

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

MOSKOWITZ FAMILY LLC.
Patent Owner

Patent No. 11,096,797

**DECLARATION OF MR. BRAD CULBERT
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,096,797**

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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. 11,096,797 (“the ’797 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 16 and 19 (the “challenged claims”) of the ’797 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 which I am a named author and identifies parties on behalf of whom I have previously provided expert testimony.

¹ In this Declaration, I refer to exhibits that I understand are to be attached to the petition for *Inter Partes* Review of the ’797 patent.

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.

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

Declaration of Mr. Brad Culbert
U.S. Patent No. 11,096,797

Ex. 1001	U.S. Patent No. 11,096,797 to Moskowitz et al. (“the ’797 patent”)
Ex. 1004	File History for U.S. Patent No. 11,096,797
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	U.S. Patent No. 7,118,579 to Michelson (“Michelson”)
Ex. 1015	U.S. Patent Application Publication No. 2005/0182416 A1 to Lim et al. (“Lim”)
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. 1039	U.S. Patent No. 5,658,335 to Allen (“Allen”)
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 would have understood the state of the art, the prior art, and the claims and the specification of the '797 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 '797 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 16 and 19 of the '797 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 '797 patent in the mid-2000s. Considering the '797 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 person of ordinary skill in the art (a "POSITA") at the time of the alleged invention

² The '797 patent issued on August 24, 2021, from U.S. Application No. 16/587,993 ("the '993 application"), filed on September 30, 2019. The '993 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.

(mid-2000s, including the time leading 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 '797 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 '797 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 '797 patent, as I explain below in Section VIII and in the Appendix. 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, ¶25.)

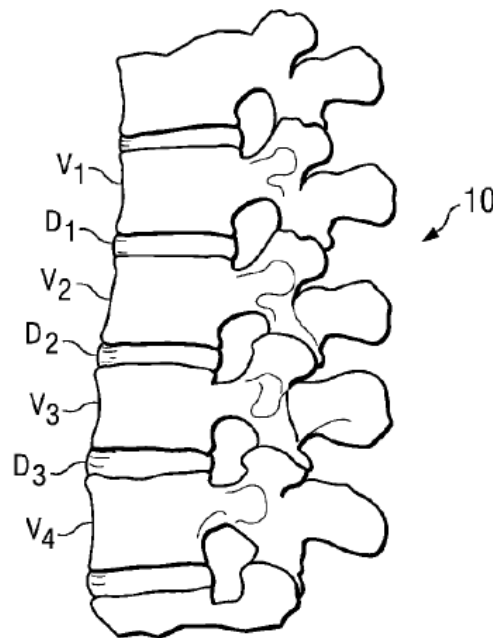


Fig. 1

(*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 involve removing 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.)

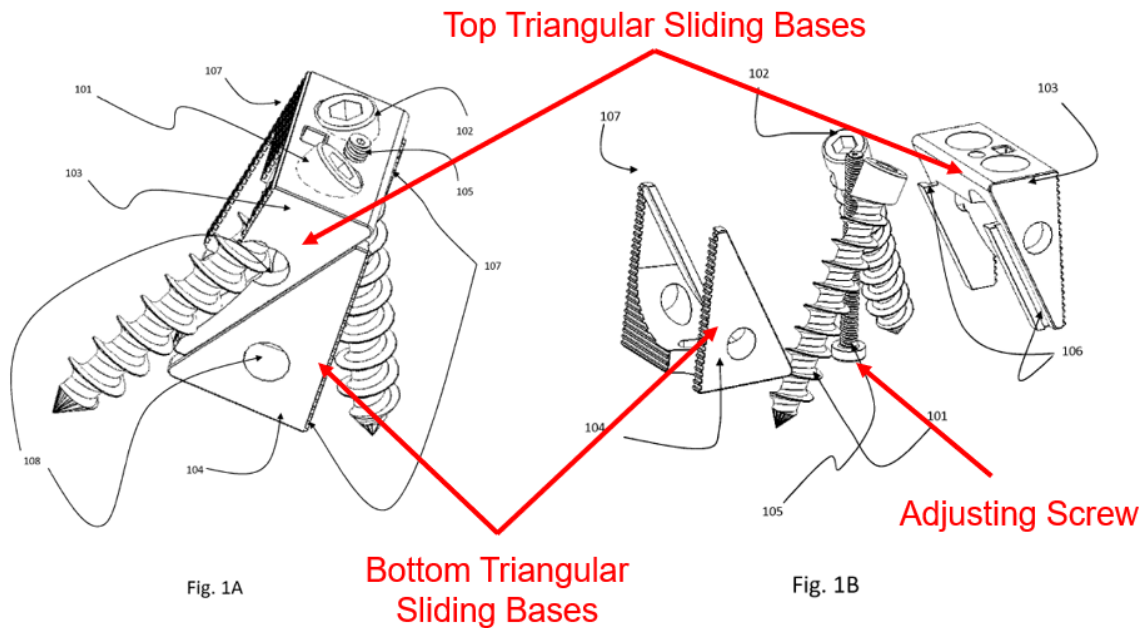
27. By the early 2000s, expandable intervertebral fusion devices emerged as a less invasive alternative to non-expandable devices. (*See* Ex. 1037, 1.) Unlike non-expandable devices, expandable devices are inserted into the disc space in a collapsed configuration and then expanded once in place. (*Id.*) As I discuss below in Section VIII.A, 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 '797 PATENT AND LACK OF SUPPORT FOR THE CLAIMS

A. Overview of the '797 Patent

28. The '797 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 '797 patent discloses a zero-profile expandable intervertebral spacer device with top and bottom triangular sliding bases 103 and 104. (*Id.*, 4:20-24, 7:16-20.) Turning adjusting screw 105 moves the triangular sliding bases 103, 104 apart, resulting in the expansion of the device. (*Id.*, 7:24-31.)



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

30. The '797 patent also discloses a tool assembly 800 for inserting and expanding the implant. (*Id.*, Figs. 8A-8G.) The tool assembly has a griper 804 with griper prongs 806, a handle 803, and Allen key 801. (*See, e.g., id.*, 10:17-22, 10:43-45.)³ As shown in figure 8C below (the exploded view of the tool assembly), griper 804, handle 803, and Allen key 801 include shafts of varying diameters.

³ While the '797 patent uses the term “griper,” the term is usually spelled as “gripper.” The '797 patent uses the correct spelling in another place. (Ex. 1001, 14:57-62 (“In another embodiment, a tool includes a handle, a gripper cooperating with the handle . . .”).)

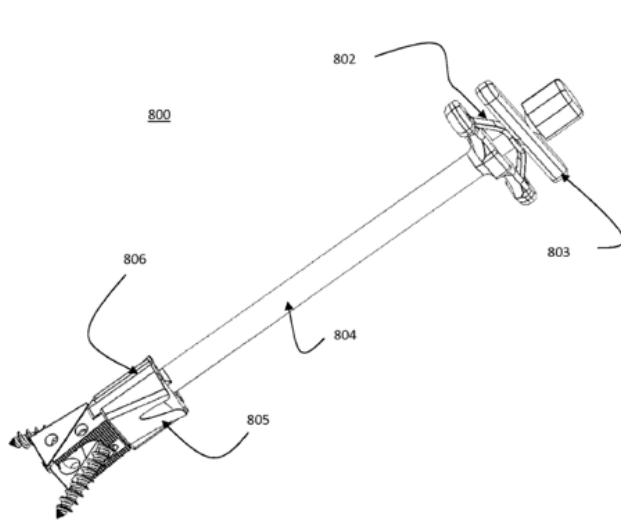


Fig. 8A

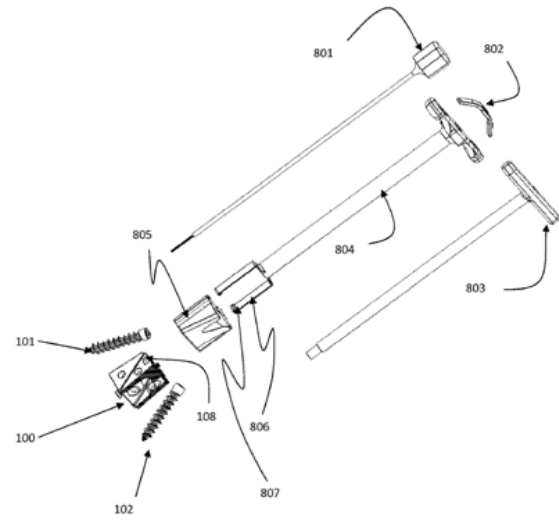


Fig. 8C

(*Id.*, Figs. 8A, 8C.)

31. The '797 patent discloses that after inserting the Allen key 801 into the handle 803, the handle 803 may then be inserted through the gripper 804, as shown in figures 8E-8F below. (*See id.*, 11:1-5.)

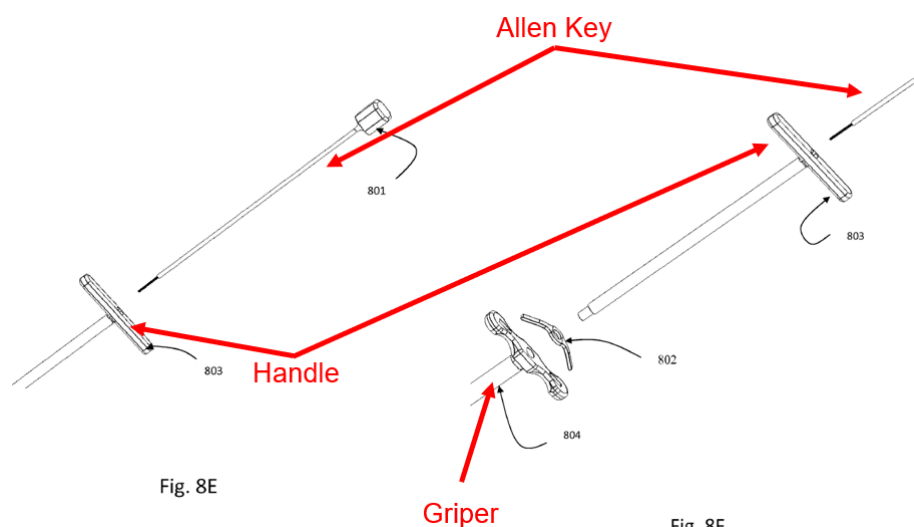
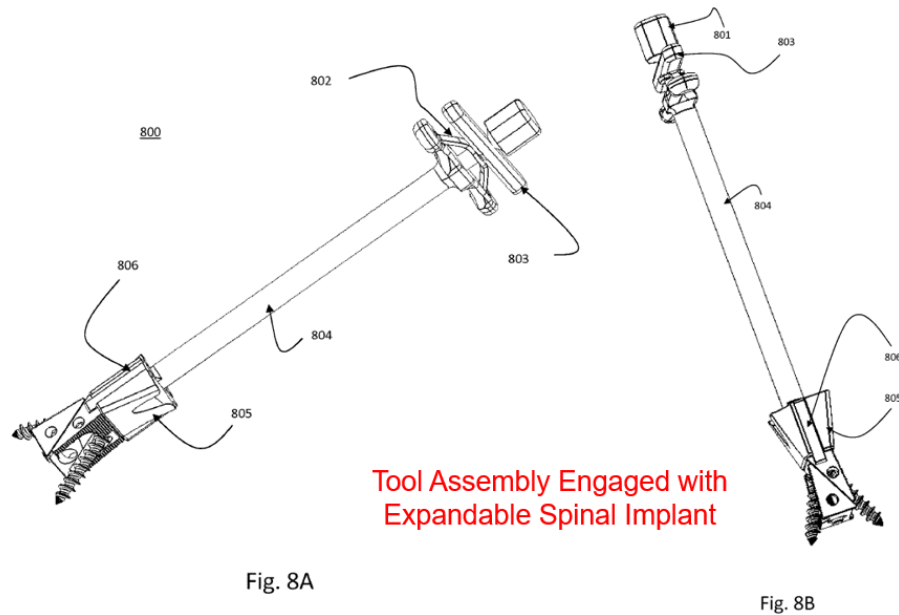


