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.: IPR2020-01310
U.S. Patent No. 10,251,643
Issued: April 9, 2019
Application No: 15/934,622
Filed: March 23, 2018

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,251,643 PURSUANT TO 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42

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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, 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

Exhibit #	*Description*
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.

Exhibit #	*Description*
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
1026	Wiseman, DB, Shaffrey, CI, Lanzino, G. Posterior Lumbar Interbody Fusion. Spine Surgery, Vol. One, Second Ed. Techniques, Complication Avoidance, and Management, Chapter 39. 2005
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I. INTRODUCTION

Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review ("IPR") of claims 1-3, 6-8, 10 and 12-17, 19 and 20 (the "Challenged Claims") of U.S. Patent No. 10,251,643, titled "Bi-Directional Fixating Transvertebral Body Screws, Zero-Profile Horizontal Intervertebral Miniplates, Expansile Intervertebral Body Fusion Devices, and Posterior Motion-Calibrating Interarticulating Joint Stapling Device for Spinal Fusion" ("the '643 patent"), issued to Mosheh T. Moskowitz, et al. and assigned to Moskowitz Family LLC ("Moskowitz"). The '643 patent is attached as EX1001.

The invention of the '643 patent is not new. Rather, the claimed invention encompasses known expansile spinal fusion implants for conducting surgical procedures to accomplish an intervertebral fusion of the human spine. In this regard, the Challenged Claims of the '643 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 '643 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, Gutlin in view of Barber renders Challenged Claims 1-3, 6, 7, 12-15, 17, 19 and 20 unpatentable as obvious under 35 U.S.C. § 103. EX1003 at ¶¶30-33; *and see,* EX1027. Additionally, Gutlin in view Barber and further in view of Sutcliffe renders Challenged Claims 8, 10 and 16 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 '643 patent.

The '643 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 '643 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. EX1033. 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"); 10,028,740 ("the '740 patent"); U.S. Patent No. 9,889,022 ("the '022 patent"); and U.S. Patent No. 8,353,913 ("the '913 patent").

These patents, although not directly related to the '643 patent, disclose similar subject matter and claim priority in a common provisional patent application No. 60/670,231. Petitioner understands that all of these patents are all commonly owned by Moskowitz.

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

Lead Counsel	Backup Counsel
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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 '643 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	1-3, 6, 7, 12-15, 17, 19 and 20	International (PCT) application Publication No. WO 2004/052245 to Gutlin et al. ("Gutlin") (EX1028, EX1029) in view of U.S. Patent No. 5,236,460 to Barber ("Barber") (EX1030)	35 U.S.C. § 103(a)
2	8, 10 and 16	Gutlin in view Barber and further in view of U.S. Patent Application Publication No. 2002/0143399 to Sutcliffe ("Sutcliffe") (EX1031)	35 U.S.C. § 103(a)

Based on the foregoing grounds, and as established by the declaration of Dr. Ochoa (as further discussed at Sections X and XI), Petitioner seeks a final, written decision that the Challenged Claims are unpatentable.

V. SUMMARY OF THE '643 PATENT (EX1001)

The '643 patent issued on April 9, 2019, on an application filed on March 23, 2018. The '643 patent is a continuation of U.S. Application Serial No. 13/093,812 filed April 25, 2011 issued as U.S. Patent No. 9,924,940, which is a continuation of

U.S. Application Serial No. 12/347,990 filed December 31, 2008 issued as U.S. Patent No. 7,951,180, which is a division 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 U.S. provisional application No. 60/670,231 filed April 12, 2005.

The earliest priority date supporting the Challenged Claims for the '643 patent is the April 12, 2005 filing date of the '231 provisional application.

A. The '643 Patent Specification and Claims

The '643 patent relates to the field of implantable spinal fixation devices and related instruments for the human body, and particularly to spinal intervertebral fixation devices for spinal fusions.

The written description and drawings of the '643 patent describe bi-directional fixating transvertebral screws which can be used to supplement other intervertebral spacers (*e.g.,* plates) and/or bone fusion materials (*e.g.,* osteoconductive substances) for use in the posterior or anterior cervical, thoracic or lumbar spine. EX1001 at 1:26-42; 7:7-11; 9:40-44.

The '643 patent issued with 25 claims, 15 of which are at issue in this Petition. Of the Challenged Claims, claim 1 is independent. Challenged Claims 2, 3, 6-8, 10 and 12-27, 19 and 20 all depend directly or indirectly from claim 1. The Challenged Claims are directed an artificial expansile spinal implant; however, they encompass known intervertebral spinal fixation devices implantable in the human spine and are

unpatentable.

B. The ‘643 Patent Prosecution History (EX1002)

The prosecution of the application leading to the ‘643 patent, Serial No. 15/934,622, included a single substantive Office Action dated September 4, 2018 (EX1002 at 44) and a Response dated November 2, 2018 (*Id.* at 22).

Following a preliminary amendment where an entirely new claim set was introduced (*see,* EX1002 at 88), all the claims were subject to a nonstatutory double patenting rejection and were substantively rejected as obvious in view of the prior art. Responding to the substantive rejection, applicant did not amend the claims but argued that the cited art did not “show[] or say[] that there is expansion between first and second shells.” Rather, the art simply “describes ‘Spinal implants with extending spikes’… [and] does not appear to have first and second ***shells*** that expand.” *Id.* at 28-29, emphasis in original. Applicant’s arguments were deemed persuasive and a Notice of Allowance issued January 24, 2019. *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."[1]

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 following, which are construed by the Petitioner in the Pending Litigation, as follows: [2]

Claim Term	**Petitioner's Construction**
"an intervertebral space"	"the disc space between two adjacent vertebrae"
"first and second shells"	"the ends of an implantable intervertebral device, which ends are capable of moving in at least two directions defined by at least two axes"

[1] 37 C.F.R. § 42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

[2] 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.

"rotatable tool engagement portion"	"the portion of the implant separate from the threaded bodies that engages a tool to rotate the first threaded body with respect to the second threaded body"
"configured to be extended from the [first/second] shell"	"originating in and extending from within the shell"

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 '643 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[3]

The '643 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.

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 (fixed height or expandable height, 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 to have the surgical techniques and procedures for performing spinal fusion surgery.

At the time of the invention of the '643 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.

[3] For a more complete discussion, *see* EX1003 at ¶¶34-42.

