

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

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,096,797**

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LIST OF EXHIBITS

Exhibit No.	Document
Ex. 1001	U.S. Patent No. 11,096,797 to Moskowitz et al. (“the ’797 patent”)
Ex. 1002	Declaration of Brad Culbert
Ex. 1003	Curriculum Vitae of Brad Culbert
Ex. 1004	File History for U.S. Patent No. 11,096,797
Ex. 1005	RESERVED
Ex. 1006	U.S. Patent Application Publication No. 2008/0249569 A1 to Waugh et al. (“Waugh”)
Ex. 1007- Ex. 1011	RESERVED
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. 1016- Ex. 1019	RESERVED
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)

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Exhibit No.	Document
Ex. 1022	Dil Patel et al., <i>Interbody options in lumbar fusion</i> , 5(1) J. SPINE SURG. S19 (2019)
Ex. 1023- Ex. 1036	RESERVED
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. 1038	RESERVED
Ex. 1039	U.S. Patent No. 5,658,335 to Allen (“Allen”)
Ex. 1040- Ex. 1052	RESERVED
Ex. 1053	U.S. Patent No. 7,846,188 to Moskowitz et al. (“the ’188 patent”)

I. INTRODUCTION

Medtronic, Inc. (“Petitioner”) respectfully requests *inter partes* review of claims 16 and 19 of U.S. Patent No. 11,096,797 (“the ’797 patent”) (Ex. 1001) assigned to Moskowitz Family LLC (“Patent Owner”). As this Petition demonstrates, these claims issued only because the Office overlooked the prior art cited in this Petition—in no small part due to Patent Owner’s deliberate occlusion of that art in a veritable forest of IDS citations.

Between most spine vertebrae are discs, which act as shock absorbers and allow for spinal flexibility. Over time, however, these discs may deteriorate or become injured, and surgery may be needed. The ’797 patent discloses an “expandable implant and tool system” that can allegedly be used to maintain the spacing between adjacent vertebrae. But, as demonstrated by the prior art cited in this Petition, such implants and tool systems were well-known to those of ordinary skill in the art at the relevant time.

While the ’797 patent claims priority to an application that was filed on April 12, 2005, the patent issued nearly two decades later on August 24, 2021. This extensive delay is the result of Patent Owner’s questionable prosecution strategy of relying on multifarious continuations and the burying of key prior art in successive IDS filings. In fact, in the family of the ’797 patent’s priority application alone, Patent Owner has filed at least 70 patent applications. And as explained below in

Section IX, the Office overlooked key prior art, McLuen (Ex. 1012) and Michelson (Ex. 1014), disclosing the very limitations forming the basis of the Office's reasons for allowance. This oversight was in no small part due to Patent Owner's prosecution strategy, which included burying McLuen and Michelson among over 320 references. (*See, e.g.*, Ex. 1004, 88-101.)

Petitioner therefore requests that this Petition be granted and that the challenged claims be found unpatentable and canceled.

II. MANDATORY NOTICES

Real Parties-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), the real party-in-interest is Medtronic, Inc. Medtronic plc is the ultimate parent of Medtronic Inc. Medtronic, Inc. is a co-defendant with Medtronic Sofamor Danek, Inc., Medtronic Sofamor Danek USA, Inc., Warsaw Orthopedic, Inc., and Titan Spine, Inc. in a suit involving the '797 patent (*see* Related Matters below).

Related Matters: Patent Owner asserted the '797 patent against Petitioner in the following civil action: *Moskowitz Family LLC v. Medtronic, Inc. et al*, U.S. District Court for the District of Minnesota, civil action no. 0:25-cv-00769, filed on February 28, 2025. Patents related to the '797 patent were previously at issue in IPRs filed by Globus Medical, Inc. (*See* IPR2020-01303, -01304, -01305, -01306, -01307, -01308, -01309, -01310.)

Counsel and Service Information: Lead counsel is Naveen Modi (Reg. No. 46,224). Backup counsel are (1) Young Park (Reg. No. 51,114), (2) Chetan Bansal (Reg. No. 81,590), and (3) Quadeer Ahmed (Reg. No. 60,835). Service information is Paul Hastings LLP, 2050 M Street NW, Washington, D.C. 20036, Tel.: 202.551.1700, Fax: 202.551.1705, email: PH-Medtronic-Moskowitz-IPR@paulhastings.com. Petitioner consents to electronic service.

III. PAYMENT OF FEES

The PTO is authorized to charge any fees due during this proceeding to Deposit Account No. 50-2613.

IV. STANDING

Petitioner certifies under 37 C.F.R. § 42.104(a) that the '737 patent is available for review and that Petitioner is not barred or estopped from requesting review on the grounds identified herein.

V. RELIEF REQUESTED AND GROUNDS RAISED

Petitioner respectfully requests review of claims 16 and 19 of the '797 patent and cancellation of these claims as unpatentable based on the following grounds:

Ground 1: Claims 16 and 19 are unpatentable under pre-AIA 35 U.S.C. § 103 as obvious over McLuen (Ex. 1012) and Michelson (Ex. 1014).

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. The ’797 patent also claims the benefit of U.S. provisional application No. 60/670,231, filed on April 12, 2005 (“the ’231 application”). The ’855 application resulted from two continuation-in-part applications claiming priority to the ’231 application. (Ex. 1001, 2.)

For purposes of this Petition, Petitioner has applied a priority date of August 21, 2007, which is the filing date of the ’855 application.¹ McLuen published on

¹ None of the applications in the priority chain of the ’797 patent with a filing date before the ’855 application disclose or provide support for the claimed expandable intervertebral fusion device and tool assembly comprising first, second, and third tools. For example, the ’855 application has completely different figures compared to prior U.S. Patent Application No. 11/536,815 (“the ’815 application”), filed on September 29, 2006. Applications prior to the ’855 application, including the ’815 application, do not provide support for the claimed expandable intervertebral fusion device (*e.g.*, “**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 limitation [16.b] below) and

November 9, 2006, from an application filed on July 10, 2006 (Ex. 1012, Cover), and thus qualifies as prior art under at least §§ 102(a) and (e). Michelson issued from an application filed February 4, 2002, and thus qualifies as prior art under at least § 102(e).

McLuen and Michelson were cited during prosecution in an IDS amongst more than 320 references. (Ex. 1004, 92 (reference no. 85), 94 (reference no. 134)²; *see also id.*, 88-101 (IDS).) The Office issued a first action allowance, and thus did not rely on McLuen or Michelson for any prior art rejections during prosecution.

VI. BACKGROUND

A. Technology Overview

1. Anatomy of the Spine and Intervertebral Discs

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; Ex. 1002, ¶24.³) It is composed of a series of bones called vertebrae, with most

tool assembly (*e.g.*, the “**first tool**,” “**second tool**,” and “**third adjusting tool**” features of limitations [16.c]-[16.i]). (Ex. 1002, ¶¶34-37; *see also id.*, ¶¶28-33.)

² The patent that issued from the McLuen publication is cited in the IDS.

³ Petitioner submits a declaration (Ex. 1002) by Mr. Brad Culbert, an expert in the field of spinal implants (Ex. 1003). (Ex. 1002, ¶¶21-22; *see also id.*, ¶¶3-20.)

vertebrae separated by fibrocartilaginous joints known as intervertebral discs. (*See* Ex. 1021, 2.) These discs act as cushions, absorbing shock and allowing flexibility for movement. (*Id.*) 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.) 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; Ex. 1002, ¶25.)

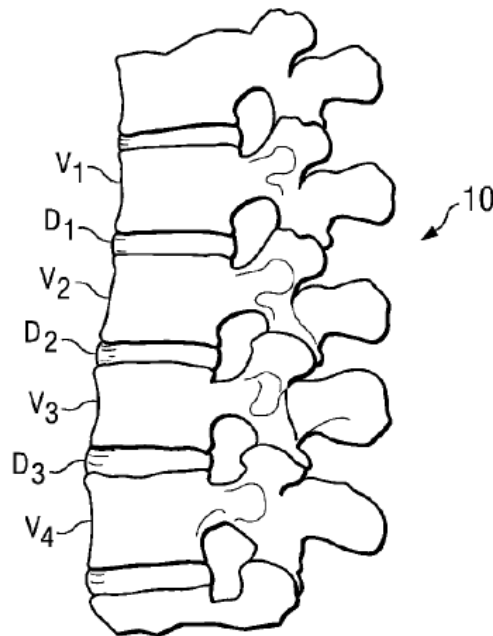


Fig. 1

(Ex. 1006, Fig. 1.)

