UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner

v.

MOSKOWITZ FAMILY LLC,
Patent Owner

Case No.: IPR2020-01307
U.S. Patent No. 8,353,913
Issued: January 15, 2013
Application No: 13/084,543
Filed: April 11, 2011

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,353,913 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42

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1004	Curriculum Vitae of Jorge A. Ochoa, Ph.D., P.E.
1005	U.S. Patent Publication No. 2005/0177236 to Mathieu et al.
1006	Auguste, KI, M.D., Chin, C, M.D., Acosta, FL, M.D., Ames, CP, M.D. Expandable cylindrical cages in the cervical spine: a review of 22 cases. J. Neurosurg Spine 4:285-291, 2006
1007	Boakye, M, Mummaneni, P, Rodts, GW, Haid, RW. The Poly-ether-ether-ketone (PEEK) Spacer. Thieme Medical Publishers, Inc., 2005
1008	Cheung KMC, Leong, JCY. "Spinal Instrumentation Overview in Lumbar Degenerative Disorders: Cages", Chapter 26 in The Lumbar Spine, 3rd Edition, Herkowitz et al. editors, 2004, Lippincott Williams & Wilkins, Philadelphia.
1009	Centinel Spine. The Gold Standard in Integrated Interbody Technologies, Centinelspine.com. © 2020 Centinel Spine, LLC
1010	Dickman, CA, M.D. Internal Fixation and Fusion of the Lumbar Spine Using Threaded Interbody Cages. Div. of Neurological

Exhibit #	*Description*
	Surgery, Barrow Neurological Institute, Mercy Healthcare Arizona, 1997
1011	Dryer, RF. Affinity Anterior Cervical Cage System. Thieme, Spinal Instrumentation, Surgical Techniques. 2005
1012	Folman, Y, Lee, S-H, Silvera, JR, Gepstein, R. Posterior Lumbar Interbody Fusion for Degenerative Disc Disease Using a Minimally Invasive B-Twin Expandable Spinal Spacer. A Multicenter Study. J. of Spinal Disorders & Techniques, Vo. 16, No. 5, pp. 455-460. 2003
1013	Guyer, RD, Ohnmeiss, DD. Degenerative Disc Disease: Fusion Cages and Dowels. The Lumbar Spine, Third Edition, Chapter 35, Degenerative Disc Disease. 2004
1014	Holte, DC, O'Brien, JP, Renton, P. Anterior lumbar fusion using a hybrid interbody graft. A preliminary radiographic report. Eur Spin J (1994) 3:32-28
1015	Lane, JD, Jr. M.D., F.A.C.S., Moore, ES, M.D.. Transperitoneal Approach to the Intervertebral Disc in the Lumbar Area. Annals of Surgery, Vol. 127, Number 3, March 1948

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1016	Michelson, GK, Griffith, SL. BAK/C Interbody Fusion System: A Threaded Cylindrical Cage for Cervical Fusion. Thieme, Spinal Instrumentation, Surgical Techniques. 2005.
1017	Prpa, B, Whitfield, MD, Lieberman, IH. Lumbar Interbody Cages. Spine Surgery, Vol. 1, Second Ed., Techniques, Complication Avoidance, and Management. 2005.
1018	Ryu, SI, Kim, DH. Cervical Carbon Fiber Interbody Fusion Cage: Bengal System. Thieme, Spinal Instrumentation Surgical Techniques, Chapter 34. 2005
1019	Schimmel, JJP, MSC, Poeschmann, MS, M.D., Horsting, PP, M.D., Schönfeld, DHW, M.D., van Limbeek, J, M.D., Ph.D., Pavlov, PW, M.D., Ph.D. PEEK Cages in Lumbar Fusion. Mid-term Clinical Outcome and Radiologic Fusion. Clin, Spine Surg. Vol. 29, Number 5, June 2016
1020	Technique Guide: SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF). © 2006 Synthes
1021	SYNFIX® EVOLUTION System https://www.jnjmedicaldevices.com/en-US/product/synfixr-evolution-system, accessed June 5, 2020.

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1022	K053508, 510 (k) Summary: SynFix-LR, Synthes Spine. 2/13/2006
1023	Wagner, PC, M.S., D.V.M., Bagby, GW, M.S., Grant, BD, D.V.M., M.S., Gallina, A, D.V.M., Ph.D., Ratzlaff, M., D.V.M., Ph.D., Sande, Ron, D.V.M., Ph.D. Surgical Stabilization of the Equine Cervical Spine. Am. Col. Of Veterinary Surgery. 1979.
1024	Weiner, BK., M.D., Fraser, RD., M.D., F.R.A.C.S. SPINE Vol. 23, Number 5, pp. 634-640. 1998
1025	Wilke, HJ, Kettler, A., Claes, L. Primary stabilizing effect of interbody fusion devices for the cervical spine: an in vitro comparison between three different cage types and bone cement. Eur. Spine J. (2000) 9:410-416
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I. INTRODUCTION

Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review ("IPR") of claims 1, 5-8, 10, 11, 14, 15, 19-22, 24, 26-28, 30, 32, 34-36, 38 and 39 (the "Challenged Claims") of U.S. Patent No. 8,353,913, titled "Bi-Directional Fixating Transvertebral Body Screws and Posterior Cervical and Lumbar Interarticulating Joint Calibrated Stapling Devices For Spinal Fusion" ("the '913 patent"), issued to Ahmnon D. Moskowitz, et al. and assigned to Moskowitz Family LLC ("Moskowitz"). The '913 patent is attached as EX1001.

The invention of the '913 patent is not new. Rather, the claimed invention encompasses known implantable intervertebral spinal fixation implants and related instruments for conducting surgical procedures to accomplish an intervertebral fusion of the human spine. In this regard, the Challenged Claims of the '913 patent describe the invention as having features that are well-known and/or inherent in the prior art.

For the reasons set forth herein, Petitioner seeks a final, written decision that the Challenged Claims of the '913 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. A specific listing of Petitioner's asserted grounds for unpatentability and a comparison of the prior art to the Challenged Claims follows below. Evidentiary support for Petitioner's conclusions is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. *See,* EX1003. Dr. Ochoa is an expert with over 35 years

of experience in the area of medical device design, manufacture, commercialization, and failure analysis, 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.

In summary, Waugh in view of Fanger renders Challenged Claims 1, 5, 7, 8, 10, 11, 14, 15, 19, 21, 22, 24, 26-28, 30, 32, 34-36, 38 and 39 unpatentable as obvious under 35 U.S.C. § 103. EX1003 at ¶¶ 31-35; *and see,* EX1027. Additionally, Waugh in view of Fanger and further in view of Neumann renders Challenged Claims 6 and 20 unpatentable as obvious under 35 U.S.C. § 103. *Id.*

Petitioner respectfully requests IPR of the Challenged Claims.

II. MANDATORY NOTICES - 37 C.F.R § 42.8

A. Real Party in Interest (37 C.F.R. § 42.8(b)(1))

Globus Medical, Inc. ("Globus") is the real party-in-interest. No other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation or filing of the Petition.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner is unaware of any disclaimers or reexamination certificates of the '913 patent.

The '913 patent is asserted in *Moskowitz Family LLC v. Globus Medical Inc.*,

U.S. District Court for the Western District of Texas, civil action no. 6:19-cv-672, filed November 20, 2019 ("the Pending Litigation"). The complaint was served on Petitioner, defendant in the Pending Litigation, on November 21, 2019. In the Pending Litigation, Moskowitz has accused certain of Globus's spinal implant devices of infringing the challenged claims of the '913 patent. ***Notably, on July 2, 2020, by Order of the U.S. District Court for the Western District of Texas, the Pending Litigation was transferred to the U.S. District Court for the Eastern District of Pennsylvania and assigned civil action no. 2:20-cv-03271. EX1032. As of the date of this Petition, a new judge has only just been assigned to the case.***

Concurrently with this Petition, Petitioner is also filing IPR Petitions for the following patents: U.S. Patent No. 10,478,319 ("the '319 patent"); U.S. Patent No. 10,307,268 ("the '268 patent"); U.S. Patent No. 9,889,022 ("the '022 patent"). The '319, '268 and '022 patents are related to the '913 patent through continuation practice. Petitioner understands that the '913 patent, the '319 patent, the '268 patent and the '022 patent are all commonly owned by Moskowitz.

Petitioner is also concurrently filing IPR Petitions for U.S. Patent Nos. 10,251,643 ("the '643 patent") and 10,028,740 ("the '740 patent"). The '643 and '740 patents, although not directly related to the '913 patent, disclose similar subject matter and claim priority in a common provisional patent application No. 60/670,231. Petitioner understands that the '643 and '740 patents are likewise

commonly owned by Moskowitz.

C. Designation of Lead and Backup Counsel (37 C.F.R.§ 42.8(b)(3))

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A Power of Attorney (37 C.F.R. § 42.10(b)) is filed concurrently with this Petition.

D. 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.

III. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the Office to charge Deposit Account No. 08-0750 for the petition fee set in 37 C.F.R. § 42.15(a). The Office is authorized to charge any fee deficiency, or credit any overpayment, to Deposit Acct. No. 08-0750.

IV. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

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

Petitioner certifies that the ‘913 patent is available for IPR and Petitioner is not barred or estopped from requesting IPR. Petitioner notes that service of the

Summons and Complaint issued in the Pending Litigation was made on Petitioner on November 21, 2019. Petitioner, therefore, is not time barred by the Pending Litigation to bring this Petition.

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioner requests an IPR of the Challenged Claims on the following grounds:

Ground	Challenged Claims	Asserted Prior Art	Statutory Grounds
1	1, 5, 7, 8, 10, 11, 14, 15, 19, 21, 22, 24, 26-28, 30, 32, 34-36, 38 and 39	U.S. Patent No. 8,425,607 to Waugh et al. ("Waugh") (EX1028) in view of U.S. Patent Application Publication No. 2004/0204717 to Fanger et al. ("Fanger") (EX1029)	35 U.S.C. § 103(a)
2	6 and 20	Waugh in view of Fanger and further in view of U.S. Patent No. 6,752,832 to Neumann ("Neumann") (EX1030)	35 U.S.C. § 103(a)

Based on the foregoing grounds and as established by the declaration of Dr. Ochoa (as further discussed below at Sections X and XI), Petitioner seeks a final, written decision that the Challenged Claims are unpatentable as obvious under 35 U.S.C. § 103.

V. SUMMARY OF THE '913 PATENT (EX1001)

The '913 patent issued on January 15, 2013, on an application filed on April 11, 2011. The '913 patent is a continuation of U.S. Application Serial No.

11/842,855 filed August 21, 2007 issued as U.S. Patent No. 7,942,903, which is a continuation-in-part of U.S. Application Serial No. 11/536,815 filed September 29, 2006 issued as U.S. Patent No. 7,846,188, which is a continuation-in-part of U.S. Application Serial No. 11/208,644 filed August 23, 2005, issued as U.S. Patent No. 7,704,279. The application claims priority to provisional application No. 60/670,231 filed April 12, 2005.

The Challenged Claims of the '913 patent, however, lack written description support under §112 at least in the '188 patent, the '279 patent and the '231 provisional application.[1] Consequently, Petitioner asserts that the earliest priority date supporting the Challenged Claims for the '913 patent is the August 21, 2007 filing date of the '855 application. The burden to prove entitlement to a priority date of a patent earlier than its filing date is on the patentee.[2]

A. The '913 Patent Specification and Claims

The '913 patent relates to the field of implantable orthopedic devices for the human body and particularly to implantable spinal intervertebral fixation devices for spinal fusions. The '913 patent generally discloses a bi-directional fixating

[1] *See* 35 U.S.C. §§119 and 120 (Pre-AIA); *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989).

