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.: IPR2020-01303
U.S. Patent No. 10,307,268
Issued: June 4, 2019
Application No: 15/976,340
Filed: May 10, 2018

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,307,268 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 Chart for U.S. Patent No. 10,307,268
1028	Intentionally Left Blank
1029	U.S. Patent Application Publication No. 2007/0270968 to Baynham et al.

Exhibit #	*Description*
1030	U.S. Patent Application Publication No. 2006/0253201 to McLuen
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I. INTRODUCTION

Globus Medical, Inc. ("Globus" or "Petitioner") petitions for *inter partes* review ("IPR") of claims 1, 3, 5, 7-11, and 21-26 (the "Challenged Claims") of U.S. Patent No. 10,307,268, titled "Intervertebral Expandable Implant" ("the '268 patent"), issued to Ahmnon D. Moskowitz, et al. and assigned to Moskowitz Family LLC ("Moskowitz") according to the USPTO records. The '268 patent is attached as EX1001.

The Challenged Claims are directed to an intervertebral expandable implant and a tool for positioning and expanding the implant. During prosecution the examiner steadfastly rejected all pending claims directed *solely* to an **intervertebral expandable implant**. In response, the applicant never amended the intervertebral expandable implant claims. Rather, the applicant added new claims directed to a **tool**, that were objected to and rewritten in independent form to gain allowance. There is nothing new about the tool or using the tool to position and expand an intervertebral expandable implant.

For the reasons set forth herein, Petitioner seeks a final written decision that the Challenged Claims of the '268 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. is the real party-in-interest. No other party had access to this Petition and no other party had any control over, or contributed to any funding of, the preparation or filing of this Petition.

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

Petitioner is unaware of any disclaimers or reexamination certificates of the '268 patent.

The '268 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. 10,478,319 ("the '319 patent"); U.S. Patent No. 8,353,913 ("the '913 patent"); U.S. Patent No. 9,889,022 ("the '022 patent"). The '319, '913 and '022 patents are related to the '268 patent through continuation practice. Petitioner

understands that the ‘268 patent, the ‘319 patent, the ‘913 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 ‘268 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 ‘268 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. As noted above, during prosecution the Baynham reference was used by the examiner to reject all pending claims directed to an intervertebral expandable implant.

Petitioner addresses the Baynham reference in section VIII.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 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 '268 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 (IPR2020-01303), then Petitioner does not seek the Boards discretion to institute the second petition (IPR2020-01304). If the Board exercises its discretion to deny institution of this petition, then Petitioner seeks institution of the second petition.[1]

[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.

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

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

D. Notice of Service (37 C.F.R. § 42.8(b)(4))

Please direct all correspondence to lead counsel at the above address. Petitioner consents to email service at the above-referenced email addresses.

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

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

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

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

Petitioner certifies that the '268 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, 3, 5, 7-11	U.S. Patent Application Publication No. 2007/0270968 to Baynham et al. ("Baynham") (EX1029) in view of U.S. Patent Application Publication No. 2006/0253201 to McLuen ("McLuen") (EX1030) and in further view of U.S. Patent No. 5,658,335 to Allen ("Allen") (EX1031)	35 U.S.C. § 103(a)
2	21-26	U.S. Patent Application Publication No. 2007/0270968 to Baynham et al. ("Baynham") (EX1029) in view of U.S. Patent Application Publication No. 2006/0253201 to McLuen ("McLuen") (EX1030), in further view of U.S. Patent No. 5,658,335 to Allen ("Allen") (EX1031) and in further view of U.S. Patent Application Publication No. 2002/0143399 to Sutcliffe ("Sutcliffe") (EX1032)	35 U.S.C. § 103(a)

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

V. SUMMARY OF THE '268 PATENT (EX1001)

The '268 patent issued on June 4, 2019 from an application filed on May 10, 2018. The '268 patent is a continuation of U.S. Application Serial No. 15/894,471 filed on February 12, 2018, which is a continuation of U.S. Patent No. 13/210,157 filed on August 15, 2011, now U.S. Patent No. 9,889,022, which is a continuation of U.S. Application Serial No. 13/084,543 filed on April 11, 2011, now U.S. Patent No. 8,353,913, and a continuation of U.S. Application Serial No. 13/108,982 filed on May 16, 2011, now U.S. Patent No. 9,005,293. Application No. 13/084,543 is a continuation of U.S. Application Serial No. 11/842,855, filed August 21, 2007, now U.S. Patent No. 7,942,903. Application No. 13/108,982 is a continuation of U.S. Application Serial No. 11/842,855, 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 for the '268 patent claims priority to provisional application No. 60/670,231 filed April 12, 2005.[2] EX1001.

[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 '268 patent is July 31, 2007." EX1034, P. 10, II.E. Petitioner relies on this admission.

A. The ‘268 Patent Specification and Claims

The ‘268 patent generally directed to intervertebral expandable implants and is most easily characterized for purposes of this petition by referencing FIGs. 1B and 1D:

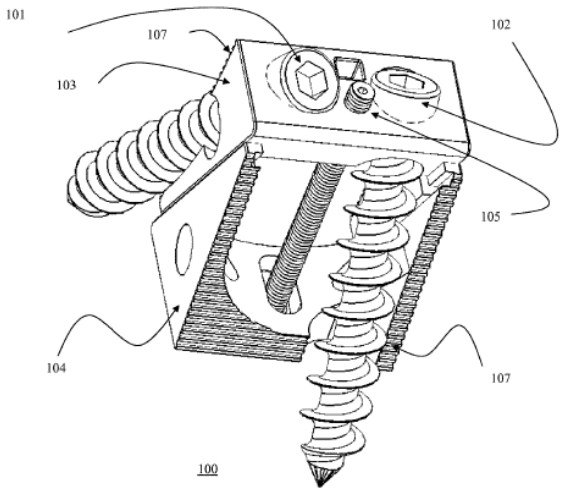


Fig. 1B

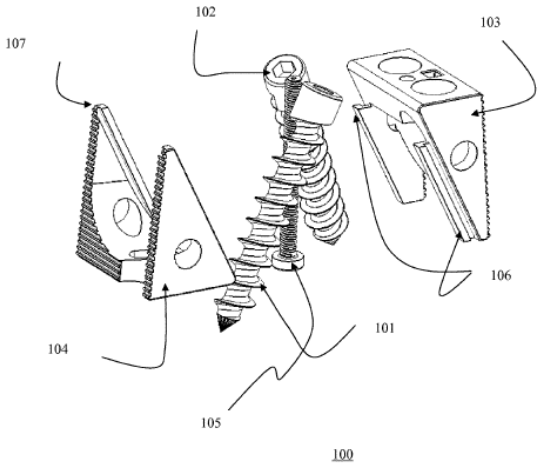


Fig. 1D

EX1001, FIGs. 1B and 1D.

In view of FIG 1B and 1D, the ‘268 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 7:52-64.

The ‘268 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:

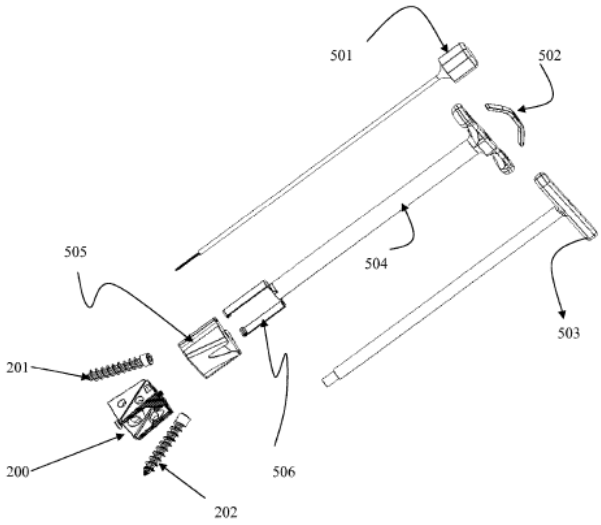


Fig. 5C

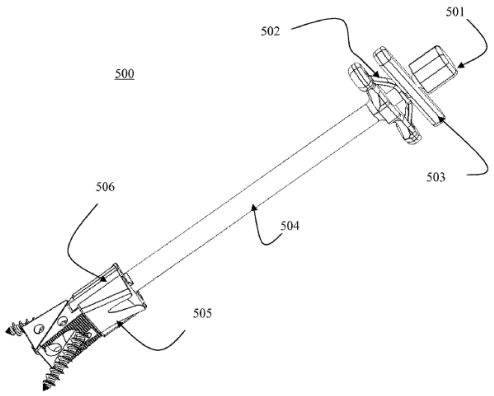


Fig. 5A

EX1001 at FIGs. 5A and 5C.

In view of Fig 5A and C, the ‘268 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 8:63-9:4.

B. The ‘268 Patent Prosecution History (EX1002)

The prosecution history for the ‘268 patent is particularly relevant to this petition as the Baynham reference was of record and used by the Examiner during prosecution as the basis for rejecting the claimed subject matter directed to an intervertebral expandable implant. EX1002

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 May 10, 2018, the Applicant filed application serial no 15/976,340, that eventually issued as the ‘268 patent. EX1002 at 365-433

On May 14, 2018, the Applicant filed a preliminary amendment cancelling original claims 1-10 and adding new claims 11-36 directed to an intervertebral expandable implant. EX1002 at 347-355.

On October 18, 2018, the Examiner issued a Non-Final Office Action rejecting claims 11, 13-18, 20-22 and 24-27 under 35 U.S.C. §102(a) as anticipated

by Baynham et al. (U.S. Pub. No. 2007/0270968), rejecting claim 19 under 35 U.S.C. § 103(a) as obvious over Baynham in view of the knowledge of one of ordinary skill in the art, and rejecting claims 12, 23 and 28-36 under 35 U.S.C. § 103(a) as obvious over Baynham in view of Euros (FR 2727003). EX1002 at 184-188. The Examiner concurrently issued a non-statutory double-patent rejection for all pending claims based on claims 1-18 of U.S. Patent No. 7,942,903. *Id.* at 188-190.

On October 23, 2018, the Applicant filed a Terminal Disclaimer to obviate the double-patenting rejection. EX1002 at 174-175. With respect to the prior art rejections, rather than amending rejected claims 11-36, the Applicant cancelled claims 16-18, 29 and 33-35 and argued that rejection of the remaining claims was ill-founded based on the Baynham reference failing to disclose certain claim limitations. *Id.* at 156-173. Additionally, the Applicant added new claims 37-47 noting that claims 37-39 carried the same claim limitations that served as the basis for arguing over the Baynham reference. *Id.* Of import to the analysis under 35 U.S.C. § 325(d), is the fact that *all* rejected claims and new claims 37-39 were directed to an **intervertebral expandable implant**. Conversely, new claims 40-47 were directed to a **tool** for positioning and expanding an intervertebral expandable implant. *Id.* at 160-173.

