on the superior side for the lower body, and on the inferior side for the upper body forming a cavity that bone may be packed into. *Id.* at Col. 4, lines 42-43; FIG. 15A. When positioned between two vertebrae, the implant endplates are roughened before inserting the device and activating (expanding) it to establish the desired intervertebral space. Id. at Col. 4, lines 11-13; Col. 4, lines 23-39. A PHOSITA would have recognized that establishing the desired intervertebral space would involve engaging the neighboring endplates with the textured surfaces of the upper and lower bodies such that superior surface of the upper body engages a first, superior vertebrae and that inferior surface of the lower body engages a second, inferior vertebra. EX1007, Ochoa Decl. at ¶ 52.

A PHOSITA would have, therefore, understood that the '806 patent discloses, an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine **and** a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine, as recited in the claims. **EX1007, Ochoa Decl. at ¶ 52.**



The phrase "an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before *insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine,*" 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.⁵ Moreover, a PHOSITA would not understand the limitation, "*configured to be positioned,*" to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at § 22.**

However, to the extent that this language limits the claims, the Cohen reference discloses these limitations. A PHOSITA would have understood that the cams (112) form an insert that abuts the upper and lower bodies ("elongated bearing surface" 110) such that when rod (111) is rotated the cams rotate and strike the interior surfaces of the two bearing surfaces (110) and are therefore configured to be positioned between their inward facing surfaces. **EX1004, Col. 10, lines 42-55; FIG. 15A.** A PHOSITA would have recognized that cam type expandable cage described in the '806 patent would be assembled prior to surgical use. **EX1007, Ochoa Decl. at ¶ 55.** A PHOSITA would have recognized that an advantage of this implant is that because of its low profile when not deployed, it could be inserted without requiring drilling procedures for threaded engagement of

⁵ *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); *and In re Danly*, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

adjacent vertebrae and subsequently expanding the device in place. EX1004, Col.

3, lines 6-24; Col. 4, lines 23-39; EX1007, Ochoa Decl. at ¶ 54.

A PHOSITA would have, therefore understood that the '806 patent discloses, an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine, as recited in the claims. **EX007, Ochoa Decl. at ¶ 54.**

| '853 patent Claim 1 vs. '806 patent | | |
|--|--|--|
| an expansion | Cohen (the '806 patent) (EX1004) discloses: | |
| member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral | FIGS. 15A through 15C show a cam type expandable cage. In this embodiment, the opposed curved elongated bearing surfaces 110 have a rod 111 interposed between them with cams 112 in each end. The rod 111 has an opening 113 at its edges which permit the rod 111 and the cams 112 to be rotated. When the rod 111 is rotated, the cams 112 will rotate and strike the interior of the two bearing surfaces 110 to move the two bearing surfaces 110 towards or away from each other. A pair of elongated guides 114 extend from the interior of one of the bearing surfaces 110, which correspond to a pair of grooves 115 on the interior of the opposite bearing surfaces 110, to prevent lateral movement and dislodgment of the opposed bearing surfaces 110 from each other. EX1004, Col. 10, lines 42-55 See e.g. EX1004 at Figs. 15A and 15C below. | |



The phrase "an expansion member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant," 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.⁶ Moreover, a PHOSITA would not understand the limitation, "configured to elevate," to disclose any intrinsic or structural limitation

⁶ In re Schreiber, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); In re Swinehart, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); and In re Danly, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

of the implant. EX1007, Ochoa Decl. at ¶ 22.

However, to the extent that this language limits the claims, the Cohen reference discloses these limitations. A PHOSITA would have understood that the separation distance between the upper and lower bodies ("elongated bearing surface" 110) of the of the cam type expandable cage described in the '806 patent is increased when the expansion member ("rod" 111) is turned. **EX1007, Ochoa Decl. at ¶ 56.** As the expansion member ("rod" 111) is turned, the insert ("cams" 112) rotate. *Id.* **at Ochoa Decl. at ¶ 56.** As a result, the centroid and highest point on the cam move upwards, striking the interior of the upper and lower bodies ("elongated bearing surfaces" 110) to move the upper and lower bodies towards or away from each other. (See Figure 1 below) **EX1004, Col. 10, lines 42-55; FIG. 15A; EX1007, Ochoa Decl. at ¶ 56.**



Figure 1. Illustration of cam movement resulting in increased separation distance (D1, D2, D3) between the upper body and lower body as the cam elevation is modified during rotation. Note the increased elevation of both the cam centroid (H_c) and highest point (H_p) as the cam is rotated clockwise

EX1007, Ochoa Decl. at ¶ 56.

A PHOSITA would have, therefore understood that the '806 patent discloses, an expansion member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, as recited in the claims. **EX1007**,

Ochoa Decl. at ¶ 56.