IX. THE PRIOR ART RELIED UPON IN THIS PETITION

A. Gutlin (EX1028 and EX1029[4])

Gutlin, entitled "Intervertebral Implant," published on June 24, 2004 on International (PCT) application No. PCT/CH2002/000674 filed December 6, 2002 and designating the United States.[5] Gutlin is prior art to the '643 patent under 35 U.S.C. § 102(a) (Pre-AIA) because it is a printed publication before the invention by the applicant for patent (*i.e.,* '643 patent's effective filing date, April 12, 2005). Gutlin was not considered by the Examiner during the prosecution of the application leading to the '643 patent.

To swear behind Gutlin, Moskowitz must prove conception of the claimed invention before Gutlin's June 24, 2004 publication 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 '643 patent is April 12, 2005, well after Gutlin's publication date. EX1032 at 9-10.

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[4] A certified English translation of Gutlin is attached as EX1029. All citations to Gutlin herein are made to the English translation.

[5] Of note, U.S. application Serial No. 11/147,139 filed June 6, 2005 issued as U.S. Patent 7,691,147 and is a continuation of PCT/CH2002/000674.

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

Gutlin discloses an expandable intervertebral implant 1 that includes upper and lower implant parts 5, 2 including upper and lower apposition parts 8, 4 having respective apposition surfaces 20, 19 (*together, i.e.,* first and second shells) that are connected by a threaded expansion mechanism (*i.e.,* a male-threaded spindle 9 engaging a female threaded bore 7, 30). *See, e.g.,* EX1029 at 1:25-2:8; 3:6-20; 4:11-5:32; FIGs. 1-4. The distance between upper and lower parts can be changed (*e.g.,* expanded) so that upper and lower apposition surfaces 20, 19 of the implant 1 bear against the endplates of adjacent vertebrae of an intervertebral space.

B. Barber (EX1030)

Barber, entitled "Vertebral Body Prosthesis," issued August 17, 1993. Barber is prior art to the '643 patent under 35 U.S.C. § 102(b) (Pre-AIA). Barber is a patent issued more than one year prior to the effective filing date of the application for the '643 patent in the United States. Barber was not considered by the Examiner during the prosecution of the application leading to the '643 patent.

Barber discloses an expandable intervertebral implant 11 including telescopingly connected bodies13, 23 including opposing platforms 19, 29 (*i.e.,* first and second shells) and a piston-type expansion mechanism 17, 25, 27, 39, positioned between the first and second shells and configured to expand the intervertebral implant (*i.e.,* increase the distance between opposed surfaces of the implant) for engaging the adjacent vertebrae 32 of an intervertebral space. EX1030 at 1:26-42;

2:11-45; FIGs. 2, 3.

C. Sutcliffe (EX1031)

Sutcliffe, entitled "Anchorable Vertebral Implant," published October 3, 2002. Sutcliffe is prior art to the '643 patent under 35 U.S.C. § 102(b) (Pre-AIA). Sutcliffe is a printed publication more than one year prior to the effective filing date of the application for the '643 patent in the United States. Sutcliffe was not considered by the Examiner during the prosecution of the application leading to the '643 patent.

Sutcliffe discloses an expandable intervertebral implant 1 including a lower part 3 and an upper part 4 (*i.e.,* first and second shells) each including a threaded stem 18, 15 that is mated to a threaded sleeve 5 (*i.e.,* an expansion mechanism) configured to expand the intervertebral implant (*i.e.,* increase the distance between opposed surfaces of the implant for engaging the adjacent vertebrae 2). EX1031 at [0008], [0022]; FIGs. 3 and 6. The lower and upper parts 3, 4 include holes 8 for accommodating bone screws 9. *Id.* at [0024].

X. GROUND 1: GUTLIN IN VIEW OF BARBER RENDERS CLAIMS 1-3, 6-7, 12-15, 17, 19 AND 20 OBVIOUS

As further discussed below, and as supported by Dr. Ochoa (*see, e.g.,* EX1003 at ¶¶43-80, 93-96), Gutlin in view of Barber renders the *expansile spinal fusion implant* recited in independent claim 1 and dependent claims 2, 3, 6, 7, 12-15, 17, 19 and 20 obvious.

A. Independent Claim 1

[1] *An artificial expansile spinal implant comprising:*

Gutlin discloses an artificial expandable intervertebral implant 1. EX1029 at 1:25-2:8; 3:6-20; 4:11-5:32; FIGs. 1-4.

A PHOSITA would have understood that Gutlin discloses an artificial expansile spinal implant as recited at [1]. EX1003 at ¶47.

[2] *first and second shells and*

Gutlin discloses that the intervertebral implant 1 includes upper and lower implant parts 5, 2 having upper and lower apposition parts 8, 4 with upper and lower apposition surfaces 20, 19 (*together, i.e.*, first and second shells). EX1029 at 4:6-24; FIG. 1.

A PHOSITA would have understood that Gutlin discloses an artificial expansile spinal implant as recited at [2]. EX1003 at ¶48.

[3] *an expansion mechanism positioned between the first and second shells and configured to expand the artificial expansile spinal implant,*

[4] *wherein the expansion mechanism comprises first and second threaded bodies and*

[5] *a rotatable tool engagement portion configured to rotate the first threaded body with respect to the second threaded body to drive expansion between the first shell and the second shell in response to turning the rotatable tool engagement portion,*

Gutlin discloses the upper and lower implant parts 5, 2 are connected by a

male-threaded spindle 9 and a female-threaded bore 7, 30 that enable the upper and lower implant parts 5, 2 to move apart from one another in the direction of the axis 11 such that a distance between the implant parts 5, 2 is increased (*i.e.,* an expansion mechanism). *See, e.g.,* EX1029 at 1:25-2:8; 3:6-20; 4:11-5:32; FIGs. 1-4.

The male-threaded spindle 9 (*i.e.*, a first threaded body) connected to the lower implant part 2 engages the female-threads 7 in a bore 30 (*i.e.*, a second threaded body) in the upper implant part 5. EX1029 at 4:11-5:32; FIGs. 3 and 4.