On November 2, 2018, the Applicant participated in a telephone conference with the Examiner. The examiner noted in the subsequent interview summary that

"[s]everal features discussed were viewed by Examiner as disclosed or obvious … Applicant will consider amending the claims to distinguish over the prior art." EX1002 at 148.

On January 5, 2019, the Examiner issued a Final Office Action in which the non-cancelled original claims were rejected on the *identical grounds* detailed in the non-final office action and new claims 37-39, were rejected under 35 U.S.C. § 103(a) as obvious over Baynham in view of the knowledge of one of ordinary skill in the art. EX1002 at 110-112. All rejected claims were directed to an **intervertebral expandable implant**. Remaining new claims 40-47 directed to a **tool** were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. *Id.* at 113.

On January 5, 2019 (the day on which the Final Office Action issued), the Applicant filed its Response After Final cancelling several claims and amending new claims 40, 44, and 46 into independent form. EX1002 at 122-134. The Applicant noted, "all pending claims are either the same claims that were identified as allowable or depend from one of the allowable base claims." *Id.* at 135.

On March 3, 2019, the Examiner issued a Notice of Allowance for the amended claims. EX1002 at 91-92.

Summarizing the file history, the Examiner rejected all implant claims and the

applicant never sought amendment to overcome the objection. Rather, the applicant added new tool claims which were objected to and rewritten in independent form to gain allowance.

In view of the facts above, the analysis under the *Becton, Dickinson* factors is clear. During prosecution, the Baynham referenced was used by the examiner *solely* to reject the intervertebral expandable implant claims. No prior art reference, including Baynham, was ever characterized or used by the examiner to reject the tool claims. Objected to new claims 40-47, directed to a **tool,** were rewritten in independent form to gain allowance.

As noted below in sections X and XI, Baynham is used to address the subject matter of an intervertebral expandable implant. In these sections, the Allen reference directed to a tool is used by the Petitioner to address the Challenge Claims that are directed to a tool for positioning and expanding an intervertebral expandable implant. The Allen reference was never of record. The prior art combination of Allen directed to a tool and Baynham directed to an intervertebral expandable implant, was never of record and NO prior art was ever cited or characterized by the examiner for the subject matter of a tool.

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 Petitioner here relies on Allen for the claimed subject matter directed to a tool. The examiner relied on Baynham for the claimed subject matter directed to an intervertebral expandable implant. 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

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

constructions in the Pending Litigation:[4]

Claim Term	**Globus's Construction**
"first implant structure"/ "second implant structure"	"a [first/second] implant structure comprising the [first/second] vertebral body engagement surface"
"adjusting screw positioned in the adjusting screw hole"	"adjusting screw located on the spacer, as opposed to on the tool"
"an adjusting tool passage extending through the first tool from the first proximal end to the first distal end"	"an adjusting tool passage that extends through the entirety of the first tool from the first proximal end to the first distal end"
"an indentation adjacent to the screw hole"	"an indentation different from the first and second tool engagement indentations"

Petitioner, however, expressly reserves its right to argue a different claim construction in a different forum for any term in the '268 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 '268 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related

[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.

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 noted 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. 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 '268 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:

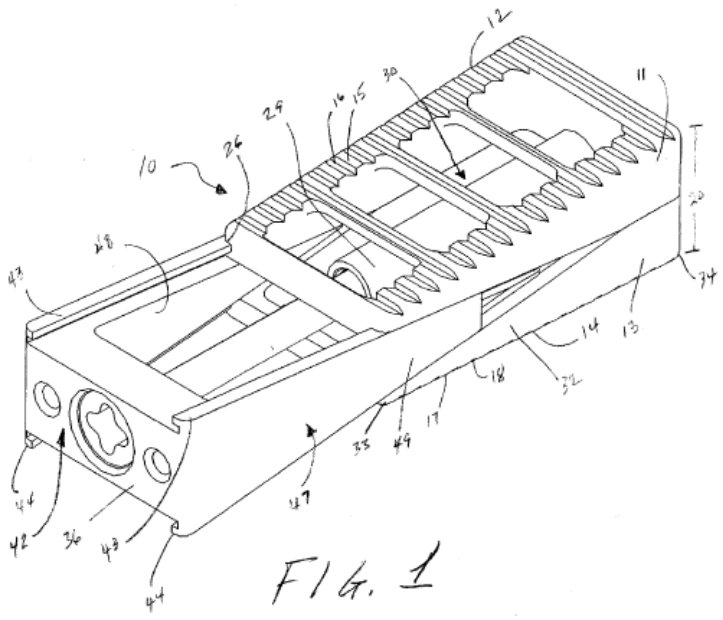


FIG. 1

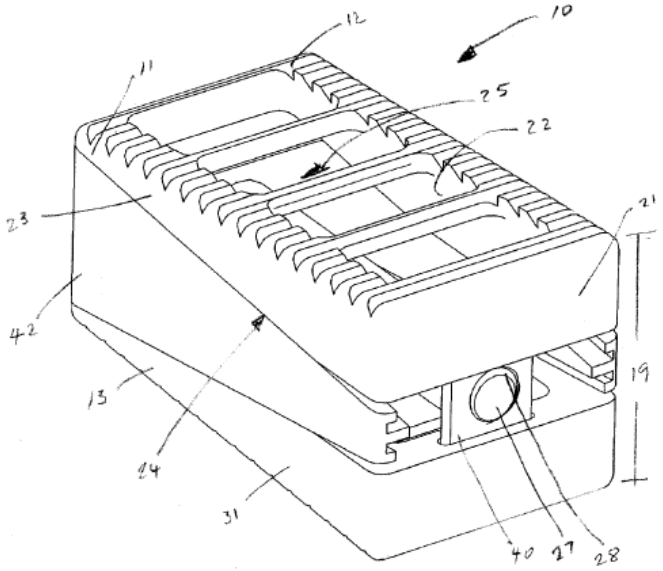


FIG. 2

(EX1029 at FIGs. 1-2)

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]

B. 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 '268 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:

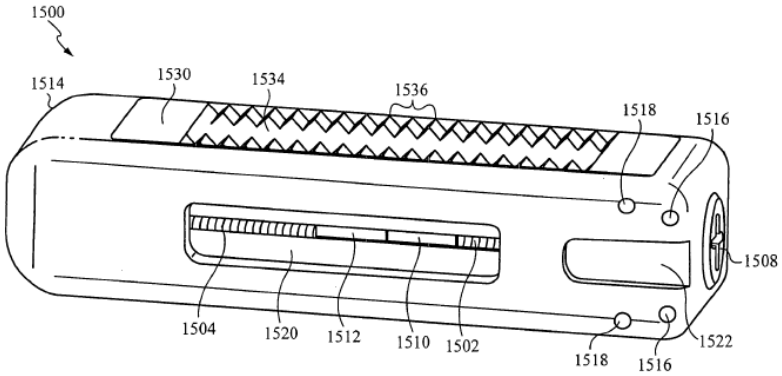


Fig. 16

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].

C. Allen (EX1031)

Allen, entitled "Spinal Fixator," issued on August 19, 1997. Allen is prior art to the '268 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 '268 patent.

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

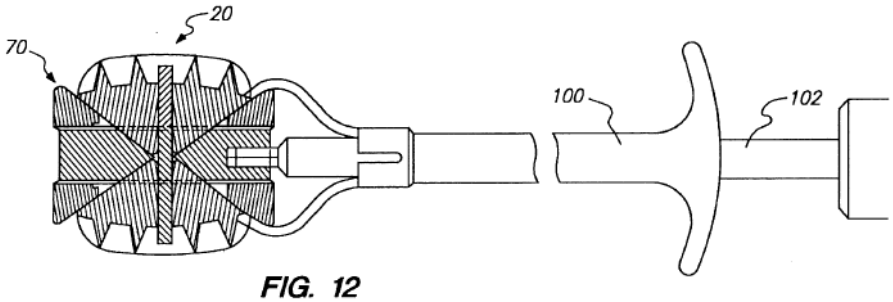


FIG. 12

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.

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 '268 patent under 35 U.S.C. § 102(b) (Pre-AIA). Sutcliffe was not considered by the Examiner during the prosecution of the application leading to the '268 patent.

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

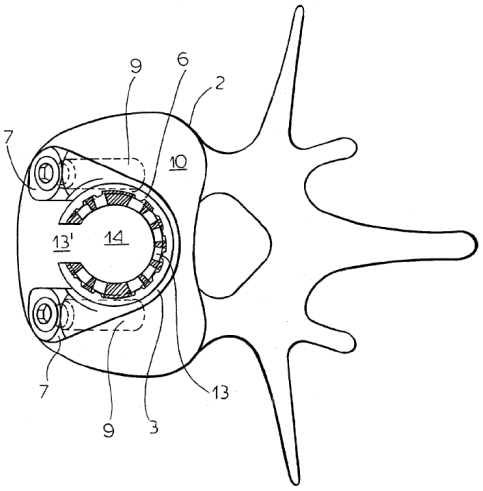


FIG.3

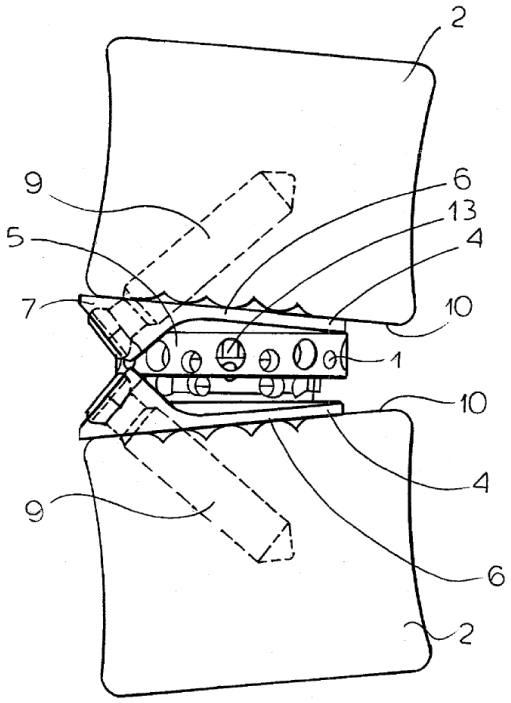


FIG.6

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: BAYNAHAM IN VIEW OF McLUEN AND FURTHER IN VIEW OF ALLEN AND FURTHER IN VIEW OF SUTCLIFFE RENDERS CLAIMS 1, 3, 5, AND 7-11 OBVIOUS

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

As discussed more below, a PHOSITA would have considered the subject matter recited in claims 1, 3, 5, and 7-11 of the '268 patent to be obvious.

