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.: IPR2020-01305
U.S. Patent No. 10,478,319
Issued: November 19, 2019
Application No: 16/280,684
Filed: February 20, 2019

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,478,319 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 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 standalone 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.
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
1027	Invalidity Claim Chart regarding U.S. Patent No. 10,478,319
1028	Intentionally Left Blank
1029	U.S. Patent Application Publication No. 2002/0270968 to Baynham
1030	U.S. Patent Application Publication No. 2006/0253201 to McLuen

Exhibit #	*Description*
1031	U.S. Patent No. 5,658,335 to Allen
1032	U.S. Patent Application Publication No. 2002/0143399 to Sutcliffe
1033	Intentionally Left Blank
1034	Moskowitz Family LLC Disclosure of Infringement Contentions
1035	Order Granting Defendant Globus Medical's Motion to Transfer Venue Under 28 U.S.C. § 1404(a)
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I. INTRODUCTION

Petitioner Globus Medical, Inc. ("Globus" or "Petitioner") hereby petitions for *inter partes* review ("IPR") of claims 1-5, 7-9, 11, 12, 14, 15, and 18-21 (the "Challenged Claims") of U.S. Patent No. 10,478,319, titled "System With Tool Assembly And Expandable Spinal Implant" ("the '319 patent"), issued to Ahmnon D. Moskowitz, et al. and assigned to Moskowitz Family LLC ("Moskowitz"). The '913 patent is attached as EX1001.

The Challenged Claims are directed to well-known expandable intervertebral implant and a surgical tool for positioning and expanding the implant into the intervertebral space. A specific listing of Petitioner's asserted grounds for unpatentability and a comparison of the prior art to the Challenged Claims is referenced below. Evidentiary support is provided in the Declaration of Jorge A. Ochoa, Ph.D., P.E. EX1003.

For the reasons set forth herein, Petitioner seeks a final written decision that the Challenged Claims of the '319 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103.

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 '319 patent.

The '319 patent was the subject of the civil action known as *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 Original Litigation"). On July 2, 2020, Judge Alan Albright granted Petitioner's motion for transfer to the Eastern District of Pennsylvania ("EDPA"). EX1035. The Original Litigation formally transferred to the EDPA on July 6, 2020 and is docketed as *Moskowitz Family LLC v. Globus Medical Inc.*, U.S. District Court for the EDPA, civil action no. 2:20-cv-03271 ("Pending Litigation").

Petitioner is concurrently filing IPR Petitions for the following patents: U.S. Patent No. 8,353,913 ("the '913 patent"); U.S. Patent No. 10,307,268 ("the '268 patent"); U.S. Patent No. 9,889,022 ("the '022 patent"). The '913, '268 and '022 patents are related to the '319 patent through continuation practice. Petitioner understands that the '319 patent, the '913 patent, the '268 patent and the '022 patent are all commonly owned by Moskowitz.

Petitioner is also concurrently filing IPR Petitions for U.S. Patent Nos. 10,251,643 ("the '643 patent") and 10,028,740 ("the '740 patent"). The '643 and

‘740 patents, although not directly related to the ‘913 patent, disclose similar subject matter and claim priority in a common provisional patent application No. 60/670,231. Petitioner understands that the ‘643 and ‘740 patents are likewise commonly owned by Moskowitz.

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 ‘319 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.

Petitioner is also concurrently filing a second IPR petition for the ‘319 patent to address the Challenged Claims, but with a different primary reference than that used in this petition to address the claimed subject matter of an intervertebral expandable implant and a tool for positioning and expanding the implant. Specifically, the primary reference utilized in Sections IX. and X. is the Baynham reference. During prosecution the Baynham reference was “made of record and not relied upon,” the examiner noting however the reference “is considered pertinent to the applicant’s disclosure.” EX1002 at p. 117.

Petitioner addresses the Baynham reference in section IX.A, how the examiner used the Baynham reference in prosecution in section V.B. and how the

Baynham reference is used in this petition in sections IX. and X. The dispositive facts taken from these sections when analyzed in section V.B. in view of the factors enumerated in *Becton, Dickinson & Co.* v. *B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) ("*Becton, Dickinson*") clearly support Petitioner's conclusion that the Board should institute an *inter partes* review.

Petitioner recognizes, however, that the analysis under the *Becton, Dickinson* factors is intensely fact driven and Petitioner addresses these factors in section V.B. Consequently, there is a lack of certainty as to whether the Board will exercise its discretion to deny institution under 35 U.S.C. § 325(d). To address this uncertainty, and in the event that the Board does not agree with Petitioner's merited analysis, a second IPR petition for the '319 patent is being concurrently filed with this petition. In ranking the two IPR petitions, this petition is ranked first. To the extent that the Board declines to exercise its discretion under 35 U.S.C. § 325(d) and otherwise institutes this petition (IPR2020-01305), then Petitioner does not seek the Boards discretion to institute the second petition (IPR2020-01306). If the Board exercises its discretion to deny institution of this petition then Petitioner seeks institution of

the second petition.[1]

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

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

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.

[1] The Board should not exercise its discretion under 35 U.S.C. § 314(a) based on at least the same basis and otherwise under the factors set forth in *General Plastic Co., Ltd. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19). Petitioner addresses § 314(a) in section XI.

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 '319 patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR. Petitioner notes that service of the Summons and Complaint in the Original Litigation occurred on November 21, 2019.

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	1-4, 7-9, 11-12, 14-15, 18-21	U.S. Patent No. 5,658,335 to Allen ("Allen") (EX1031) in view of U.S. Patent Application Publication No. 2007/0270968 to Baynham et al. ("Baynham") (EX1029) in further view of U.S. Patent Application Publication No. 2006/0253201 to McLuen ("McLuen") (EX1030)	35 U.S.C. § 103(a)
2	5	U.S. Patent No. 5,658,335 to Allen ("Allen") (EX1031) in view of U.S. Patent Application Publication No. 2007/0270968 to Baynham et al. ("Baynham") (EX1029) in further view of U.S. Patent Application Publication No.	35 U.S.C. § 103(a)

Ground	Challenged Claims	Asserted Prior Art	Statutory Grounds
		2006/0253201 to McLuen ("McLuen") (EX1030) and further in view of U.S. Patent Application Publication No. 2002/0143399 to Sutcliffe ("Sutcliffe") (EX1032)	

Based on the foregoing grounds, and as supported by the declaration of Dr. Jorge Ochoa (EX1003) (detailed in Sections X and XI), Petitioner seeks a final written decision that the Challenged Claims are unpatentable as obvious under 35 U.S.C. § 103.

V. SUMMARY OF THE '319 PATENT (EX1001)

The '319 patent issued on November 19, 2019, on an application filed on February 20, 2019. The '319 patent is a continuation of U.S. Application Serial No. 15/894,471 filed February 12, 2018, which is a continuation of 13/210,157, filed August 15, 2011, now U.S. Patent No. 9,889,022 which is a continuation of U.S. Application Serial No. 13/108,982, filed on May 16, 2011, now U.S. Patent No. 9,005,293, and a continuation of U.S. Application Serial No. 13/084,543 filed on April 11, 2011, now U.S. Patent No. 8,353,913, which is a continuation of U.S. Application Serial No. 11/842,855, filed August 21, 2007, now U.S. Patent No. 7,942,903, said application No. 13/108,982 is a continuation of U.S. Application Serial No. 11/842,855 filed on August 21, 2007, now U.S. Patent No. 7,942,903,

which is a continuation-in-part of U.S. Application Serial No. 11/536,815 filed September 29, 2006 issued as U.S. Patent No. 7,846,188, which is a continuation-in-part of U.S. Application Serial No. 11/208,644 filed August 23, 2005, issued as U.S. Patent No. 7,704,279. The application claims priority to provisional application No. 60/670,231 filed April 12, 2005.[2] EX1001.

A. The '319 Patent Specification and Claims

The '319 patent is generally directed to intervertebral expandable implants and is most easily characterized for purposes of this petition by referencing FIGs. 1B and 1D.

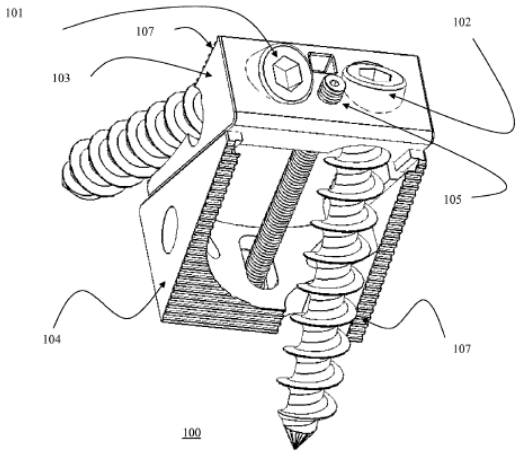

Fig. 1B

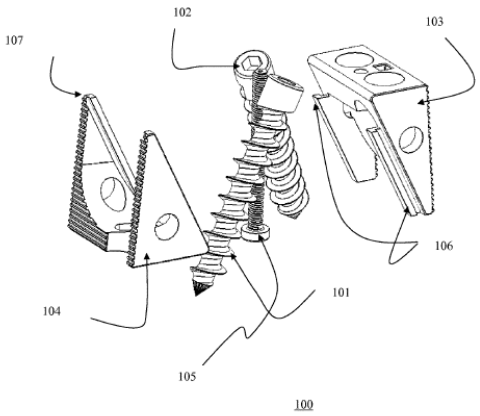

Fig. 1D

EX1001, FIGs. 1B and 1D.

[2] Patentee in the Pending Litigation de-designated the Disclosure of Infringement Contentions. In the disclosure the patentee confirms "[t]he earliest date of invention for each asserted claim of the '319 patent is July 31, 2007." EX1034 at p. 10, II. H. Petitioner relies on this admission.

In view of FIG 1B and 1D, the '319 patent states:

> The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (FIGS. 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (FIG. 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (FIG. 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

EX1001 at 7:49-61.

The '319 patent also discloses a tool for positioning and expanding an intervertebral expandable implant and is most easily characterized for purposes of this petition by referencing FIGs. 5A and C:

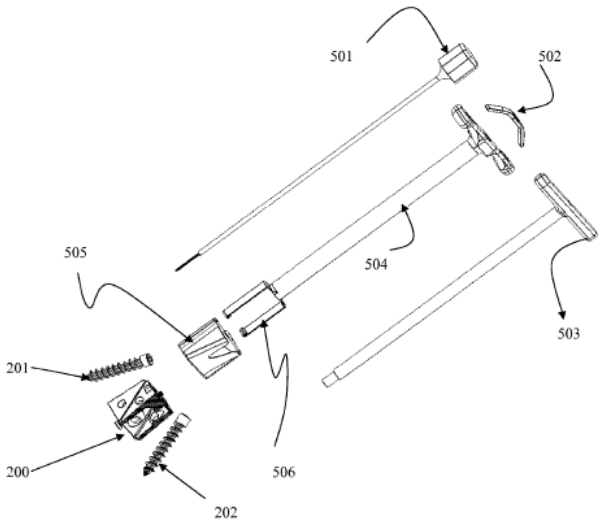

Fig. 5C

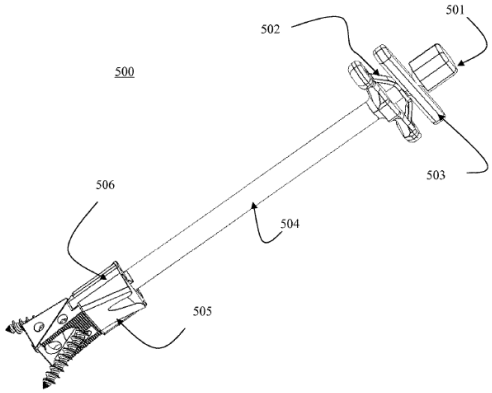

Fig. 5A

EX1001, FIGs. 5A and 5C.

In view of Fig 5A and C, the '319 patent states:

> The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (FIG. 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (FIGS. 5A-D) thus perfectly aligning them.

EX1001 at 8:62-9:3.

B. The '319 Patent Prosecution History (EX1002)

The prosecution history for the '319 patent is relevant here to the extent that the Baynham reference was of record, but not used by the Examiner during prosecution. The Examiner did note, however, that the reference was "considered pertinent to applicant's disclosure." EX1002 at 117.

Petitioner acknowledges the precedential opinion of *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,* IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential), and the factors cited in *Becton, Dickinson & Co. v. B. Braun Melsungen AG,* IPR2017-01586, Paper 8 (Dec. 15, 2017). Petitioner notes, however, that the Baynham reference, including what it discloses and how it is used in this petition versus how it was used by the examiner in prosecution, does not support the Board exercising its discretion to deny institution under 35 U.S.C. § 325(d). The facts and details are addressed in view of the prosecution history that follows.

On February 20, 2019, the applicant filed U.S. Application No. 16/280,684, that eventually issued as the '319 Patent. EX1002 at 250-279.

On March 19, 2019, the Examiner issued a Restriction Requirement noting that the claims were directed to three distinct species, one of which was identified as "…species III, claims a tool assembly." EX1002 at 206. This was further identified by the Examiner as "Figs. 5A-5C relating to claims 13-14." *Id.*

On May 6, 2019, the Applicant filed a response to the Restriction Requirement, cancelling claims 1-12, amending claims 13 and 14, and adding claims 15-32. Of note, the claims as amended were all directed to a tool for positioning and expanding an intervertebral implant, the applicant noting that "the third identified species corresponding to Figs. 5A-5C (as well as 5D-5I) and claims 13-14 (as well as new claims 15-32)" were elected for examination." EX1002 at 193-202.

