

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

MOSKOWITZ FAMILY LLC.
Patent Owner

Patent No. 11,376,136

**DECLARATION OF MR. BRAD CULBERT
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,376,136**

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I, Brad Culbert, declare as follows:

I. INTRODUCTION

1. I have been retained as an independent expert consultant by Medtronic, Inc. (“Petitioner”) in this proceeding before the United States Patent and Trademark Office regarding U.S. Patent No. 11,376,136 (“the ’136 patent”) (Ex. 1001) assigned to Moskowitz Family LLC (“Patent Owner”).¹ I have been asked to consider whether prior art references disclose or suggest the features recited in claims 9-12, 14-18, and 20 (the “challenged claims”) of the ’136 patent. My opinions are set forth below.

2. I am being compensated at my standard rate for services provided in this matter and reimbursed for reasonable expenses, including travel. My compensation is not contingent upon my opinions, the outcome of this matter, or any of the technical positions I present in this declaration.

II. BACKGROUND AND QUALIFICATIONS

3. My qualifications are stated more fully in my curriculum vitae (“CV”), which is attached as Exhibit 1003. My CV also lists patents and publications on

¹ In this Declaration, I refer to exhibits that I understand are to be attached to the petition for *Inter Partes* Review of the ’136 patent.

which I am a named author and identifies parties on behalf of whom I have previously provided expert testimony.

4. I believe that I qualify as an expert in the field of intervertebral spinal implants, and as at least a person of ordinary skill in the art (*see* Section IV below). Below is a summary of my education, work experience, and other qualifications.

5. I am a medical device engineer with substantial experience designing and developing spinal implants for treating damaged and diseased vertebrae.

6. I earned a Bachelor of Applied Science in Metals and Materials Engineering from the University of British Columbia in 1992, followed by a Master of Business Administration from California State University, Fullerton in 2001.

7. From 1994 to 1996, I worked as a manufacturing engineer and later served as the Angioplasty Product Team Leader at Vas-Cath, a medical device company specializing in dialysis and angioplasty catheters. In that role, I oversaw a multi-functional team of R&D, manufacturing, and quality engineers to improve the company's product lines.

8. From 1996 to 1998, I worked as an R&D Project Manager at CVD, a medical device company specializing in angioplasty balloons and stents. In that role, I designed and developed new catheters and stent delivery systems. I also contributed to the preparation and submission of regulatory documents for those products.

9. From 1998 to 2000, I worked as Senior R&D Project Manager at Endicor Medical, Inc, a medical device company specializing in percutaneous thrombectomy and atherectomy systems for cardiovascular and neurovascular applications. In that role, I designed and prototyped a new thrombectomy system, including developing animal models to satisfy FDA requirements.

10. From 2000 to 2010, I worked at Interventional Spine, Inc. (formerly known as Triage Medical, Inc.), a medical device company specializing in spinal and orthopedic trauma products. I was their first employee and started as Director of Engineering before being promoted to Vice President of R&D, and ultimately Chief Technology Officer. In these roles, I oversaw the design and development of a series of percutaneous spine procedures and devices, while leading and managing employees who were also considered persons of ordinary skill in the art.

11. With nearly 10 years of experience designing spinal fusion implants, I gained extensive familiarity with the surgical techniques used in these procedures. I attended many surgical conferences and lectures worldwide and was present for dozens of spinal fusion surgeries, collaborating closely with surgeons to develop implants, instruments, and surgical techniques. My work also included hosting hands-on cadaver laboratories, where I both assisted in surgical practice and trained new surgeons in the use of the implants, including performing cadaver surgeries myself as part of the training process.

12. Based on my experience at Interventional Spine, I am highly familiar with the anatomy of the spine and vertebrae, as well as intervertebral fusion devices designed for insertion into the intervertebral disc space. I also have extensive knowledge of supplemental fixation methods, such as anterior plates, used to secure implants after insertion, along with the surgical procedures and tools associated with intervertebral fusion devices.

13. Since 2010, I have operated a consulting business advising medical device companies, including those focused on spinal implant technology. My work spans a wide range of areas, including product development, regulatory approval, manufacturing, and intellectual property.

14. In addition to my professional experience and education discussed above, I am also listed as an inventor on over 30 U.S. patents relating to devices and methods for treating the spine. Many of my patents relate specifically to intervertebral spinal implants for insertion into the intervertebral space, including, for example, U.S. Patent Nos. 8,105,382; 8,568,481; and 10,390,963.

III. MATERIALS REVIEWED

15. The opinions contained in this Declaration are based on the documents I reviewed, my professional judgment, as well as my education, experience, and knowledge regarding spinal implants, including those that are inserted in the disc space between vertebrae.

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16. In forming my opinions expressed in this Declaration, I reviewed the following materials:

Ex. 1001	U.S. Patent No. 11,376,136 to Moskowitz et al. (“the ’136 patent”)
Ex. 1004	File History for U.S. Patent No. 11,376,136
Ex. 1006	U.S. Patent Application Publication No. 2008/0249569 A1 to Waugh et al. (“Waugh”)
Ex. 1012	U.S. Patent Application Publication No. 2006/0253201 A1 to McLuen (“McLuen”)
Ex. 1013	U.S. Patent Application Publication No. 2005/0278026 A1 to Gordon et al. (“Gordon”)
Ex. 1014	International Publication No. WO 02/062272 A2 to Michelson (“Michelson”)
Ex. 1020	Phulchand Prithvi Raj, <i>Intervertebral Disc: Anatomy-Physiology-Pathophysiology-Treatment</i> , 8(1) PAIN PRACT. 18 (2008)
Ex. 1021	Fabio Galbusera et al., <i>Ageing and degenerative changes of the intervertebral disc and their impact on spinal flexibility</i> , 23(3) EUR. SPINE J. 324 (2014)
Ex. 1022	Dil Patel et al., <i>Interbody options in lumbar fusion</i> , 5(1) J. SPINE SURG. S19 (2019)
Ex. 1037	Daniel Orr et al., <i>Expandable interbody cages for lumbar spinal fusion: a systematic review</i> , 25(8) SPINE J. 1773 (2025)
Ex. 1053	U.S. Patent No. 7,846,188 to Moskowitz et al. (“the ’188 patent”)

17. I also considered any other documents and materials I refer to in this Declaration.

18. My opinions have also been guided by my appreciation of how a person of ordinary skill in the art (a “POSITA”) would have understood the state of the art, the prior art, and the claims and the specification of the ’136 patent at the time of the alleged invention, which I discuss below.

19. I have been asked to consider that the time of the alleged invention of the ’136 patent was mid-2000s (including the time leading up to August 21, 2007).²

20. Based on my experience and expertise, it is my opinion that certain references disclose or suggest all of the features recited in claims 9-12, 14-18, and 20 of the ’136 patent, as I discuss in detail below.

IV. PERSON OF ORDINARY SKILL IN THE ART

21. I am familiar with the level of ordinary skill in the art regarding the ’136 patent in the mid-2000s. Considering the ’136 patent, the technology, the educational level and experience of workers in the field relating to the patent, and problems and solutions in that field, and drawing on my own experience, I believe a POSITA at the time of the alleged invention (mid-2000s, including the time leading

² The ’136 patent issued on July 5, 2022, from U.S. Application No. 16/744,755 (“the ’755 application”), filed on January 16, 2020. The ’755 application claims priority, through a series of continuation applications, to U.S. Application No. 11/842,855 (“the ’855 application”), filed on August 21, 2007.

up to August 21, 2007) would have a bachelor's or equivalent degree in Mechanical Engineering or a related discipline (*e.g.*, biomechanics, biomedical or metals and materials engineering), and at least five years of experience. A person could have qualified as a POSITA with some combination of (a) more formal education and less technical or professional experience in the listed fields, or (b) less formal education and more technical or professional experience in the listed fields. In other words, more education can supplement practical experience and vice versa. For example, a POSITA could have an advanced degree in the technical disciplines provided above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

22. My opinions in this Declaration regarding the '136 patent and the prior art (including the state of the art) are from the perspective of a POSITA during the relevant timeframe, as I defined above.

V. TECHNICAL BACKGROUND

23. Below, I present a brief overview of the anatomy of the spine and intervertebral fusion devices, including several advancements in the field. The functionalities and concepts I describe below in this technical background section reflect the state of the art that a POSITA would have understood prior to and at the time of the alleged invention of the '136 patent. I rely on and incorporate as applicable (even if not expressly mentioned below) the following disclosures and

opinions to support my opinions in this Declaration, including those opinions relating to how the prior art discloses or suggests the subject matter of the challenged claim of the '136 patent, as I explain below in Section VIII and in the Appendices. The concepts below would have been within the knowledge and mindset of a POSITA during the relevant time frame (mid-2000s, including the time leading up to August 21, 2007).

A. Anatomy of the Spine and Intervertebral Discs

24. The human spine, or spinal column, is the body's central support structure that protects the spinal cord and allows flexibility for movement. (See Ex. 1020, 1-2.) The figure below "shows a lateral view of a portion of a spinal column 10, illustrating a group of adjacent upper and lower vertebrae V1, V2, V3, V4 separated by natural intervertebral discs D1, D2, D3." (Ex. 1006, [0025].)

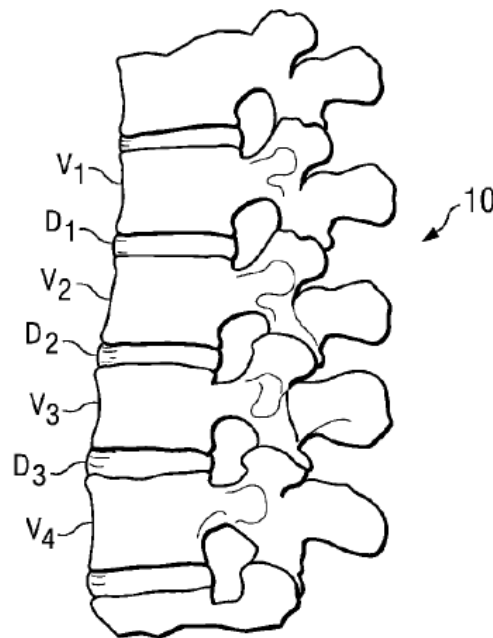


Fig. 1

(*Id.*, Fig. 1.)

25. These discs, however, can become damaged due to various degenerative diseases, aging, trauma, and mechanical stress. (*See* Ex. 1020, 6-9; *see also* Ex. 1021, 2-3.) Damaged discs can bulge and lose height, which, in turn, can cause compression of nearby nerves, reduce the discs' ability to absorb mechanical loads, and lead to decreased mobility. (*See* Ex. 1020, 9-10.)

B. Expandable Intervertebral Fusion Devices and Surgical Tools for Installing the Devices

26. When spinal disc injury is severe, surgical intervention may be needed. For example, in a discectomy, the surgeon removes all or part of the damaged disc, followed by placement of an implant that can fuse adjacent vertebrae. (*See id.*,

15-20; *see also* Ex. 1022, 2.) These implants, known as intervertebral or interbody fusion devices, are positioned between adjacent vertebrae and may employ various components, such as screws, to achieve fusion with the vertebrae. (*See* Ex. 1022, 1-3.)

27. By the early 2000s, expandable intervertebral fusion devices emerged as a less invasive alternative to non-expandable devices. (*See* Ex. 1037, 1.) Unlike non-expandable devices, expandable devices are inserted into the disc space in a collapsed configuration and then expanded once in place. (*Id.*) As I discuss below in Section VIII, various expandable intervertebral fusion devices and the surgical tools for installing these devices were known before the time of the alleged invention (mid-2000s, including the time leading up to August 21, 2007).

VI. THE '136 PATENT

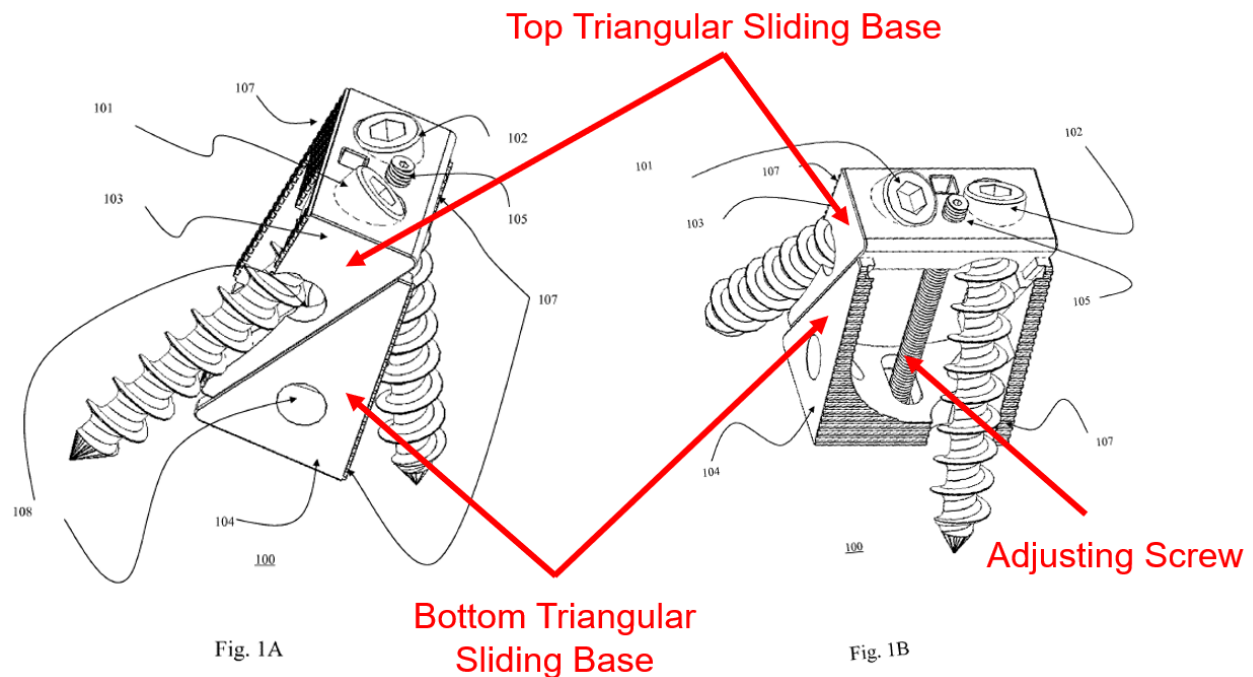
A. Overview of the '136 Patent

28. The '136 patent generally relates to spinal devices, expandable and non-expandable, designed for insertion into the disc space between adjacent vertebrae. (*See generally* Ex. 1001.)

29. With reference to the embodiment shown in figures 1A-1B (reproduced below), the '136 patent discloses an expanding screw box with top and bottom triangular sliding bases 103 and 104. (*Id.*, 2:64-3:1, 7:48-51, 7:55-56.) Turning adjusting screw 105 moves the triangular sliding bases 103, 104 apart, resulting in

the expansion of the device. (*Id.*, 7:59-67.) This allows for an “individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.”

(*Id.*)



(*Id.*, Figs. 1A-1B (both annotated).)

30. The '136 patent also discloses a tool assembly 500 for inserting and expanding the implant. (*Id.*, Figs. 5A-5G.) The tool assembly has a griper 504 with griper prongs 506, a handle 503, and an Allen key 501. (*See, e.g., id.*, 8:61-9:7.)³

³ While the '136 patent uses the term “griper,” the term is usually spelled as “gripper.” The '136 patent uses the correct spelling in another part of the

As shown in figure 5C below (the exploded view of the tool assembly), griper 804, handle 503, and Allen key 501 include shafts of varying diameters.

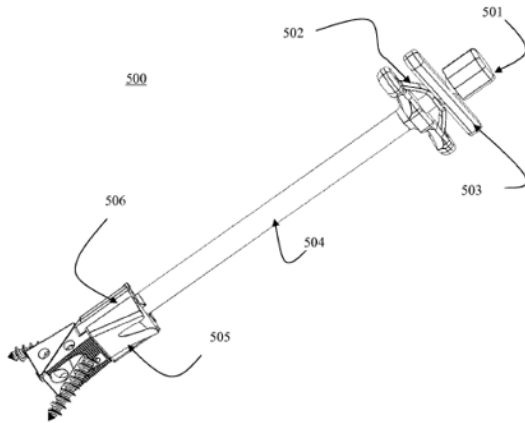


Fig. 5A

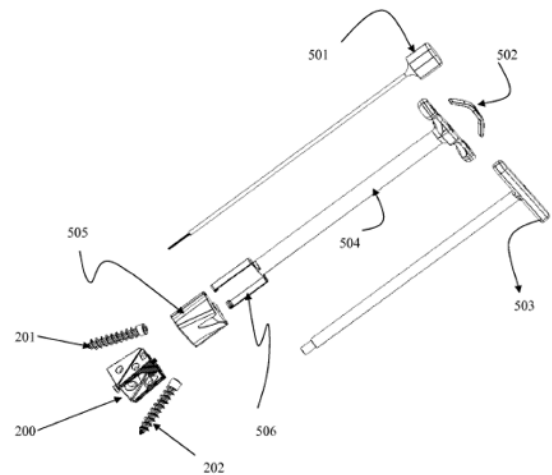


Fig. 5C

(*Id.*, Figs. 5A, 5C.)

31. The '136 patent discloses that after inserting the Allen key 501 into the handle 503, the handle 503 may then be inserted through the griper 504, as shown in figures 5E-5F below. (*See id.*, 9:13-16.)

specification. (Ex. 1001, 5:57-62 (“In another general aspect, a tool assembly ... includes a handle, a gripper cooperating with the handle . . .”).)

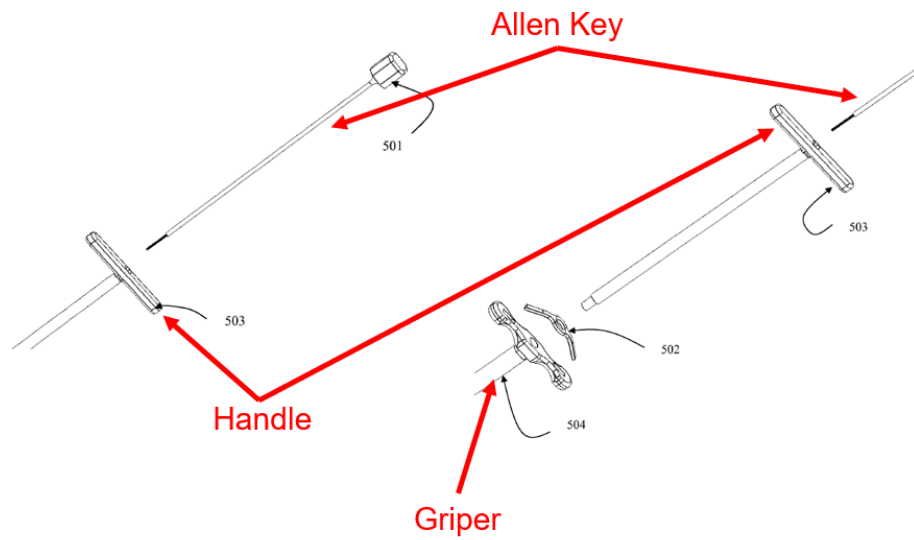
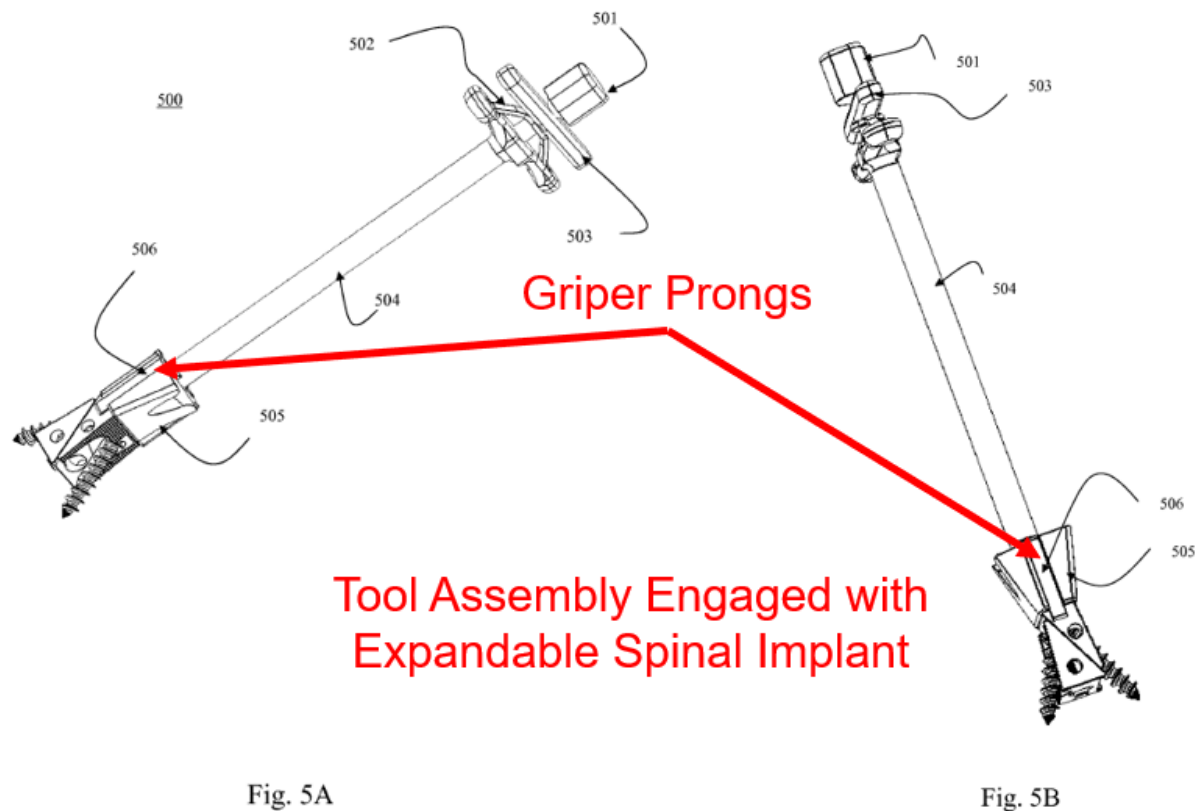


Fig. 5E

Fig. 5F

(*Id.*, Figs. 5E-5F (both annotated).)

