

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.,  
Petitioner,  
v.

MOSKOWITZ FAMILY LLC,  
Patent Owner.

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IPR2026-00124  
Patent 11,096,797

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**DECLARATION OF KEN GALL, PH. D.**

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I, Ken Gall, Ph. D., declare as follows:

## **I. INTRODUCTION**

1. I have been retained as an expert witness to provide my independent opinions in regard to the matters at issue in the *inter partes* review of U.S. Patent No. 11,096,797 (the '797 patent") in the IPR2026-00124 proceeding. I have been retained by Avantech Law, LLP on behalf of Patent Owner Moskowitz Family LLC ("Moskowitz" or "Patent Owner").

2. Unless otherwise noted, the statements made in this declaration are based on my personal knowledge, and if called to testify about this declaration, I could and would do so competently and truthfully.

3. I am being compensated at my standard rate for services provided in this matter. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this matter, including travel. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

4. A detailed record of my professional qualifications including cases in which I was an expert is being submitted herewith as Exhibit 2030 and is also summarized in Section II below.

5. I am not a legal expert and offer no opinions on the law. However, I have been informed by counsel of the various legal standards that apply, and I have applied those standards in arriving at my conclusions.

## **II. QUALIFICATIONS**

6. I am currently a Professor of Mechanical Engineering and Materials Science at Duke University and a Professor of Orthopedic Surgery at the Duke School of Medicine. I was appointed to the position of tenured Full Professor by the Dean of Engineering in 2015, and prior to this I was a tenured Professor of Mechanical Engineering, Materials Science, and Bioengineering at the Georgia Institute of Technology from 2005 to 2015. I began my academic career at the University of Colorado in the Mechanical Engineering Department in 1999, and I was granted tenure four years later in 2003. I received my B.S., M.S., and Ph.D. in mechanical engineering from the University of Illinois at Urbana-Champaign in 1995, 1996, and 1998, respectively. I completed my Ph.D. studies and defended my thesis in two years, and my post doctorate training was completed in one year at Sandia National Laboratories in Livermore, CA.

7. My university research is at the interface of the mechanical behavior of biomaterials and implant design. I have experience in a broad range of topics spanning biomaterials and medical implants with emphasis on the design of orthopedic implants and surgical instruments/devices. I have authored over one

hundred published journal articles on the behavior of current and future biomaterials and medical implants. I also teach mechanical design and materials science to undergraduate/graduate engineering students (at Duke and previously at Georgia Tech and Colorado). I have taught and advised thousands of mechanical and biomedical engineers and have extensive knowledge on the skills possessed by engineers in designing orthopedic implants and surgical instruments/devices.

8. In addition to my research and teaching, I have extensive experience in the commercialization of orthopedic medical devices. In 2005, I founded MedShape, a company that has cleared five product families through the FDA: DynaNail for hindfoot fusion; Morphix a suture anchor for soft tissue attachment; Eclipse a tenodesis anchor for soft tissue attachment; DynaClip a staple for fracture fixation and fusion; and DynaNail Mini for sub talar fusion and midfoot reconstruction. All of these products are being sold in the orthopedic medical implant market and are being used in surgeries today. MedShape also marketed an ACL reconstruction interference fixation device, ExoShape, which was successfully sold to ConMed (CNMD) in 2017. MedShape was acquired in full by Colfax (CFX) in 2021. I founded Vertera, a spine company that commercialized the first porous polymer (PEEK) fusion cages. Vertera was acquired by NuVasive (NUVA) in 2017. Recently, I founded restor3d, a company that designs and manufactures 3D printed

patient-specific implants and instruments (including patient specific surgical guides) in the orthopedic space, including foot and ankle, spine, upper extremity, and trauma.

9. As the founder of MedShape and a consultant to many businesses for over 15 years, I have been involved in the design, testing, approval, marketing, and sales of many product lines. I was directly involved in the design, testing, and evaluation of at least one hundred various design iterations of implants and surgical instruments. I have witnessed live surgeries with my own products and competitive products, and implanted various orthopedic devices, including spinal implants, myself into synthetic and cadaver bone. Over the past 15 years, I have had varying strategic and technical discussions with many companies in the orthopedic and spine medical device space.

