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.: IPR2020-01308 U.S. Patent No. 9,889,022 Issued: February 13, 2018 Application No: 13/210,157 Filed: August 15, 2011

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,889,022 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42

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EXHIBITS

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1001	U.S. Patent No. 9,889,022		
1002	Prosecution history of U.S. Patent No. 9,889,022		
1003	Declaration of Jorge A. Ochoa, Ph.D., P.E.		
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,		
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1008	Cheung KMC, Leong, JCY. "Spinal Instrumentation Overview in		
	Lumbar Degenerative Disorders: Cages", Chapter 26 in The Lumbar		
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	Williams & Wilkins, Philadelphia.		
1009	Centinel Spine. The Gold Standard in Integrated Interbody		
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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			
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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			
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1020	Technique Guide: SynFix-LR. Implant and instrumentation for stand			
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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.,			
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	Interbody Fusion. Spine Surgery, Vol. One, Second Ed. Techniques,			
	Complication Avoidance, and Management, Chapter 39. 2005			
1027	Invalidity Claim Chart regarding U.S. Patent No. 9,889,022			
1028	French Patent Publication No. 2,727,003 to Tisserand			
1029	Certified English Translation of French Patent Publication No.			
	2,727,003 to Tisserand			

Exhibit #	Description
1030	U.S. Patent No. 7,001,385 to Bonutti
1031	U.S. Patent No. 5,192,327 to Brantigan
1032	U.S. Patent No. 8,425,607 to Waugh et al.
1033	Moskowitz Family LLC Disclosure of Infringement Contentions
1034	Order Granting Defendant Globus Medical's Motion to Transfer
	Venue Under 28 U.S.C. § 1404(a)
1035	Lex Machina Report

I. INTRODUCTION

Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review ("IPR") of claims 47, 49 and 51-70 (the "Challenged Claims") of U.S. Patent No. 9,889,022, titled "Bi-Directional Fixating Transvertebral Body Screws and Posterior Cervical and Lumbar Interarticulating Joint Calibrated Stapling Devices For Spinal Fusion" ("the '022 patent"), issued to Ahmnon D. Moskowitz, et al. and assigned to Moskowitz Family LLC ("Moskowitz"). The '022 patent is attached as EX1001.

The invention of the '022 patent is not new. Rather, the claimed invention encompasses known implantable intervertebral spinal fixation implants to accomplish an intervertebral fusion of the human spine. In this regard, the Challenged Claims of the '022 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 '022 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, Tisserand in view of Bonutti renders Challenged Claims 47, 49, 51-53, 56, 59, 60-63 and 65-69 unpatentable as obvious under 35 U.S.C. § 103. EX1003 at ¶¶30-35; *and see*, EX1027.

Additionally, Tisserand in view of Bonutti and further in view of Mathieu renders Challenged Claims 54, 55 and 64 unpatentable as obvious under 35 U.S.C. § 103. *Id.*

Tisserand in view of Bonutti and further in view of Brantigan renders Challenged Claim 57 unpatentable as obvious under 35 U.S.C. § 103. *Id.*

Finally, Tisserand in view of Bonutti and further in view of Waugh renders Challenged Claims 58 and 70 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. <u>Real Party in Interest (37 C.F.R. § 42.8(b)(1))</u>

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.

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

Petitioner is unaware of any disclaimers or reexamination certificates of the '022 patent.

The '022 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. Notably, in the Pending Litigation, Moskowitz has accused certain of Globus's spinal implant devices of infringing the challenged claims of the '022 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. EX1034. 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. 8,353,913 ("the '913 patent"). The '319, '268 and '913 patents are related to the '913 patent through continuation practice. Petitioner understands that the '022 patent, the '319 patent, the '268 patent and the '913 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 '022 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. <u>Designation of Lead and Backup Counsel (37 C.F.R.§ 42.8(b)(3))</u>

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

D. <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.

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. <u>Grounds for Standing (37 C.F.R. § 42.104(a))</u>

Petitioner certifies that the '022 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:
1	U	66

Ground	Challenged Claims	Asserted Prior Art	Statutory Grounds
1	47, 49, 51-53, 56, 59, 60-63 and 65-69	French Patent Application Publication No. 2,727,003 to Tisserand ("Tisserand") (EX1028, EX1029) in view of U.S. Patent No. 7,001,385 to Bonutti ("Bonutti") (EX1030)	35 U.S.C. § 103(a)
2	54, 55 and 64	Tisserand in view of Bonutti and further in view of U.S. Patent Application Publication No. 2005/0177236 to Mathieu et al. ("Mathieu") (EX1005)	35 U.S.C. § 103(a)
3	57	Tisserand in view of Bonutti and further in view of U.S. Patent No.	35 U.S.C. § 103(a)

		5,192,327 to Brantigan ("Brantigan") (EX1031)	
4	58 and 70	Tisserand in view of Bonutti and further in view of U.S. Patent No. 8,425,607 to Waugh et al. ("Waugh") (EX1032)	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, XI, XII, XIII), Petitioner seeks a final, written decision that the Challenged Claims are unpatentable as obvious under 35 U.S.C. § 103.

V. SUMMARY OF THE '022 PATENT (EX1001)

The '022 patent issued on February 13, 2018, on an application filed on August 15, 2011. On its face, the '022 patent claims the following priority: A continuation of U.S. Application Serial No. 13/084,543 filed April 11, 2011 issued as U.S. Patent No. 8,353,913, and a continuation of Application Serial No. 13/108,982 filed May 16, 2011 issued as U.S. Patent No. 9,005,293. The '543 application is a division of U.S. Application Serial No. 11/842,855 filed August 21, 2007 issued as U.S. Patent No. 7,942,903 and the '982 application is a continuation of the '855 application. The '855 application 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 further claims priority to provisional application No. 60/670,231 filed April 12, 2005.

The Challenged Claims of the '022 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 '022 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. <u>The '022 Patent Specification and Claims</u>

The '022 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 '022 patent generally discloses a bi-directional fixating transvertebral screw system that can be used as an intervertebral spacer and a transvertebral bone fusion screw apparatus. EX1001 at 1:33-40.