32. The '136 patent further discloses that “[t]he griper 504 has griper prongs 506 which insert into grooves of the screw guide 505” for alignment. (*See, e.g., id.*, 9:4-7.)



(*Id.*, Figs. 5A-5B (both annotated).)

B. Claims 9-12, 14-18, and 20 Are Not Supported by Any Pre-2007 Applications in the Priority Chain of the '136 Patent

33. I have reviewed the pre-2007 applications in the priority chain of the '136 patent. Specifically, as I noted above in footnote 2, the '136 patent claims priority, through a series of continuation applications, to the '855 application, filed on August 21, 2007. The '855 application is a *continuation-in-part* of U.S. Application No. 11/536,815 ("the '815 application"), filed on September 29, 2006, now U.S. Patent No. 7,846,188 issued on Dec. 7, 2010, which is a continuation-in-part of U.S. Application No. 11/208,644, filed on August 23, 2005, now U.S. Patent

No. 7,704,279 issued on April 27, 2010. The '136 patent also claims the benefit of U.S. Provisional Application No. 60/670,231, filed on April 12, 2005.

34. None of the applications prior to the '855 application disclose or provide support for a system comprising an expandable spinal implant, **“wherein the expandable spinal implant defines first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, wherein the first tool engagement portion is formed in first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant,”**⁴ as recited in claim 9 of the '136 patent. (Ex. 1001, 15:55-62.)

35. Similarly, none of the applications prior to the '855 application disclose or provide support for a system comprising two tools that cooperate with each other for implanting the expandable spinal implant, let alone the details of these two tools required by claim 9:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes

⁴ From here onwards, I bold all claim language and show any special emphasis in italics.

first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis, *wherein the first tool defines an adjusting tool passage through the first tool*; and

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

(*Id.*, 15:22-41.)

36. For example, the '855 application has totally different figures compared to the '815 application filed on September 29, 2006, which issued as U.S. Patent No. 7,846,188 ("the '188 patent") (Ex. 1053). The '815 application does not disclose the limitation, **"wherein the expandable spinal implant defines first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, wherein the first tool engagement portion is formed in first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant,"** as recited in claim 9. Instead, as shown

below, figures 1A and 1B of the '815 application allegedly depict a “bidirectional fixating transvertebral screw.” (Ex. 1053, 4:59-63.)

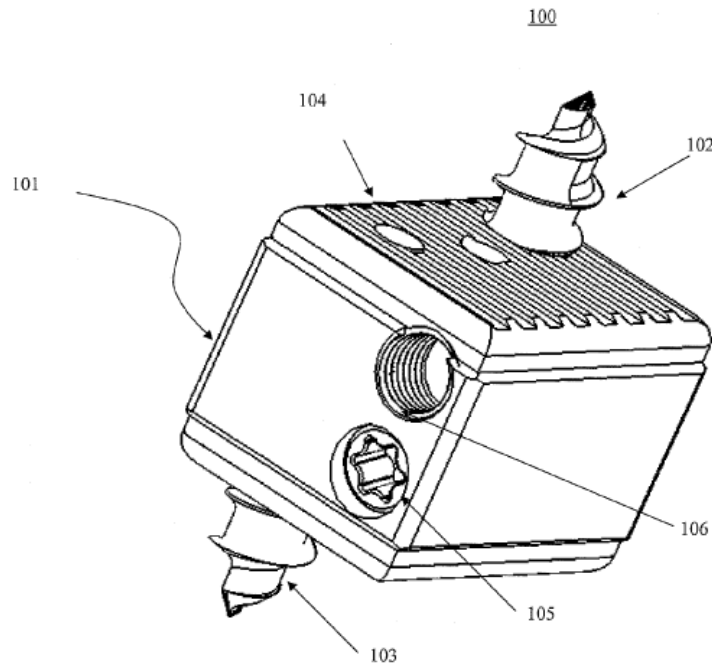


Fig. 1A

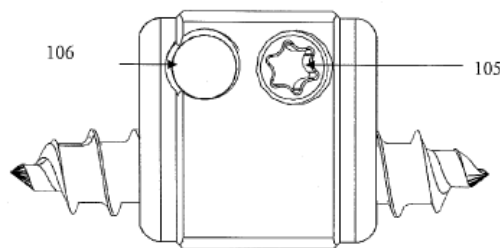


Fig. 1B

(*Id.*, Figs. 1A-1B.)

37. Moreover, none of the figures in the '815 application disclose “a **first tool**” and “a **second adjusting tool . . . includ[ing] a screw engagement portion positioned at the second distal end**” with tool passages in which the second tool can pass through the first tool passage as required by claim 9 (*e.g.*, “**wherein the**

first tool defines an adjusting tool passage through the first tool” and “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 the extent the ’815 application discloses any tool, it is an “interarticular joint stapling device with staple,” as depicted below in figures 8A-8B. (Ex. 1053, 5:25-27, 9:51-54.) The ’815 application does not disclose that this interarticular joint stapling device includes the above-noted features related to a **“first tool”** and **“second adjusting tool”** of claim 9.

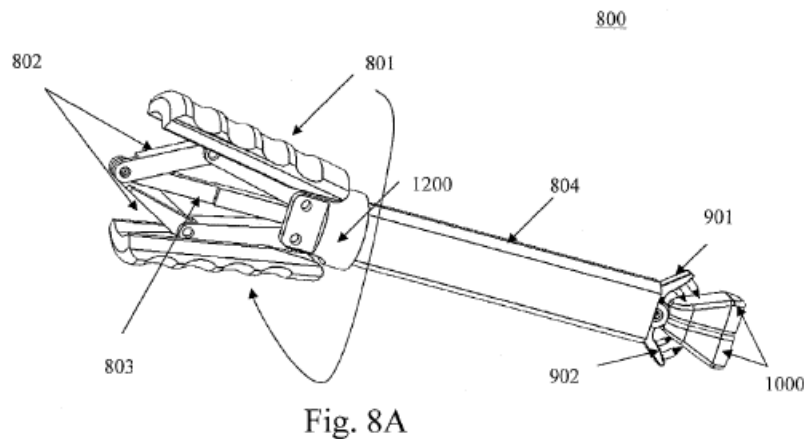


Fig. 8A

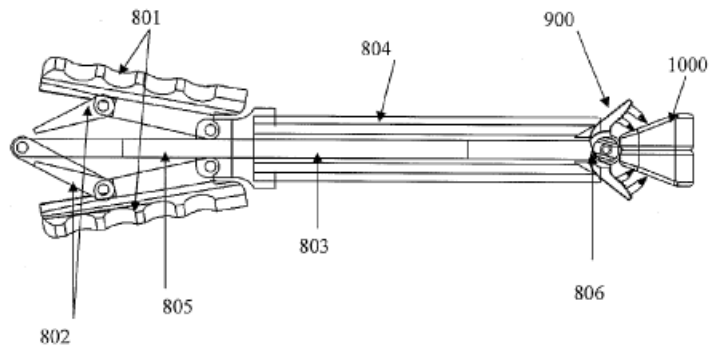


Fig. 8B

(*Id.*, Figs. 8A-8B.)

38. The '815 application and its prior applications also do not support the limitations of claim 18 of the '136 patent for similar reasons. For example, claim 18 recites features similar to those discussed above with respect to claim 9, which are not supported by the '815 application:

A system comprising:

...

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement extensions positioned at the first distal end axially offset from the first tool axis, *wherein the first tool defines an adjusting tool passage through the first tool*; and a second adjusting tool having a second proximal end and a second distal end, *wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool*; and an expandable spinal implant sized and configured to be implanted in a human spine,

...

wherein the expandable spinal implant defines one or more tool engagement portions sized, shaped, and configured for engaging with the gripper of the first tool,

...

wherein at least one of the one or more tool engagement portions of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more

engagement extensions of the gripper is positioned in the one or more tool engagement portions on the one or more side surfaces of the expandable spinal implant when the first tool is engaged with the expandable spinal implant.

(*Id.*, 17:1-53.)

39. The '815 application and its prior applications do not support the features of claims 10-12, 14-17, and 20 because they are dependent on claims 9 or 18.

VII. CLAIM CONSTRUCTION

40. I understand that when considering the meaning of patent claims, one must consider the language of the claims, the specification, and the prosecution history of the patent. I also understand that claim terms are typically given their ordinary and customary meanings as would have been understood by a POSITA at the time of the invention for the patent. For purposes of my opinions in this Declaration, I have not expressly construed any claim term because the prior art discloses or suggests each claim limitation under any reasonable construction.

VIII. THE PRIOR ART

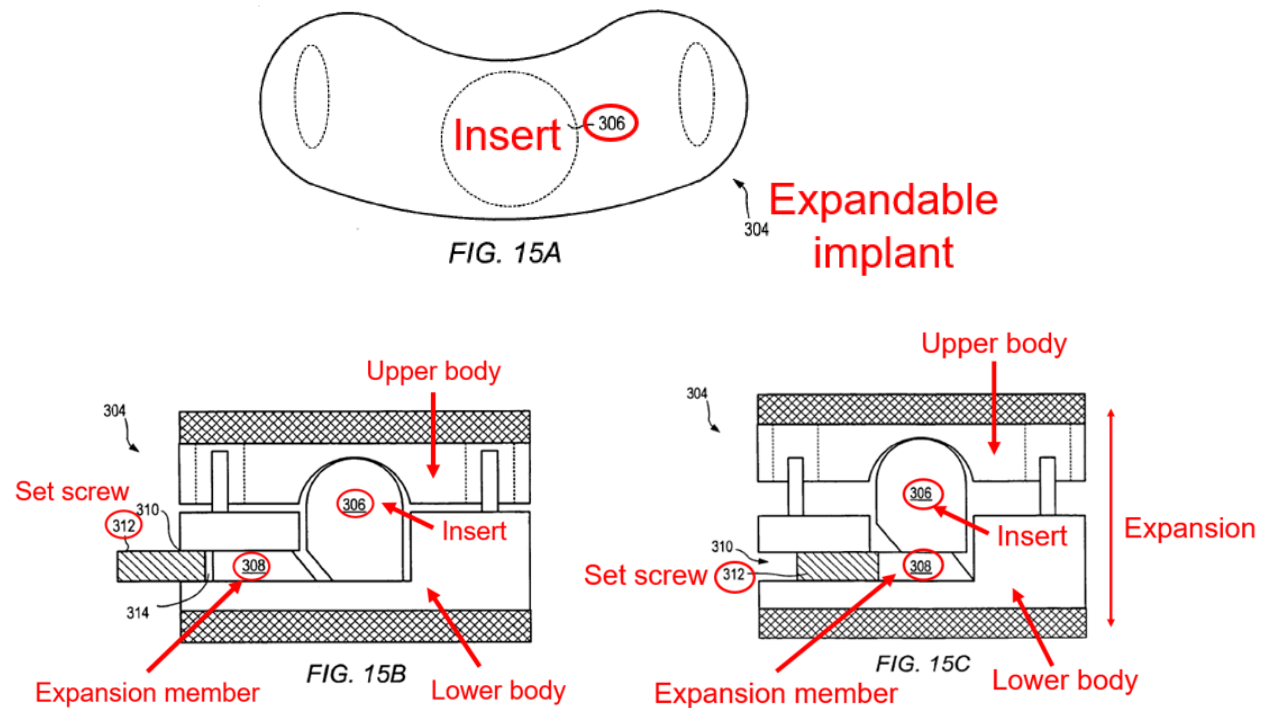
41. I provide a detailed explanation of my opinions for each element of the challenged claims in the Appendices. In this section, I address the relevant disclosures of Gordon, McLuen, and Michelson, as well as concepts known in the art at the time of the alleged invention. I also address some of the key issues.

A. Gordon

1. Overview of Gordon

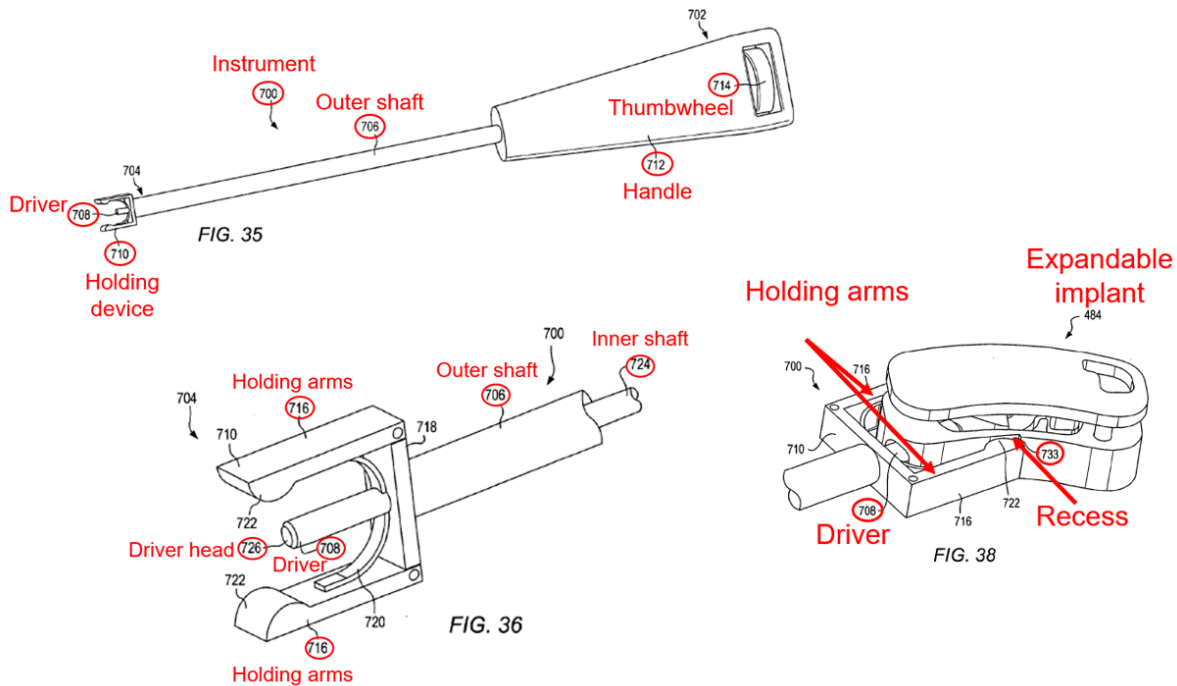
42. Gordon is titled “Expandable Intervertebral Implant with Wedged Expansion Member.” Gordon discloses examples of expandable intervertebral implants for insertion between adjacent vertebrae and associated tool assemblies. (Ex. 1013, [0177]; *see also id.*, [0006]-[0008], [0013]-[0015], [0022]-[0025], [0137]-[0139].) According to Gordon, “[e]mbodiments of the invention generally relate to functional spinal implant assemblies for insertion into an intervertebral space between adjacent vertebrae of a human spine” (*Id.*, [0003].)

43. As shown below, Gordon’s figure 15A below “depicts a top view” of its expandable implant 304, and figures 15B and 15C below illustrate “cross-sectional views of implant 304 before and after expansion, respectively.” (*Id.*, [0177].) Gordon’s implant 304 includes an upper expandable body, lower expandable body, insert 306, expansion member 308, and advancing element 312, which may be a set screw. (*Id.*, [0177], [0197], Figs. 15A-15C.) The screw 312 moves expansion member 308 beneath insert 306, which pushes insert 306 upward. (*Id.*)



(*Id.*, Figs. 15B-15C (all annotated).)

44. Furthermore, as shown below in figures 35-36 and 38 below, Gordon discloses an instrument 700 for insertion of its expandable implants. Instrument 700 includes outer shaft 706, handle 712, and holding device 710 with holding arms 716. (*Id.*, [0226]-[0243], Figs. 35-38; *see also id.*, Abstract, [0003], [0022]-[0025], [0137]-[0144], Figs. 39-42.) Holding arms 716 have lobes 722, which fit into side recesses 733 of the expandable implant to secure the implant during insertion and/or expansion of the implant. (*Id.*, [0231], [0237].)



(*Id.*, Figs. 35-36, 38 (all annotated).)

45. As shown above, Gordon's tool assembly also includes driver 708, which comprises an inner shaft 724 extending through outer shaft 706 and driver head 726 at the driver 708's distal end, which engages a screw of the implant. (*Id.*, [0230], [0233]-[0238].) Attached to proximal end of shaft 724 is a "control member" . . . that is operable by a user to control position, orientation, or motion of" driver 708. (*Id.*, [0228].)

2. Gordon Discloses and/or Suggests a System Including an Expandable Spinal Implant and a Tool Assembly

46. Independent claim 9 recites "[a] system" (limitation [9.pre]) comprising two tools, namely "**a first tool . . . , wherein the first tool includes first and second engagement prongs**" (limitation [9.a]) and a "**second adjusting tool**

wherein the second adjusting tool includes a second handle” (limitation [9.c]), and **“an expandable spinal implant”** (limitation [9.e]).

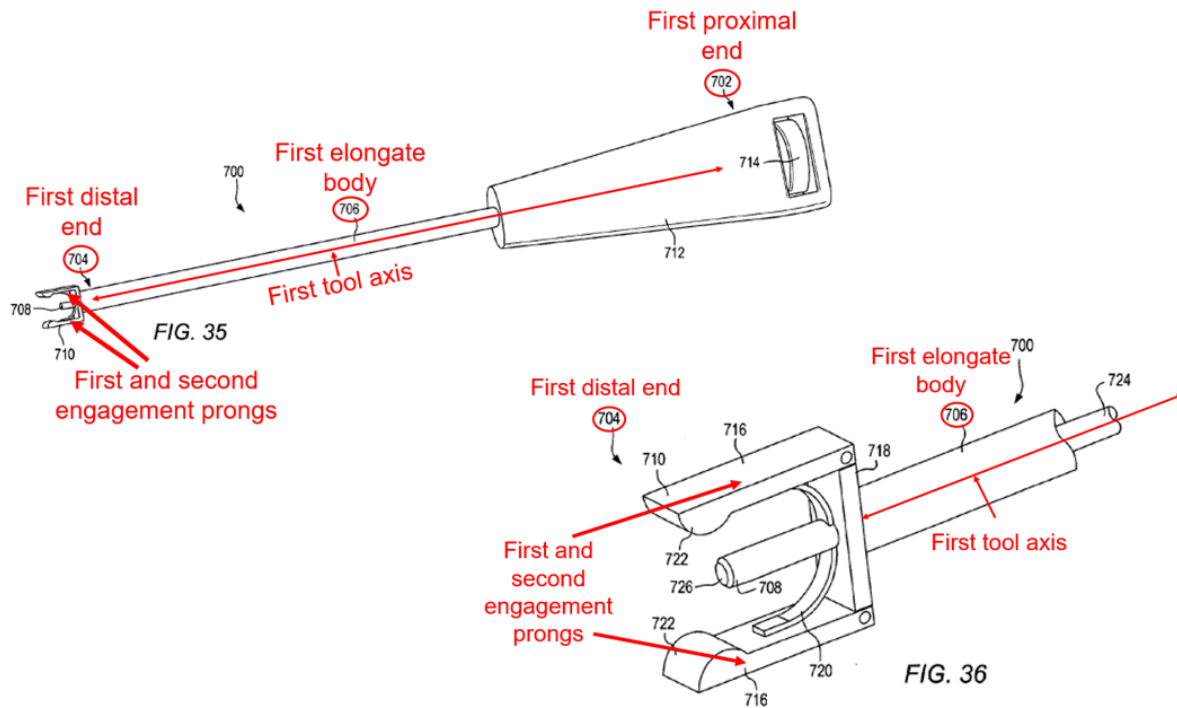
47. To the extent the preamble of claim 9, *i.e.*, “[a] system,” is limiting, Gordon discloses this limitation, as I explain below.