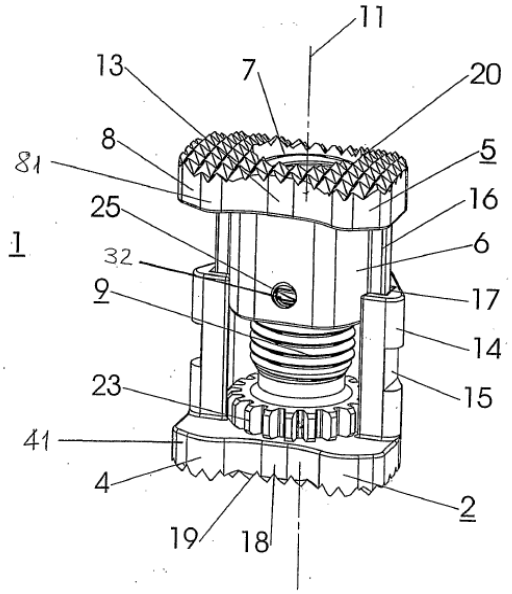


Fig. 1:

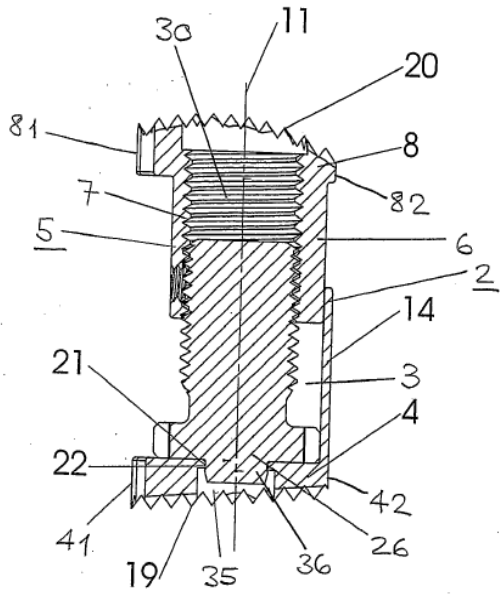


Fig. 3:

The spindle 9 includes a rotatable gear crown 23 (*i.e.,* a rotatable tool engagement portion) which can be brought into engagement with a tool for rotating the gear crown 23 and threaded spindle 9 relative to the threaded bore 7, 30 of the upper implant part 5 for adjusting the distance between the upper and lower implant parts 5, 2 (and the apposition parts 8, 4 together with apposition (*i.e.,* bone engaging)

surfaces 20, 19,(*i.e.*, shells)). *Id.* at 2:5-7; 5:20-32; FIGs. 1, 3, 4.

A PHOSITA would have understood that Gutlin discloses an artificial expansile spinal implant as recited at [3], [4] and [5]. EX1003 at ¶¶48, 49.

> [6] *wherein the artificial expansile spinal implant is configured to be introduced into an intervertebral space with the first and second shells engaging opposing vertebral bodies when inserted into the intervertebral space, and*

Gutlin discloses an implant 1 for introduction into an intervertebral space. EX1029 at 1:2-3; 1:25-28. The distance between upper and lower implant parts 5, 2 of the intervertebral implant 1 can be changed (*e.g.,* expanded) so that upper and lower apposition surfaces 20, 19 of the upper and lower apposition parts 8, 4 bear against the vertebral endplates of adjacent vertebrae when implanted in a patient. *Id.* at 1:25-2:8; 3:6-20; 4:11-5:32.

A PHOSITA would have understood that Gutlin discloses an artificial expansile spinal implant as recited at [6]. EX1003 at ¶50.

> [7] *wherein the tool engagement portion is positioned and configured to be engaged by a tool extending along a direction of insertion for rotating the rotatable tool engagement portion,*

Gutlin discloses that the gear crown 23 is configured to be brought into engagement with a tool for rotating the gear crown 23 (and the male-threaded spindle 9) relative to the female-threaded bore 7, 30. EX1029 at 2:5-7; 5:20-32; FIGs. 1, 3, 4. The implant 1 includes two slots 15 on lateral sides (*i.e.,* the mantle 14) of the lower implant part 2. The tool is received in the slots 15 from the anterior side of

the implant 1. *Id.*

A PHOSITA would understand from Gutlin that the implant is intended for implantation (*i.e.,* insertion) into a patient anteriorly. EX1003 at ¶51. The gear crown is configured to be engaged for rotation by the tool from the same side (*i.e.,* the anterior side) of the implant. EX1029 at 2:5-7; EX1003 at ¶51.

A PHOSITA would have understood that Gutlin discloses an artificial expansile spinal implant as recited at [7]. EX1003 at¶51.

> [8] *wherein each of the first and second shells comprises*
>
> *a first set of engagement features extending from the first and second shells that are configured for engaging vertebral endplates of the opposing vertebral bodies to hold the artificial expansile spinal implant in place and*
>
> [9] *a second set of engagement features extending from the first and second shells that are configured for engaging the vertebral endplates of the opposing vertebral bodies to hold the artificial expansile spinal implant in place,*
>
> [10] *wherein the second set of engagement features are larger than the first set of engagement features, extend further than the first set of engagement features, and have substantially tapered tips configured for piercing the vertebral endplates when introduced into the intervertebral space and expanded.*

Gutlin discloses that the upper and lower apposition surfaces 20, 19 of the upper and lower apposition parts 8, 4 can include a dome in the sagittal direction for optimal adaptation to the adjacent vertebrae. EX1029 at 3:15-17; 4:21-22. Further, Gutlin discloses that the upper and lower apposition surfaces 20, 19 can include a

dome in the coronal direction for optimal adaptation to the adjacent vertebrae. *Id.* at 3:18-20. Thus, a PHOSITA would understand that Gutlin discloses at least a first set of engagement features, as claimed. EX1003 at ¶52.

Additionally, Gutlin discloses that each of the respective upper and lower apposition surfaces 20, 19 have three-dimensional texturing (*i.e.,* spikes protruding outwardly from the apposition surfaces) for engaging the vertebral end plates of adjacent vertebrae. EX1029 at 4:18-19; FIGs. 1, 3, 4.