A PHOSITA would have understood that the cams (112) mounted at each end of the rod (111) are larger in diameter than the rod. **EX1007, Ochoa Decl. at ¶ 57.** A PHOSITA would have understood that the upwards extensions of the lower body ("elongated guides" 114) which are flanked by the grooves (115) would include a receptacle such as a bushing or groove sized to receive the rod (111). *Id.* **at ¶ 57.** A PHOSITA would therefore have understood that the geometric interference between the inside surface of the cams and the upwards extensions of the lower body ("elongated guides" 114), flanked by the grooves (115) would inhibit backout of the expansion member ("rod" 111) from between the upper and lower bodies (see Figure 2 below). *Id.* **at ¶ 57.**



Figure 2. Excerpt from figure 15 of the '806 patent demonstrating geometric interference inhibiting backout of the expansion member.

EX1007, Ochoa Decl. at ¶ 57.

A PHOSITA would have, therefore understood that the '806 patent discloses, and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant, as recited in the claims.

A summary image also illustrating certain of the claim elements discussed

above is included in Figure 3 below:



Figure 3. Excerpt from figure 15 of the '806 patent demonstrating the various claim elements.

EX1007, Ochoa Decl. at ¶ 57.

The claim chart attached as **EX1023** provides additional details supporting the information that would have been conveyed by the '806 patent and understood by a PHOSITA at the time of the invention of the '853 patent. **EX1007, Ochoa**

Decl. at ¶ 58.

Consequently, and as supported by Dr. Ochoa, the Cohen reference renders claim 1 as obvious and unpatentable under 35 U.S.C. § 103.

B. Ground 2: Claim 1 is unpatentable under 35 U.S.C. § 103 as obvious over the '832 patent (EX1005) in view of the '724 patent (EX1026)

The'832 patent discloses an intervertebral implants for insertion within an intervertebral space for supporting the vertebrae in a predetermined space relation during fusion procedures. **EX1005, Col. 1, line 65-Col. 2, line 1; Col. 2, lines 59-63.** The disclosed implants include lower and upper plate members having

contacting surfaces for engaging end faces of adjacent vertebrae in a camming arrangement. Id. at Col. 2, lines 59-63. One disclosed embodiment includes an intervertebral implant for use in spinal fusion surgical procedures comprising an upper body ("upper support member" 402) and lower body ("lower support member" 404). Id. at Col. 8, lines 8-15. Pyramid shaped projections (410) on the outer surfaces of the upper and lower bodies facilitate engagement with the adjacent vertebrae. Id. at Col. 8, lines 8-15. An insert, integral to the upper body, is positioned between the upper and lower bodies such that its inner surface (416) engages an inclined camming surface. EX1007, Ochoa Decl. at ¶ 41. Rotation of a threaded element, e.g. screw 418, which traverses a bore 422 in the lower support member, advances the inclined camming block elevating the upper body while articulating about a pin (432). EX1005, Col. 8, lines 24-37; EX1007, Ochoa Dec., ¶ 41.

A PHOSITA would have understood that the implant of claim 1 is obvious as demonstrated with reference to the chart below.

1. <u>Claim 1</u>

Claim 1 is directed to an implant device. Claim 1 is obvious in view of Larsen. This is demonstrated with reference to the chart below and accompanying text.

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| | '853 patent Claim 1 vs. '832 patent |
|--|--|
| 1. An | Larsen (the '832 patent) (EX1005) discloses: |
| intervertebral implant for a human spine, comprising: | An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined space relation. EX1005, Col. 1, line 65-Col. 2, line 1. The implant further discloses at least the first and second support member having engaging surfaces for engaging vertebral implants of the vertebrae and a camming arrangement having at least one camming member operatively engaging with the first and second support members. EX1005, Col. 2, line 59-63 The apparatus of the present disclosure is intended for fusing adjacent bone structures and has particular application in the spinal fusion of adjacent vertebrae subsequent to a discectomy procedure. The apparatus may be implanted using any conventional surgical approach, e.g., anterior and/or posterior approaches, or may be implanted utilizing minimally invasive or endoscopic surgical techniques currently being utilized to carry out discectomy and spinal implant procedures. EX1005, Col. 4, lines 24-32 See e.g. EX1005 at Fig. 23 below. |
| | Larsen discloses an intervertebral implant for a human spine. EX1007, Ochoa Decl. at ¶ 42. |

The preamble of claim 1 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's

limitations.⁷

To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of Larsen is for use for implantation in a human spine. **EX1005, Col. 1, line 65-Col. 2, line 1**. A PHOSITA would have understood that the spinal implant described in the '832 patent is an interbody spacer for use in spinal fusion procedures. **EX1005, Col. 4 lines 24-32; FIG. 23;**

EX1007 Ochoa Decl. at ¶ 42.