[2] *Natural Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018).

transvertebral screw system that can be used as an intervertebral spacer and a transvertebral bone fusion screw apparatus. EX1001 at 1:28-35.

The '913 patent issued with 44 claims, 24 of which are at issue in this Petition. Of the Challenged Claims, claims 1 and 15 are independent apparatus claims, and claims 38 and 39 are each independent method claims. Challenged Claims 5-8, 10, 11 and 14 depend directly from claim 1, claims 19-22, 24, 26-28, 30 and 34-36 depend directly from claim 15, while claim 32 depends from claim 30. The Challenged Claims, however, encompass known implantable spinal fixation spacers and surgical procedures and techniques for implanting such spacers for fusing adjacent vertebrae of a human spine and are unpatentable.

The written description and drawings of the '913 patent describe a bi-directional fixating transvertebral screw system that includes an intervertebral bone fusion spacer and an insertion tool for surgically implanting the spacer in the spine and securing the spacer with screws. It also teaches methods for the inserting and securing the spacer. FIGs. 2A-2E and FIGs. 5A-5J are particularly relevant and show embodiments of the spacer 200 and screws 201, 202, and an associated tool 500 for inserting and manipulating the spacer 200 and providing a guide for inserting the screws. *See, e.g.,* EX1001 at 8:6-24; 8:60-9:3; FIGs. 2B, 2D, 5C.

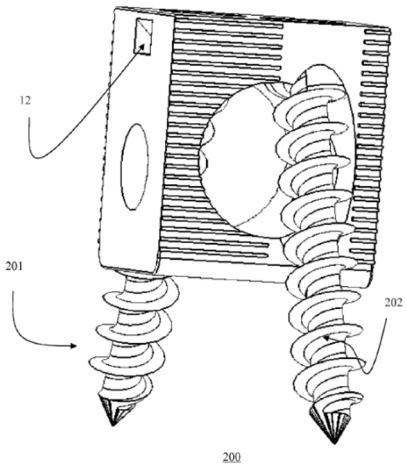


Fig. 2B

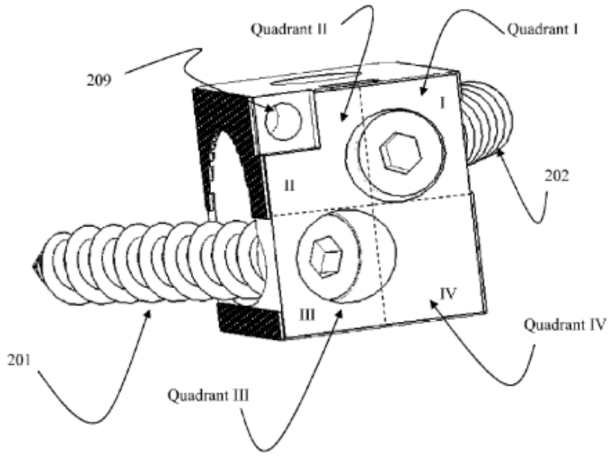


Fig. 2D

The screws 201, 202 are received in and pass through holes in the spacer which serve as integral screw guides (*see, e.g.,* FIG. 2D). The screws 201, 202 are oriented in opposing, superior and inferior directions. *Id.* at 8:6-24. The internal screw guides, however, can have different angles and/or different positions within the spacer. *Id.* Holes 208 and hollow spaces in the spacer 200 allow packing with bone graft materials. *Id.* The superior and inferior surfaces of the spacer include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. *Id.* An end of the spacer can include a slot or indentation 12 formed adjacent to an edge of an upper surface for engaging a protuberant extension of the insertion tool 500. *Id.*

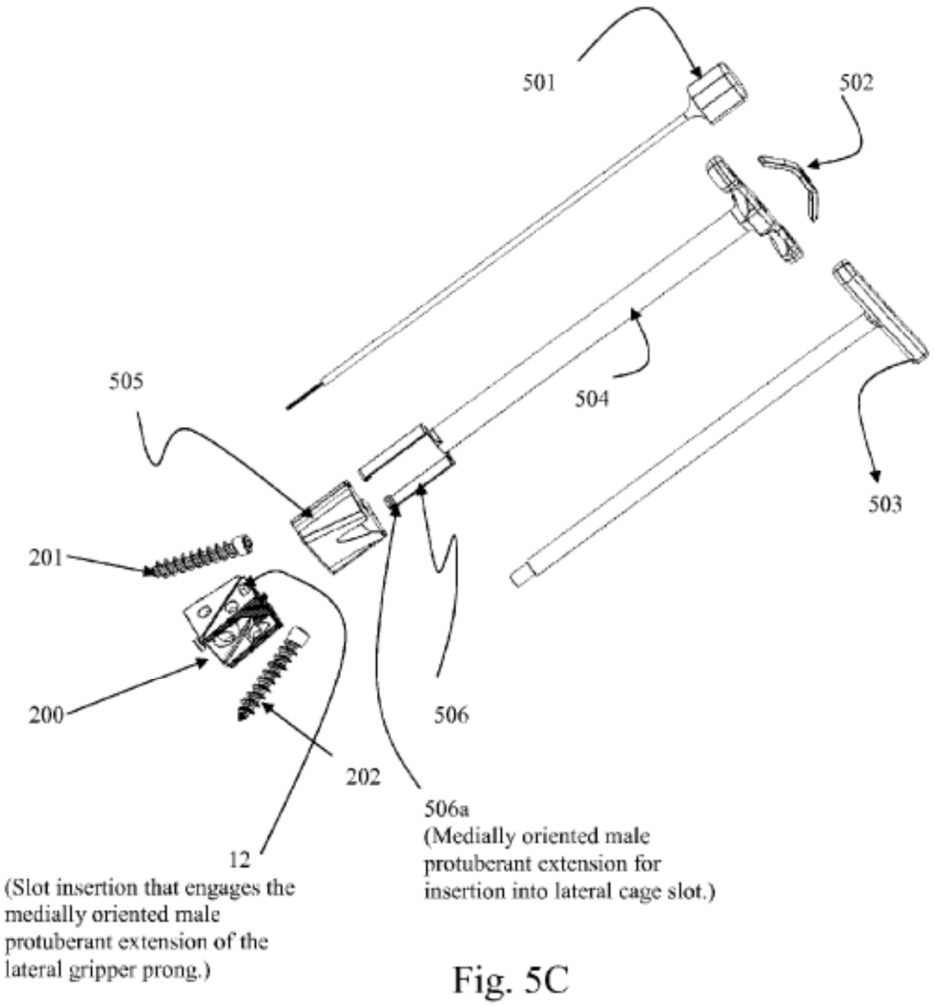


Fig. 5C

The insertion tool includes a handle 503, a gripper 504 and a screw guide 505. *Id.* at 8:55-9:30. The gripper 504 has prongs 506 which insert into grooves of the screw guide 505. *Id.* The prongs 506 include male protuberant extensions 506a that engage the slot or indentation 12 of the spacer 200. *Id.*

The Challenged Claims are directed to the spacer and the tool for implanting the spacer, as well as methods for implanting the spacer using the tool.

B. The '913 Patent Prosecution History (EX1002)

The prosecution of the application leading to the '913 patent, Serial No.

13/084,543, included a series of several Office Actions, corresponding Responses and interviews between the applicant and the Office.

Following two preliminary amendments, (EX1002 at 318, 400), a first non-final Office Action issued including rejecting all of the claims for double patenting and as anticipated or obvious in view of the prior art (*id.* at 290). After a responsive Amendment overcame the substantive rejections (but not the double patenting rejection), (*id.* at 245), a first Final Office Action issued. (*id.* at 100). Applicant's response to the FOA included an IDS citing an additional reference. *Id.* at 85. The added reference was then cited in a second FOA to reject substantially all of the claims (including all of the dependent claims, although 4 dependent claims were considered to contain allowable subject matter. *Id.* at 64. Applicant's response to the second FOA amended the rejected independent claims to incorporate "features of the screw guide [of the tool] from claim 27 into independent claim 26 [Challenged Claim 1], and features of the screw guide [of the tool] from claim 42 into independent claim 41 [Challenged Claim 15], and similar amendments to the other independent claims." *Id.* at 36, 56. Thereafter, the claims were allowed. *Id.* at 19.

VI. CLAIM CONSTRUCTION

In an IPR, a claim of a patent "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary

and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent."[3]

Petitioner submits that the claim terms require no express construction and that they should be given their ordinary and customary meaning. This is true for all limitations except the claim terms identified in the table below. Petitioner submits that the following claim terms should be construed in accordance with the intrinsic record. Petitioner has offered the same constructions in the Pending Litigation, as follows:[4]

Claim Term	**Petitioner's Construction**
"… intervertebral bone fusion spacer"	"an intervertebral bone fusion spacer designed to be inserted between two adjacent vertebrae…"

[3] 37 C.F.R. § 42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

[4] Moskowitz has asserted in the Pending Litigation that all claims take their plain and ordinary meaning. Under either Petitioner's proposed constructions or the plain and ordinary meaning, application of the cited art herein leads to the same conclusion that the Challenged Claims are unpatentable.

"universal, intervertebral bone fusion spacer"	"an intervertebral bone fusion spacer designed to be inserted between two adjacent vertebrae in any region of the spine, i.e., cervical, thoracic, or lumbar, using any approach, e.g., posterior, anterior, or lateral"
"screw fusion"	"fusion between two adjacent intervertebral bodies based on the use of screws having a predetermined, fixed trajectory"
"integral screw guide"	"screw guide located on the spacer, as opposed to on the tool"
"screw guide"	"screw guide located on the tool, as opposed to on the spacer"
"gripper having a plurality of prongs"	"a tool used to grasp the space and the screw guide using the slots or indentations of the spacer and the grooves of the screw guide"
"wherein the plurality of prongs engage and hold the screw guide in place"	"wherein the prongs connect to and hold in place the screw guides on the tool"

"integral trajectory guide"	"a portion of the screw guide located on the tool (as opposed to the spacer) that provides a predetermined angle of trajectory for a bone screw through the tool"
"wherein the screw guide is positioned between the plurality of prongs"	"wherein the prongs of the tool surround the screw guide on the tool"

VII. THE LEVEL OF SKILL IN THE ART

As established in the Declaration of Dr. Ochoa (EX1003 at ¶¶ 25-30) a person having ordinary skill in the art (PHOSITA) of the '913 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 POSITA 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.

VIII. THE STATE OF THE RELEVANT ART AT THE TIME OF THE

INVENTION[5]

The '913 patent generally describes an implantable spinal fixation device for arthrodesis (*i.e.,* immobilization by fusion) of the adjacent bones, or vertebrae, in the human spine and the tool used to implant the device in an intervertebral space.

Implantable spinal fixation devices ("spinal fixation implants") used for spinal fusion have evolved over the years and included various type(s) and design(s) of spinal fixation implants (*e.g.*, screws, rods, plates and spacers and/or cages (with or without screws)) for stabilizing the spine with the intent of promoting fusion between adjacent vertebrae. Further, as the type(s) and design(s) of spinal fixation implants have changed, so too have the surgical techniques and procedures for performing spinal fusion surgery.