Fig. 8E

Fig. 8F

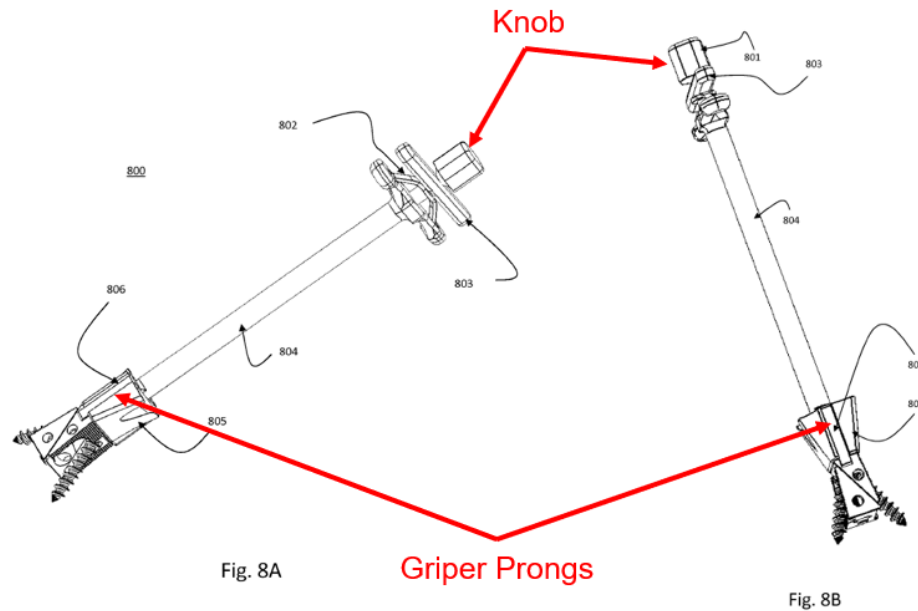
(*Id.*, Figs. 8E-8F (annotated).)

32. The '797 patent further discloses that “[t]he griper 804 has griper prongs 806, which insert into grooves 509 of the screw guide 505 and the screw box indentations ... (as shown in FIGS. 8A-8D),” for alignment. (*See, e.g., id.*, 10:48-55.)



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

33. Allen key 801 engages a screw head of adjusting screw 105 while griper prongs 806 engage grooves of screw guide 805, as shown in figure 8A-8B below. (*See, e.g., id.*, 10:45-55.). Allen key 801 has its own handle with a knob/wheel-like portion at the proximal end and a screw engagement portion at the distal end. (*See, e.g., id.*, 10:45-48, Figs 8A-8C.)



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

B. Claim 16 Is Not Supported by Any Pre-2007 Applications in the Priority Chain of the '797 Patent

34. I have reviewed the pre-2007 applications in the priority chain of the '797 patent. Specifically, as I noted above in footnote 2, the '797 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 '797 patent also claims the benefit of U.S. Provisional Application No. 60/670,231, filed on April 12, 2005.

35. None of the applications prior to the '855 application disclose or provide support for a system comprising an expandable intervertebral fusion device, **“wherein the expandable intervertebral fusion device defines first and second tool engagement indentations on first and second sides of the expandable intervertebral fusion device.”** (Ex. 1001, 17:34-44.) Similarly, none of the applications prior to the '855 application disclose or provide support for a system comprising three tools that cooperate with each other for implanting the expandable intervertebral fusion device, let alone the details of these three tools as set forth in claim 16:

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, *wherein the first tool defines a first tool passage that extends through the first tool from a first tool passage inlet at the first proximal end to a first tool passage outlet at the first distal end*, wherein the first tool outlet is positioned between the first and second engagement prongs;

a second tool having a second proximal end, a second distal end, and a second elongate body between the second proximal end and the second distal end, wherein the second tool defines a second tool passage that extends through the second tool from a second tool

passage inlet at the second proximal end to a second tool passage outlet at the second distal end, and *wherein an outer diameter of the second elongate body is less than an inner diameter of the first tool passage of the first tool such that the second elongate body can pass through the first tool passage; and*

a third adjusting tool having a third proximal end and a third distal end, wherein the third adjusting tool includes a third handle positioned at the third proximal end, *a screw engagement portion positioned at the third distal end, and a third shaft extending from the third handle to the screw engagement portion, and wherein an outer diameter of the third shaft is less than an inner diameter of the second tool passage of the second tool such that the third shaft can extend through the second tool passage while the second tool is positioned in the first tool passage of the first tool.*

(*Id.*, 17:45-18:11.)

36. For example, the '855 application has totally different figures compared to the '815 application filed on September 29, 2006. The '815 application issued as U.S. Patent No. 7,846,188 ("the '188 patent") (Ex. 1053). The '815 application does not disclose an expandable intervertebral fusion device, "**wherein the expandable intervertebral fusion device defines first and second tool engagement indentations on first and second sides of the expandable intervertebral fusion device,**" as recited in claim 16. Instead, as shown below, figures 1A and 1B of the '815 application, allegedly depict a "bidirectional fixating transvertebral screw."

(Ex. 1053, 4:59-63.) Nor do any of the figures in the '815 application disclose the **“first tool”** and **“second tool”** with tool passages as set forth in claim 16 (e.g., **“wherein the first tool defines a first tool passage that extends through the first tool from a first tool passage inlet at the first proximal end to a first tool passage outlet at the first distal end”** and **“wherein the second tool defines a second tool passage that extends through the second tool from a second tool passage inlet at the second proximal end to a second tool passage outlet at the second distal end”**), where the second tool can pass through the first tool passage and the third adjusting tool can pass through the second tool passage, as claimed (**“wherein an outer diameter of the second elongate body is less than an inner diameter of the first tool passage of the first tool such that the second elongate body can pass through the first tool passage”** and **“wherein an outer diameter of the third shaft is less than an inner diameter of the second tool passage of the second tool such that the third shaft can extend through the second tool passage while the second tool is positioned in the first tool passage of the first tool.”**). Nor do any of the figures in the '815 application disclose a **“third adjusting tool”** including **“a screw engagement portion positioned at the third distal end.”**

37. Instead, to the extent the '188 patent 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 '188 patent does not disclose that this

interarticular joint stapling device or any other tool with the above-noted tool-related features of claim 16.

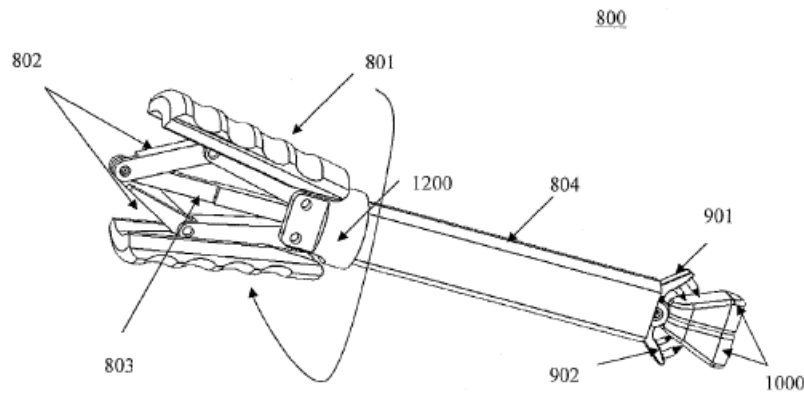


Fig. 8A

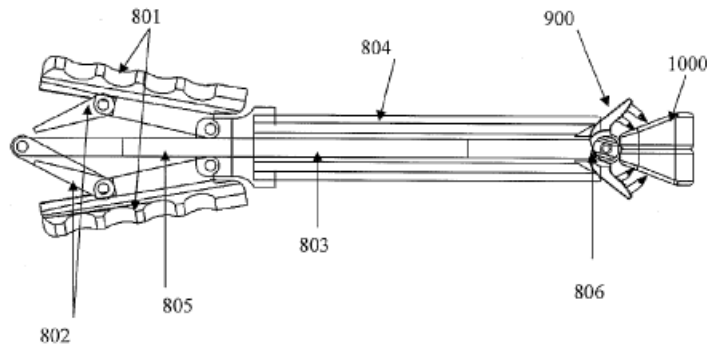


Fig. 8B

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

VII. CLAIM CONSTRUCTION

38. 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

39. I provide a detailed explanation of my opinions on each element of the challenged claims in the Appendix. In this section, I address the relevant disclosures of 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.

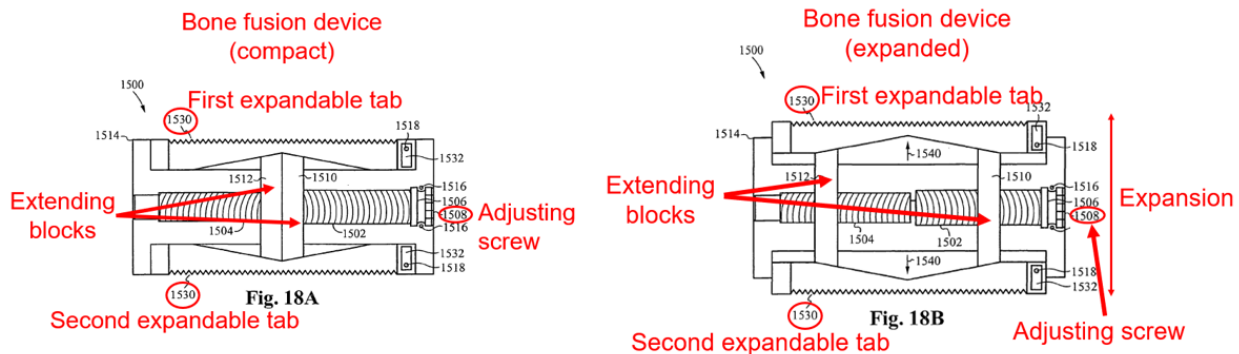
A. McLuen and Michelson

1. Overview of McLuen

40. McLuen is titled “Bone Fusion Device.” McLuen discloses “devices for fusing vertebrae of the spine that can be inserted arthroscopically.” (Ex. 1012, ¶2; *see also id.*, Abstract, ¶¶13-15 (“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 . . .”).)

41. 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. (Ex. 1012, ¶74; *see also id.*, ¶¶72-73.) The bone fusion device 1500 also includes positioning means 1508 comprising first screw 1502 and second screw 1504 coupled

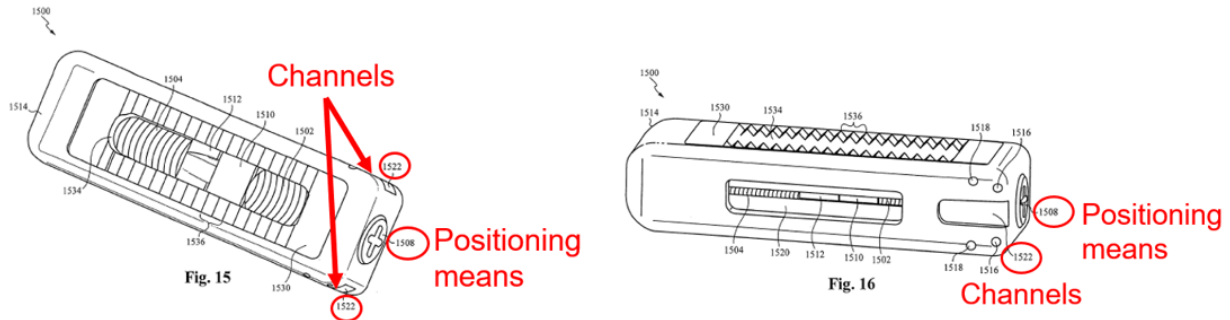
together. (*Id.*, ¶74.) “The positioning means 1508 is coupled to a first extending block 1510 and a second extending block 1512,” as shown in figure 18A below. (*Id.*) McLuen also discloses that, “[w]hen the positioning means 1508 is turned appropriately, the extending blocks 1510 and 1512 each travel outwardly on their respective screws 1502 and 1504.” (*Id.*) Moreover, “[a]s the extending blocks 1510 and 1512 travel outwardly, they push the tabs 1530 outward,” as shown in figure 18B below. (*Id.*; see also *id.*, ¶¶72, 75-81.)