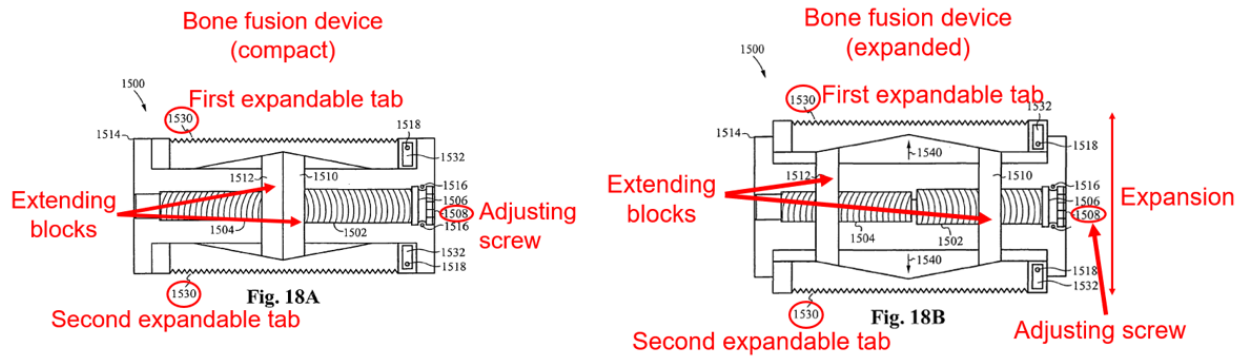
2. Expandable Intervertebral Fusion Devices and Surgical Tools for Installing the Devices

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* Ex. 1020, 15-20; *see also* Ex. 1022, 2.) These implants, known as intervertebral or interbody fusion devices are implants that are positioned between adjacent vertebrae and may employ various components, such as screws, to fuse with the vertebrae. (*See* Ex. 1022, 1-3; Ex. 1002, ¶26.)

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.*; Ex. 1002, ¶27.)

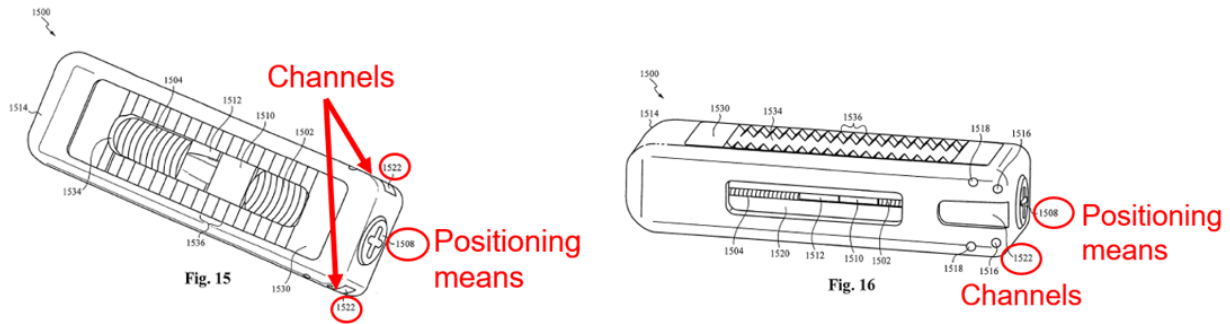
For example, as shown in figures 18A and 18B below, McLuen (Ex. 1012) discloses a bone fusion device 1500 including two expandable tabs 1530 on either side of device 1500. (Ex. 1012, ¶74, Figs. 15-18B; *see also id.*, ¶¶72-73; Ex. 1002, ¶¶40-43.) Bone fusion device 1500 also includes positioning means 1508 (including screws 1502, 1504). (Ex. 1012, ¶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 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.*) “As 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.)



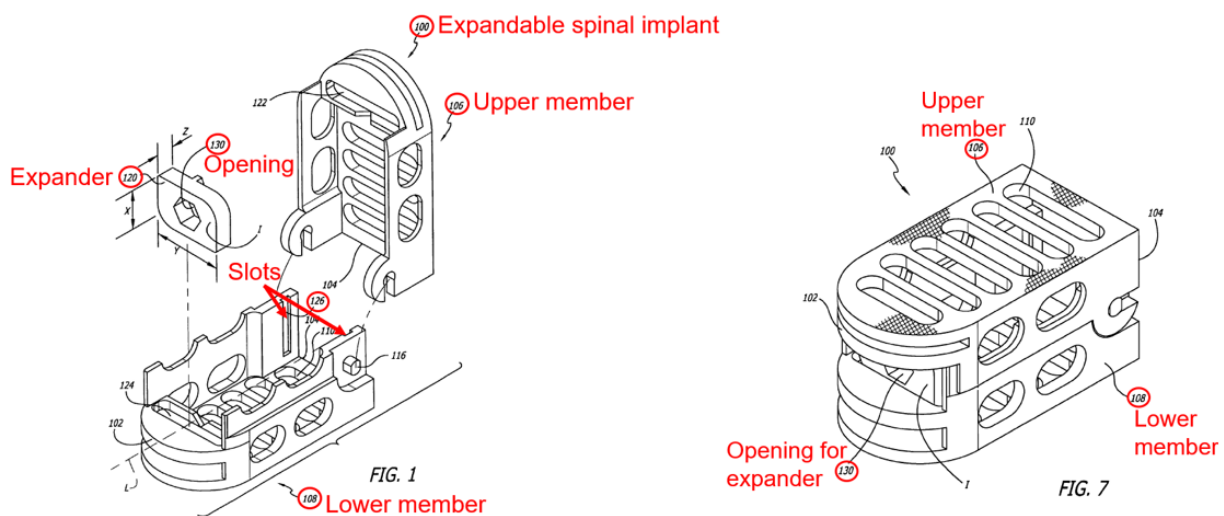
(*Id.*, Figs. 18A-18B (both annotated); Ex. 1002, ¶41.)

McLuen also discloses a tool assembly for implanting and expanding bone fusion device 1500. As shown in figures 15-16 below, while McLuen does not illustrate the specific surgical tools for implanting and expanding bone fusion device 1500, it discloses that a first tool (*e.g.*, a screw driver) is used to turn positioning means 1508. (Ex. 1012, ¶76.) McLuen further discloses 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.*; *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.)



(*Id.*, Figs. 15-16 (both annotated); Ex. 1002, ¶42.)

Michelson (Ex. 1014) also discloses an expandable spinal implant 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; Ex. 1002, ¶¶44-53.) As shown in figure 1 below, Michelson discloses an expandable interbody spinal fusion implant 100 with upper member 106 and lower member 108. (Ex. 1014, 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.*)

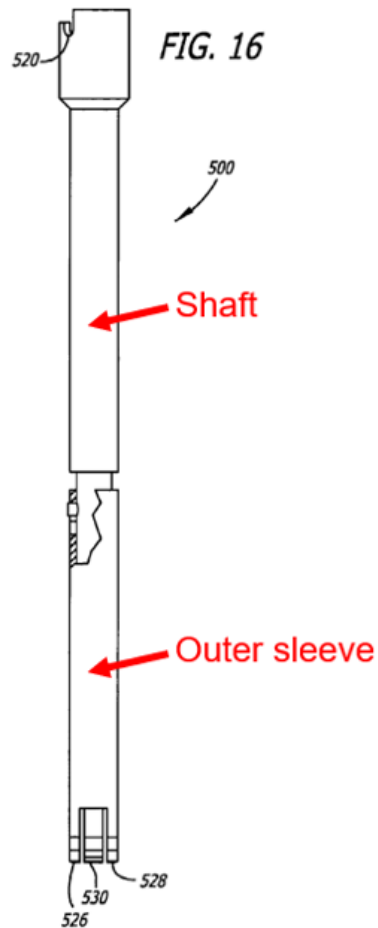
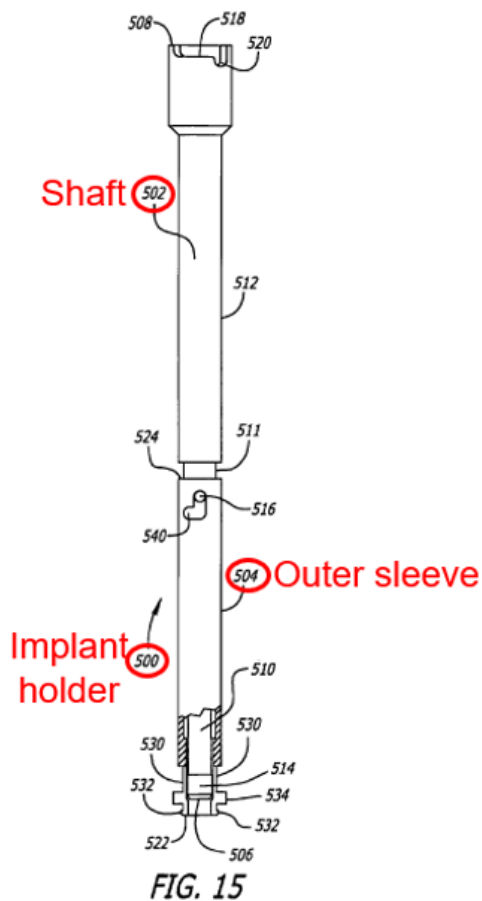


(*Id.*, Figs. 1, 7 (both annotated); Ex. 1002, ¶¶45-46.)

“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.” (Ex. 1014, 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.)

Tools for inserting and expanding expandable intervertebral fusion devices were also well-known before the alleged invention of the ’797 patent. (Ex. 1002, ¶¶27, 40-53.) For example, Michelson discloses a tool assembly including an implant holder 500, and expander driver 600. (Ex. 1014, 12:38-42.) As explained below, the expander driver 600 passes through the implant holder 500 to engage and rotates expander 120 of implant 100 to adjust the implant’s height.

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.)