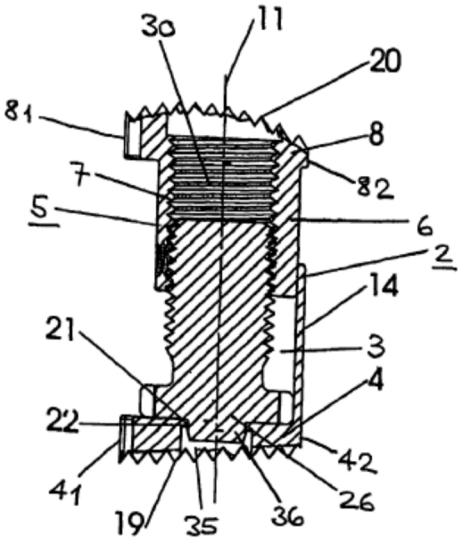


Fig. 3:

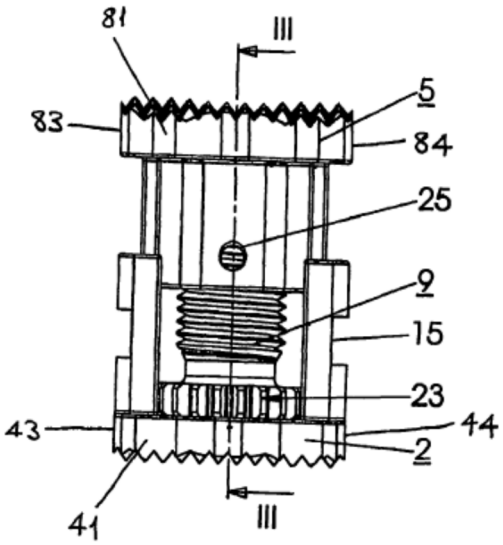


Fig. 4:

Gutlin further discloses that the second set of engagement features (*i.e.*, spikes) protrude beyond the dome shape(s) of the apposition surfaces 20, 19 and have tapered tips. EX1029 at FIGs. 3, 4. A PHOSITA would understand that the tips serve to pierce the vertebral end plates of adjacent vertebrae. EX1003 at ¶¶53, 54. Thus, a PHOSITA would understand that Gutlin discloses the limitations describing the second set of engagement features, as claimed. *Id.*

To the extent that Gutlin does not disclose first and/or second shells and a first and/or second set of engagement feature as claimed, Gutlin in view of Barber teaches the artificial expansile spinal implant of claim 1.

Barber also discloses an artificial expansible spinal implant 11. EX1030 at 1:12-14. The implant 11 includes an outer (lower) body 13 and an inner (upper) body 23. EX1030 at 1:26-42; 2:11-45 and FIG. 1. The inner body 23 is telescopingly mounted to the outer body 13. *Id.* A lower platform 19 is at the lower end of the outer body 13 and an upper platform 29 is at an upper end of the inner body 23. *Id.*

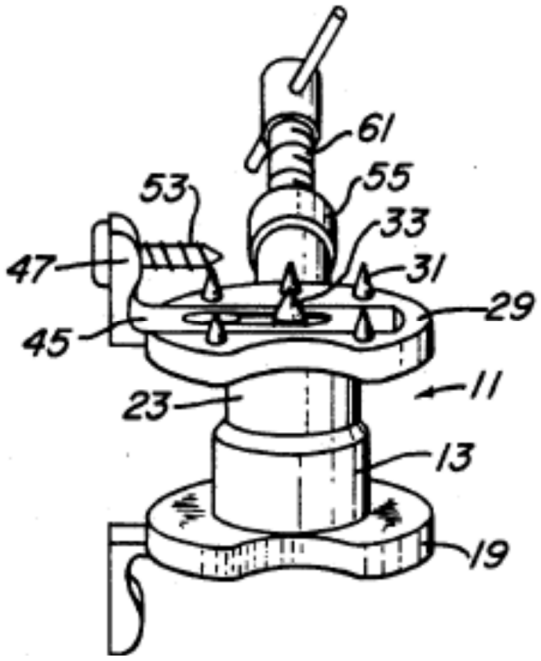


Fig. 1

Barber also discloses that brackets 45 mount to each of the respective platforms 19, 29. EX1030 at 2:49-64, FIGs. 1, 4. The brackets are located within respective slots 43 in the platforms 19, 29. *Id.* Each bracket 45 has a 90º flange 47 located on one side of the bracket 45. *Id.* The flange 47 of each bracket 45 includes

a hole 48. *Id.* Each bracket 45 is laterally slidable along the slot 43 in the respective platform 19, 29 relative to the vertical axis of the implant 11 to a desired width. *Id.* A pin 51 retains the bracket to the platform 19, 29 but allows lateral movement. *Id.*

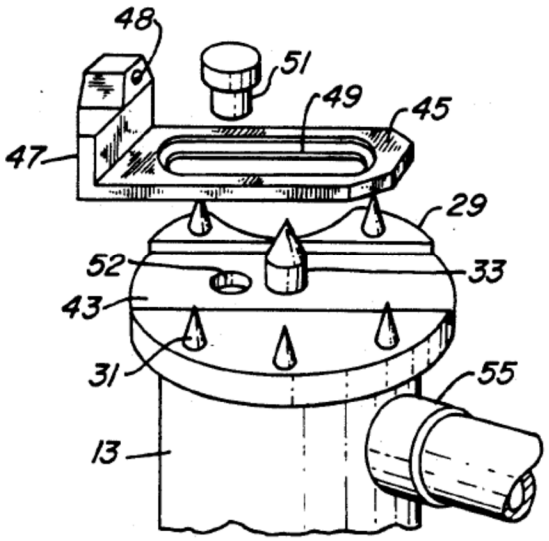


Fig. 4

The outer and inner bodies 13, 23 and respective platforms 19, 29 (including the brackets 45) comprise first and second shells of the implant 11.

Further, in addition to being expandable laterally via the slidable bracket 45, the first and second shells of the implant 11 of Barber are vertically expandable. *Id.* at 1:12-14. In this respect, the lower and upper shells (13, 19, 23, 29, 45) of the implant 11 can move apart from one another by operation of a piston-type expansion mechanism including a port 17, a cavity 25, a port 27, and a piston 39. *Id.* at 1:26-42; 2:11-45; 3:7-28; FIGs. 2, 3. The expansion mechanism is located between the first and second shells and enables the lower and upper platforms 19, 29 of the implant 11 to move between a retracted position (FIG. 2) and an extended position