The '022 patent issued with 70 claims, 21 of which are at issue in this Petition. Of the Challenged Claims, claim 47 is an independent apparatus claim. Challenged

¹ See pre-AIA §§119 and 120; 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).

Claims 49 and 51-61 and 63-70 depend directly from claim 47, while claim 62 depends from claim 61. The Challenged Claims, however, encompass known implantable spinal fixation apparatus for fusing adjacent vertebrae of a human spine and are unpatentable.

The written description and drawings of the '022 patent describe an intervertebral combination internal screw guide and fixation apparatus that includes an intervertebral bone fusion cage for surgical implantation in the spine that is secured with screws. FIGs. 2A-2C are particularly relevant and show embodiments of the cage 200 and screws 201, 202. *See, e.g.*, EX1001 at 8:20-33; FIGs. 2B, 2C.



The screws 201, 202 are received in and pass through holes in the cage which serve as integral screw guides (*see, e.g.,* FIG. 2C). The screws 201, 202 are oriented in opposing, superior and inferior directions. *Id.* These screw guides, however, can have different angles and/or different positions within the cage. *Id.* Holes 208 and

hollow spaces in the cage 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.*

The Challenged Claims are directed to the intervertebral combination internal screw guide and fixation apparatus.

B. <u>The '022 Patent Prosecution History (EX1002)</u>

The prosecution of the application leading to the '022 patent, Serial No. 13/210,157, took place over a period of 6 ¹/₂ years and included numerous Office Actions and corresponding Responses, an interview and 3 RCEs.

Following a preliminary amendment (EX1002 at 629) and a first non-final Office Action (NFOA) (*id.* at 567), the applicant cancelled all of the pending claims and added new claims which became the basis for the substantial majority of the issued claims (*id.* at 439).

Thereafter, the new claims were rejected in a first final Office Action (FOA) for double patenting and as anticipated by US 2008/0249575 A1 to Waugh et al. *Id.* at 415. The applicant's response included a first RCE and arguments attempting to overcome the rejection. *Id.* at 283. A second NFOA followed, *inter alia*, maintaining the rejections. *Id.* at 233. Applicant's response sought to distinguish Waugh arguing the "unique arrangement" of "the entry opening of the internal bore is formed at least

partially in a bottom surface of the top wall and at least partially in a side surface of the top wall." *Id.* at 224. The Examiner was not persuaded. *Id.* at 210.

A second RCE followed. *Id.* at 187. The applicant again sought to distinguish Waugh arguing "the screws [in Waugh are] at a steep angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in two surfaces." *Id.* at 199. Again the Examiner was unpersuaded. *Id.* at 139. *In response, the applicant amended claims and added new independent claim 135 (which corresponds to Challenged Claim 47). Id.* at 114, 125-126.

Thereafter, the applicant initiated an examiner interview in which applicant's amendment to include language such as

"wherein a threaded hole extends through the top wall in a direction substantially normal to the top surface of the top wall with a diameter of the threaded hole being smaller than a diameter of the internal screw guide...wherein the side surface of the top wall is patterned with a plurality of surface features to create a rough side surface, wherein at least some of the plurality of surface features are positioned on the side surface closer to the top surface of the top wall than the exit opening...a circular hole extending into the top wall in a direction substantially normal to the top wall and positioned between the internal screw guide and the second screw guide at the top surface of the top wall..."

seemed to overcome the rejection in the last office action. *Id.* at 105. Thereafter the application was initially allowed. *Id.* at 86.

A third RCE after allowance submitting an IDS (*id.* at 77) was met with another NFOA issuing a double patenting rejection (*id.* at 58). The applicant's response included a terminal disclaimer and new claims, including claims 136-138 and 145-165 depending from independent claim 135 (and encompassing Challenged Claims 49 and 51-70). *Id.* at 37. Thereafter the application was finally allowed. *Id.* at 9.

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

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

follows:⁴

Claim Term	Petitioner's Construction
"a disc space between a first	"the disc space between two adjacent
intervertebral body and a second	vertebrae"
intervertebral body"	
"universal, intervertebral combination	"an intervertebral bone fusion spacer
internal screw guide and fixation	designed to be inserted between two
apparatus"	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"

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.

"counterbore"	"a flat-bottomed enlargement of the
	mouth of a cylindrical bore"

Otherwise, Petitioner submits that the claim terms require no express construction and that they should be given their ordinary and customary meaning.

VII. THE LEVEL OF SKILL IN THE ART

As established in the Declaration of Dr. Ochoa (EX1003 at ¶¶25-29), a person having ordinary skill in the art (PHOSITA) of the '022 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 INVENTION⁵

The '022 patent generally describes an implantable spinal fixation device for

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

arthrodesis (*i.e.*, immobilization by fusion) of the adjacent bones, or vertebrae, in the human spine.

The use of implantable spinal fixation devices ("spinal fixation implants") to stabilize vertebral bodies with the intent of promoting fusion between adjacent vertebrae for treatment of various conditions including deformity, disease, degeneration, and trauma has long been well-known. EX1003 at ¶37. Spinal fixation implants 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. 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. *Id.* at ¶¶36, 38, 40-43.

At the time of the invention of the '022 patent, this entire body of art relating to spinal fusions, including knowledge of anatomic regions of the spine (cervical, thoracic, or lumbar) and surrounding anatomical structures, 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, including anterior, posterior, or lateral approaches, would have been well known to a PHOSITA. EX1003 at ¶36.

IX. THE PRIOR ART RELIED UPON IN THIS PETITION

A. <u>Tisserand (EX1028 and EX1029⁶)</u>

Tisserand, entitled "Lumbar-Sacral Vertebrae Anterior Stabilizer," published May 24, 1996 as publication no. 2,727,003. Tisserand is prior art to the '022 patent under 35 U.S.C. § 102(b) (Pre-AIA). Tisserand is a printed publication in a foreign country more than one year prior to the date of the application for patent (*i.e.*, '022 patent's effective filing date, August 21, 2007). Tisserand was not considered by the Examiner during the prosecution of the application leading to the '022 patent.