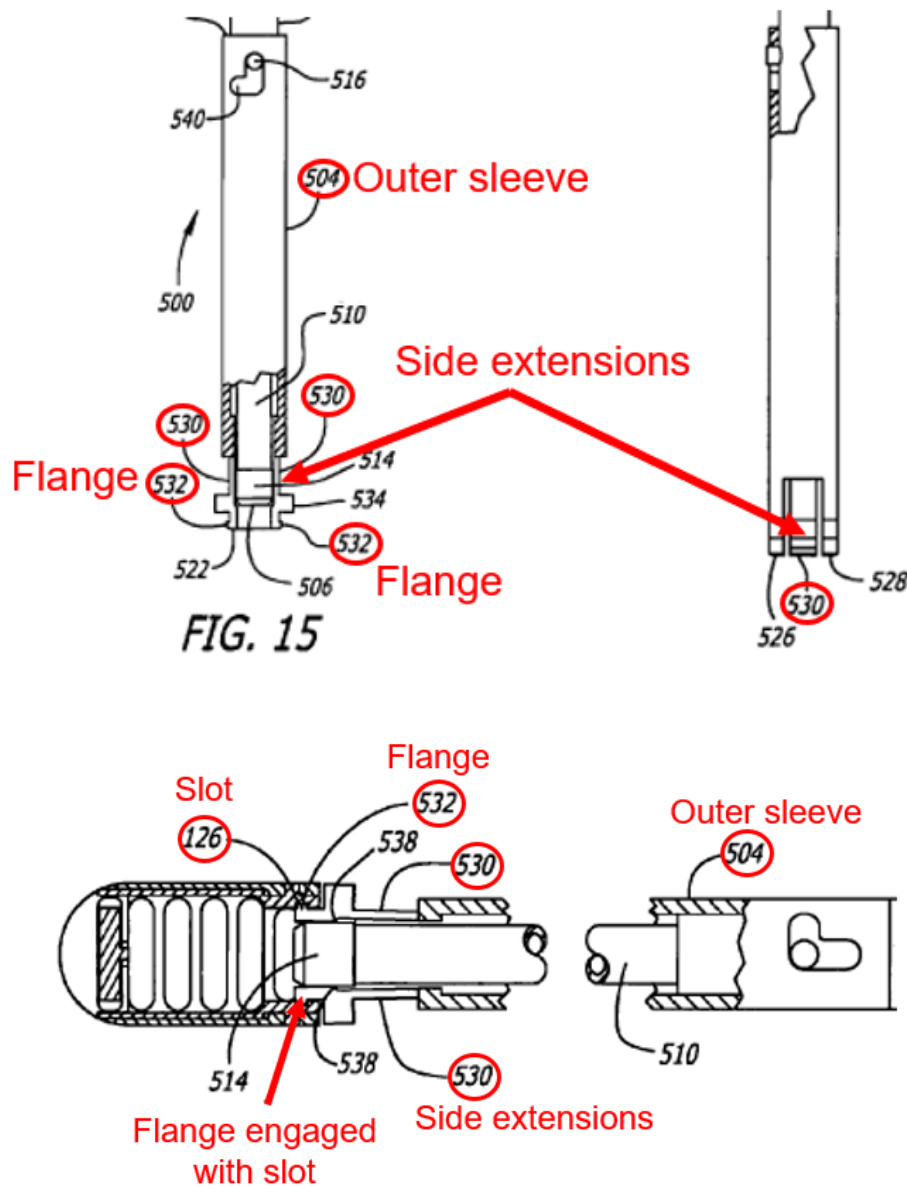


(*Id.*, Figs. 15-16 (both annotated); Ex. 1002, ¶48.)

As shown in excerpted portions of figures 15-16 and 20 below, outer sleeve 504 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.

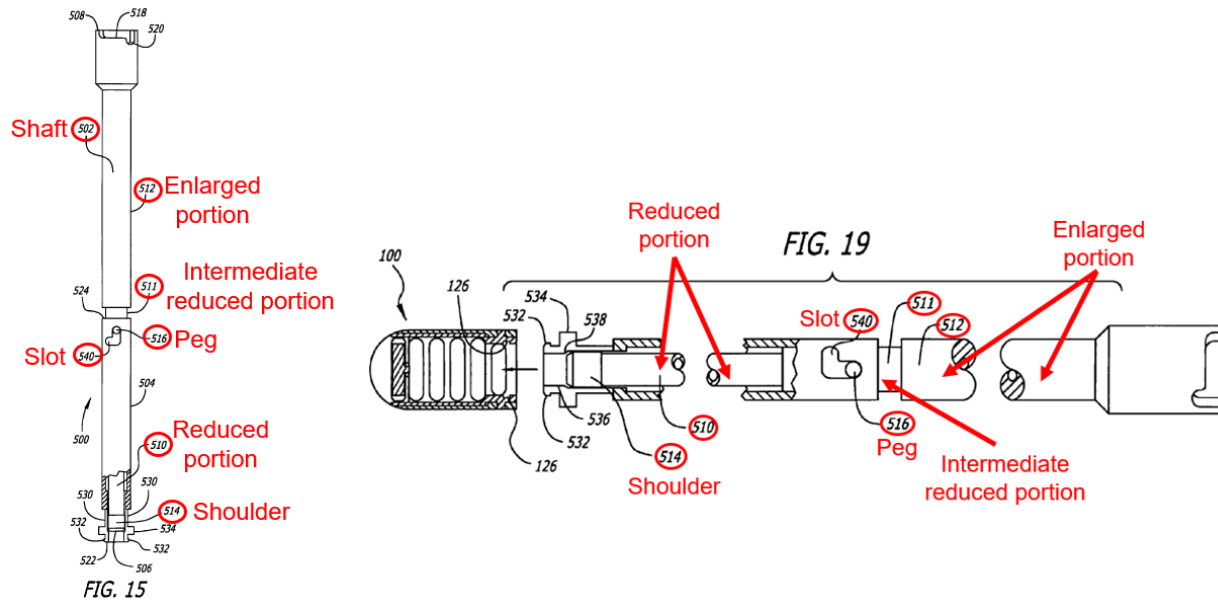
(Ex. 1014, 13:7-19.)



(*Id.*, Figs. 15-16 (top) (both excerpted and annotated), Fig. 20 (bottom) (excerpted and annotated); Ex. 1002, ¶49.)

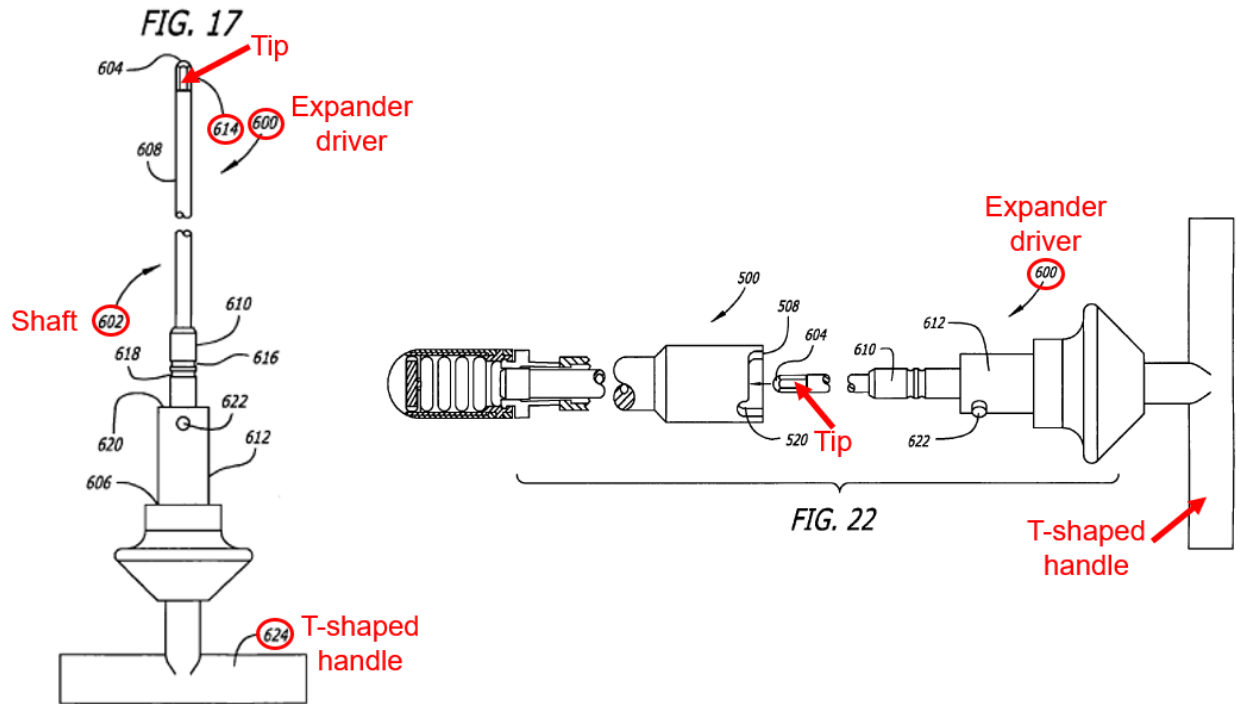
As shown in figures 15 and 19 below, shaft 502 has a distal end 506 and a proximal end 508. (Ex. 1014, 12:46-50.) Shaft 502 includes a reduced portion 510, an intermediate reduced portion 511, and an enlarged portion 512. (*Id.*) The reduced

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.) Shaft 502 locks other components of Michelson's tool assembly during insertion of the implant. For example, shaft 502 locks outer sleeve 504 so the implant does not disengage from implant holder 500 during insertion into the body and also locks expander driver 600 to prevent driver 600 from rotating relative to implant holder 500. (*Id.*, 12:55-13:6 ("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 . . . 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.*, Figs. 15, 19 (both annotated); Ex. 1002, ¶50.)