10. I have received several dozen awards for my research, teaching, and entrepreneurial activities. On the academic side, I received the Presidential Early Career Award for Scientists and Engineers (PECASE), an award given to me in person at the White House by then President George W. Bush for my work in pioneering new approaches to incorporate high performance materials into novel engineering designs. In the field of orthopedics, my engineering team and I won a Medical Design Excellence Award (MDEA) for the unique design and clearance of a novel suture anchor device based on shape memory polymers. After winning over \$7M in Small Business Innovation in Research (SBIR) grants, MedShape and I won

a Tibbetts Award, which is a national honor that recognizes “a visible technological impact on the socio-economic front and exemplif[ies] the very best in SBIR achievements.” I have worked on numerous classified projects within the U.S. Government and held secret security clearances in the Central Intelligence Agency, the Department of Defense, and the Department of Energy nuclear weapons program.

11. I hold multiple patents and have served as an expert witness on approximately a dozen product and patent litigation cases, including several patent cases involving medical implants. My CV, which includes a list of all publications I have authored in the past 10 years is attached as Exhibit 2030.

### III. MATERIALS CONSIDERED

12. In forming my opinions herein, I have considered the following documents:

| Materials Considered                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------|
| Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,096,797                                                     |
| Ex. 1001, U.S. Patent No. 11,096,797 to Moskowitz et al.                                                                  |
| Ex. 1002, Declaration of Brad Culbert in support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,096,797 |
| 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”)                             |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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”)                                                                                                 |
| Ex. 2029, Transcript of Deposition of Mr. Brad Culbert, July 22, 2026                                                                                                       |
| Ex. 2032, Excerpts of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,376,136                                                                                 |
| Ex. 2033, Excerpts of Declaration of Brad Culbert in support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,376,136                                       |
| Ex. 2034, Excerpts of Declaration of Brad Culbert in support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,864,755                                       |

13. Additionally, I have considered any exhibits that I have relied upon herein.

#### IV. LEGAL STANDARDS

##### A. Obviousness

14. I understand that a claim is unpatentable for obviousness if the differences between the claims and the applied references would have been obvious

to a person of ordinary skill in art before the effective filing date of the claimed invention.

15. I understand that this process involves understanding the scope and content of the applied references, the differences between the claims and the applied references, and the level of ordinary skill in the art. I also understand that in some cases, the obviousness inquiry involves “secondary considerations” such as, for example, commercial success, long felt but unsolved needs, the failure of others, copying by competitors, industry praise, or unexpected results.

16. I also understand that to prove obviousness, a party must do more than just show that the claimed elements are known in separate references. Specifically, I understand that Petitioner must show that references teach or suggest the claimed elements, there would be a motivation to combine the teachings of the references to arrive at the claimed invention, and that a person of ordinary skill in the art would have had a reasonable expectation of success in performing the combination.

17. Additionally, I understand that obviousness cannot be sustained by mere conclusory statements. I have been informed that obviousness must be supported by articulated reasoning with some rational underpinning. Without an explanation as to the how or why references would be combined, an obviousness analysis is susceptible to hindsight reconstruction. I have been informed that hindsight reconstruction is a process in which the Patent Owner’s claims are used as

a roadmap for combining teachings in different references. I have also been informed that obviousness cannot be proven using hindsight reconstruction.

18. I have also been informed that a proposed modification in an obviousness analysis cannot change the principal of operation of a reference or render the reference unsatisfactory for its intended purpose. If a proposed modification were to do so, the teachings of the references are not sufficient to render the claims obvious or there may be no motivation to make the proposed modification.

#### **B. Claim Construction**

19. I understand that the invention in a patent is defined by its claims and that the purpose of claim construction is to understand how a person skilled in the relevant art would have understood disputed claim terms at the time of the invention.

20. I understand that there can be two types of claims in a patent: independent and dependent. An independent claim stands alone and does not include limitations from any other claim, whereas a dependent claim depends from an independent claim or another dependent claim and includes the limitations that it recites, in addition to the limitations recited in the claim(s) from which it depends.