Tisserand discloses an intervertebral spinal fixation implant that may be used in a spinal fusion surgical procedure to replace a degenerated spinal disc. *See, e.g.*,

⁶ A certified English translation of Tisserand is attached as EX1029. All citations to Tisserand herein are made to the English translation.

EX1029 at FIG. 3. Bone screws 2, 3 may be configured to extend through apertures 1g, 1h integral to a cage 1 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 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.

B. Bonutti (EX1030)

Bonutti, entitled "Joint Spacer With Compartment for Orthobiologic Material," issued February 21, 2006. Bonutti is prior art to the '022 patent under 35 U.S.C. § 102(b) (Pre-AIA). Bonutti is a patent in this country more than one year prior to the effective filing date of the application for the '022 patent in the United States. Bonutti was not considered by the Examiner during the prosecution of the application leading to the '022 patent.

Bonutti teaches a method and apparatus for changing the spatial relationship between interconnected bones in a patient's body. EX1030 at 1:62-2:49. Bonutti discloses an intervertebral fusion implant 44b (*id.* at 2:41-49) including internal screw guides having internal bores (*i.e.*, passages 64, 66). *Id.* at 7:55-64, FIGs. 6, 7,



The entry opening of each passage is formed in a top surface of a top wall of the implant and the exit opening is formed at least partially in a side surface of the top wall. *Id.* at FIG. 10. A counterbore is also included at the entry opening of each of the passages in the top surface of the top wall. *Id.* The counterbores are larger than and coaxial with the passages. *Id.* The entry openings of the counterbores are formed only in the top surface of the top wall of the implant. *Id.*

C. <u>Mathieu (EX1005)</u>

Mathieu, entitled "Intervertebral Implant," published August 11, 2005. Mathieu is prior art to the '022 patent under 35 U.S.C. § 102(b) (Pre-AIA). Mathieu is a printed publication in this country more than one year prior to the effective filing date of the application for the '022 patent in the United States. Mathieu later issued as U.S. Patent No. 7,232,464 on June 19, 2007. The '464 patent is among the more than 175 references cited on the face of the '022 patent. The '464 patent, however, was not referenced or applied by the Examiner to reject any claim during the prosecution of the application leading to the '022 patent.

Mathieu discloses an intervertebral spinal fixation implant with at least two mutually divergent boreholes that accept and direct the path of screws, thereby acting as screw guides. EX1005 at [0003]; [0017]; FIGs. 1-6. In addition, Mathieu teaches that the boreholes extend along axes that are 25° to 70° from a horizontal center plane of the implant. *Id.* at [0017]. Mathieu teaches this range of angles to enable the bone screws to move into a region of the adjacent vertebrae that offers better bone quality than found at the vertebra's center and to improve access for inserting the screws into the implant. *Id.*

D. Brantigan (EX1031)

Brantigan, entitled "Surgical Prosthetic Implant for Vertebrae," issued March 9, 1993. Brantigan is prior art to the '022 patent under 35 U.S.C. § 102(b) (Pre-AIA). Brantigan is a patent in this country more than one year prior to the effective filing date of the application for the '022 patent in the United States. Brantigan was not considered by the Examiner during the prosecution of the application leading to the '022 patent.

Brantigan discloses an intervertebral implant 10 to promote fusion of adjacent vertebrae. EX1031 at Abstract; 1:64-68; FIG. 1. Brantigan discloses the implant includes a body 11 with sidewalls 11b into which horizontal peripheral slots 11e are placed that communicate with the central aperture 11d to receive bone graft material

and to provide free spaces for blood flow to speed up the fusion process. Id. at 4:8-14; 4:53-56; FIGs. 1-6. The central aperture 11d and slots 11e can receive bone graft material. Id. at 4:50-56.

E. <u>Waugh (EX1031)</u>

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 '022 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.*, '022 patent's effective filing date, August 21, 2007). As discussed above, Waugh⁷ was considered by Examiner during the prosecution of the application leading to the '022 patent and was applied to reject claims of the application as the primary reference under 35 U.S.C. § 102. Notably, however, Waugh was <u>never applied in a rejection to the Challenged Claims</u>. Further, Waugh is cited and applied herein by Petitioner as a tertiary reference in a combination with other references not considered by the Examiner, which combination renders certain of the Challenged Claims unpatentable as obvious.

To swear behind Waugh, Moskowitz must prove conception of the claimed

⁷ That is, U.S. Publication no. US 2008/0249575 to Waugh et al., which preceded issuance of the '607 patent.

invention before Waugh's April 3, 2007 filing date and diligence in reducing the invention to practice after that date.⁸ However, in the Pending Litigation Moskowitz has already asserted that its earliest invention date for the '022 patent is July 16, 2007, well after Waugh's filing date. EX1033 at 9-10.

Waugh discloses an intervertebral spinal fixation implant 100 that may be used in a spinal fusion surgical procedure. *See, e.g.,* EX1032 at FIGs. 3, 4. Anchor members 104 (*i.e.* bone screws) extend through apertures 122 integral to a cage 102 that act as screw guides to receive and direct the bone screws 104. The apertures may be positioned on a front surface 114 of a front wall of the spacer 102 and in diagonal opposition.



⁸ Apator Miitors APS v. Kamstrup A/S, 887 F.3d 1293, 1295 (Fed. Cir. 2018).

The cage 102 has side surfaces 110a-b that each include a recessed slot 120. EX1032 at 3:59-64; FIG. 3. The slots 120 are configured to cooperate with an insertion tool that connects to the spacer 102 for manipulating and inserting the spacer during spinal fusion surgery. *Id*.

X. GROUND 1: TISSERAND IN VIEW OF BONUTTI RENDERS CLAIMS 47, 49, 51-53, 56, 59, 60-63, and 65-69 OBVIOUS

As further discussed below, it would have been obvious to combine the teachings of Tisserand and Bonutti at the time of the invention of the '022 patent to arrive at the intervertebral screw guide and fixation apparatus recited in these Challenged Claims. EX1003 at ¶31 [Ochoa].