48. As discussed above in Section VIII.A, and below in Appendix A [9.a]-[9.j], Gordon discloses and/or suggests a system comprising **a tool assembly** and **an expandable spinal implant**.

i. Gordon Discloses a Tool Assembly Comprising Two Tools

49. First, Gordon discloses the claimed **“tool assembly,”** as recited in limitation [9.a]-[9.d]. Gordon discloses an instrument 700, *i.e.*, **“a tool assembly,”** which includes an outer shaft 706, driver 708, holding device 710, and handle 712. (Ex. 1013, [0227], [0230], Fig. 35 (reproduced below).) Outer shaft 706, holding device 710, and handle 712 collectively comprise a **“first tool,”** as they are used in coordination to hold the implant during insertion. (*Id.*, [0227]-[0236].) The **“first tool”** has a proximal end 702, *i.e.*, **“a first proximal end,”** a distal end 704, *i.e.*, **“a first distal end,”** and an outer shaft 706, *i.e.*, **“a first elongate body,”** which is between proximal end 702 and distal end 706. (*Id.*, [0227] (“Instrument 700 may include outer shaft 706 As used herein, ‘shaft’ includes elongated members having various regular and irregular cross-sections, including, but not limited to, round, square, rectangular, hexagonal, or irregular. A shaft may be solid or hollow.”))

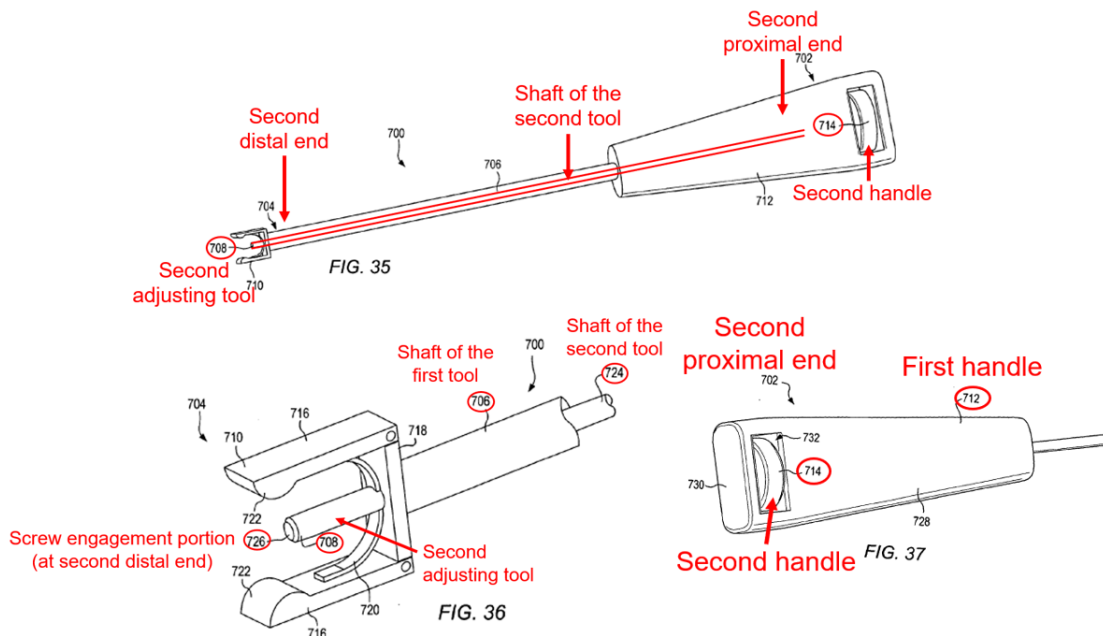
(emphasis added), [0230], Fig. 35 (reproduced below).) As shown below in figures 35-36, outer shaft 706 defines a “**first tool axis**” from its proximal end to distal end. (*Id.*, [0227].)



(*Id.*, Figs. 35-36 (both annotated).)

50. Holding device 710 “hold[s] an implant during insertion of the implant between two vertebrae.” (*Id.*, [0227], [0230].) As shown in figures 35-36 above, holding device 710 includes two holding arms 716 (“**first and second engagement prongs**”) at distal end 704 (“**positioned at the first distal end**”), where the holding arms 716 are positioned on either side of the first tool axis (“**on opposite sides of the first tool axis**”). (*Id.*, [0227], [0230]-[0231], Figs. 35-36, 38.)

51. Gordon's driver 708 is a **"second adjusting tool"** because it expands the implant by engaging with a screw of the implant with driver head 726. (*Id.*, [0230], [0233]-[0238], Fig. 36.) As shown below in figure 35, driver head 726, which may be "slotted, Phillips, square, hexagonal, or hexalobular," is **"a screw engagement portion,"** and is provided at a **"second distal end"** of driver 708. (*Id.*, [0233], Fig. 35.) Driver 708 also includes inner shaft 724 (**"a shaft"**) coupled to driver head 726. (*Id.*, [0226]-[0233], Figs. 35-36.) The "inner shaft 724 may be coupled with thumbwheel 714", which is a **"second handle"** of driver 708 and is positioned at a **"second proximal end"** of driver 708. (*Id.*; *see also id.*, [0228], Figs. 35, 37.)



(*Id.*, Figs. 35-37 (all annotated).)

52. The handle 712 is designed to be held with the thumb and forefinger of one hand on the distal end of the handle. The other hand would hold and operate thumbwheel 714 (**a second handle**) to rotate driver 708. (*Id.*, [0229].) A second hand would also be needed to “control position, orientation, or motion of” driver 708 with thumbwheel 714. (*Id.*, [0228], [0234].) Gordon further discloses that “[o]ther examples of control members include, but are not limited to, a knob, a lever, or a button.” (*Id.*, [0228].) A POSITA would have recognized that an alternative embodiment in Gordon, which uses a “knob” or “lever,” instead of a thumbwheel, would also disclose **a second handle**.

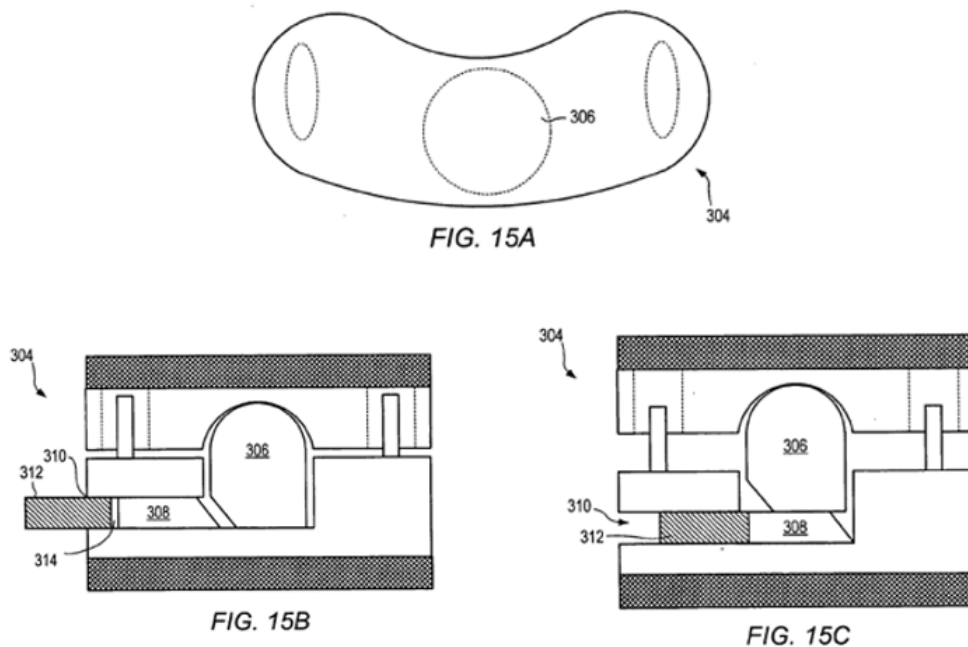
53. In my opinion, a POSITA would have understood that this understanding of Gordon’s thumbwheel 714 (or a “knob” or “lever” in an alternative embodiment) is consistent with how the ’136 patent describes the function of **a second handle**. According to the ’136 patent, Allen key 501, which corresponds to the **second adjusting tool**, has a knob similar to Gordon’s thumbwheel 714 (or a “knob” or “lever” in an alternative embodiment), to turn adjusting screw 105 with the hand that is not on the first handle. (Ex. 1001, 8:66-9:17, Figs. 5A-5D.)

ii. Gordon Discloses and/or Suggests an Expandable Spinal Implant

54. Second, Gordon discloses the claimed “**expandable spinal implant**,” as recited in limitations [9.e]-[9.j]. According to Gordon, “[e]mbodiments of [its] invention generally relate to functional spinal implant assemblies for insertion into

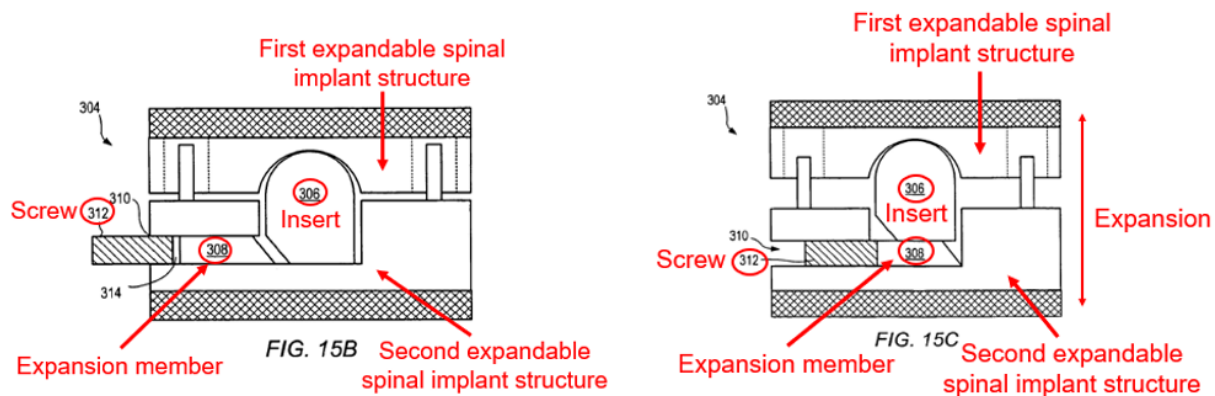
an intervertebral space between adjacent vertebrae of a human spine.” (Ex. 1013, [0003].) Gordon further discloses that “[t]he shape and/or size of an implant . . . may be chosen according to factors including, but not limited to, the surgical approach employed for insertion . . . , the intended position in the spine . . . , and a size of the patient.” (*Id.*, [0137]; *see also id.*, [0138]-[0139].)

55. As discussed in Section VIII.A, and shown in figures 15A-C below, Gordon discloses a c-shaped expandable implant for insertion between two vertebrae, *i.e.*, “**an expandable spinal implant sized and configured to be implanted in a human spine.**” (*Id.*, [0177].) Figure 15B shows the implant before expansion and figure 15C shows the implant after expansion. (*Id.*)



(*Id.*, Figs. 15A-C.)

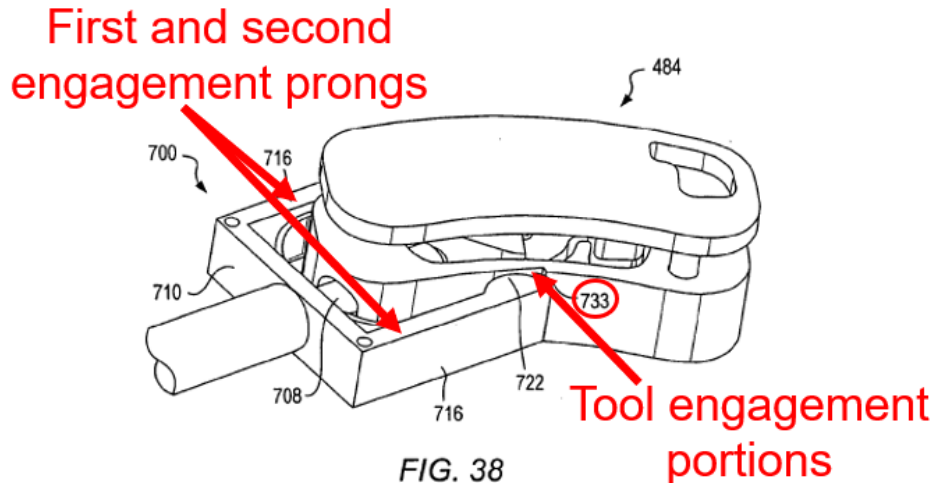
56. As shown in figures 15B-C below, Gordon's expandable spinal implant includes two expandable bodies on either side of the implant, *i.e.*, “**a first [and second] expandable spinal implant structure.**” (*Id.*, [0177].) As shown in figure 15C below, the first and second bodies expand in the vertical direction in response to rotation of advancing element 312, which moves expansion member 308 towards insert 306. (*Id.*)



(*Id.*, Figs. 15B-C (both annotated).)

57. Gordon further discloses and/or suggests that “**the expandable spinal implant defines first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool,**” as recited in limitation [9.h]. For example, Gordon discloses that holding arms 716 (**the first and second engagement prongs of the first tool**) are configured to hold securely a c-shaped expandable implant 484 by engaging holding side recesses (**first and second tool engagement portions**) of the implant. As shown in figure 38 below, implant 484 is c-shaped, just like the implant shown in figure 15, and

expressly includes holding recesses 733 configured to engage with holding arms 716. (*Id.*, [0237].)



(*Id.*, Fig. 38 (annotated).)

58. A POSITA would have understood that Gordon also suggests this limitation. In view of the above-noted disclosures within Gordon, and for additional reasons provided below, a POSITA would have been motivated to configure Gordon's c-shaped implant 304 (figures 15B-15C) to include side recesses 733, as shown in figure 38, such that implant 304 **“defines first and second tool engagement portions each defining a space that is sized, shaped, and configured for receiving the first and second engagement prongs of the first tool.”** A POSITA would have been motivated to do so in order to allow Gordon's c-shaped implant 304 to be inserted and expanded using a tool such as instrument 700. Gordon expressly teaches that instrument 700 is used “to position an implant in an

intervertebral space and to actuate an expansion member to expand the implant in the intervertebral space.” (*Id.*, [0226].) Gordon’s instrument 700 further holds a c-shaped implant 484 “after driver 708 has been operated to expand the implant,” as shown in figure 38 below. (*Id.*, [0237]; *see also id.*, [0204] (describing c-shaped implant 484 with reference to figure 25).) Holding arms 716 engage side recesses 733 of the c-shaped implant to “maintain a position of the implant during insertion and/or expansion of the implant” and to help “place implant 484 in a desired alignment for insertion between the vertebrae and engagement with an expansion tool.” (*Id.*, [0237].) For these same reasons, a POSITA would have been motivated to modify implant 304 to include recesses 733, like implant 484.

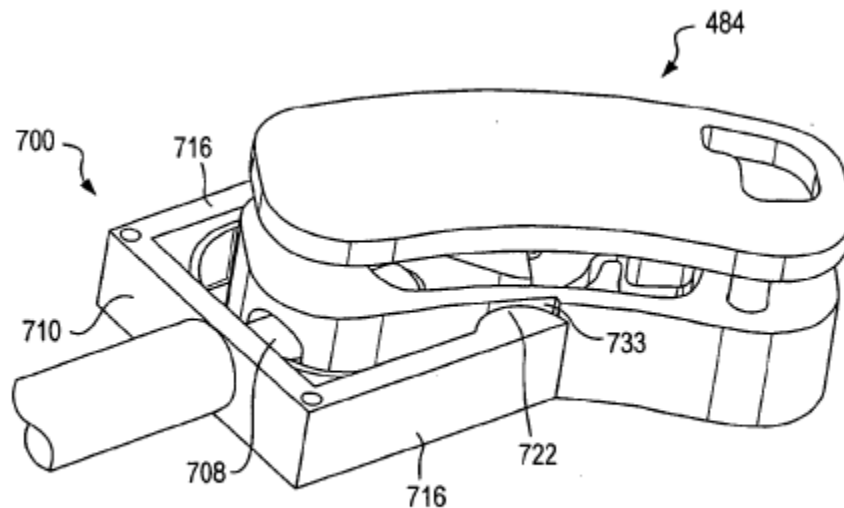


FIG. 38

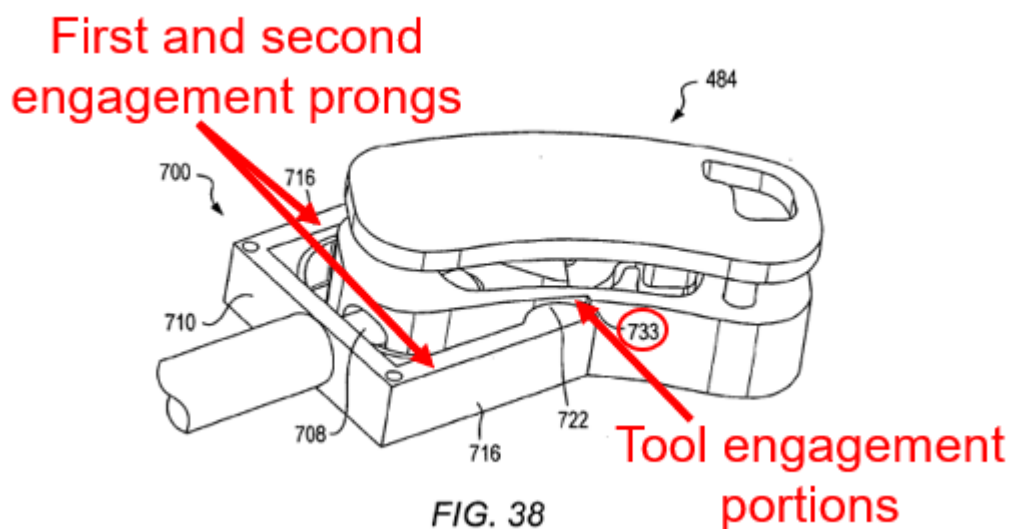
(*Id.*, Fig. 38.)

59. A POSITA would have also had a reasonable expectation of success in including recesses 733 on the sides of the implant given Gordon expressly discloses and shows such recesses in another similar embodiment, *i.e.*, the c-shaped implant 484 shown in figures 25 and 38. Gordon's implant 484 shown in figures 25 and 38 is similar to the implant 304 shown in figure 15, *e.g.*, both implants are expandable with expandable c-shaped structures on either side of the device, which are expanded based on actuation of an expansion element like a screw using driver 708. (Ex. 1013, [0177], [0204], [0233], [0237], Figs. 15-16, 25, 38.) Furthermore, instrument 700's driver head 726 "may engage a set screw . . . of an implant" to expand the implant (*id.*, [0237]), which demonstrates compatibility with implant 304 whose advancement element can also be a "set screw." (*Id.*, [0177].)

60. Limitation [9.i] recites that **"the first tool engagement portion is formed in first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant."** Gordon discloses and/or suggests this limitation.

61. For example, as shown in figure 38 below, a first recess 733 is formed in a first side surface of the implant (**"the first tool engagement portion is formed in first side surface of the expandable spinal implant"**). (Ex. 1013, [0237].) While figure 38 below does not illustrate the recess 733 on the other side, it explains that, "[w]hen implant 484 is initially coupled to holding device 710, lobes 722 of

holding arms 716 may engage in holding recesses 733 on either side of lower body 488.” (*Id.*) Based on the context of this disclosure, a POSITA would have recognized that a second recess 733 is formed in a second side surface of the implant. (*Id.*) Thus, the second recess 733 discloses “**the second tool engagement portion is formed in a second side surface of the expandable spinal implant.**” (*Id.*)



(*Id.*, Fig. 38 (annotated).)

62. Moreover, a POSITA would have understood that modification of implant 304 to include recesses 733, as I discussed with respect to limitation [9.h], implies that implant 304 also discloses limitation [9.i]. That is, a POSITA would have understood that in the modification to implant 304 to include the recesses 733, a first recess 733 would have been formed in a first side surface of the implant (“**the first tool engagement portion is formed in first side surface of the expandable spinal implant**”) and a second side recess 733 would have been formed in a second

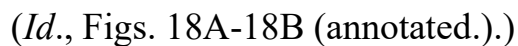
side surface of the implant (“**the second tool engagement portion is formed in a second side surface of the expandable spinal implant**”). (Ex. 1013, [0237].) As I discussed with respect to limitation [9.h], this would have allowed holding arms 716 of instrument 700 to hold securely the implant 304 on its sides during insertion and placement at the target site. (*Id.*)

B. McLuen

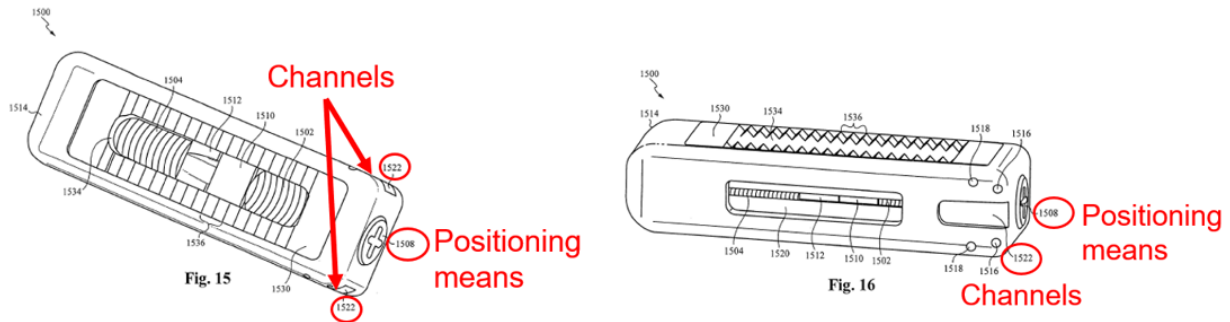
1. Overview of McLuen

63. McLuen is titled “Bone Fusion Device.” McLuen discloses “devices for fusing vertebrae of the spine that can be inserted arthroscopically.” (Ex. 1012, [0002]; *see also id.*, Abstract, [0013]-[0015] (“The present invention is a bone fusion device for insertion between bones that are to be fused together, such as, for example, the vertebrae of a spinal column . . .”).)