A spinal fusion surgical procedure requires, among multiple other steps, determining the size of the intervertebral disc space(s) at the level(s) of interest, removing portions of or the entire intervertebral disc(s), preparing the disc space and the endplates of the adjacent vertebrae to receive the spinal fixation implant(s) and implanting the spinal fixation implant(s) in the disc space(s) (with associated bone graft material – *i.e.* allograft or autograft) to stabilize the adjacent vertebrae. The surgical procedure would necessarily involve a set of accompanying surgical tools

[5] For a more complete discussion, *see* EX1003 at ¶¶ 36-44.

used to measure, prepare, manipulate, insert and secure the spinal fixation implants. It should be appreciated that there are a number of surgical tools that are used during a spinal fusion surgery to perform a variety of tasks, including tools to approach the vertebra, remove the intervertebral discs, prepare the endplates of the adjacent vertebrae contacting the implants, determine the appropriate size of the spinal fixation implant(s), guide drills and screws, hold and align implant components, and insert bone grafting material in spaces where it may be needed. The types of surgical tools used in spinal fusion surgeries are not only general in nature, but some are also specifically designed to interface with the spinal fixation implants to aid in attachment, insertion, and release of the implants at their final position and orientation.

At the time of the invention of the '913 patent, this entire body of art relating to spinal fusions, including the various types of spinal fixation implants, the associated surgical tools for implanting the spinal fixation implants and surgical techniques for carrying out a spinal fusion procedure would have been well known to a PHOSITA.

IX. THE PRIOR ART RELIED UPON IN THIS PETITION

A. Waugh (EX1028)

Waugh, entitled "Anchor Member Locking Features," issued April 23, 2013 on application No. 11/695,939 filed April 3, 2007. Waugh is prior art to the '913

patent under 35 U.S.C. § 102(e)(2) (Pre-AIA). Waugh is a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent (*i.e.,* '913 patent's effective filing date, August 21, 2007). Waugh was not considered by the Examiner during the prosecution of the application leading to the '913 patent.

To swear behind Waugh, Moskowitz must prove conception of the claimed invention before Waugh's April 3, 2007 filing date and diligence in reducing the invention to practice after that date.[6] It should be noted that in the Pending Litigation Moskowitz has already asserted that its earliest invention date for the '913 patent is August 5, 2007. EX1031 at 9-10.

Waugh discloses an intervertebral spinal fixation implant 100, 200, 300 that may be used in a spinal fusion surgical procedure to replace a degenerated spinal disc. *See, e.g.,* EX1028 at FIGs. 3, 4. One or more anchor members 104 (*i.e.* bone screws) may be configured to extend through a plurality of apertures 122 integral to a spacer 102 that act as screw guides to receive and direct the bone screws 104. These apertures may be positioned on a front surface 114 of a front wall of the spacer 102 and in diagonal opposition. A hollow center 116 of the spacer 102 allows placement of bone growth materials to promote bonding and fusion of the implant

[6] *Apator Miitors APS v. Kamstrup A/S*, 887 F.3d 1293, 1295 (Fed. Cir. 2018).

100 to the adjacent vertebrae 14, 16. The spacer 102 of the spinal fixation implant 100 may include an arcuate surface 114 which can comprise a wall of the implant. In addition, the spacer 102 may feature bone engaging features 118 that can take the form of ridges on upper 106 and lower 108 surfaces of the spacer 102.

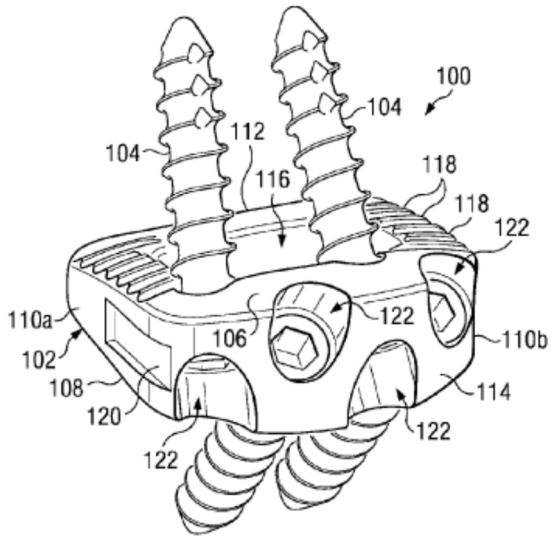


Fig. 3

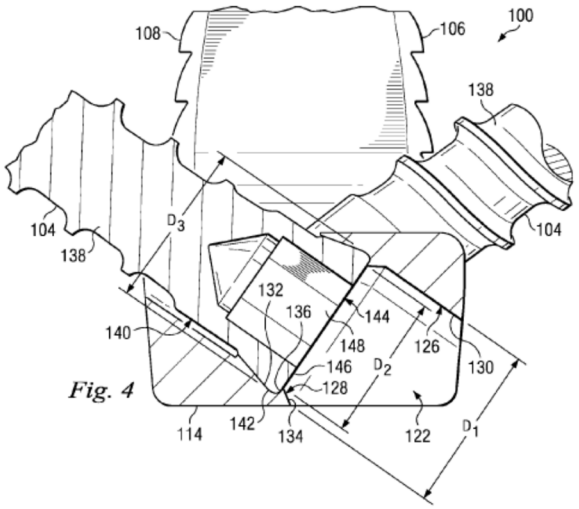
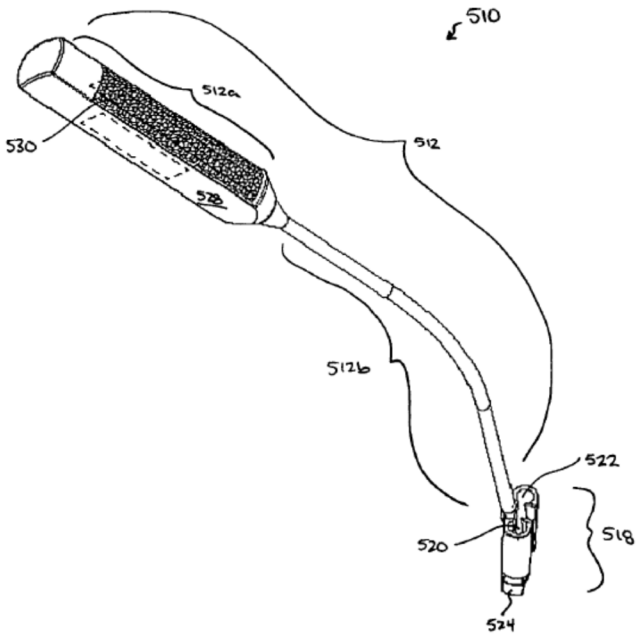


Fig. 4

Waugh discloses that the implant 100 can be introduced into a disc space formed between adjacent vertebrae 14, 16 with the insertion tool. An insertion tool can connect to the implant 100 by engaging with slots 120 in side surfaces 110a, 110b of the spacer 102. Once the implant 100 is positioned within the disc space using the insertion tool, bone screws 104 are introduced into the apertures 122 so that the bone screws 104 extend through the front wall 114 and hollow space 116 and into the endplates of the adjacent vertebrae to secure the implant in the disc space. The bone screws 104 can be arranged at various angles relative to each other and through the spacer 102.

B. Fanger (EX1029)

Fanger, entitled "Guide for Spinal Tools, Implants, and Devices," published October 14, 2004. Fanger is prior art to the '913 patent under 35 U.S.C. § 102(b) (Pre-AIA). Fanger is a printed publication in this country more than one year prior to the effective filing date of the application for the '913 patent in the United States. Fanger was not considered by the Examiner during the prosecution of the application leading to the '913 patent.



Fanger discloses a guide device 510 for use with use with a spinal fixation implant (*e.g.* a spacer, cage, fusion device, etc.). *See, e.g.,* EX1029 at FIGs. 5A-5D. The guide device 510 is a tool that includes an elongated shaft 512 having a handle 528[sic] attached at a proximal end 512a and a guide member 518 coupled to a distal end 512b of the shaft 512. The guide member 518 includes sidewalls 518c, 518d

defining pathways 520, 522 extending through the guide member 518 that are aligned with corresponding bores in a spinal fixation implant (*see*, FIG. 3). The pathways 520, 522 are configured to receive and guide fasteners, such as bone screws, as well as receive and guide tools (such as an awl, drill bit, fastener, or driver device) toward the spinal fixation implant. Fanger, thus, discloses a guide device that can be used to constrain the location, orientation, and/or paths of fasteners and/or tools.

Fig. 5B

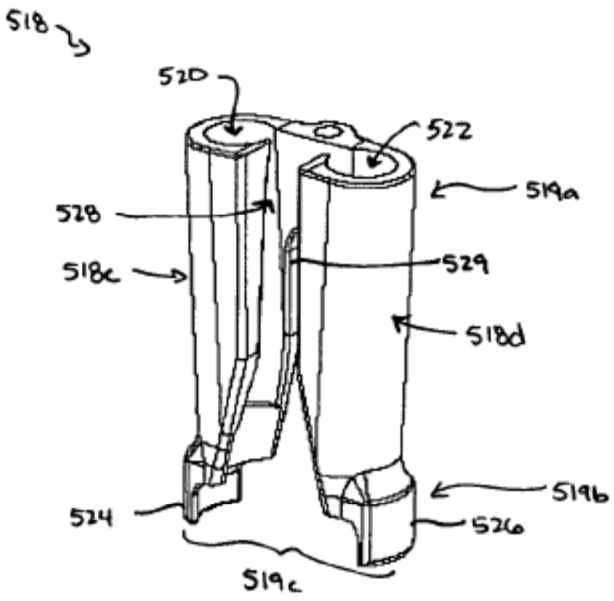
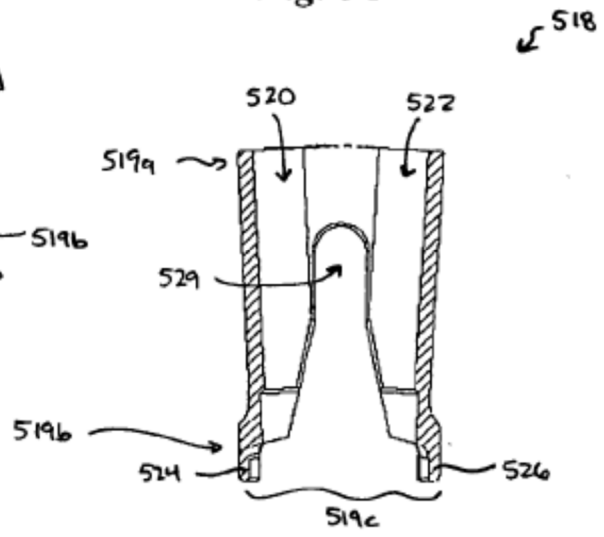


Fig. 5C



The guide device 510 of Fanger also includes one or more tabs 524, 526 (*i.e.,* prongs) extending distally and laterally outwardly from the sidewalls 518c, 518d. The tabs 524, 526 can engage opposed outer surfaces or edges of the spinal fixation

implant and can retain the implant between the tabs 524, 526.

Fanger further discloses that the handle 528 can have virtually any shape and size (*e.g.,* the handle can be rectangular and/or circular).

C. Neumann (EX1030)

Neumann, entitled "Vertebral Implant and Setting Tool Therefor," issued June 22, 2004. Neumann is prior art to the '913 patent under 35 U.S.C. § 102(b) (Pre-AIA). Neumann is a patent in this country more than one year prior to the effective filing date of the application for the '913 patent in the United States. Neumann was not considered by the Examiner during the prosecution of the application leading to the '913 patent.