(FIG. 3) to engage the adjacent vertebrae 32. *Id.* t

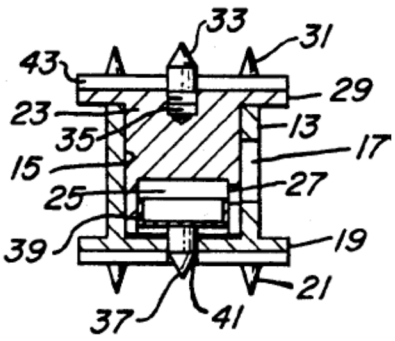


Fig. 2

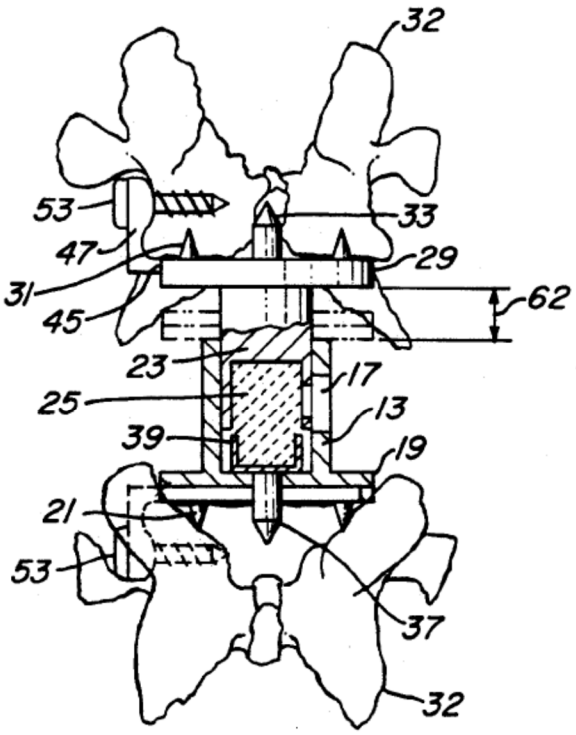


Fig. 3

Barber further discloses multiple engagement features extending or protruding from each of the respective lower and upper platforms 19, 29. In particular, a first set of engagement featured disclosed in Barber are first pins 21, 31 extending axially outward from platforms 19, 29. *Id.* at 2:11-33; FIG. 3. The pins 21, 31 each have sharp tips to pierce the adjacent vertebral bodies 32 between which the implant 11 is placed. *Id.*

Additionally, Barber discloses a second set of engagement features including

axially-extending second pins 33, 37 each also having sharp tips that project, respectively, from the upper and lower platforms 29, 19. *Id.* at 2:34-45; FIGs. 2, 3. The second pins 33, 37 likewise pierce the adjacent vertebrae and protrude a greater distance from the platforms 19, 29 than do the first pins 21, 31. *Id.* In addition, the second pins 33, 37 are larger than first pins 31, 21. *Id.* The second pin 37 mounts to a piston 39 and moves from an upper to lower position (*i.e.* expands) when urged by the expansion mechanism 17, 25, 27, 39. *Id.* at 2:38-41. The pins 21, 31, 33, 37 serve to secure the implant to the vertebrae 32. *Id.* at 2:46-48.

Further, the second set of engagement features disclosed in Barber also includes screws 53 that pass through the holes 48 of the flanges 47 of the bracket 45. *Id.* at 2:55-57. The screws 53 engage the vertebral bodies 32 and supplement the pins' 33, 37 engagement and operate to further secure the implant 11.

It would have been obvious to a PHOSITA to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features as taught by Barber. EX1003 at ¶60. A PHOSITA would have understood and recognized that it is advantageous to provide multiple features for engaging the adjacent vertebrae to enhance stability and reduce migration of the intervertebral implant. *Id.* at ¶61. The practice of combining features such as spikes, keels, screws and roughened or porous surfaces to achieve enhanced fixation was common in the field of spinal fixation implants. *Id.*

A PHOSITA would have also known that the spikes and screws disclosed by Barber offered more aggressive purchase in the bone during implantation. *Id.* at ¶62. A PHOSITA would have motivated to apply the features disclosed by Barber to the spinal fixation implant disclosed by Gutlin to provide a more aggressive fixation of the implant within the intervertebral space. *Id.* Including the engagement features of Barber in the implant disclosed by Gutlin would have been well within the ability of a PHOSITA. *Id.* Further, the modification would have yielded a predictable effect in the resulting design and would not have changed the principal of operation of the spinal fixation implant disclosed by Gutlin. *Id.*

A PHOSITA would have understood that Gutlin as modified by Barber discloses the artificial expansile spinal implant as recited in claim 1. *Id.* at ¶63.

The artificial expansile spinal implant recited in claim 1 would have been obvious to a PHOSITA at the time of the invention of the '643 patent over Gutlin in view of Barber. EX1003 at ¶¶60-63.

B. Dependent Claim 2

Claim 2 depends from independent claim 1 and reads:

> *wherein the second set of engagement features extend from the first and second shells in directions substantially perpendicular to the first and second shells.*

Gutlin discloses the second set of engagement features includes three-dimensional texturing (*i.e.,* spikes) protruding outwardly, substantially

perpendicularly from the apposition surfaces 29, 19 of the apposition parts 8, 4 (*i.e.,* together the first and second shells) for engaging the vertebral end plates of adjacent vertebrae. EX1029 at 4:18-19; FIGs. 1, 3, 4.

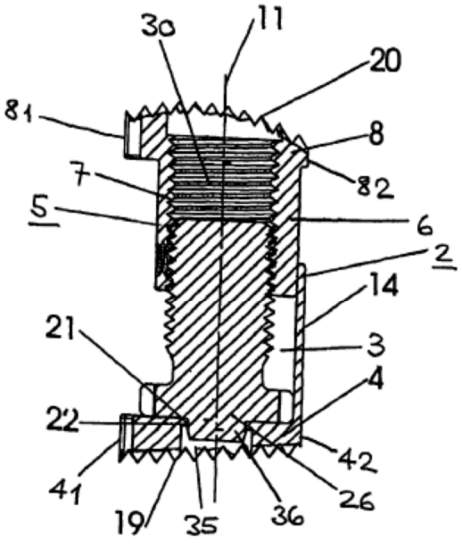


Fig. 3:

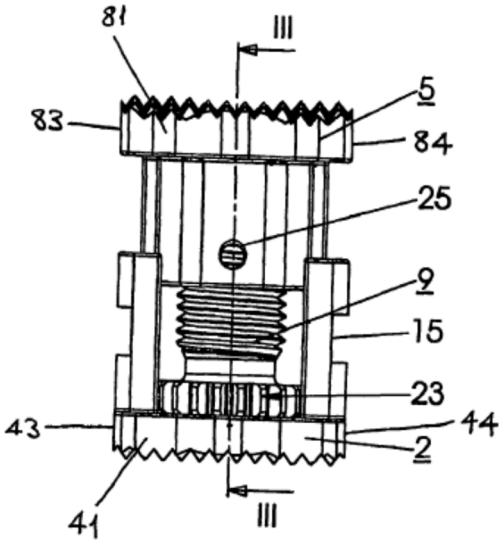
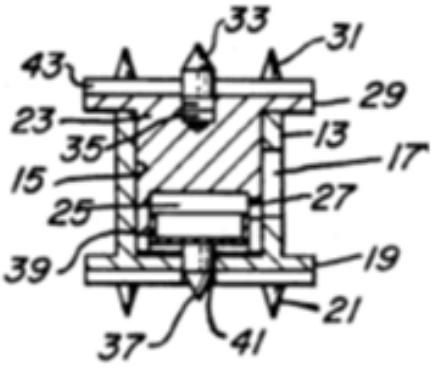


Fig. 4:

Barber discloses the second set of engagement features includes the pins 33, 37 extending substantially perpendicularly, respectively, from each of the upper and lower platforms 29, 19 (*i.e,* first and second shells). EX1030 at 2:34-45; FIGs. 2, 3.