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

42. As shown in figures 15-16 below, while McLuen does not disclose the specific tools for implanting and expanding bone fusion device 1500, it does disclose that “channels 1522 are implemented to receive a tool [which] has attachments that fit within the channels 1522 to secure the tool . . . in place.” (*Id.*, ¶76; see also *id.*, ¶78 (“To ensure that a device (not shown) does not slip while turning the positioning means 1508, channels 1522 are utilized to secure the device.”); ¶¶58-60 (describing

a method with reference to figure 8 to implant bone fusion device 1500 using surgical tools), Fig. 8.)



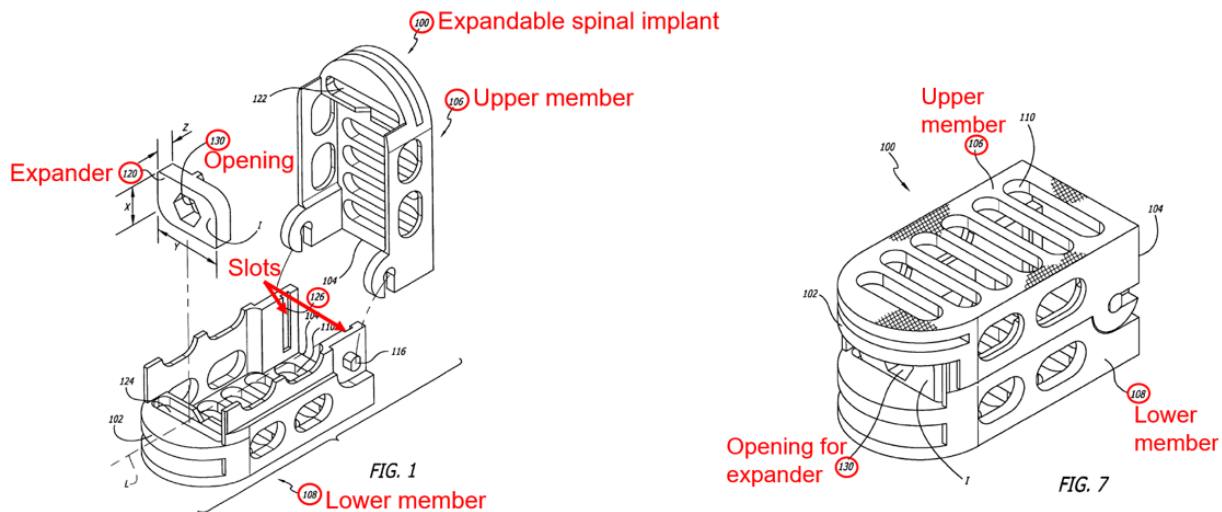
(Ex. 1012, Figs. 15-16 (annotated).)

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

2. Overview of Michelson

44. 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.)

45. Michelson (Ex. 1014) also discloses an expandable spinal implant like McLuen along with a tool assembly for inserting the implant in a human spine. (Ex. 1014, Abstract, 1:15-21, 2:48-40, 8:38-59.) As shown in figure 1 below, Michelson discloses an expandable interbody spinal fusion implant 100 with an upper member 106 and a lower member 108. (*Id.*, 9:5-14.) Upper member 106 and lower member 108 are configured to be placed “toward and at least in part within the upper and lower of two adjacent vertebral bodies, respectively.” (*Id.*)



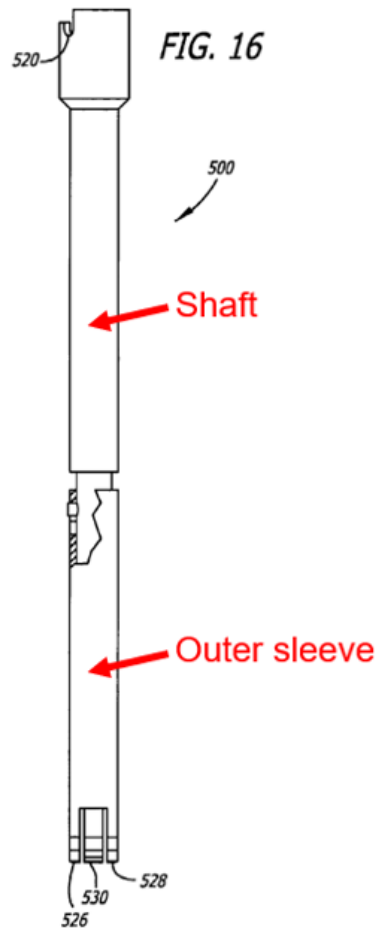
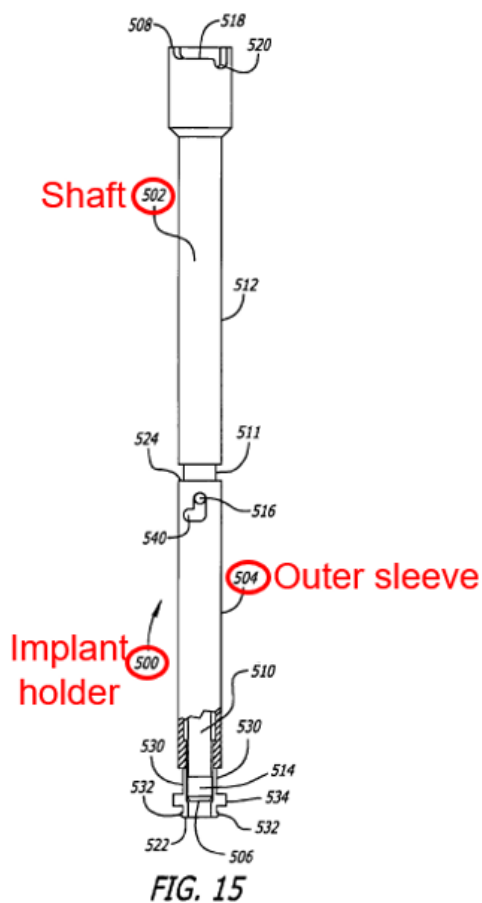
(*Id.*, Figs. 1, 7 (both annotated).)

46. “Upper and lower members 106, 108 are moveable relative to one another and have a first position that allows for a collapsed implant height and a second position that allows for an increased height.” (*Id.*, 9:53-56.) The relative movement between the upper and lower members 106,108 is controlled by rotation of expander 120. (*Id.*, 10:6-11, 10:48-53.) Implant 100 further includes slots 126

for engagement by a tool during insertion of the implant, as discussed below. (*Id.*, 10:12-15.)

47. Michelson further discloses a tool assembly including an implant holder 500 and expander driver 600. (*Id.*, 12:38-42.) As explained below, the expander driver 600 passes through the implant holder 500 to engage and rotate expander 120 of implant 100 (shown above in annotated figure 1) to adjust the implant's height.

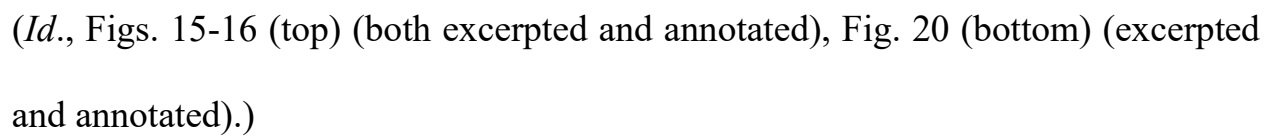
48. As shown in figures 15-16 below, "implant holder 500 [is used] for inserting implant 100 into a disc space." (*Id.*, 12:43-45.) "Implant holder 500 has a shaft 502 and an outer sleeve 504." (*Id.*, 12:45-46.)



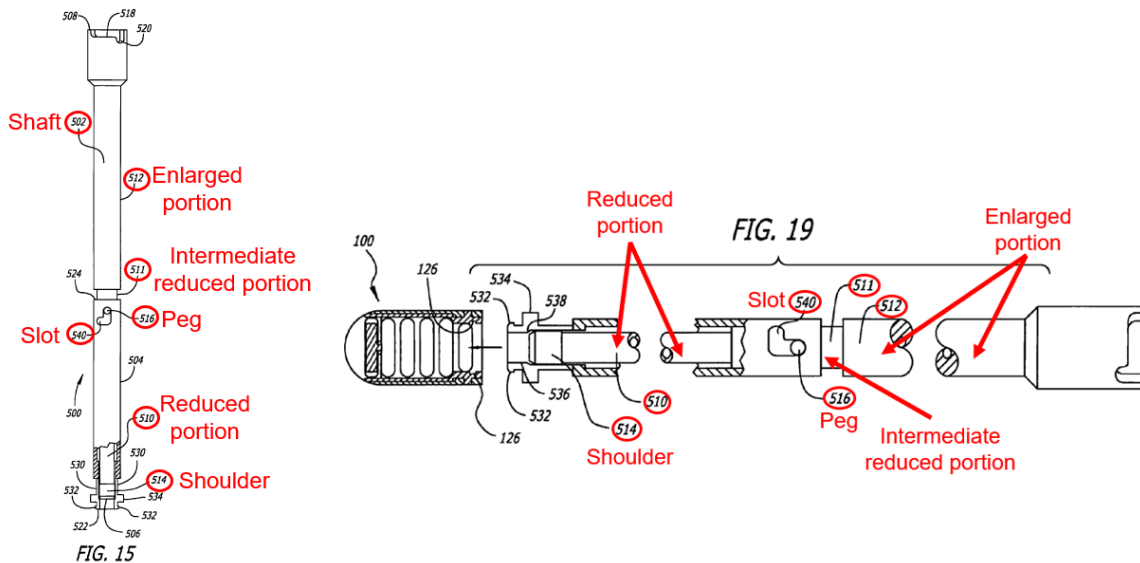
(*Id.*, Figs. 15-16 (both annotated).)

49. As shown in excerpted portions of figures 15-16 and 20 below, implant holder 500 includes an outer sleeve 504, which holds the expandable implant 100 during insertion of the implant.

Outer sleeve 504 has a distal end 522 and proximal end 524. Distal end 522 to has upper and lower extensions 526, 528, and side extensions 530 adapted to cooperatively engage trailing end 104 of implant 100. Side extensions 530 each have a flange 532 to cooperatively engage slot 126 of implant 100 and a stop 534 for limiting further advancement of implant holder 500 into trailing end 104 of implant 100.



50. As shown in figures 15 and 19 below, implant holder 500 further includes shaft 502 having a distal end 506 and a proximal end 508. (Ex. 1014, 12:46-50.) Shaft 502 includes a reduced portion 510, an intermediate reduced portion 511, and an enlarged portion 512. (*Id.*) The reduced portion 510 passes through the outer sleeve 504 and extends towards distal end 506. (*Id.*, 12:55-59, 14:65-15:4.) The enlarged portion 512 is positioned between intermediate reduced portion 511 and proximal end 508. (*Id.*, 12:46-50.)



(*Id.*, Figs. 15, 19 (both annotated).)