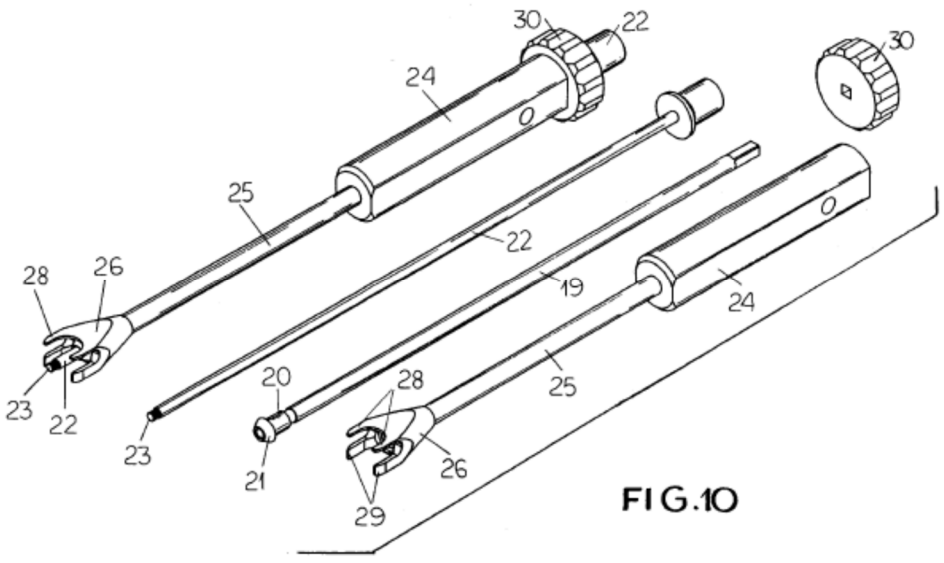


FIG.10

Neumann discloses a tool 18 for inserting and manipulating a spinal fixation implant 1 between adjacent vertebrae in a spinal fusion surgical procedure. *See, e.g.,*

EX1029 at 4:1-38, FIG. 10. The tool 18 comprises a tubular and coaxial assembly of components, including an inner rod 22 disposed within a shaft 19 that is disposed within an outer tube 25 that is connected at proximal end to an outer-end handle 24. At a distal end, the outer tube 25 includes a holder 26 with an upper fork 28 and lower fork 29 that serve to grip the spinal fixation implant during implantation. Both the shaft 19 and rod 22 are operable to engage features of the spinal fixation implant 1 to place and expand the implant 1 in the disc space.

X. GROUND 1: WAUGH IN VIEW OF FANGER RENDERS CLAIMS 1, 5, 7, 8, 10, 11, 14, 15, 19, 21, 22, 24, 26-28, 30, 32, 34-36, 38 AND 39 OBVIOUS

As further discussed below, Waugh teaches each and every element and limitation of the *intervertebral bone fusion spacer* recited in independent claims 1 and 15 and dependent claims 5, 7-8, 10, 11, 14, and 19-22, 24, 24-28, 30, 32 and 34-36. Waugh further teaches that the spacer is *used with an insertion tool* for implanting and manipulating the spacer between adjacent vertebrae that cooperates with slots in the sides of the spacer to connect to the spacer to the insertion tool. Fanger expressly discloses *a guide tool for use with a spinal fixation implant* including connecting features of the type contemplated by Waugh, and meeting each and every element and limitation of the of the tool recited in the Challenged Claims.

A PHOSITA would have considered it obvious to modify the guide tool of Fanger for use with the spacer of Waugh to provide a tool for manipulating and

inserting the spacer into the intervertebral disc space between first and second vertebrae in a spinal fusion surgical procedure. EX1003 at ¶¶31-35, 49-85. Moreover, a PHOSITA would have considered it obvious that, *in a spinal fusion surgery*, a spacer like those taught by Waugh may be manipulated and inserted into the intervertebral disc space, with a guide or insertion tool that is operable to connect to the bone fusion spacer like those taught by Fanger, for carrying out each and every step the methods of the Challenged Claims 38 and 39. *Id.*

A PHOSITA would have considered it obvious to combine the teachings of Waugh and Fanger at the time of the invention of the '913 patent to arrive at the invention recited in the Challenged Claims. *Id.*

A. Independent Claim 1

[1] *A tool for manipulating and inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body for providing fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion,*

[2] *wherein the universal, intervertebral bone fusion spacer includes an intervertebral cage having a first integral screw guide and a second integral screw guide,*

[3] *wherein each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage*

Waugh discloses an intervertebral spinal fixation implant 100, 200, 300 (FIGs. 3, 5 and 9) utilized in a spinal fusion surgical procedure, *e.g.,* to replace a

degenerated natural spinal disc. EX1028, 3:4-52; 4:12-14 and 62-67; 5:43-56; 7:18-27. The device includes a spacer 102, 202, 302 and anchors 104, 204, 304 (*e.g.,* bone screws).

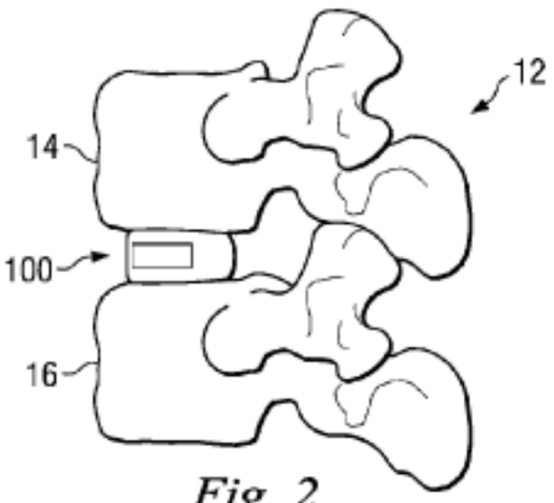


Fig. 2

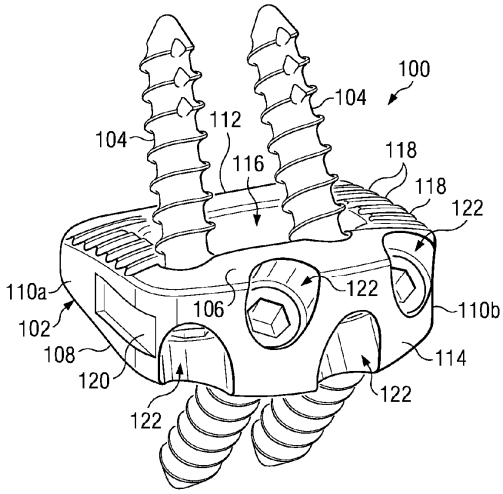


Fig. 3

Waugh discloses using an insertion tool to manipulate and insert the spacer into a prepared disc space between adjacent vertebrae 14, 16. *Id.* at 3:59-64; 4:62-67; FIG. 2. Waugh further discloses that the insertion tool engages and connects with the spacer. *Id.* at 3:59-64.

Once positioned between adjacent vertebrae, the spacer is anchored to the adjacent vertebral bodies by the bone screws 104. *Id.* at 3:65-4:1; 4:62-5:3.

The spacer 102 is a cage defined by an upper surface 106, a lower surface 108, side surfaces, 110a-b, a rear surface 112, a front surface 114 and a hollow center 116 (which allows placement of bone growth materials, such as allograft to promote bonding and fusion of the implantable device 100 to the adjacent vertebrae. *Id.* at

3:36-52; FIG. 3.

A plurality of apertures 122 integral to the spacer 102 receive and direct the bone screws 104 to act as screw guides. *Id.* at 3:65-4:14; 4:62-5:21; FIGs. 4 and 7. The bone screws 104 are introduced through the apertures 122 and extend through the surface 114 out of hollow center 116 and engage the vertebral endplates. *Id.* 3:65-4:14; 4:67-5:3 and FIGs. 3, 9-11, and 14.

Each of the side surfaces 110a-b of the spacer includes a recessed slot 120. The slots 120 are configured to cooperate with an insertion tool that selectively connects to the spacer 102 for manipulating and inserting the spacer during spinal fusion surgery. *Id.* at 3:59-61. As seen, *e.g.,* in FIGs. 5 and 7, the slot 120 is at each longitudinal end of the spacer (i.e., the sides) and adjacent to an edge of the front surface of the spacer (i.e. the upper surface).

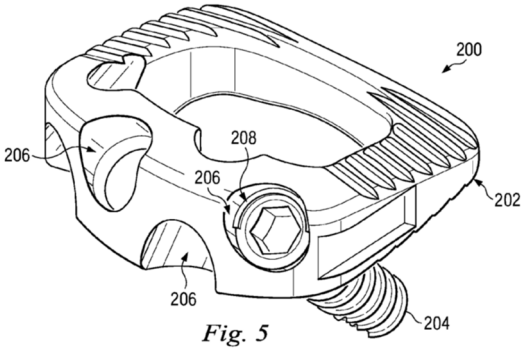


Fig. 5

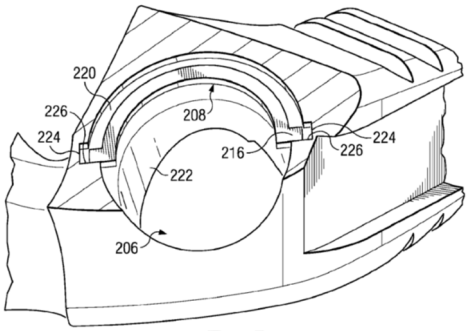


Fig. 7

A PHOSITA would have understood that the insertion tool disclosed in Waugh would have engagement features, such as prongs or tabs that would engage with the slots 120 to connect the insertion tool to the spacer. EX1003 at ¶50.

A PHOSITA would have understood that Waugh discloses a bone fusion spacer meeting each limitation recited at [2] and [3]. *Id.* at ¶¶49-53.

Fanger discloses a tool for inserting and manipulating a spinal fixation implant that is adapted to couple to the implant at a distal end of the tool via engagement features on the tool. EX1029 at [0002]; [0007]; [0041]-[0049]; FIGs. 3, 5A-5D. The tool 510 includes an elongate shaft 512 having a proximal end 512a and a distal end 512b. *Id.* A guide member 518 is coupled to the distal end and includes pathways 520, 522 extending therethrough. *Id.* Tabs 524, 526 are positioned laterally outwardly and distally of the sidewalls 518c, 518d of the guide member. *Id.* Each tab is adapted to interact with a spinal fixation implant 50 to position the guide member with respect to the spinal fixation implant such that each pathway in the guide member is aligned with a corresponding through bore 52a-b, 54a-b, 56a-b formed in the spinal fixation implant. *Id.*

Fig. 5A

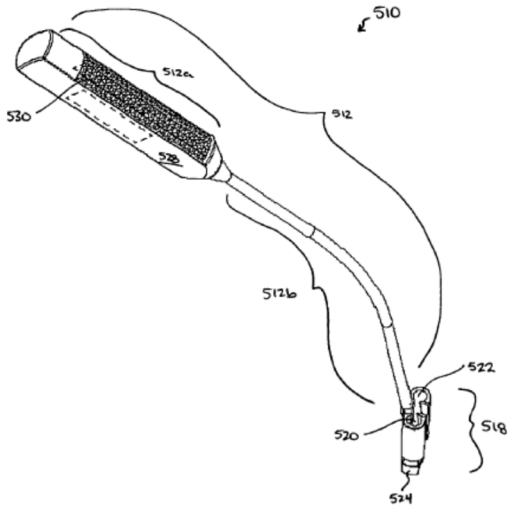


Fig. 5B

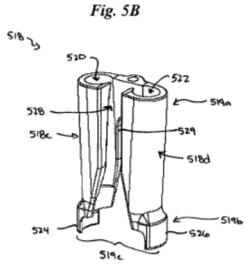


Fig. 5C

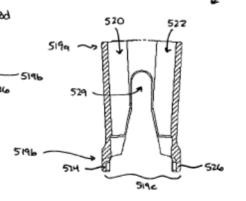
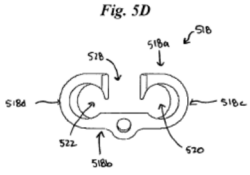