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. (Ex. 1014, 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 60 has a T-shaped handle 624 for manual rotation of expander driver 600. (*Id.*, 13:42-44.)



(*Id.*, Figs. 17, 22 (both annotated); Ex. 1002, ¶52.)

Thus, expandable implants and corresponding tool assemblies, using one tool to secure the implant in a desired location and another tool to expand/contract the implant were well-known before the alleged invention of the '797 patent. (Ex. 1002, ¶27.)

VII. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“POSITA”) at the time of the alleged invention (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. (Ex. 1002, ¶¶21-22.) 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.

VIII. CLAIM CONSTRUCTION

For IPR proceedings, the Board applies the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). See 83 Fed. Reg. 51,340-59 (Oct. 11, 2018). Under *Phillips*, claim terms are typically given their ordinary and customary meanings, as would have been understood by a POSITA, at the time of the invention, having taken into consideration the language of the claims, the specification, and the prosecution history of record. (Ex. 1002, ¶38.) *Phillips*, 415 F.3d at 1313; see also *id.* at 1312-16. The Board need not construe any claim terms, as the claims are unpatentable under any reasonable construction, or any interpretation offered by Patent Owner. *Toyota Motor Corp. v. Cellport Systems, Inc.*, IPR2015-00633, Paper No. 11 at 16 (P.T.A.B. Aug. 14, 2015).⁴

⁴ Petitioner reserves all rights to raise claim construction and other arguments in other venues. Specifically, Petitioner is not conceding that each claim satisfies all statutory requirements, nor waiving any arguments concerning claim scope or grounds that can only be raised in district court. Nor is Petitioner conceding that any

IX. DETAILED EXPLANATION OF GROUNDS

As detailed below, each of the challenged claims are unpatentable. (Ex. 1002, ¶¶54-72, Appendix [16] and [19].)

A. Ground 1: McLuen in View of Michelson Renders Claim 16 and 19 Obvious

1. Claim 16

i) [16.pre] “A system comprising:”⁵

To the extent the preamble is limiting, McLuen discloses this limitation. (Ex. 1002, ¶¶54-56, Appendix [16.pre].)

As discussed above in Sections VI.A.2, 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.” (Ex. 1002, ¶¶54-56, Appendix [16.pre]; *see also infra*, Sections IX.A.1.ii-x.)

interpretation offered by Patent Owner thus far in the corresponding litigation is reasonable.

⁵ Claim language is bolded throughout.

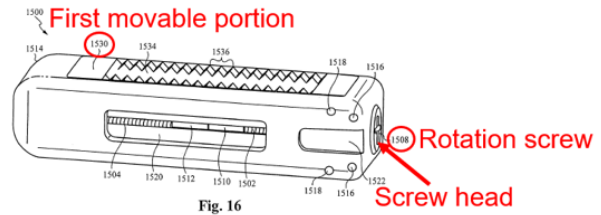
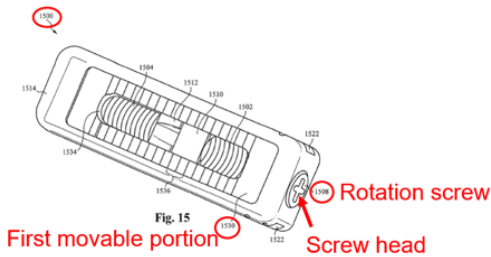
- ii) [16.a] **“an expandable intervertebral fusion device comprising first and second movable portions and an expansion mechanism configured to move the first movable portion with respect to the second movable portion, wherein the expansion mechanism comprises at least a rotation screw having a screw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

McLuen discloses this limitation. (Ex. 1002, ¶¶58-59, Appendix [16.a].) 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**

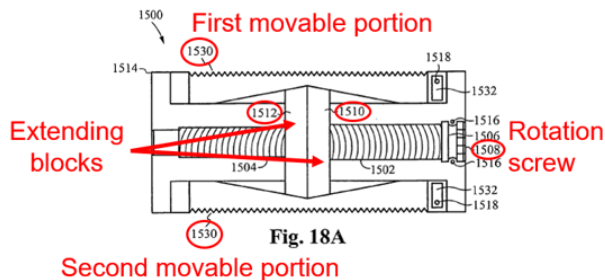
respect to the second movable portion.” (*Id.*, ¶74, Figs. 18A-B; *see also id.*, ¶¶75-81, Figs. 15-17.)

Expandable intervertebral
fusion device

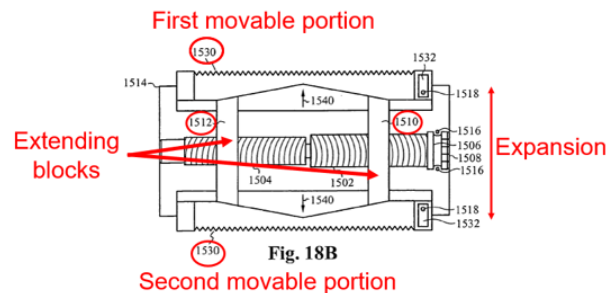


(*Id.*, Figs. 15-16 (both annotated); Ex. 1002, ¶58.)

Expandable intervertebral
fusion device (compact)

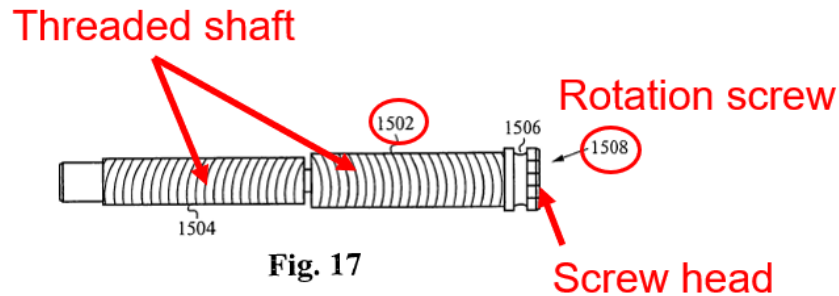


Expandable intervertebral
fusion device (expanded)



(Ex. 1012, Figs. 18A-18B (both annotated); Ex. 1002, ¶58.)

As shown in the figures above and figure 17 below, McLuen’s positioning means 1508 (portion of the “**expansion mechanism**”) 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**.” (Ex. 1012, ¶¶78, 81, Figs. 15-18B.)

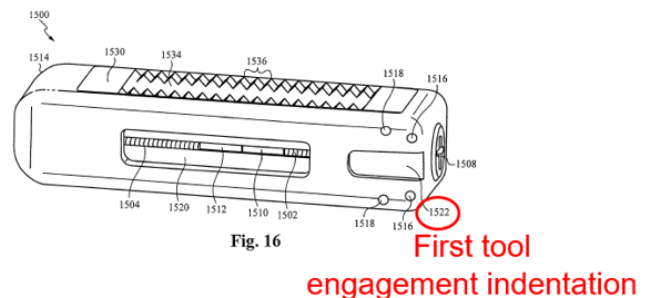
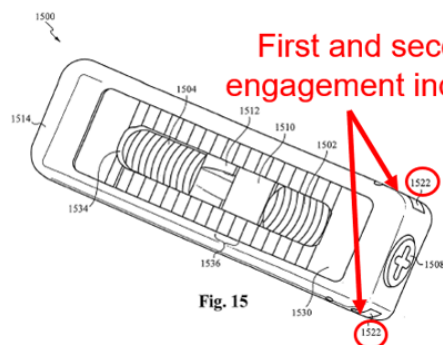


(*Id.*, Fig. 17 (annotated); Ex. 1002, ¶59.)

McLuen thus discloses limitation [16.a].

- iii) [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. (Ex. 1002, ¶¶58, 60, Appendix [16.b].) 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.)



(Ex. 1012, Figs. 15-16 (both annotated); Ex. 1002, ¶60.)

- iv) **[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 this limitation. (Ex. 1002, ¶¶57, 61-72, Appendix [16.c].)

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.) McLuen further discloses 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.”).)