On May 7, 2019, the applicant filed a Supplemental Amendment in which claims 18, 20 and 31 were amended to "correct clarity and antecedent bases" and claims 33-34 directed to a tool for positioning and expanding an intervertebral expandable implant were added. EX1002 at 175-185.

On July 16, 2019, the Examiner issued a non-statutory double-patenting rejection as to all pending claims as unpatentable over claims over 1-26 of U.S. Patent No. 10,307,268. The Examiner further noted that "the prior art made of record and not relied upon is considered to pertinent to applicant's disclosure." This

prior art included the Baynham reference. EX1002 at 115-117.

On July 16, 2019 (the same day on which the Non-Final Office Action issued), the applicant filed its response, wherein it submitted a Terminal Disclaimer, an amendment to claim 31 to amend for clarity and the addition of claim 35. EX1002 at 140-155.

On August 30, 2019, the examiner issued a Notice of Allowance (EX1002 at 84) and on the same day the applicant filed an Amendment After Allowance cancelling claims 33-34. EX1002 at 96-106.

On September 19, 2019, the applicant filed a Corrected Application with substitute drawings correcting Fig. 1A and Substitute Specification adding missing numerals. EX1002 at 10-65.

On September 25, 2019, the examiner entered the Amendment filed by the applicant on September 19, 2019. EX1002 at 5.

As noted below in sections X and XI, the prior art combination of Allen (never of record) directed to a tool and Baynham (never applied by examiner) directed to an intervertebral expandable implant, was never of record. In fact as noted above, the examiner never relied on any prior art combination to reject any claim. By definition under the *Becton, Dickinson* factors, there are significant and material differences between the prior art and arguments asserted in this petition and the prior art and arguments asserted in prosecution. Under factors (a), (b) and (d) of the

Becton, Dickinson factors, the same or substantially the same art was previously NOT presented to the Patent Office. The factors weigh heavily in favor of institution as the same or substantially the same art and arguments were not presented or relied on by the examiner during prosecution. The remaining factors are not addressed as the first factors are dispositive on subject.

VI. CLAIM CONSTRUCTION

In an IPR proceeding, 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 Petitioner submits that the following claim terms should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the Pending Litigation:[4]

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

[4] Moskowitz asserted in the Pending Litigation that all claim terms take their plain and ordinary meaning. Under the 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.

Claim Term	Globus's Construction
"first expandable spinal implant structure" / "second expandable spinal implant structure"	"a [first/second] implant structure comprising the [first/second] vertebral body engagement surface"

Petitioner, however, expressly reserves its right to argue a different claim construction in a different forum for any term in the '319 patent, as appropriate in that proceeding.

VII. THE LEVEL OF SKILL IN THE ART

As established in the Declaration of Dr. Ochoa (EX1003 at 26-30; EX1004), a person having ordinary skill in the art (PHOSITA) of the '319 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

VIII. THE PRIOR ART RELIED UPON IN THIS PETITION

A. Allen (EX1031)

Allen, entitled "Spinal Fixator," issued on August 19, 1997. Allen is prior art

to the '319 patent under 35 U.S.C. § 102(b) (Pre-AIA). Allen was not considered by the Examiner during the prosecution of the application leading to the '319 patent.

Allen discloses a tool for positioning and expanding an intervertebral expandable implant, as best characterized for purposes of this petition by FIG 12:

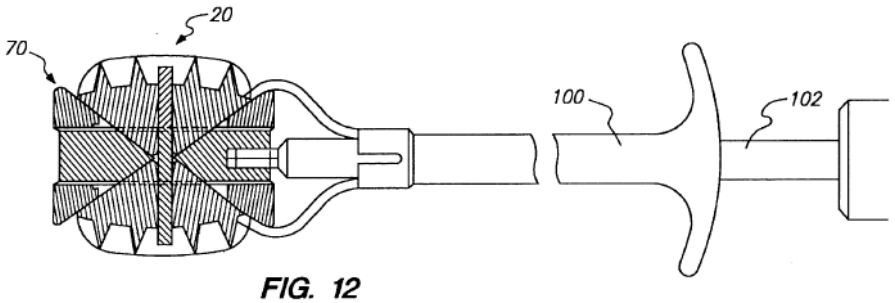


FIG. 12

EX1031, FIG. 12.

Allen discloses that:

> A conventional, hollow insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between the two vertebrae bodies 4. Following placement as in FIG. 1, a tool 102 having a terminus defining a hex configuration is inserted through the insertion tool 100 to engage in aperture 60 in the core member 50. The tool 102 is used to rotate core member 50 to extend the crowns 90 outwardly thereby forcing the teeth 98 into the vertebral body 4. As shown in FIG. 13, rotation of the core member 50 by the tool 102 causes the nut assemblies 70 to retract inside the housing. Retraction of the nut assemblies 70 forces the teeth 98 upward as the flanges 92 slide within the channels 76. As the four separate crown members 90 extend outwardly, the teeth 98 penetrate the vertebral bodies 4.

EX1031 at 5:19-31.

B. Baynham (EX1029)

Baynham, entitled "PLIF Opposing Wedge Ramp," published on November

22, 2007 and has an effective filing date of February 10, 2004. Baynham is prior art to the '319 patent under 35 U.S.C. §102(a) (Pre-AIA). Baynham discloses an intervertebral expandable implant, as best characterized for purposes of this petition by FIGS. 1 - 2:

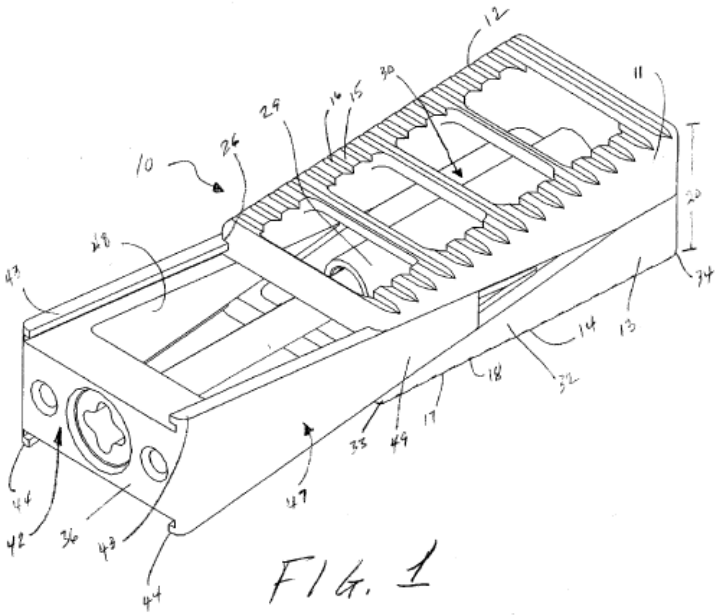


FIG. 1

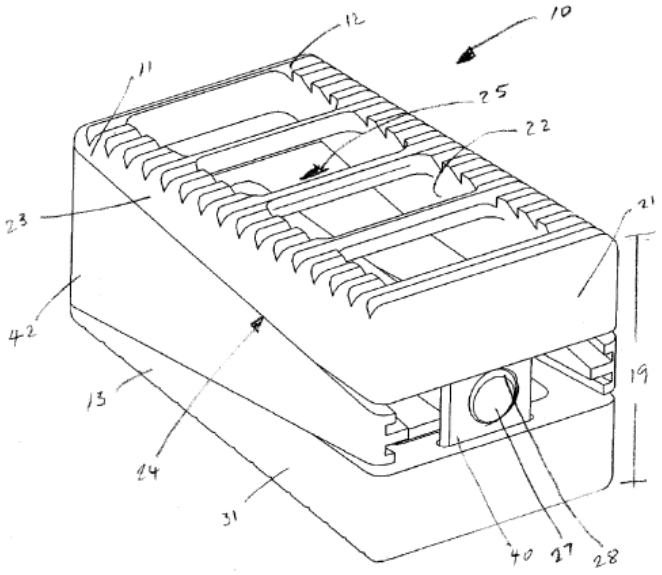


FIG. 2

EX1029, FIGs. 1 and 2.

Baynham discloses that "spinal fusion device 10 is inserted in the intervertebral space in the insertion mode, shown in FIG. 1, to replace damaged, missing or excised disk material." EX1029 at [0022].

Baynham also discloses that:

> The upper section 11 has a top surface 12 for engaging the end plate of a vertebra and the lower section 13 has a bottom surface 14 for engaging the end plate of an adjacent vertebra. The top surface 12 and the bottom surface 14 are planar to provide a large contact area with each vertebra.… As shown, the top and bottom surfaces have a series of lands and grooves 15, 16, 17 and 18 though other stippled treatment may be employed….The upper section 11 is formed with an end wall 21 a top surface 12 and depending sidewalls 22 and 23. The sidewalls terminate in an inclined plane 24 which extends from the end wall 21 to the top surface 12. The top surface 12 has a large aperture 25 therethrough to provide for bone ingrowth.

EX1029 at [0022]; [0025].

Baynham also discloses that:

> …ramp or distractor 42 is dimensioned to be inserted into the trailing end of the interior cavity between the upper section and the lower section of the spinal infusion device 10, as shown in FIG. 1. An end wall 36 is dimensioned to close the opening formed in the trailing end between the upper section 11 and the lower section 13 by the depending and upstanding sidewalls. The upper surface of the plug [distractor 42] has an inclined ramp on each side to accommodate the inclined plane 24 of the depending walls 22 and 23 of the upper section. …. The end plug 36 has a bore 61 aligned with bore 60 in link 40. The bore 61 has a larger countersunk bore 63 in the end wall 36. These bores are aligned with the threaded tube 29 attached to the link 40, as shown in FIG. 3.

EX1029 at [0028].

Baynham also discloses that:

> …jack screw 67 is inserted through bore 61 engaging the threads in the tube [29]…. The surgeon turns the jack screw 67 causing the upper and lower sections to move along the complementary inclined plane to shorten the fusion device and increase the distance between the end plates of the adjacent vertebrae.

EX1029 at [0029]; [0030].

C. McLuen (EX1030)

McLuen, entitled "Bone Fusion Device," was published on November 9, 2006 and has an effective filing date of November 3, 2004. McLuen is prior art to the '319 patent under 35 U.S.C. § 102(a) (Pre-AIA). McLuen was not considered by the Examiner during the prosecution.

McLuen discloses an intervertebral expandable implant, as best characterized for purposes of this petition by FIG 16:

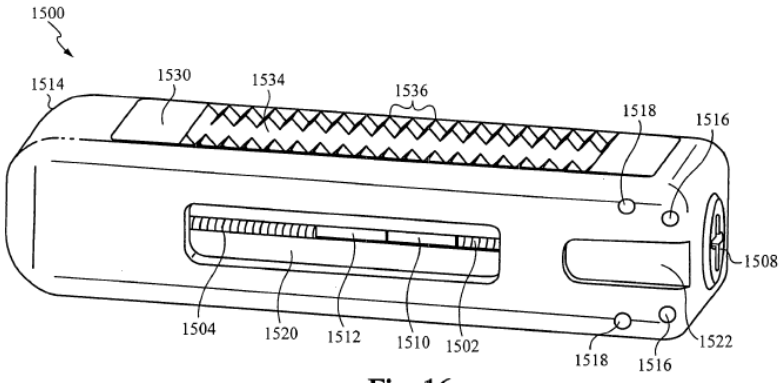


Fig. 16

EX1030, FIG. 16.

McLuen discloses that:

> To secure the bone fusion device 1500 in place, a user generally utilizes an implement such as a screw driver to turn the positioning means 1508. Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

EX1030 at [0076].

D. Sutcliffe (EX1032)

Sutcliffe, entitled "Anchorable Vertebral Implant" was published on October 3, 2002 and has an effective filing date of April 2, 2001. Sutcliffe is prior art to the '319 patent under 35 U.S.C. § 102(b) (Pre-AIA). Sutcliffe was not considered by the Examiner during the prosecution.

Sutcliffe discloses an intervertebral expandable implant as best characterized for purposes of this petition by FIGs 3 and 6:

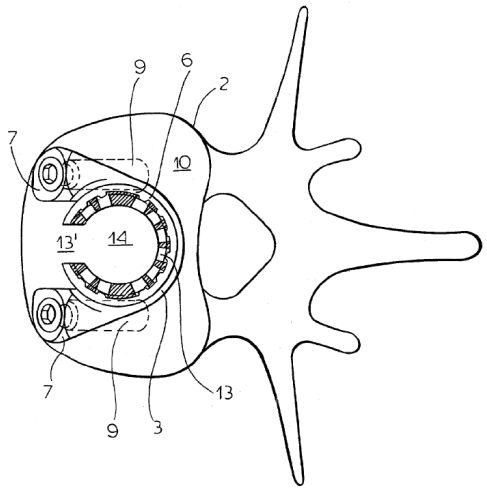


FIG.3

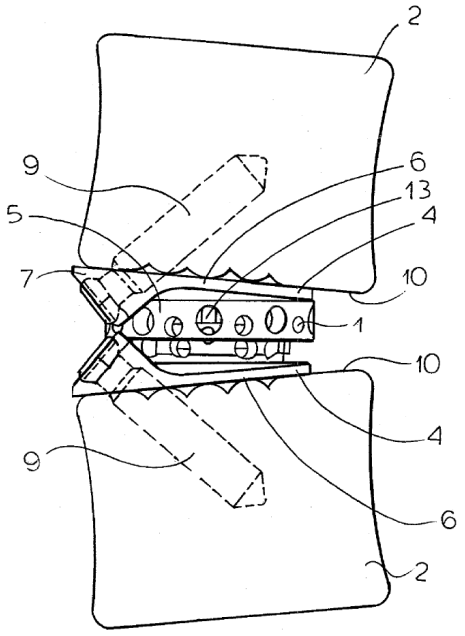


FIG.6

EX1032, FIGs. 3 and 6.