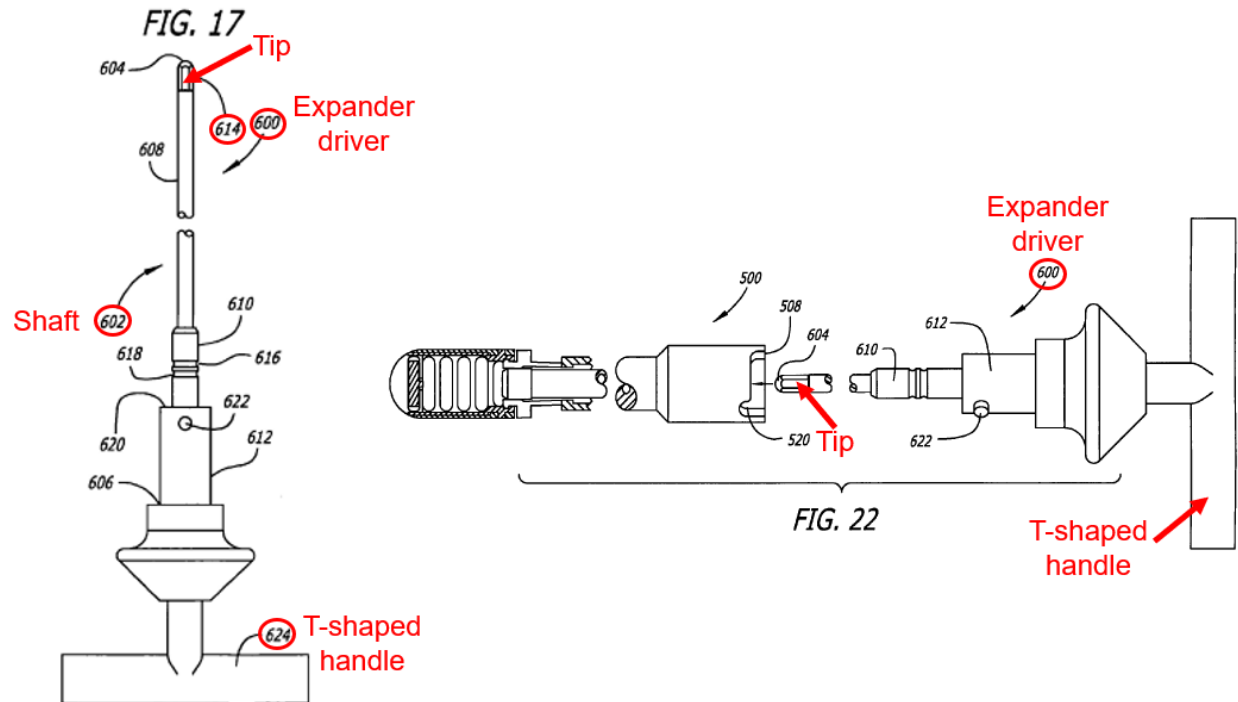
51. Michelson discloses that shaft 502 locks other components of Michelson's tool assembly during insertion of the implant:

Reduced portion 510 has a shoulder 514 at distal end 506 sized and shaped to cooperatively engage with the distal end of outer sleeve 504 to lock implant holder 500 to implant 100 in order to hold and

manipulate the implant during insertion into the disc space. As used herein, the term “lock” is intended to describe the securing of an implant to the implant holder such that the implant holder may rotate, push, pull, or otherwise orient the implant into the implantation space without the inadvertent disassociation of the implant from the implant holder. Extending from intermediate reduced portion 511 is a peg 516 proximate the leading edge of enlarged portion 512 for insertion into a slot 540 of outer sleeve 504. Proximal end 508 of enlarged portion 512 has an increased diameter adapted to receive enlarged portion 612 of an expander driver 600. Proximal end 508 has a cutout 518 for receiving a peg 622. Cutout 518 has a slot 520 for receiving peg 622 of expander driver 600 to prevent expander driver 600 from rotating relative to implant holder 500.

(Id., 12:55-13:6.)

52. As shown in figures 17 and 22 below, expander driver 600, which passes through the shaft 502, engages and rotates expander 120 of implant 100 to adjust the implant's height. *(Id., 13:20-32.)* Expander driver 600 includes shaft 602 between distal end 604 and proximal end 606. *(Id., 13:20-25.)* Distal end 604 has a tip 614 to engage opening 130 of expander 120, where tip 614 “may be of any shape suitable to engage expander 120.” *(Id., 13:28-32.)* Proximal end 606 has a T-shaped handle 624 for manual rotation of expander driver 600. *(Id., 13:42-44.)*



(*Id.*, Figs. 17, 22 (both annotated).)

53. 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.

3. McLuen and Michelson, Alone or in Combination, Disclose or Suggest A System Including An Expandable Intervertebral Fusion Device and Tools For Installing the Expandable Device

54. Independent claim 16 recites “[a] system.”⁴ (limitation [16.pre]) comprising “an expandable intervertebral fusion device” (limitation [16.a]) along

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

with three tools, namely “**a first tool . . . , wherein the first tool includes first and second engagement prongs**” (limitation [16.c]), “**a second tool**” (limitation [16.e]), and “**a third adjusting tool . . . , wherein the third adjusting tool includes . . . a screw engagement portion positioned at the third distal end**” (limitation [16.h]).

55. To the extent the preamble of claim 16, *i.e.*, “[a] **system**,” is limiting, McLuen discloses this limitation, as I explain below.

56. As discussed above in Section VIII.A.1, McLuen discloses a system comprising a spinal implant and a tool for securing the implant while the implant is expanded by another tool such as a “screw driver.” McLuen thus discloses “[a] **system**.” (*See also* my analysis below in Appendix [16.a]-[16.i].)

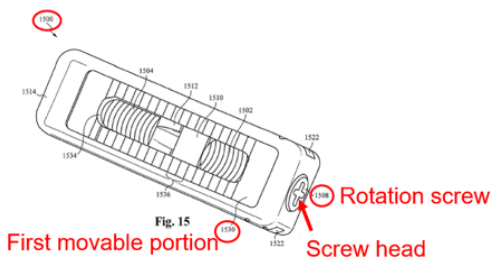
57. The combination of McLuen in view of Michelson further discloses and/or suggests claim 1’s “**system**” which includes “**an expandable intervertebral fusion device**” and a tool assembly comprising “**a first tool**,” “**a second tool**,” and “**a third adjusting tool**,” as required by claim 16. There are several reasons why a POSITA would have been motivated to combine the teachings of McLuen and Michelson.

i. McLuen Discloses “An Expandable Intervertebral Fusion Device”

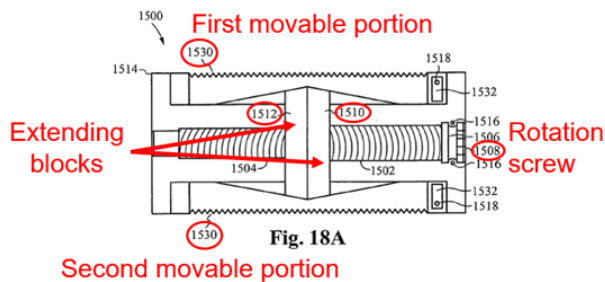
58. First, McLuen discloses the claimed “**expandable intervertebral fusion device**,” as recited in limitations [16.a] and [16.b]. McLuen discloses an expandable bone fusion device 1500 with two expandable tabs 1530 on the top and

bottom sides, *i.e.*, “**an expandable intervertebral fusion device comprising first and second movable portions,**” as required by limitation [16.a]. (Ex. 1012, ¶¶72-81, Figs. 15-18B.) As also shown in 15-16 and 18A-18B below, McLuen discloses that its bone fusion device 1500 includes positioning means 1508 (screw) coupled with a first extending block 1510 and second extending block 1512. (*Id.*, ¶¶74-75, 79-80, Figs. 15-18B.) In response to positioning means 1508 being rotated, “the extending blocks 1510 and 1512 each travel outwardly” and “[a]s the extending blocks 1510 and 1512 travel outwardly, they push the tabs 1530 outward,” *i.e.* it is “**an expansion mechanism configured to move the first movable portion with respect to the second movable portion,**” as further required by limitation [16.a]. (*Id.*, ¶74, Figs. 18A-B; *see also id.*, ¶¶75-81, Figs. 15-17.)

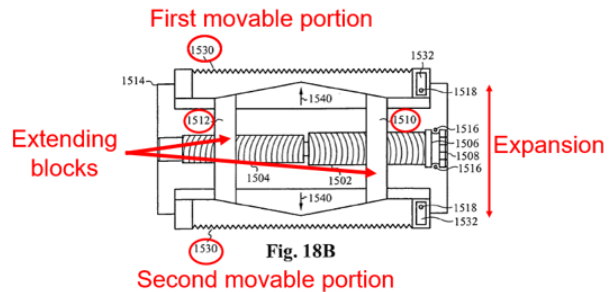
Expandable intervertebral
fusion device



Expandable intervertebral
fusion device (compact)

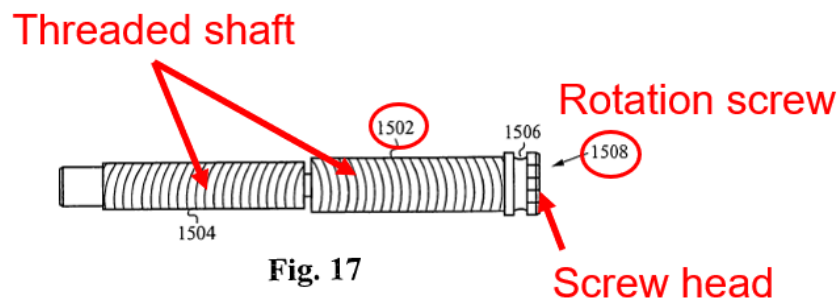


Expandable intervertebral
fusion device (expanded)



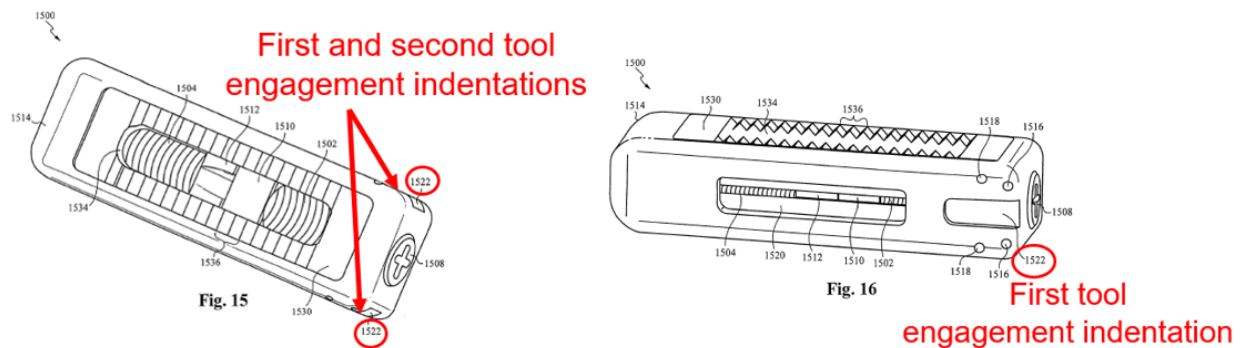
(*Id.*, Figs. 18A-18B (both annotated).)

59. As shown in the figures above and figure 17 below, McLuen's positioning means 1508 has a screw 1502, *i.e.*, “a **rotation screw**” with “a **screw head**,” to control placement of bone fusion device 1500, and “a **threaded shaft**,” as further required by limitation [16.a]. (*Id.*, ¶¶78, 81, Figs. 15-18B.)



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

60. As shown in figures 15-16 below, McLuen's bone fusion device 1500 defines channels 1522, *i.e.*, “**first and second tool engagement indentations**,” on side surfaces of device 1500, *i.e.*, “**on first and second sides of the expandable intervertebral fusion device**.” (*Id.*, ¶76; *see also id.*, ¶¶77-78.)