Therefore, a PHOSITA would have recognized that the Larsen reference discloses an intervertebral implant for a human spine, as recited in claim 1,

| EX1007 | Ochoa | Decl. | at ¶ | 42. |
|--------|-----------|-------|---------|-----|
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| | '853 patent Claim 1 vs. the '832 patent |
|--|--|
| an upper body | Larsen (the '832 patent) (EX1005) discloses: |
| comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine; | • Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V ₁ , V ₂ " upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an |
| AND | open and a closed position. EX1005, Col. 8, lines 8-19 FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of |

⁷ 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.

| a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to | camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402. EX1005 , Col. 8, lines 38-47 |
|---|---|
| engage a secona | • See e.g. $EX1005$ at Figs. 22 and 24 below. |
| vertebra of the | |
| human spine; | 40 40 40 40 40 40 40 40 40 40 |
| | • Larsen discloses an unner body comprising an inferior |
| | • Larsen discloses an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine and a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine. EX1007, Ochoa Decl. at ¶ 43. |

The phrase "an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine," **and** "a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a second vertebra of the human spine," 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.⁸ Moreover, a PHOSITA would not understand the limitation, "*configured to engage*," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would have understood that the intervertebral implant ("implant" 400) described in the '832 patent comprises an upper body ("upper support member" 402) and a lower body ("lower support member" 404). **EX1005, Col. 8, lines 8-19; FIG. 22.** The upper and lower bodies comprise a plate-shaped form, each including upper and lower surfaces. *Id.* **at FIGS. 22 and 23.** Pyramid-shaped projections (410) on the superior surface (406) of the upper body and inferior surface (404) of the lower body facilitate engagement with the vertebral end plates of the adjacent vertebrae. *Id.* **at Col. 8,**

lines 8-19; FIG. 23 and 24; EX007, Ochoa Decl. ¶ 43.

Therefore, a PHOSITA would have understood that the Larsen reference discloses an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a first vertebra of the human spine, **and** a lower body comprising a superior surface and

⁸ *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); *and In re Danly*, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

an inferior surface, wherein the inferior surface of the lower body is configured to

engage a second vertebra of the human spine, as recited in claim 1. Id. at ¶ 43.

| | '853 patent Claim 1 vs. '832 patent |
|---|---|
| an insert | Larsen (the '832 patent) (EX1005) discloses: |
| configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine; and | Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebra "V₁, V₂" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404. EX1005, Col. 8, lines 8-28 Support members 402, 404 are interconnected through a pin and slot arrangement. More particularly, support member 402 has a pair of traverses each slot and opening arrangement to connect upper support member 402 and lower support member 404. EX1005, Col. 8, lines 29-37 See e.g. EX1005 at Fig. 23 and 24 below. |



The phrase "an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine," 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.⁹ Moreover, a PHOSITA would not understand the limitation, "configured to be positioned," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen

⁹ *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); *and In re Danly*, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

reference discloses these limitations. A PHOSITA would have understood that the upper body ("upper support member" 402) includes an insert, integral to the inferior surface, in the form of a block with an inclined surface (416). EX1005, FIG. 23; EX1007, Ochoa Decl. at ¶ 44. A PHOSITA would have understood that the upper and lower bodies ("upper support member" 402 and "lower support member" 404) are interconnected through a pin and slot arrangement, thus positioning the insert between superior surface of the lower body and inferior surface of the upper body when assembled. **EX1005, Col. 8, lines 29-37; FIGS.** 23 and 24. Because the '832 patent does not discuss assembly of this device in vivo, and the additional unwieldiness of the assembly of such elements while in the surgical wound, a PHOSITA would have understood that assembly of the pin and slot arrangement would be performed before insertion of the implant into the patient's body. EX1007, Ochoa Decl. at ¶ 44.

Insofar as it may be contended that the insert disclosed in Figures 21-24 of the '832 patent does not comprise a superior and inferior surface, a PHOSITA would have recognized that the choice to combine the functionality of the plate element and wedge shaped insert element of the upper body in a single member would constitute one of many design choices. **EX1007, Ochoa Decl. at ¶ 45.** An equally viable choice would have been to form the plate element and wedgeshaped insert using two separate members which could then be assembled using fasteners such as screws, a snap-fit, or other known assembly methods (see Figure

4). EX1007, Ochoa Decl. at ¶ 45.



Figure 4. Excerpt from figure 24 of the '832 patent demonstrating the location of the interface between the upper body and insert as denoted by the dashed line (top) and after removing insert (bottom).

V,

EX1007, Ochoa Decl. at ¶ 45.