A. Independent Claim 1

[1.1] *A system comprising:*
an intervertebral expandable implant having a first vertebral body engagement surface for engaging a first vertebral body and a second vertebral body engagement surface for engaging a second vertebral body, wherein the second vertebral body engagement surface is positioned opposite of the first vertebral body engagement surface, the intervertebral expandable implant comprising:

Baynham discloses an intervertebral expandable implant (10) having a first vertebral body engagement surface (12) for engaging a first vertebral body (inferior or superior) and a second vertebral body engagement surface (14) for engaging a second vertebral body (superior or inferior), the second vertebral body engagement surface (14) is positioned opposite of the first vertebral body engagement surface (12). *See, e.g.,* EX1029 at paras. [0010], [0022], [0025], [0026], and [0030]; and FIG 1; EX1003 at ¶ 60.

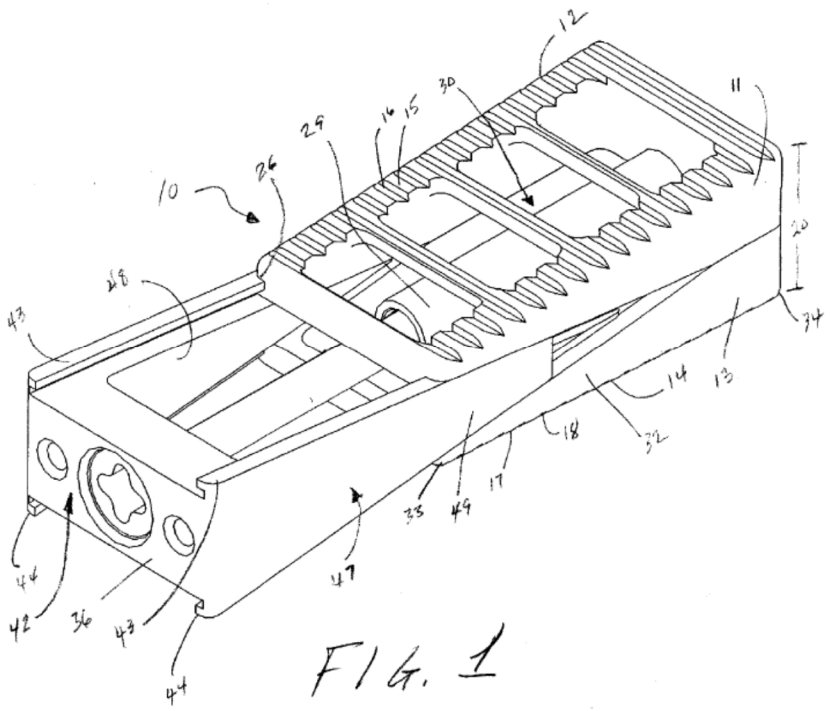


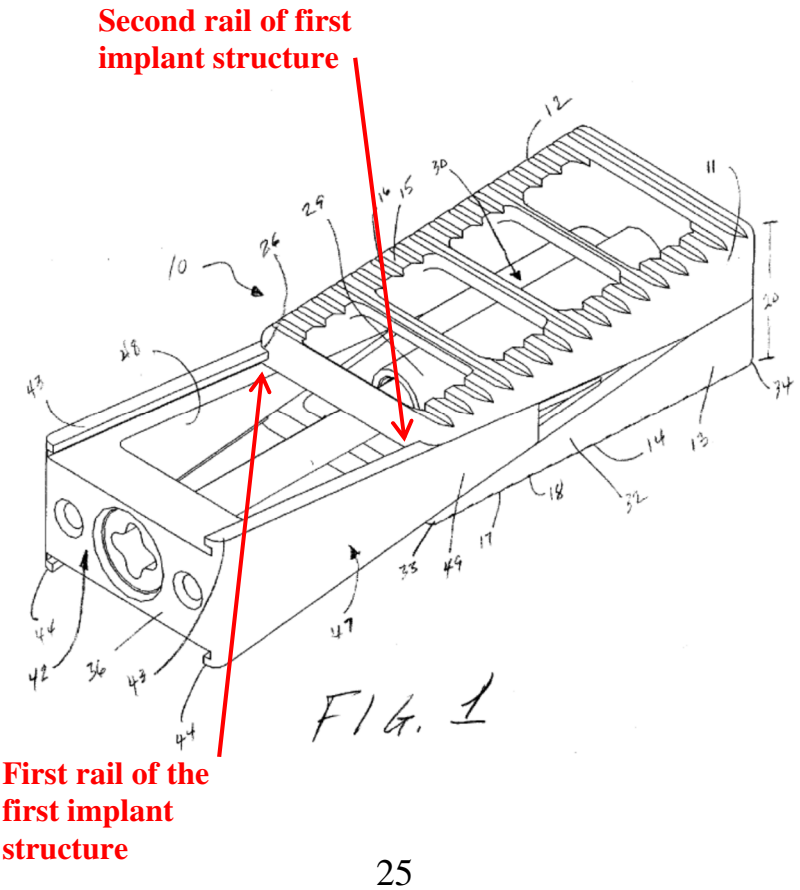
FIG. 1

Baynham discloses that the spinal fusion device (10) is inserted in the intervertebral space in the insertion mode, shown in FIG. 1 above, 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. EX1029 at [0022]; EX1003 at ¶¶ 60-61.

[1.2] *a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion 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 between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a*

location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface,

Baynham discloses a first implant structure (11) defining the first vertebral body engagement surface (12) and a first angled wedge portion (24) that is angled with respect to the first vertebral body engagement surface (12). The first angled wedge portion engages with first and second rails and has a corresponding first slot (26) located adjacent to the first rail between the first rail and the first vertebral body engagement surface (12) and a corresponding second slot (26) located adjacent the second rail between the second rail and the first vertebral body engagement surface (12). *See, e.g.,* EX1029 at paras. [0010] and [0025]; and FIGs. 1-2; EX1003 at ¶ 62.



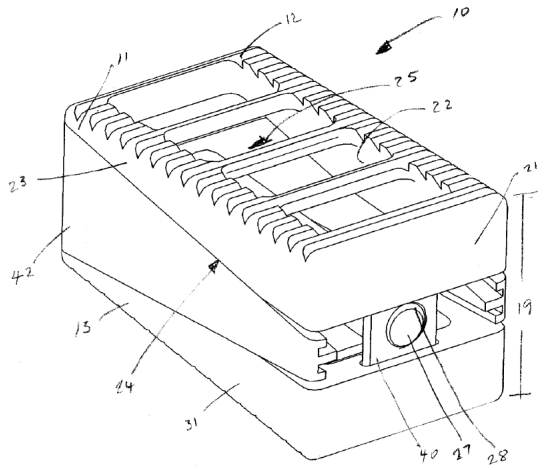


FIG. 2

Baynham also discloses that the first and second slots (26) of the first implant structure (11) engage complimentary first and second rails (43) of a second implant structure (42 and 13) to guide movement of the first implant structure (11) relative to the second implant structure (42 and 13) to maintain the first and second implant structure in alignment. *See, e.g.,* EX1029 at [0010], [0025], [0026], and FIGs. 1-2 (shown above); EX1003 at ¶ 62.

A PHOSITA would have understood that the relative movement of the first and second implant structures along an inclined plane of the angled wedge portion (24) is not mandated by the facing direction of the first and second rails and slots of the first implant structure. EX1003 at ¶ 63.

A PHOSITA would have understood that modifying the Baynham reference to provide the first implant structure with inwardly-facing rails and slots is a simple

and predictable substitution that would involve nothing more than an obvious design choice, yielding the identical function of providing guidance during movement of the first implant structure relative to the second implant structure. Therefore, to the extent that Baynham does not explicitly disclose a first implant structure having first and second inwardly-facing rails and slots, it would have been obvious to a PHOSITA to modify the first implant structure to reverse the facing direction (inward verses outward) of the rails and corresponding slots. *Id.* at ¶¶ 63-64.

> [1.3] *wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface, wherein the first 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,*

Baynham discloses that the first 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 para. [0025]; and FIGs. 1-2 (shown below); EX1003, at ¶ 65.

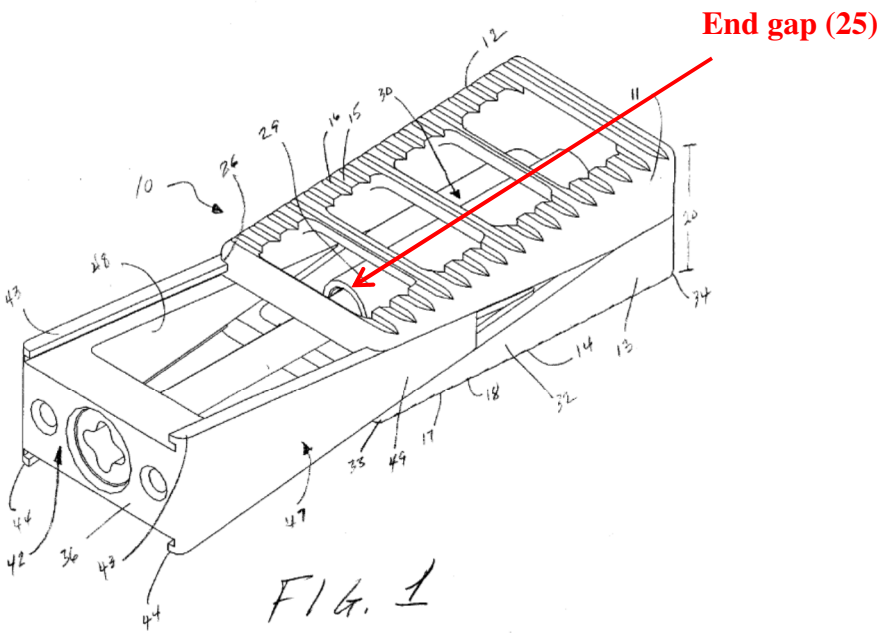


FIG. 1

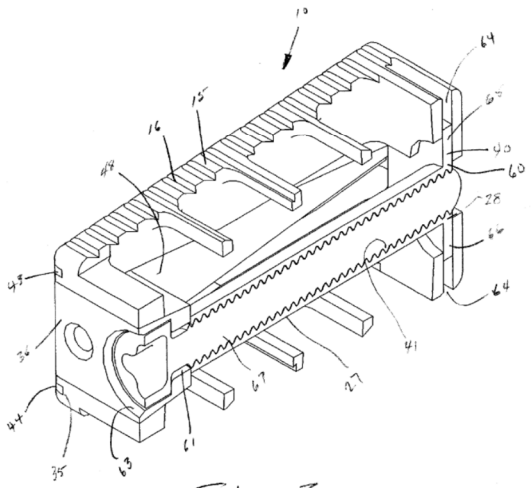


FIG. 3

[1.4] *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 that 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 para. [0022] and [0025]; and FIGs 1 and 2 (shown below); EX1003 at ¶ 66.