Sutcliffe discloses that:

> …lower part 3 is unitarily formed with a pair of eyes 6 having collars 7 defining holes or passages 8 with cylindrical inner surfaces 12 extending at an acute angle of between 25° and 65° to the lower vertebral surface 10, here 45°. Cortical screws 9 extend through these eyes 6 and into the lower vertebra 2 to solidly anchor the lower part 3 to the lower vertebra 2. FIG. 6 shows how a similar pair of eyes 6 can be formed on the upper end part 4 in an arrangement allowing the implant 1 to be installed through a very small surgical opening.

EX1032 at [0024].

IX. GROUND 1: ALLEN IN VIEW OF BAYNHAM AND McLUEN RENDERS CLAIMS 1-4, 7-9, 11-12, 14-15, AND 18-21 OBVIOUS

As further discussed below, the combination of prior art references meets each and every element and limitation of the Challenged Claims.

A. Independent Claim 1

[1.1] *A system comprising:*

a tool assembly which comprises:

a first tool having a first proximal end and a first distal end with a first handle and a gripper,

Allen discloses a first tool (100) having a first proximal end and a first distal end with a first handle and a gripper (first and second engagement prongs). *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 60.

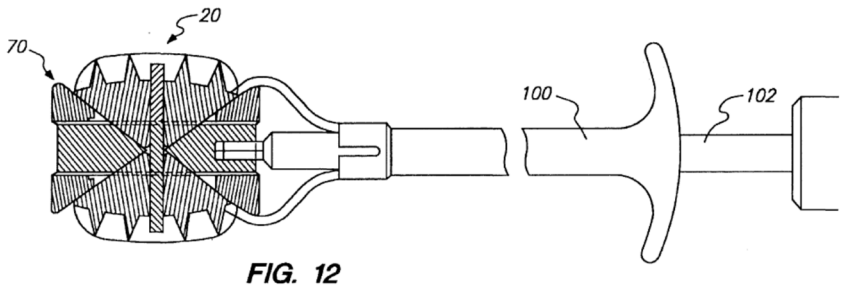


FIG. 12

[1.2] *the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end,*

Allen discloses the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 61.

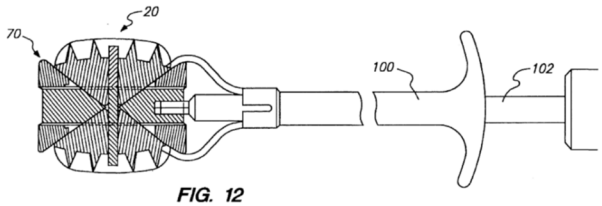


FIG. 12

[1.3] *wherein the first tool defines an adjusting tool passage through the first tool; and*

Allen discloses the hollow first tool (100) defines an adjusting tool passage through the first tool. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 62.

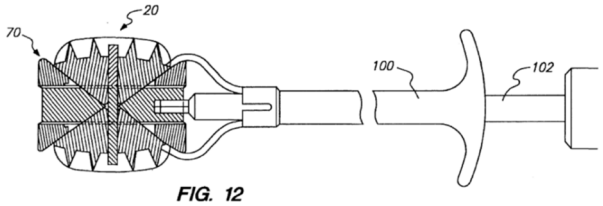


FIG. 12

[1.4] *a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end,*

Allen discloses a second adjusting tool (102) having a second proximal end and a second distal end with a second handle positioned at the second proximal end. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 63.

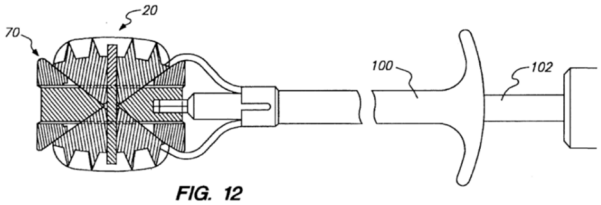


FIG. 12

Allen discloses the tool (102) is used to rotate via a second handle positioned

at the second proximal end for adjusting the screw to extend the implant outwardly. EX1031 at 5:19-47; EX1003 at ¶ 63.

[1.5] *a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion,*

Allen discloses a screw engagement portion (terminus defining a hex configuration) positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 64.

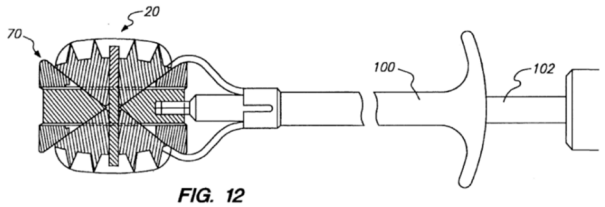


FIG. 12

[1.6] *wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and*

Allen discloses the shaft of the second adjusting tool (102) is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool (102) can extend through the adjusting tool passage of the first tool (100). *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 65.

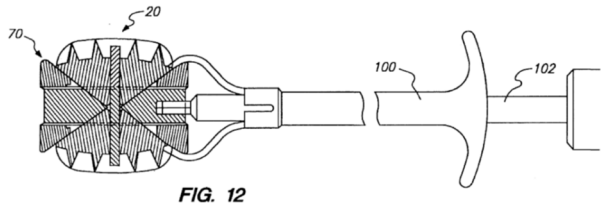


FIG. 12

[1.7] *an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion,*

Allen discloses an expandable implant. *See e.g.,* EX1031 at 5:5-47; FIG. 12; EX1003 at ¶ 66. A PHOSITA would have understood that the tool assembly disclosed in Allen is configured to interface with any number of expandable spinal implants. A PHOSITA would have further understood the tool assembly in Allen is of a typical design for engaging spinal implants and that the tool assembly in Allen could be combined/used with the expandable spinal implant in Baynham or in McLuen. EX1003 at ¶ 66.

Baynham discloses an intervertebral expandable implant (10) sized and configured to be implanted in a human spine, the expandable spinal implant (10) having a first expandable spinal implant structure (11), a second expandable spinal implant structure (42 and 13), and an adjusting screw (67) having a screw head and a threaded portion. *See, e.g.,* EX1029 at [0010]; [0025]; [0026]; [0029]; [0030]; FIGs. 1-3; EX1003 at ¶ 67.

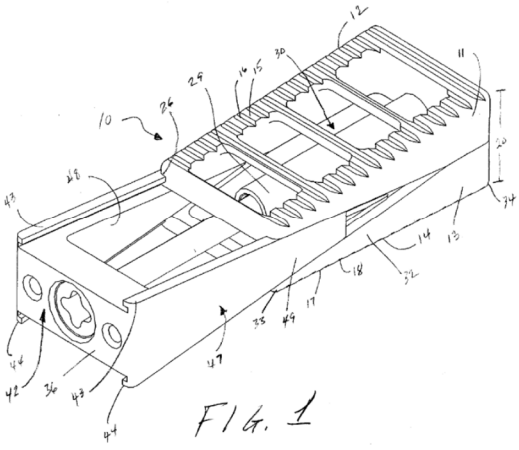


FIG. 1

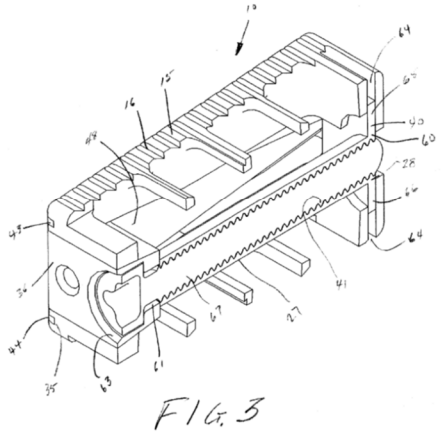


FIG. 3

Baynham discloses the spinal fusion device (10) is inserted in the intervertebral space in the insertion mode, shown in FIG. 1, to replace damaged, missing or excised disk material. This extended position allows the leading end of the implant to be inserted in a small intervertebral space without the necessity of excising structurally sound bone. The upper section (11) has a top surface (12) for engaging the end plate of a vertebra and the lower section (13) has a bottom surface (14) for engaging the end plate of an adjacent vertebra. The top surface (12) and the bottom surface (14) are planar to provide a large contact area with each vertebra. Each contact surface has a roughened finish to provide better purchase on the end plates of the vertebrae. EX1029 at [0022]; EX1003 at ¶ 67.

[1.8] *wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,*

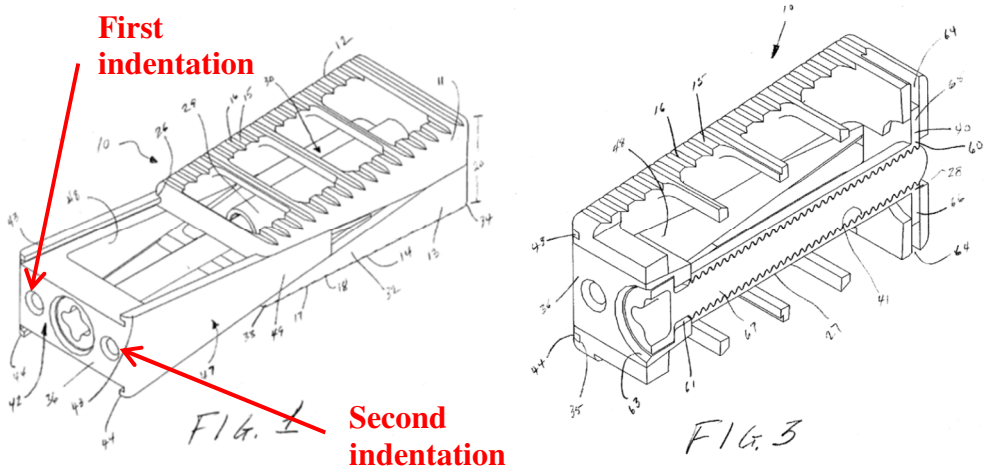
Baynham discloses the expandable spinal implant (10) is configured to

expand the first expandable spinal implant structure (11) with respect to the second expandable spinal implant structure (42 and 13) in response to turning of the adjusting screw (67). *See, e.g.,* EX1029 at [0028]-[0030]; FIG. 2; EX1003 at ¶ 68.

Baynham discloses the spinal fusion device is inserted in the disk space between adjacent vertebrae in the extended position with the top surface in contact with the end plate of one vertebra and the bottom surface in contact with the end plate of an adjacent vertebra. The surgeon turns the jack screw (67) causing the upper and lower sections to move along the complementary inclined plane to shorten the fusion device and increase the distance between the end plates of the adjacent vertebrae. The adjustment may continue until the optimum distance between vertebrae has been reached. EX1029 at [0030]; EX1003 at ¶ 68.

[1.9] *wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool,*

Baynham discloses the implant defines first and second indentations on the end wall (36) on either side of the countersink (63). *See, e.g.,* EX1029 at [0028]; FIGs. 1 and 3; EX1003 at ¶ 69.



While the function of the first and second tool engagement indentations is not expressly disclosed in Baynham, a PHOSITA would have understood that these indentations could function as tool engagement indentations. EX1003 at ¶ 69.

A PHOSITA would have understood that the inserter disclosed by Allen could be used to insert and expand the implant disclosed by Baynham. To the extent that the tool disclosed by Allen functions by interfacing with the outside surfaces of the implant, a PHOSITA would have understood that the implant could be modified as a matter of simple substitution to move the indentations from the end (36) to opposing side surfaces of the implant so that the first and second tool engagement indentations would be positioned at the proximal end of the implant. Stated another way, placement and positioning of indentations for insertion tool engagement at the proximal or trailing end of the implant is a predictable substitution that does not affect its function. EX1003 at ¶¶ 70.

McLuen discloses an expandable intervertebral implant (e.g. 1500). EX1030

at [0077]; FIG. 16; EX1003 at ¶ 71.

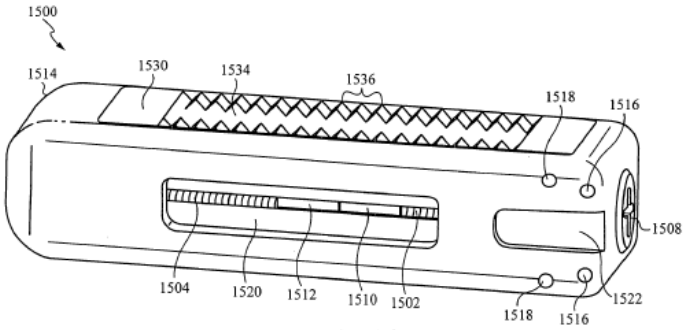


Fig. 16

A positioning screw (1508) is located proximate to a proximate end of implant (1500). EX1030 at [0076]; [0077]; FIG. 16. McLuen discloses that to secure the implant (1500), a user would generally use a tool such as a screwdriver to turn screw (1508). McLuen also discloses that screwdrivers may slip out of place when performing surgery. Because of the proximity to the patient's spine it is preferable to prevent or at least minimize slipping. EX1030 at [0076]. To achieve this, McLuen discloses channels or indentations (1522) on opposing sides of the implant to receive a tool. EX1030 at [0076]; FIG. 16; EX1003 at ¶ 71.