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Addition of modularity would provide added benefit of allowing the surgeon

to select inserts and camming blocks of varying sizes and/or angles at the time of

surgery to allow varying independent degrees of elevation or angulation and reducing the need to hold inventory of various sizes. EX1007, Ochoa Decl. at **¶45.** The concept of using modular components to allow for increased flexibility in sizing was well-known and widely used in the orthopedic industry and would have been recognized by a PHOSITA. EX1015 Mayer, 2002, EX1017 Tropiano, 2003, EX1011 '071 Patent FIG. 1; EX1007, Ochoa Decl. at ¶ 45. For example, Mayer, 2002, discloses the Pro Disc implant, a modular implant for minimally invasive implantation (Figure 1), **EX1015**, page 2 of 7. The ProDisc implant has a polyethylene inlay (insert) that mates with a corresponding intervertebral plate (body), the polyethylene inlay having various sizes: 10 mm, 12 mm and 14 mm. *Id.* at page 5 of 7. A PHOSITA would have recognized that performing the simple substitution of a modular insert for the integrated insert disclosed in the '832 patent would have increased the functionality of the device in a predictable manner without any alteration in the way which the device functioned. EX1007, Ochoa **Decl. at** ¶ **45.**

A PHOSITA, therefore, would have been motivated in view of the benefits referenced above to combine the use of a modular insert with the device disclosed in the '832 Patent to form a plate element and wedge-shaped insert using two separate members which could then be assembled using fasteners such as screws, a snap-fit, or other known assembly methods. **EX1007, Ochoa Decl. at [] 46.**

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Therefore, a PHOSITA would have understood that the Larsen reference discloses an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine, as recited in claim 1. *Id.* at ¶ 44-46.

| '853 patent Claim 1 vs. '832 patent and '724 patent | | |
|--|--|--|
| an expansion Larse | en (the '832 patent) (EX1005) discloses: | |
| member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant. | Referring now to FIGS. 21-24, there is illustrated another lternate embodiment of the spinal implant of the present lisclosure. Implant 400 includes two support members, e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 08. Each contacting surface 406, 408 has a plurality of yramid-shaped projections 410 which facilitate ngagement with the vertebral end plates of the adjacent ertebrae "V ₁ , V ₂ " upon insertion within the intervertebral pace "i". Implant 400 further includes a camming rrangement for moving upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming lock 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 efines an inclined camming surface 414 which engages a orrespondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes threaded element, e.g., screw 418, which traverses a ore 420 within camming block 412 and threadably ngages an internal threaded bore 422 of lower support member 404. EX1005, Col. 8, lines 8-28 Support members 402, 404 are interconnected through a in and slot arrangement. More particularly, support member 402 has a pair of transversely extending slots 424 ormed in side plates 426. Support member 404 has a pair | |





The phrase "an expansion member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant," 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.¹⁰ Moreover, a PHOSITA would not understand the limitation, *configured to elevate*," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Larsen reference discloses these limitations. A PHOSITA would have understood the '832 patent discloses an expansion member in the form of a camming block (412) which is adapted for traversing movement within the interior of the implant (400). EX1005, Col. 8, lines 8-28; FIGS. 22 and 23. A PHOSITA would have understood that the inclined superior surface ("inclined camming surface" 414) of the expansion member ("camming block" 412) engages the corresponding inclined surface (416) of the insert. EX1007, Ochoa Decl. at ¶ 47. Translation of the camming block is induced by rotation of a screw (418), advancing the camming block (412) and engaging the inclined inferior surface of the insert (416) such that the insert moves upwards and the upper body (402) is displaced from the lower body (404). EX1005, Col. 8, lines 8-28; Col. 8, lines 37-47. A PHOSITA would have understood that the separation distance between the upper (402) and lower (404) bodies of the implant (400) described in the '832 patent is increased when

¹⁰ In re Schreiber, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); In re Swinehart, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); and In re Danly, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

screw (418) is rotated in a clockwise direction, or generally progressing the screw into the implant. **EX1007, Ochoa Decl. at ¶ 47.** This causes the screw to advance within threaded bore (422) thereby advancing the expansion member ("camming block" 412) and in so doing displacing the insert upwards and thus increasing the separation distance between the upper (402) and lower (404) bodies. **EX1005, Col. 8, lines 8-28; Col. 8, lines 37-47.** A PHOSITA would have understood that upon activation by rotation of the screw (418), the contacting surfaces of the lower and upper plate members would engage the vertebral faces and therefore the actuation would occur after insertion of the intervertebral implant in the spine. **EX1005, '832 patent, Abstract; EX1007, Ochoa Decl. at ¶ 47.**