64. With reference to figures 15-18B, McLuen discloses a bone fusion device 1500 that includes two expandable tabs 1530 on either side of device 1500. (*Id.*, [0074]; *see also id.*, [0072]-[0073].) The bone fusion device 1500 also includes positioning means 1508 comprising first screw 1502 and second screw 1504 coupled together. (*Id.*, [0074].) “The positioning means 1508 is coupled to a first extending block 1510 and a second extending block 1512,” as shown in figure 18A below. (*Id.*) McLuen also discloses that, “[w]hen the positioning means 1508 is turned appropriately, the extending blocks 1510 and 1512 each travel outwardly on their



36



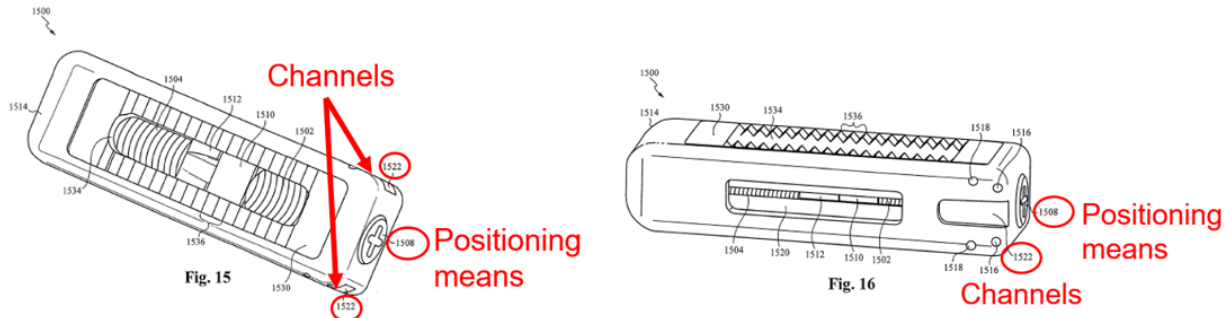
(*Id.*, Figs. 15-16 (annotated).)

66. Thus, McLuen discloses a system comprising bone fusion device 1500 and the type of tools needed to install bone fusion device 1500.

2. McLuen in View of Gordon Discloses and/or Suggests a System Including an Expandable Spinal Implant and a Tool Assembly

67. McLuen and Gordon disclose and/or suggest this limitation. The “**system**” recited in claim 9 claims the combination of an expandable implant (limitations [9.e]-[9.j]) and a tool assembly for use in securing and expanding the implant (limitations [9.a]-[9.d]). As discussed above in Section VIII.B.1 and further below in Appendix B [9.e]-[9.j], McLuen discloses a system comprising a spinal implant (*e.g.*, bone fusion device 1500) and a tool for securing and expanding that implant. For example, McLuen explains that use of its spinal implant requires tools with both (1) a screwdriver or similar implement; and (2) another tool that fits into channels on the implant to secure it in place and keep the screwdriver from slipping. (Ex. 1012, [0076] (“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 . . .

[C]hannels 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.”.)



(*Id.*, Figs. 15-16 (annotated).)

68. As discussed above in Section VIII.A.2, Gordon also discloses “[a] **system**” including a spinal implant and a tool assembly for use therewith.

69. The combination of McLuen in view of Gordon further suggests claim 9’s “**system**” limitation and the subject matter of claim 9, as a whole. While McLuen provides significant discussion about its expandable implant, it does not illustrate its complete tool assembly for securing and expanding the implant. McLuen nevertheless provides sufficient disclosure for a POSITA to recognize other prior art tool assemblies that would achieve those functions, such as the Gordon tool assembly.

70. There are several reasons why a POSITA would have been motivated to combine the teachings of McLuen and Gordon. Like McLuen, Gordon discloses

a spinal implant that uses a tool assembly to expand the implant, as explained in Appendix A [9.a]-[9.d]. The Gordon implant is expanded in response to a tool rotating a screw 312 located at the proximal end of the implant, like the McLuen implant. (*Compare* Ex. 1013, [0177], [0233], [0237], Fig. 38 *with* Ex. 1012, [0076], Fig. 15.) Gordon also discloses an implant with recesses 733, which are similar to channels 1522 in McLuen, for engagement with a tool assembly. Given these structural similarities, a POSITA would have been motivated to use Gordon's tool assembly to deliver and expand McLuen's bone fusion device 1500.

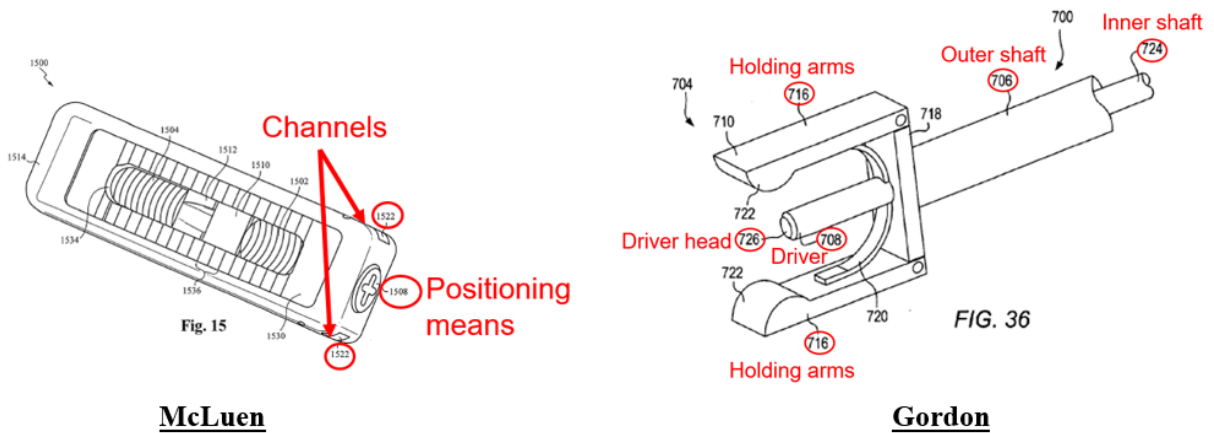
71. A POSITA would have been particularly motivated to use Gordon's tool assembly with McLuen's implant because Gordon's tool assembly is designed to prevent the screwdriver from slipping off the implant during the expansion process. According to McLuen, one skilled in the art would have recognized that "[s]crew drivers unfortunately have the ability to slip out of place" and "[w]hen performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability." (Ex. 1012, [0076].) Gordon's tool assembly addressed this problem by providing a mechanism for holding the implant securely at the target site (with holding device 710) while driver 708 rotates the implant's expansion screw. A POSITA would have recognized that McLuen's spinal implant could also use that mechanism because it has a recess 1522 for engaging the lobes 722 in Gordon's tool assembly, just like Gordon's implant.

72. A POSITA would have also been motivated to use the Gordon tool assembly with the McLuen implant because it offers the advantage of a tool assembly that can both deliver the implant to its desired location and securely expand it when it is in position. (Ex. 1013, [0226]-[0243].) A tool assembly that could be used for both insertion and expansion of the implant, like Gordon's, would be ideal because use of multiple, standalone tools could disrupt the patient's surgical opening and require more time and effort by the surgeon. Moreover, if the tool used to hold and deliver the implant is pulled out after the implant is delivered at a target site, then it would have been difficult to find the screw and insert the screw driver into the screw. Gordon's tool assembly design allows for alignment of the holding tool and the screw driver such that they can easily lock in place.

73. Given the apparent cooperative nature between Gordon's tool assembly and McLuen's implant, a POSITA would have also had a reasonable expectation of success in using Gordon's tool assembly to deliver and securely expand McLuen's fusion device 1500. For instance, Gordon discloses that driver head 726 in its tool assembly can take "various forms suitable for actuating (*e.g.*, rotating, advancing) a portion of an expansion member or insert" to expand the implant. (*Id.*, [0233], Figs. 36, 38.) As shown in the figures below, in the McLuen-Gordon combination, Gordon's driver head 726 would have engaged the screw head of McLuen's

positioning means 1508 to adjust the height of the bone fusion device 1500. (*Id.*)⁵

Moreover, Gordon's holding device 710 includes holding arms 716, which as shown below, are shaped such that they would engage channels 1522 of McLuen's bone fusion device 1500 to secure it in place, just like the surgical tools McLuen describes for its implantation technique.



(Ex. 1012, Fig. 15 (annotated); Ex. 1013, Fig. 37 (annotated).)

74. The McLuen-Gordon combination thus discloses and/or suggests “[a] **system.**” As explained above, the combination involves the use of Gordon's tool assembly for securing and expanding McLuen's implant.

⁵ In my opinion, a POSITA would have known to make any minor modifications to Gordon's driver head 726 that would have been needed for the driver head 726 to engage with the screw head of McLuen's positioning means 1508.

3. McLuen in View of Gordon Discloses and/or Suggests an Expandable Spinal Implant

75. As I discussed above in Section VIII.A, Gordon discloses the claimed **“tool assembly”** comprising the **“first tool”** and **“second adjusting tool”** as I explain in Appendix A [9.a]-[9.d]. Limitations [9.e]-[9.j] recite features related to the **“expandable spinal implant.”** As I further explained above in Section VIII.B.2, the McLuen-Gordon combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant.

76. The McLuen-Gordon combination thus discloses the claimed **“expandable spinal implant,”** as recited in limitations [9.e]-[9.j]. According to McLuen, “[t]he present invention is a bone fusion device for insertion between bones that are to be fused together, such as, for example, the vertebrae of a spinal column,” where “[t]he bone fusion device comprises one or more extendable tabs.” (*See* Ex. 1012, [0013]-[0015]; *see also id.*, Abstract, [0002]-[0003], [0037]-[0038], [0045]-[0046], [0065], [0072]-[0081], Figs. 3A-3B, 12, 15-18B; *supra*, Section VIII.B.1.) For example, as shown in figures 16 and 18A below, McLuen discloses an expandable bone fusion device 1500 (**“an expandable spinal implant”**) with two expandable tabs 1530 on the top and bottom of the implant. (Ex. 1012, [0072]-[0081], Figs. 15-18B; *see also id.*, [0072]-[0073].)

Expandable
spinal implant

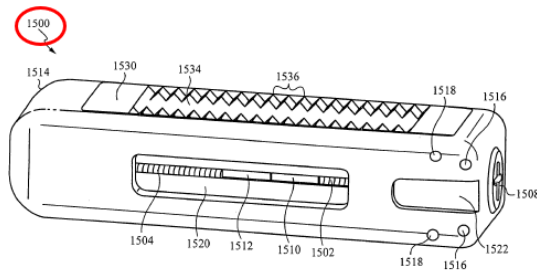


Fig. 16

Expandable
spinal implant

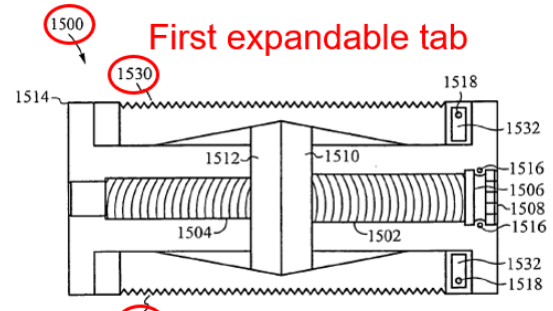


Fig. 18A

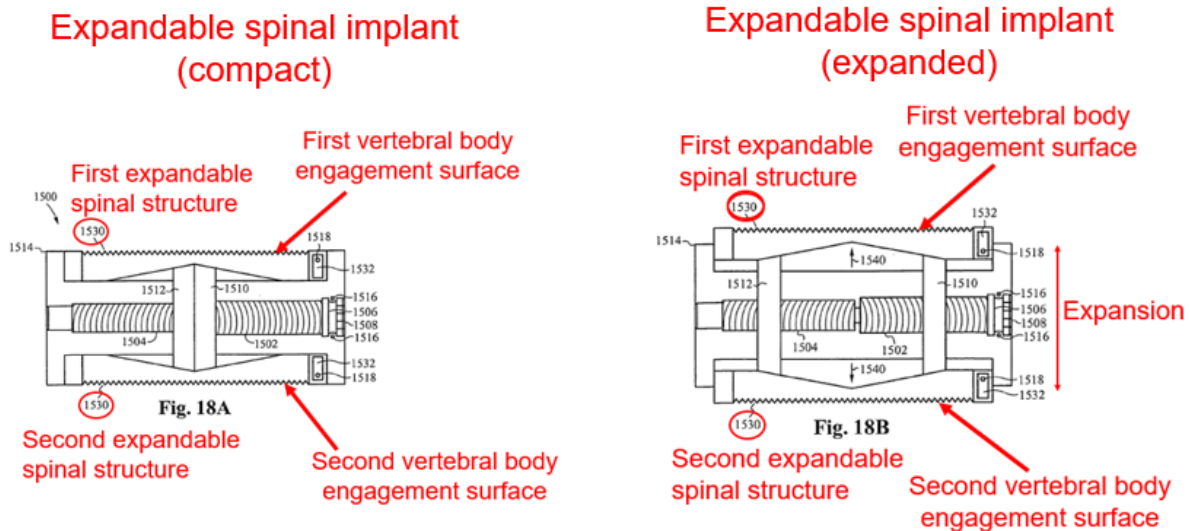
Second expandable tab

(*Id.*, Figs. 16, 18A (both annotated).)

77. Given that McLuen's bone fusion device 1500 is intended to be inserted between vertebrae of a spinal column (*Id.*, [0013]), device 1500 is **“sized and configured to be implanted in a human spine.”**

78. As discussed above in this section, McLuen discloses a bone fusion device 1500 (**expandable spinal implant**) that has two expandable tabs 1530 on either side of device 1500, which correspond to **“a first expandable spinal implant structure”** and **“a second expandable spinal implant structure,”** respectively. As shown below in figures 18A-18B, expandable tabs 1530 define surfaces designed to engage the vertebrae, *i.e.*, **“[first]/[second] vertebral body engagement surface sized and configured to engage a [first]/[second] vertebral body.”** (*Id.*, [0073] (“The bone graft material and *the surface texturing of the device 1500* encourage the growth and fusion of bone from the neighboring vertebrae.”) (emphasis added),

[0074]-[0077]; *see also id.*, [0013] (“[T]he tabs of the bone fusion device provide a larger surface area to which the bones attach and fuse during a healing period.”).)



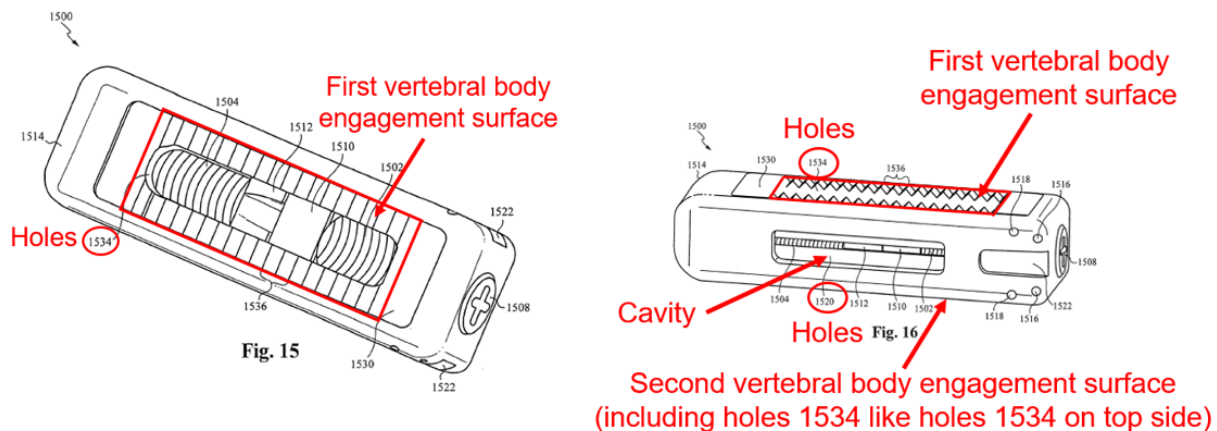
(*Id.*, Figs. 18A-18B (annotated).)

79. As shown in figures 18A and 18B above, the two expandable tabs 1530 can be expanded by turning positioning means 1508, which causes two extending blocks 1510, 1512 to move away from the middle. (*Id.*, [0074]-[0075], [0079]-[0080].)

4. McLuen in View of Gordon Discloses and/or Suggests Limitation [20.d]

80. Claim 20 depends from claim 18. Limitation [20.d] of claim 20 recites that the expandable spinal implant further comprises “**first and second openings extending through the first and second engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material.**”

81. As shown in figures 15 and 16 of McLuen below, McLuen discloses “holes 1534 within the tabs 1530 [that] allow the bone graft material to contact the vertebral bone after the device 1500 has been inserted between the vertebrae of the patient,” *i.e.*, holes 1534 of device 1500 are “**first and second openings extending through the first and second engagement surfaces.**” (Ex. 1012, [0077], Figs. 15-16.) Holes 1534 extend through the surfaces of tabs 1530 to a cavity within bone fusion device 1500 defined by holes/conduit 1520, *i.e.*, “**a cavity within the expandable spinal implant.**” (*Id.*, [0077]-[0078] (“The frame 1514 of the bone fusion device 1500 contains a set of holes 1520 within the frame 1514 for allowing bone graft material to be inserted.”), Figs. 15-18B.)



(*Id.*, Figs. 15-16 (both annotated).)

82. According to McLuen, “material for fusing the bones together is inserted through the holes and openings within the bone fusion device,” *i.e.*, holes/conduits 1520, 1534 are provided for receiving bone graft material (**bone**

material) and the cavity defined by holes 1520 is “**sized to receive bone material.**” (*Id.*, [0072]-[0073], [0077]-[0078].)

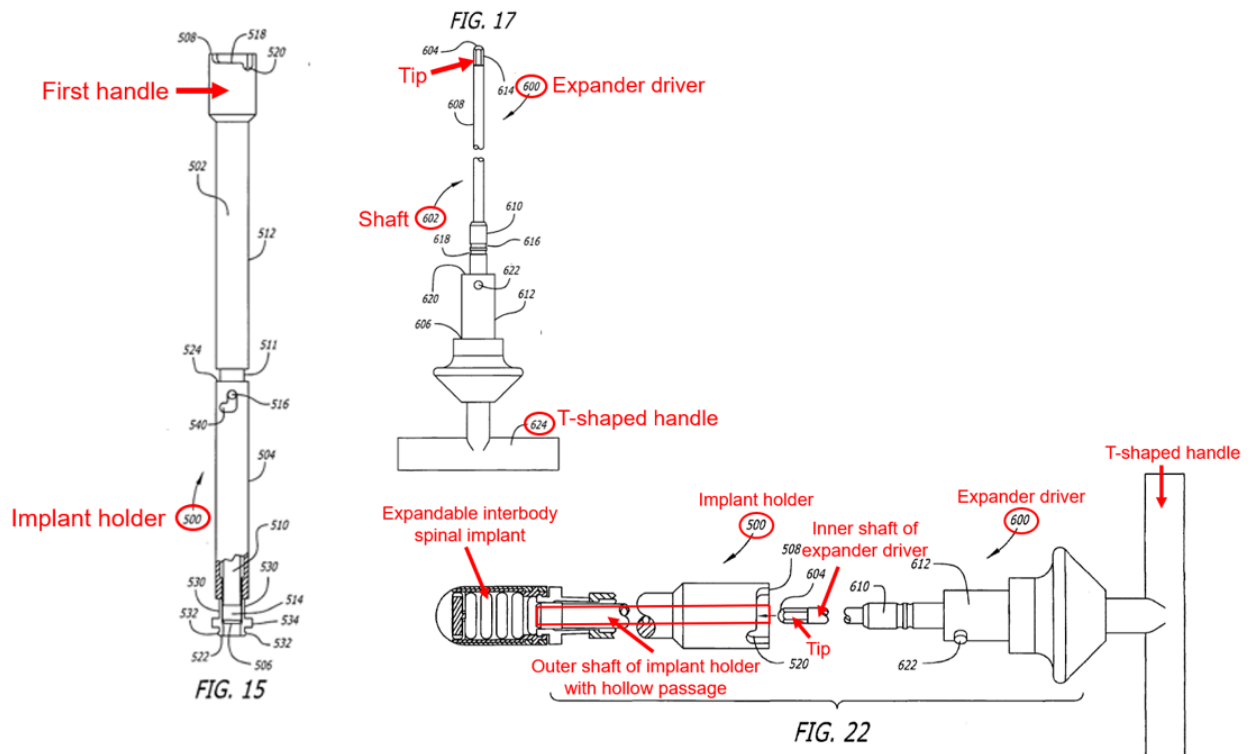
83. In my opinion, a POSITA would have understood that the holes 1534 on the top/bottom tabs 1530 of McLuen’s bone fusion device 1500 extend through the first and second vertebral body surfaces to the cavity defined by holes 1520 within device 1500 because bone graft material inserted in holes 1520 and 1534 allows for device 1500 to “becom[e] embedded within the two adjacent vertebrae of the spine which eventually fuse together during the healing period.” (*Id.*, [0073].)