- A. Independent Claim 47
 - [1] A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

Tisserand discloses an intervertebral spinal fixation implant configured to be inserted into a disc space between a first vertebral body L1 and a second vertebral body L2 and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion. EX1029 at Abstract; 1:1-11; FIGs. 1-3.

FIG. 3



The implant comprises an intervertebral cage 1 including through holes 1g, 1h having internal recesses (*i.e.*, internal screw guides) that are pre-formed in the cage and through which bone screws 2, 3 can be introduced and oriented for engaging the cortico-cancellous bone of the adjacent vertebrae L1, L2. *Id.* at 2:35-3:9.

A PHOSITA would have understood that pre-formed holes intended to receive and guide the direction and location of screws would act as screw guides. EX1003 at ¶51, 54.

Further, a PHOSITA would have understood that pre-formed holes were commonly used in spinal fixation implants and related devices to avoid issues that may occur with *in situ* drilling of holes in a spinal fixation implant (*e.g.*, wasted surgical time, possibility for inaccuracy, adverse impact of heat generated during drilling, generating undesirable particulates by-products from drilling, etc.) and were well-known and desirable. Id. at ¶51.

A PHOSITA would have understood that Tisserand discloses an intervertebral screw guide and fixation apparatus as recited at [1]. *Id.* at ¶51.

[2] an intervertebral cage including:

Tisserand discloses an intervertebral cage 1. EX1029 at Abstract; 1:1-11;

FIGs. 1-3. Tisserand meets the limitation of claim 47 at [2]. EX1003 at ¶52.

[3] a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

Tisserand discloses that the intervertebral cage 1 includes a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion. EX1029 at 2:20-33; 4:7-8; FIGs. 1-3.



Tisserand meets the limitation of claim 47 at [3]. EX1003 at ¶53.

- [4] an internal screw guide having an internal bore with an entry opening and an exit opening,
- [5] *the entry opening of the internal bore formed only in a top surface of the top wall and*

- [6] the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall,
- [7] wherein the internal screw guide further includes a counterbore that is larger than and coaxial with the internal bore and
- [8] has a counterbore entry opening that is formed only in the top surface of the top wall;

Tisserand discloses holes 1g, 1h that allow for the passage, integration, and direction of bone screws 2, 3 into the cortico-cancellous bone of the intervertebral bodies above and below the intervertebral cage 1. EX1029 at 2:35-3:9; FIGs. 1-3.



Holes 1g, 1h are through-holes and serve as internal screw guides in the implant. EX1003 at ¶54. Each of the holes includes an internal bore with an entry opening and an exit opening. The entry openings are formed only in a top surface of the top wall and the exit openings are formed at least partially in a bottom surface of the top wall and at least partially in side surfaces 1i, 1j of the top wall. *Id.* at 3:14-15; FIGs. 1-2. Holes 1g, 1h include recesses or bores formed in the top surface of

the top wall that are larger than and coaxial with the internal bore. *Id.* at 3:1-3; FIG.3. The heads of the bone screws 2, 3 can reside in the top wall of the body of the cage via the recesses. *Id.*; EX1003 at ¶54.

To the extent that Tisserand does not expressly disclose a counterbore entry opening that is formed only in the top surface of the top wall, it is of note that Moskovitz does not disclose any reason for the specific configuration recited at [4]-[8], such as a problem that is addressed or a solution that is provided by the recited structure. A PHOSITA would have understood that the choice of a counterbore and the exact location and size of the entry opening would vary depending on known design factors such as the size of the screw head, the selected screw angle, lordotic angle, and the wall thickness and height of the intervertebral cage. EX1003 at ¶58. The exact location of the opening would reflect these known design choices together with considerations of accessibility and aesthetics. *Id.*

Bonutti also discloses a fusion implant which can be implanted between adjacent vertebrae in a patient's spine. EX1030 at 2:41-49; 10:52-12:5; 11:21-40; FIGs. 5-7, 10. The implant 44b includes a top wall 50b, a bottom wall 52b, and two sidewalls defining an open space 100 capable of receiving bone filling for the biological bone fusion. *Id.* The bottom wall may be blunt or truncated. *Id.* at 14:1-14:4; FIG. 10.



Passages 64, 66 through the implant define internal screw guides. *Id.* at FIG. 5-7, 10. The entry opening of each passage is formed in a top surface of the top wall of the implant. *Id.* at FIG. 10; EX1003 at ¶55. A counterbore is also included at the entry opening of each of the passages in the top surface of the top wall. *Id.* The counterbores are larger than and coaxial with the passages. *Id.* The entry openings of the counterbores are formed only in the top surface of the top wall of the implant. *Id.* The heads of the screws 70b, 72b are recessed in the implant via the counterbores. *Id.*

A PHOSITA would have understood that there are benefits to recessing the heads of the fasteners in the body of the implant using counterbores, to prevent the heads from projecting from the anterior of the implant. EX1003 at ¶56. For example, recessing the screw heads can help prevent irritation to the overlying muscle tissue and/or neighboring anatomic structures such as the esophagus (in the case of cervical cages) and/or the neighboring aorta and/or inferior vena cava (in the

case of thoracic or lumbar cages). *Id.* A PHOSITA would have understood, therefore, that it is desirable to recess the heads of the fasteners. *Id.*

Therefore, it would have been an obvious matter of design choice to a PHOSITA to include the counterbore formed only in the top surface as taught in Bonutti in place of the recesses or bores in the top surface as disclosed in Tisserand to recess the heads of the fasteners in the implant. EX1003 at ¶57. Further, the counterbore in place of the recesses would have yielded a predictable effect in the resulting design and would not have changed the principle of operation of the spinal implant of Tisserand. *Id*.

Tisserand in view of Bonutti meets the limitations of claim 47 at [4]-[8]. EX1003 at ¶58.

[9] a second internal screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

Tisserand discloses a second internal screw guide having identical features to the first internal screw guide, but oriented so as to allow the screw to engage a vertebral body below the intervertebral cage. EX1029 at 2:35-37; FIG. 3.