A PHOSITA would have recognized that the horizontal component of the force between the inclined surface (416) of the insert and the inclined camming surface ("414") of the expansion member could lead to reverse rotation of the screw (418) within the threaded bore of the lower support member (422) resulting in backout of the expansion member ("camming block" 412). **EX1007, Ochoa Decl. at ¶ 48.** A PHOSITA would have also understood that backout of the expansion member would be inhibited by frictional forces between the inferior surface of the expansion member and the superior surface of the lower body (404). *Id.* **at ¶ 48.** A PHOSITA would have also recognized that complete backout of the screw (418) from the threaded bore and backwards translation of the expansion

member would lead to dissociation of the device and instability. *Id.* at **[] 48.** This could potentially result in retropulsion of the expansion member into either the patient's abdominal aorta or vena cava (if inserted through an anterior approach), or into the posterior neural structures (if inserted through a posterior approach) and consequently the potential for injury. *Id.* at **[] 48.** A PHOSITA would have understood that adding a plurality of parallel teeth to the opposed surfaces of tongue and grove feature located on the superior surface of the lower body and the inferior surface of the expansion member ("camming block" 412) would allow for intraoperative deployment of the intervertebral device while preventing backout once deployed (See Figure 5 below). *Id.* at **[] 48.**



Figure 5. Illustration of features added to the tongue and groove interface between the lower body and the expansion member to inhibit backout of the expansion member.

A PHOSITA therefore would have been motivated in view of the combined teachings of Larsen and Ferree to include a plurality of parallel teeth to the opposed surfaces of the tongue and groove feature since the use of either symmetric or ratcheting toothed structures was well known in the field of modular expandable interbody devices for provision of a secure interfit between surfaces that prevents relative displacement in situ. **EX1026, Col. 5, lines 41-51; FIG. 1; EX1007, Ochoa Decl. at § 48.**

Therefore, a PHOSITA would have understood that the Larsen reference discloses an expansion member configured to elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, and wherein a portion of the superior surface of the lower body is configured to inhibit backout of the expansion member from the intervertebral implant, as recited in claim 1. *Id.* at ¶ 48-49.

A summary image illustrating certain other elements discussed above is included in Figure 6 below.



Figure 6. Excerpt from figures 23 and 24 of the '832 patent demonstrating the various claim elements including the difference between the initial separation distance (D1) and final separation distance (D2).

EX1007, Ochoa Decl. at ¶ 48-49.

The claim chart attached as EX1024 provides additional details as to the

information that would have been conveyed by the '832 patent and understood by a

PHOSITA at the time of the invention of the '853 patent. EX1007, Ochoa Decl.

at ¶ 49.

Consequently, and as supported by Dr. Ochoa, Larsen in view of Ferree renders claim 1 obvious and unpatentable under 35 U.S.C. § 103.

C. Ground 3: Claim 5 is unpatentable under 35 U.S.C. § 103 as obvious over the '899 patent (EX1006) in view of the knowledge of one of ordinary skill in the art

The'899 patent discloses an intervertebral implant for use in spinal fusion surgical procedures after removal of a spinal disc without the need of specialized instrumentation or surgical technique. This allows the implant to rigidly occupy the intervertebral space while eliminating motion between the adjacent vertebrae until permanent fusion is achieved. The implant is configured such that once implanted it is self-stabilizing and able to prevent dislodgement. The disclosed implant comprises an upper member (84), a lower member (82), wedged inserts (86, 88) and an expansion member ("screw" 94). **EX1006, FIG. 10; EX1007, Ochoa Decl. at ¶ 32.**

A PHOSITA would have understood that the spinal implant described in the '899 patent is an interbody spacer for use in spinal fusion procedures. For example, the upper member's superior surface and the lower member's inferior surface are configured to engage the endplates of adjacent vertebrae after the disc has been removed and the implant inserted into the intervertebral space. The bone-engaging surfaces, among others, are equipped with holes (100) to assist with bone ingrowth to achieve permanent fusion. **EX1006, Col. 9, lines 21-27; FIG. 10; EX1007, Ochoa Decl. at ¶ 33.**

A PHOSITA would understand that the intervertebral implant of Michelson,

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when considered in combination with its own teachings renders obvious claim 5 of the '853 patent. The claim charts and accompanying analysis below evidence this conclusion.

1. <u>Claim 5</u>

Claim 5 is directed to an implant device. Claim 5 is obvious in view of Michelson. This is demonstrated with reference to the chart below and accompanying text.

| '853 patent Claim 5 vs. '899 patent | | |
|--|---|--|
| 5. An | Michelson (the '899 patent) (EX1006) discloses: | |
| intervertebral implant for a human spine, comprising: | A spinal implant which when placed within the disc space stabilizes the spinal segment and materially participates in, and is incorporated in, the ensuing fusion. EX1006, Abstract An implant to be placed within the intervertebral disc space to provide for the permanent elimination of all motion at that location. EX1006, Col. 1, lines 15-19. The technique for insertion of the implant is consistent with the established methods of disc removal, and requires neither specialized instrumentation nor specialized surgical technique. EX1006, Col. 4, lines 5-8. | |
| | • With the implant no significant bone is removed and the correct size implant is fitted directly to the insterspace eliminating the need to guess at the correct implant size | |
| | before the fact. EX1006, Col. 4, lines 22-26. | |
| | • See e.g. EX1006 at Fig. 8 below. | |



The preamble of claim 5 merely states the intended use of the invention and does not provide any distinct definition of any of the claimed invention's limitations.¹¹

To the extent that the preamble limits the claim, a PHOSITA would have understood that the spinal implant of Michelson is for use for implantation in a human spine. **EX1006**, **Abstract.** A PHOSITA would have understood that the spinal implant described in the '899 patent is an interbody spacer for use in spinal fusion procedures. **EX1006**, **Col. 1**, **lines 15-19**; **Col. 4**, **lines 5-8**; **Col. 4**, **lines 22-26**; **FIG. 8**; **EX1007**, **Ochoa Decl. at ¶ 34**.