C. Michelson

1. Overview of Michelson

84. Michelson is titled “Instrumentation and Method for Inserting and Deploying an Expandable Interbody Spinal Fusion Implant.” Michelson discloses expandable spinal implants. (Ex. 1014, Abstract, 1:15-21, 2:48-3:29, 8:38-9:14, 12:38-13:53, Figs. 1, 7, 15-25, 33-34.) According to Michelson, “[t]he present invention relates generally to instruments and methods for inserting interbody spinal implants into an implantation space in the spine, and more particularly for use with expandable interbody (for placement at least in part between adjacent vertebral bodies in the space previously occupied by disc material) spinal fusion implants for the immobilization of vertebrae.” (*Id.*, 1:15-21.)

85. Michelson discloses another example of a tool assembly for expandable spinal implants, where the tool assembly includes implant holder 500 and expander driver 600. (*Id.*, Abstract, 1, 3-4, 13-14, 19-24, Figs. 1, 7, 15-25.)⁶ As shown in the figures below, implant holder 500 includes shaft 502 with a hollow passageway permitting passage of expander driver 600. (*Id.*, 19-20.) Expander driver 600 includes a T-shaped handle 624 for rotating driver 600, a tip 614 at the distal end to engage and control (*e.g.*, by rotating) the expansion mechanism on the implant side.



(*Id.*, Figs. 15, 17, 22 (all annotated).)

⁶ Citations to Michelson are to its native page numbers.

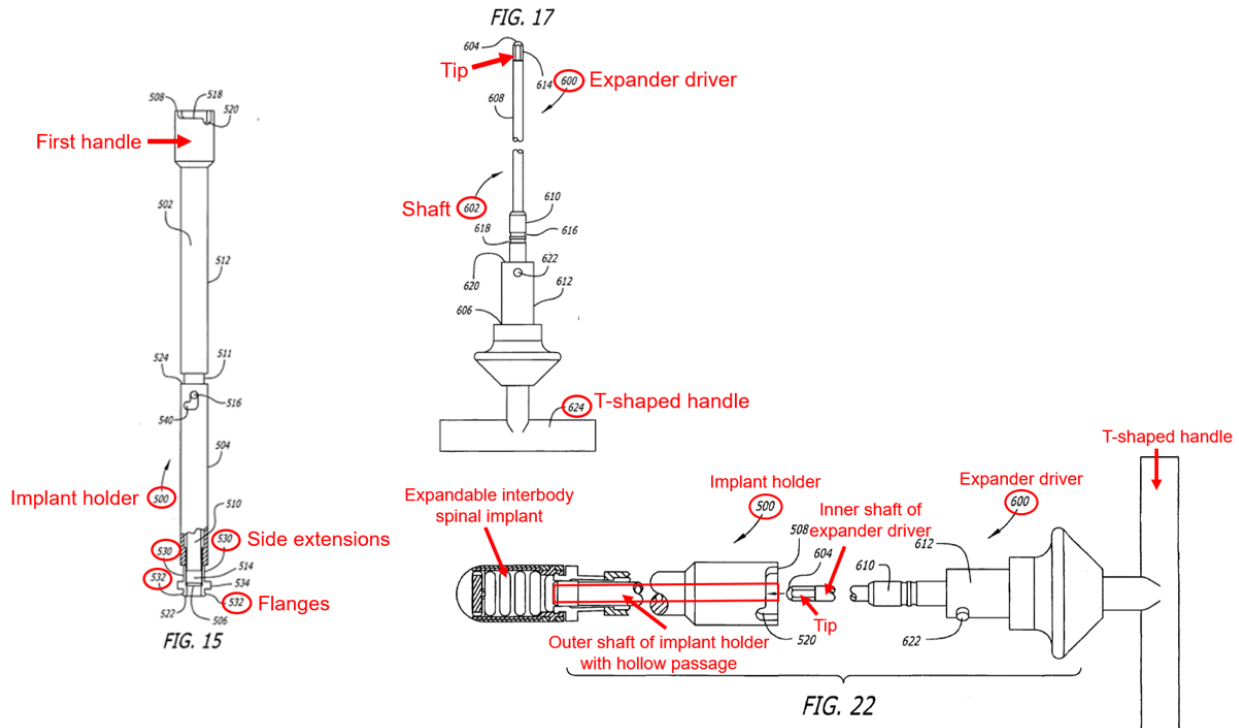
86. Thus, like McLuen, Michelson also discloses a system comprising an expandable interbody spinal fusion implant 100 and a tool assembly including an implant holder 500 and expander driver 600 for installing the implant.

2. Gordon in View of Michelson Discloses and/or Suggests the Second Adjusting Tool

87. Limitation [9.c] is directed to the claimed second adjusting tool, *e.g.*, limitation [9.c] recites “**a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion.**”

88. It is my opinion that Gordon in view Michelson discloses and/or suggests the features of limitation [9.c], as I discuss below.

89. Like Gordon, Michelson discloses expandable spinal implants and a tool assembly for implanting and expanding such implants. (*See* Ex. 1014, 19-21; *supra*, Section VIII.C.1.) As shown in the figures below, Michelson discloses a tool assembly including implant holder 500 to hold an implant in at a desired location while expander driver 600 securely engages the implant for expansion/contraction. (Ex. 1014, 23-24.)

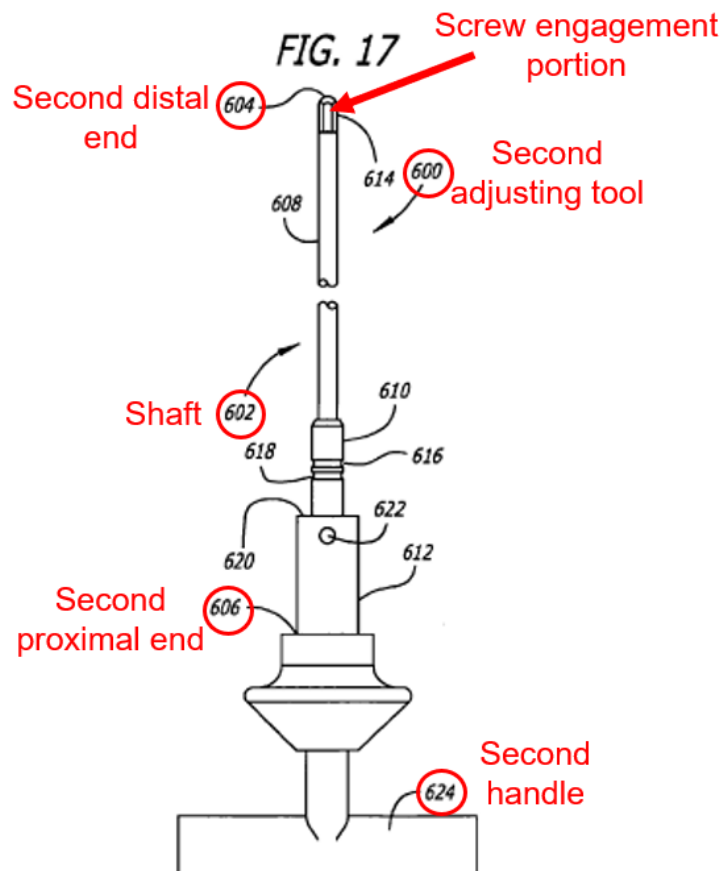


(*Id.*, Figs. 15, 17, 22 (all annotated).)

90. Michelson's tool assembly is thus similar to Gordon's tool assembly in that it teaches a **first tool** (implant holder 500) that securely holds an expandable spinal implant in place at a desired implant site while a **second tool** (expander driver 600) passes through the first tool and engages the implant for adjusting its height. Gordon and Michelson are thus in the same field of art and a POSITA would have been motivated to consider the teachings of Michelson in modifying the Gordon tool assembly.

91. In particular, Michelson discloses that "expander driver 600 [is] for engaging and rotating expander 120," *i.e.*, expander driver 600 is "**a second adjusting tool.**" (*Id.*, 20.) As shown in figure 17 below, expander driver 600

includes proximal end 606 (“**second proximal end**”) and distal end 604 (“**second distal end**”). (*Id.*) “Proximal end 606 has a T-shaped handle 624 for manual rotation of expander driver 600,” *i.e.*, the T-shaped handle 624 is “**a second handle positioned at the second proximal end.**” (*Id.*, 21.) “Distal end 604 has a tip 614 adapted to cooperatively engage opening 130 of expander 120,” where tip 614 suggests “**a screw engagement portion positioned at the second distal end,**” as discussed below. (*Id.*, 20-21.) Expander driver 600 further includes shaft 602 extending from T-shaped handle 624 to tip 614, *i.e.*, shaft 602 discloses “**a shaft extending from the second handle to the screw engagement portion.**” (*Id.*)



(*Id.*, Fig. 17 (annotated).)

92. A POSITA would have been motivated to modify Gordon's **tool assembly** to include Michelson's expander driver 600 as the **second adjusting tool**. Expander driver 600 is structured similar to Gordon's driver 708, but expander driver 600 allows for Gordon's **tool assembly** to include the **second adjusting tool** as a separable component that works together with Gordon's **first tool** (outer shaft 706, holding device 710, and handle 712) for inserting and expanding the implant. (*Id.*, 19-21.) Such separable components would have allowed for separate manufacturing of individual components of the **tool assembly** and greater flexibility to maintain, replace, repair, clean, and/or sterilize the components. Moreover, a POSITA would have been motivated to draw from Michelson's teachings of its **tool assembly** employing a locking mechanism for holding the implant securely at the target site while expander driver 600 rotates the implant's expansion mechanism. (*Id.*, 15, 19-20, 24.)

93. As discussed in Section VIII.A.2.i., Gordon discloses that the control member for driver 708 could be "any element that is operable by a user to control position, orientation, or motion of another element." (Ex. 1013, [0227].) Gordon identifies several alternatives to thumbwheel 14, including "a knob, a lever, or a button." (*Id.*) A POSITA would have recognized that Michelson's T-shaped handle 624 would have been another suitable option for driver 708's control member in

Gordon's **tool assembly**, as it would have been "operable by a user to control position, orientation, or motion" of driver 708. A POSITA would have recognized that Michelson's **second adjusting tool** with the T-shaped handle would have been advantageous to the Gordon **tool assembly**, as its "T"-shape would have allowed more control over the rotation of the **second adjusting tool** because, *e.g.*, one could wrap their fingers around the handle to rotate the second tool if additional leverage was needed. The T-shaped handle would have also provided a more mechanical advantage to turn and expand the implant compared to Gordon's thumbwheel. A POSITA would have also recognized that Michelson's T-shaped handle would have been another variation of Gordon's knob embodiment and thus the proposed modification would have been a simple substitution of one known element for another to obtain the predictable result of providing a control mechanism for driver 708.

94. A POSITA would have had the skill to implement and reasonable expectation of success in achieving the proposed Gordon-Michelson combination. For example, Gordon discloses that a "knob" could be used as the control member of driver 708 instead of thumbwheel 714. (*Id.*, [0228].) A POSITA would have understood that modifying Gordon's **second adjusting tool** by replacing thumbwheel 714 with a knob in Gordon's tool assembly would have required the same modification needed to replace thumbwheel 714 with Michelson's T-shaped

handle. For example, both modifications would have required the inner shaft of the **second adjusting tool** in Gordon's tool assembly to be configured to be inserted through an opening at a proximal end of handle 712 to pass through the **adjusting tool passage** of the **first tool**, and extend past the proximal end of handle 712 so that the knob or T-shaped handle could be positioned proximal to the handle 712. A POSITA would have also had a reasonable expectation of success in the Gordon-Michelson combination because the mechanism of the thumbwheel would be the same as the mechanism of either a knob or a T-handle—each of them would operate to rotate a screw to expand the implant.

95. A POSITA would have also had a reasonable expectation of success in using Michelson's **second adjusting tool** to expand Gordon's implant. Michelson discloses that tip 614 of expander driver 600 in its tool assembly "may be of any shape suitable to engage expander 120" to expand the implant. (Ex. 1014, 20-21, 24, Figs. 17-18.) Given that Gordon's implant is expanded by rotating screw 312 (which has a screw head), a POSITA would have shaped Michelson's tip 614 like a screw driver so it can expand Gordon's implant. (Ex. 1013, [0074]-[0075].) Thus, in the Gordon-Michelson combination, Michelson's tip 614 would have engaged the screw head of Gordon's screw 312 to adjust the height of Gordon's implant.

96. The proposed combination would have involved a combination of known technologies (*e.g.*, a known tool assembly (Gordon) incorporating a known

second adjusting tool (Michelson)) according to known methods to yield the predictable result of a Gordon-Michelson combination where, during implantation, a surgeon would have been able to precisely control rotation of the second adjusting tool using a T-shaped handle as disclosed by Michelson.

97. Implementing a tool like Michelson's expander driver 600 in place of Gordon's mechanism for engaging and rotating the implant screw does not impact the reliance on Gordon for the remaining limitations of independent claim 9 or dependent claims 10-12 and 14-17.

98. Therefore, it is my opinion that Gordon in view of Michelson also discloses and/or suggest claims 9-12 and 14-17.

**3. Gordon in View of Michelson Discloses and/or Suggests
Extending the Second Adjusting Tool to Engage the
Adjusting Screw (Limitation [17.c])**

99. Limitation [17.c] recites **"extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and expanding the expandable spinal implant by turning the adjusting screw of the expandable spinal implant."** Gordon in view of Michelson discloses and/or suggests this limitation.

100. As discussed in Section VIII.C.2, the Gordon-Michelson combination includes a **tool assembly** with Michelson's expander driver 600 as the **second adjusting tool**, where the inner shaft of the **second adjusting tool** would have been

configured to be inserted through an opening at a proximal end of handle 712 to pass through the **adjusting tool passage** of the **first tool**. Such a configuration would have allowed the **first tool** in the **tool assembly** to be used to first insert Gordon's implant in the disc space and securely hold the implant at the desired location, and then the expander driver 600 would have been extended through an opening at the proximal end of handle 712 so that the tip of driver 600 engages with screw 312 on the implant side ("**extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant**") and the implant would have been expanded by turning the screw 312 using the driver 600 ("**expanding the expandable spinal implant by turning the adjusting screw of the expandable spinal implant**").

101. Accordingly, the Gordon-Michelson combination also discloses and/or suggests claim 17.

4. McLuen in View of Gordon and Michelson Discloses and/or Suggests the Second Adjusting Tool

102. McLuen in view of Gordon and Michelson disclose and/or suggest the limitations of claims [9.c] and [17.c] for the same reasons given above in Sections VIII.C.2 and VIII.C.3, respectively. For example, a POSITA would have understood that the Gordon-Michelson tool assembly would have functioned similarly to the Gordon tool assembly for engaging McLuen's implant for delivery to the target site and expansion at the target site. Thus, modifying Gordon's **tool assembly** to include

Michelson's **second adjusting tool** would not impact the reliance on McLuen's implant under the McLuen-Gordon combination I discussed above in Sections VIII.B.2-3. Accordingly, the McLuen-Gordon-Michelson combination also discloses and/or suggests claims 9-12 and 14-17.

IX. CONCLUSION

103. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: December 1, 2025


By: _____

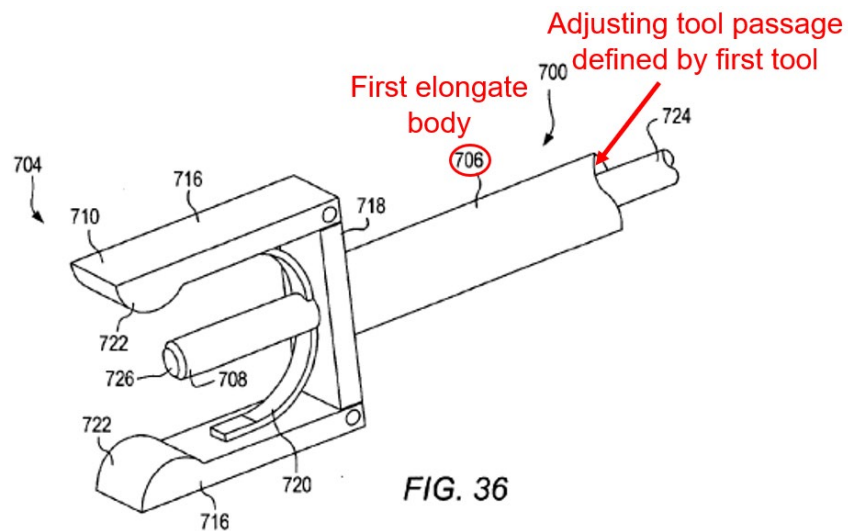
Brad Culbert

APPENDIX A

'136 Patent Claim Element	Prior Art Analysis
Claim 9	
[9.pre] “A system comprising:”	To the extent the preamble is limiting, Gordon discloses this limitation. As discussed above in Section VIII.A.1 and below in Appendix A [9.pre]-[9.j], Gordon discloses and/or suggests a system comprising a tool assembly and a spinal implant.
[9.a] “a tool assembly comprising: a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis,”	Gordon discloses this limitation. (<i>See supra</i> , Section VIII.A.2.i.)

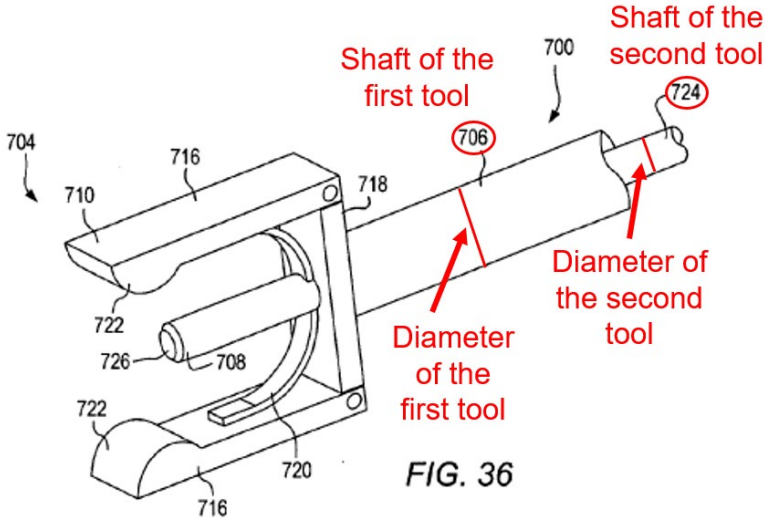
[9.b] “wherein the first tool defines an adjusting tool passage through the first tool; and”

Gordon discloses this limitation. As shown below, inner shaft 724 of driver 708 passes through outer shaft 706 (“**first elongate body**”). (Ex. 1013, [0230], [0233]-[0238].) As discussed above in Section VIII.A.2.i, driver 708 is an “**adjusting tool**,” and therefore the hollow passage in shaft 706 is an “**adjusting tool passage**” in the “**first tool**.”



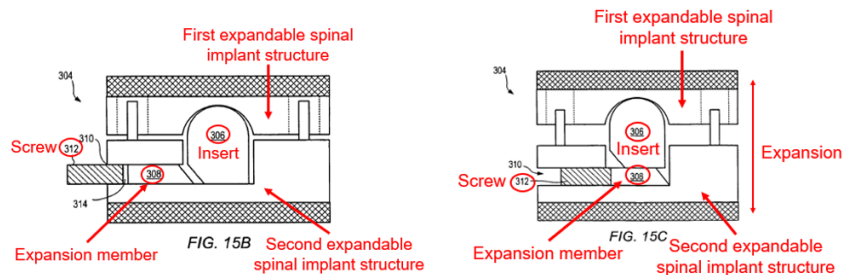
(*Id.*, Fig. 36 (annotated).)