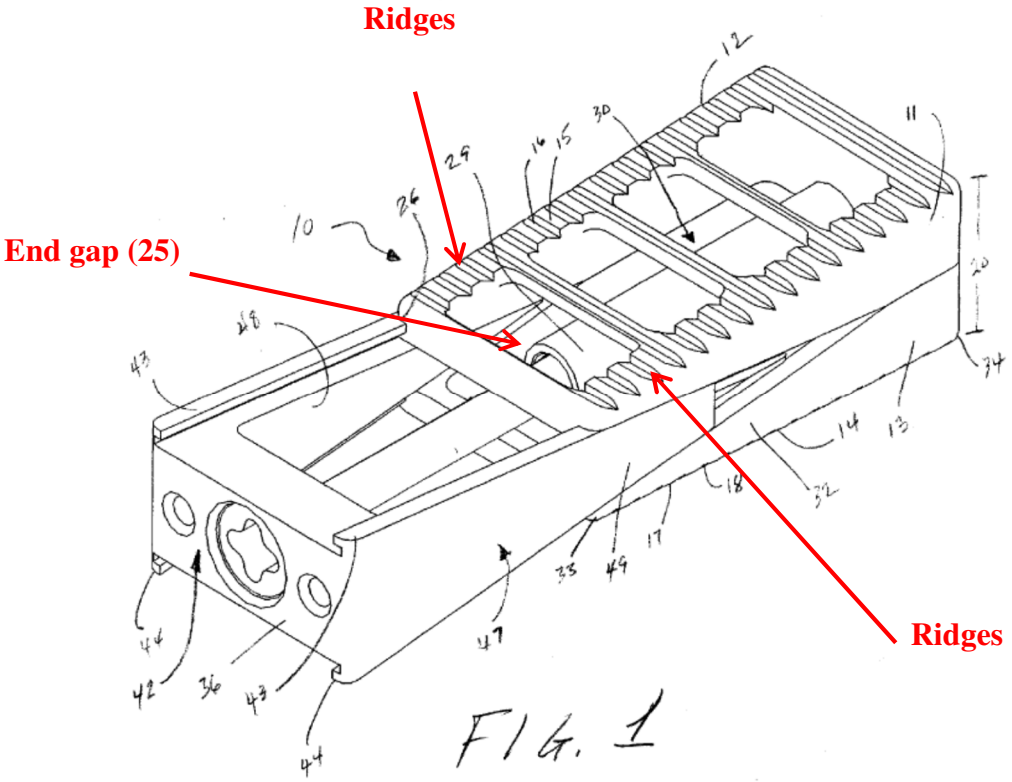


FIG. 1

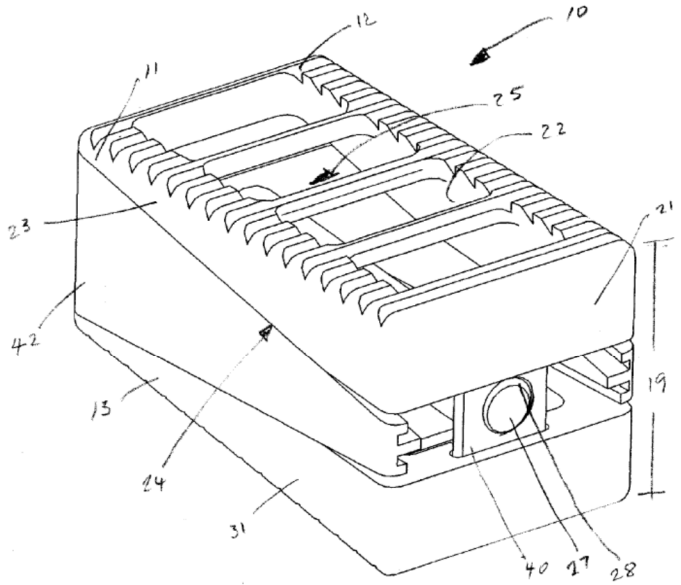
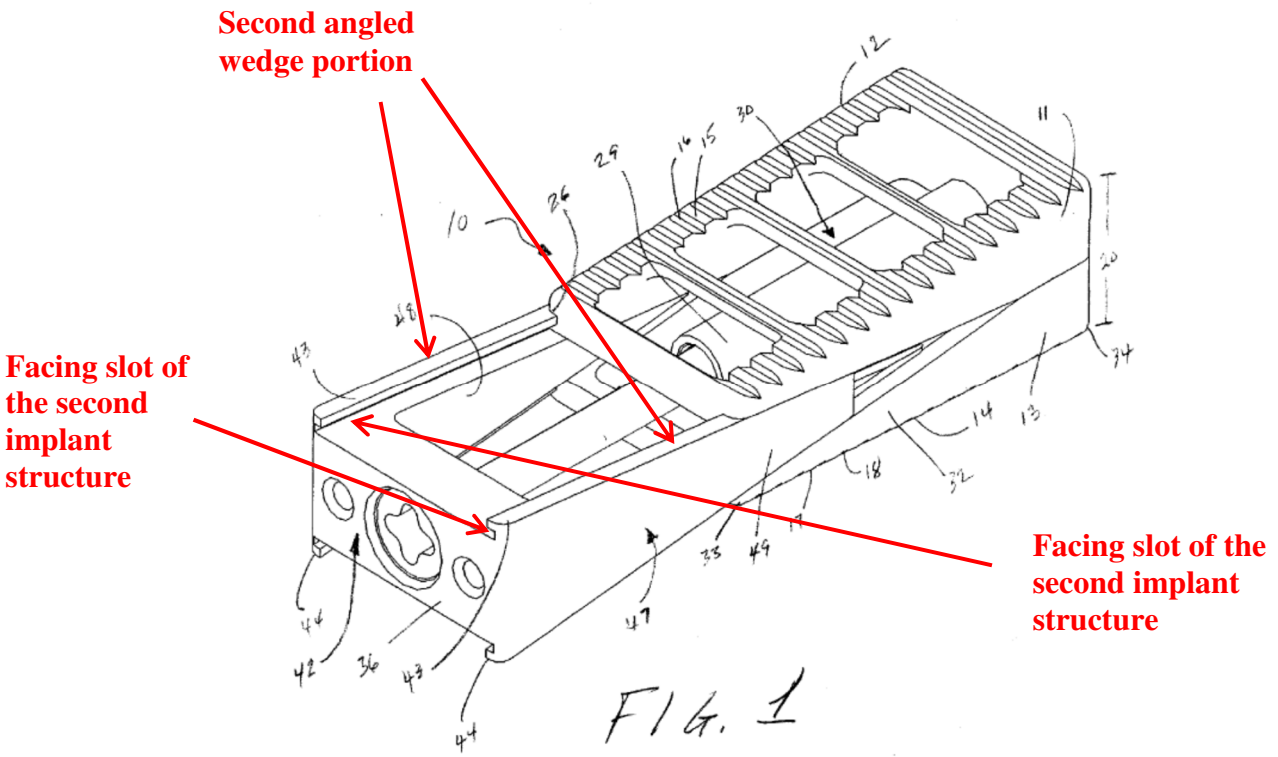


FIG. 2

[1.5] *a second implant structure defining 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 implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,*

Baynham discloses a second implant structure (42 and 13) defining a second angled wedge portion that has first and second rails (43) that face in a direction opposite to each other and engage a first slot defined at a location adjacent the first rail (43) and a second slot defined at a location adjacent the second rail (43). *See, e.g.,* EX1029 at paras. [0010], [0025], and [0026]; and FIGs 1-2; EX1003 at ¶ 67.

The first implant structure (11) is slidably-engaged with the second implant structure (42 and 13) such that the first angled wedge portion (24) engages the second angled wedge portion of the second implant structure (42 and 13). *See, e.g.,* EX1029 at paras. [0010], [0025], and [0027]; and FIGs 1-2 (shown below); EX1003 at ¶ 67.



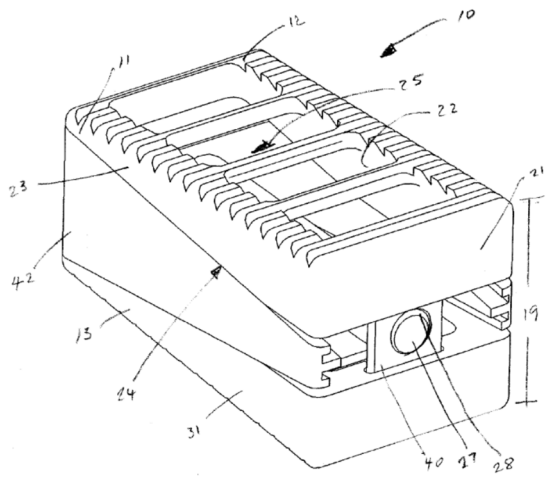


FIG. 2

A PHOSITA would have understood that the relative movement of the first and second implant structures along an inclined plane of the angled wedge portion (24) is not mandated by the facing direction of the first and second rails and slots of the first implant structure or the second implant structure. As noted above, a PHOSITA would have understood that modifying the Baynham reference 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 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 implant structures. This predicable substitution is equally as applicable to the second implant structure as it is to the first implant structure and when the modification is made to the first implant structure it also drives the modification to the second implant structure. Therefore, to the extent that Baynham does not explicitly disclose

a second implant structure that has first and second outwardly-facing rails and slots, it would have been obvious to a PHOSITA to modify the second implant structure to reverse the facing direction (outward versus inward) of the rails and corresponding slots . EX1003 at ¶ 68.

[1.6] *wherein the second implant structure defines third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface,*

Baynham discloses the second implant structure (42 and 13) having third and fourth opposing side surfaces (48, 49, 31, 32) positioned on opposite sides of the second vertebral body engagement surface (14). *See, e.g.,* EX1029 at paras. [0022], and [0025] to [0028]; and FIGs. 1 and 2 (shown below); EX1003 at ¶ 69.