Therefore, a PHOSITA would have recognized that the Michelson reference discloses an *intervertebral implant for a human spine*, as recited in claim 5.

EX1007 Ochoa Decl. at ¶ 34.

¹¹ 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.

| | '853 patent Claim 5 vs. '899 patent |
|---|--|
| a lower body | Michelson (the '899 patent) (EX1006) discloses: |
| comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a first vertebra of the human spine, and wherein the superior surface of the lower | Referring to FIG. 8 an adjustable implant 81 having means for adjusting the width of the implant 81 is shown. The implant 81 comprises a lower member 82 and an upper member 84 which when fitted together form an essentially rectangular implant. The upper member 84 and the lower member 82 have hollow portions that face one another and receive tapered wedges 86 and 88 that fit within the hollow portion of the upper and lower members 82 and 84. The wedges 82 and 84 are such that at their large and they are higher than the combined hollow space between the upper and lower members 84 and 82, and shallower at the other end than the hollow space between the upper and lower members. EX1006, Col. 9, lines 9-20. |
| body comprises | • See e.g. EX1006 at Fig. 8 below. |
| upwardly projecting extensions; | 9 Fig. 8 |
| AND an upper body comprising an inferior surface | |
| surface, wherein | • Referring to FIGS. 9 through 11 the expandable implant 81 |

- Referring to FIGS. 9 through 11 the expandable implant 81 is shown positioned between the two vertebrae V. In FIG. 10 the expandable implant 81 is illustrated in its contracted position. The wedges 86 and 88 abutt the interior sloped surfaces 104 of the upper and lower members 82 and 84. EX1006, Col. 9, lines 28-32
- As the screw 94 is turned, as shown in FIG. 11, the wedges 86 and 88 are drawn together, arid the sloped portions of the wedges force the upper member 82 away from the lower member 84. Once the screw 94 has been turned sufficiently, the screw head 98 is hit, causing the deformable burrs to be crimped so as to prevent the reverse

the superior

surface of the

upper body is

configured to

engage a second

vertebra of the

and wherein the

human spine,

upper body

comprises

recesses



The phrase "a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a first vertebra of the human spine, and wherein the superior surface of the lower body comprises upwardly projecting extensions," and "an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a second vertebra of the human spine, and wherein the upper body comprises recesses configured to accept the upwardly projecting extensions of the lower body," 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.¹² Moreover, a PHOSITA would not understand the limitation, "configured to engage," and "configured to accept" to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Michelson reference discloses these limitations. A PHOSITA would have understood that the adjustable intervertebral implant ("adjustable implant" 81) described in the '899 patent comprises an upper body ("upper member" 84) and a lower body ("lower member" 82). **EX1006, Col. 9, lines 9-20; FIG. 8.** Interior sloped surfaces (104) are included on the inferior surface of the upper body and the superior surface of the lower body. *Id.* at Col. 9, lines 28-32; FIG. 10. When positioned between two vertebrae, the implant is expanded (*Id.* at Col. 9, lines 28-39) such that

¹² In re Schreiber, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); In re Swinehart, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); and In re Danly, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

superior surface of the upper body engages a first, superior vertebrae and that inferior surface of the lower body engages a second, inferior vertebra, such that after the implants are fitted directly to the interspace, they can be expanded, creating a custom intraoperative fit. *Id.* at FIGS. 8, 10 AND 11; EX1007, Ochoa Decl. at ¶ 35.

A PHOSITA would have understood that superior surface of the lower body ("lower member" 82) of the adjustable intervertebral implant ("adjustable implant" 81) described in the '899 patent comprise upwardly projecting extensions in the form of tabs. **EX1007, Ochoa Decl. at ¶36.** These tabs are configured to mate with recesses in the upper and side surfaces of the upper body ("upper member" 84) (See Figure 7 below). **EX1006, FIGS. 8 and 9; EX1007, Ochoa Decl. at ¶ 36.**



Figure 7. Excerpt from Figure 8 of the '899 patent. **EX1007, Ochoa Decl. at** ¶ **36.**