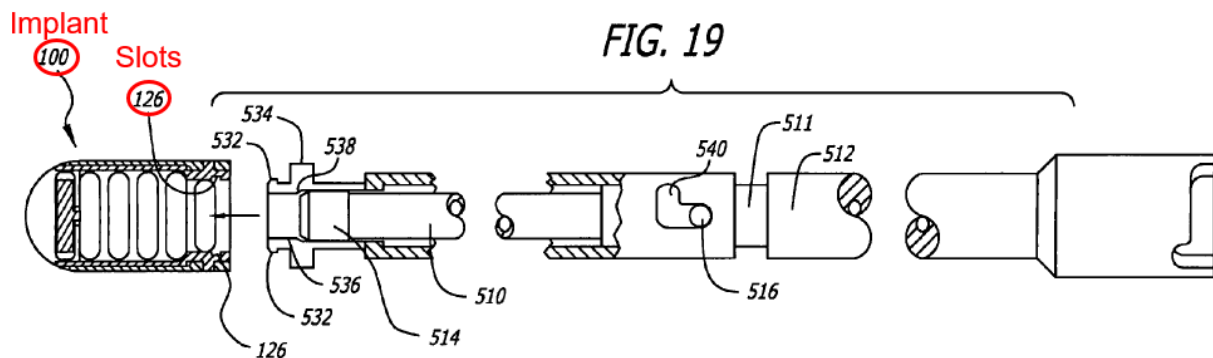
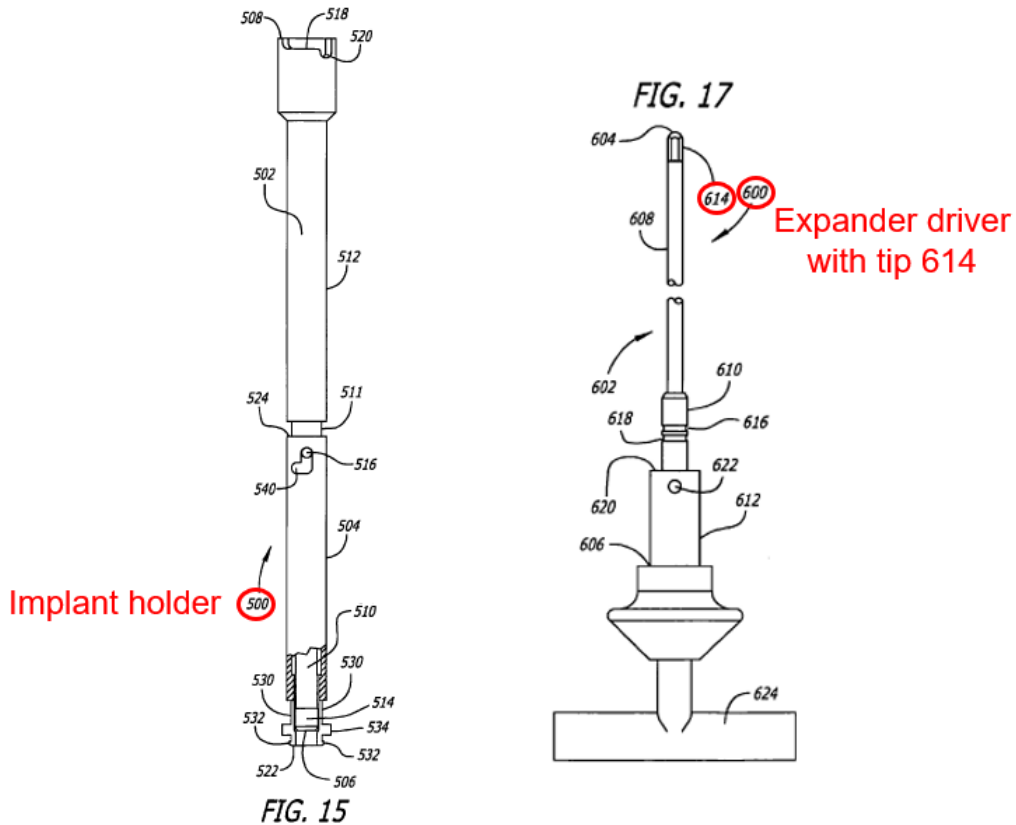
McLuen, however, does not illustrate its complete tool assembly. McLuen nevertheless provides sufficient disclosure for a POSITA to recognize that other prior art tool assemblies that would achieve those functions, such as the Michelson tool assembly. (Ex. 1002, ¶¶61-72.) There are several reasons why it would have

been obvious to a POSITA to combine the teachings of McLuen and Michelson. (*Id.*, ¶¶65-72.)

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. (Ex. 1002, ¶63; *see also* Ex. 1014, Abstract, 2:48-3:29, 8:38-9:14, 12:38-13:53, Figs. 1, 7, 15-25, 33-34, *supra* Section VI.A.2.)

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. (Ex. 1002, ¶63.)



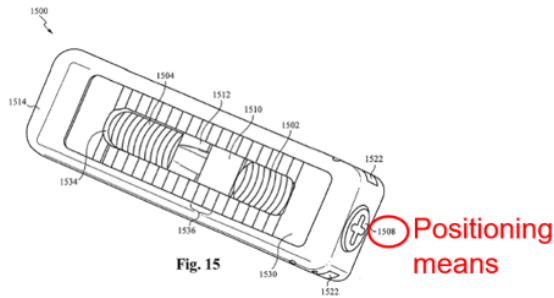
(Ex. 1014, Figs. 15-16 (top), 19 (bottom) (all annotated); Ex. 1002, ¶63.)

A POSITA would have been also 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. (Ex. 1002, ¶65.) 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.)

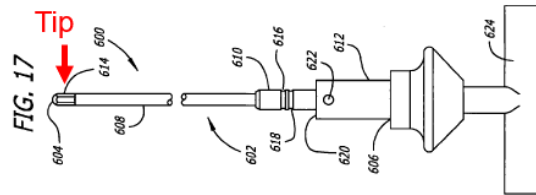
Michelson's tool assembly addressed the problem identified by McLuen, and known to a POSITA, by providing a shaft 502 with a locking mechanism for holding the implant securely at the target site (with outer sleeve 504) while another portion of the tool assembly (expander driver 600) rotates the implant's 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."); Ex. 1002, ¶66.)

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. (Ex. 1002, ¶67; Ex. 1014, 12:38-53.) As Mr. Culbert explains, 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. (Ex. 1002, ¶67.)

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. (*Id.*, ¶68.) 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. (Ex. 1014, 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, Ex. 1002, ¶68.) 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. (Ex. 1002, ¶68.)



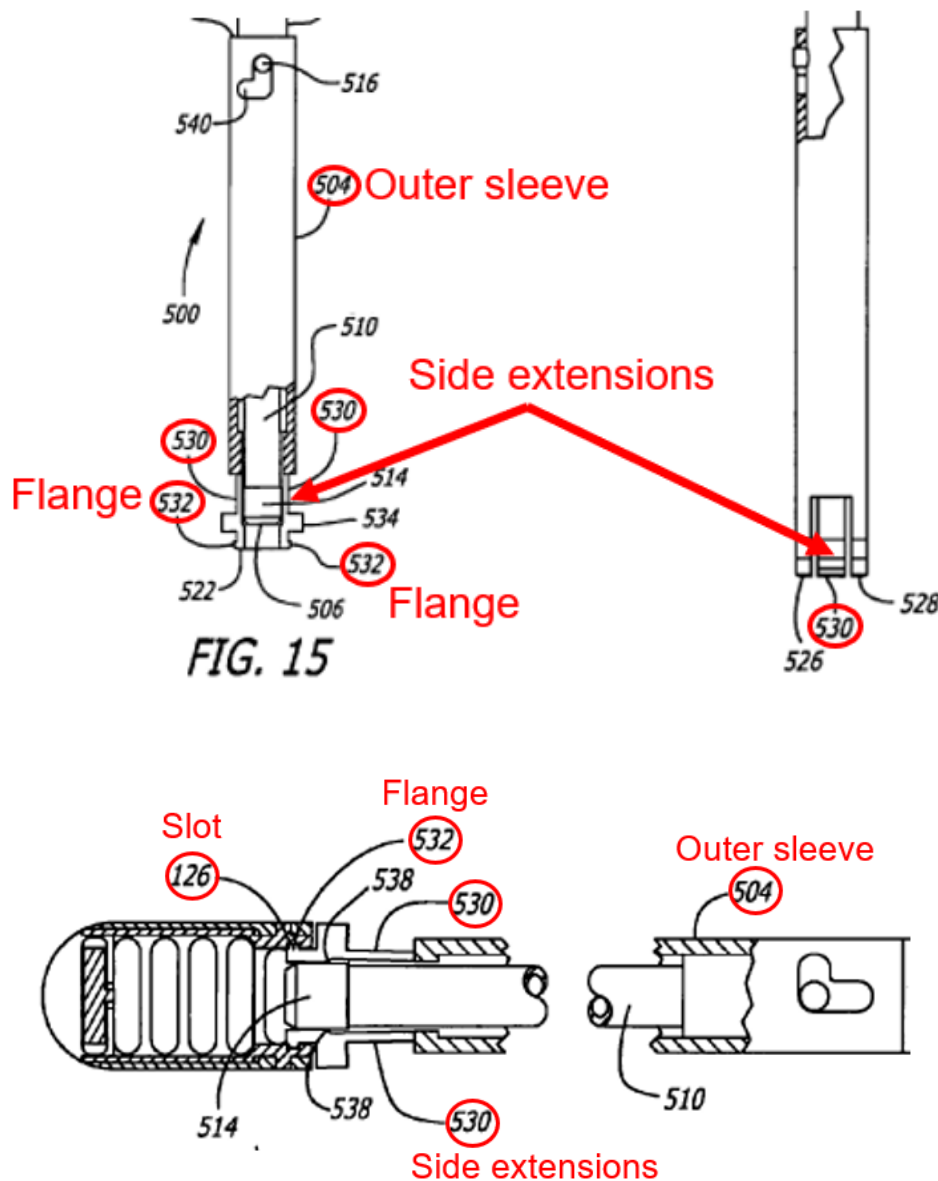
McLuen



Michelson

(Ex. 1012, Fig. 15 (annotated); Ex. 1014, Fig. 17 (annotated); Ex. 1002, ¶¶68.)

Moreover, 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; Ex. 1002, ¶¶69-70.) 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. (Ex. 1002, ¶70.)



(Ex. 1014, Figs. 15-16 (top) (both excerpted and annotated), Fig. 20 (bottom) (excerpted and annotated); Ex. 1002, ¶70.)