21. I have been informed that the Board construes claim using the same “Phillips” standard as district court. I understand that, as a general rule, claim terms are given their ordinary and customary meaning, namely the meaning that the term

would have had to a person of ordinary skill in the art at the time of the invention. In construing patent claims, courts consider publicly-available sources that shed light on how a person of ordinary skill in the art would have understood the claim language. Those sources include the claim language itself, the remainder of the specification, and the prosecution history, which is known as “intrinsic evidence.”

22. I understand that because the claims define the scope of the patentee’s rights, claim construction begins and ends in all cases with the actual words of the claim.

23. I understand that the specification of a patent is considered to be the best guide for construing its claims. I further understand that a construction which stays true to the claim language and aligns most naturally with the patent’s description of the invention is usually the proper construction. But I also understand that particular embodiments appearing in the specification should not be used to limit claim language that has broader effect.

24. I understand that a claim construction that renders claims facially nonsensical cannot be correct and a claim construction that renders the claimed invention inoperable should be viewed with extreme skepticism.

25. I also understand that, when appropriate, extrinsic evidence such as technical literature, expert testimony, and information regarding the state of the art may be considered. For example, this may be necessary in order to understand the

background of the technology or the meaning of a term in the relevant art at the time of the invention.

26. I further understand there are two recognized exceptions to the general rule that claim terms are given their ordinary and customary meaning. The first is where the patentee has clearly set forth a special definition for the term, thereby acting as their own lexicographer. The second is where the patentee has clearly and unmistakably disavowed the full scope of a claim term, either in the specification or during prosecution.

#### **V. LEVEL OF ORDINARY SKILL IN THE ART.**

27. My opinions in this declaration are based on the understandings of a person of ordinary skill in the art, which I understand is sometimes referred to as a “POSITA,” as of the time of the invention. I understand that Petitioner and its expert have applied a priority date of August 21, 2007 for purposes of its Petition. For purposes of this Declaration, I have been instructed to use August 21, 2007 as the time of the invention, although I understand that ‘797 patent claims priority to earlier applications, including Provisional Application No. 60/670,231, filed on April 12, 2005. My analysis and conclusions are the same whether the relevant time period is April 2005 or August 2007.

28. I understand that there are several factors relevant to determining the level of ordinary skill in the art at the time of the claimed invention, which include:

(1) the educational level of the inventor(s); (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.

29. In my opinion, a person of ordinary skill in the art as of the 2007 time period, would have had a bachelor's degree in mechanical engineering, biomechanical engineering, or similar discipline, and five years relevant industry experience relating to medical device design or manufacture; or a master's degree in mechanical engineering, biomechanical engineering, or similar discipline, and either three years relevant industry experience relating to medical device design or manufacture and/or three years teaching at the collegiate level as a professor; or a doctorate in mechanical engineering, biomechanical engineering, or similar discipline; or a medical degree and residency training in neurosurgery or orthopedic surgery, and three to five years of post-residency spinal surgery and spinal instrumentation experience as a primary surgeon. However, I recognize that someone with less technical education but more experience, or more technical education but less experience, could also meet this standard.

30. I understand that Petitioner has stated that a person of ordinary skill in the art, which Petitioner refers to as a POSITA, "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.” Pet. 7. I understand that Petitioner also states that “[m]ore education can supplement practical experience and *vice versa*.” *Id.* I understand that Mr. Culbert has made the exact same statements. Ex. 1002. This definition is broader as it would include people with general engineering experience rather than specialized medical-device or spinal-instrumentation experience or advanced technical training. My opinions below are the same under either definition.

31. I was at the time of the invention, and am currently, one of more than ordinary skill in the art through my education and experience.

## **VI. BACKGROUND OF THE TECHNOLOGY AND THE '797 PATENT**

32. Expandable intervertebral fusion procedures generally involve inserting an implant into the intervertebral disc space in a reduced-height configuration and then expanding the implant after placement to restore disc height and promote spinal stability. The implant must remain securely stabilized during expansion mechanism actuation so that rotational input can be applied in a controlled manner without losing the implant's position. The '797 patent discloses a coordinated implant-and-instrumentation system for performing those functions.