A PHOSITA would have understood that the mating configuration of these tabs and recesses would inhibit anterior-posterior dislocation of the upper body with respect to the lower body during and after implantation. *Id.* **at Ochoa Decl. at ¶ 36.** The geometry of the tabs would also guide the expansion of the device in a cephalocaudal direction during expansion of the implant, thus inhibiting dislocation in the anterior-posterior direction. *Id.* **at Ochoa Decl. at ¶ 36.** Therefore, the '899 patent discloses both a superior surface of the lower body that comprises recesses configured to accept the upwardly projecting extensions of the lower body. *Id.* **at Ochoa Decl. at ¶ 36.**

Therefore, a PHOSITA would have understood that the Michelson reference discloses a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is configured to engage a first vertebra of the human spine, and wherein the superior surface of the lower body comprises upwardly projecting extensions, and an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is configured to engage a second vertebra of the human spine, and wherein the superior surface of the upper body comprises recesses configured to accept the upwardly projecting extensions of the lower body, as recited in claim 5. *Id.* at ¶ 35-36.

| | '853 patent Claim 5 vs. '899 patent |
|--|---|
| an insert | Michelson (the '899 patent) (EX1006) discloses: |
| configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine; | The present implants are available in varying lengths to accommodate the changing depths of the interspace from central to lateral. The devices are available in varying heights or are infinitely adjustable as to the height within the physiological range. The widths are standardized, and the various embodiments can be used in any combination (e.g. in the lumbar spine two auto-expanding implants could be used in conjunction with two anchor deploying implants to completely fill the interspace). EX1006, Col. 4, lines 28-36 It is another object of the present invention to provide for a modular prosthesis, allowing complimentary subunits to be inserted individually through a small opening and to then be reassembled within the interspace, so as to reconstitute an interspace occupying device much larger than would be insertable as a whole. EX1006, Col. 6, lines 36-41 The wedges 86 and 88 have a central threaded opening 90 and 92 in alignment with each other for receiving threaded screw 94. Deformable burrs 95 on the head 98 of the screw 94 are used for locking the screw in place. The implant has a series of holes 100 throughout the body of the implant to assist in the ingrowth process. EX1006, Col. 9, lines 22-27 See e.g. EX1006 at Fig. 8 below. |
| | Pig. 8 Pig. 9 Pig. 8 Pig. 9 Pig. 8 Pig. 9 Pig. 9 Pig |
| | • Referring to FIGS. 9 through 11 the expandable implant 81 |
| | is shown positioned between the two vertebrae V. In FIG. |
| | 10 the expandable implant 81 is illustrated in its contracted |



The phrase "an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine," 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.¹³ Moreover, a PHOSITA would not understand the limitation, "*configured to be positioned*," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at [] 22.**

However, to the extent that this language limits the claims, the Michelson reference discloses these limitations. A PHOSITA would have understood that the wedges (86 and 88) form an insert that abuts the interior sloped surfaces (104) of the upper and lower bodies (82 and 84) and are therefore configured to be positioned between their inward facing surfaces. EX1006, Col. 9, lines 28-32; FIGS. 9, 10 and 11. A PHOSITA would have recognized that the expandable implant (81) would be assembled prior to surgical use. **EX1007, Ochoa Decl. at** ¶ **37.** A PHOSITA would have recognized that an advantage of this implant is that because of its low profile when not deployed, it could be inserted through a small surgical field before expanding the device in place. Id. at Ochoa Decl. at ¶ 37. A PHOSITA would have, therefore understood that the '899 patent discloses, an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine, as

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

recited in the claims. *Id.* at Ochoa Decl. at ¶ 37.

Therefore, a PHOSITA would have understood that the Michelson reference discloses an insert configured to be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine, as recited in claim 5. *Id.* at ¶ 37.

| '853 patent Claim 5 vs. '899 patent | | |
|---|--|--|
| an expansion | Michelson (the '899 patent) (EX1006) discloses: | |
| member configured to engage the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine; and | The wedges 86 and 88 have a central threaded opening 90 and 92 in alignment with each other for receiving threaded screw 94. Deformable burrs 95 on the head 98 of the screw 94 are used for locking the screw in place. The implant has a series of holes 100 throughout the body of the implant to assist in the ingrowth process. EX1006 Col. 9, lines 22-27 See e.g. EX006 at Fig. 8 below. | |
| | Fig. 8 | |
| | • Referring to FIGS. 9 through 11 the expandable implant 81 is shown positioned between the two vertebrae V. In FIG. 10 the expandable implant 81 is illustrated in its contracted position. The wedges 86 and 88 abutt the interior sloped surfaces 104 of the upper and lower members 82 and 84. EX1006. Col. 9. lines 28-32 | |
| | • As the screw 94 is turned, as shown in FIG. 11, the wedges 86 and 88 are drawn together, arid the sloped portions of | |