<p>[9.c] “a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion,”</p>	<p>Gordon discloses this limitation. (<i>See supra</i>, Section VIII.A.2.i.)</p>
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<p>[9.d] “wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and”</p>	<p>Gordon discloses this limitation. As discussed in Appendix A [9.b], and as shown in figure 36 below, shaft 724 (shaft) of driver 708 is “sized with a smaller diameter than that of” outer shaft 706 (adjusting tool passage) so that shaft 724 can pass through shaft 706. (Ex. 1013, [0227]-[0233], [0237], Figs. 35-36, 38.) Gordon thus discloses that the “second adjusting tool” (<i>i.e.</i>, driver 708) “can extend through the adjusting tool passage of the first tool.”</p>  <p>(<i>Id.</i>, Fig. 36 (annotated).)</p>
<p>[9.e] “an expandable spinal implant sized and configured to be implanted in a human spine,”</p>	<p>Gordon discloses this limitation. (<i>See supra</i>, Section VIII.A.2.ii.)</p>

[9.f] “the expandable spinal implant comprising a first expandable spinal implant structure defining a first vertebral body engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second vertebral body engagement surface sized and configured to engage a second vertebral body and”

Gordon discloses this limitation. As shown in figures 15B-C below, Gordon’s expandable spinal implant includes two expandable bodies on either side of the implant, *i.e.*, “**a first [and second] expandable spinal implant structure.**” (Ex. 1013, [0177].) As shown in figure 15C below, the first and second bodies expand in the vertical direction in response to rotation of advancing element 312, which moves expansion member 308 towards insert 306. (*Id.*)

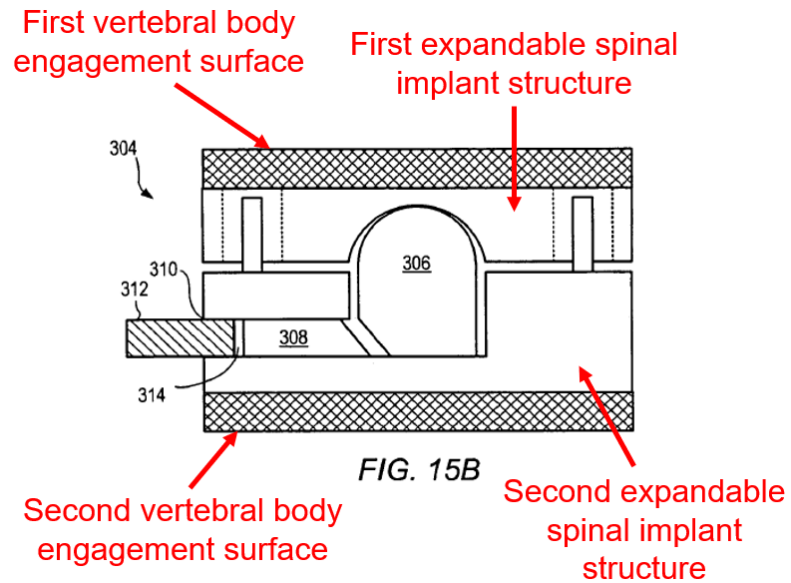


(*Id.*, Figs. 15B-C (both annotated).)

Gordon discloses that its “method of performing a minimally invasive surgical procedure may include removing a portion of a disc *between two vertebrae* of a human spine” and “placing an implant in a disc space *between the vertebrae.*” (*Id.*, [0025] (emphasis added); *see also id.*, [0022] (“The driver may engage an insert of the implant while the implant is *between two vertebrae* of a human spine.”) (emphasis added), [0226] (“In some embodiments, instruments may be used to install elements of an implant in a spine.”).) Gordon’s implant is thus implanted between two vertebrae of the spine, *i.e.*, “[**first/second**] vertebral body.”

Gordon further discloses that “*an endplate engaging surface* of any implant may have regularly or irregularly spaced protrusions of uniform or various shapes and sizes *to facilitate retention of the implant in a desired position between vertebrae.*” (*Id.*, [0138] (emphasis added).) As shown in figure 15B below, the first and second expandable structures have an “osteochonductive scaffolding,” like scaffolding 110 in figures 2A-2B, for securing the implant “against the bony endplates of the adjacent vertebral bodies upon expansion of the implant.” (*Id.*, [1046], Figs. 2A, 2B.) Thus, the two

expandable structures in implant 304 respectively “**defin[e] a [first/second] vertebral body engagement surface sized and configured to [respectively] engage a [first/second] vertebral body.**”

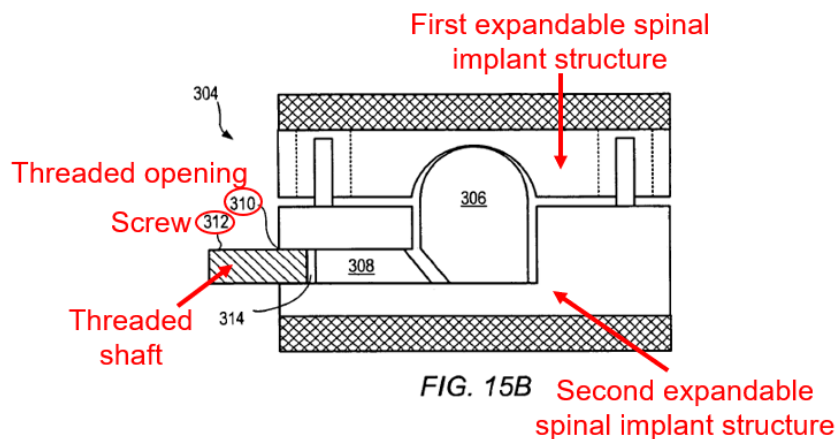


(*Id.*, Figs. 15B (annotated).)

[9.g] “an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,”

Gordon discloses this limitation. As shown in figure 15B below, Gordon’s expandable implant includes an advancing element 312 for expanding the implant. (Ex. 1013, [0177].) Gordon illustrates the same advancing element 312 in figures 16A-16B as a screw having “**a screw head.**” (*Id.*, [0178], Figs. 16A-16B.⁷) Advancing element is therefore, “**an adjusting screw having a screw head.**”

Gordon discloses that screw 312 is inserted in threaded opening 310. (*Id.*, [0177] (“In some embodiments, opening 310 may be threaded. Advancing element 312 may be inserted in opening 310.”).) Thus, a POSITA would have understood that screw 312 must include a “**threaded shaft**” to securely engage with opening 310. This is further confirmed by the shading of screw 312, as shown in figure 15B below.



(*Id.*, Fig. 15B (annotated).)

As discussed in Appendix A [9.f], Gordon’s expandable spinal implant is configured to expand one of the expandable bodies (**first expandable spinal implant structure**) with respect to the other expandable body (**second expandable spinal implant structure**) “**in response to turning of**” screw 312 (**adjusting screw**). (*Supra* Section VIII.A.1; Ex. 1013, [0177].)

[9.h] “wherein the expandable spinal implant defines first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool,” ⁸	Gordon discloses and/or suggests this limitation. (<i>See supra</i> , Section VIII.A.2.ii.)
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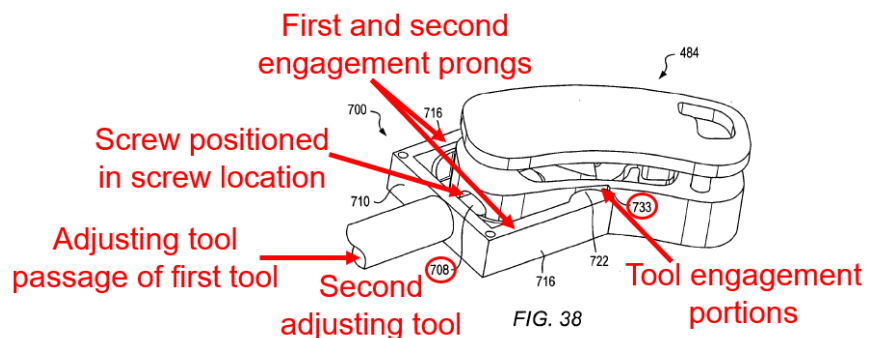
⁷ Gordon discloses that advancing element may be a “set screw” (Ex. 1013, [0177]), which Gordon illustrates as a screw with a screw head in other embodiments, *e.g.*, set screw 166 in Figures 7A-7B, set screw 394 in figures 21A-21B, and set screw 624 in figures 31-32 and 34. (*Id.*, [0159]-[0160], [0197], [0216], [0219], [0223].)

⁸ The ’136 patent specification does not provide textual support for limitation [9.h]. (*See generally* Ex. 1004, 18-87.)

<p>[9.i] “wherein the first tool engagement portion is formed in first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant,”</p>	<p>Gordon discloses and/or suggests this limitation. (<i>See supra</i>, Section VIII.A.2.ii.)</p>
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[9.j] “wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement portions of the expandable spinal implant.”

Gordon discloses and/or suggests this limitation. As shown in figure 38 below, Gordon discloses that the screw (“**adjusting screw**”) is positioned within the expandable spinal implant in a location, *i.e.*, “**a screw location**,” such that driver 708 (**the second adjusting tool**) extends through “**the adjusting tool passage of the first tool**” defined by outer shaft 706 to engage with the screw head of the implant’s screw. (Ex. 1013, [0233] (“In some embodiments, the driver head may engage a set screw in the implant.”), [0237], Figs. 36, 38; *see also id.*, [0226]-[0231].) Moreover, as shown in figure 38 below, Gordon’s holding arms 716 (**first and second engagement prongs of the first tool**) engage side recesses of the implant (**first and second tool engagement portions of the expandable spinal implant**) while the **second adjusting tool** is engaged with **the adjusting screw**. (*Id.*, [0233], [0237].)



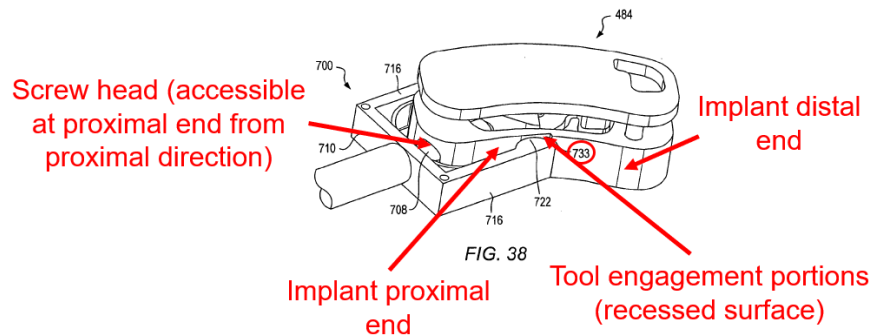
(*Id.*, Fig. 38 (annotated).)

The above disclosure equally applies to the use of instrument 700 with implant 304. That is, when instrument 700 is used with implant 304 (*see supra* Section VIII.A.2.ii), a POSITA would have understood that driver head 708 and holding arms 716 would similarly interact with the screw head of advancing element 312 (**adjusting screw**) and recesses in the implant 304.

Claim 10

“The system of claim 9, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, wherein the first and second tool engagement portions are formed as recessed surfaces and positioned at or near the implant proximal end, and wherein the screw head of the adjusting screw is accessible at the implant proximal end from a proximal direction.”

Gordon discloses and/or suggests this limitation. As discussed in Appendix A [9.h]-[9.j], and shown in figure 38 below, Gordon’s expandable spinal implant includes “**an implant proximal end and an implant distal end,**” where side recesses (**first and second tool engagement portions**) are “**formed as recessed surfaces**” and “**positioned at or near the implant proximal end,**” and the screw head of screw 312 (**adjusting screw**) is accessible at the implant proximal end from a proximal direction.

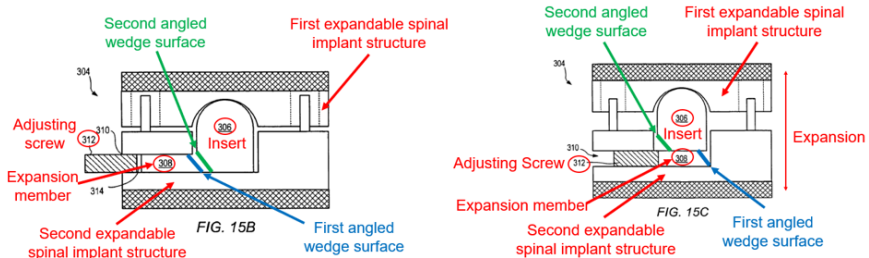


(Ex. 1013, Figs. 38.)

Claim 11

“The system of claim 9, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjusting screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.”

Gordon discloses this limitation. As shown in figures 15B-C below, Gordon’s implant includes expansion member 308 with a “**first [] angled wedge surface[]**” (in **blue**) and insert 306 includes a “**second angled wedge surface[]**” (in **green**). (Ex. 1013, [0177].) As discussed in Appendix A [9.f]-[9.g] and [9.j], Gordon further discloses that rotation of screw 312 (**adjusting screw**) by driver 708 (**second adjusting tool**) drives relative motion of the **first angled wedge surface** of expansion member 308 **with respect to the second angled wedge surface** of insert 306 **to expand the expandable spinal implant**.



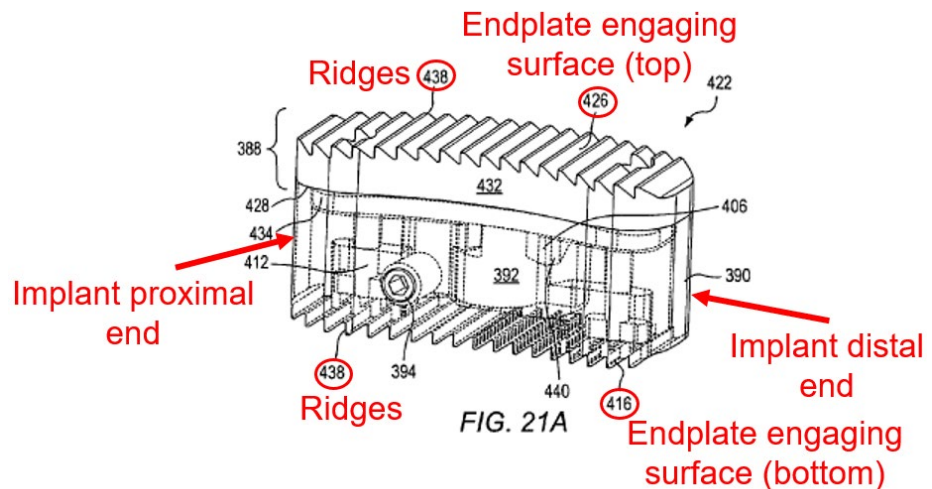
(*Id.*, Figs. 15B-15C (annotated).)

Claim 12

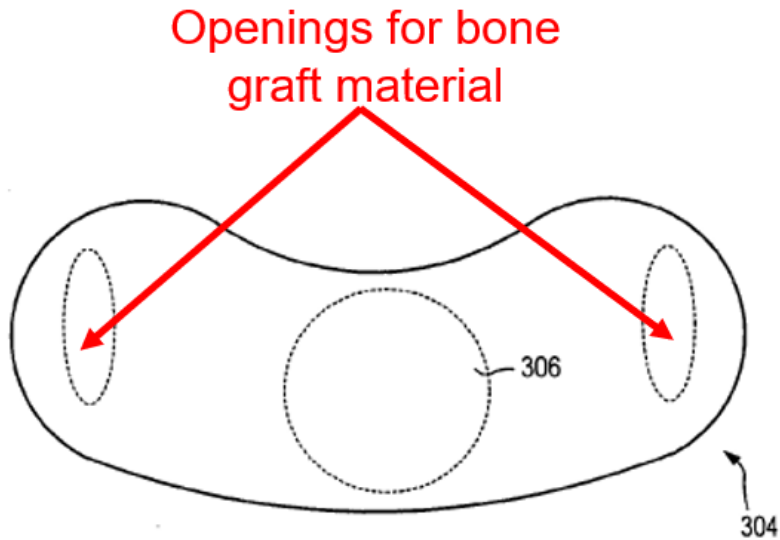
“The system of claim 9, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.”

Gordon discloses this limitation. For example, Gordon discloses that the implant’s endplate engaging surface (“**first vertebral body engagement surface**”) “may include teeth or ridges,” *i.e.*, “**a plurality of ridges extending from a first vertebral body engagement surface.**” (Ex. 1013, [0138]; *see supra* Appendix A [9.f].)

A POSITA would have understood that at least some of these ridges “**are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.**” Providing at least some ridges at a distal end (and at a proximal end) of the first vertebral body engagement surface would accomplish Gordon’s purpose for the ridges, *e.g.*, “to facilitate retention of the implant in a desired position between vertebrae.” (Ex. 1013, [0138].) Indeed, when Gordon depicts ridges on the top and bottom endplate engaging surfaces in figure 21A below, they extend from the implant’s distal end to its proximal end, and thus include the distal end of the engaging surfaces. (*Id.*, [0196].)



(*Id.*, Fig. 21A (annotated).)

Claim 14	
<p>“The system of claim 9, wherein the first and second expandable spinal implant structures each include a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.”⁹</p>	<p>Gordon discloses this limitation. Gordon discloses that “members of an implant may include one or more openings to accommodate packing of bone graft material and/or to allow for bone ingrowth.” (Ex. 1013, [0138].)</p> <p>Gordon depicts such openings (“through-hole[s]”) on the top body of the implant (“first [] expandable spinal implant structure[s]”) of the figure 15 implant. (<i>Id.</i>, [0177].)</p>  <p style="text-align: center;">FIG. 15A</p> <p>(<i>Id.</i>, Fig. 15A (annotated).)</p> <p>A POSITA would have understood that in order for the implant to fuse with the adjacent vertebrae, similar openings would be provided on the bottom body of the implant</p>

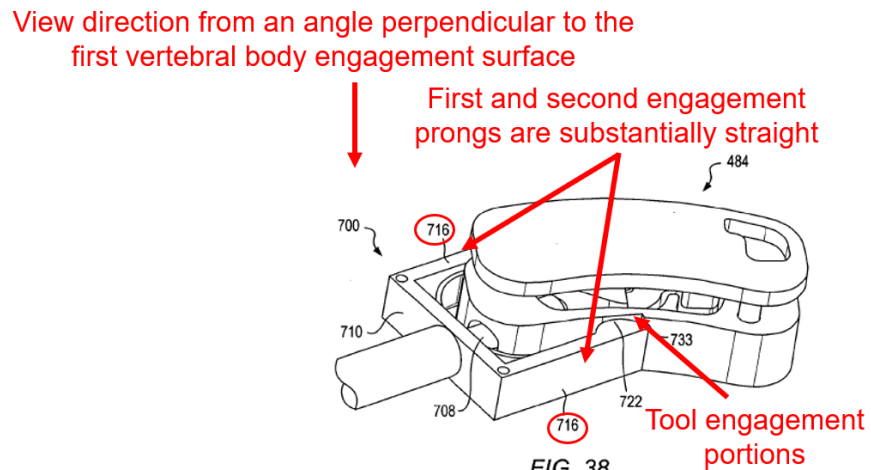
⁹ The '136 patent specification does not provide textual support for the claimed “bone material.” Instead, it describes “slots 308 a, 308 b for bone graft placement.” (Ex. 1004, 78 (¶67).) Thus, to the extent “bone material” in the claims can be understood, I have been asked to assume it encompasses bone graft material.

	<p>(“second expandable spinal implant structure[s]”). (<i>Id.</i>, [0008], [0014], [0138], [0196] (“In certain embodiments, upper body 388 and/or lower body 390 may include openings to allow for bone ingrowth into an interior portion of implant 422.”).) A POSITA would have further understood that these openings would extend through the top and bottom surfaces to hollow portions within the implant (<i>e.g.</i>, a cavity) to allow for fusion of the vertebrae and bone ingrowth, <i>i.e.</i>, these openings are “through-hole[s] sized to allow for placement of bone material into the expandable spinal implant for fusion.” (<i>Id.</i>)</p>
Claim 15	
<p>“The system of claim 9, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.”</p>	<p>Gordon discloses this limitation. As shown in figure 15B below, both the first and second expandable spinal structures are discrete and unitary, <i>i.e.</i>, “single integral” structures. (Ex. 1013, [0177], Figs. 15B-15C; <i>see also id.</i>, [0145] (describing similar upper body 102 and lower body 104 as being “of unitary construction”).)</p> <div data-bbox="571 1152 1362 1680" data-label="Image"> <p style="text-align: center;">FIG. 15B</p> </div> <p>(<i>Id.</i>, Fig. 15B (annotated).)</p>

Claim 16

“The system of claim 9, wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to the first vertebral body engagement surface when the first and second engagement prongs are engaged with the first and second tool engagement portions on the first and second side surfaces of the expandable spinal implant.”

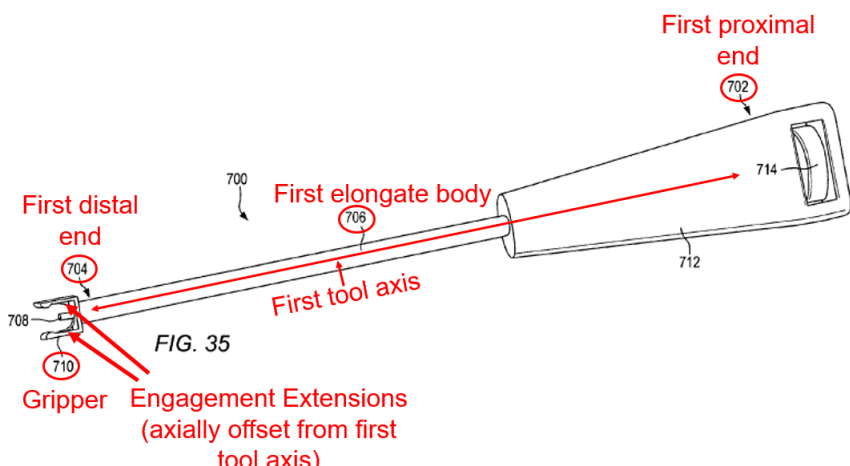
Gordon discloses and/or suggests this limitation. As shown in figure 38 below, outer sides of Gordon’s holding arms 716 (**first and second engagement prongs**) are “**substantially straight when viewed from an angle perpendicular to the first vertebral body engagement surface**” (e.g., the top surface of Gordon’s upper body) while “**the first and second engagement prongs are engaged**” with recesses 733 (**first and second tool engagement portions**) on “**the first and second side surfaces**” of Gordon’s implant, and driver 708 (**second adjusting tool**) engages the screw head of screw 312 (**adjusting screw**). (Ex. 1013, [0177], [0226], [0237].)