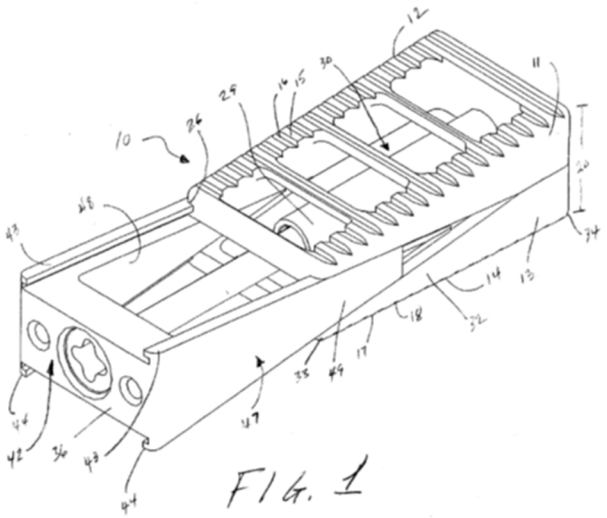


FIG. 1

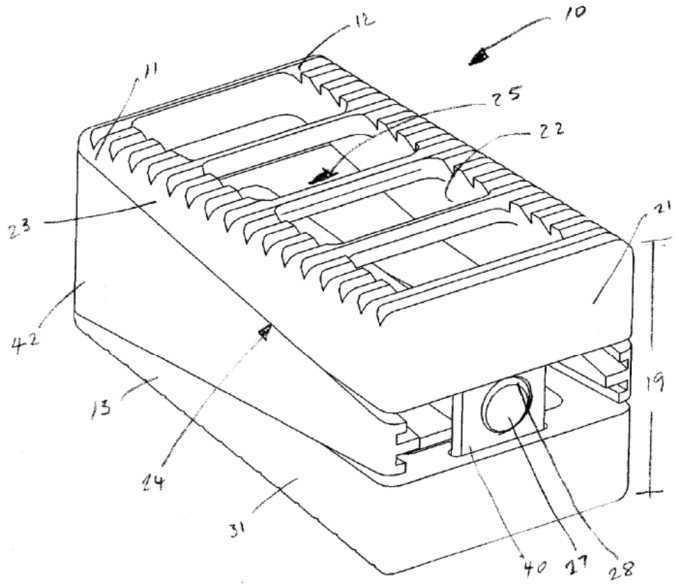
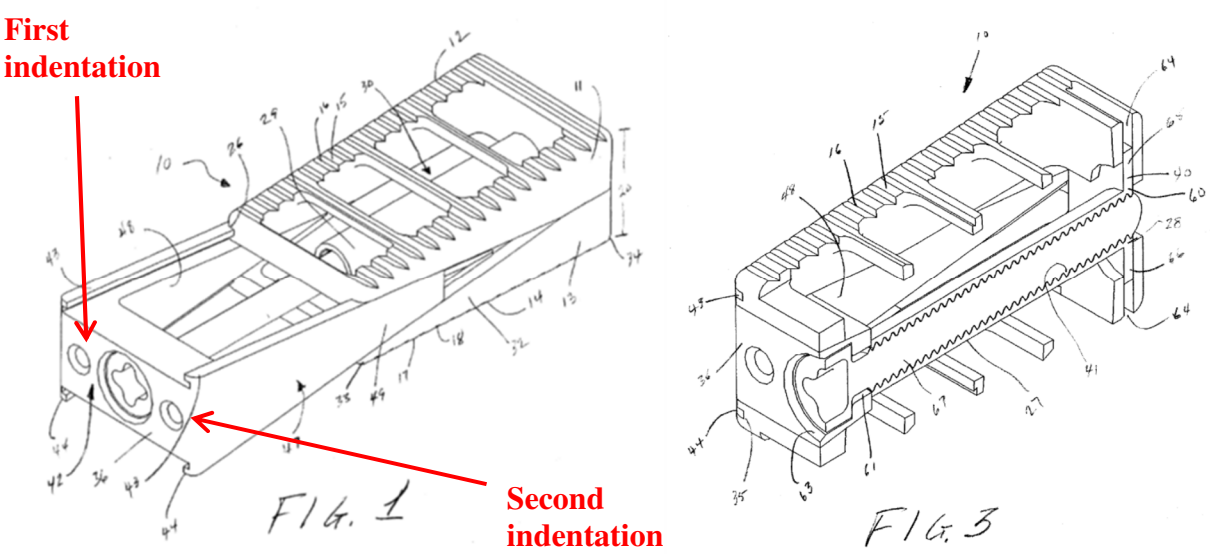


FIG. 2

[1.7] *wherein the second implant [structure] defines first and second tool engagement indentations on the third and fourth opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure, and*

Baynham discloses the second implant [structure] (42 and 13) defines first and second indentations on the end wall (36) on either side of the countersink (63). *See, e.g.,* EX1029 at para. [0028]; and FIGs. 1 and 3 (shown below); EX1003 at ¶ 70.



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. *Id.* at ¶ 70.

To the extent that Baynham does not explicitly disclose first and second tool engagement indentations on the third and fourth opposing side surfaces of the second implant (42 and 13), it would have been obvious to a PHOSITA as a matter of simple substitution to modify the implant disclosed to move the indentations from the end (36) to the third and fourth opposing side of the second implant structure, so that the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure. Stated another way, placement and positioning of indentations for insertion tool engagement at the trailing end of the second implant is a predictable substitution that does not affect the function of the implant. *Id.* at ¶¶ 72.

McLuen discloses an intervertebral expandable implant (e.g. 1500). EX1030 at [0077]; and FIG. 16; EX1003 at ¶ 71.

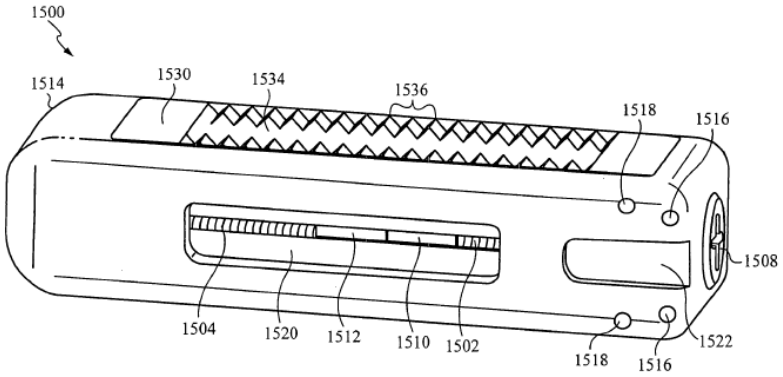


Fig. 16

In McLuen, a positioning screw (1508) is located proximate to a proximate end of implant (1500). EX1030. at [0076]; [0077]; and 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 para. [0076]. To achieve this, McLuen discloses channels or indentations (1522) on opposing sides the implant to receive a tool. EX1030 at para. [0076]; and 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 a position proximate a proximate (trailing) end of the second implant structure 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.

> [1.8] *wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces; and*

Baynham discloses that the second implant structure (42 and 13) has an adjusting screw hole (61) sized for receiving an adjusting screw (67) at a proximal portion of the second implant structure (42 and 13) between the third and fourth side surfaces. *See, e.g.,* EX1029 at paras. [0028] and [0029]; and FIGs. 1 and 3 (shown below); EX1003 at ¶ 73.

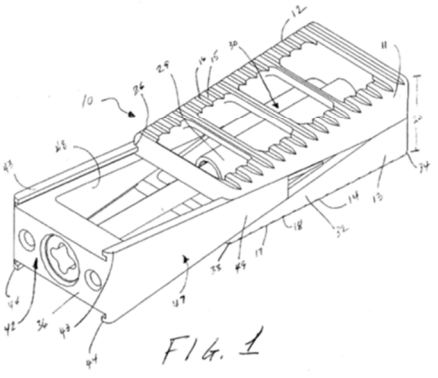


FIG. 1

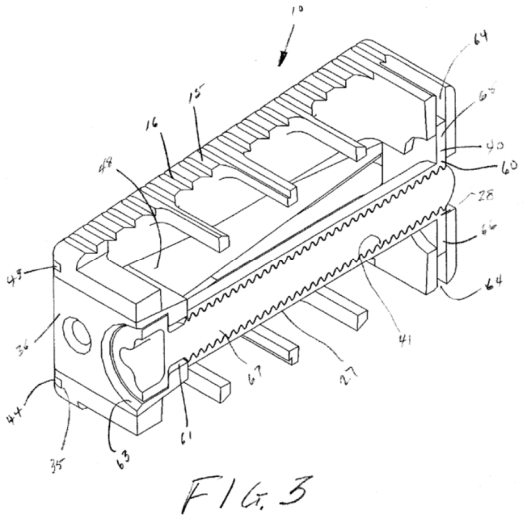


FIG. 3

[1.9] *an adjusting screw positioned in the adjusting screw hole;*

Baynham discloses an adjusting screw (67) positioned in the adjusting screw hole (61). *See, e.g.,* EX1029 at paras. [0028] and [0029]; and FIGs. 1 and 3. A jack screw (67) is inserted through bore (61) engaging the threads in the tube (27). EX1029 at para. [0029]; EX1003 at ¶ 74.

> [1.10] *a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and*

Although Baynham does not expressly disclose a tool, a PHOSITA would have understood that an insertion tool would be used to insert the disclosed implant. EX1003 at ¶ 75.

Allen discloses a tool that is used to insert and expand an intervertebral expandable implant in an intervertebral space. 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 col. 5, lines 5-47; and FIG. 12 (shown below); EX1003 at ¶ 75.

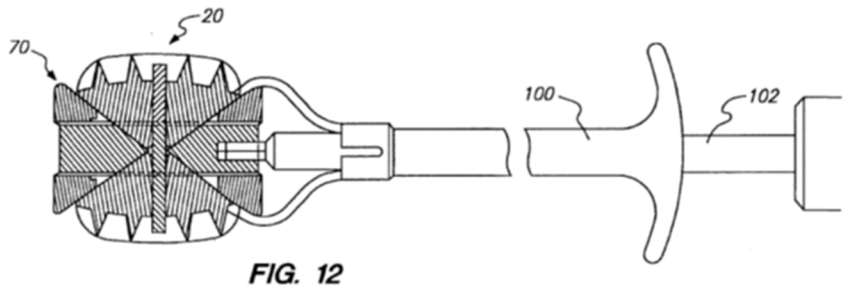


FIG. 12

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 implant structure (42 and 13) of Baynham in combination with McLuen, to allow the first tool to engage the intervertebral expandable implant. EX1003 at ¶¶ 75.

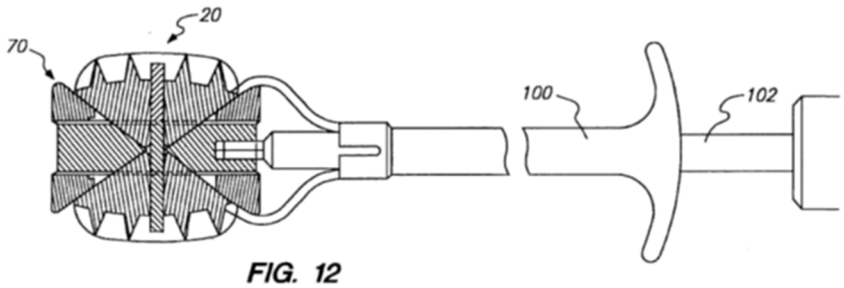


FIG. 12

It would have been obvious to a PHOSITA to use prongs on the tool disclosed by Allen to engage the first and second tool engagement indentations of the implant structure disclosed by Baynham in combination with McLuen on placement of the indentations, to insert the implant into the disk space between adjacent vertebrae . *Id.* at ¶¶ 76.