Fig. 5D



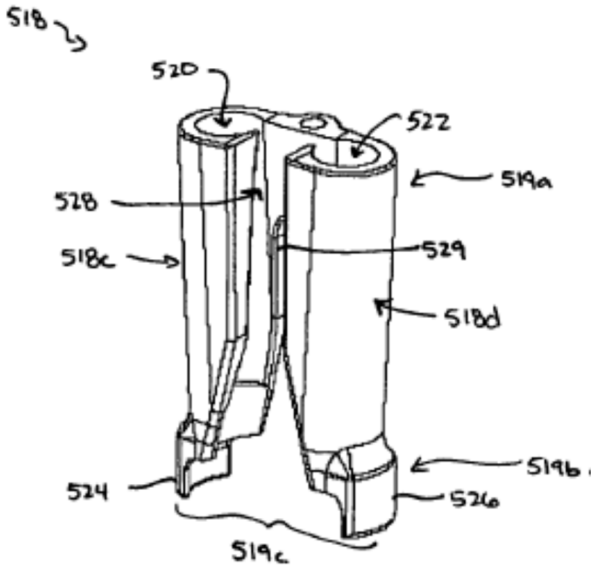
At the time of the invention of the '913 patent, a PHOSITA would have considered it obvious to combine the teachings of Waugh and Fanger to provide an insertion tool for manipulating and inserting a bone fusion spacer as recited at [1]. EX1003 at ¶¶31-35. A PHOSITA would have understood that modifying the tool of Fanger for use with the spacer of Waugh would have yielded a predictable outcome and would not have changed the principal of operation of either the spacer or the tool. *Id.*

[4] *the tool comprising:*

a gripper having a plurality of prongs;

Fanger teaches that the guide member 518 of the tool 510 includes distally-extending tabs 524, 526 (*i.e.,* prongs) formed on each sidewall 518c, 518d. EX1029 at [0043]; [0049]. The tabs 524, 526 are configured to engage opposed outer surfaces of the spinal fixation element and attach or seat the spinal fixation implant therebetween (*e.g.,* to provide a sliding interference fit with outer edges of the spinal fixation element to engage the fixation element). *Id.* "A person skilled in the art will appreciate that the guide member 518 can include any number of tabs formed on any sidewall thereof, and that the guide member 518 can include a variety of other mating elements." *Id.* at [0049].

Fig. 5B



A PHOSITA would have understood that these tabs serve a gripping function. EX1003 at ¶58. Moreover, the tool retains the spacer until the latter is in its implanted position. *Id.* Consequently, a PHOSITA would have understood Fanger to disclose a tool including the gripper and prongs recited at [4]. *Id.*

[5] *wherein a distal end of each of the plurality of prongs is capable of engaging a respective slot or indentation of the intervertebral cage; and*

Waugh teaches an insertion tool that connects to the side slots 120 of the spacer 102. EX1028 at 3:59-61.

Fanger teaches that the guide member 518 of the tool 510 includes distally extending tabs 524, 526 formed on each sidewall 518c, 518d. EX1029 at [0049]. The extending tabs can engage and/or fixedly interact with the spinal fixation implant to connect the tool to the implant. *Id.* at [0043], [0049]; FIG. 3. The shape,

size and position of each extending tab can vary, and they can be adapted to match the contour of particular portions of a spinal fixation implant. *Id.* at [0041]. The extending tabs 524, 526 can be adapted to extend into corresponding slots 120 formed in the spinal fixation implant, and/or they can provide a snap-fit engagement with the spinal fixation implant. *Id.* at [0043], [0049].

A PHOSITA would have understood Fanger to disclose a tool capable of engaging spinal fixation implant as recited at [5]. EX1003 at ¶¶59-60. Moreover, a PHOSITA would have considered adapting the implant engagement features (*i.e.,* the tabs 524, 526) of the insertion tool of Fanger to connect to the tool engagement features (*i.e.,* the side slots 120) of the spacer 102 of Waugh to be an obvious modification that would have yielded a predictable result without changing the principal of operation of either the spacer or the tool. *Id.* A PHOSITA would have considered it obvious to combine the teachings of Waugh and Fanger at the time of the invention of the '913 patent to arrive at the invention recited at [5].

> [6] *a screw guide for controlling a direction of screws that are inserted into the first integral screw guide and the second integral screw guide,*

Fanger teaches a guide member 518 coupled to the distal end 512b of the tool 510. EX1029 at [0046]. The guide member 518 includes pathways 520, 522 extending through the guide member 518 that are aligned with a corresponding thru bore 52a-b, 54a-b, 56a-b formed in the spinal fixation implant. EX1029 at [0046]-

[0049]; FIGs. 5A-5D. The pathways can have a variety of configurations for receiving, *e.g.,* fasteners (such as bone screws) and controlling the directions of the fasteners toward and into the spinal fixation implant. *Id.* at [0038].

A PHOSITA would have understood and appreciated that geometries that constrain the location and orientation of fasteners and tools are found in instrumentation for many applications and, in the case of medical instruments, guide members enable accurate device placement while reducing the likelihood of patient injury. EX1003 at ¶61. A PHOSITA would have understood Fanger to disclose a tool including a screw guide having the limitations recited at [6]. *Id.*

> [7] *wherein the screw guide is positioned between the plurality of prongs.*

Fanger teaches that the sidewalls 518c, 518d of the guide member 518 define pathways 520, 522 extending through the guide member 518 and configured to receive and guide fasteners, such as bone screws, toward the spinal fixation implant. EX1029 at [0038], [0046]. Tabs 524, 526 extending laterally outwardly and distally from the side walls 515c, 518d engage opposed outer surfaces or edges of the spinal fixation implant to retain the implant between the tabs 524, 526. *Id.* at [0049], FIGs. 3, 5B. Thus, the pathways 520, 522 are located between the distally-extending tabs 524, 526. *Id.* at FIGs. 5B, 5C.

Fig. 5B

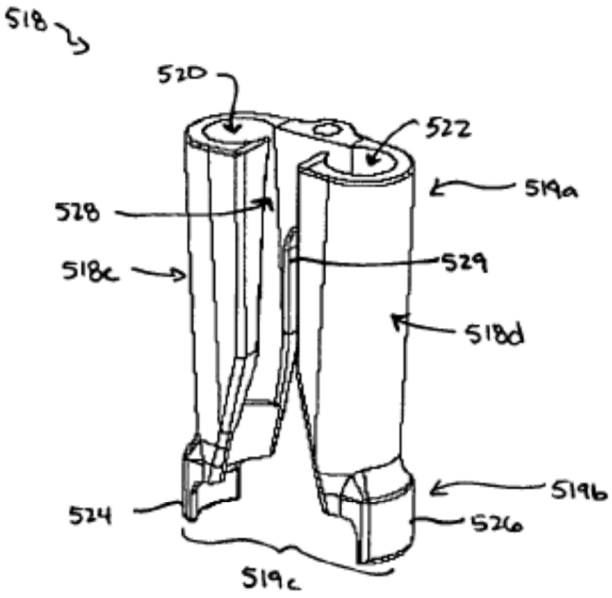
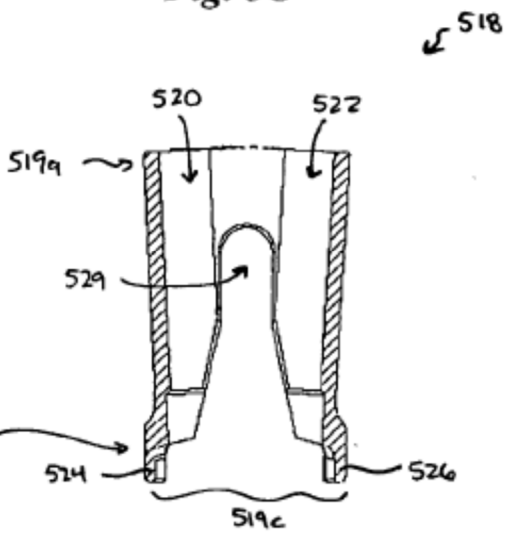


Fig. 5C



A PHOSITA would have understood Fanger to disclose a tool including the screw guide as recited at [7]. EX1003 at ¶62.

The intervertebral spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claim 1 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

B. Independent Claim 15

Petitioner submits that the limitations of the tool assembly of claim 15 are substantively the same as claim 1 and, therefore, the detailed foregoing analysis with regard to claim 1 applies equally to claim 15. *See,* EX1003 at ¶¶54-61.

[1] *A tool assembly comprising:*

[2] *a universal, intervertebral bone fusion spacer for insertion into a disc space between a first vertebral body and a second vertebral body and fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion,*

Waugh in view of Fanger discloses the limitations [1]-[2], above. *See,* sub-section X. A. [1]-[3]; *and see,* EX1003 at ¶¶54-61.

[3] *the universal, intervertebral bone fusion spacer comprising:*

[4] *an intervertebral cage including a first integral screw guide and a second integral screw guide; and*

[5] *a first screw disposed in the first integral screw guide and at least partially within the intervertebral cage;*

[6] *a second screw disposed in the second integral screw guide and at least partially within the intervertebral cage,*

Waugh in view of Fanger discloses the limitations [3]-[6], above. *See,* sub-section X. A. [1]-[3]; *and see,* EX1003 at ¶¶54-61.

[7] *wherein a surface of each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage for receiving a distal end of a prong of an implantation tool; and*

Waugh in view of Fanger discloses the limitations [7], above. *See,* sub-section X. A. [1]-[3]; *and see,* EX1003 at ¶¶54-61.

[8] *a tool for manipulating and inserting the universal, intervertebral bone fusion spacer into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:*

Waugh in view of Fanger discloses the limitations [8], above. *See,* sub-section X. A. [1]-[3]; *and see,* EX1003 at ¶¶54-61.

[9] *a gripper having a plurality of prongs,*

Waugh in view of Fanger discloses the limitations [9], above. *See,* sub-section X. A. [4].

[10] *wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage; and*

Waugh in view of Fanger discloses the limitations [10], above. *See,* sub-section X. A. [5].

[11] *a screw guide for controlling a direction of the first screw and the second screw that are inserted into the first integral screw guide and the second integral screw guide,*

Waugh in view of Fanger discloses the limitations [11], above. *See,* sub-section X. A [6].

[12] *wherein the screw guide is positioned between the plurality of prongs.*

Waugh in view of Fanger discloses the limitations [12], above. *See,* sub-section X. A. [7].

The tool assembly directed to an intervertebral bone fusion spacer and a tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claim 15 would have been obvious to a PHOSITA at the time of the invention of the ‘913 patent over Waugh in view of Fanger for at least the same

reasons already discussed above at section X. A.

C. Dependent Claims 5 and 19

Claims 5 and 19 depend respectively from independent claims 1 and 15. They recite:

> *wherein the screw guide includes an integral trajectory guide that is capable of receiving and guiding one of the screws of the universal, intervertebral bone fusion spacer.*

Fanger teaches a guide member 518 coupled to the distal end 512b of the tool 510. The guide member includes pathways 520, 522 (*i.e.*, trajectory guide(s)) extending through the guide member 518 that are aligned with a corresponding thru bore 52a-b, 54a-b, 56a-b formed in the spinal fixation implant. EX1029 at [0046]-[0049]; FIGs. 5A-5D. The pathways can have a variety of configurations for receiving fasteners (such as bone screws) and controlling the directions of the fasteners toward and into the spinal fixation implant. *Id.* at [0038].