(*Id.*, Fig. 38 (annotated); see also *supra* Appendix A [9.j].)

Claim 17	
[17.a] “A method of using the system of claim 9, the method comprising: connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement portions;”	<p>Gordon discloses and/or suggests this limitation. As discussed in Appendix A [9.h]-[9.j], Gordon discloses and/or suggests a system including instrument 700 for implanting its expandable spinal implant. Thus, Gordon discloses and/or suggests a “method of using the system” set forth in claim 9.</p> <p>For example, as discussed in Appendix A [9.h]-[9.j], Gordon’s method includes “connecting” Gordon’s holding device 710 (part of the first tool) to the expandable spinal implant with holding arms 716 (first and second engagement prongs) engaging side recesses of the implant (first and second tool engagement portions).</p>
[17.b] “implanting the expandable spinal implant into a disc space in the human spine via the first tool;”	<p>Gordon discloses and/or suggests this limitation. Gordon discloses that its “method of performing a minimally invasive surgical procedure may include removing a portion of a disc between two vertebrae of a human spine” and “placing an implant in a disc space between the vertebrae.” (Ex. 1013, [0025]; <i>see also id.</i>, [0022] (“The driver may engage an insert of the implant while the implant is between two vertebrae of a human spine.”), [0226] (“In some embodiments, instruments may be used to install elements of an implant in a spine.”).) As discussed above in Section VIII.A.2.i. and Appendix A [9.j], Gordon’s implantation method includes usage of the “first tool.”</p>

<p>[17.c] “extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and expanding the expandable spinal implant by turning the adjusting screw of the expandable spinal implant.”</p>	<p>Gordon discloses and/or suggests this limitation. As discussed in Appendix A [9.j], Gordon discloses use of a tool assembly that includes a driver 708 (second adjusting tool) that extends through outer shaft 706 (part of first tool) to engage screw 312 (adjusting screw) of the expandable spinal implant. (Ex. 1013, [0229] (“[T]humbwheel 714 may be threadably coupled to driver 708 such that driver 708 translates along its axis when thumbwheel 714 is rotated.”).) Moreover, as discussed in Appendix A [9.f]-[9.g], the expandable spinal implant is expanded by turning the screw 312.</p>
<p>Claim 18</p>	
<p>[18.pre] “A system comprising:”</p>	<p>To the extent the preamble is limiting, see above analysis for preamble of claim 9. (<i>Supra</i>, Appendix A [9.pre].)</p>

<p>[18.a] “a tool assembly comprising: a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement extensions positioned at the first distal end axially offset from the first tool axis,”</p>	<p>See above analysis for limitation [9.a]. (<i>Supra</i>, Appendix A [9.a].)</p> <p>Limitation [18.a] recites “wherein the first tool includes a gripper having one or more engagement extensions positioned at the first distal end axially offset from the first tool axis.” As discussed in Section IX.A.1.ii, Gordon’s holding device 710 is part of “the first tool.” Holding device 710 “includes any element or combination of elements that may be used to hold, support, or grip another element, such as an implant,” <i>i.e.</i>, holding device 710 is “a gripper.” (Ex. 1013, [0230].) As shown in figure 35 below, holding device 710 is at distal end 704, and includes two holding arms 716 on either side of the first tool axis, <i>i.e.</i>, holding arms 716 disclose “one or more engagement extensions positioned at the first distal end axially offset from the first tool axis.” (<i>Id.</i>, [0230]-[0231].)</p>  <p>(<i>Id.</i>, Fig. 35 (annotated).)</p>
<p>[18.b] “wherein the first tool defines an adjusting tool passage through the first tool; and”</p>	<p>See above analysis for limitation [9.b]. (<i>Supra</i>, Appendix A [9.b].)</p>

<p>[18.c] “a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion,”</p>	<p>See above analysis for limitation [9.c]. (<i>Supra</i>, Appendix A [9.c].)</p>
<p>[18.d] “wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and”</p>	<p>See above analysis for limitations [9.d]. (<i>Supra</i>, Appendix A [9.d].)</p> <p>Limitation [18.d] additionally recites that “the second adjusting tool can . . . turn within the adjusting tool passage of the first tool.” Gordon discloses this feature. For example, Gordon’s driver 708 (second adjusting tool) turns “within the adjusting tool passage” created by outer shaft 706 when the control member of driver 708 (<i>e.g.</i>, thumbwheel 714) is used to control rotation of driver 708. For example, Gordon discloses that “thumbwheel 714 may be fixedly coupled to driver 708 such that driver 708 rotates as thumbwheel 714 is rotated.” (Ex. 1013, [0229].)</p>

[18.e] “an expandable spinal implant sized and configured to be implanted in a human spine,”	<i>See</i> above analysis for limitation [9.e]. (<i>Supra</i> , Appendix A [9.e].)
[18.f] “the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and”	<i>See</i> above analysis for limitation [9.f]. (<i>Supra</i> , Appendix A [9.f].)

<p>[18.g] “an adjusting screw having a tool engagement feature and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,”</p>	<p><i>See</i> above analysis for limitation [9.g]. (<i>Supra</i>, Appendix A [9.g].)</p> <p>Limitation [18.g] recites that the adjusting screw has “a tool engagement feature” instead of “a screw head,” as recited in limitation [9.g]. A POSITA would have understood that a screw head is a particular type of tool engagement feature, and thus Gordon’s screw head discloses “a tool engagement feature,” for the same reasons discussed in Appendix A [9.g].</p> <p>Limitation [18.g] also recites that the adjusting screw has “a threaded portion” instead of “a threaded shaft,” as recited in limitation [9.g]. A POSITA would have understood that a threaded shaft includes a threaded portion, and thus Gordon’s screw 312 discloses “a threaded portion,” for the same reasons discussed in Appendix A [9.g].</p>
<p>[18.h] “wherein the expandable spinal implant defines one or more tool engagement portions sized, shaped, and configured for engaging with the gripper of the first tool,”</p>	<p><i>See</i> above analysis for limitations [9.h] and [9.j]. (<i>Supra</i>, Appendix A [9.h] and [9.j].)</p>

<p>[18.i] “wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the tool engagement feature of the adjusting screw while one or more engagement extensions of the first tool are engaged with the one or more tool engagement portions of the expandable spinal implant,”</p>	<p><i>See above analysis for limitations [9.h] and [9.j]. (Supra, Appendix A [9.h] and [9.j].)</i></p>
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<p>[18.j] “wherein at least one of the one or more tool engagement portions of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more engagement extensions of the gripper is positioned in the one or more tool engagement portions on the one or more side surfaces of the expandable spinal implant when the first tool is engaged with the expandable spinal implant.”</p>	<p><i>See</i> above analysis for limitations [9.h]-[9.j] and claim 10. (<i>Supra</i>, Appendix A [9.h]-[9.j] and [10].)</p> <p>Limitation [18.j] recites that “at least one of the one or more tool engagement portions of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more engagement extensions of the gripper is positioned in the one or more tool engagement portions.” Gordon discloses these features for reasons similar to those given in Appendix A [10] with respect to claim 10, which recites that the first and second tool engagement portions are “formed as recessed surfaces.” As explained in that section, Gordon’s side recesses (first and second tool engagement portions) are formed as recessed surfaces on the side of the implant (indented into one or more side surfaces of the expandable spinal implant) such that holding arms 716 of Gordon’s holding device 710 (one or more engagement extensions of the gripper) are positioned in the side recesses. (Ex. 1013, [0237].)</p>
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Claim 20	
[20.a] “The system of claim 18, the expandable spinal implant further comprising: an implant proximal end and an implant distal end, the one or more tool engagement portions positioned at or near the implant proximal end, and the tool engagement feature of the adjusting screw is accessible at the implant proximal end from a proximal direction, such that the second adjusting tool engages with the tool engagement feature of the adjusting screw at the implant proximal end;”	<i>See above analysis for limitation [9.j] and claim 10. (Supra, Appendix A [9.j] and [10].)</i>

<p>[20.b] “a plurality of ridges extending from the first engagement surface, wherein at least some of the ridges are positioned on the first engagement surface at or near the implant distal end, said ridges configured to contact the first vertebral body;”</p>	<p><i>See above analysis for claim 12. (Supra, Appendix A [12].)</i></p> <p>Limitation [20.b] recites that “at least some of the ridges are positioned on the first engagement surface at or near the implant distal end” while claim 12 recites that “some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.” As explained in Appendix A [12], Gordon discloses that ridges on the top endplate engaging surface (“first engagement surface”) extend from the implant’s distal end, <i>i.e.</i>, “at or near the implant distal end.”</p>
<p>[20.c] “first and second angled wedge surfaces, wherein rotation of the adjusting screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant; and”</p>	<p><i>See above analysis for claim 11. (Supra, Appendix A [11].)</i></p>

<p>[20.d] “first and second openings extending through the first and second engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material;”¹⁰</p>	<p><i>See above analysis for claim 14. (Supra, Appendix A [14].)</i></p> <p>As explained in Appendix A [14], Gordon discloses that the engagement surfaces on the top and bottom bodies of the implant include openings to accommodate packing of bone graft material. As further explained, these openings would extend through the top and bottom surfaces to hollow portions within the implant (<i>e.g.</i>, a cavity) to allow for fusion of the vertebrae and bone ingrowth, <i>i.e.</i>, Gordon discloses “first and second openings extending through the first and second engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material.”</p>
<p>[20.e] “wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure; and”</p>	<p><i>See above analysis for claim 15. (Supra, Appendix A [15].)</i></p>

¹⁰ The ’136 patent specification does not provide textual support for the claimed “bone material.” *See n.9.*

<p>[20.f] “wherein outer sides of the one or more engagement extensions are substantially straight when viewed from an angle perpendicular to the first engagement surface when the one or more engagement extensions are engaged with the one or more tool engagement portions on the one or more side surfaces of the expandable spinal implant, and the second adjusting tool is engaged with the tool engagement feature of the adjusting screw.”</p>	<p><i>See above analysis for claim 16. (Supra, Appendix A [16].)</i></p>
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APPENDIX B

'136 Patent Claim Element	Prior Art Analysis
Claim 9	
[9.pre] “A system comprising:”	McLuen in view of Gordon discloses and/or suggests this limitation. (<i>See supra</i> , Section VIII.B.2.)
[9.a] “a tool assembly comprising: a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis,”	The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [9.a]. (<i>Supra</i> , Appendix A [9.a].)

<p>[9.b] “wherein the first tool defines an adjusting tool passage through the first tool; and”</p>	<p>The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [9.b]. (<i>Supra</i>, Appendix A [9.b].)</p>
<p>[9.c] “a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion,”</p>	<p>The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [9.c]. (<i>Supra</i>, Appendix A [9.c].)</p>

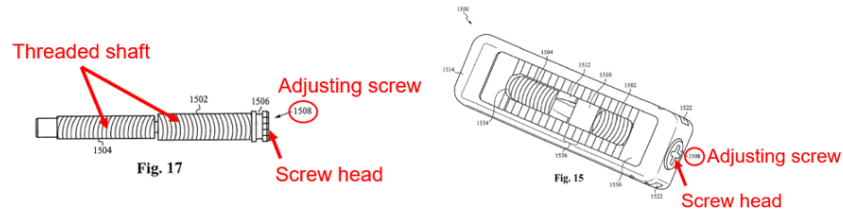
[9.d] “wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and”	The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [9.d]. (<i>Supra</i> , Appendix A [9.d].)
[9.e] “an expandable spinal implant sized and configured to be implanted in a human spine,” ¹¹	The McLuen-Gordon combination discloses this limitation. (<i>See supra</i> , Section VIII.B.3.)

¹¹ Limitations [9.e]-[9.j] recite the implant. As explained above in Section VIII.B.2, the McLuen-Gordon combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. For limitations [9.e]-[9.j], McLuen’s bone fusion device 1500 is being relied upon.

[9.f] “the expandable spinal implant comprising a first expandable spinal implant structure defining a first vertebral body engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second vertebral body engagement surface sized and configured to engage a second vertebral body and”	McLuen discloses this limitation. (<i>See supra</i> , Section VIII.B.3.)
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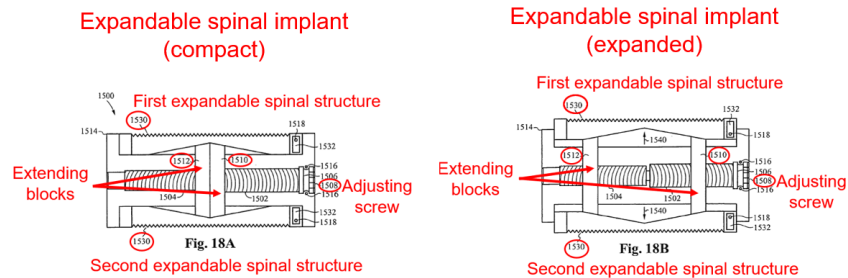
[9.g] “an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,”

McLuen discloses this limitation. McLuen’s bone fusion device 1500 includes positioning means 1508, *i.e.*, “**an adjusting screw**.” (Ex. 1012, [0074], Figs. 15-18B.) As shown in figures 15 and 17 below, positioning means 1508 has a screw 1502 with “**a screw head**,” to control placement of bone fusion device 1500, and “**a threaded shaft**.” (*Id.*, [0078], [0081], Figs. 15-18B.)



(*Id.*, Figs. 17, 15 (both annotated).)

McLuen discloses that bone fusion device 1500 is configured to expand one of the tabs 1530 (**first expandable spinal implant structure**) with respect to the other tab 1530 (**second expandable spinal implant structure**) “in response to turning of” positioning means 1508 (**adjusting screw**). (*Id.*, [0072], [0074]-[0081], Figs. 18A-18B.)



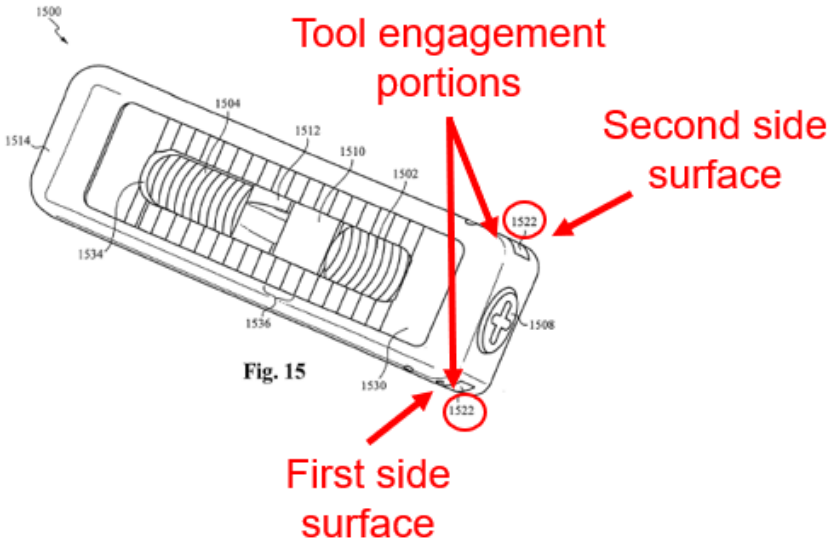
(*Id.*, Figs. 18A-18B (annotated).)

Moreover, “positioning means 1508 is coupled to a first extending block 1510 and a second extending block 1512,” as shown above in figure 18A. (*Id.*, [0074].) “When the positioning means 1508 is turned appropriately, the extending blocks 1510 and 1512 each travel outwardly on their respective screws 1502 and 1504,” and “[a]s the extending blocks 1510 and 1512 travel outwardly, they push the tabs

	<p>1530 outward,” as shown above in figure 18B. (<i>Id.</i>; <i>see also id.</i>, [0072], [0075]-[0081].)</p>
<p>[9.h] “wherein the expandable spinal implant defines first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool,”¹²</p>	<p>The McLuen-Gordon combination discloses this limitation. As shown in figure 16 below, McLuen’s bone fusion device 1500 has channels 1522, <i>i.e.</i>, “first and second tool engagement portions,” “to receive a tool (not shown),” where “[t]he tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.” (Ex. 1012, [0076]; <i>see also id.</i>, [0078].)</p> <p>As shown in figure 36 below, Gordon discloses instrument 700 with holding arms 716, <i>i.e.</i>, “the first and second engagement prongs of the first tool,” which “engage complementary surfaces (<i>e.g.</i>, notches, grooves) on an implant or spacer.” (Ex. 1013, [0231], Figs 36, 38.) Gordon thus discloses holding arms 716 that are configured to engage complementary surfaces, like channels 1522 in McLuen’s bone fusion device 1500, which “defin[e] a space that is sized, shaped, and configured” to receive lobes 722 on Gordon’s holding arms 716.</p> <div data-bbox="532 1119 1377 1633"> <p style="text-align: center;">McLuen Gordon</p> </div>

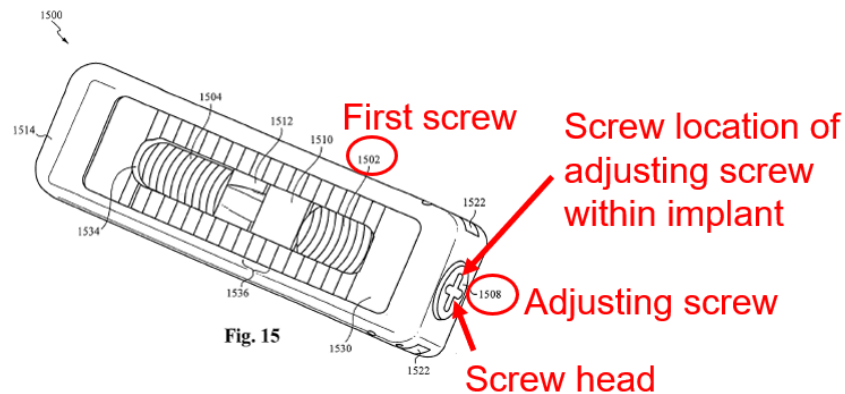
¹² The ’136 patent specification does not provide textual support for limitation [9.h].

(*See generally* Ex. 1004, 18-87.)

	(Ex. 1012, Figs. 15-16 (left) (annotated); Ex. 1013, Figs. 36, 38 (right) (annotated).)
<p>[9.i] “wherein the first tool engagement portion is formed in first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant,”</p>	<p>The McLuen-Gordon combination discloses this limitation. As discussed in Appendix B [9.h], and shown in figure 15 below, McLuen discloses that one of the channels 1522 (first tool engagement portion) is formed in a “first side surface” of bone fusion device 1500 and another one of the channels 1522 (second tool engagement portion) is formed in “a second side surface” of device 1500.</p>  <p>(Ex. 1012, Fig. 15 (annotated).)</p>

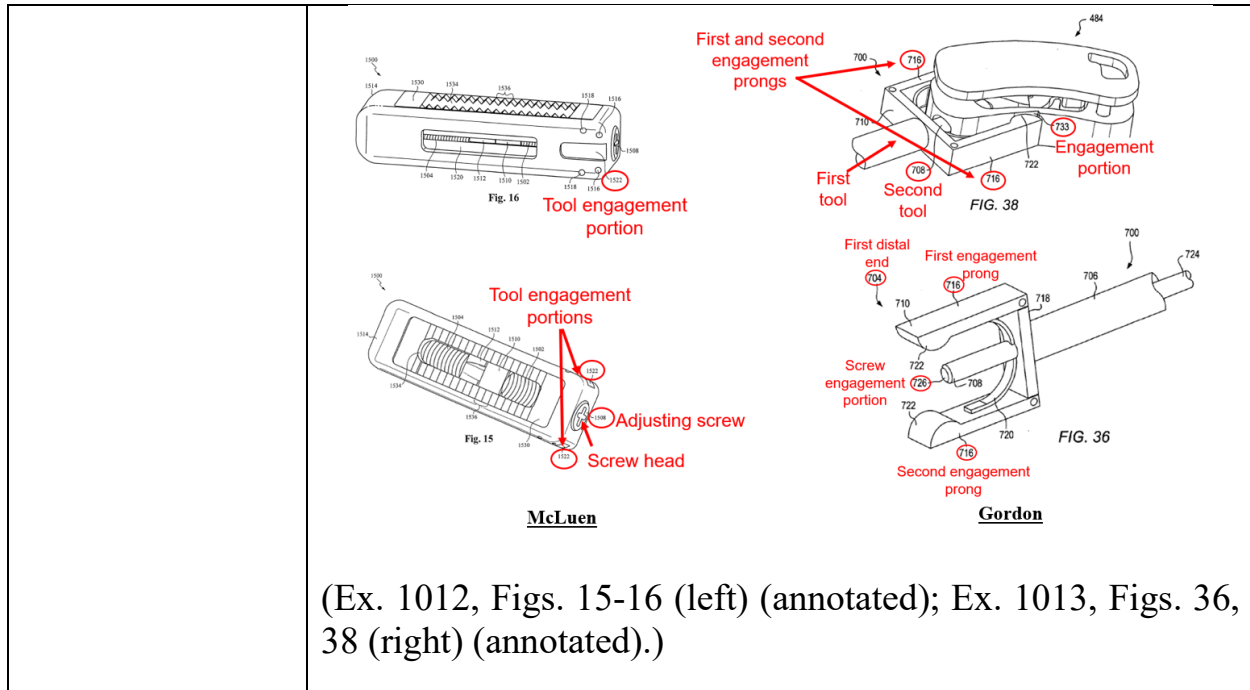
[9.j] “wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of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

The McLuen-Gordon combination discloses this limitation. As shown in figure 15 below, McLuen’s positioning means 1508 (**the adjusting screw**) is positioned within bone fusion device 1500 (**expandable spinal implant**) in a location, *i.e.*, “**in a screw location**,” such that it can be accessed from the outside using a screwdriver. (Ex. 1012, [0074], [0076].)