Fig. 2



The artificial expansile spinal implant recited in claim 2 would have been obvious to a PHOSITA at the time of the invention of the '643 patent over Gutlin in

view of Barber. EX1003 at ¶¶64-68.

C. Dependent Claims 3 and 12

Claim 3 depends from independent claim 2. Claim 12 depends directly from claim 1. Both claims 3 and 12 recite:

> *wherein the first shell, the second shell, and the first set of engagement features extending from both the first and second shells comprise PEEK (poly-ether-ketone).*

Gutlin teaches that the intervertebral implant is produced from a material permeable for X-rays, preferably from PEEK (poly-ether-ether-ketone). EX1029 at 3:24-26; 6:61-62. PEEK makes it possible to achieve the advantage that the fusion can be assessed more readily after the operation. *Id.*

Making a spinal fixation implant from PEEK was well-known and obvious to a PHOSITA. EX1003 at ¶¶39, 41, 42, 44, 69. Thus, utilizing PEEK for the first and second shells and the engagement features of the implant of Gutlin alone, or as modified by Barber, would have been obvious. *Id.*

At the time of the invention of the '643 patent, therefore, the artificial expansile spinal implant as recited in claims 3 and 12 would have been obvious to a PHOSITA over Gutlin in view of Barber. EX100X at ¶69.

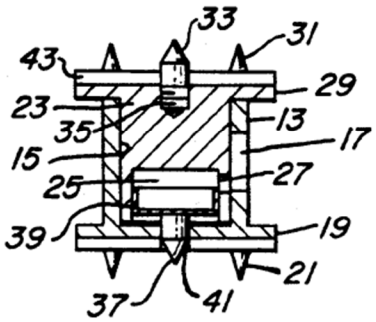
D. Dependent Claim 6

Claim 6 depends directly from independent claim 1. Claim 6 adds the limitation:

each of the first and second shells define holes into which the second set of engagement features at least partially extend.

Barber discloses that the upper and lower platforms 29, 19 (*i.e.,* first and second shells) each include a hole through which the pins 33, 37 (*i.e.,* second set of engagement features) extend. EX1030 at 2:34-35; 2:41-43; FIGs. 2, 3.

Fig. 2



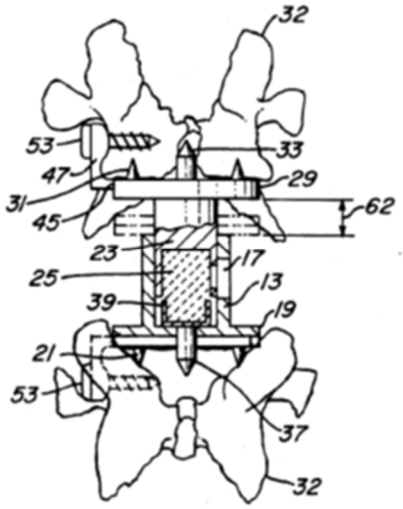


Fig. 3

It would have been obvious to a PHOSITA to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features recited in claim 6 as taught by Barber for at least the reasons stated with respect to claim 1. EX1003 at ¶70.

The artificial expansile spinal implant as recited in claim 6 would have been obvious to a PHOSITA over Gutlin in view of Barber. *Id*.

E. Dependent Claim 7

Claim 7 depends directly from independent claim 1. Claim 7 recites:

wherein each of the first and second shells define holes into which the second set of engagement features at least partially extend and

> *the second set of engagement features extend from the holes of the first and second shells in directions substantially perpendicular to the first and second shells and*
>
> *wherein the first set of engagement features are more numerous than the second set of engagement features.*

Barber discloses that the upper and lower platforms 29, 19 (*i.e.,* first and second shells) each include a hole through which the axially-extending second pins 33, 37 extend. EX1030 at 2:34-35; 2:41-43; FIGs. 2, 3. Barber also discloses the pins 33, 37 (*i.e.,* the second set of engagement features) extend substantially perpendicularly, respectively, from each of the upper and lower platforms 29, 19. *Id.* at 2:34-45; FIGs. 2, 3.

Barber further discloses that the axially-extending first pins 31, 21 (*i.e.,* first set of engagement features) are more numerous than the axially-extending second pins 33, 37 (and screws 53) (*i.e.,* second set of engagement features). EX1030 at FIGs. 1-3. In this respect, Barber shows at least 7 first pins 31, 21 and two second pins 33, 37 (and 2 screws 53). *Id.*

It would have been obvious to PHOSITA to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features as taught by Barber for the reasons stated with respect to claim 1. EX1003 at ¶74-75.

The artificial expansile spinal implant as recited in claim 7 would have been obvious to a PHOSITA over Gutlin in view of Barber at the time of the invention of the '643 patent. *Id.*

F. Dependent Claims 13 and 14

Claim 13 depends directly from claim 1 and includes the limitation:

> *wherein the first and second shells define screw holes.*

Claim 14 depends from claim 13 and adds the limitation:

> *wherein the second set of engagement features comprise threaded screws extending through the screw holes.*

Barber discloses the brackets 45 mounted to the respective platforms 19, 29 include flanges 47 with holes 48 for receiving screws 53 (*i.e.,* part of the second set of engagement features). EX1030 at 2:46-64, FIGs. 3, 4. Thus, PHOSITA would have understood Barber to disclose the first and second shells defining screw holes as recited in claim 13, as well as threaded screws extending through the screw holes as recited in claim 14. EX1003 at ¶¶71-72.

It would have been obvious to a PHOSITA to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features taught by Barber for at least the reasons stated with respect to claim 1. *Id.*

The artificial expansile spinal implant as recited in claims 13 and 14 would have been obvious to a PHOSITA over Gutlin in view of Barber. *Id*.