It would therefore have been obvious to a PHOSITA to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to opposing sides at the proximal end of the implant to provide the disclosed advantage of prevention or minimization of screw driver slippage. This substitution would represent a design choice which would yield a predictable result

with a reasonable expectation of success. EX1003 at ¶¶ 72.

[1.10] *wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.*

Baynham discloses an adjusting screw (67) positioned in the adjusting screw hole (61). *See, e.g.,* EX1029 at [0028]; [0029]; FIGs 1-3; EX1003 at ¶ 73.

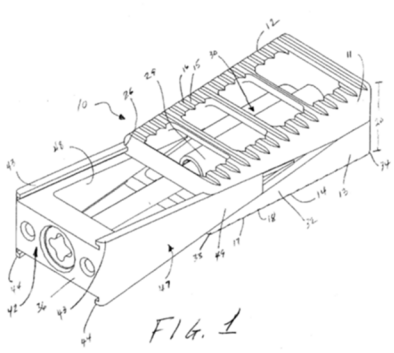


FIG. 1

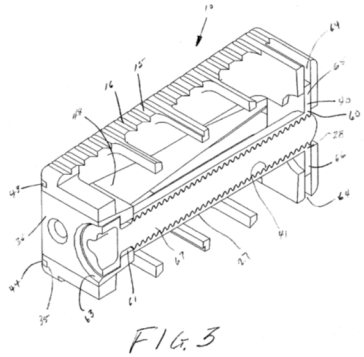


FIG. 3

Allen discloses a hollow first tool (100) having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and an adjusting tool passage extending through the first tool from the first proximal end to the first distal end. A tool (102) can be inserted through the insertion tool (100). EX1031 at 5:5-28; FIG 12; EX1003 at ¶ 74.

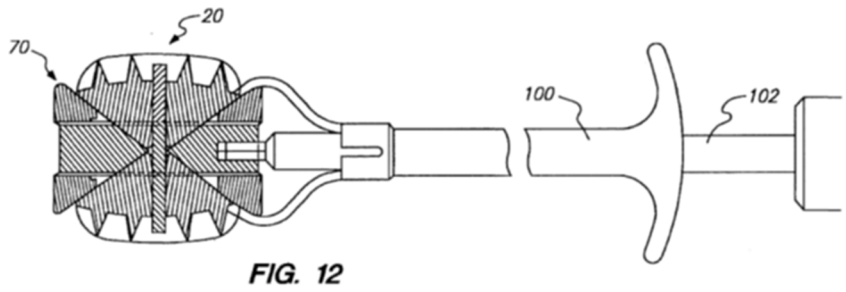


FIG. 12

A PHOSITA would have understood that the first and second engagement prongs of the insertion tool (100) are sized and positioned to extend into the first and second tool engagement indentations of a structure (such as the second expandable spinal implant structure (42 and 13) of Baynham) to allow the first tool to engage the expandable spinal implant. EX1003 at ¶ 74.

Allen discloses the second adjusting tool (102) can extend through the adjusting tool passage of the first tool (100) to engage the screw head of the adjusting screw (67) while the first and second engagement prongs of the first tool (100) are engaged with the first and second tool engagement indentations of the expandable spinal implant. EX1031 at 5:19-28. Allen discloses that following placement of the implant, the tool (102) having a terminus defining a hex configuration is inserted through the hollow insertion tool (100) to engage an adjusting screw. EX1031 at 5:19-28; EX1003 at ¶ 75.

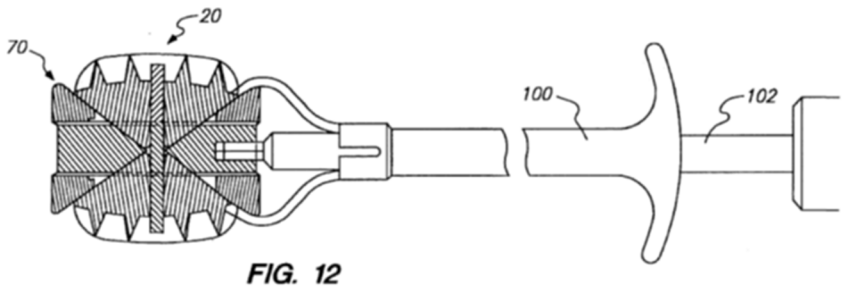


FIG. 12

A PHOSITA would have known and understood that orthopedic surgical instruments with cannulated handle bodies, through which instruments and devices could be delivered from the proximal (at the surgeon's hands) to the distal (implantation location) intrasurgical sites, were in common use at the time. Similar devices were also used in arthroscopic and endoscopic surgery. EX1003 at ¶ 76.

It would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable spinal implant into the disk space between adjacent vertebrae. Then, using the second adjusting tool of Allen to pass through a cannula in a first tool to turn the adjusting screw to expand the implant of Baynham. EX1003 at ¶¶ 76.

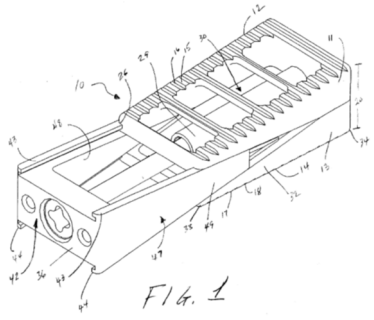
2. *The system of claim 1,*

   wherein the screw engagement portion of the second adjusting tool comprises a key for engaging the head of the adjusting screw to turn the adjusting screw and controlling height of the expandable spinal implant.

As discussed above with respect to claim 1, it would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable spinal implant into the disc space between adjacent vertebrae and to use the second adjusting tool of Allen to pass through a cannula in a first tool to turn the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 77.

Allen discloses the screw engagement portion of the second adjusting tool (102) comprises a key (i.e. terminus with hex configuration) for engaging the head of an adjusting screw to turn the adjusting screw and control the height of the expandable spinal implant (10). EX1031 at 5:5-47; FIG. 12; EX1003 at ¶ 78.

Baynham discloses a jack screw (67) is inserted through bore (61) engaging the threads in the tube (27). EX1029 at [0029]; EX1003 at ¶ 79.



Baynham discloses the surgeon turns the jack screw (67) causing the upper and lower sections to move along the complementary inclined plane to shorten the

fusion device and increase the distance between the end plates of the adjacent vertebrae. The adjustment may continue until the optimum distance between vertebrae has been reached. EX1029 at [0030]; EX1003 at ¶ 79.

3. *The system of claim 1,*

wherein the expandable spinal implant defines a longitudinal axis,

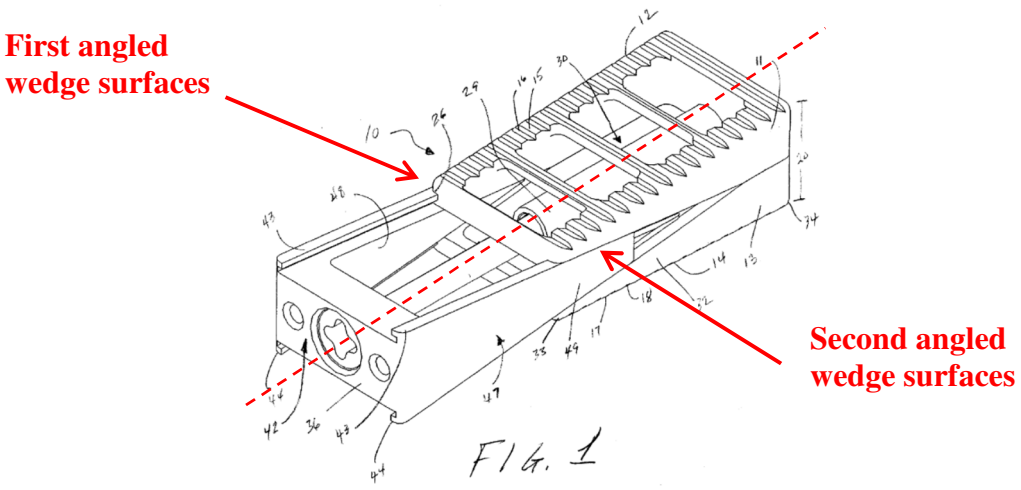
wherein the first and second expandable spinal implant structures have first and second angled wedge surfaces that engage one another,

wherein the adjusting screw is connected to the second expandable spinal implant structure so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant.

As discussed above with respect to claim 1, it would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable spinal implant into the disk space between adjacent vertebrae and to use the second adjusting tool of Allen to pass through a cannula in a first tool to turn the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 80.

Baynham discloses the expandable spinal implant defines a longitudinal axis (labeled below). The implant is inserted in an "extended thin mode" between

adjacent vertebrae and the ramp is inserted between the sections through one end. *See, e.g.,* EX1029 at [0010]; FIG. 1; EX1003 at ¶ 81.



Baynham discloses the first and second expandable spinal implant structures (11 and 42/13) have first (24) and second angled wedge surfaces (labeled above) that engage one another, wherein the adjusting screw (67) is connected to the second expandable spinal implant structure (42 and 13) so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant. *See, e.g.,* EX1029 at [0010]; [0025]-[0027]; [0030]; FIG. 1-2; EX1003 at ¶ 81.

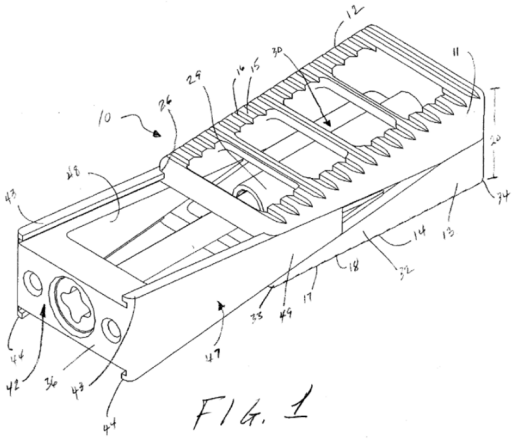


FIG. 1

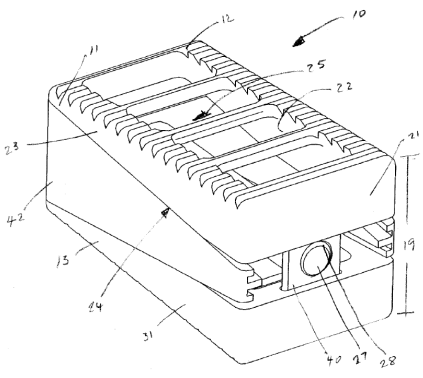


FIG. 2

4. The system of claim 1,

wherein the first expandable spinal implant structure defines a first angled wedge portion that comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail,

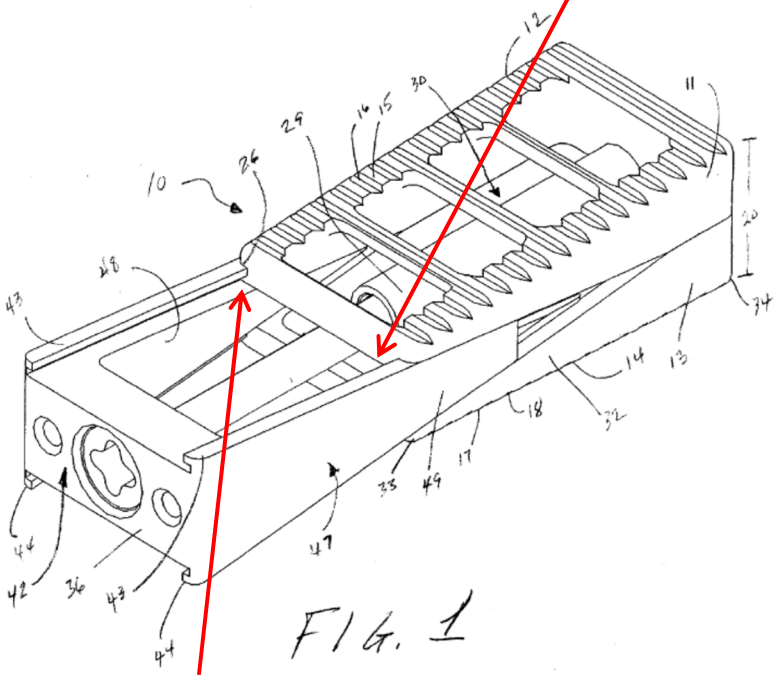
wherein the second expandable spinal implant structure defines a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail,

wherein the first expandable spinal implant structure is slidably-engaged with the second expandable spinal implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first expandable spinal implant structure positioned in the first outwardly-facing slot of the second expandable spinal implant structure, the second inwardly-facing rail of the first expandable spinal implant structure positioned in the second outwardly facing slot of the second expandable spinal implant structure, the first outwardly-facing rail of the second expandable spinal implant structure positioned in the first inwardly-

facing slot of the first expandable spinal implant structure, and the second outwardly-facing rail of the second expandable spinal implant structure positioned in the second inwardly-facing slot of the first expandable spinal implant structure.