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

proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw,

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 to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

To the extent that Baynham does not expressly disclose a second adjusting tool, a PHOSITA would have understood that an adjusting tool would be used to turn the adjusting screw to expand the implant. EX1003 at ¶ 77.

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 second adjusting tool (102) can be inserted through the insertion tool (100). EX1031 at col. 5, lines 5-47; and FIG. 12 (shown below); EX1003 at ¶ 75.

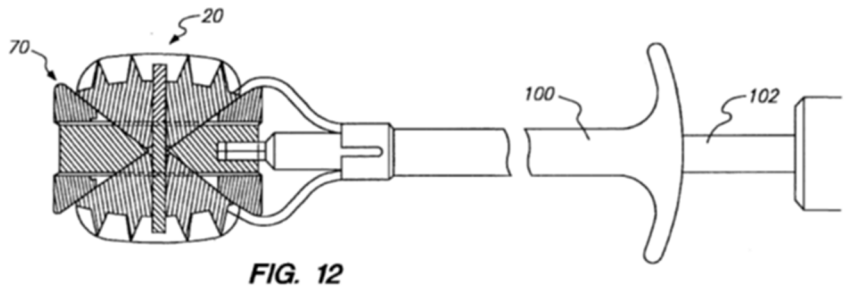


FIG. 12

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 implant structure (42 and 13) of Baynham in combination with McLuen, to allow the first tool to engage the intervertebral expandable implant. *Id.* at ¶ 75.

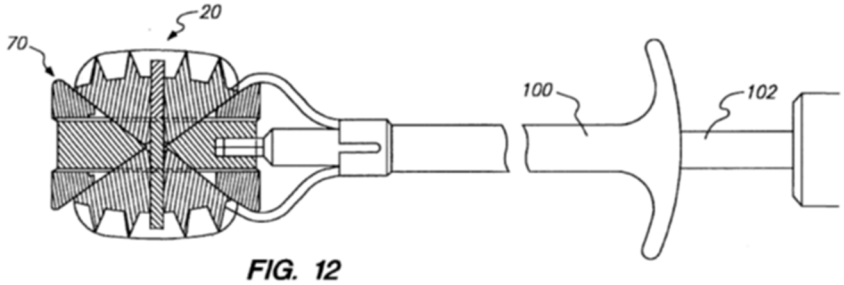


FIG. 12

Allen discloses that following placement of the implant, the tool (102) has a handle positioned at a proximal end and a screw engagement portion positioned at a distal end, the screw engagement position having a terminus defining a hex configuration that is inserted through the hollow insertion tool (100) to engage an adjusting screw. The tool (102) is used to rotate the adjusting screw to expand the implant outwardly thereby forcing the ridges/teeth of the vertebral engagement surface into the vertebral body. EX1031 at col. 5, lines 19-26; EX1003 at ¶ 76.

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 the time. Similar devices were also used in arthroscopic and endoscopic surgery. 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 second implant structure of Baynham in combination with McLuen on placement of the indentations, to insert the intervertebral 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 drive the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 77.

3. The system of claim 1, and further comprising means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies.

Baynham discloses a spinal fusion device to facilitate incorporation into and fusion with the superior and inferior vertebral bodies. *See, e.g.,* EX1029 at para. [0022]. Baynham also discloses an aperture (25) to provide for bone ingrowth and/or for receiving bone graft to facilitate interbody fusion. EX1029 at [0014], [0025] and [0028]; EX1003 at ¶ 78.

A PHOSITA would have understood that the apertures (25) provide a pathway for bone ingrowth and resulting incorporation and fusion with the superior and inferior vertebral bodies. *Id.* at ¶ 78.

> *5. The system of claim 1, wherein the second implant structure defines an indentation adjacent the screw hole.*

Baynham discloses the trailing end of the second implant structure has an end wall (36) with a bore (61). The bore (61) has a larger countersunk bore (63) in the end wall (36). EX1029 at para. [0028]. Baynham also discloses the second implant [structure] (42 and 13) has at least one indentation on the end wall (36) on either side of the countersink (63). *See, e.g.,* EX1029 at para. [0028]; and FIGs. 1 and 3; EX1003 at ¶ 79.

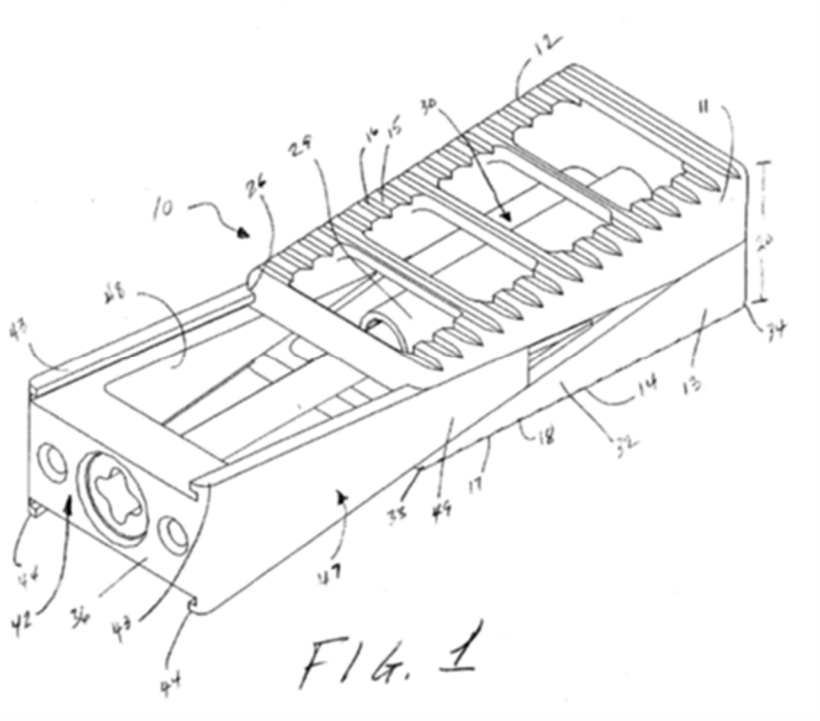
> *7. The system of claim 1, wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.*

Baynham discloses rotation of the adjusting screw (67) with respect to the second implant structure (42 and 13) moves the second implant structure with respect to the first implant structure (11) to slide the first angled wedge portion (24) with respect to the second angled wedge portion of the second implant structure (42 and 13) and expand the intervertebral expandable implant. *See, e.g.,* EX1029 at[0030]; and Fig 2; EX1003 at ¶ 80.

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 para. [0030]; EX1003 at ¶ 80.

> *8. The system of claim 1, wherein the adjusting screw extends through a portion of the first implant structure that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface of the first implant structure when the intervertebral expandable implant is expanded.*

Baynham discloses that the adjusting screw (67) extends through a portion of the first implant structure (11) that is larger (tube 29) than a diameter of the threaded shaft of the adjusting screw (67) so as to allow the first implant structure to move with respect to the adjusting screw (67) along a direction normal to the first vertebral body engagement surface (12) of the first implant structure (11) when the intervertebral expandable implant is expanded. *See, e.g.,* EX1029 at paras. [0022], [0029], and [0030]; and Fig 1 (shown below); EX1003 at ¶ 81.



Baynham discloses 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 para. [0029]; EX1003 at ¶ 81.

[9.1] *A method of using the system of claim 1, the method comprising: connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;*

As discussed above with respect to claim 1, it would have been obvious to a PHOSITA to use prongs on the tool disclosed by Allen to engage the first and second indentations of the implant structure disclosed by Baynham in combination with

McLuen to insert the intervertebral expandable implant into the disk space between adjacent vertebrae and to resist torque during screw rotation. EX1003 at ¶ 82.

> [9.2]*implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach;*

Baynham discloses that it is an objective of the invention to teach a posterior surgical approach for placement of an intervertebral expandable implant for interbody fusion allowing the implant to be inserted through a small incision and increased in size (*i.e.* expanded) in situ. EX1029 at [0011]; EX1003 at ¶ 83.

Baynham discloses that the implant is inserted in an "extended thin mode" between adjacent vertebrae. The adjacent vertebrae are forced apart as the height of the implant increases. The spinal fusion device may be used unilaterally or bilaterally. EX1029 at para. [0010]; EX1003 at ¶ 83.

A PHOSITA would have understood that when using the transforaminal approach, the surgical window is created by excising a facet joint to provide access to the disk space. A PHOSITA would further have understood that this narrow surgical window requires an appropriately shaped cage. EX1003 at ¶ 84.

To the extent that Baynham does not expressly disclose the TLIF approach, a PHOSITA would have understood that both the TLIF approach and PLIF (posterior lumbar interbody fusion) approaches are posterior procedures. A PHOSITA would

have further understood that the narrow, low profile geometry of the cage disclosed by Baynham would be appropriate for use in a TLIF procedure. Further modifications for use in this application would be a matter of additional optimization of the geometry that would not affect the function of the invention and would therefore be an obvious design choice. EX1003 at ¶ 84.

> [9.3] *extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and*

As discussed above with respect to claim [1.11], 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 the time. Similar devices were also used in arthroscopic and endoscopic surgery. EX1003 at ¶ 85.

It would therefore have been obvious to a PHOSITA to 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 second implant structure of Baynham in combination with McLuen, to insert the intervertebral 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 drive the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 85.

> [9.4] *expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.*

As discussed above with respect to claim [1.11], it would have been obvious to a PHOSITA to 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 second implant structure of Baynham in combination with McLuen, to insert the intervertebral 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 ¶ 85.

> *10. A method of using the system of claim 1, the method comprising: connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations; implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a posterior lumbar interbody fusion (PLIF) approach; extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.*

As discussed above with respect to claims 1 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 second implant structure of Baynham in combination with McLuen, to insert

the intervertebral 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 ¶ 86.

Baynham discloses it is an objective of the invention to teach a posterior surgical approach for placement of an adjustable spinal implant for interbody fusion allowing the implant to be inserted through a small incision and increased in size in situ. EX1029 at [0011]; EX1003 at ¶ 43. A PHOSITA would have understood that the lumbar spine is almost exclusively the location in which interbody cages are implanted using a posterior approach. To the extent that Baynham does not expressly disclose the posterior lumbar interbody fusion (PLIF) approach, a PHOSITA would have understood that both the TLIF approach and PLIF approaches are posterior procedures. Therefore, it would have been obvious and commonly known that the posterior approach disclosed by Baynham would include PLIF. EX1003 at ¶ 87.