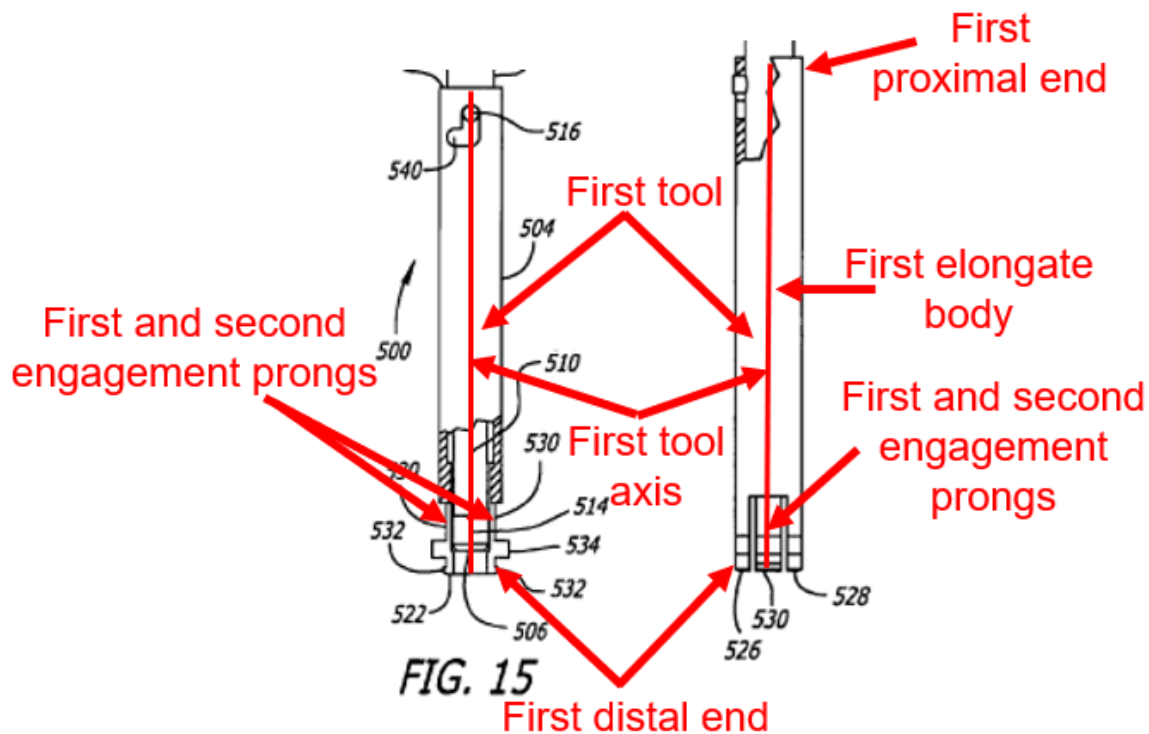
To function with the McLuen implant, a POSITA would have modified Michelson's holding mechanism (*e.g.*, side extensions 530 on the distal end of holder 500) to have prongs that could engage channels 1522 located on an outer wall of

McLuen's implant. (Ex. 1002, ¶71.) 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. (Ex. 1014, 15:8-13 (emphasis added); Ex. 1002, ¶71.) Indeed, instruments 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 (Allen), 5:18-26, Fig. 12, Ex. 1013 (Gordon), Figs. 35-36, ¶¶226-33; Ex. 1015 (Lim), ¶¶19, 22, Figs. 5-8; Ex. 1002, ¶71.) 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; Ex. 1002, ¶71.) 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. (Ex. 1002, ¶71.) *See also In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) ("It is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements.").

In view of the foregoing, a POSITA would have found it obvious to combine McLuen with Michelson such that Michelson's tool assembly would have been used to implant and expand McLuen's bone fusion device. (Ex. 1002, ¶72.) As discussed below, the McLuen-Michelson combination discloses limitations [16.c]-[16.i] and claim 19.

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.e.*, **"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."** (*Id.*, 13:7-8.) As also shown below, outer sleeve 504 defines a tool axis from its proximal end 524 to distal end 522, *i.e.*, **"the first tool defines a first tool axis from the first proximal end to the first distal end."** (*Id.*, 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.e.*, “the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis.” (*Id.*, 13:7-19, 14:65-15:13.)

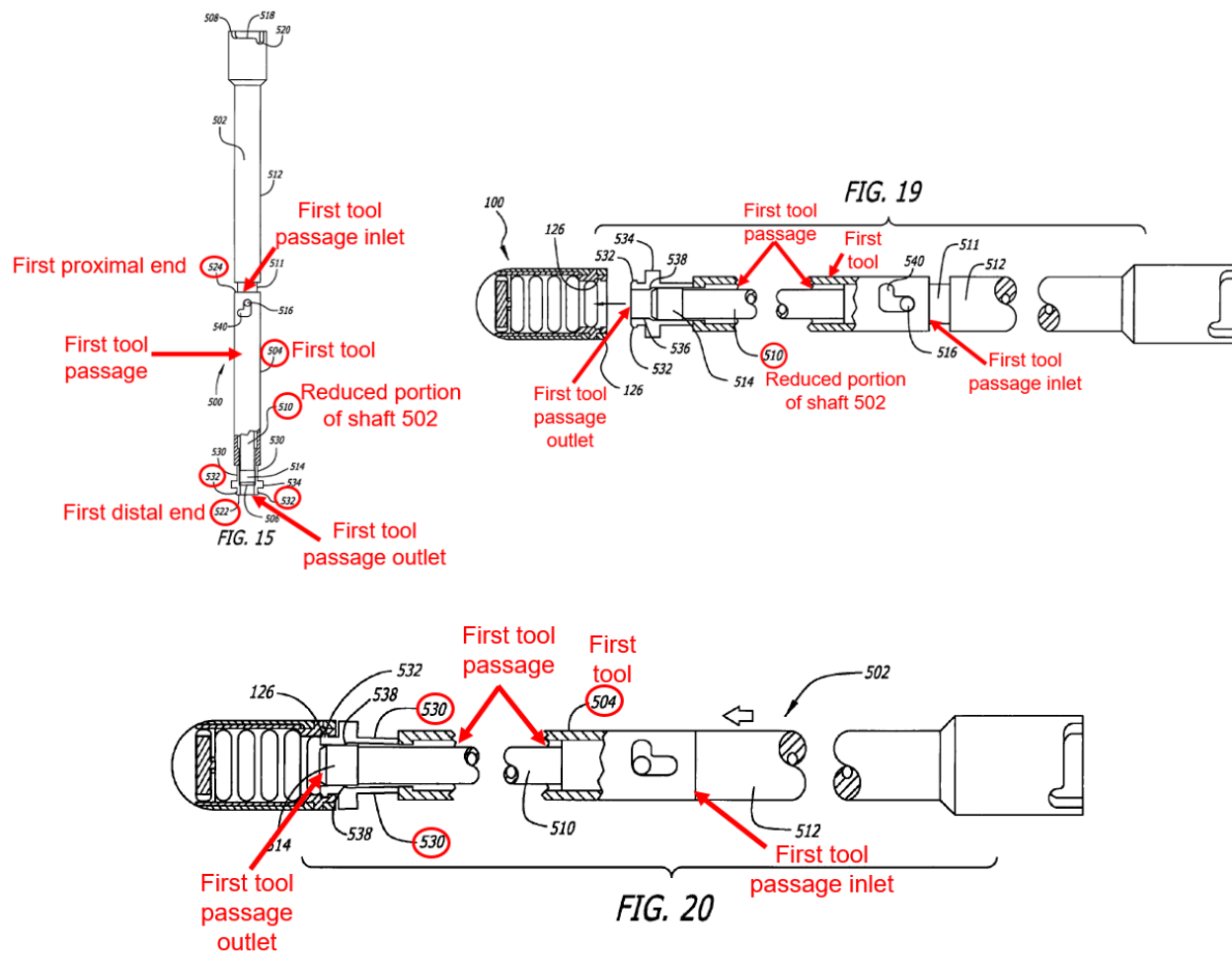


(*Id.*, Figs. 15-16 (both excerpted and annotated); Ex. 1002, Appendix [16.c].)

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

- v) [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. (Ex. 1002, Appendix [16.d].) 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; Ex. 1002, Appendix [16.d].) 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.**”



(Ex. 1014, Figs. 15, 19, 20 (all annotated); Ex. 1002, Appendix [16.d].)

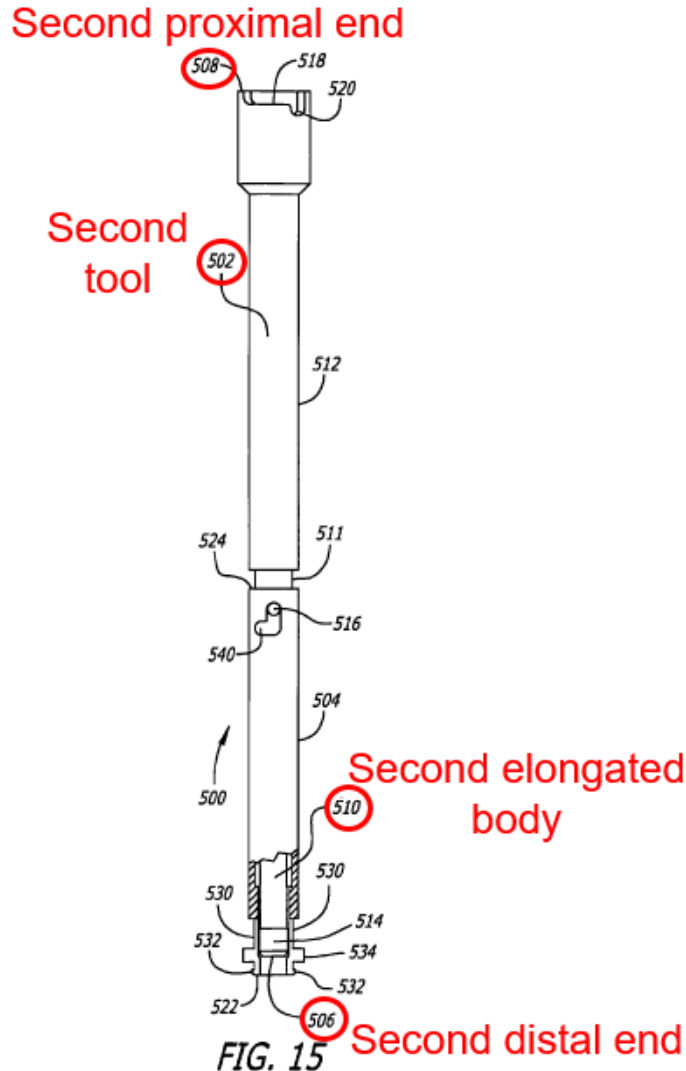
McLuen and Michelson thus disclose and/or suggest limitation [16.d].