As discussed above with respect to claim 1, Baynham discloses a first expandable spinal implant structure (11) defining a first angled wedge portion (24) having first and second rails (labeled below) and has a corresponding first slot (26) located adjacent to the first rail (labeled below) and a second slot (26) located adjacent the second rail (labeled below). *See, e.g.*, EX1029 at [0010]; [0025]; FIGs. 1-2; EX1003 at ¶ 83.

Second rail of first implant structure



First rail of the first implant structure

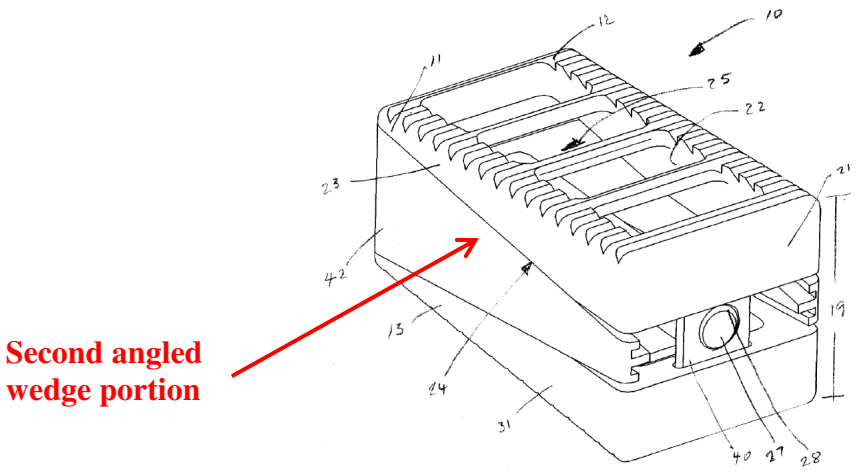
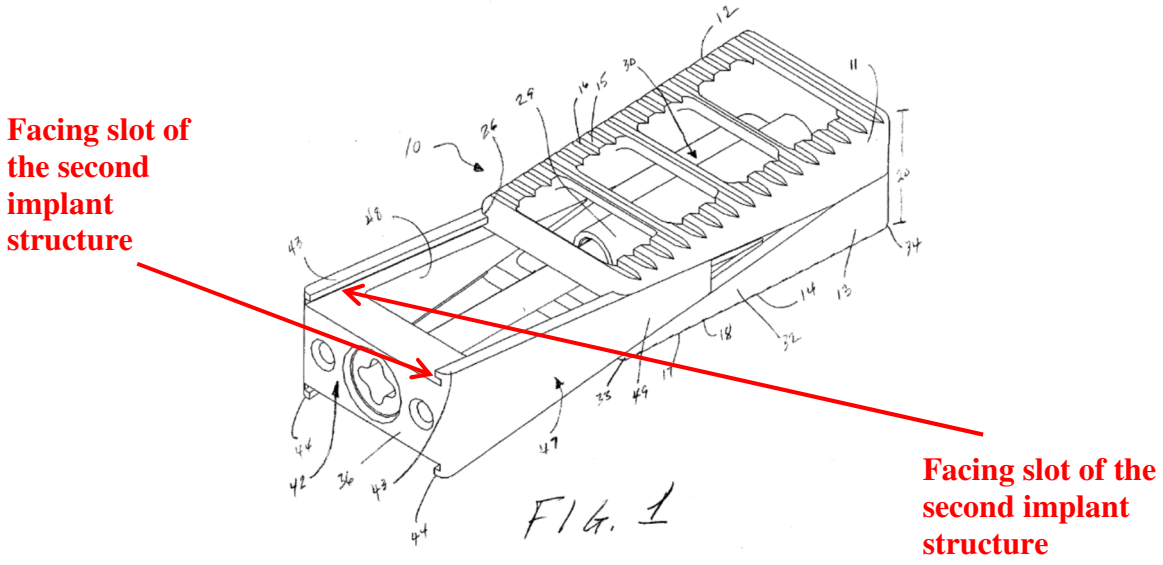


FIG. 2

Baynham discloses a second expandable spinal implant structure (42 and 13) defining a second angled wedge portion (labeled above) that has first and second rails (43) that face in a direction opposite to each other and a first slot (labeled below) defined at a location adjacent the first rail (43) and a second slot (labeled below) defined at a location adjacent the second rail (43). *See, e.g.,* EX1029 at [0010]; [0025]; [0026]; FIGs. 1-2; EX1003 at ¶ 84.



Baynham discloses that the first and second slots (26) of the first expandable spinal implant structure (11) engage complimentary first and second rails of a second expandable spinal implant structure (42 and 13) to guide movement of the first expandable spinal implant structure (11) relative to the second expandable spinal implant structure (42 and 13) to maintain the first and second implant structure in alignment. *See, e.g.,* EX1029 at [0010]; [0025]; [0026]; FIGs. 1-2; EX1003 at ¶ 83.

Baynham discloses that first expandable spinal implant structure (11) is slidably-engaged with the second expandable spinal implant structure (42 and 13) such that the first angled wedge portion (24) of the first expandable spinal implant structure (11) engages the second angled wedge portion (labeled above) of the second expandable spinal implant structure (42 and 13). *See, e.g.,* EX1029 at [0010]; [0025]; [0027]; FIGs. 1-2; EX1003 at ¶¶ 83-84.

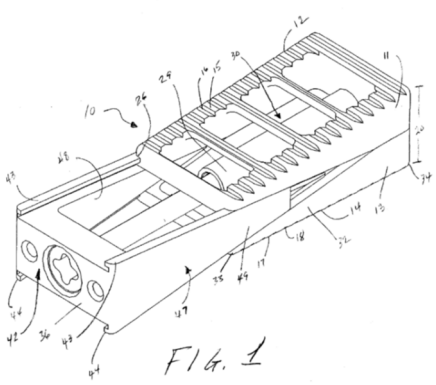


FIG. 1

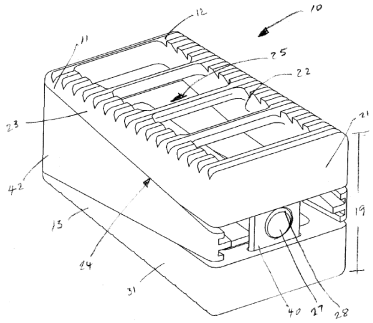


FIG. 2

A PHOSITA would have understood that the relative movement of the first and second expandable spinal implant structures along an inclined plane of the angled wedge portion is not mandated by the facing direction of the first and second rails and slots of the first expandable spinal implant structure or the second expandable spinal implant structure. A PHOSITA would have understood that modifying the implant disclosed by Baynham to provide a first implant structure with inwardly-facing rails and inwardly-facing slots is a simple and predictable substitution that would involve nothing more than an obvious design choice that would yield the identical function of providing guidance during movement of the contacting surfaces of the inclined planes of the first and second expandable spinal implant structures. This predicable substitution is equally as applicable to the second implant structure as it is to the first expandable spinal implant structure and when the modification is made to the first implant structure it also drives the modification to the second expandable spinal implant structure. Therefore, to the extent that Baynham does not disclose a first expandable spinal implant structure that has first

and second inwardly-facing rails and slots and second expandable spinal implant structure that has first and second outwardly-facing rails and slots, it would have been obvious to a PHOSITA to reverse the facing direction (inward versus outward and outward versus inward) of the rails and corresponding slots. EX1003 at ¶ 85.

> 7. *A method of using the system of claim 1, the method comprising: connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;*
>
> *implanting the expandable spinal implant into a disc space in the human spine via the first tool;*
>
> *extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and*
>
> *expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.*

As discussed above with respect to claim 1, it would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable spinal implant into the disk space between adjacent vertebrae. Then, using the second adjusting tool of Allen to pass through a cannula in the first tool to turn the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 86.

8. *The system of claim 1,*

and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

Baynham discloses it is an objective of the invention to teach an implant facilitating interbody fusion through bone graft or an ingrowth-type implant. EX1029 at [0014]. Baynham discloses the top surface (12) has a large aperture (25) therethrough to provide for bone ingrowth. EX1029 at [0025]. A PHOSITA would have understood that aperture (25) could also be used for the placement of bone graft material. A PHOSITA would have also understood that one would also place bone graft material outside the expandable spinal implant. EX1003 at ¶ 87.

[9.1] *A system comprising:*

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end,

Allen discloses a tool assembly including a hollow first tool (100) having a first proximal end (labeled below), a first distal end (labeled below), and a first elongate body between the first proximal end and the first distal end. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 88.

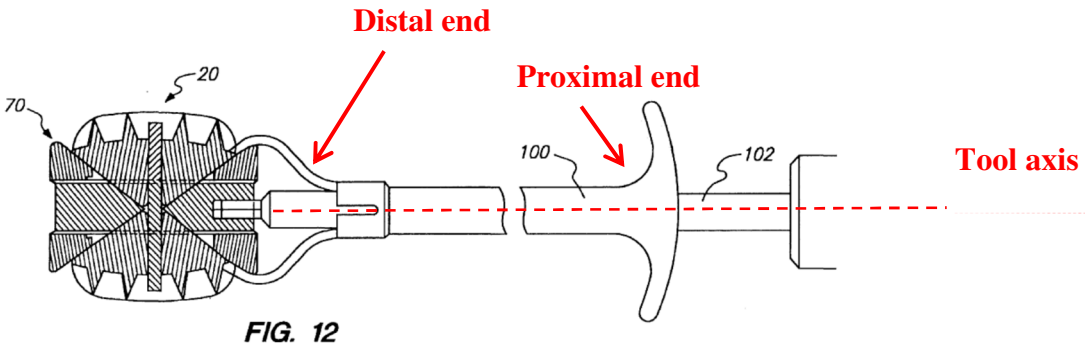


FIG. 12

[9.2] *wherein the first tool defines a first tool axis from the first proximal end to the first distal end,*

Allen discloses a first tool (100) defining a first tool axis (labeled above) from the first proximal end to the first distal end. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 89.

[9.3] *wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis,*

Allen discloses the hollow first tool (100) includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis. *See e.g.,* EX1031 at 5:19-28; Fig 12; EX1003 at ¶ 89.

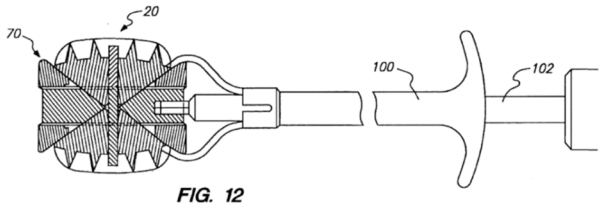


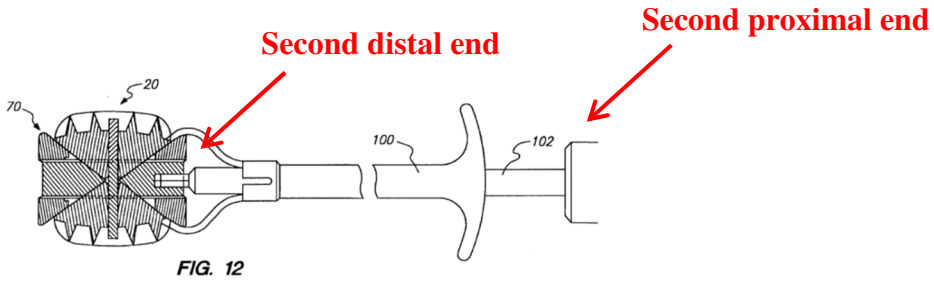
FIG. 12

[9.4] *wherein the first tool defines an adjusting tool passage through the first tool; and*

As discussed above with respect to claim [1.3], Baynham discloses all of these claim elements. EX1003 at ¶ 90.

[9.5] *a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion,*

Allen discloses a second adjusting tool (102) having a second proximal end (labeled below) and a second distal end (labeled below) with a second handle positioned at the second proximal end and a screw engagement portion (a terminus defining a hex configuration) positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion. *See e.g.*, EX1031 at 5:19-28; FIG 12; EX1003 at ¶ 91.



[9.6] *wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and*

As discussed above with respect to claim [1.6], Baynham discloses all of these claim elements. EX1003 at ¶ 92.

> [9.7] *an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw head and a threaded shaft,*

Allen discloses an expandable implant. *See e.g.,* EX1031 at 5:5-47; FIG 12. A PHOSITA would have understood that the tool assembly disclosed in Allen is configured to interface with any number of expandable spinal implants. A PHOSITA would have further understood that the tool assembly in Allen is of a typical design for engaging spinal implants and that the tool assembly in Allen could be combined/used with the expandable spinal implant in Allen or in Baynham. EX1003 at ¶ 93.

Baynham discloses an expandable spinal implant (10) sized and configured to be implanted in a human spine, the expandable spinal implant (10) having a first expandable spinal implant structure (11) defining a first vertebral body engagement surface (12), a second expandable spinal implant structure (42 and 13) defining a second vertebral body engagement surface (14), and an adjusting screw (67) having a screw head and a threaded shaft. *See, e.g.,* EX1029 at [0010]; [0025]; [0026];

[0030]; FIG 1-3; EX1003 at ¶ 94.