Bonutti also discloses a second internal screw guide having identical features to the first internal screw guide, but oriented so as to allow the screw to engage a vertebral body below the intervertebral cage. EX1030 at FIG. 10. A PHOSITA would understand that Tisserand discloses the limitation at [9] both alone or in combination with Bonutti for the reasons already discussed. EX1003 at ¶59.

- [10] a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall,
- [11] wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

Tisserand discloses a circular hole (see arrow, in annotated FIG. 1, below) extending through the top wall in a direction substantially normal to the top surface of the top wall. EX1029 at FIG. 1. The circular hole is positioned between the internal screw guide 1g and the second internal screw guide 1h at the top surface 1d of the top wall. *Id.*; EX1003 at ¶60.

The internal screw guide and fixation apparatus of claim 47 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti.



B. <u>Dependent Claim 49</u>

Claim 49 depends from claim 47 and states:

wherein the side surface of the top wall comprises means to facilitate integration and fusion with superior and inferior vertebral bodies,

Tisserand discloses surfaces 1i, 1j of the cage 1 are "notched in order to facilitate primary stability" with the adjacent vertebra. EX1029 at 3:14-15; FIGs. 1-3. A PHOSITA would have understood that the notched surfaces 1i, 1j perform the function to facilitate integration and fusion of the intervertebral cage with respect to the upper and lower vertebrae L1, L2. EX1003 at ¶62. Thus, Tisserand teaches the limitations recited in claim 49.

Therefore, at the time of the invention of the '022 patent, a PHOSITA would have considered the internal screw guide and fixation apparatus of claim 49 obvious over Tisserand in view of Bonutti.

C. Dependent Claims 51, 52, 53

Claim 51 depends from claim 47 and states:

wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

Claim 52 is directly dependent on claim 47 and states:

wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space. Claim 53 depends directly from claim 47 and states:

wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

Tisserand discloses holes 1g, 1h through the intervertebral cage 1 that function as screw guides and allow the passage of bone screws 2, 3 through the cage 1 and into the adjacent vertebrae above and below the cage 1. EX1029 at FIGs. 1-3. The holes 1g, 1h are continuous through the cage 1 and comprise internal surfaces extending from the entry to exit openings. *Id*.

Tisserand discloses internal screw guides that have internal surfaces extending continuously from the entry to the exit openings, as recited in claim 51. EX1003 at ¶63.

The holes 1g, 1h enter from the top wall, extend entirely through the top wall from the top surface to the bottom surface, and exit at the openings 1a, 1b. *Id.* at 2:31-37; FIGs. 1-2. Tisserand, therefore, discloses holes that function as screw guides and allow the passage of screws through entirety of the top wall and exiting at least into the open space as recited in claim 52. EX1003 at ¶64.



The holes 1g, 1h each direct a bone screw 2, 3 (*i.e.*, one downward and the other upward) at an angle such that the "screws are oriented at an angle of very substantially 45°, in order to be implanted in the cortico-cancellous bone of the intervertebral bodies." *Id.* at 3:3-9; FIGs. 1-3.EX1003 at ¶65 Tisserand discloses the screw guides permit only a predetermined angled trajectory of a screw through the cage as recited in claim 53. *Id.*

A PHOSITA would have understood that Tisserand discloses a screw guide as recited in claims 51-53. EX1003 at ¶¶63-65. Therefore, the internal screw guide and fixation apparatus of claims 51, 52 and 53 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti.

D. <u>Dependent Claim 56</u>

Claim 56 depends directly from claim 47 and states:

wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls. Tisserand discloses that the intervertebral cage 1 has a top wall and sidewalls, each having a thickness. EX1029 at FIGs. 1-3. Tisserand discloses that the top wall of the intervertebral cage 1 has a thickness that is greater than a thickness of each of the sidewalls. *Id.*; *and see* annotated FIGs. 1 and 2, below.



At the time of the invention of the '022 patent, a PHOSITA would have considered the internal screw guide and fixation apparatus of claim 56 obvious over Tisserand in view of Bonutti. EX1003 at ¶66.

E. Dependent Claim 59

Claim 59 depends directly from independent claim 47. Claims 59 recites:

wherein a surface of each of the two sidewalls includes a plurality of ridges,

Tisserand discloses a surface of each of the two sidewalls 1i, 1j of the intervertebral cage 1 includes a plurality of ridges. EX1029 at FIGs. 1-3, 3:14-15. EX1003 at ¶67.

Therefore, at the time of the invention of the '022 patent, a PHOSITA would have considered the internal screw guide and fixation apparatus of claim 59 obvious over Tisserand in view of Bonutti.

F. Dependent Claim 60

Claim 60 depends directly from independent claim 47. Claims 60 recites:

wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

Tisserand discloses that the spinal fixation implant including an intervertebral cage 1 provides for anterior stabilization of the lumbar vertebrae. EX1029 at Abstract; 1:5-20. Tisserand further identifies the risk of graft expulsion resulting in injury of the blood vessels anterior to the lumbar vertebrae in the event of instability and displacement of prior art plates and provides a simple, safe effective and expedient manner to address these drawbacks. *Id.*

A PHOSITA would have understood that the advantages of the spinal fixation

implant and intervertebral cage taught by Tisserand are equally applicable to the cervical disc space. EX1003 at ¶¶68-69. Hardware migration after anterior cervical discectomy and fusion is similarly disadvantageous in the cervical spine where it can cause injury of the pharynx or esophagus. *Id*.

A PHOSITA would have further understood that applying the teachings of Tisserand for use in the cervical disc space would require a simple substitution of the lumbar cage and screws disclosed by Tisserand, alone or in combination with Bonutti, for an intervertebral cage and screws sized appropriately for the cervical disc space to achieve the same benefits. *Id.* at ¶70.

The internal screw guide and fixation apparatus recited in claim 60 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti.

G. Dependent Claims 61, 62 and 63

Claim 61 depends directly from independent claim 47. Claims 61 recites:

wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

Claim 62 depends from claim 61. Claims 62 adds:

wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.