G. Dependent Claim 15

Claim 15 depends directly from claim 1 and includes the limitation:

> *wherein the second set of engagement features comprise rotatable threaded screws.*

Barber discloses screws 53 (*i.e.,* the second set of engagement features) are received in the holes 48 of the flanges 47 of the brackets 45 mounted to the respective platforms 19, 29. EX1030 at 2:46-64, FIGs. 3, 4. A PHOSITA would have understood that the screws 53 are inherently rotatable and threaded. EX1003 at ¶73.

It would have been obvious to a PHOSITA to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features as taught by Barber, at least for the reasons stated with respect to claim 1 above. *Id.*

The artificial expansile spinal implant as recited in claim 15, therefore, would have been obvious to a PHOSITA over Gutlin in view of Barber at the time of the invention of the '643 patent. *Id.*

H. Dependent Claim 17

Claim 17 depends directly from independent claim 1. Claim 17 reads:

> *The artificial expansile spinal implant of claim 1, and further comprising means for placement of bone material.*

Gutlin discloses that the implant includes anterior recesses 13, 18 in the upper and lower apposition parts 8, 4 (*i.e.,* first and second shells) are for accumulating substances that support fusion, for example spongiosa (*i.e.,* spongy cancellous bone). EX1029 at 3:3-5; 4:33-34; FIG. 1. The recesses 13, 18, therefore, provide a void which can receive bone material to promote fusion between the implant and the vertebral bodies. EX1003 at ¶77. The recesses 13, 18 disclosed in Gutlin, therefore, perform the function recited and meet the limitations of claim 17. *Id*

The artificial expansile spinal implant as recited in claim 17 would have been obvious to a PHOSITA at the time of the invention of the '643 patent over Gutlin in view of Barber. *Id.*

I. Dependent Claims 19 and 20

Claims 19 and 20 each depend directly from independent claim 1 and both claims further limit the recited expansion mechanism. Claim 19 reads:

wherein the expansion mechanism comprises a rotatable gear.

Claim 20 recites:

wherein the expansion mechanism comprises a pinion.

Gutlin discloses the male-threaded spindle 9 of the expansion mechanism includes a rotatable gear crown 23 (*e.g.* a rotatable gear) which can be brought into engagement with a gear wheel on an instrument for rotating the gear crown 23 and threaded spindle 9 relative to the female-threaded 7 bore 30 of the upper implant part, thus adjusting the distance between the upper and lower apposition parts 8, 4 and apposition surfaces 20, 19. *Id.* at 4:47-5: 32; FIGs. 1-4; EX1003 at ¶78. Gutlin, thus, discloses the expansion mechanism comprises a rotatable gear as recited in claim 19. *Id.*

To the extent that a pinion gear (*e.g.,* a smaller gear) is located on the instrument rather than the implant, a PHOSITA would have understood that it would be trivial to instead mount the pinion on the implant itself. EX1003 at ¶80. Such an

arrangement would allow engagement and adjustment of the instrument using a hex driver, Hexalobe driver, or similar well-known driver device. *Id.* This would also improve the torque transmission between the gears by stabilizing the position of the gear wheel relative to the crown gear, independent of the engagement between the implant and the instrument. *Id.* This simple modification of Gutlin would have yielded a predictable effect in the resulting design and would not have changed the principle of operation of the spinal implant of Gutlin, alone or in combination with Barber. *Id.* Thus, claim 20 would have been obvious.

The artificial expansile spinal implant as recited in claims 19 and 20 would have been obvious to a PHOSITA at the time of the invention of the '643 patent. EX1003 at ¶¶78-80.

In summary, as confirmed by Dr. Ochoa, Gutlin in view of Barber renders the Challenged Claims 1-3, 6, 12-15, 17, 19 and 20 unpatentable as obvious under 35 U.S.C. § 103.

XI. GROUND 2: GUTLIN IN VIEW OF BARBER AND FURTHER IN VIEW OF SUTCLIFFE RENDERS CLAIMS 8, 10 AND 16 OBVIOUS

Gutlin in view of Barber and further in view of Sutcliffe, as further discussed below and as supported by Dr. Ochoa (*see, e.g.,* EX1003 at ¶¶81-92, 93-96), renders the *expansile spinal fusion implant* recited in dependent claims 8, 10 and 16 obvious.

A. Dependent Claim 8

Claim 8 depends directly from independent claim 1 and recites:

wherein the first shell, the second shell, and the first set of engagement features extending from both the first and second shells comprise PEEK (poly-ether-ketone),

wherein each of the first and second shells define screw holes, and

wherein the second set of engagement features comprise screw members extendable through the holes at least partially into the vertebral endplates.

As previously discussed with respect to claims 3 and 12, Gutlin discloses an intervertebral implant that can be made from a material permeable for X-rays, preferably from PEEK, which makes it possible to achieve the advantage that the fusion can be assessed more readily after the operation. EX1029 at 3:24-26; EX1003 at ¶ 81. Further, making a spinal fixation implant from PEEK was well-known and obvious to a PHOSITA. EX1003 at ¶¶39, 41, 42, 44, 81. Thus, utilizing PEEK for first and second shells and the engagement features of the implant would have been obvious. *Id.*

As discussed above at Section X. A. [8]-[10], Barber discloses that brackets 45 mount to each of the respective platforms 19, 29. EX1030 at 2:49-64, FIGs. 1, 4. Each bracket 45 has a flange 47 that includes a hole 48 for a screw. *Id.* Additionally, Barber discloses the second set of engagement features can include screws 53 that pass through the holes 48 of the flanges 47 of the bracket 45 and engage the adjacent vertebral bodies 32. *Id.*

Sutcliffe discloses an expandable intervertebral implant 1 for implantation

between adjacent vertebrae 2. EX1031 at [0008], [0022]; FIGs. 3 and 6. The implant includes a lower part 3 and an upper part 4 (*i.e.,* first and second shells) and a center threaded sleeve 5 all of which are made from PEEK. The upper and lower parts 4, 3 each include a threaded stem 18, 15 that is mated to the threaded sleeve 5. *Id.* Rotation of the sleeve 5 in one direction causes the upper and lower parts, 3, 4 to move apart and engage the vertebrae 2 and rotation of the sleeve in the opposite direction causes the upper and lower parts 3, 4 to move together (*i.e.,* an expansion mechanism). *Id.*