A PHOSITA would have understood Fanger to disclose a tool including a screw guide as claimed. EX1003 at ¶63. The intervertebral bone fusion spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 5 and 19 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

D. Dependent Claims 7, 8, 21 and 22

Claims 7 and 8 each depend directly from independent claim 1 and claims 21

and 22 each depend directly from independent claim 15. Claims 7 and 21 recite:

> *further comprising a handle, wherein an end of the handle includes a rectangular handle portion.*

and claims 8 and 22 recite:

> *further comprising a handle, wherein an end of the handle includes a circular handle portion.*

Fanger discloses that the proximal portion 12a of the tool includes a handle 28. EX1029 at [0035], FIGs. 1, 3, 5A. Fanger shows the handle 28 illustrated in the figures to be rectangularly-shaped. *Id.* at FIGs. 1, 3, 5A. Fanger also teaches that the handle can have virtually any shape and size. *Id.* at [0035].

As such, a rectangular handle portion as recited in claims 7 and 21 would have been obvious to a PHOSITA. EX1003 at ¶69.

Similarly, A PHOSITA would have understood that tool handle shapes with circular portions have been used for a variety of reasons, including ergonomic comfort, aesthetics, and ease of manufacturing via methods such as lathe turning and pipe formation. *Id.* at ¶70. Moreover, a PHOSITA would have known and understood that handle shape was a matter of simple design choice, and was routinely accomplished through the use of "off-the-shelf" handle components from OEM catalogs, which included three-sided, four-sided (Square), "T," palm, round, ball, paddle, throttle, pistol grip and other standard shapes. The final configuration of such an instrument would have been determined by a PHOSITA based on

standard, readily available components and surgeon preference. *Id.* The use of a handle with a circular portion as recited in claims 8 and 22 would also have been obvious to a PHOSITA. *Id.*

The intervertebral bone fusion spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 7, 8, 21 and 22 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

E. Dependent Claims 10 and 11

Claims 10 and 11 each depend directly from independent claim 1. Both claims 10 and 11 include an identical recitation that:

> *wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,*
>
> *wherein the wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis,*
>
> *wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,*
>
> *wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,*
>
> *wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and*

Claim 10 further adds:

> *wherein one of:*
>
> *a majority of an area of the entry opening of the first integral screw guide is in the first quadrant and a majority of an area of the entry opening of the second integral screw guide is in the third quadrant; and*
>
> *the majority of the area of the entry opening of the first integral screw guide is in the second quadrant and the majority of the area of the entry opening of the second integral screw guide is in the fourth quadrant.*

Claim 11 further adds:

> *wherein one of:*
>
> *a center of the entry opening of the first integral screw guide is in the first quadrant and a center of the entry opening of the second integral screw guide is in the third quadrant; and*
>
> *the center of the entry opening of the first integral screw guide is in the second quadrant and the center of the entry opening of the second integral screw guide is in the fourth quadrant.*

A PHOSITA would have understood that Waugh discloses an intervertebral spinal fixation implant 100, 200, 300 (FIGs. 3, 5 and 9) including one or more entry openings for integral screw guides located in diagonally opposed quadrants of a wall of the spacer. EX1028 at FIG. 3. In particular, FIG. 3 shows the spacer 102 is a cage defined by an upper surface 106, a lower surface 108, side surfaces, 110a-b, a rear surface 112, a front surface 114 and a hollow center 116. EX1028 at 3:36-52; FIG. 3. The surface 114 includes a plurality of apertures 122 that receive and direct

the bone screws 104 and act as screw guides. *Id.* at 3:65-4:14; 4:62-5:21. The bone screws are introduced through the apertures and then rotated to engage with and advance into the vertebral endplates. *Id.* at 4:67-5:3. FIG. 3, as annotated below, shows that two of the apertures 122 are disposed in diagonally opposed quadrants of the surface 114. *See,* EX1003 at ¶71.

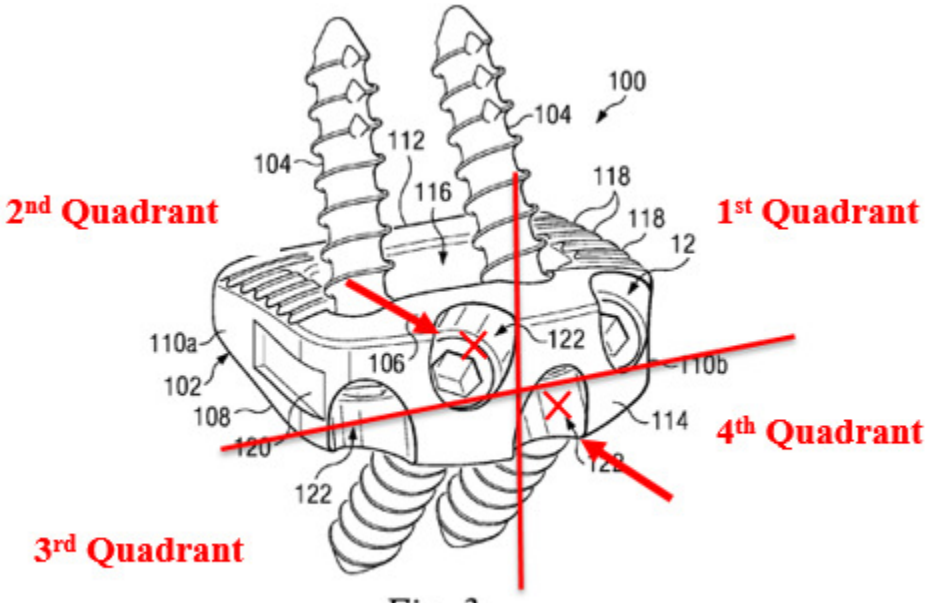


Fig. 3

A PHOSITA, therefore, would have recognized that a diagonally opposed arrangement of two bone screws is disclosed in Waugh. *Id.* Moreover, diagonal opposition of the entry openings would have been obvious to a PHOSITA based on the widely held and established biomechanical precepts that fixation or bone screws should not collide with each other or breach the vertebral bodies, yet be angled relative to each other to increase holding power. *Id.* Further, a PHOSITA would also have considered diagonal opposition of the entry openings for the bone screws to be

obvious. *Id.* Based on basic machine design principles, a PHOSITA would have known that diagonal opposition of the entry openings could prevent overlap of closely spaced integral screw guides and/or permit the use of shorter bone screws, which would decrease the amount of material to be implanted within the body. *Id.*

Regarding claim 10, a PHOSITA would have known that the use of "quadrants" to describe the location of the integral screw guide openings on the anterior aspect of the spacer was simply a restatement of basic principles of elements of machine design. *Id.* As shown in the annotated FIG. 3, above, a majority of an area of the entry opening of the first identified aperture 122 is in the second quadrant and a majority of an area of the entry opening of the second identified aperture 122 is in the fourth quadrant, as recited in the claim. .

Regarding claim 11, as shown in annotated FIG. 3, above, a PHOSITA would have also understood that Waugh shows a center of the entry opening of the first identified aperture 122 (annotated as an "X") is in the second quadrant and a center of the entry opening of the second identified aperture 122 (annotated as an "x") is in the fourth quadrant, as recited in the claim. EX1003 at ¶72.

The intervertebral bone fusion spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 10 and 11 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

F. Dependent Claim 14

Claim 14 depends directly from claim 1 and recites:

wherein the intervertebral cage includes an arcuate wall.

A PHOSITA would have understood that the spacer of the spinal fixation implant disclosed in Waugh comprises an intervertebral cage with an arcuate wall. EX1003 at ¶73. For example, surface 114 is an arcuate surface that comprises a front wall of the intervertebral spacer 102. *Id.* Similarly, surfaces defining the hollow center 116 have arcuate profiles. *Id.* and *see* EX1028 at FIGs. 3, 5, 9.

The intervertebral spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claim 14 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger. *Id.*

G. Dependent Claims 24, 28, 34, 35 and 36

Claims 24, 28, 34, 35 and 36 all depend directly from claim 15 and all of the claims include further limitations regarding the orientation of the first and second internal screw guides of the intervertebral cage.

Claim 24 further limits the first and second internal screw guides to be "angled to orient the first screw and the second screw bi-directionally in opposite directions." Claim 35 further recites that the first and second internal screw guides "diverge from each other."

A PHOSITA would have understood that Waugh discloses that the apertures 122 in the spacer 102 are angled to diverge from each other and orient the bone screws 104 bi-directionally in opposite directions, as recited in claims 24 and 35. EX1028 at 4:2-11; FIGs. 3-5, 7-9, 10, 14; EX1003 at ¶74. A PHOSITA would have understood that a screw guide would necessarily define the path or paths of one or more bone screws and/or follow a corresponding path or paths defined by the part to which the screw guide is engaged (*i.e.,* the aperture on the spacer). EX1003 at ¶74. Waugh discloses all of the limitations of claims 24 and 35.

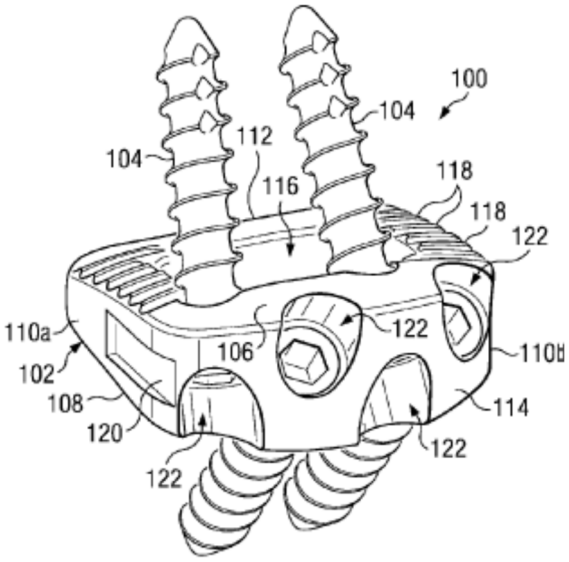


Fig. 3

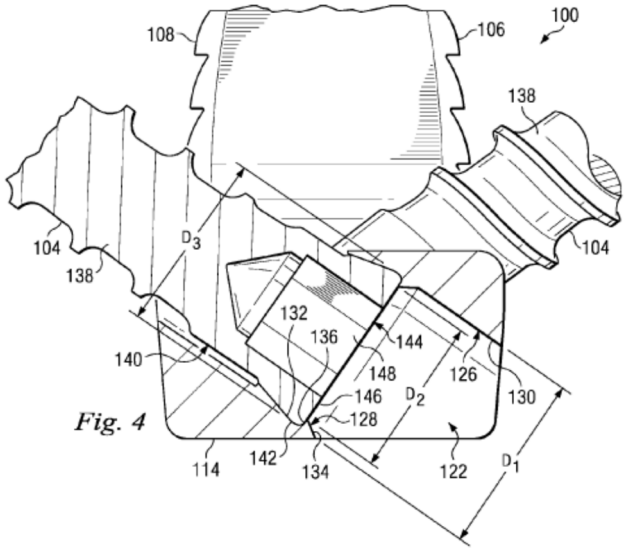


Fig. 4

Claims 28, 34 and 36 all recite that the first and second internal screw guides are "at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide." Claim 28 also adds that the screw guides are "adjacent to each other;" and claim 36 also adds that the screw guides diverge from

each other as in claim 35.