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

**ii. A POSITA Would Have Been Motivated to Use
Michelson's Tool Assembly with McLuen's Implant**

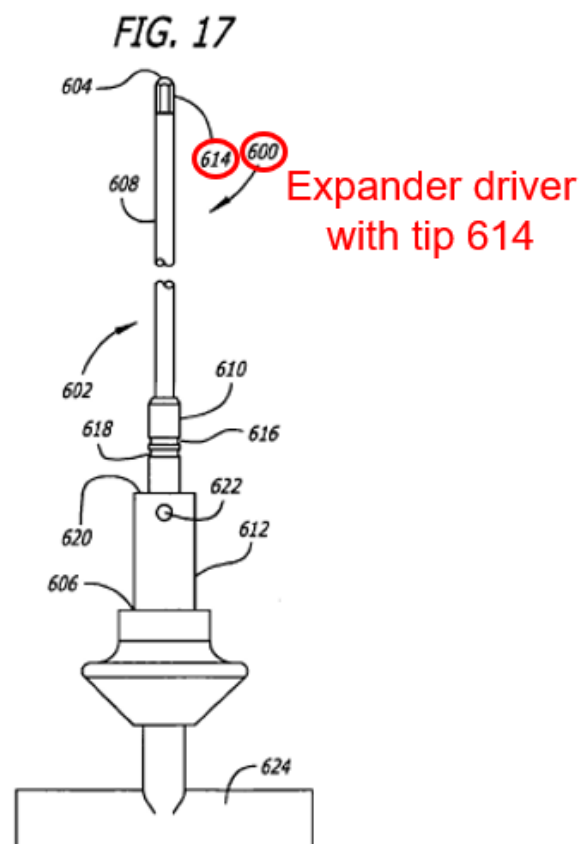
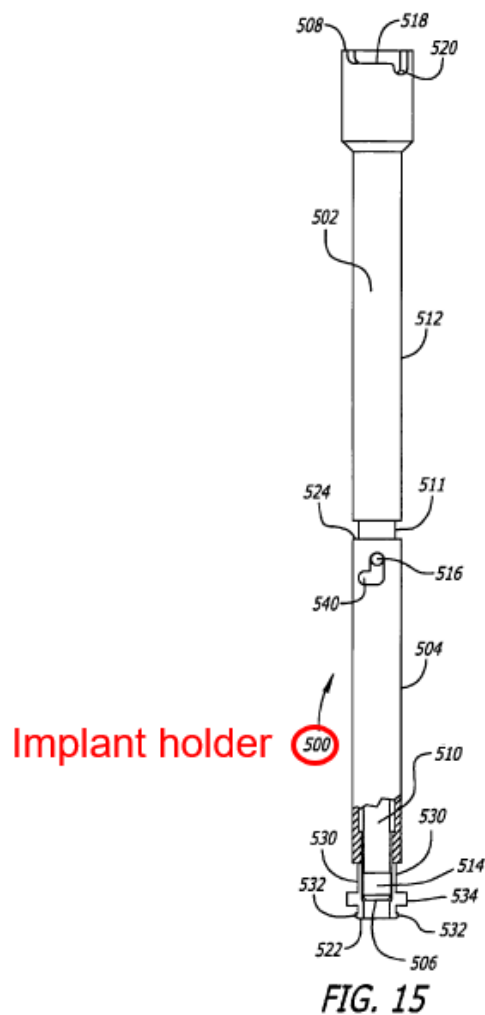
61. McLuen discloses that “[i]nsertion and delivery of the bone fusion device are performed by using arthroscopic tool(s),” including positioning the device in the target site. (Ex. 1012, ¶¶58-59, Fig. 8.) As I discussed in Section VIII.A.1, McLuen further explains that use of its spinal implant requires tools with both (1) a screwdriver or similar implement to expand the implant; and (2) another tool that fits into channels on the implant to secure it in place and keep the screwdriver from slipping. (*Id.*, ¶76 (“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.”).)

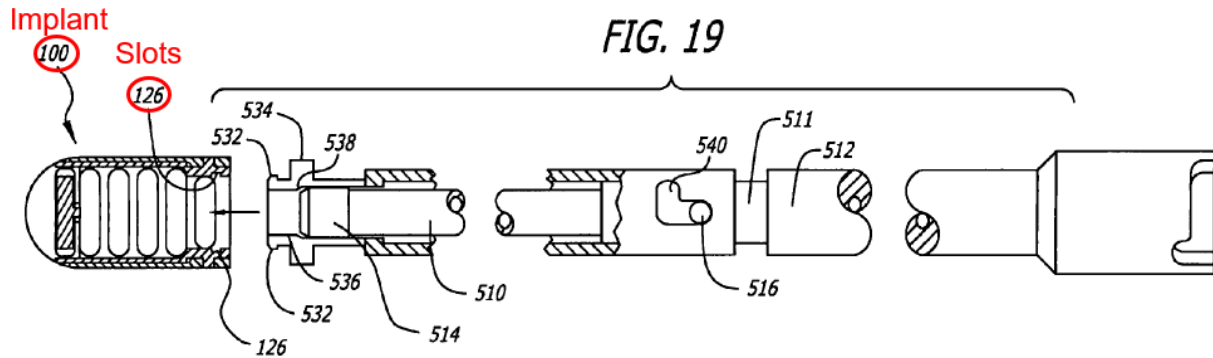
62. McLuen, however, does not disclose or illustrate the tool combination capable of providing the above-described functions. Nevertheless, McLuen

provides sufficient disclosure for a POSITA to select tool assemblies that would achieve those functions in the prior art, such as the Michelson tool assembly. There are several reasons why it would have been obvious to a POSITA to combine the teachings of McLuen and Michelson.

63. As I discussed above in Section VIII.A.2, like McLuen, Michelson discloses “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.” (Ex. 1014, 1:15-21.) Michelson is thus directed to expandable spinal implants and tool assemblies for implanting and expanding such an expandable spinal implant. (*Id.*, Abstract, 2:48-3:29, 8:38-9:14, 12:38-13:53, Figs. 1, 7, 15-25, 33-34.) For example, Michelson’s implant 100 is expanded in response to an expander driver 600 with tip 614 rotating the implant’s expanding mechanism, like the McLuen implant. (*Compare* Ex. 1012, ¶¶74-80, Figs. 15-18B *with* Ex. 1014, 10:6-11, 10:36-11:17, Figs. 1, 7, 15-25, 33-34.) Michelson also discloses that its implant 100 has slots 126 on its side for engagement with the distal end of an outer sleeve 504 of implant holder 500 so the implant can be held securely during delivery and expansion. (Ex. 1014, 12:38-13:53, Figs. 15-24.) Given these functional and structural similarities between the McLuen and Michelson implants

and the tool assemblies suggested in both references, a POSITA would have been motivated to combine the teachings of McLuen and Michelson such that a tool assembly like Michelson's is used to deliver and expand McLuen's bone fusion device 1500.





(*Id.*, Figs. 15-16 (top), 19 (bottom) (all annotated).)

64. As I discuss in my analysis in Appendix [16.c]-[16.i], Michelson's tool assembly discloses the features related to "**a first tool**", "**a second tool**", and "**a third adjusting tool**", as required by claim 16.

65. A POSITA would have been motivated to use Michelson's tool assembly with McLuen's implant because Michelson's tool assembly is designed to hold the implant securely in place during insertion into the body and expansion at the target site, which prevents the tool expanding the implant from slipping off the implant during the expansion process and/or prematurely expanding the implant. Indeed, the problem of the expansion tool slipping was well-known to a POSITA as evidenced by McLuen, which discloses 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, ¶76.)

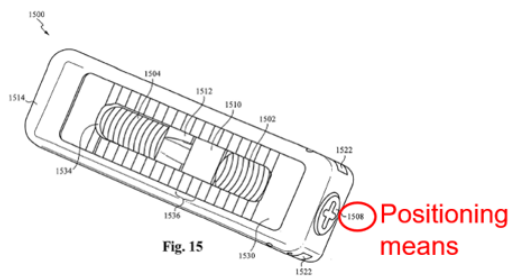
66. Michelson's tool assembly addressed the problem identified by

McLuen, and known to a POSITA, by providing a shaft 502 with a locking mechanism for holding the implant securely at the target site (with outer sleeve 504) while another portion of the tool assembly (expander driver 600) rotates the implant's expansion mechanism. (Ex. 1014, 10:12-15, 12:55-13:6, 15:35-53 (disclosing that locking expander driver 600 to implant holder 500 "allows handle 624 of expander driver 600 to control the manipulation of the implant itself and allows for the driving forward of implant holder 500 and implant 100 into the disc space without movement of the expander so that the implant remains in the collapsed position during insertion.").)

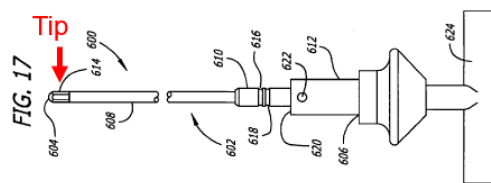
67. A POSITA would have also been motivated to use a tool assembly like Michelson's with the McLuen implant because it offers the advantage of a tool assembly that can both deliver the implant to its desired location and securely expand it when the implant is in position. (*Id.*, 12:38-53.) A tool assembly that could be used for both insertion and expansion of the implant, like Michelson'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.

68. A POSITA would have also had a reasonable expectation of success in using Michelson's tool assembly to deliver and securely expand McLuen's fusion device 1500. For instance, 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. (*Id.*, 13:28-32, 15:28-35, Figs. 17-18.) Given that McLuen's implant is expanded by rotating positioning means 1508 with screw 1502 (which has a screw head), a POSITA would have shaped Michelson's tip 14 like a screw driver so it can expand McLuen's implant. (Ex. 1012, ¶¶74-75.) Thus, as shown in the figures below, in the McLuen-Michelson combination, Michelson's tip 614 would have engaged the screw head of McLuen's positioning means 1508 to adjust the height of bone fusion device 1500. (*Id.*).



McLuen



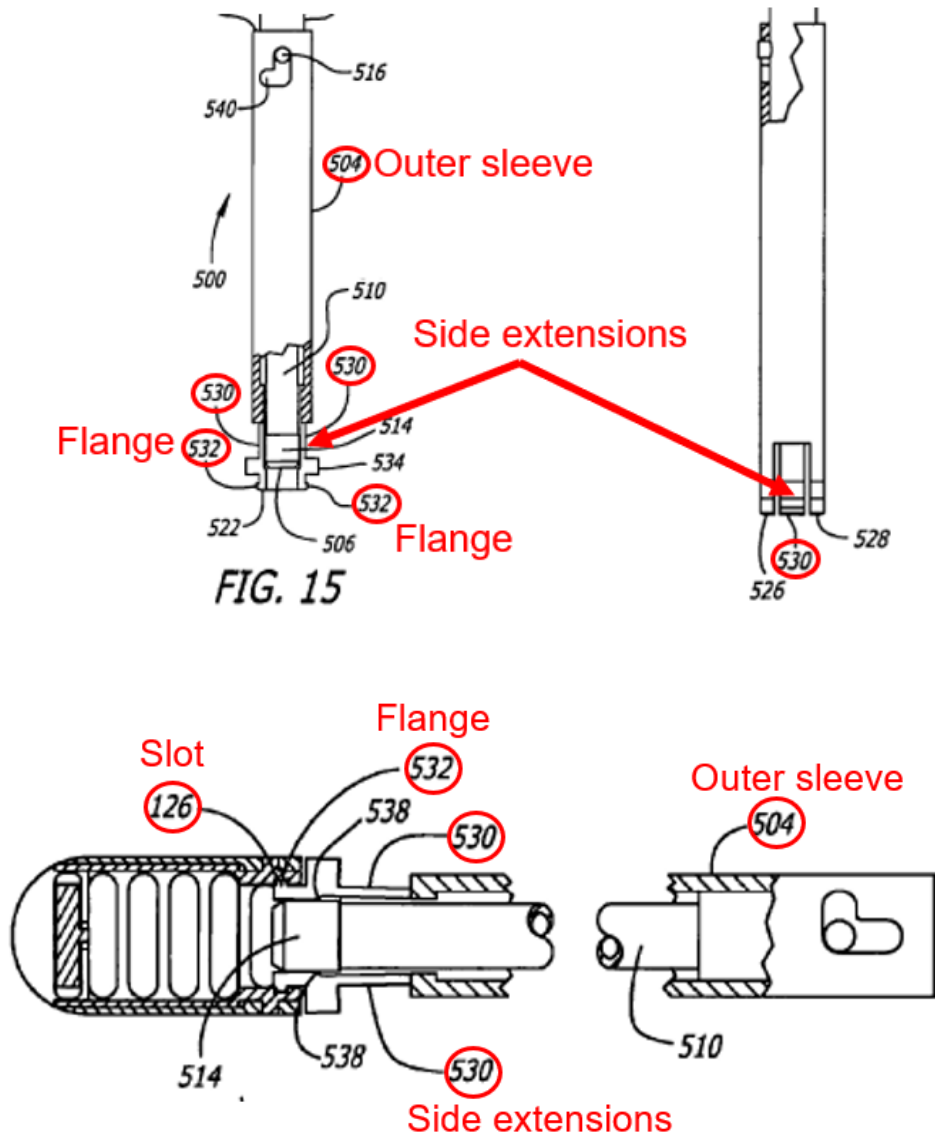
Michelson

(*Id.*, Fig. 15 (annotated); Ex. 1014, Fig. 17 (annotated).)