> *11. A method of using the system of claim 1 to insert the intervertebral expandable implant into a disc space of a spine from an anterior or lateral path, the method comprising: connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations; implanting the intervertebral expandable implant into the disc space via the first tool; extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral*

expandable implant.

As discussed above with respect to claims 1 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 second implant structure of Baynham in combination with McLuen, to insert the intervertebral 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 ¶ 88.

Furthermore, Baynham discloses an embodiment 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 para. [0031]. The upper section has a bracket (70) attached to the trailing end wall. As shown, the bracket extends normal to the top surface (12) in a direction away from the distractor (42). The lower section (13) has a bracket (71) attached to the trailing end wall and extending in the opposite direction from the lower section. Each bracket (70, 71) has counter sunk apertures (72, 73, 74 and 75). Bone screws (76, 77, 78 and 79) are inserted into the apertures and threaded into the vertebrae. EX1029 at para. [0032]; and FIGs. 1 and 4 (shown below). EX1003 at ¶ 88.

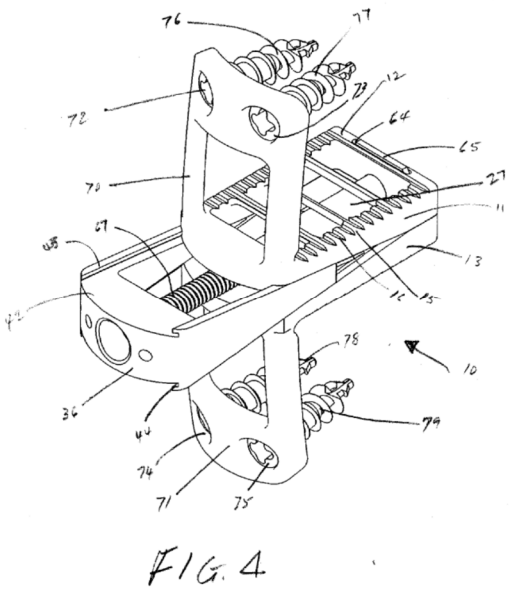


FIG. 4

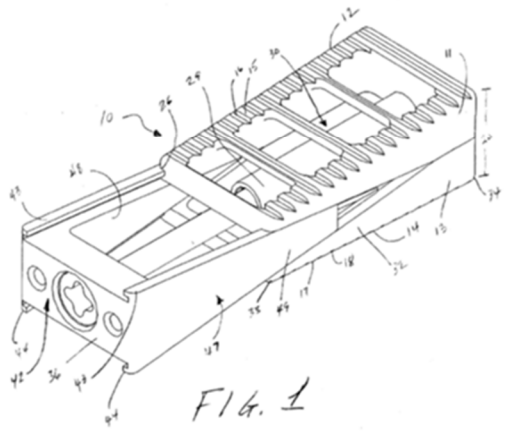


FIG. 1

A PHOSITA would have understood that certain embodiments depicted in Baynham would be typical for a lateral or anterior approach for an intervertebral fusion device. For example, a plate structure shown in FIG. 4 would require a larger surgical window than can be achieved through a posterior approach and the posterior elements would obstruct the passage of the bracket through surgical window; the embodiment is for a lateral or anterior approach. This geometry is more typically used for an anterior or lateral approach. Further, a PHOSITA would have understood that form factor and size of the implant depicted in FIG. 1 could be further adapted for use in an anterior application, which would be a simple design choice that would yield a predictable result. EX1003 at ¶ 89.

X. GROUND 2: BAYNHAM IN VIEW OF McLUEN, FURTHER IN VIEW OF ALLEN AND FURTHER IN VIEW OF SUTCLIFFE RENDER CLAIMS 21-26 OBVIOUS

As further discussed below, Baynham in view of McLuen and Allen, as already discussed above, and further in view of Sutcliffe, teach each and every element and limitation of independent claim 21 and dependent claims 22-26.

As discussed more below, a PHOSITA would have considered the subject matter recited in claims 21-26 of the '268 patent to be obvious.

A. Independent Claim 21

> [21.1] *A system comprising:*
> *an intervertebral expandable implant having a first vertebral body engagement surface and a second vertebral body engagement surface positioned opposite of the first vertebral body engagement surface for engaging inferior and superior vertebral bodies, the intervertebral expandable implant comprising:*
>
> *a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion 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 between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface; and*

As discussed above with respect to claim [1.1-1.3], Baynham discloses all of these claim elements. EX1003 at ¶ 90.

> [21.2] *a second implant structure defining 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 implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,*

As discussed above with respect to claim [1.5], Baynham discloses all of these claim elements. EX1003 at ¶ 90.

> [21.3] *wherein the intervertebral expandable implant defines first and second screw guides positioned and configured to guide screws into the superior and inferior vertebral bodies, wherein at least one of the first and second implant structures defines at least one of the first and second screw guides,*

Baynham discloses in FIGS. 4 (shown below), 5 and 6, an embodiment of the implant (10) with integral brackets (70), (71) on the upper and lower sections for engaging adjacent vertebrae. Each bracket has apertures (72), (73), (74) and (75) therethrough for placing bone screws (76), (77), (78) and (79) into the adjacent

vertebra. A PHOSITA would have understood the bone screws add primary stability to the implant and provide additional security to prevent dislodgement of the implant under normal activity. EX1029 at para. [0031]; [0032]; and FIGS. 4, 5 and 6; EX1003 at ¶ 91.

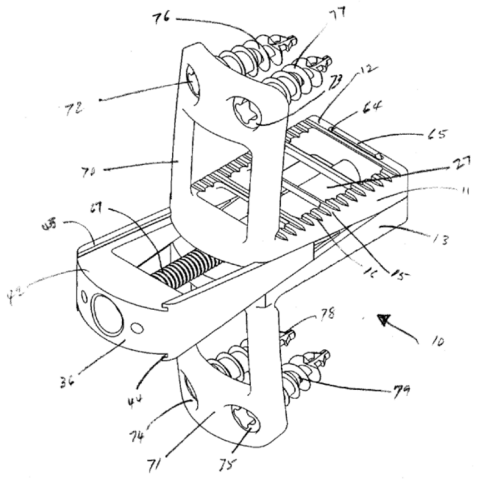


FIG. 4

A PHOSITA would have understood that counter sunk apertures (*e.g.* 72) serve as screw guides to guide the paths of screws into the superior and/or inferior vertebral bodies. EX1003 at ¶ 91.

To the extent that Baynham does not explicitly disclose first and second screw guides positioned and configured to guide screws into the superior and inferior vertebral bodies, a PHOSITA would have understood that modifying the implant disclosed by Baynham to provide screw guides would have been a well-known method to achieve enhanced implant stability through the predictable solution of orienting and directing screws into vertebral bodies. EX1003 at ¶ 93.

Sutcliffe discloses an intervertebral implant (1). EX1032 at para. [0022]; EX1003 at ¶ 92.

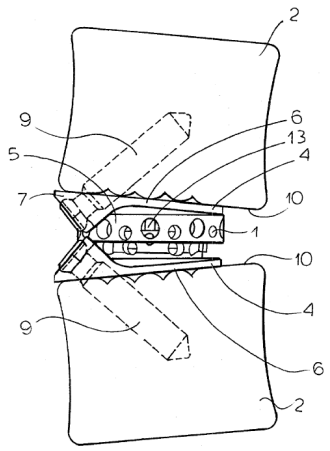


FIG.6

Sutcliffe discloses a lower part (3) that 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). FIG. 6 shows how a similar pair of eyes (6) can be formed on the upper end part (4) to anchor it to the superior vertebra. *Id.* at para. [0024]; and FIG. 6. One or more through-going holes (13) are present in upper and lower parts (3) and (4). EX1032 at para. [0023]; and FIG. 6 (shown above and below). EX1003 at ¶ 92.

A PHOSITA would have understood that collars (7) defining holes or passages (8) serve as first and second screw guides that constrain the position and

direction of screws (9) into the superior and inferior intervertebral bodies. EX1003 at ¶ 92.

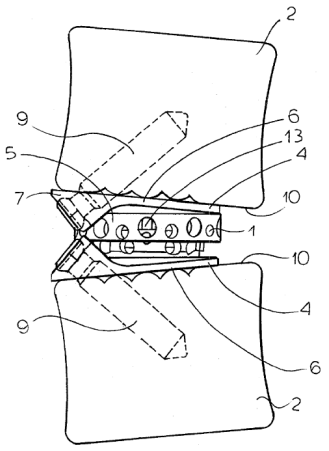


FIG.6

A PHOSITA would have understood that Baynham alone or in view of the teachings of Sutcliffe would provide screws guides that would use a well-known technique to orient and direct screws into superior and/or inferior vertebral bodies and therefore yield enhanced implant stability with a reasonable expectation of success. EX1003 at ¶ 93.

> [21.4] *wherein the intervertebral expandable implant further comprises an adjusting screw, and wherein the second implant structure defines first and second tool engagement indentations on opposing side surfaces of the second implant structure;*

As discussed above with respect to claim [1.7-1.9], it would have been obvious to a PHOSITA to combine the teachings of Baynham with McLuen to modify the position of the indentations disclosed in Baynham as disclosed in McLuen, to opposing side surfaces of the second implant structure to provide the

disclosed advantage of prevention or minimization screw driver slippage. EX1003 at ¶ 94.

> [21.5] *a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and*

As discussed above with respect to claim [1.10], it would have been obvious to a PHOSITA to use prongs on the tool disclosed by Allen to engage the first and second tool engagement indentations of the implant structure disclosed by Baynham in combination with McLuen to insert the implant into the disk space between adjacent vertebrae and to resist torque during screw rotation. EX1003 at ¶ 95.

> [21.6] *a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, 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 to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the*

first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

As discussed above with respect to claim [1.11], 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 second implant structure of Baynham in combination with McLuen to insert the intervertebral expandable 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 drive the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 96.

22. The system of claim 21, wherein the adjusting screw has a threaded shaft, wherein the second implant structure defines a screw hole, wherein the threaded shaft of the adjusting screw is positioned in the screw hole of the second implant structure, wherein the first implant structure defines a space that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

As discussed above with respect to claims [1.8-1.9], 7 and 8, Baynham discloses that the second implant structure (42 and 13) has an adjusting screw hole

(61) sized for receiving an adjusting screw (67) at a proximal portion of the second implant structure (42 and 13) between the third and fourth side surfaces. *See, e.g.,* EX1029 at paras. [0028] and [0029]; and FIGs. 1-3. EX1003 at ¶ 97.

Baynham further discloses that the jack screw (67) extends through a portion of the first implant structure (11) that is larger (29) than a diameter of the threaded shaft to the adjusting screw (67) so as to allow the first implant structure to move respective to the adjusting screw (67) along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded. A PHOSITA would have understood that the first implant structure (11) defines a space (tube 29) which has a length and at least a portion of its diameter (i.e. major internal thread diameter) that is larger than the diameter of the adjusting screw (67). *Id.*

Baynham discloses that rotation of the adjusting screw (67) with respect to the second implant structure (42 and 13) moves the second implant structure with respect to the first implant structure (11) to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant. *See, e.g.,* EX1029 at para. [0030]; and Fig 2; EX1003 at ¶ 97.