33. The '797 patent discloses a coordinated implant-and-instrumentation system in which an expandable intervertebral fusion device is inserted into the disc space and subsequently expanded using dedicated surgical instrumentation. The

specification explains that the disclosed embodiments include expansion mechanisms that are mechanically actuated after implantation and further describes a universal surgical tool configured both to implant the device and mechanically expand it once positioned within the patient. Ex. 1001, 3:44-67; 10:23-60; 11:1-13.

34. The patent describes a nested instrumentation architecture comprising three separate cooperating tools. A first tool includes engagement prongs which engage opposing tool-engagement indentations formed on opposite sides of the implant, ensuring that the tool is properly aligned with the implant and that the implant is stabilized. The first tool defines a passage extending through the instrument. A second tool is receivable through that passage and serves as an intermediate guide for a third adjusting tool. The third tool, such as an Allen key or similar driver, is receivable through the second tool and engages the implant's expansion mechanism to transmit rotational input for expansion. Ex. 1001, 10:23-60, 11:1-13, 11:42-64, 12:11-17, Figs. 8A-8C, 8E-8G.

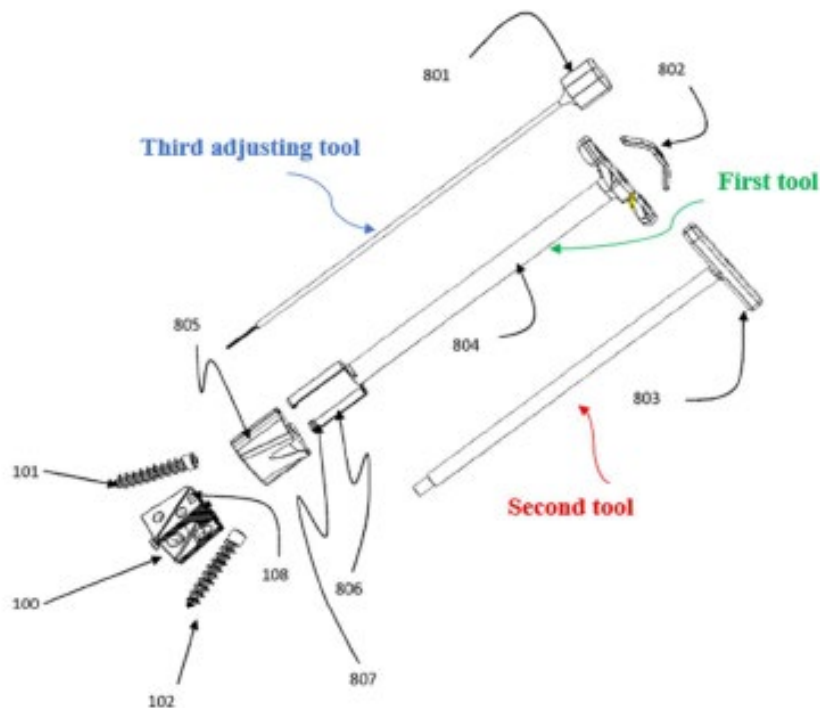


Fig. 8C

Ex. 1001, Fig. 8C (Annotated).

35. The disclosed instruments cooperate in a telescoping arrangement while remaining separate surgical tools. The first tool aligns and stabilizes the implant, the second tool provides further alignment and a passage for the third tool, and the third tool actuates the implant's expansion mechanism. Figures 8E-8G illustrate this nested relationship by showing the third tool received within the second tool, which is itself received within the first tool, thereby permitting

controlled expansion while the implant remains securely stabilized. Ex. 1001, 11:1-13, 11:42-64, 12:11-17, Figs. 8E-8G.