69. I note that limitation [16.c] requires that **“the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis.”**

70. As shown in excerpted portions of figures 15-16 and 20 below, Michelson's implant holder 500 includes side extensions 530 each having a flange 532 to cooperatively engage corresponding slots 126 of the implant, like the surgical

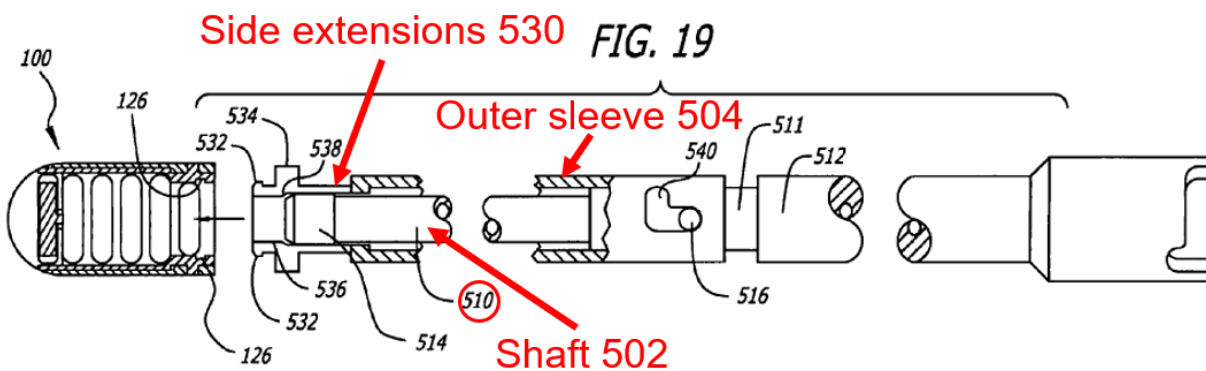
tool envisioned by McLuen to engage channels 1522 of its bone fusion device 1500. (Ex. 1014, 13:7-19, 14:65-15:13, Figs. 15-16, 19-20.) As can be seen below, the side extensions 530 are designed like prongs because they project out from the body of outer sleeve 504 to engage with the implant's slots 126.



(*Id.*, Figs. 15-16 (top) (both excerpted and annotated), Fig. 20 (bottom) (excerpted and annotated).)

71. So that Michelson's tool assembly functions with the McLuen implant, a POSITA would have modified Michelson's holding mechanism (e.g., side extensions 530 on the distal end of holder 500) to have prongs that could engage channels 1522 located on an outer wall of McLuen's implant. Indeed, Michelson recognized that its holding mechanism may be modified depending on the engagement structure on the implant: "It will be appreciated that instead of forcing side extensions 530 away from one another, *the implant holder may be adapted so that the side extensions may be forced toward one another to lock the implant to the implant holder,*" which is the mechanism that would allow Michelson's tool assembly to attach to McLuen's implant. (*Id.*, 15:8-13 (emphasis added).) Indeed, tools for delivering implants which included mechanisms like prongs or arms that secured the outer sides of the implant during delivery were well-known during the time of the alleged invention of the '797 patent. (Ex. 1039, 5:18-26, Fig. 12, Ex. 1013, Figs. 35-36, ¶¶226-33; Ex. 1015, Figs. 5-8, ¶¶19, 22.) Locking features in such instruments were also known to allow various tools to interlock with each other to securely hold and deliver an implant to a target site. (Ex. 1015, ¶¶34-37, Figs. 7-12.) Thus, such a modification would have been within the routine skill of a POSITA as the purpose of Michelson's tool assembly is to insert and manipulate the implant securely without undesirable movement or rotation thereof, as discussed above. For example, with reference to Michelson's figure 19 below, a POSITA

would have modified the side extensions 1530 of outer sleeve 504 such that they would have engaged McLuen's channels 1522 and correspondingly modified the distal portion of shaft 502 (which includes reduced portion 510) such that it would lock the side extensions 1530, e.g., through dovetail joints. Such modifications and other minor alterations are well within the level of ordinary skill.



(Ex. 1014, Fig. 19 (annotated).)

72. In view of the foregoing, a POSITA would have been motivated to combine McLuen with Michelson such that Michelson's tool assembly would have been used to implant and expand McLuen's bone fusion device.

IX. CONCLUSION

73. 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.

Brad Culbert

Dated: November 10, 2025

By: _____

Brad Culbert

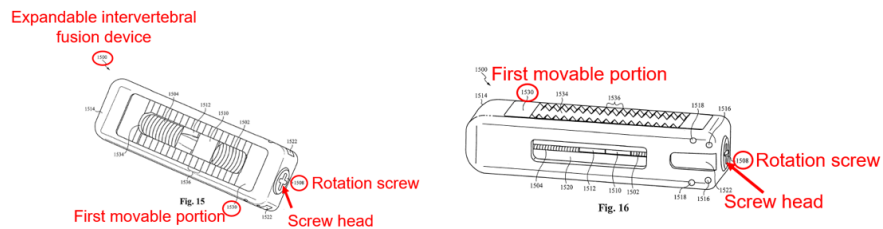
APPENDIX

'797 Patent Claim Element	Prior Art Analysis
Claim 16	
[16.pre] “A system comprising:”	To the extent the preamble is limiting, McLuen discloses this limitation. As I discussed above in Section VIII.A.1, McLuen discloses a system comprising a spinal implant and a tool for securing the implant while the implant is expanded by another tool such as a “screw driver.” McLuen thus disclose “[a] system.” (<i>See also</i> my analysis below in Appendix [16.a]-[16.i].)

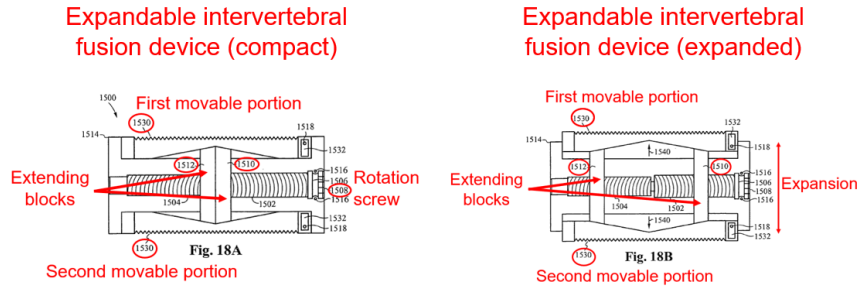
[16.a] “an expandable intervertebral fusion device comprising first and second movable portions and an expansion mechanism configured to move the first movable portion with respect to the second movable portion, wherein the expansion mechanism comprises at least a rotation screw having a screw head and a threaded shaft,”

McLuen discloses this limitation. As shown in figures 15-16 and 18A-18B below, McLuen discloses an expandable bone fusion device 1500, “which is inserted between the vertebrae” and has two expandable tabs 1530 on the top and bottom sides. (Ex. 1012, ¶¶72-81, Figs. 15-18B.) The bone fusion device 1500 is therefore, an “**expandable intervertebral fusion device**,” where the expandable tabs 1530 constitute “**first and second movable portions**.”

As also shown in 15-16 and 18A-18B below, McLuen discloses that its bone fusion device 1500 includes positioning means 1508 (screw) coupled with a first extending block 1510 and second extending block 1512. (*Id.*, ¶¶74-75, 79-80, Figs. 15-18B.) In response to positioning means 1508 being rotated, “the extending blocks 1510 and 1512 each travel outwardly” and “[a]s the extending blocks 1510 and 1512 travel outwardly, they push the tabs 1530 outward.” Therefore, positioning means 1508 along with extending blocks 1510 and 1512 collectively disclose “**an expansion mechanism configured to move the first movable portion with respect to the second movable portion**.” (*Id.*, ¶74, Figs. 18A-B; *see also id.*, ¶¶75-81, Figs. 15-17.)

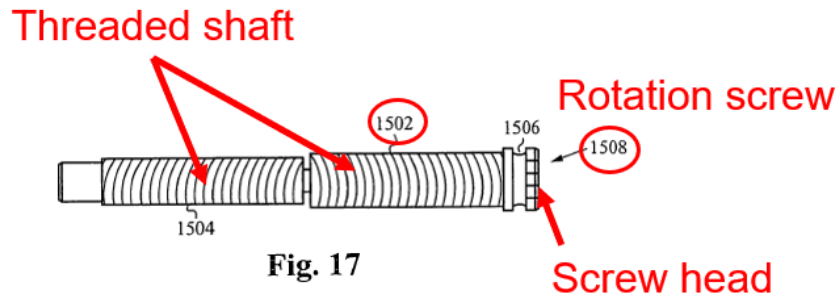


(*Id.*, Figs. 15-16 (both annotated).)



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

As shown in the figures above and figure 17 below, McLuen’s positioning means 1508 (portion of the “**expansion mechanism**”) is a screw 1502, *i.e.*, “**a rotation screw**” with “**a screw head**,” to control placement of bone fusion device 1500, and “**a threaded shaft**.” (*Id.*, ¶¶78, 81, Figs. 15-18B.)

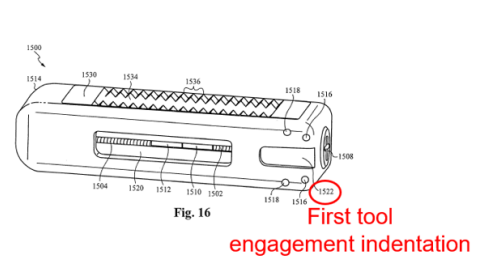
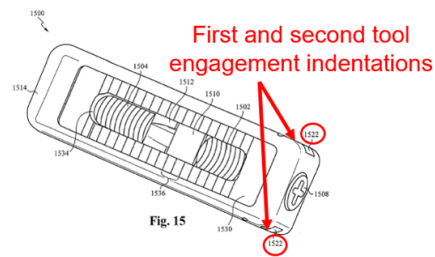


(*Id.*, Fig. 17 (annotated).)

McLuen thus discloses limitation [16.a].