Tisserand discloses the holes 1g, 1h each direct a bone screw 2, 3 such that the "screws are oriented at an angle of very substantially 45°, in order to be implanted in the cortico-cancellous bone of the intervertebral bodies." *Id.* at 3:3-9; FIGs. 1-3; EX1003 at ¶65. Tisserand further discloses "recess (1g) is oriented upwards, while the recess (1h) is oriented downwards...Therefore, following introduction of screws (2) and (3), one (2) will be directed downwards [i.e. caudally], while the other (3) will be directed upwards [i.e. rostrally]." EX1029 at 3:2-7; FIGs. 1-3.

Tisserand, therefore discloses that screw guides that are angled to orient a first screw member and a second screw bi-directionally in opposite directions as recited in claim 61, with one screw guide configured to orient a screw rostrally and the other screw guide configured to orient another screw caudally, as recited in claim 62. EX1003 at ¶72.

Claim 63 depends directly from independent claim 47. Claims 63 recites:

wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

As just discussed, Tisserand discloses the internal screw guide 1g and the second internal screw guide 1h are at an angulation with respect to the top surface 1d of the top wall "in order to [implant the screws] in the cortico-cancellous bone of the intervertebral bodies." EX1029 at Abstract; 3:3-9; FIGs. 1-3. EX1003 at ¶73.

Therefore, at the time of the invention of the '022 patent, a PHOSITA would have considered the internal screw guide and fixation apparatus of claims 61-63 to be obvious over Tisserand in view of Bonutti.

H. Dependent Claim 65, 66 and 67

Claim 65 depends directly from independent claim 47. Claims 65 recites:

wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

Tisserand discloses that the internal screw guide 1g and the second internal screw guide 1h are aligned along a longitudinal axis (*i.e.*, see, the solid red line in annotated FIG. 1, below) of the top surface 1d of the top wall of the intervertebral cage 1, as recited in claim 65. EX1029 at FIG. 1; EX1003 at ¶74.



Claim 66 depends directly from independent claim 47. Claims 66 recites:

wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

Tisserand discloses the internal screw guide 1g and the second internal screw

guide 1h are symmetrically disposed on each side of a center point (i.e., marked by

the intersection of the lines in the annotated FIG. 1, above) of the intervertebral cage

1 along a longitudinal axis (i.e., the solid red line) of the top surface 1d of the top

wall of the intervertebral cage 1, as recited in claim 66. EX1029 at FIGs. 1-3;

EX1003 at ¶75.

Claim 67 depends directly from independent claim 47. Claims 67 recites:

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

Tisserand discloses this limitation. The "recess (1g) is oriented upwards,

while the recess (1h) is oriented downwards...Therefore, following introduction of screws (2) and (3), one (2) will be directed downwards, while the other (3) will be directed upwards." EX1029 at 3:2-7; FIGs. 1-3. Thus, Tisserand discloses the internal screw guides are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall, as recited in claim 67. EX1003 at ¶76.

The internal screw guide and fixation apparatus as recited in claims 65, 66 and 67 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti.

I. Dependent Claims 68 and 69

Claims 68 and 69 each depends directly from independent claim 47. Both claims 68 and 69 recite:

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 68 adds:

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

Alternatively to claim 68, claim 69 adds:

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

Tisserand discloses a spinal fixation implant configured to be inserted into a disc space between a first vertebral body L1 and a second vertebral body L2 and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion. EX1029 at Abstract; 1:1-11; FIGs. 1-3. The implant comprises an intervertebral cage 1 including through holes 1g, 1h having internal recesses that are pre-formed in the cage and through which screws 2, 3 can be introduced and oriented (e.g., upwards and downwards) for engaging the cortico-cancellous bone of the adjacent vertebrae L1, L2. Id. at 2:35-3:9.

Regarding claims 68 and 69, a PHOSITA would have understood that the use of "quadrants" to describe the location of the internal screw guide openings on the anterior aspect of the fusion spacer was simply a restatement of basic principles of elements of machine design that were in practice at the time of the invention. EX1003 at ¶101. The first and second axes in a plane of the wall of the cage 1 at right angles to one another and defining the four quadrants as recited in claims 68 and 69 is provided in Tisserand. See, e.g., FIG. 1 as annotated below; and see, EX1027.



A PHOSITA would have understood that the holes 1g, 1h act as internal screw guides, receiving, locating and guiding the direction of the first and second screws 2, 3. EX1003 at ¶97.

As shown in the annotated figure, above, Tisserand discloses that the entry openings for the internal screw guides of the cage 1 lie in the diagonally-opposed first quadrant (hole 1h) and third quadrant (hole 1g). As recited in claim 68, Tisserand also discloses (as seen in the annotated figure) that the majority of the area of each of the entry openings of the internal screw guides 1g, 1h lies in the respective first and third quadrants of the top wall. *Id*.

Further, as recited in claim 69, Tisserand discloses that the centers of the entry

openings of the internal screw guides (*i.e.*, as indicated by their centerlines (*see*, the annotated figure)) are likewise located in the diagonally-opposed first and third quadrants. *Id.* at ¶102.

Thus, Tisserand in view of Bonutti meets the all the limitations of claims 68 and 69. The internal screw guide and fixation apparatus as recited in claims 68 and 69 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti. EX1003 at ¶¶101-102.

In summary, as confirmed by Dr. Ochoa, Tisserand in view of Bonutti renders claims 47, 49, 51-53, 56, 59, 60-63 and 65-69 unpatentable as obvious under 35 U.S.C. § 103.

XI. GROUND 2: TISSERAND IN VIEW OF BONUTTI AND FURTHER IN VIEW OF MATHIEU RENDERS CLAIMS 54, 55 AND 64 OBVIOUS

As further discussed below, Tisserand in view of Bonutti, as already discussed above, and further in view of Mathieu, teaches each and every element and limitation of the dependent claims 54, 55 and 64 and renders those claims obvious.

A. Dependent Claims 54 and 64

Each of dependent claims 54 and 64 depends directly from independent claim

47. Claim 54 recites that:

wherein the internal screw guide has a 25 degree angulation.