36. The claims reflect this same structural architecture. Independent claim 16 is directed to an intervertebral fusion device comprising both an expandable implant and a coordinated system of surgical instruments. The implant includes opposing first and second tool-engagement indentations and an expansion mechanism comprising a screw. Ex. 1001, claim 16. The claim further recites a first tool having first and second engagement prongs configured to engage the corresponding tool-engagement indentations and defining a passage extending therethrough, a second tool receivable within that passage, and a third adjusting tool receivable within the second tool and configured to engage the screw of the expansion mechanism. *Id.* Dependent claim 19 further specifies that the second tool includes a passage extending therethrough, that the third adjusting tool is receivable through that passage, and that the third adjusting tool includes a screw-engagement portion configured to engage the implant's expansion mechanism. Ex. 1001, claim 19. A POSITA would therefore understand the claimed invention to require complementary structural features on both the implant and the surgical instruments that cooperate in a nested, multi-tool architecture to maintain implant stability while permitting controlled actuation of the implant's expansion mechanism. Ex. 1001, 10:23-60, 11:1-13, 11:42-12:17.

## **VII. CLAIM CONSTRUCTION**

37. Aside from the term discussed below, I have applied the plain and ordinary meaning, as understood by a POSITA at the time of the invention of the '797 patent, to all remaining claim terms in forming my opinions.

### **A. Engagement Prongs.**

38. Claim 16 of the '797 patent recites “first and second tool engagement indentations on first and second sides of the expandable intervertebral fusion device,” and “a first tool having ... first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis.” Ex. 1001, claim 16. Read together, a POSITA would understand these limitations to define corresponding engagement structures on the tool and the expandable intervertebral fusion device. Specifically, the claimed engagement prongs are configured to engage the claimed tool engagement indentations located on opposite sides of the device exterior. The claim describes a coordinated structural relationship between these respective features, rather than merely requiring protrusions on a tool that are capable of contacting the implant in some unspecified manner.

39. The specification describes this same relationship, requiring the engagement prongs to engage with corresponding indentations formed on opposite sides of the exterior of the expandable intervertebral fusion device. Ex. 1001 at 8:25-

29; 8:54-59; 9:13-17; 9:44-49; 10:17-22; 10:33-38; 10:48-55; 11:7-11; 11:55-58; 12:7-11.

40. Accordingly, in my opinion, a POSITA would understand claim 16's "engagement prongs" to mean "protruding members located on opposite sides of the first tool and configured to engage corresponding tool engagement indentations on opposite lateral sides of the exterior of the expandable intervertebral fusion device."

### **VIII. SUMMARY OF THE ASSERTED REFERENCES**

41. I have reviewed each of the prior art references relied upon by Petitioner. The following discussion summarizes the portions of each reference that are relevant to my technical opinions regarding the structure, operation, and functionality of the disclosed implant systems.

#### **A. U.S. Patent Application Publication No. 2006/0253201 A1 to McLuen (Ex. 1012)**

42. McLuen discloses an expandable spinal implant that is inserted in a reduced-height configuration and expanded in situ by rotating an internal positioning means 1508, such as a positioning screw. Ex. 1012 ¶¶ 74-75. McLuen identifies a compact insertion profile as an important design objective because it allows the implant to be introduced through a minimally invasive surgical corridor, minimizing incision size, tissue retraction, and trauma to surrounding anatomical structures. Ex. 1012 ¶¶ 39; 74 ("In an arthroscopic procedure, a smaller surgical incision is employed as compared to the size of the incision required for conventional invasive

Surgery. Moreover, arthroscopic procedures minimize or eliminate the need for excessive retraction of a patient's tissues such as muscles and nerves, thereby minimizing trauma and injury to the muscles and nerves and further reducing the patient's recovery time.”). McLuen explains that, during implantation, the surgeon rotates positioning means 1508 to drive extending blocks along corresponding screw components. As the extending blocks move outward, they force tabs 1530 away from one another, thereby increasing the implant height and wedging the implant between adjacent vertebral bodies. *Id.* at ¶ 75.

43. McLuen further recognizes that this expansion procedure presents a practical challenge when performed using a conventional screwdriver. Specifically, McLuen explains that the screwdriver may slip while rotational force is being applied to positioning means 1508, particularly because the procedure is performed in a confined surgical field adjacent to sensitive anatomical structures. *Id.* at ¶ 76. McLuen identifies this as a safety concern because unintended movement of the instrument could damage surrounding tissue. *Id.*

44. To address this concern, McLuen discloses engagement channels 1522 formed in the implant body, as shown in the figure below. *Id.* at ¶¶ 76, 78.