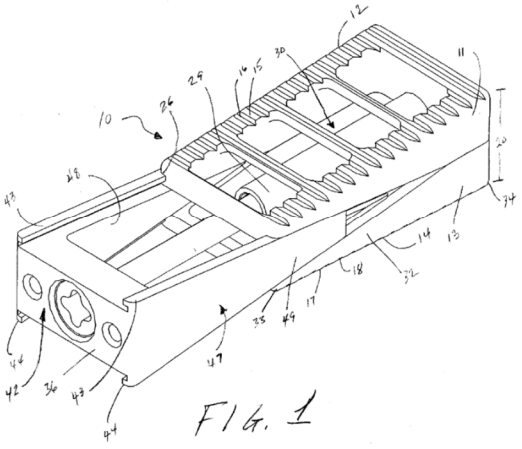


FIG. 1

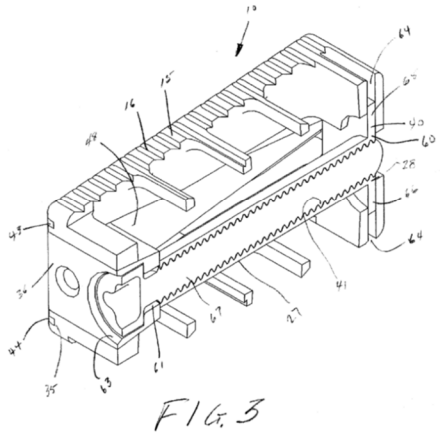


FIG. 3

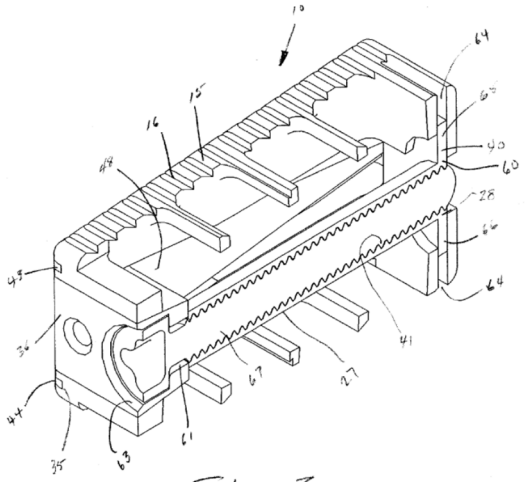


FIG. 3

Baynham discloses the spinal fusion device (10) is inserted in the intervertebral space in the insertion mode, shown in FIG. 1, to replace damaged, missing or excised disk material. This extended position allows the leading end of the implant to be inserted in a small intervertebral space without the necessity of excising structurally sound bone. The upper section (11) has a top surface (12) for engaging the end plate of a vertebra and the lower section (13) has a bottom surface

(14) for engaging the end plate of an adjacent vertebra. EX1029 at [0022]; EX1003 at ¶ 95.

> [9.8] *wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,*

As discussed above with respect to claim [1.8], Baynham discloses all of these claim elements. EX1003 at ¶ 96.

> [9.9] *wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool,*

As discussed above with respect to claim [1.9], Baynham discloses all of these claim elements. EX1003 at ¶ 97.

> [9.10] *wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.*

As discussed above with respect to claim [1.10], Baynham in combination with McLuen discloses all of these claim elements. EX1003 at ¶ 97.

11. The system of claim 9,

> *wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjustment screw by*

the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.

Baynham discloses the first and second expandable spinal implant structures (11 and 42/13) have first and second angled wedge surfaces that engage one another, wherein the adjusting screw (67) is connected to the second expandable spinal implant structure (42 and 13) so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant. *See, e.g.,* EX1029 at [0010]; [0025]-[0027]; [0030]; FIG. 1-2; EX1003 at ¶ 98.

It would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable spinal implant into the disk space between adjacent vertebrae and to use the second adjusting tool of Allen turn the adjusting screw to drive relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the implant of Baynham. EX1003 at ¶ 99.

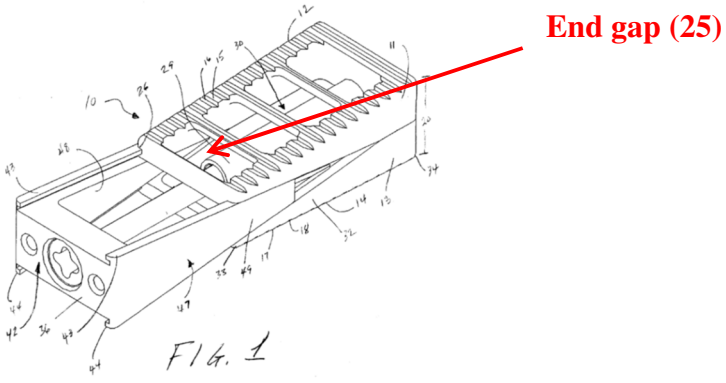
12. The system of claim 9,

wherein the first expandable spinal implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface,

wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface,

wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap.

Baynham discloses the first expandable spinal implant structure (11) has first and second opposing side surfaces (22 and 23) positioned on opposite sides of the first vertebral body engagement surface (12), and an end gap (25) between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface. *See, e.g.,* EX1029 at [0025]; FIGs 1-2; EX1003 at ¶ 100.



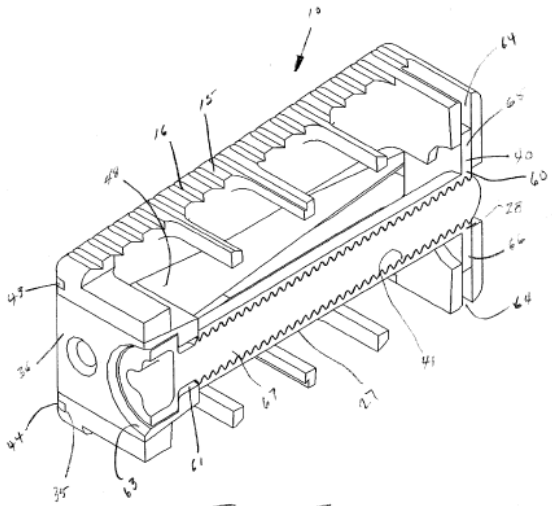


FIG. 3

Baynham discloses the first vertebral body engagement surface (12) has a plurality of ridges (15 and 16) extending from the first vertebral body engagement surface (12), at least some of the ridges being positioned on the first vertebral body engagement surface on opposite sides of the end gap (25). *See, e.g.,* EX1029 at [0022]; [0025]; FIGs. 1 and 2; EX1003 at ¶ 100.

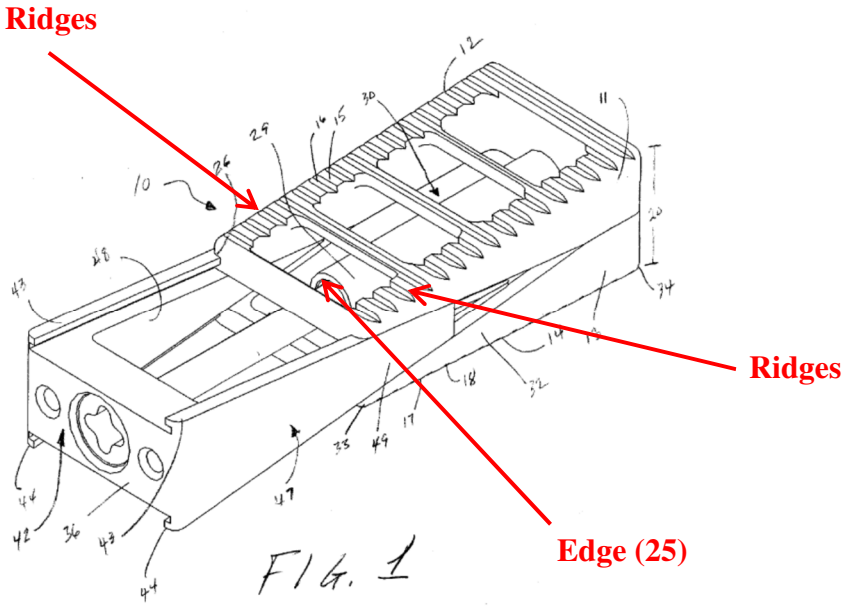


FIG. 1

14. The system of claim 9,

> *wherein a distal end of the adjusting screw has a distal diameter, wherein the head of the adjusting screw has a head diameter, and wherein the distal diameter is larger than the head diameter.*

Baynham discloses an adjusting screw wherein the head of the adjusting screw has a head diameter. The adjusting screw is coupled through threaded engagement to tube (29) and to a distal flange (65, 66) with a distal diameter of a size and shape to slide within the vertical slot 64. EX1029 at [0028]-[0029]; FIG.3; EX1003 at ¶ 101.

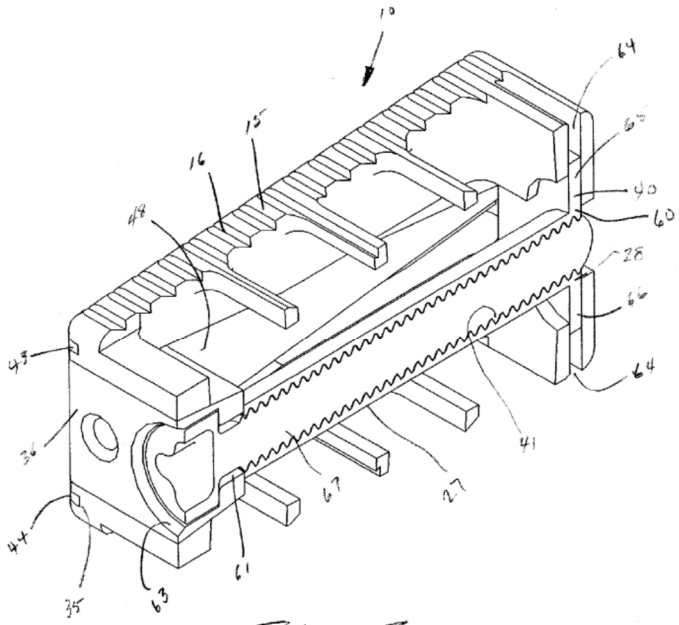


FIG. 3

The leading ends of the upper and lower sections are formed with a vertical slot 64. Link 40 includes an upper flange 65 and a lower flange 66 of *a size and shape to slide within the vertical slot* 64 as the distractor 42 moves into the central

cavity foreshortening the implant and increasing the distance between the leading ends of the sections. The threaded tube 29 surrounds the bore 60 and extends toward the bore 61. A jack screw 67 is inserted through bore 61 engaging the threads in the tube 27. As the jack screw 67 is tightened, the ramp is drawn toward the leading end of the implant and the leading ends of the upper and lower sections slide apart along flanges 65 and 66. EX1029 at [0029]; EX1003 at ¶ 101.

A PHOSITA would have understood that the thread relationship disclosed by Baynham could be reversed to move the female threads from the link and tube (40, 27) to the bore (61) in end wall (36). In this configuration, the jackscrew (67) would be fed through the resulting unthreaded tube (27) into the resulting threaded bore (61) and an enlarged distal diameter would be used to capture the screw on the link 40. This simple substitution would yield predictable results and would be obvious to try with a reasonable expectation of success. EX1003 at ¶ 102.

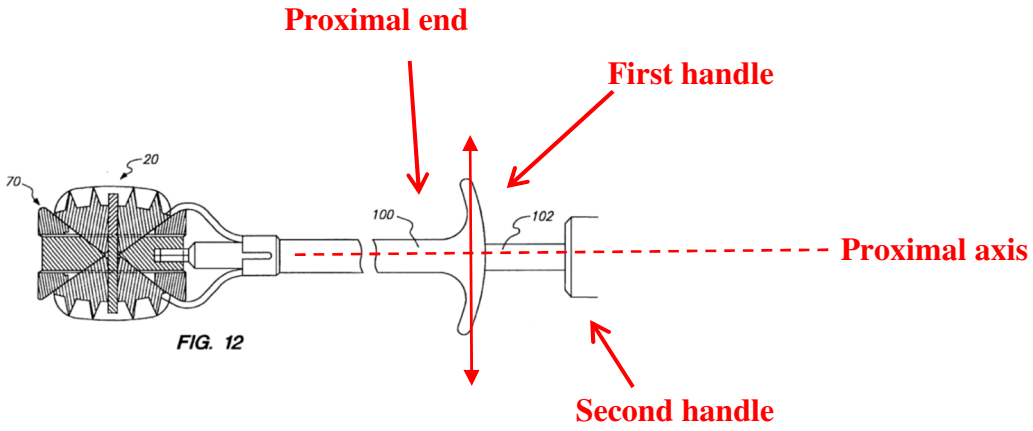
15. The system of claim 9,

wherein the first tool comprises a first handle positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis,

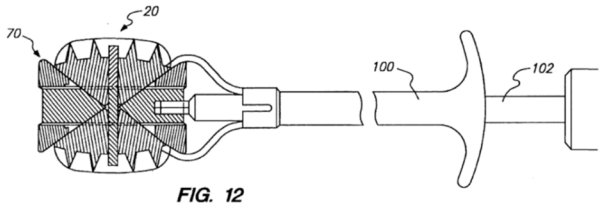
wherein the second handle of the second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage.

Allen discloses a first tool (100) having a first handle (labeled below)

positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis. EX1031 at 5:19-28; EX1003 at ¶ 103.



Allen discloses the tool (102) is inserted through the hollow insertion tool (100) to engage an adjusting screw. The second handle (labeled above) of the second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage. EX1031 at 5:19-28; EX1003 at ¶ 103.