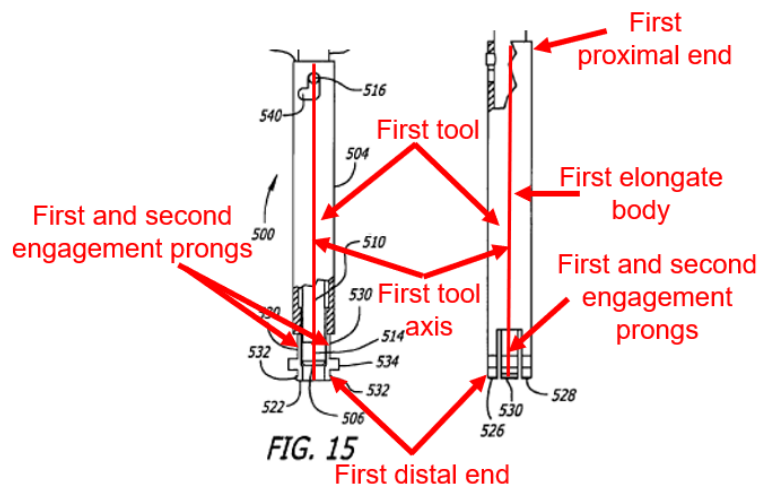
[16.b] “wherein the expandable intervertebral fusion device defines first and second tool engagement indentations on first and second sides of the expandable intervertebral fusion device;”

McLuen discloses this limitation. As shown in figures 15-16 below, McLuen’s bone fusion device 1500 defines channels 1522, *i.e.*, “**first and second tool engagement indentations,**” on side surfaces of device 1500, *i.e.*, “**on first and second sides of the expandable intervertebral fusion device.**” (Ex. 1012, ¶76; *see also id.*, ¶¶77-78.)



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

[16.c] “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,”	McLuen and Michelson disclose and/or suggest a system including “an expandable intervertebral fusion device” and a tool assembly comprising “a first tool,” as recited in this limitation ([16.c]) along with “a second tool” and “a third adjusting tool,” as recited in limitations [16.d]-[16.i], for the reasons I discussed in Section VIII.A.3. Michelson discloses “a first tool,” as claimed in limitation [16.c]. For example, Michelson’s implant holder 500, shown in excerpted portions of figures 15-16 below, includes a “shaft 502 and an outer sleeve 504.” (Ex. 1014, 12:4-56.) As shown below, outer sleeve 504 is a first tool for holding the expandable implant 100 during insertion of the implant. Outer sleeve 504 has a proximal end 524, distal end 522, and an elongate body between the proximal and distal ends, <i>i.e.</i>, “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.” (<i>Id.</i>, 13:7-8.) As also shown below, outer sleeve 504 defines a tool axis from its proximal end 524 to distal end 522, <i>i.e.</i>, “the first tool defines a first tool axis from the first proximal end to the first distal end.” (<i>Id.</i>, 13:7-13.) As also shown below in figures 15-16, distal end 522 of outer sleeve 504 includes side extensions 530 with flanges 532, which are designed as prongs, on opposite sides of the first tool axis to engage slots 126 of implant 100. As discussed above, in the McLuen-Michelson combination, a POSITA would have been motivated to modify Michelson’s side extensions 530 so they are configured to engage channels 1522 located on the outer wall of McLuen’s implant, <i>i.e.</i>, “the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis.” (<i>Id.</i>, 13:7-19, 14:65-15:13.)
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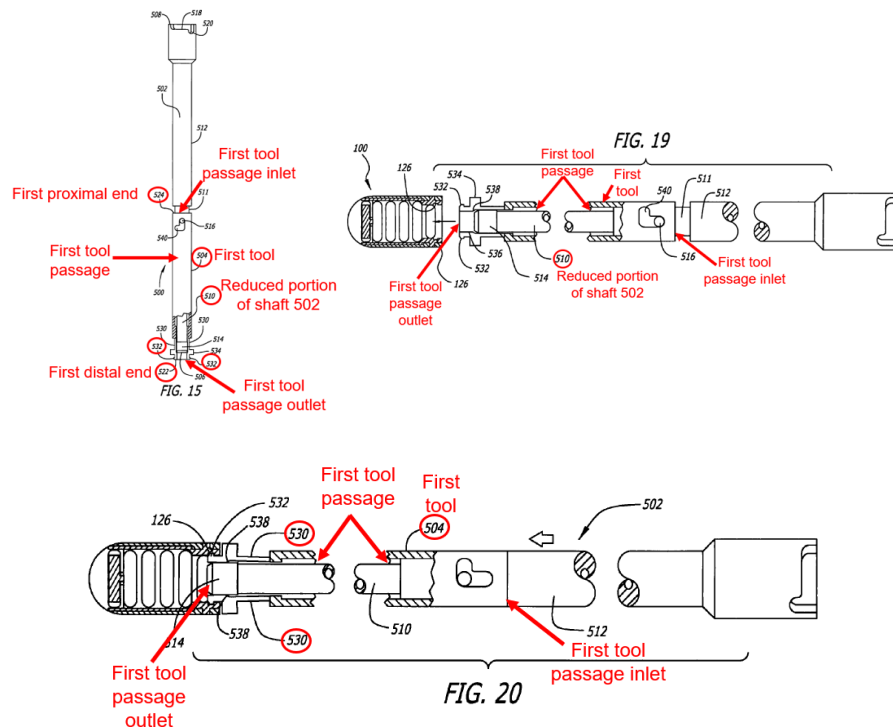


(*Id.*, Figs. 15-16 (both excerpted and annotated).)

McLuen and Michelson thus disclose and/or suggest limitation [16.c].

[16.d] “wherein the first tool defines a first tool passage that extends through the first tool from a first tool passage inlet at the first proximal end to a first tool passage outlet at the first distal end, wherein the first tool outlet is positioned between the first and second engagement prongs;”

McLuen and Michelson disclose and/or suggest this limitation. As shown in figures 15 and 19 below, outer sleeve 504 is hollow inside to allow a portion of shaft 502 (e.g., reduced portion 510 of shaft 502) to pass through the sleeve 504 from an inlet at proximal end 524 to an outlet at distal end 522, *i.e.*, “**the first tool defines a first tool passage that extends through the first tool from a first tool passage inlet at the first proximal end to a first tool passage outlet at the first distal end.**” (Ex. 1014, 15:1-8; *see also id.*, 12:43-67, 13:7-19.) As can be seen in figures 19 and 20 below, the outlet at the distal end of outer sleeve 504 allows the distal end of shaft 502 to pass through the outer sleeve 504 (e.g., shaft 502 includes a shoulder 514 at its distal end that passes through the outlet at the outer sleeve 504’s distal end). (*Id.*, 13:13-19, 15:1-8.) As also shown in figures 19 and 20 below, the outlet at distal end 522 is positioned between side extensions 530, *i.e.*, “**the first tool outlet is positioned between the first and second engagement prongs.**” (*Id.*)



(*Id.*, Figs. 15, 19, 20 (all annotated).)

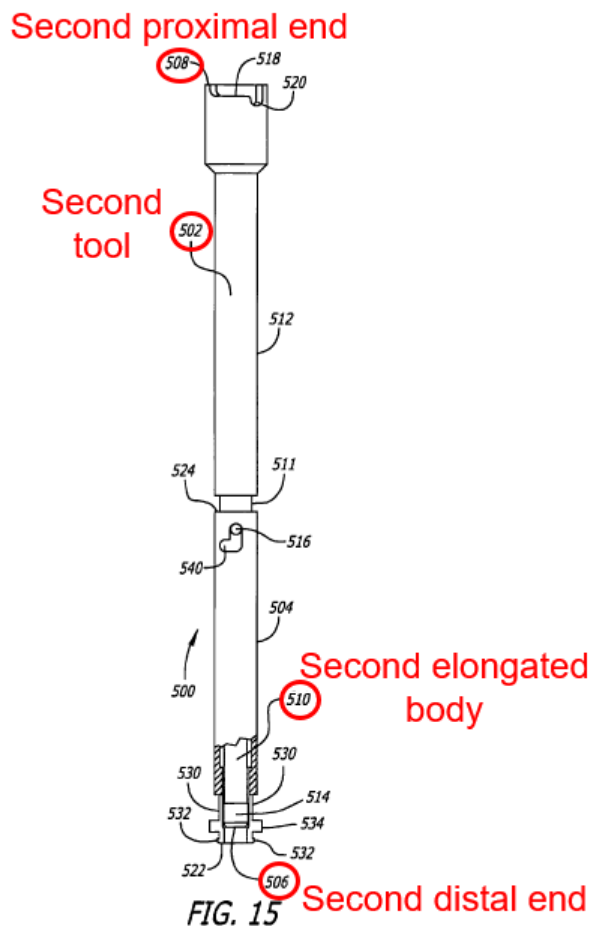
Declaration of Mr. Brad Culbert

U.S. Patent No. 11,096,797

	McLuen and Michelson thus disclose and/or suggest limitation [16.d].
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[16.e] “a second tool having a second proximal end, a second distal end, and a second elongate body between the second proximal end and the second distal end,”

McLuen and Michelson disclose and/or suggest this limitation. As shown in figure 15 below, Michelson discloses a shaft 502 having a proximal end 508, a distal end 506, and a reduced portion 510 with an elongate body between proximal end 508 to distal end 506. (Ex. 1014, 12:45-52.) As discussed in Sections VIII.A.2 and VIII.A.3.ii, shaft 502 includes a locking mechanism to hold the implant 100 in place during insertion. (*Id.*, 12:43-13:6, Figs. 15-16.) Therefore, shaft 502 is a “**second tool**,” where the proximal end 508 and distal end 506 constitute “**a second proximal end**” and “**a second distal end**,” respectively, and the reduced portion 510 constitutes “**a second elongate body between the second proximal end and the second distal end.**”



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

[16.f] “wherein the second tool defines a second tool passage that extends through the second tool from a second tool passage inlet at the second proximal end to a second tool passage outlet at the second distal end, and”

McLuen and Michelson disclose and/or suggest this limitation. As shown in figures 15 and 22 below, shaft 502 is hollow inside to allow shaft 602 of expander driver 600 to pass through the shaft 502 from an inlet at proximal end 508 to an outlet at distal end 506, *i.e.*, “**the second tool defines a second tool passage that extends through the second tool from a second tool passage inlet at the second proximal end to a second tool passage outlet at the second distal end.**” (Ex. 1014, 12:53-55 (“Shaft 502 is preferably hollow and is adapted to permit the passage of other instruments therethrough as described below” (emphasis added), 13:25-28 (“Shaft 602 [of expander driver 600] has a generally circular cross section and is adapted to preferably coaxially engage the interior of shaft 502 of implant holder 500 to maintain vertical alignment between expander driver 600 and implant holder 500.”); *see also id.*, 15:28-30.) As can be seen below in figure 23, the outlet at the distal end of shaft 502 allow for the distal end of expander driver 600 including its tip 614 to pass through the outlet to engage with the implant. (*Id.*, 5:20-26, 15:28-42.)