A PHOSITA would have understood that Waugh discloses that the apertures 122 in the surface 114 of the spacer 102 are adjacent to one another and at an angle relative to the surface 114 in which they are located, which would have been understood as a "wall" as recited in claims 28, 34, and 36. EX1028 at 4:2-11; FIGs. 3-5 and 7-9; EX1003 at ¶¶74, 77, 78. A PHOSITA would have understood that Waugh also discloses embodiments in which the screw apertures are at angles relative to one another. *Id.* Waugh also discloses that the screw apertures diverge from each other as previously discussed. Such an arrangement permits the bone screws to penetrate the vertebral endplates above and below the spacer and also to have screw heads that are accessible from the anterior side. *Id.* Waugh discloses all of the limitations of claims 28, 34 and 36.

The intervertebral spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 24, 28, 34, 35 and 36 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

H. Dependent Claims 26 and 27

Claims 26 and 27 both depend directly from claim 15. Claim 26 recites:

> *a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body.*

Claim 27 recites:

> *wherein the intervertebral cage includes a side having a plurality of ridges.*

Waugh discloses that the spacer 102 may include a hollow center 116. EX1028 at 3:49-52. The hollow center 116 allows for placement of bone growth materials, such as allograft to promote bonding and fusion of the implant 100 to the adjacent vertebrae. *Id.* A PHOSITA would have understood that it was well-known to include a bone graft cavity, or "graft window," in a spinal fixation implant for spinal fusion into which bone packing material could be placed. EX1003 at ¶75.

Waugh also discloses that the upper and lower surfaces 106, 108 of the spacer 102 include bone engaging features 118 configured to reduce slipping or movement of the implant 100 relative to adjacent vertebrae. EX1028 at 3:53-59, FIGs. 3, 5 and 9. The bone engaging features 118 are angled teeth that permit introduction into the disc space, but also restrict removal. *Id.* These features are depicted as multiple ridges on the upper and lower surfaces. *Id.*; EX1003 at ¶76.

The intervertebral spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 26 and 27 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

I. Dependent Claims 30, and 32

Claim 30 depends directly from claim 15 and recites that:

the first integral screw guide and the second integral screw guide are adjacent to each other along a longitudinal extent of a wall having the first integral screw guide and the second integral screw guide, and

wherein the first integral screw guide and the second integral screw guide are offset in opposite directions with respect to a center line of the longitudinal extent.

A PHOSITA would have understood that Waugh discloses screw apertures 122 through the surface 114 of the spacer 102 that are adjacent to one another along the long axis of surface 114 and at an angle relative to the surface, which would have been understood as a "wall" as recited in claim 30. EX1028 at 4:2-11; FIG. 3; EX1003 at ¶¶ 74, 77, 78.

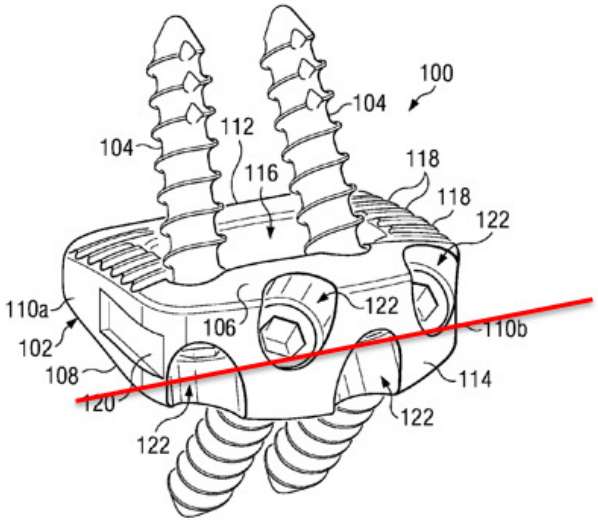


Fig. 3

Further, A PHOSITA would have understood that Waugh further discloses the apertures to be offset in opposite directions relative to this long axis as recited in claim 30. EX1003 at ¶79. As stated above, this arrangement permits the bone screws

to penetrate the vertebral endplates above and below the spacer and also to have heads of the bone screws that are accessible from the anterior side. EX1028 at 4:2-11; FIGs. 3-5 and 7-9; EX1003 at ¶¶74, 77, 78.

Claim 32 depends from claim 30 and adds the further limitation that:

> *the first integral screw guide and the second integral screw guide are at an angulation with respect to the wall having the first integral screw guide and the second integral screw guide.*

(as is also recited in claim 34, *see* section X. G., above). As already discussed in connection with claim 34, above, Waugh also discloses this arrangement. EX1003 at ¶¶74, 77, 78. Specifically, Waugh discloses that the apertures 122 in the surface 114 of the spacer 102 are an angle relative to the surface 114 in which they are located, which would have been understood as a "wall" as recited in the claims. EX1028 at 4:2-11; FIGs. 3-5 and 7-9; EX1003 at ¶¶74, 77, 78.

The intervertebral spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 30 and 32 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger.

J. Independent Claims 38 and 39

Claims 38 and 39 are each directed to a method using the tool for implanting the bone fusion spacer between adjacent vertebrae of a human spine in a spinal fusion procedure. For those elements of claims 38 and/or 39 relating to the structures

of the bone fusion spacer and tool for its implantation that are substantially identical to elements of claim 1 and/or 15, reference is made to the analysis detailed above with regard to those claims, with the understanding that the corresponding analysis equally applies to claims 38 and/or 39. *See* EX1003 at ¶¶80-85.

Claim 38 reads:

> [1] *A method of inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body using a tool for manipulating and inserting the universal, intervertebral bone fusion spacer into the disc space between the first vertebral body and the second vertebral body,*
>
> [2] *wherein the universal, intervertebral bone fusion spacer includes:*
>
> *an intervertebral cage having a first integral screw guide and a second integral screw guide, wherein a surface of each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage for receiving a distal end of a prong of tool; and*
>
> [3] *wherein the tool includes:*
>
> *a gripper having a plurality of prongs,*
>
> [4] *wherein a distal end of each of the plurality of prongs is capable of engaging a respective slot or indentation of the intervertebral cage, and*
>
> [5] *a screw guide for controlling a direction of a first screw and a second screw that are inserted into the first integral screw guide and the second integral screw guide, wherein the screw guide is positioned between the plurality of prongs, and*

Waugh in view of Fanger discloses the limitations [1]-[5], above. *See,* sub-section X. A.

[6] *the method comprising:*

> *measuring a dimension of the disc space between the first vertebral body and the second vertebral body;*

A PHOSITA would have understood that Waugh discloses a spinal fixation implant 100 including a spacer 102 that is sized to fit the intervertebral disc space height between two adjacent vertebrae. EX1003 at ¶80. A PHOSITA would have understood that there are dimensional differences in the skeletons of individuals and that it has been a common practice for medical device manufacturers to offer orthopedic implants of different sizes to account for these dimensional differences. *Id.* Moreover, there have long been multiple means for a clinician to evaluate skeletal features and dimensions, prior to and during a surgical procedure, including radiographs, fluoroscopy, and trial implants. *Id.* Therefore, it would have been obvious and inherent to a PHOSITA that use of an intervertebral spacer would involve measuring the dimension of a disc space between two vertebral bodies, as recited at step [6]. *Id.*; EX1028, 3:29-32, 10:25-26, 12:19-20.

[7] *determining that the disc space is a lateral disc space, an anterior lateral disc space, a posterior lumbar disc space, an anterior lumbar disc space, or an anterior cervical disc space;*

Waugh discloses that the spinal fixation implant 100 can be used in an intervertebral spinal fusion procedure and in various approaches in the cervical, thoracic, and lumbar regions. EX1028 at 3:10-18; 9:12-21. A PHOSITA would have understood that determining the nature of the disc space as recited at step [7] is a

necessary and obvious step in an intervertebral fusion procedure. EX1003 at ¶81.

> [8] *selecting the universal, intervertebral bone fusion spacer based on the measured dimension of the disc space and based on the determination of the disc space being the lateral disc space, the anterior lateral disc space, the posterior lumbar disc space, the anterior lumbar disc space, or the anterior cervical disc space;*

Waugh discloses a spinal fixation implant 100 including a spacer 102 that is suitable for use in all regions of the vertebral column, including the cervical, thoracic, and lumbar regions. Exhibit EX1028, 3:10-18. Further, Waugh discloses an implant whose implantation could involve any surgical approach that would allow adequate visualization and/or manipulation of the bone structures. *Id.* at 9:12-21. These approaches include lateral, antero-lateral, and posterior. *Id.* A PHOSITA would have understood that it would have been obvious to select a spacer based on the size of the disc space and/or the desired surgical approach as recited at step [8]. EX1003 at ¶82.

> [9] *selecting the screw guide based on the selected universal, intervertebral bone fusion spacer and positioning the screw guide between the plurality of prongs;*

> [10] *positioning the intervertebral cage between the plurality of prongs such that each slot or indentation of the intervertebral cage corresponds with the distal end of each of the plurality of prongs;*

Fanger discloses a guide member 518 coupled to the distal end 512b of spinal fixation implant insertion tool 510 that includes pathways 520, 522 extending through the guide member that are aligned with a corresponding thru bore formed in

the spinal fixation implant. EX1029 at [0046]-[0049]; FIGs. 5A-5D. In addition, Fanger teaches that distally-extending tabs 524, 526 are formed on sidewalls 518c, 518d of the guide member and engage opposed outer surfaces or edges of the spinal fixation implant to retain the implant between the tabs. *Id.* at [0049]; FIG. 5B. Fanger discloses an insertion tool that matches the geometry of the selected implant. *Id.* at [0041]. Further, it would have been obvious to a PHOSITA that, for proper function, the screw guide would necessarily need to be compatible with the selected implant. EX1003 at ¶¶62, 83; *and see*, sub-section X. A. [7].

A PHOSITA would have considered the steps recited at [9] and [10] obvious over Waugh in view of Fanger.

> [11] *inserting the selected universal, intervertebral bone fusion spacer into a midline of the disc space using the tool until the selected universal, intervertebral bone fusion spacer is flush or countersunk relative to the first vertebral body and the second vertebral body; and*

Waugh discloses a spinal fixation implant intended to reside within the intervertebral space between adjacent vertebrae. EX1028 at 3:24-32, FIG. 2. Figure 2 illustrates that the implant is positioned such that it is countersunk relative to the adjacent vertebrae. *Id.* Waugh further discloses the implant is configured for connection with an insertion tool. *Id.* at 3:59-64. Further, it would have been obvious to a PHOSITA that implantation of the spacer would occur approximately in the midline of the intervertebral space or disc space, as placing the spacer at or near the

midline would prevent instability in the spine from having an implant placed too far medially or laterally in the disc space. EX1003 at ¶84.

A PHOSITA would have considered the steps recited at [11] to have been obvious over the teachings of Waugh in view of Fanger.