(*Id.*, Fig. 15 (annotated).)

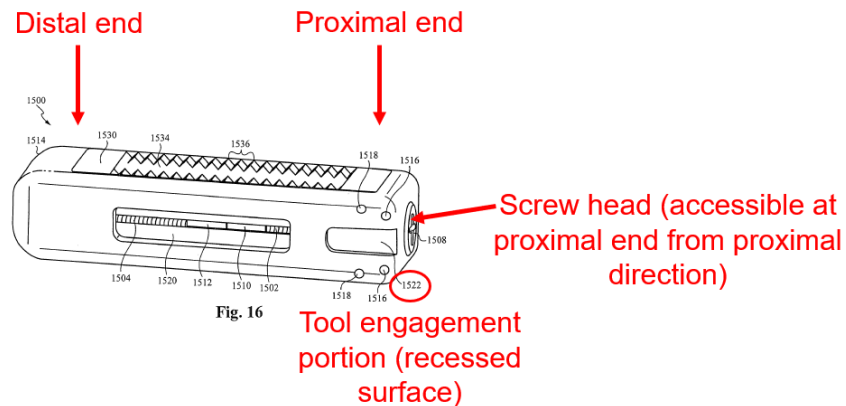
As discussed in Section VIII.B.2, in the McLuen-Gordon combination, McLuen’s positioning means 1508 (**the adjusting screw**) is positioned in the screw location such that Gordon’s driver 708 (**the second adjusting tool**) extends through “**the adjusting tool passage of the first tool**” defined by outer shaft 706 to engage the screw head of positioning means 1508 (**adjusting screw**). Moreover, as discussed in Section VIII.B.2, Gordon’s holding arms 716 (**the first and second engagement prongs of the first tool**) engage channels 1522 of McLuen’s bone fusion device 1500 (**the first and second tool engagement portions of the expandable spinal implant**) while the second adjusting tool is engaged with **the adjusting screw**.



Claim 10

“The system of claim 9, wherein the expandable spinal implant comprises an implant proximal end and an implant distal end, wherein the first and second tool engagement portions are formed as recessed surfaces and positioned at or near the implant proximal end, and wherein the screw head of the adjusting screw is accessible at the implant proximal end from a proximal direction.”

The McLuen-Gordon combination discloses this limitation. As discussed in Appendix B [9.g]-[9.j], and shown in figure 16 below, McLuen’s bone fusion device 1500 includes “**an implant proximal end and an implant distal end,**” where channels 1522 (**first and second tool engagement portions**) are “**formed as recessed surfaces**” and “**positioned at or near the implant proximal end,**” and the screw head of positioning means 1508 (**adjusting screw**) is “**accessible at the implant proximal end from a proximal direction.**” (Ex. 1012, [0076]-[0078], Figs. 15-18B.)

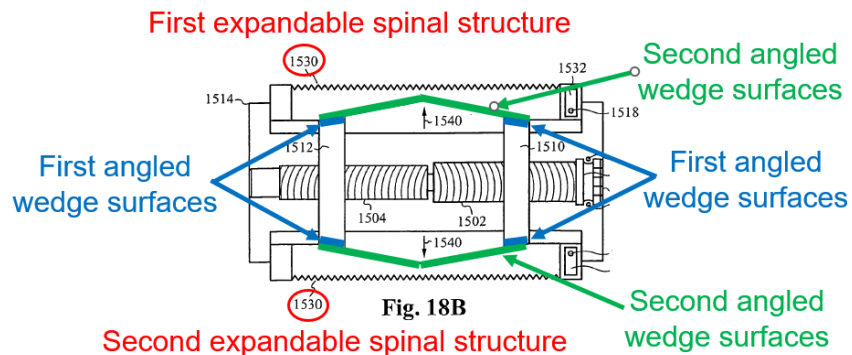


(*Id.*, Fig. 16 (annotated).)

Claim 11

“The system of claim 9, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjusting screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.”

The McLuen-Gordon combination discloses this limitation. As shown below, the portions of McLuen’s extending blocks 1510 and 1512, which interface with the top and bottom tabs 1530, include “**first angled wedge surface[s]**” (in **blue**) and the corresponding portions of the top/bottom tabs 1530 bottom expandable tab 1530 that interface with the extending blocks 1510 and 1512 include “**second angled wedge surface[s]**” (in **green**). As discussed in Appendix B [9.g], McLuen’s bone fusion device 1500 (**expandable spinal implant**) expands in response to rotation of positioning means 1508 (**adjustable screw**).



(Ex. 1012, Fig. 18B (annotated).)

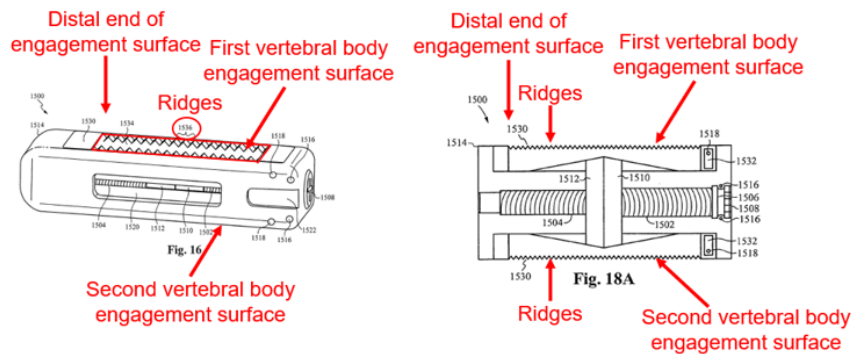
McLuen’s positioning means 1508 (**adjustable screw**) can be rotated by Gordon’s driver 708 (**second adjusting tool**), which drives extending blocks 1510, 1512 such that their **first angled wedge surfaces** move along the axis of positioning means 1508 and push up the **second angled wedge surfaces** of the top/bottom tabs 1530 to expand device 1500, *i.e.*, “**rotation of the adjusting screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.**” (*Id.*, [0072], [0074]-[0081], Figs. 18A-18B.)

Claim 12

“The system of claim 9, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.”

The McLuen-Gordon combination discloses this limitation. As discussed in Section VIII.B.3, McLuen discloses a bone fusion device 1500 with expandable tabs 1530 (**first and second expandable spinal implant structures**) defining surfaces that contact the vertebrae (**first and second vertebral body engagement surfaces**).

McLuen further discloses that “tabs 1530 have serrated edges 1536 to further increase the bone fusion device's gripping ability to secure it in place between the bones,” *i.e.*, “**a plurality of ridges**.” (Ex. 1012, [0075].) Moreover, as shown in figures 16 and 18A below, serrated edges 1536 (**ridges**) on McLuen's bone fusion device 1500 are positioned “**at a distal end of the first vertebral body engagement surface**.” (*Id.*, Figs. 16, 18A.)



(Ex. 1012, Figs. 16, 18A (both annotated).)

Claim 14	
<p>“The system of claim 9, wherein the first and second expandable spinal implant structures each include a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.”¹³</p>	<p>The McLuen-Gordon combination discloses this limitation. For example, as shown in figures 15 and 16 below, McLuen further discloses “<i>holes 1534 within the tabs 1530 [that] allow the bone graft material to contact the vertebral bone after the device 1500 has been inserted between the vertebrae of the patient,</i>” <i>i.e.</i>, the tabs 1530 (“the first and second expandable spinal implant structures”) each include “a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.” (Ex. 1012, [0077] (emphasis added), Figs. 15-16; <i>see also id.</i>, [0078], Figs. 17-18B.)¹⁴</p> <div data-bbox="565 793 1334 1066"> </div> <p>(<i>Id.</i>, Figs. 15-16 (both annotated).)</p>

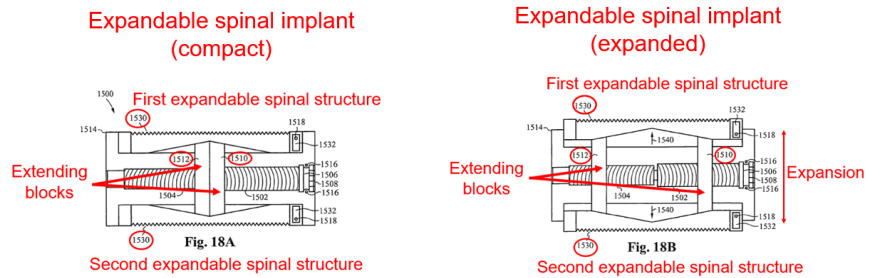
¹³ The '136 patent specification does not provide textual support for the claimed “bone material.” Instead, it describes “slots 308 a, 308 b for bone graft placement.” (Ex. 1004, 78 (¶67).) Thus, to the extent “bone material” in the claims can be understood, I have been asked to assume it encompasses bone graft material. *See* n.9.

¹⁴ McLuen also refers to the holes/conduits 1520, 1534 as “openings.” (Ex. 1012, [0072] (“Thereafter, material for fusing the bones together is inserted through the holes and openings within the bone fusion device.”).)

Claim 15

“The system of claim 9, wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.”

The McLuen-Gordon combination discloses this limitation. As discussed in Section VIII.B.3, McLuen’s tabs 1530 are “**the first**” and “**second expandable spinal implant structures.**” As shown in figures 18A and 18B below, both tabs 1530 are discrete, unitary structures, *i.e.*, “**single integral**” structures. (Ex. 1012, [0072]-[0074], Figs. 15-18B.)



(*Id.*, Figs. 18A-18B (both annotated).)

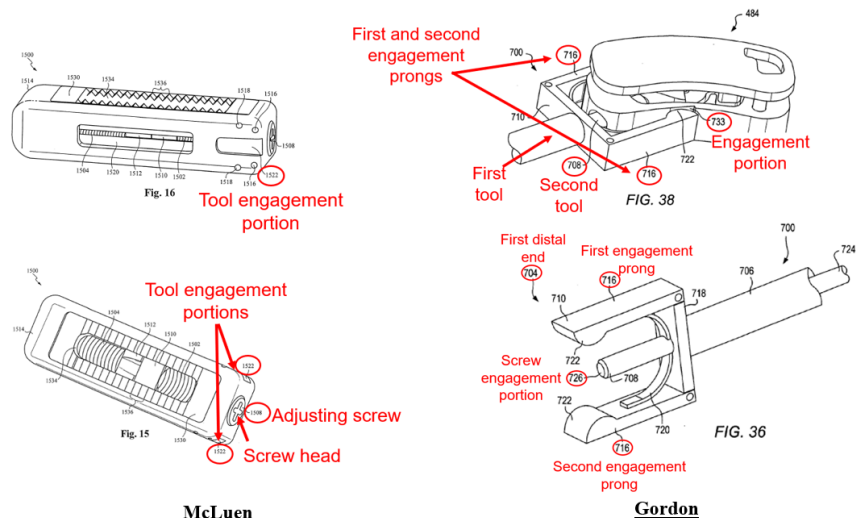
Claim 16	
“The system of claim 9, wherein outer sides of the first and second engagement prongs are substantially straight when viewed from an angle perpendicular to the first vertebral body engagement surface when the first and second engagement prongs are engaged with the first and second tool engagement portions on the first and second side surfaces of the expandable spinal implant.”	The McLuen-Gordon combination discloses this limitation for at least the same reasons as those given for claim 16 in Appendix A [16.]

Claim 17

[17.a] “A method of using the system of claim 9, the method comprising: connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement portions;”

The McLuen-Gordon combination discloses this limitation. As discussed in Appendix B [9.pre]-[9.j], the McLuen-Gordon combination discloses a “**system**” comprising “**a tool assembly**” and “**an expandable spinal implant sized and configured to be implanted in a human spine.**” According to McLuen, “[t]he compact bone fusion device is [] inserted into position within the patient” and “[t]he surgeon is able to then the expand the bone fusion device by rotating the positioning means which moves the extending blocks towards the opposing ends of the bone fusion device.” (Ex. 1012, [0081].) As discussed in Appendix A [17.a], Gordon also discloses and/or suggests this limitation.

As discussed in Appendix B [9.j], the McLuen-Gordon method includes “**connecting**” Gordon’s holding device 710 (part of the **first tool**) to McLuen’s bone fusion device 1500 (**expandable spinal implant**) with Gordon’s holding arms 716 (**first and second engagement prongs**) engaging McLuen’s channels 1522 (**first and second tool engagement portions**).



(Ex. 1012, Figs. 15-16 (left) (annotated); Ex. 1013, Fig. 36 (right) (annotated).)

<p>[17.b] “implanting the expandable spinal implant into a disc space in the human spine via the first tool;”</p>	<p>The McLuen-Gordon combination discloses this limitation. McLuen discloses that bone fusion device 1500 (the expandable spinal implant) can be implanted into a space between two vertebrae that would normally be occupied by an intervertebral disc, <i>i.e.</i>, “a disc space in the human spine,” with an insertion tool. (Ex. 1012, [0004] (“One method for correcting disc-related disorders is to insert a fusion cage between the vertebrae to act as a structural replacement for the deteriorated disc.”).) As discussed in Appendix A [17.b], Gordon also discloses and/or suggests this limitation. Moreover, as discussed in Section VIII.B.2, a POSITA would have used Gordon’s first tool with McLuen’s bone fusion device 1500 for implantation into a disc space.</p>
<p>[17.c] “extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant; and expanding the expandable spinal implant by turning the adjusting screw of the expandable spinal implant.”</p>	<p>The McLuen-Gordon combination discloses this limitation. As discussed in Section VIII.B.2, Gordon discloses use of a tool assembly that includes a driver 708 (second adjusting tool), which extends through outer shaft 706 (part of first tool), to engage McLuen’s positioning means 1508 (adjusting screw) of bone fusion device 1500 (expandable spinal implant). Moreover, as discussed in Appendix B [9.g], McLuen’s bone fusion device 1500 can be expanded by turning positioning means 1508.</p>
<p>Claim 18</p>	
<p>[18.pre] “A system comprising:”</p>	<p>To the extent the preamble is limiting, see above analysis for preamble of claim 9. (<i>Supra</i>, Appendix B [9.pre].)</p>

<p>[18.a] “a tool assembly comprising: a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement extensions positioned at the first distal end axially offset from the first tool axis,”</p>	<p>The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [18.a]. <i>See</i> above analysis for limitation [18.a]. (<i>Supra</i>, Appendix A [18.a].)</p>
<p>[18.b] “wherein the first tool defines an adjusting tool passage through the first tool; and”</p>	<p>The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [18.b]. <i>See</i> above analysis for limitation [18.b]. (<i>Supra</i>, Appendix A [18.b].)</p>

<p>[18.c] “a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion,”</p>	<p>The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [18.c]. <i>See</i> above analysis for limitation [18.b]. (<i>Supra</i>, Appendix A [18.c].)</p>
<p>[18.d] “wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and”</p>	<p>The McLuen-Gordon combination discloses this limitation. As explained above, the combination involves the use of Gordon’s tool assembly for securing and expanding McLuen’s implant. Gordon’s tool assembly discloses limitation [18.d]. <i>See</i> above analysis for limitation [18.d]. (<i>Supra</i>, Appendix A [18.d].)</p>

[18.e] “an expandable spinal implant sized and configured to be implanted in a human spine,”	<i>See</i> above analysis for limitations [9.e]. (<i>Supra</i> , Appendix B [9.e].)
[18.f] “the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and”	<i>See</i> above analysis for limitations [9.f]. (<i>Supra</i> , Appendix B [9.f].)

<p>[18.g] “an adjusting screw having a tool engagement feature and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw,”</p>	<p><i>See</i> above analysis for limitation [9.g]. (<i>Supra</i>, Appendix B [9.g].)</p> <p>As discussed in Appendix A [18.g], a POSITA would have understood that a screw head is a particular type of “a tool engagement feature” and that a threaded shaft includes “a threaded portion.” Thus, McLuen’s screw 312 includes a tool engagement feature and a threaded portion, as claimed.</p>
<p>[18.h] “wherein the expandable spinal implant defines one or more tool engagement portions sized, shaped, and configured for engaging with the gripper of the first tool,”</p>	<p><i>See</i> above analysis for limitation [9.h]. (<i>Supra</i>, Appendix B [9.h].)</p>

<p>[18.i] “wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the tool engagement feature of the adjusting screw while one or more engagement extensions of the first tool are engaged with the one or more tool engagement portions of the expandable spinal implant,”</p>	<p><i>See above analysis for limitation [9.h] and [9.j]. (Supra, Appendix B [9.h] and [9.j].)</i></p>
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<p>[18.j] “wherein at least one of the one or more tool engagement portions of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more engagement extensions of the gripper is positioned in the one or more tool engagement portions on the one or more side surfaces of the expandable spinal implant when the first tool is engaged with the expandable spinal implant.”</p>	<p><i>See</i> above analysis for limitations [9.h]-[9.j] and claim 10. (<i>Supra</i>, Appendix A [9.h]-[9.j] and [10].)</p> <p>Limitation [18.j] recites that “at least one of the one or more tool engagement portions of the expandable spinal implant is indented into one or more side surfaces of the expandable spinal implant such that the one or more engagement extensions of the gripper is positioned in the one or more tool engagement portions.” As discussed in Appendix B [10], the McLuen-Gordon combination discloses these features for reasons similar to those given above with respect to claim 10, which recites that the first and second tool engagement portions are “formed as recessed surfaces.” As explained in that section, channels 1522 (at least one of the one or more tool engagement portions) are formed as recessed surfaces on the side of McLuen’s bone fusion device 1500 (indented into one or more side surfaces of the expandable spinal implant) such that holding arms 716 of Gordon’s holding device 710 (one or more engagement extensions of the gripper) are positioned in channels 1522.</p>
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Claim 20	
[20.a] “The system of claim 18, the expandable spinal implant further comprising: an implant proximal end and an implant distal end, the one or more tool engagement portions positioned at or near the implant proximal end, and the tool engagement feature of the adjusting screw is accessible at the implant proximal end from a proximal direction, such that the second adjusting tool engages with the tool engagement feature of the adjusting screw at the implant proximal end;”	<i>See above analysis for limitation [9.j] and claim 10. (Supra, Appendix B [9.j] and [10].)</i>

<p>[20.b] “a plurality of ridges extending from the first engagement surface, wherein at least some of the ridges are positioned on the first engagement surface at or near the implant distal end, said ridges configured to contact the first vertebral body;”</p>	<p>See above analysis for claim 12. (<i>Supra</i>, Appendix B [12].)</p> <p>Limitation [20.b] recites that “at least some of the ridges are positioned on the first engagement surface at or near the implant distal end,” while claim 12 recites that “some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.” As explained in Appendix B [12], and as shown in figures 16 and 18A below, serrated edges 1536 (ridges) are positioned “at or near the implant distal end.” (Ex. 1012, Figs. 16, 18A.)</p> <div data-bbox="535 693 1380 1029"> </div> <p>(<i>Id.</i>, Figs. 16, 18A (both annotated).)</p>
<p>[20.c] “first and second angled wedge surfaces, wherein rotation of the adjusting screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant; and”</p>	<p>See above analysis for claim 11. (<i>Supra</i>, Appendix B [11].)</p>

<p>[20.d] “first and second openings extending through the first and second engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material;”</p>	<p>McLuen in view of Gordon discloses and/or suggests this limitation. (<i>See supra</i>, Section VIII.B.4.)</p>
<p>[20.e] “wherein the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure; and”</p>	<p><i>See above analysis for claim 15. (Supra, Appendix B [15].)</i></p>

<p>[20.f] “wherein outer sides of the one or more engagement extensions are substantially straight when viewed from an angle perpendicular to the first engagement surface when the one or more engagement extensions are engaged with the one or more tool engagement portions on the one or more side surfaces of the expandable spinal implant, and the second adjusting tool is engaged with the tool engagement feature of the adjusting screw.”</p>	<p><i>See above analysis for claim 16. (Supra, Appendix B [16].)</i></p>
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