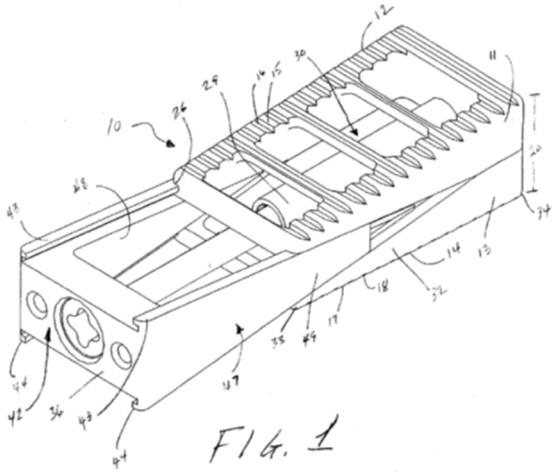
18. The system of claim 9,

> *wherein the first tool indentation extends into a first side of the expandable spinal implant with a first substantially rectangular shape as viewed from a direction perpendicular to the first side and the*

second tool indentation extends into a second side of the expandable spinal implant with a second substantially rectangular shape as viewed from a direction perpendicular to the second side.

As discussed above with respect to claims 1 and 9, A PHOSITA would have understood that Baynham discloses that the second implant structure (42 and 13) define first and second indentations on the end wall (36) on either side of the countersink (63). *See, e.g.,* EX1029 at [0028]; FIG 1 and 3. While the function of the first and second tool engagement indentations is not expressly disclosed in Baynham, a PHOSITA would have understood that these indentations could function as tool engagement indentations. EX1003 at ¶ 104.

To the extent that Baynham does not disclose substantially rectangular shaped indentations, it would have been obvious to PHOSITA as a design choice and a matter of simple substitution to modify the disclosed implant to move the indentations from the end (36) to the first and second side of the expandable spinal implant. *Id.*



McLuen discloses an expandable spinal implant (e.g. 1500). EX1030 at [0077]; FIG. 16; EX1003 at ¶ 105.

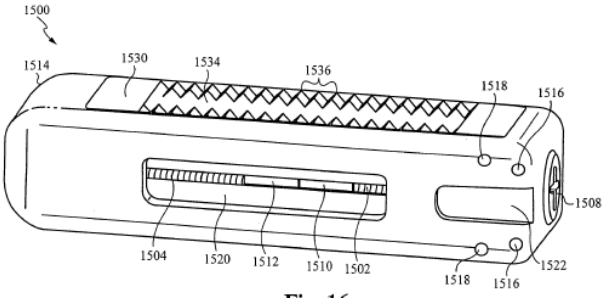


Fig. 16

A positioning screw (1508) is located proximate to a proximate end of implant (1500). EX1030 at [0076]; [0077]; FIG. 16. McLuen discloses to secure the implant (1500), a user would generally use a tool such as a screwdriver to turn screw (1508). McLuen also discloses that screwdrivers may slip out of place when performing surgery. Because of the proximity to the patient's spine, it is preferable to prevent or at least minimize slipping. EX1030 at [0076]. To achieve this, McLuen discloses channels or indentations (1522) that are substantially rectangular in shape on opposing sides of the implant to receive a tool. EX1030 at [0076]; FIG. 16; EX1003 at ¶ 105.

It would therefore have been obvious to a PHOSITA to combine the teachings of Baynham with McLuen to substitute the indentations that are disclosed in Baynham for the substantially rectangular shaped indentations as disclosed in McLuen, moving the indentations from either side of the countersink (63) to

opposing first and second sides of the expandable spinal implant to provide the disclosed advantages of prevention or minimization of screw driver slippage. This substitution would represent a design choice which would yield a predictable result with a reasonable expectation of success. EX1003 at ¶ 106.

19. A method of using the system of claim 9, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the expandable spinal implant into a disc space in the human spine via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and

expanding the expandable spinal implant by turning the second adjusting tool to turn the adjusting screw of the expandable spinal implant.

As discussed above with respect to claims 7 and 9, it would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable spinal implant into the disk space between adjacent vertebrae. Then, using the second adjusting tool of Allen to pass through a cannula in a first tool to turn the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 109.

[20.1] *A system comprising:*

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end,

wherein the first tool defines a first tool axis from the first proximal end to the first distal end,

Allen discloses a first tool (100) having a first proximal end (labeled below), a first distal end (labeled below), and a first elongate body between the first proximal end and the first distal end, the first tool defining a first tool axis (labeled below) from the first proximal end to the first distal end. *See e.g.,* EX1031 at 5:19-28; FIG 12; EX1003 at ¶ 108.

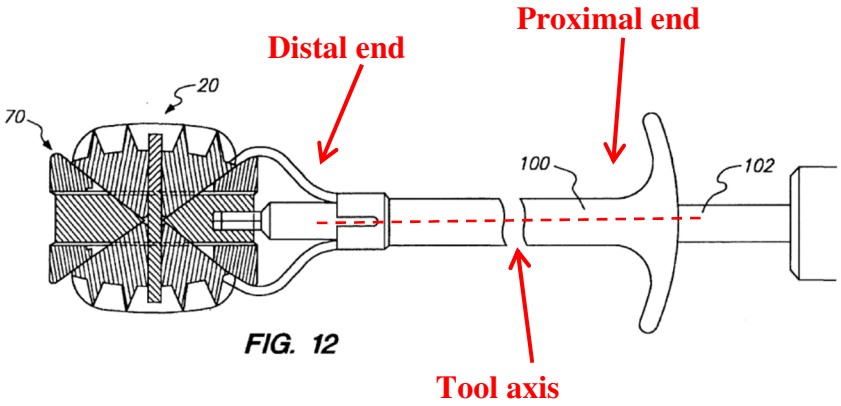


FIG. 12

[20.2] *wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis,*

wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion,

wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

Allen discloses a first hollow tool (100) defining as adjusting tool passage and having a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis. EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 109.

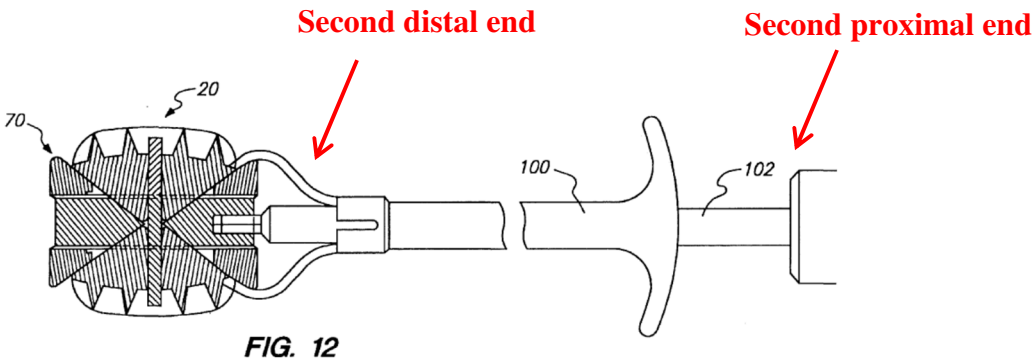


FIG. 12

Allen discloses a second adjusting tool (102) having a second proximal end (labeled above) and a second distal end (labeled above), with a second handle positioned at the second proximal end and a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion. *See e.g.,* EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 110.

Allen discloses the tool (102) having a terminus defining a hex configuration is inserted through the adjusting tool passage of the insertion tool (100) to engage an adjusting screw. The tool (102) can turn within the adjusting tool passage of the first tool (100 via a second handle positioned at the second proximal end for adjusting screw to extend the implant outwardly. EX1031 at 5:19-28; EX1003 at ¶ 110.

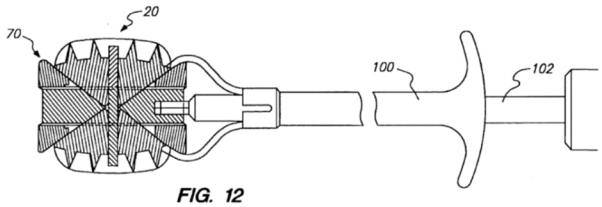
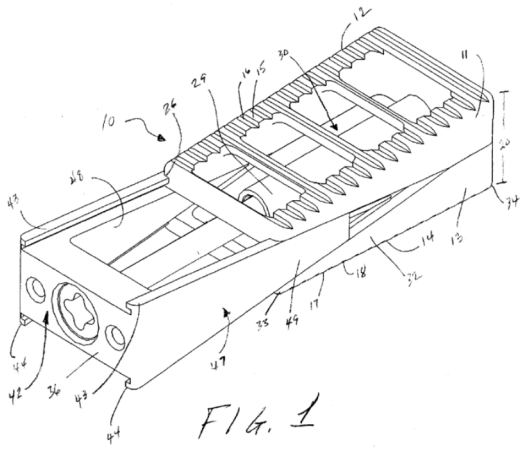


FIG. 12

[20.3] *an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw engagement portion and a threaded portion,*

Baynham discloses an expandable spinal implant (10) sized and configured to be implanted in a human spine, the expandable spinal implant (10) having a first expandable spinal implant structure (11) having a first engagement surface (12) to engage a first vertebral body, a second expandable spinal implant structure (42 and 13) having a second engagement surface (14) to engage a second vertebral body, and an adjusting screw (67) having a screw engagement portion and a threaded portion.

See, e.g., EX1029 at [0010]; [0025]; [0026]; [0029]; [0030]; FIG 1; EX1003 at ¶ 112.



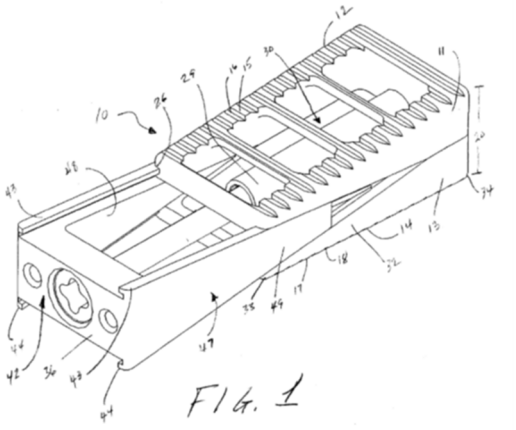
[20.4] *wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,*

Baynham discloses the expandable spinal implant (10) is configured to expand the first expandable spinal implant structure (11) with respect to the second expandable spinal implant structure (42 and13) in response to turning of the adjusting screw (67). *See, e.g.,* EX1029 at [0028]-[0030]; FIG. 2; EX1003 at ¶ 113.

Baynham discloses the surgeon turns the jack screw (67) causing the upper and lower sections to move along the complementary inclined plane to shorten the fusion device and increase the distance between the end plates of the adjacent vertebrae. EX1029 at [0030]; EX1003 at ¶ 114.

[20.5] *wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool,*

Baynham discloses that the implant defines first and second indentations on the end wall (36) on either side of the countersink (63). *See, e.g.,* EX1029 at [0028]; FIG. 1 and 3. While the function of the first and second tool engagement indentations is not expressly disclosed in Baynham, a PHOSITA would have understood that these indentations could function as tool engagement indentations. EX1003 at ¶ 115.



A PHOSITA would have understood that the inserter disclosed by Allen could be used to insert and expand the implant disclosed by Baynham. To the extent that the tool disclosed by Allen functions by interfacing with the outside surfaces of the implant, a PHOSITA would have understood that the implant could be modified as a matter of simple substitution to move the indentations from the end (36) to opposing side surfaces of the implant so that the first and second tool engagement

indentations would be positioned at the proximal end of the implant. Stated another way, placement and positioning of indentations for insertion tool engagement at the proximal or trailing end of the implant is a predictable substitution that does not affect its function. EX1003 at ¶ 116.

McLuen discloses an expandable spinal implant (e.g. 1500). EX1030 at [0077]; FIG. 16. A positioning screw (1508) is located proximate to a proximate end of implant (1500). *Id.* at [0076]; [0077]; FIG. 16. McLuen discloses to secure the implant (1500), a user would generally use a tool such as a screwdriver to turn screw (1508). McLuen also discloses that screwdrivers may slip out of place when performing surgery. Because of the proximity to the patient's spine, it is preferable to prevent or at least minimize slipping. *Id.* at [0076]. To achieve this, McLuen discloses channels or indentations (1522) on opposing sides of the implant to receive a tool. *Id.* at [0076]; FIG. 16; EX1003 at ¶ 117.