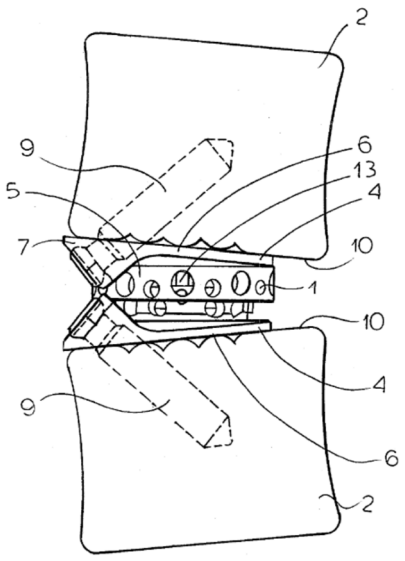


FIG.6

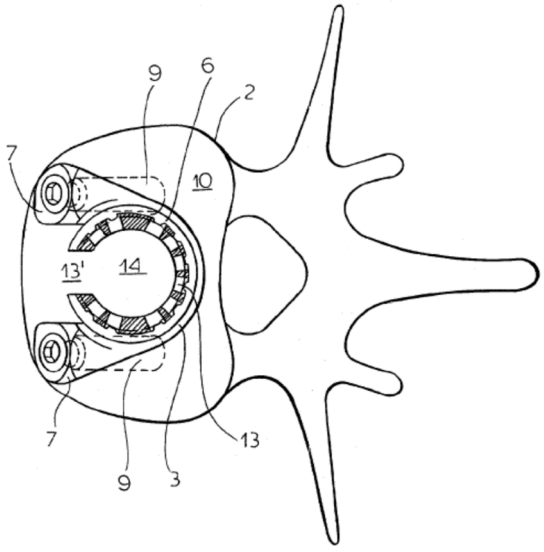


FIG.3

Sutcliffe also discloses that the upper and lower parts 4, 3 can each be formed with a pair of eyes 6 having collars 7 defining two holes or passages 8 with cylindrical inner surfaces 12 extending at an acute angle of between 25 and 65 degrees to the vertebral surfaces 10 (*i.e.,* vertebral endplates) of the adjacent

vertebrae 2. EX1031 at [0024].

Cortical screws 9 extend through the eyes 6 and into the surfaces 10 (*i.e.*, vertebral endplates) of the vertebra 2 to solidly anchor the upper and lower parts 4, 3 to the vertebra 2. *Id.* Two screws 9 engage the vertebral surface 10 (*i.e.*, vertebral endplate) of the upper vertebra and two screws engage the vertebral surface 10 (*i.e.*, vertebral endplate) of the lower vertebra 2. *Id.* at FIGs. 3, 6. Sutcliffe teaches that this configuration with 2 screws angled upward and 2 screws angled downward is particularly advantageous because it is more accommodating for implantation, particularly at the lower end of the vertebrae above the sacral vertebrae. *Id.* at [0010].

A PHOSITA would have understood that the integral screw guides disclosed by Sutcliffe provide equivalent function to the flange and screw disclosed by Barber. EX1003 at ¶84, 96. Further, a PHOSITA would have understood that the recessed screw heads disclosed by Sutcliffe offer advantages compared to a flange and screw. *Id.* Particularly, relocating and recessing the screw heads as disclosed in Sutcliffe eliminates the presence of prominent hardware on the anterior vertebral surface. *Id.* Recessing the screw heads can help prevent irritation of 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 eliminate the presence of prominent hardware. *Id.*

Therefore, it would have been obvious to a PHOSITA to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features as taught by Barber and Sutcliffe for the foregoing reasons and those stated with respect to claim 1. *Id.* at ¶84.

The artificial expansile spinal implant as recited in claim 8, therefore, would have been obvious to a PHOSITA at the time of the invention of the '643 patent over Gutlin in view of Barber and further in view of Sutcliffe.

B. Dependent Claims 10 and 16

Claim 10 depends directly from independent claim 1 and recites:

> *wherein the second set of engagement features comprise at least first and second screw members configured to be extended from the first shell into one of the vertebral endplates and*
>
> *at least third and fourth screw members configured to be extended from the second shell into another of the vertebral endplates.*

Claim 16 depends directly from independent claim 1 and recites:

> *wherein the first shell comprises a first plurality of screw holes and the second shell comprises a second plurality of screw holes.*

As discussed above, Barber discloses the second set of engagement features can further include screws 53 for engaging the vertebral bodies 32 that are received in holes 48 of the flanges 47 of the brackets 45 mounted to each of the respective platforms 29, 19. EX1030 at 2:46-64, FIGs. 3, 4.

Sutcliffe discloses each upper and lower part 3, 4 can each be formed with a pair of eyes 6 having collars 7 defining two holes or passages 8 with cylindrical inner surfaces 12 extending at an acute angle of between 25º and 65º to the vertebral surfaces 10. EX10031 at [0024]. Cortical screws 9 extend through each of the eyes 6 and into the endplates of the vertebra 2 to solidly anchor the upper and lower parts 4, 3 to the vertebra 2. *Id.* As shown in FIGs. 2-4, Sutcliffe, thus, teaches that two screws 9 engage the vertebral endplate 10 of the upper vertebra 2 and two screws engage the vertebral endplate 10 of the lower vertebra 2. *Id.* at FIGs. 3, 6.

A PHOSITA would have understood that use of multiple screws on anterior and lateral fixation systems was common and would provide increased purchase in patients with low bone mass, as well as providing increased resistance to moments perpendicular to the screw axes. EX1003 at ¶88. It would have been obvious to a PHOSITA, therefore, to modify the implant disclosed in Gutlin to incorporate the vertebral engagement features as taught by Barber and Sutcliffe for the reasons stated above and with respect to claims 1 and 8. *Id.* at ¶¶89-92.

Therefore, the artificial expansile spinal implant as recited in claims 10 and 16, then, would have been obvious to a PHOSITA at the time of the invention of the '643 patent over Gutlin in view of Barber and further in view of Sutcliffe. *Id.* at ¶¶86-92.

In summary, as confirmed by Dr. Ochoa, Gutlin in view of Barber and further

in view of Sutcliffe renders the Challenged Claims 8, 10 and 16 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 reasons.

First, Lex Machina reports that the median number of days to trial in the EDPA for patent cases is 572 days. EX1034. 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

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

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 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

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

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 '643 patent.

Dated: July 21, 2020

By: / George D. Moustakas /

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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. 10,251,643 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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