- vi) [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. (Ex. 1002, Appendix [16.e].) 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 VI.A.2 and IX.A.1.iv, shaft 502 includes a locking mechanism to hold the implant 100 in place during insertion. (*Id.*, 12:43-13:6, Figs. 15-16; Ex. 1002, Appendix [16.e].) 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**.” (Ex. 1002, Appendix [16.e].)

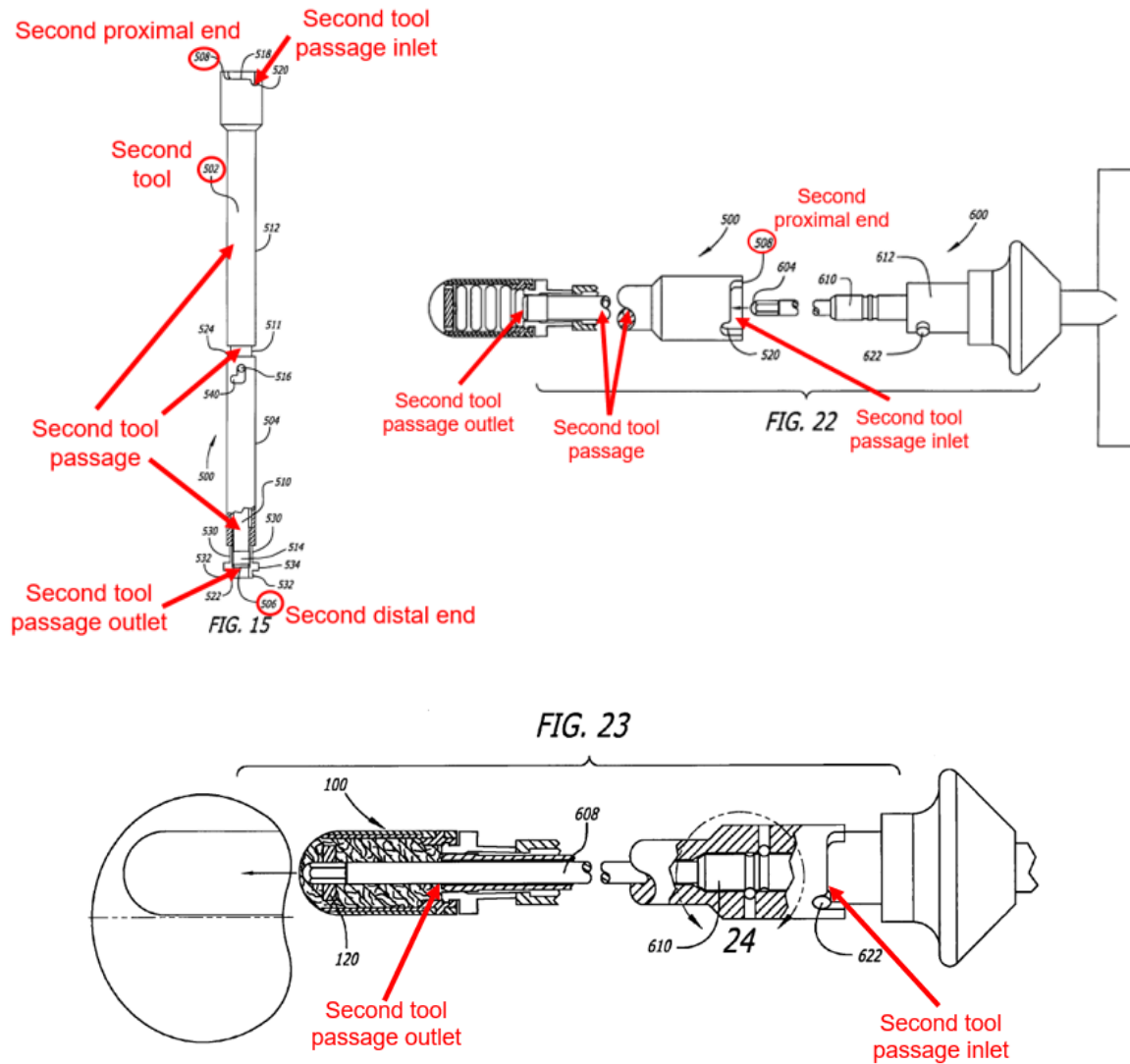


(Ex. 1014, Fig. 15 (annotated); Ex. 1002, Appendix [16.e].)

- vii) [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. (Ex. 1002, Appendix [16.f].) 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; Ex. 1002, Appendix [16.f].)

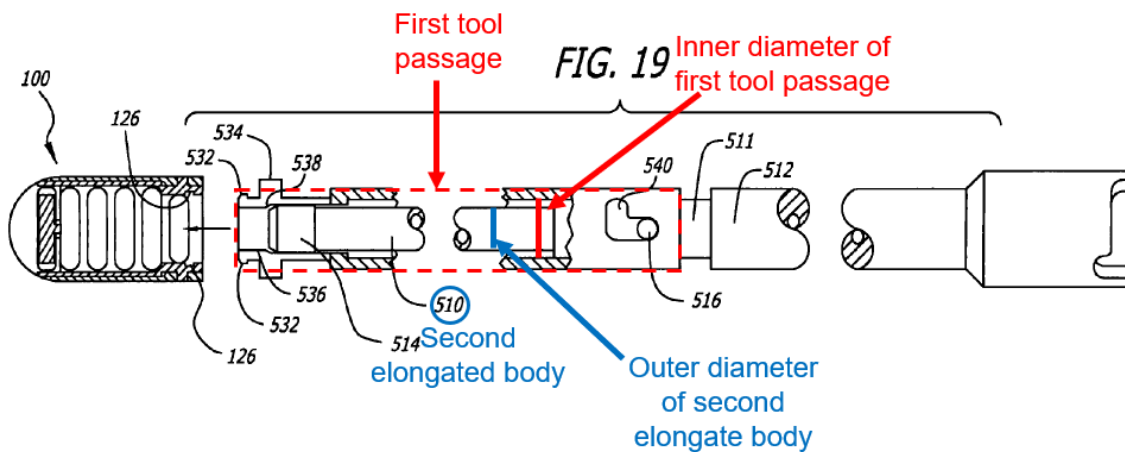


(Ex. 1014, Figs. 15, 22, 23 (all annotated); Ex. 1002, Appendix [16.f].)

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

- viii) [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. (Ex. 1002, Appendix [16.g].) As discussed in Section IX.A.1.v, 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; *see also id.*, 12:43-67, 13:7-19.)



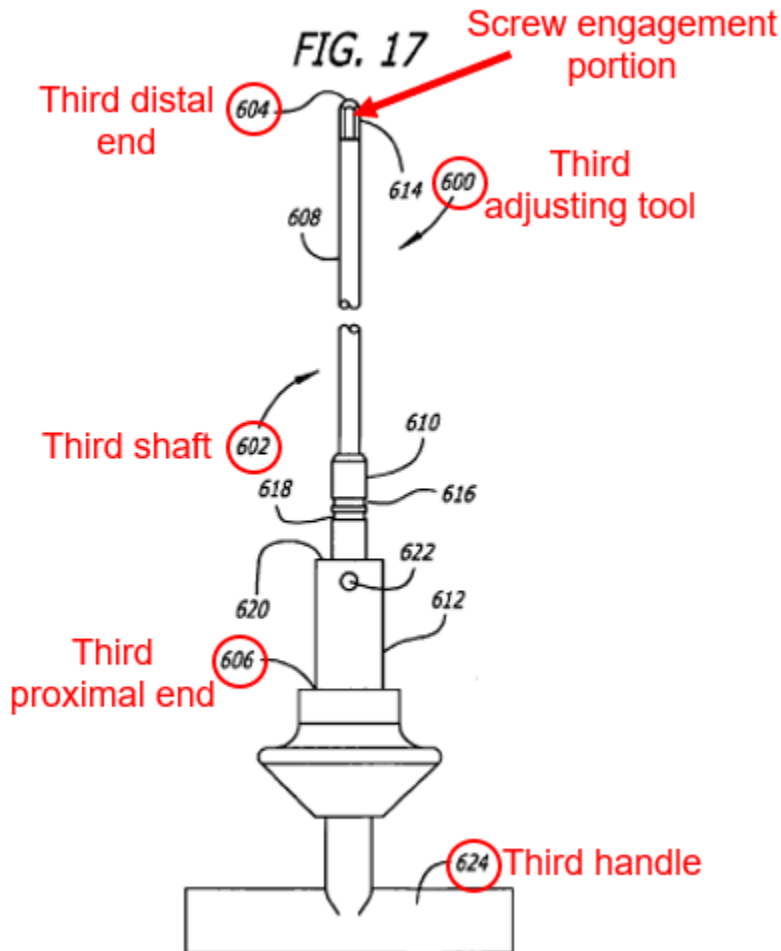
(*Id.*, Fig. 19 (annotated); Ex. 1002, Appendix [16.g].)