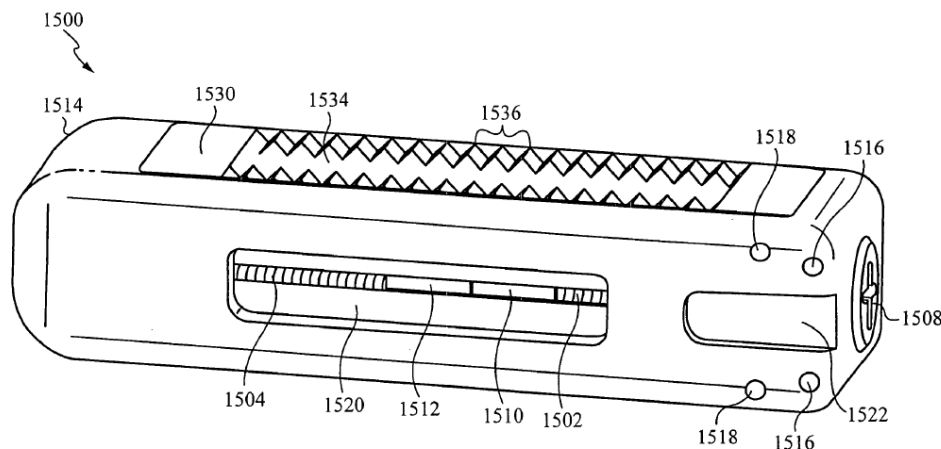


**Fig. 16**

45. McLuen also discloses a tool having protruding attachments configured to fit within the engagement channels while a screwdriver engages positioning means 1508. *Id.* According to McLuen, the protruding attachments engage the channels to position and stabilize the instrument relative to the implant, helping maintain alignment with positioning means 1508 during expansion and reducing the likelihood that the screwdriver will slip while rotational force is applied. *Id.* at ¶¶ 76-78.

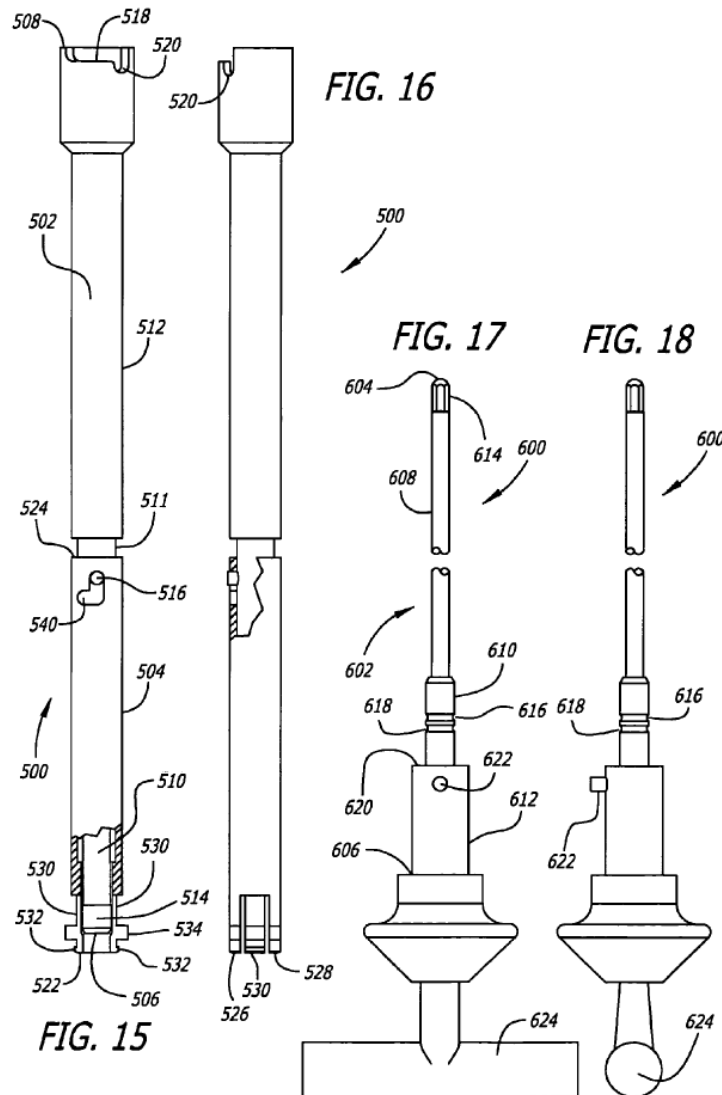
46. Engagement channels 1522 provide a stabilizing interface between the tool and the implant. By engaging the channels, the tool is retained in a desired position relative to the implant during the expansion procedure while rotational input is applied to positioning means 1508. McLuen explains that this arrangement