23. The system of claim 21, wherein a threaded shaft of the adjusting screw is threaded around an exterior circumference of the threaded shaft.

Baynham discloses a jack screw (67) is inserted through bore (61) engaging the threads in the tube (29). 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 para. [0029]; and FIG. 3 (shown below). A PHOSITA would have understood that the threads of adjusting screw (67) are located on the exterior circumference of the screw shaft. EX1003 at ¶ 98.

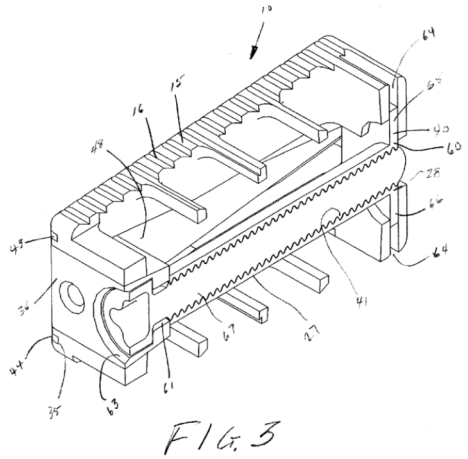


FIG. 3

24. The system of claim 21, wherein a threaded shaft of the adjusting screw is threaded along substantially a full length of the threaded shaft.

Baynham discloses 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 para. [0029]; and FIG. 3 (shown below). A PHOSITA would have understood that the threads of adjusting screw (67) are along substantially a full length of the screw shaft. EX1003 at ¶ 99.

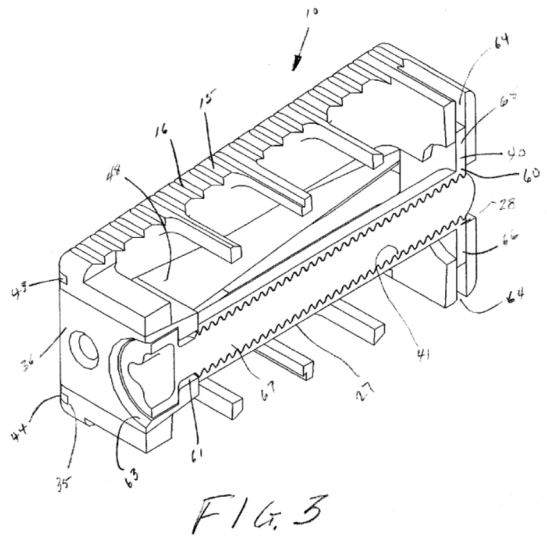


FIG. 3

25. The system of claim 21, wherein the second implant structure defines a first hole having a first centerline axis, wherein the first screw guide has a second centerline axis that is angled with respect to the first centerline axis so as to guide a first screw into one of the superior and inferior vertebral bodies, and wherein the second screw guide has a third centerline axis that is angled with respect to both of the first and second centerline axes so as to guide a second screw into the other of the superior and inferior vertebral bodies.

Baynham discloses that the second implant structure has a bore (61) that defines a first centerline axis. FIG. 4 discloses 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 paras. [0028]; and [0031]; and FIG. 4; EX1003 at ¶ 100.

In Baynham, each bracket (70), (71) is shown with counter sunk apertures (72), (73), (74) and (75). Bone screws (76), (77), (78) and (79) are inserted into the apertures and threaded into the vertebrae. EX1029 at para. [0032], and FIG. 4 (shown below). A PHOSITA would have understood that counter sunk apertures (*e.g.* 72) serve as screw guides to guide the paths of screws into the superior and/or inferior vertebral bodies. EX1003 at ¶ 100.

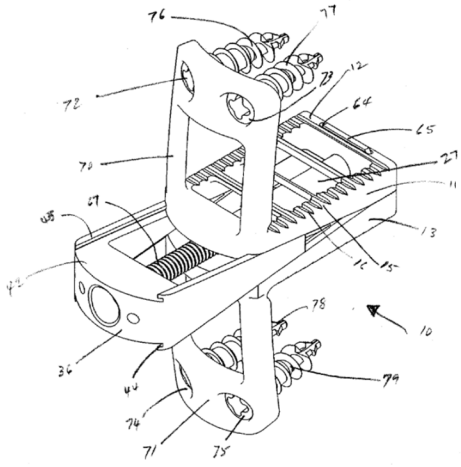


FIG. 4

Sutcliffe discloses an intervertebral expandable implant (1). EX1032 at para. [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). FIG. 6 shows how a similar pair of eyes (6) can be formed on the upper end part (4) to anchor it to the superior vertebra. EX1032 at para. [0024]; and FIG. 6. One or more through-going holes (13) are present in upper and lower parts (3) and (4). *Id.* at para. [0023]; and FIG. 6 (shown below). Sutcliffe teaches that this configuration with the screws angled is particularly advantageous because it is more accommodating for implantation, particularly at the lower end of the vertebrae above the sacral vertebrae. EX1032 at para. [0010]. EX1003 at ¶ 101.

A PHOSITA would have understood that collars (7) defining holes or passages (8) serve as screw guides that constrain the position and direction of screws (9) into the superior and inferior vertebral bodies. Further, a PHOSITA would have understood that one or more through-going holes (61) in Baynham define a first centerline axis and the upper and lower collars (7) define first and second screw guides with centerline axes at mutual angles to each other and to the first centerline axis. EX1003 at ¶ 102.

A PHOSITA would have understood that the integral screw guides disclosed by Sutcliffe provide equivalent function to the brackets and screws disclosed by Baynham. Further, a PHOSITA would have understood that the recessed screw

heads disclosed by Sutcliffe offer advantages compared to a bracket and screw. Particularly, relocating and recessing the screw heads as disclosed in Sutcliffe eliminates the presence of prominent hardware on the anterior vertebral surface. Recessing the screw heads can help prevent irritation of the overlying muscle tissue and/or neighboring anatomic structures such as the esophagus (in the case of cervical cages) and/or the neighboring aorta and/or inferior vena cava (in the case of thoracic or lumbar cages). A PHOSITA would have understood, therefore, that it is desirable to eliminate the presence of prominent hardware. A PHOSITA would have further understood that the use of screws that are angled with respect to each other provides a higher pullout strength of the construct compared to parallel screw configurations. EX1003 at ¶ 103.

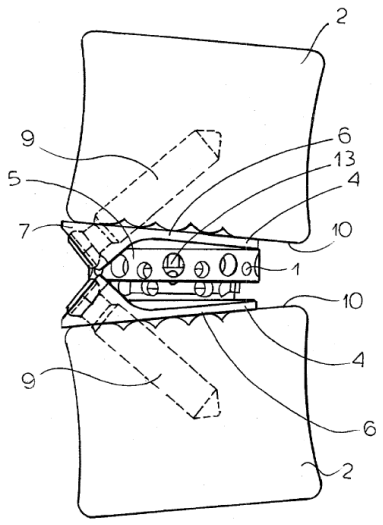


FIG.6

26. A method of using the system of claim 21 to insert the intervertebral expandable implant into a disc space of a spine from an anterior or lateral path, the method comprising:

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

implanting the intervertebral expandable implant into the disc space via the first tool;

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

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

As discussed above with respect to claim [1.10-1.11], 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 second implant structure of Baynham in combination with McLuen, to insert the intervertebral expandable 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 drive the adjusting screw to expand the implant of Baynham. EX1003 at ¶ 104.

Furthermore, Baynham discloses an embodiment 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 para. [0031]. EX1003 at ¶ 105.

The upper section has a bracket (70) attached to the trailing end wall. As shown, the bracket extends normal to the top surface (12) in a direction away from the distractor (42). The lower section (13) has a bracket (71) attached to the trailing end wall and extending in the opposite direction from the lower section. Each bracket (70), (71) is shown with counter sunk apertures (72), (73), (74) and (75). Bone screws (76), (77), (78) and (79) are inserted into the apertures and threaded into the vertebrae. EX1029 at para. [0032]; and FIG. 4 (shown below). EX1003 at ¶ 105.

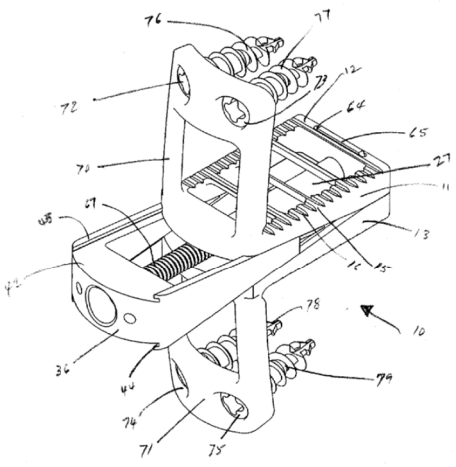


FIG. 4

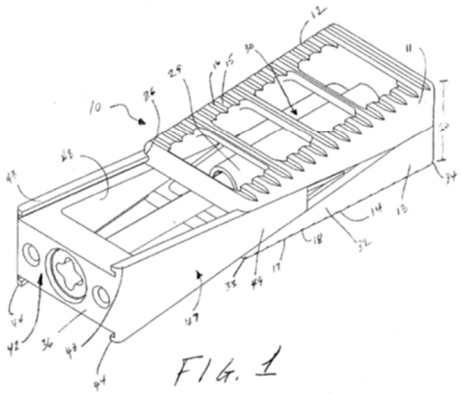


FIG. 1

A PHOSITA would have understood that certain embodiments depicted in Baynham would be typical for a lateral or anterior approach for an intervertebral fusion device. For example, a plate structure shown in FIG. 4 would require a larger surgical window than can be achieved through a posterior approach and the posterior

elements would obstruct the passage of the bracket through surgical window; the embodiment is for a lateral or anterior approach. This geometry is more typically be used for an anterior or lateral approach. Further, a PHOSITA would have understood that form factor and size of the implant depicted in FIG. 1 (shown above) could be further adapted for use in an anterior application, which would be a simple design choice that would yield a predictable result. EX1003 at ¶ 106.

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

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

all other cases that are on Judge Goldberg's docket, even those subsequently filed, and at a time when many cases are delayed because of COVID-19. The expectation is for a trial date in 2022/2023.[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

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

intent—to refuse Petitioner access to the efficiencies intended through this forum.

XII. CONCLUSION

Petitioner has demonstrated in this Petition that the Challenged Claims are unpatentable. Petitioner, therefore, respectfully requests institution of an IPR of the '268 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. 10,307, 268 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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