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

- ix) [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. (Ex. 1002, Appendix [16.h].) Michelson discloses an “expander driver 600 for engaging and rotating expander 120,” *i.e.*, **“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.e.*, **“a third proximal end and a third distal end.”** (*Id.*, 13:22-25.) “Proximal end 606 has a T-shaped handle 624 for manual rotation of expander driver 600,” *i.e.*, **“the third adjusting tool includes a third handle positioned at the third proximal end.”** (*Id.*, 13:42-44.) “Distal end 604 has a tip 614 adapted to cooperatively engage opening 130 of expander 120.” (*Id.*, 13:28-30.) As discussed in Section IX.A.1.i, in the McLuen-Michelson combination, it would have been obvious to a POSITA 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.e.*, **“a screw engagement portion positioned at the third distal end.”** (Ex. 1002, ¶¶67-68, Appendix [16.h].) As also shown in figure 17 below, expander driver 600 further includes shaft 602 extending from T-shaped handle 624 to tip

614, *i.e.*, “a third shaft extending from the third handle to the screw engagement portion.” (Ex. 1014, 13:20-32, 13:42-44.)

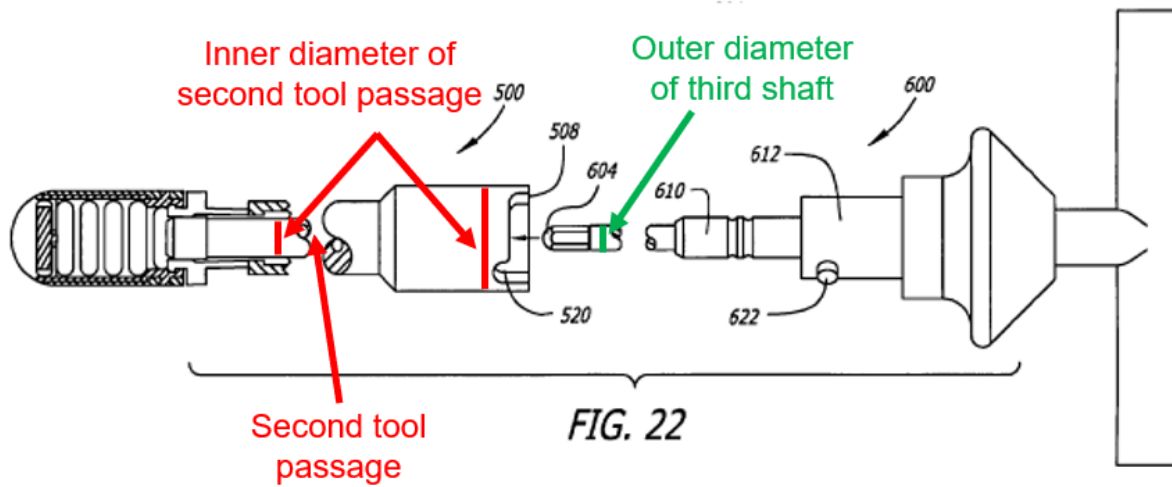


(*Id.*, Fig. 17 (annotated); Ex. 1002, Appendix [16.h].)

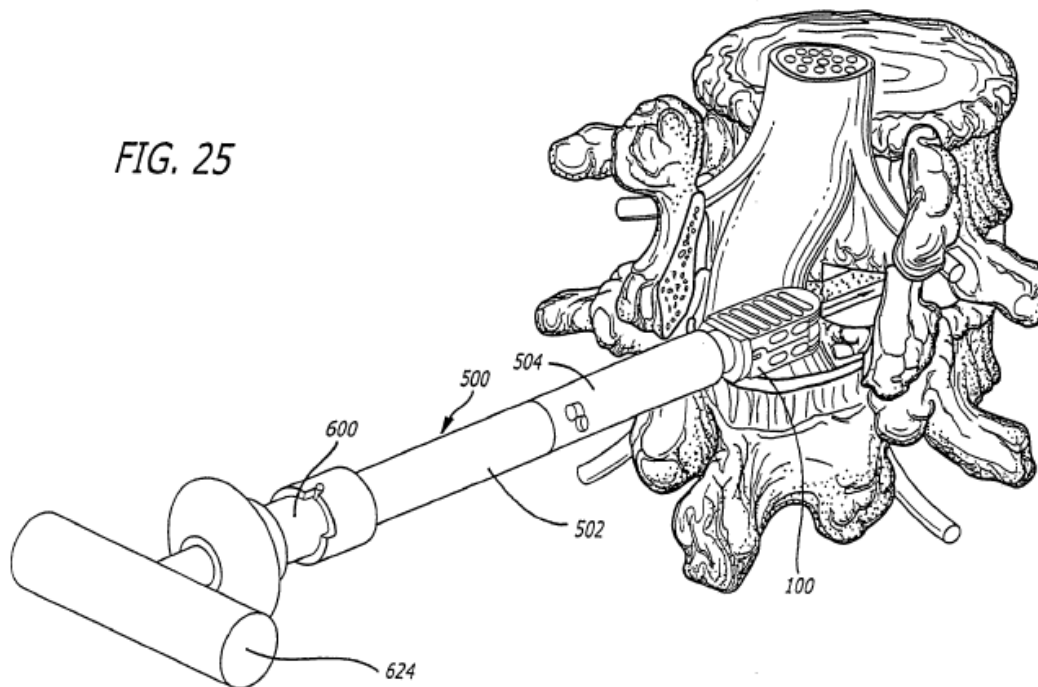
McLuen and Michelson thus disclose and/or suggest limitation [16.h].

- x) [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. (Ex. 1002, Appendix [16.i].) As discussed in Section IX.A.1.vii, 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 shaft 602 (“**third shaft**”) is inserted through shaft 502 while shaft 502 is positioned inside sleeve 504. (*Id.*)



(*Id.*, Fig. 22 (annotated); Ex. 1002, Appendix [16.i].)



(*Id.*, Fig. 25; Ex. 1002, Appendix [16.i].)

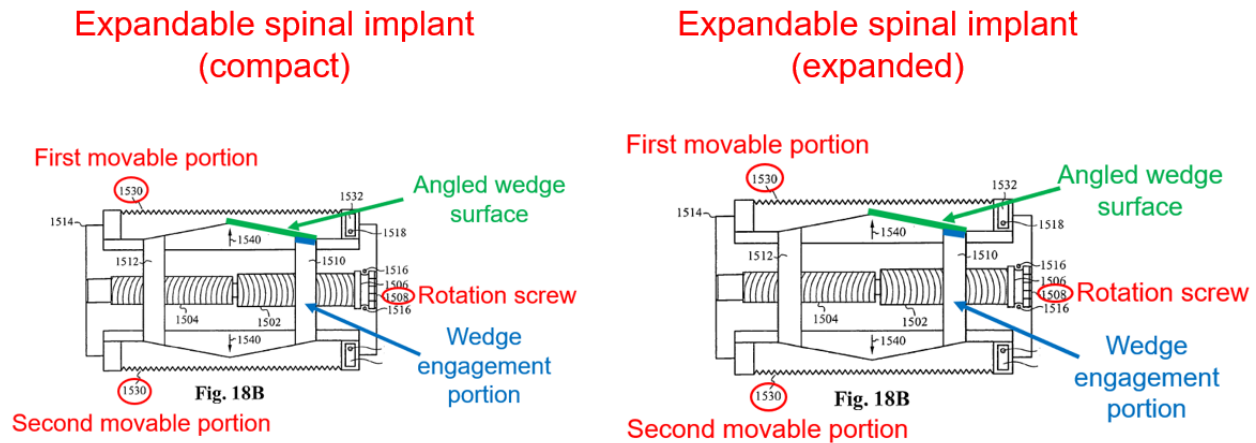
McLuen and Michelson thus disclose and/or suggest limitation [16.i].

2. Claim 19

- i) **“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. (Ex. 1002, Appendix [19].) 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 discussed in Section IX.A.1.ii, 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.” (Ex. 1002, Appendix [19].)



(Ex. 1012, Figs. 18A-18B (annotated); Ex. 1002, Appendix [19].)

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

X. CONCLUSION

Petitioner requests institution of IPR for the challenged claims of the '797 patent.

Respectfully submitted,

Dated: November 10, 2025

By: /Naveen Modi /
Naveen Modi (Reg. No. 46,224)
Counsel for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing
Petition for *Inter Partes* Review of U.S. Patent No. 11,096,797 contains, as
measured by the word-processing system used to prepare this paper, 7,063 words.
This word count does not include the items excluded by 37 C.F.R. § 42.24 as not
counting towards the word limit.

Respectfully submitted,

Dated: November 10, 2025

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2025, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 11,096,797 and supporting exhibits to be served via express mail on the Patent Owner at the following correspondence address of record as listed on Patent Center:

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UNITED STATES

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)