Claim 64 recites:

wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of the first screw member and the second screw member.

Tisserand teaches an intervertebral spinal fixation implant including a cage 1 having internal screw guides 1g, 1h at an angulation of approximately 45° to enable the bone screws 2, 3 to be implanted in the cortico-cancellous bone of the adjacent vertebral bodies L1, L2. EX1029 at 3:2-9.

Mathieu discloses an intervertebral spinal fixation implant with at least two mutually divergent boreholes that accept and direct the path of screws, thereby acting as screw guides. EX1005 at [0003]; [0017]; FIGs. 1-6. In addition, Mathieu teaches that the boreholes extend along axes that are 25° to 70° from a horizontal center plane of the implant. *Id.* at [0017]. Mathieu teaches this range of angles to enable the bone screws to move into a region of the adjacent vertebrae that offers better bone quality than found at the vertebra's center and to improve access for inserting the screws into the implant. *Id.*

Moskovitz does not disclose that limiting the internal screw guide to a 25° angulation is intended to address a particular problem. A PHOSITA would have understood that there were a range of potential screw angles that could be chosen in order to access a region offering better bone quality than found at the vertebra's center. EX1003 at ¶79. The specific angle chosen for a particular design would

depend on factors including the anatomical location where the device would be implanted, dimensions of the implant, lengths of screws, the location of the screw guide entry opening, frictional properties of the implant/bone interface, lordotic angle, surgical access, etc. *Id*.

Further, a PHOSITA would have understood that it was common to treat multiple spinal levels in the same patient and that geometric interference between screws at adjacent levels of the spine was disadvantageous. *Id.* at ¶84. A PHOSITA, therefore, would have further understood that limiting the screw guide angulation to only 25° would reduce the propensity for interference of screws between adjacent levels of the spine. *Id.* Consequently, a PHOSITA would have been motivated to apply the teachings Mathieu to the intervertebral cage disclosed by Tisserand. *Id.* at ¶85. According to Mathieu, this would enable a screw guide axis as shallow as 25°. EX1005 at [0017].

A PHOSITA, therefore, would have understood that, as taught by Mathieu, a screw angle of 25° could be employed in the intervertebral cage disclosed by Tisserand, either alone or combination with Bonutti. *Id.* at ¶80.

The internal screw guide and fixation apparatus as recited in claims 54 and 64 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti and further in view of Mathieu.

B. <u>Dependent Claim 55</u>

Dependent claim 55 depends from independent claim 47. Claim 55 recites:

wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

Tisserand discloses that the intervertebral cage 1 has a top wall with a thickness extending from the top surface 1d of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage 1, a height of the intervertebral cage extending in a direction perpendicular to the depth. EX1029 at FIGs. 1-3; and annotated FIG. 1, below.



Tisserand discloses internal screw guides such that the "screws are oriented at

an angle of very substantially 45° , in order to be implanted in the cortico-cancellous bone of the intervertebral bodies." EX1029 at 3:6-9. Tisserand also discloses internal recesses, "formed starting from the front face of the element, one of the recesses being directed towards the bottom, while the other is directed towards the top, being oriented with respect to one another, according to an angle of approximately 90°." *Id.* at 1:29-33; FIGs. 1-3.

A PHOSITA would have understood that Tisserand discloses screw guide angulations that can be *less than* 45°, and therefore discloses, "the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage," as claimed. EX1003 at ¶¶82, 83, 86.

Further, as already discussed, Mathieu discloses an internal screw guide axes can be at 25° to 70° from a horizontal center plane of the implant. EX1005 at [0017]. A PHOSITA would have understood that it was common to treat multiple spinal levels in the same patient and that geometric interference between screws at adjacent levels of the spine was disadvantageous. *Id.* at ¶84. A PHOSITA, therefore, would have further understood that limiting the screw guide angulation would reduce the propensity for interference of screws between adjacent levels of the spine. *Id.*

Consequently, a PHOSITA would have been motivated to apply an angle of less than 45 degrees to the intervertebral cage disclosed by Tisserand in view of the teachings Mathieu. *Id.* at \P 85. According to Mathieu, this would enable a range of screw guide axis as shallow as 25° such that the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of its height. *Id.*

The internal screw guide and fixation apparatus as recited in claim 55, therefore, would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti and further in view of Mathieu.

In summary, as confirmed by Dr. Ochoa, Tisserand in view of Bonutti and further in view of Mathieu renders claims 54, 55 and 64 unpatentable as obvious under 35 U.S.C. § 103.

XII. GROUND 3: TISSERAND IN VIEW OF BONUTTI AND FURTHER IN VIEW OF BRANTIGAN RENDERS CLAIM 57 OBVIOUS

Claim 57 depends directly from independent claim 47 and further recites:

wherein each of the two sidewalls includes a means for receiving placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

Tisserand discloses openings 1a and 1b in the cage 1 for receiving the

placement of bone graft material. EX1029 at 5:29-30; EX1003 at ¶88.

Brantigan discloses an intervertebral implant 10 to promote fusion of adjacent vertebrae. EX1031 at Abstract; 1:64-68; FIG. 1. Brantigan discloses the implant includes a body 11 with sidewalls 11b into which horizontal peripheral slots 11e are provided that communicate with a central aperture 11d to receive bone graft material

and to provide free spaces for blood flow to speed up the fusion process. *Id.* at 4:8-14; 4:53-56; FIGs. 1-6. Thus, the central aperture 11d and slots 11e also perform the function to receive the placement of bone graft material. *Id.* at 4:50-56. Thus, Brantigan teaches each of the sidewalls includes a means for receiving placement of bone filling into the open space of the intervertebral cage for the biological bone fusion the limitations, as recited in claim 57. EX1003 at \P 91.