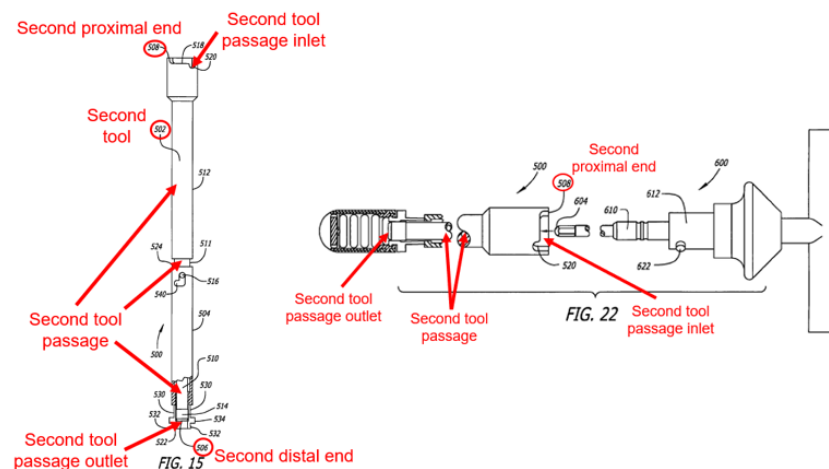
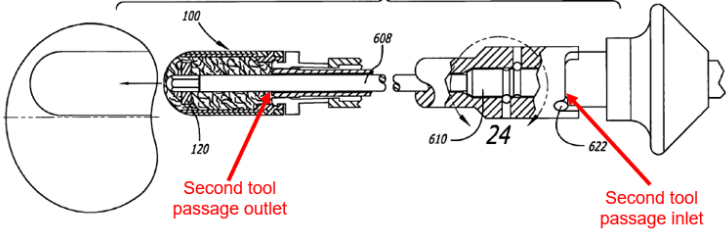
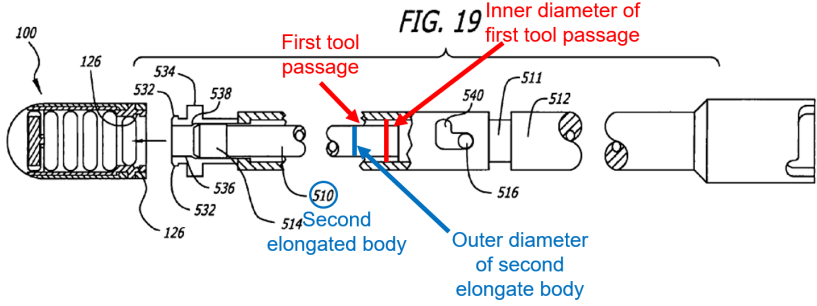
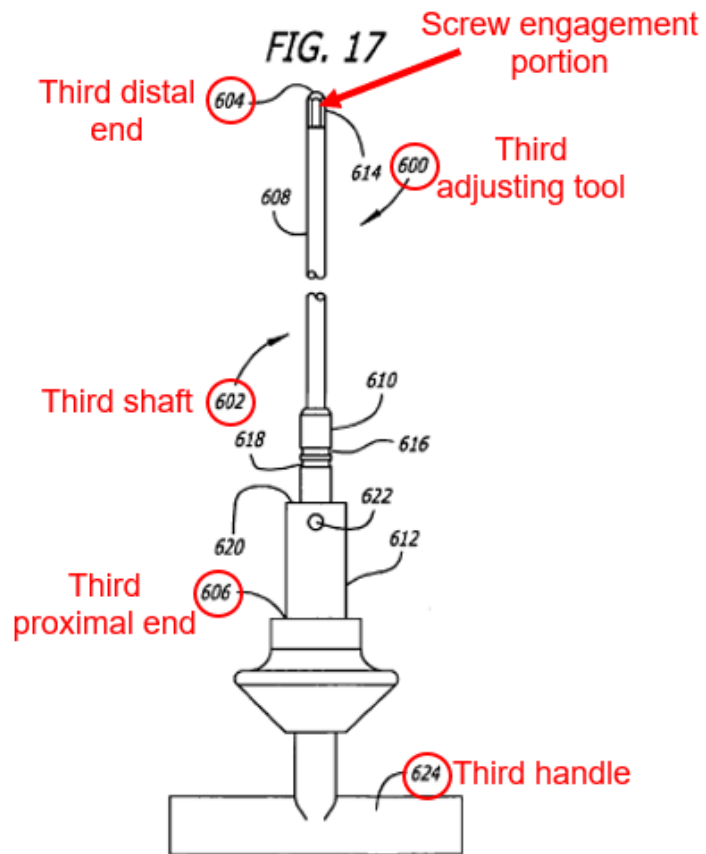


	FIG. 23  (<i>Id.</i>, Figs. 15, 22, 23 (all annotated)) McLuen and Michelson thus disclose and/or suggest limitation [16.f].
[16.g] “wherein an outer diameter of the second elongate body is less than an inner diameter of the first tool passage of the first tool such that the second elongate body can pass through the first tool passage; and”	McLuen and Michelson disclose and/or suggest this limitation. As I discussed with respect to limitation [16.d] above (<i>see</i> Appendix [16.d]), and as shown in figure 19 below, reduced portion 510 (“second elongate body”) of shaft 502 is passed through the outer sleeve 504 (“first tool passage of the first tool”), and thus “an outer diameter of the second elongate body” must be “less than an inner diameter of the first tool passage of the first tool” such that reduced portion 510 (“second elongate body”) can pass through outer sleeve 504 (“first tool passage”). (Ex. 1014, 15:1-8; <i>see also id.</i>, 12:43-67, 13:7-19.) FIG. 19  (<i>Id.</i>, Fig. 19 (annotated).) McLuen and Michelson thus disclose and/or suggest limitation [16.g].

[16.h] “a third adjusting tool having a third proximal end and a third distal end, wherein the third adjusting tool includes a third handle positioned at the third proximal end, a screw engagement portion positioned at the third distal end, and a third shaft extending from the third handle to the screw engagement portion, and”	McLuen in view of Michelson discloses and/or suggests this limitation. Michelson discloses an “expander driver 600 for engaging and rotating expander 120,” <i>i.e.</i>, “a third adjusting tool.” (Ex. 1014, 13:20-21.) As shown in figure 17 below, expander driver 600 includes a proximal end 606 and distal end 604, <i>i.e.</i>, “a third proximal end and a third distal end.” (<i>Id.</i>, 13:22-25.) “Proximal end 606 has a T-shaped handle 624 for manual rotation of expander driver 600,” <i>i.e.</i>, “the third adjusting tool includes a third handle positioned at the third proximal end.” (<i>Id.</i>, 13:42-44.) “Distal end 604 has a tip 614 adapted to cooperatively engage opening 130 of expander 120.” (<i>Id.</i>, 13:28-30.) As I discussed in Section VIII.A.3.ii above, in the McLuen-Michelson combination, a POSITA would have been motivated to configure tip 614 at distal end 604 to include a screw driver tip such that it engaged with McLuen’s screw head of positioning means 1508, <i>i.e.</i>, “a screw engagement portion positioned at the third distal end.” As also shown in figure 17 below, expander driver 600 further includes shaft 602 extending from T-shaped handle 624 to tip 614, <i>i.e.</i>, “a third shaft extending from the third handle to the screw engagement portion.” (<i>Id.</i>, 13:20-32, 13:42-44.)
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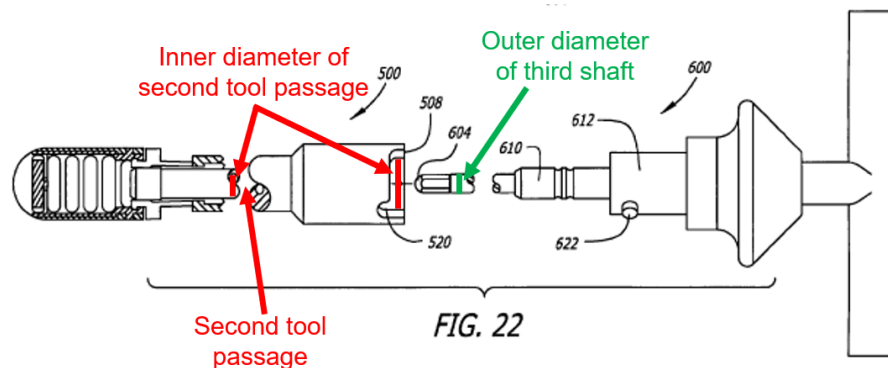


(*Id.*, Fig. 17 (annotated).)

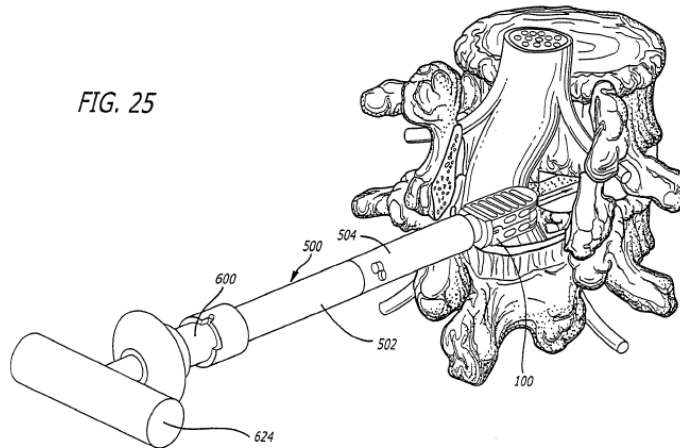
McLuen and Michelson thus disclose and/or suggest limitation [16.h].

[16.i] “wherein an outer diameter of the third shaft is less than an inner diameter of the second tool passage of the second tool such that the third shaft can extend through the second tool passage while the second tool is positioned in the first tool passage of the first tool.”

McLuen and Michelson disclose and/or suggest this limitation. As discussed with respect to limitation [16.f] above (*see* Appendix [16.f]), and as shown in figure 22 below, shaft 602 (“**third shaft**”) is passed through shaft 502 (“**second tool passage of the first tool**”). Thus, “**an outer diameter of the third shaft**” must be “**less than an inner diameter of the second tool passage of the second tool**” such that shaft 602 (“**third shaft**”) can extend through shaft 502 (“**second tool passage**”). (Ex. 1014, 13:25-28 (“Shaft 602 [of expander driver 600] has a generally circular cross section and is adapted to preferably coaxially engage the interior of shaft 502 of implant holder 500 to maintain vertical alignment between expander driver 600 and implant holder 500.”); *see also id.*, 12:53-55, 15:28-30.) As shown in figure 25 below, shaft 502 (“**second tool**”) is first inserted through outer sleeve 504 (“**first tool passage**”), and then the shaft 602 (“**third shaft**”) is inserted through shaft 502 while the shaft 502 is positioned inside the sleeve 504. (*Id.*)



(*Id.*, Fig. 22 (annotated).)



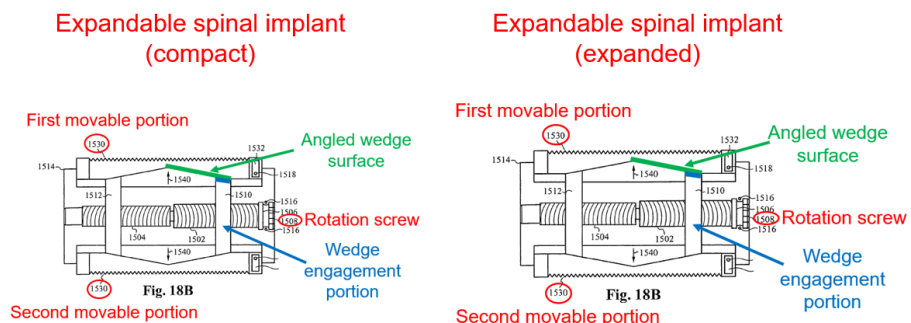
(*Id.*, Fig. 25.)

McLuen and Michelson thus disclose and/or suggest limitation [16.i].

Claim 19

“The system of claim 16, wherein the expansion mechanism further comprises an angled wedge surface defined by the first movable portion of the expandable intervertebral fusion device and a wedge engagement portion operably connected to the rotation screw such that rotation of the rotation screw causes the wedge engagement portion to slide along an axis of the rotation screw to push against the angled wedge surface of the first movable portion to expand the first movable portion with respect to the second movable portion.”

McLuen and Michelson disclose and/or suggest this limitation. As shown in figures 18A-18B below, McLuen’s expansion mechanism includes an angled wedge surface (in **green**) defined by the top expandable tab 1530 of bone fusion device 1500, *i.e.*, “**an angled wedge surface defined by the first movable portion of the expandable intervertebral fusion device.**” (Ex. 1012, ¶¶74-81.) Moreover, as I discussed with respect to limitation [16.a] (*see* Appendix [16.a]), and shown in figure 18A below, McLuen’s expansion mechanism includes a first extending block 1510 coupled to positioning means 1508 (“**rotation screw**”). (*Id.*) As shown in figure 18B below, turning of positioning means 1508, *i.e.*, “**rotation of the rotation screw,**” causes an angled surface of the first extending block 1510 (in **blue**) to slide along an axis of positioning means 1508 to push against the angled wedge surface of the top expandable tab 1530 (“**first movable portion**”) to expand the top expandable tab 1530 with respect to the bottom expandable tab 1530 (“**second movable portion**”). (*Id.*) Accordingly, the first extending block 1510 coupled to positioning means 1508 corresponds to the “**wedge engagement portion operably connected to the rotation screw.**”



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

McLuen and Michelson thus disclose and/or suggest the features set forth in claim 19.