> [12] *confirming a position and placement of the universal, intervertebral bone fusion spacer relative to the first vertebral body and the second vertebral body.*

Waugh discloses a spinal fixation implant that employs radiopaque materials that allow locations of the components of the devices to be tracked. EX1028 at 8:48-53. Vertebral bodies are radiopaque as well. EX1003 at ¶85. A PHOSITA would have understood that confirming a position and placement of the implant relative to the vertebrae after implantation as recited in [12] to be taught by Waugh. *Id.*

Petitioner submits that the limitations of claim 39 are substantively the same as claim 38 and, therefore, the foregoing detailed analysis with regard to claim 38 applies equally to claim 39. Although nearly identical to claim 38, claim 39, includes certain additional limitations, as follows:

Regarding claimed features of the spacer, claim 39 recites that the universal, intervertebral bone fusion spacer of the claim further includes:

> *a first screw disposed in the first integral screw guide and at least partially within the intervertebral cage;*
>
> *a second screw disposed in the second integral screw guide and at least partially within the intervertebral cage,*

Waugh in view of Fanger discloses an intervertebral bone fusion spacer including these limitations. Waugh teaches the spacer 102 is a cage including a plurality of apertures 122 that receive and direct the bone screws 104 and act as screw guides. EX1028 at 3:65-4:14; 4:62-5:21. *See also,* sub-section X. A.

Also, the method of claim 39 alternatively requires the step of:

> *engaging each slot or indentation of the intervertebral cage with the distal end of each of the plurality of prongs;*

Waugh teaches that each of the side surfaces 110a-b of the spacer 102 includes a recessed slot 120 that is configured to cooperate with an insertion tool to connect the tool to the spacer. EX1028 at 3:59-61. The insertion tool would have features, such as prongs, that would engage with these slots. EX1003 at ¶60. Fanger discloses a tool for inserting and manipulating a spinal fixation implant that is adapted to couple to the implant at a distal end of the tool via tabs 524, 526 on the tool. EX1029 at [0002]; [0007]; [0041]-[0049]; FIGs. 3, 5A-5D.

A PHOSITA would have considered above step of *engaging* to have been obvious over the teachings of Waugh in view of Fanger. EX1003 at ¶60.

Further, the method of claim 39 additionally recites, subsequent to inserting the spacer into the disc space and before confirming the position and placement of the spacer, the steps of:

> *inserting the first screw into the first internal screw guide of the selected universal, intervertebral bone fusion spacer;*

inserting the second screw into the second internal screw guide of the selected universal, intervertebral bone fusion spacer;

screwing the first screw and the second screw into the first vertebral body and the second vertebral body respectively;

Waugh in view of Fanger discloses these steps. EX1003 at ¶56. Waugh teaches the spacer 102 is a cage including a plurality of apertures 122 that receive and direct the bone screws 104 and act as screw guides. EX1028 at 3:65-4:14; 4:62-5:21. The bone screws are introduced through the apertures and then rotated to engage with and advance into the vertebral endplates. *Id.* at 4:67-5:3. FIG. 3. *See also,* sub-section X. A.

The methods for inserting a bone fusion spacer into an intervertebral disc space recited in claims 38 and 39 would have been obvious to a PHOSITA at the time of the invention of the '913 patent. EX1003 at ¶86-88.

In summary, as confirmed by Dr. Ochoa, Waugh in view of Fanger renders claims 1, 5, 7, 8, 10, 11, 14, 15, 19-22, 24, 26-28, 30, 32, 34-36, 38 and 39 unpatentable as obvious under 35 U.S.C. § 103.

XI. GROUND 2: WAUGH IN VIEW OF FANGER AND FURTHER IN VIEW OF NEUMANN RENDERS CLAIMS 6 AND 20 OBVIOUS

As further discussed below, Waugh in view of Fanger, as already discussed above, and further in view of Neumann, teaches each and every element and limitation of the dependent claims 6 and 20.

As discussed more below, a POSITA would have considered the subject

matter recited in claims 6 and 20 of the '913 obvious. EX1003 at ¶¶66-68, 87.

A. Dependent Claims 6 and 20

Dependent claims 6 and 20 respectively depend from independent claims 1 and 15. Both claims 6 and 20 add the limitation that the tool further comprises a "handle," as in dependent claims 7, 8, 21 and 22 discussed, supra. Claims 6 and 20 further recite that:

> *the gripper includes a tubular portion that is capable of receiving and guiding a portion of the handle therein.*

A PHOSITA would have known, based on the need for surgical manipulation during implantation of a spinal fixation implant, that surgical steps after the positioning of the implant require the ability to deliver and use components such as screws and screwdrivers to the distal site in the surgical wound. EX1003 at ¶66. These steps include driving the bone screws into bone, and depending on design choice, connecting multiple components in situ, making fine adjustments, and ultimately detaching the insertion tool from the spacer. *Id.*

A PHOSITA would have known and understood that orthopedic surgical instruments with cannulated handles and bodies (*i.e.,* a "gripper"), through which instruments and devices could be delivered to intrasurgical sites from a proximal end (*i.e.,* at the surgeon's hands) to a distal end (*i.e.,* at the implantation location), were in common use at the time of the invention of the '913 patent. *Id.* at ¶67. Similar devices were also used in arthroscopic and endoscopic surgery. *Id.* These devices

included "off-the-shelf" handle components from OEM catalogs. *Id.* The final configuration of such instruments would have been determined by a PHOSITA based on standard, readily available components and surgeon preference. *Id.* A PHOSITA would have known that a tool having a handle as described in claims 6 and 20 were already in practice at the time and readily available. *Id.*

As already described above, Waugh in view of Fanger discloses a spinal fixation implant and an insertion tool having a guide device and attachable to the implant to manipulate and insert the implant into an intervertebral disc space between adjacent vertebrae. *See,* EX1003 at ¶¶49-85. Thus, a PHOSITA would understand that the guide device at the distal end of the tool is designed to perform one or both functions of retaining the spinal fixation implant for delivery to its definitive anatomic location, as well as providing a reliable and reproducible way to prepare the host bone for (*i.e.* with an awl, drill bit, rasp, broach, punch, etc.), and subsequently deliver adjuvant fixation components (*i.e.,* drivers and screws, staples, pins, tacks, etc.) to the spinal fixation implant in situ through the aligned integrated pathways of the guide member and bores of the implant. *Id.* at ¶64. Therefore, Fanger would have been understood to provide a guide that can be used to constrain the location, orientation, and/or paths of fasteners and/or tools. *Id.* A PHOSITA would have been familiar and known that the tool disclosed in Fanger includes a handle 528[sic] that can have a variety of shapes, including those with rectangular

and/or circular cross sections and would be available as of-the-shelf catalog components. *Id.* at ¶65.

Neumann discloses a tool 18 for inserting and manipulating a spinal fixation implant 1 between adjacent vertebrae in a spinal fusion surgical procedure. *See, e.g.,* EX1030 at 4:1-38, FIG. 10. The tool 18 comprises a tubular and coaxial assembly of components, including an inner rod 22 disposed within a shaft 19 that is disposed within an outer tube 25. *Id.* Both the shaft 19 and rod 22 are operable to engage features of the spinal fixation implant 1 to place and expand the implant 1 in the disc space. *Id.*

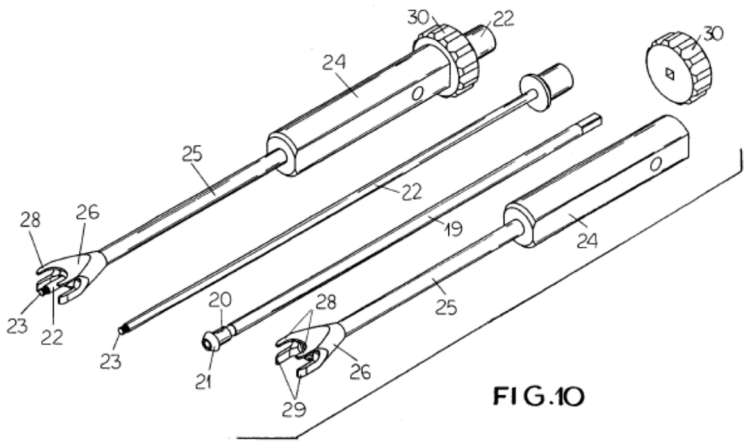


FIG.10

A PHOSITA would have understood that combining the teachings for an insertion tool as disclosed in Waugh and Fanger with the well-known cannulation features disclosed in Neumann would have yielded predictable results. EX1003 at ¶¶66-68. A PHOSITA would, therefore, have understood and considered it obvious that the spinal fixation implant of Waugh could be used in conjunction with the

insertion tool disclosed in Fanger, as modified in light of the commonly used cannulation features of the tool described in Neumann, to allow for the capability of receiving and guiding a portion of the handle. *Id.*

The intervertebral spacer and tool for its manipulation and insertion into a disc space between adjacent vertebrae as recited in claims 6 and 20 would have been obvious to a PHOSITA at the time of the invention of the '913 patent over Waugh in view of Fanger, and further in view of Neumann. EX1003 at ¶¶68, 87.

In summary, as confirmed by Dr. Ochoa, Waugh in view of Fanger as applied to claims 1 and 15, and further in view of Neumann, renders claims 6 and 20 unpatentable as obvious under 35 U.S.C. § 103.

XII. SECONDARY CONSIDERATIONS

There are no secondary considerations known to Petitioner that affect—let alone overcome—the strong showing of obviousness set out above.

XIII. THIS PETITION SHOULD NOT BE DISCRETIONARILY DENIED

Patent Owner may argue that this Petition should be discretionarily denied under 35 U.S.C. § 314(a) in view of the Pending Litigation, based on *NHK Spring*[7] and its progeny. Any such argument by Patent Owner should be rejected for several

[7] *NHK Spring Co. v. Intri-Plex Techs., Inc.,* IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018).

reasons.

First, Lex Machina reports that the median number of days to trial in the EDPA for patent cases is 572 days. EX1033. The Pending Litigation however involves eight asserted patents, one hundred thirty-one asserted claims and twenty three accused products. *Id.* The Pending Litigation needs to go through full fact discovery, Markman, expert discovery, summary judgment and trial. This will require significantly more than the median of 572 days to address the number of claims and products, not to mention the Pending Litigation enters the queue behind all other cases that are on Judge Goldberg's docket, even those subsequently filed, and at a time when many cases are delayed because of COVID-19. The expectation is for a trial date in 2022/2023.[8]

Second, the most likely scenario is that a final decision will issue before and perhaps well before trial in the EDPA. Any appeal of a final decision would, at best, overlap with any appeal of the District Court decision. The Federal Circuit may consolidate such appeals, and enable the decision of this Board to impact the final outcome of the District Court case. Either way, any remand from appeal to the EDPA would delay the conclusion of the District Court action by years.

Third, Congressional intent militates against discretionary denial. Through 35

[8] Globus intends on filing a motion for stay in the Pending Litigation.

U.S.C. § 315(b), Congress established a one-year bar to file a petition for inter parties review after service of a complaint. In so doing, Congress was intending to "afford defendants a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation." 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011). Indeed, as is the case here, "[h]igh-technology companies . . . are often sued by [patent owners] asserting multiple patents with large numbers of vague claims, making it difficult to determine in the first few months of the litigation which claims will be relevant and how those claims are alleged to read on the defendant's products." Id. Thus, it would be unfair—and in clear contravention of legislative intent—to refuse Petitioner access to the efficiencies intended through this forum.

XIV. CONCLUSION

Petitioner has demonstrated in this Petition that the Challenged Claims are unpatentable. Petitioner, therefore, respectfully requests institution of an IPR of the '913 patent.

Dated: July 21, 2020

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this Petition complies with the word count limitations of 37 CFR § 42.24. This brief contains less than the 14,000 words permitted under 37 C.F.R. § 42.24(a)(1)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

Petitioner relies on the word count feature of the word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, this is to certify that I caused a true, correct and complete copy of the PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,353,913 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42 and related documents to be served via electronic mail and FedEx, next day delivery, on the Patent Owner, on this 21st day of July, 2020:

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