A PHOSITA would also have understood that including the peripheral slots disclosed by Brantigan provides additional locations to pack graft material and increase the surface area available for vascularization. *Id.* at ¶¶89, 90. A PHOSITA would have further understood that the presence of the peripheral slots would be advantageous for promoting bone growth and fusion. *Id.* A PHOSITA, therefore, would have been motivated to include additional openings to the sidewalls of the intervertebral cage 1 disclosed by Tisserand, either alone or in combination with Bonutti, to provide additional locations to pack graft material and thereby increase the surface available for vascularization, thus promoting fusion. *Id.*

In summary, as confirmed by Dr. Ochoa, Tisserand in view of Bonutti and further in view of Brantigan renders claim 57 unpatentable as obvious under 35 U.S.C. § 103. *Id.* at ¶91.

XIII. GROUND 4: TISSERAND IN VIEW OF BONUTTI AND FURTHER IN VIEW OF WAUGH RENDERS CLAIMS 58 AND 70 OBVIOUS

As further discussed below, Tisserand in view of Bonutti, as already discussed

above, and further in view of Waugh, teaches each and every element and limitation of the dependent claims 58 and 70 and renders those claims obvious.

A. <u>Dependent Claim 58</u>

Dependent claim 58 depends from independent claim 47. Claim 58 adds the limitation:

wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

Although Tisserand does not expressly disclose a feature of the intervertebral cage 1 for engaging an implantation tool, a PHOSITA would have understood that such a tool would be required for the implantation procedure. EX1003 at ¶92. A PHOSITA would have also understood that the most likely function of the center hole located in top surface 1d would have been to interface with an implantation tool. *Id.*



Waugh discloses an intervertebral cage 102 having side surfaces 110a-b on opposite ends of the intervertebral cage that each include a recessed slot 120. EX1032 at 3:59-64; FIGs. 3, 5, 7, 9. The slots 120 are configured to cooperate with an insertion tool that connects to the cage 102 for manipulating and inserting the spacer during spinal fusion surgery. *Id.* A PHOSITA would have understood that the insertion tool disclosed in Waugh connects to the side slots of the spacer 102, and would have features, such as prongs, that would engage with these slots. EX1003 at ¶93.

A PHOSITA would have also understood that including recessed slots in the sidewalls of the intervertebral cage disclosed by Tisserand, alone or in combination with Bonutti, would yield the predictable result and enabled the use of a similar implantation tool. *Id.* at ¶94. Therefore, a PHOSITA would have considered it obvious to modify Tisserand to include the indentations for receiving the ends of prongs of an implantation tool. *Id.* The indentations disclosed by Waugh would have been a simple substitution for the central hole disclosed by Tisserand or supplementary to the central hole. In either case, it would have yielded a predictable effect in the resulting design and would not have changed the principle of operation of the spinal implant of Tisserand, alone or in combination with Bonutti. *Id.*

The internal screw guide and fixation apparatus as recited in claims 58 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti and further in view of Waugh.

B. <u>Dependent Claim 70</u>

Claim 70 depends directly from independent claim 47 and recites that the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall; and

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall,

As already discussed, Tisserand in view of Bonutti discloses the internal

screw guide and fixation apparatus recited at claim 47. Tisserand and Bonutti, however, disclose only two screw guides in the respective cages.

Waugh, though, teaches the cage 102 having four (4) internal screw guides 122 each being located at least partially on the top surface of a top wall 114. *See* EX1032 at FIG. 3. The exit openings of the screw guides are formed at least partially in the bottom surface of the top wall and at least partially in the respective side surfaces of the top wall. *Id*.

wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

Both Tisserand and Bonutti disclose the two screw guides, with one oriented downwards [*i.e.* caudally] and the other oriented upwards [*i.e.* rostrally]. EX1029 at 3:2-7; FIGs. 1-3; EX1030 at FIG. 10. Similarly, Waugh shows four screw guides with two oriented downwards [*i.e.* caudally] and two oriented upwards [*i.e.* rostrally]. EX1032 at FIG. 3.

A PHOSITA would have understood that the screw guide configuration disclosed by Waugh would be advantageous as it would allow for up to four screws to be used without geometrically interfering with screws from neighboring levels of the spine. EX1003 at ¶¶100, 104. The advantages of this configuration of screw guides would have been obvious to a PHOSITA based on the widely held and established biomechanical precepts that fixation screws should not collide with each

other or breach the vertebral bodies. *Id.* Moreover, it was also well known that it is advantageous to angle screws relative to each other (*e.g.*, upwards and downwards) to increase their holding power and pullout strength. *Id.* A PHOSITA would have further understood that the ability to use more screws would be advantageous in patients with low bone mass. *Id.*

Therefore, it would have been an obvious matter of design choice for a PHOSITA to modify the implant disclosed by Tisserand (alone or in combination with Bonutti), to include a third and fourth screw guide as disclosed in Waugh. *Id.* Further, the selection of this screw pattern would have yielded a predictable effect in the resulting design and would not have changed the principle of operation of the spinal implant of Tisserand, alone or in combination with Bonutti. *Id.*

Therefore, a PHOSITA would have understood that Tisserand in view of Bonutti and further in view of Waugh, discloses internal screw guide and fixation apparatus recited in claim 70.

The internal screw guide and fixation apparatus as recited in claim 70 would have been obvious to a PHOSITA at the time of the invention of the '022 patent over Tisserand in view of Bonutti and further in view of Waugh.

In summary, as confirmed by Dr. Ochoa, Tisserand in view of Bonutti as applied to claim 47, and further in view of Waugh, renders claims 58 and 70 unpatentable as obvious under 35 U.S.C. § 103.

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XV. SECONDARY CONSIDERATIONS

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

XVI. 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*⁹ and its progeny. Any such argument by Patent Owner should be rejected for several reasons.

First, Lex Machina reports that the median number of days to trial in the EDPA for patent cases is 572 days. EX1035. 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

⁹ NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018).

is for a trial date in 2022/2023.¹⁰

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 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.

¹⁰ Globus intends on filing a motion for stay in the Pending Litigation.

XVII.CONCLUSION

Petitioner has demonstrated in this Petition that the Challenged Claims are unpatentable. Petitioner, therefore, respectfully requests institution of an IPR of the '022 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 C.F.R. § 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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