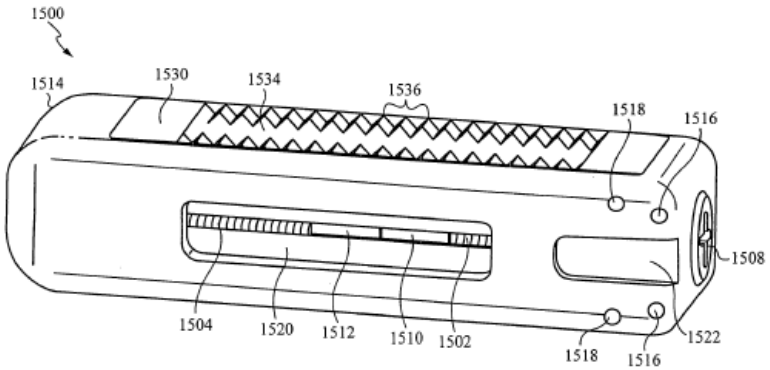
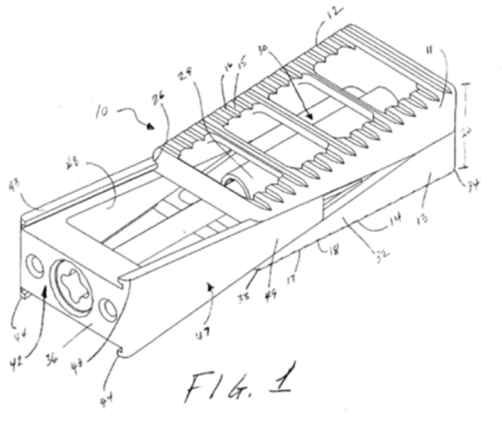


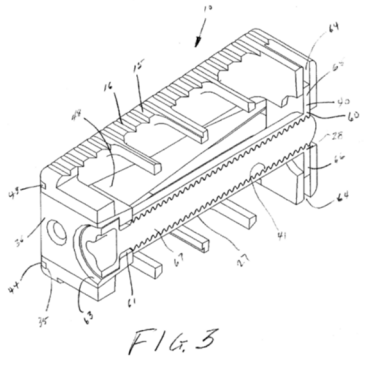
Fig. 16

It would therefore have been obvious to a PHOSITA to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to opposing sides of the expandable spinal implant to provide the disclosed advantages of prevention or minimization of screw driver slippage. This substitution would represent a design choice which would yield a predictable result with a reasonable expectation of success. EX1003 at ¶ 118.

> [20.6] *wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw while one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the expandable spinal implant,*

Baynham discloses an adjusting screw (67) positioned in the adjusting screw hole (61). *See, e.g.,* EX1029 at [0028]-[0029]; FIGs 1 and 3; EX1003 at ¶ 119.





Allen discloses a hollow first tool (100) having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and an adjusting tool passage extending through the first tool from the first proximal end to the first distal end. EX1031 at 5:5-28; FIG 12; EX1003 at ¶ 120.

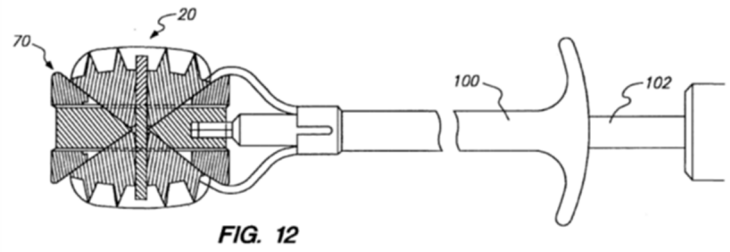


FIG. 12

A PHOSITA would have understood that the first and second engagement prongs of the insertion tool (100) are sized and positioned to extend into the first and second tool engagement indentations of a structure (such as the second expandable spinal implant structure (42 and 13) of Baynham) to allow the first tool to engage the expandable spinal implant. EX1003 at ¶ 120.

Allen discloses that the second adjusting tool (102) can extend through the adjusting tool passage of the first tool (100) to engage the screw head of the adjusting screw while the engagement prongs of the first tool (100) are engaged with the engagement indentations of the expandable spinal implant (20). EX1031 at 5:19-28; FIG. 12; EX1003 at ¶ 121.

A PHOSITA would have known and understood that orthopedic surgical instruments with cannulated handles bodies, through which instruments and devices could be delivered from the proximal (at the surgeon's hands) to the distal

(implantation location) intrasurgical sites, were in common use at that time. Similar devices were also used in arthroscopic and endoscopic surgery. EX1003 at ¶ 122.

It would have been obvious to a PHOSITA to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the expandable spinal implant of Baynham in combination with McLuen, to insert the expandable implant into the disk space between adjacent vertebrae. Then, using the second adjusting tool of Allen to pass through a cannula in the first tool to turn the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 123.

> [20.7] *wherein at least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.*

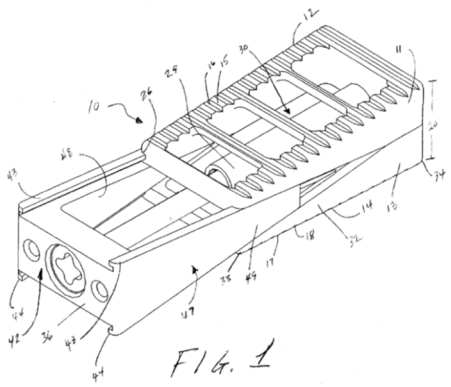
As discussed above, a PHOSITA would have understood that the tool assembly disclosed in Allen is configured to interface with any number of expandable spinal implants. A PHOSITA would have further understood the tool assembly in Allen is of a typical design for engaging spinal implants and that the tool assembly in Allen could be combined/used with the expandable spinal implant in Baynham. EX1003 at ¶ 124.

Additionally as discussed above, it would therefore have been obvious to a

PHOSITA to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to opposing sides of the expandable spinal implant so that the engagement prongs of the gripper can be positioned on the one or more side surfaces of the expandable spinal implant when the first tool engages with the expandable spinal implant to provide the disclosed advantages of prevention or minimization of screw driver slippage. This substitution would represent a design choice which would yield a predictable result with a reasonable expectation of success. EX1003 at ¶ 125.

> *21. The system of claim 20, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the expandable spinal implant.*

Baynham discloses it is an objective of the invention to teach an implant facilitating interbody fusion through bone graft or an ingrowth-type implant. EX1029 at [0014]. Baynham further discloses that aperture (25) provides for bone ingrowth. EX1029 at [0025]; EX1003 at ¶ 132.



Sutcliffe discloses throughgoing holes (13) so that interior (14) can be packed with bone chips and so that bone growth through the implant is possible. EX1032 at [0023], FIGs. 1, 4-6; EX1003 at ¶ 134.

Baynham discloses an angled wedge portion that has first and second rails and corresponding slots. *See, e.g.,* EX1029 at [0010]; [0025]; FIGs 1-3; EX1003 at ¶ 133.

Baynham also discloses that the slots and rails are configured to allow movement of the first implant structure (11) relative to the second implant structure (42 and 13) during the expansion of the expandable spinal implant. *See, e.g.,* EX1029 at [0010]; [0025]; [0026]; FIGs 1-3; EX1003 at ¶ 133.

A PHOSITA would also have understood that including the use of side openings provides additional locations to pack graft material and increase the surface area available for vascularization. A PHOSITA would have further understood that the presence of side openings would be advantageous for promoting bone growth

and fusion. The specific shape of the hole would have been a simple design choice with no bearing on the hole's function to admit graft material and promote fusion and therefore a cylindrical hole such as that disclosed by Sutcliffe could be used. A PHOSITA would have therefore been motivated to include additional cylindrical openings on the sidewalls of the intervertebral cage disclosed by Baynham to provide additional locations to pack graft material and thereby increase the surface available for vascularization, thus promoting fusion. EX1003 at ¶ 135

In summary, as confirmed by Dr. Ochoa, Allen in view of Baynham in view of McLuen render claims 1-4, 7-9, 11-12, 14-15, 18-21 unpatentable as obvious under 35 U.S.C. § 103.

X. GROUND 2: ALLEN IN VIEW OF BAYNHAM, IN FURTHER VIEW OF McLUEN, AND IN FURTHER VIEW OF SUTCLIFFE RENDER CLAIM 5 OBVIOUS

As further discussed below, Allen in view of Baynham and McLuen, as already discussed above, in further view of Sutcliffe, teaches each and every element and limitation of the dependent claim 5.

> 5. *The system of claim 1,*
>
> *and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies.*

As discussed above with respect to claim 1, Baynham discloses in FIG. 4, the

implant (10) with integral brackets on the upper and lower sections for engaging adjacent vertebrae. Each bracket has apertures therethrough for placing bone screws into the adjacent vertebra. The bone screws add stability to the implant and provide additional security to prevent dislodgement of the implant under normal activity. EX1029 at [0031], FIG. 4; EX1003 at ¶ 126.

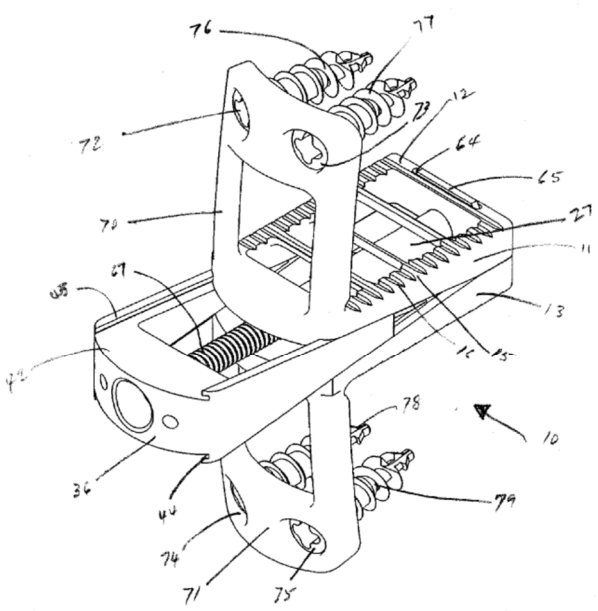


FIG. 4

Baynham discloses each bracket (70), (71) has countersunk apertures (72), (73), (74) and (75). Bone screws (76), (77), (78) and (79) (anchors) are inserted into the apertures and threaded into the vertebrae. EX1029 at [0032], FIG. 4; EX1003 at ¶ 127.

A PHOSITA would have understood that countersunk apertures (*e.g.* 72) serve as anchor guides to guide the paths of anchors into superior and/or inferior

vertebral bodies. Though not expressly disclosed in Baynham, a PHOSITA would have understood from the embodiment depicted in FIG. 4 that brackets (70) and (71) could be angled relative to each other and to the centerline axis of a first hole (bore 61) both to allow the brackets to conform to the geometry of superior and/or inferior vertebrae, and to increase the pullout strength in comparison to a parallel screw configuration. This would achieve the predictable solution of robust fixation of the implant to the vertebrae. Therefore, a PHOSITA would have understood that Baynham discloses anchor guides that guide anchors bidirectionally into first and second vertebral bodies. EX1003 at ¶ 128.

To the extent that Baynham does not expressly disclose this claim element, a PHOSITA would have understood that modifying the implant disclosed by Baynham to provide anchor guides angled to bi-directionally direct the anchors (screws) was a well-known way to achieve the solution of directing screws into superior and inferior vertebral bodies, thereby achieving the predictable result of enhanced fixation of the implant. It was well-known and understood that constructs with mutually angled screw paths provided increased pullout strength compared to constructs with parallel screw paths. EX1003 at ¶ 129.

Sutcliffe discloses an expandable intervertebral implant (1). EX1032 at [0022]. Sutcliffe discloses a lower part (3) is unitarily formed with a pair of eyes (6) having collars (7) defining holes or passages (8) with cylindrical inner surfaces (12)

extending at an acute angle of between 25º and 65º to the lower vertebral surface (10). Cortical screws (9) extend through these eyes (6) and into the lower vertebra (2) to solidly anchor the lower part (3) to the inferior vertebra (2). A similar pair of eyes (6) can be formed on the upper end part (4) to anchor it to the superior vertebra. *Id.* at [0024]; FIG. 6. One or more through going holes (13) are present in upper and lower parts (3) and (4). *Id.* at [0023]; FIG. 6; EX1003 at ¶ 130.

A PHOSITA have understood that collars (7) defining holes or passages (8) serve as first and second anchor guides that constrain the position and direction of anchors (9) into the superior and inferior intervertebral bodies. EX1003 at ¶ 131.

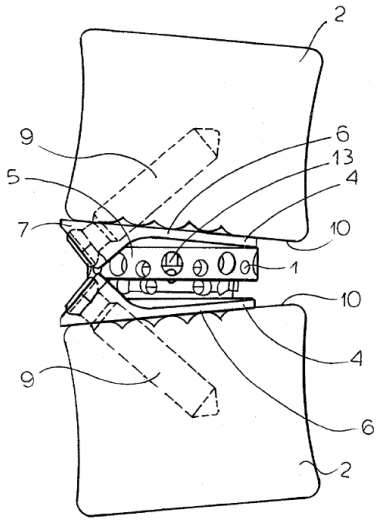


FIG.6

A PHOSITA would have understood that the implant disclosed by Baynham could have been readily modified to incorporate the angulated passages and anchors

(screws) disclosed by Sutcliffe. Therefore, PHOSITA would have understood that Baynham alone or in combination with Sutcliffe would disclose first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies. EX1003 at ¶ 131.

XI. 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*[5] 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 867 days. EX 1036. The Pending Litigation however involves eight asserted patents, one hundred and thirty-one asserted claims and twenty three accused products. 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 867 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,

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

and at a time when many cases are delayed because of COVID-19. The expectation is for a trial date in 2022/2023.[6]

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.

[6] Globus intends on filing a Motion for Stay in the Pending Litigation.

XII. CONCLUSION

Petitioner has demonstrated in this Petition that the Challenged Claims are unpatentable. Petitioner, therefore, respectfully requests institution of an IPR of the '319 patent.

Dated: July 20, 2020

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this Petition complies with the word count limitations of 37 CFR § 42.24. This brief contains less than 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 20th day of July, 2020:

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