The phrase "an expansion member configured to engage the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine," 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.¹⁴ Moreover, a PHOSITA would not understand the limitation, "*configured to engage*," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22.**

However, to the extent that this language limits the claims, the Michelson reference discloses these limitations. A PHOSITA would have understood the separation distance between the upper and lower bodies of the adjustable intervertebral implant ("adjustable implant" 81) described in the '899 patent is increased when the expansion member ("screw" 94) is turned. EX1006, Col. 9, lines 28-39; FIGS. 10 and 11; EX1007, Ochoa Decl. at ¶ 38. As the expansion member ("screw" 94 is turned, the threads engage the central threaded openings (90 and 92) of the insert ("wedges" 86 and 88) drawing them together, and forcing apart the upper and lower bodies (82 and 84). EX1006, Col. 9, lines 22-39; FIGS. 10 and 11; EX1007, Ochoa Decl. at ¶ 38. A PHOSITA would have, therefore understood that the '899 patent discloses, an expansion member configured to engage the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, as recited in the claims. EX1007, Ochoa Decl. at ¶ 38.

Therefore, a PHOSITA would have understood that the Michelson reference

¹⁴ In re Schreiber, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); In re Swinehart, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); and In re Danly, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

discloses an expansion member configured to engage the insert to increase a separation distance between the upper body and the lower body after insertion of





The phrase "wherein the upwardly projecting extensions of the lower body, when positioned in the recesses of the upper body, are configured to inhibit dislocation of the upper body from the lower body after insertion of the *intervertebral implant in the human spine*," 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.¹⁵ Moreover, a PHOSITA would not understand the limitation, "*configured to inhibit dislocation*," to disclose any intrinsic or structural limitation of the implant. **EX1007, Ochoa Decl. at ¶ 22**.

However, to the extent that this language limits the claims, the Michelson reference discloses these limitations. A PHOSITA would have understood that superior surface of the lower body ("lower member" 82) of the adjustable intervertebral implant ("adjustable implant" 81) described in the '899 patent comprises upwardly projecting extensions in the form of tabs. **EX1007, Ochoa Decl. at ¶ 36.** These tabs are configured to mate with recesses in the upper and side surfaces of the upper body ("upper member" 84). **EX1006, FIGS. 8 and 9. EX1007, Ochoa Decl. at ¶ 36.** A PHOSITA would have understood that the mating configuration of these tabs and recesses would inhibit anterior-posterior dislocation of the upper body with respect to the lower body during and after implantation. **EX1007, Ochoa Decl. at ¶ 36.** The geometry of the tabs would also guide the expansion of the device in a cephalocaudal direction during expansion of

¹⁵ In re Schreiber, 128 F.3d 1473, 1477-78, 44 U.S.P.Q.2d 1429, 1431-32 (Fed. Cir. 1997); In re Swinehart, 439 F.2d 210, 212-13, 169 U.S.P.Q. 226, 228-29 (C.C.P.A. 1971); and In re Danly, 263 F.2d 844, 847, 120 U.S.P.Q. 528, 531 (C.C.P.A. 1959). M.P.E.P. § 2114.

the implant, thus inhibiting dislocation in the anterior-posterior direction. **EX1007**, **Ochoa Decl. at** ¶ **36**.

Therefore, a PHOSITA would have understood that the Michelson reference discloses wherein the upwardly projecting extensions of the lower body, when positioned in the recesses of the upper body, are configured to inhibit dislocation of the upper body from the lower body after insertion of the intervertebral implant in the human spine, as recited in claim 5. *Id.* at ¶ 36.

The claim charts attached as **EX1025** provide additional details supporting the information that would have been conveyed by the '899 patent and understood by a PHOSITA at the time of the invention of the '853 patent. **EX1007, Ochoa Decl. at ¶ 40.**

Consequently, and as supported by Dr. Ochoa, the Michelson reference renders claims 1 and 5 obvious and unpatentable under 35 U.S.C. § 103.

IX. CONCLUSION

Petitioner has demonstrated in this Petition that claims 1 and 5 of the '853 patent are unpatentable. Petitioner, therefore, respectfully requests institution of an *inter partes* review of the '853 patent.

Dated: August 17, 2015

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

Attorneys for Petitioner, Globus Medical, Inc.

CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, this is to certify that I caused a

true and correct copy of the PETITION FOR INTER PARTES REVIEW OF U.S.

PATENT NO. 7,204,853 to be served via FedEx, next day delivery, on the below

listed counsel, on this 17th day of August, 2015:

Eric B. Meyertons Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. 1120 S. Capital of Texas Hwy. Building 2, Suite 300 Austin, TX 78746 emeyertons@intprop.com

> Mark D. Strachan SAYLES WERBNER, P.C. 1201 Elm Street, Suite 4400 Dallas, Texas 75270 mstrachan@swtriallaw.com

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

> > > Attorneys for Petitioner, Globus Medical, Inc.