improves the stability of the expansion instrument during actuation and reduces the likelihood of unintended movement while the implant is being expanded. *Id.* at ¶¶ 76-78.

47. A POSITA would understand that McLuen's disclosed attachment-and-channel interface is designed to accomplish two functions: (1) secure the tool for transmitting rotational torque to positioning means 1508 while minimizing rotational slippage, and (2) allow the surgeon to easily disengage the tool from the implant once expansion is complete. Because the tool attachments are simply received within channels 1522, the surgeon can remove the tool by withdrawing it from the channels without first releasing any retaining mechanism. McLuen's engagement interface is thus designed to provide rotational coupling while permitting straightforward disengagement of the tool after the implant has been positioned and expanded.

**B. U.S. Patent No. 7,118,579 to Michelson (Ex. 1014)**

48. Michelson discloses an expandable interbody implant used with an instrumentation assembly comprising two instruments: an implant holder 500 and an expander driver 600, shown in the figures below. Ex. 1014, 12:43-13:13.



*Id.*, Figs. 15-18.

49. Implant holder 500 comprises a shaft 502 positioned within an outer sleeve 504. *Id.* at 12:45-46. The shaft and outer sleeve components are mechanically interlocked, with a peg 516 on shaft 502 cooperating with an L-shaped slot 540 in outer sleeve 504 to guide and constrain movement of the shaft relative to the sleeve. *Id.* at 15:1-8, 17:65-18:2. Michelson describes peg 516 as extending from

intermediate reduced portion 511 of the shaft 502. *Id.* at 12:64-67. Because Michelson does not describe any possibility for shaft 502 to be removed from outer sleeve 504, and instead describes its peg-and-slot mechanism as an internal retention mechanism that permits relative rotation while maintaining the assembled relationship between shaft 502 and outer sleeve 504, a POSITA therefore would have understood shaft 502 and outer sleeve 504 to be cooperating components of a single tool.

50. During use, advancement of shaft 502 causes side extensions of outer sleeve 504 to move outward so that flanges 538 on the sleeve engage and lock into corresponding slots 126 on the inside of the implant, as shown in the figures below. *Id.* at 15:1-8; Figs. 20-21. Retraction of shaft 502 permits the side extensions to move inward, disengaging the flanges from the implant interior and releasing the holder. *Id.* at 17:65-18:2. Thus, the shaft and outer sleeve cooperate to grip and release the implant during implantation.

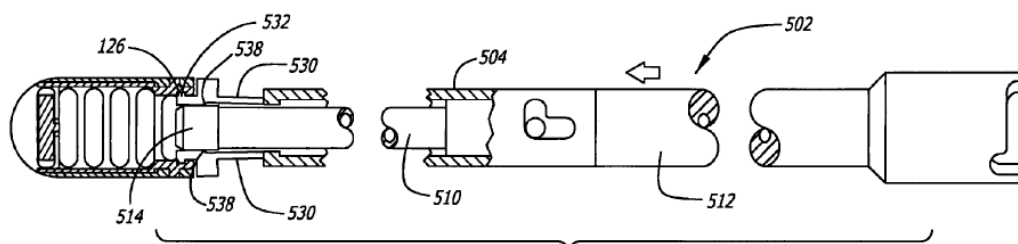
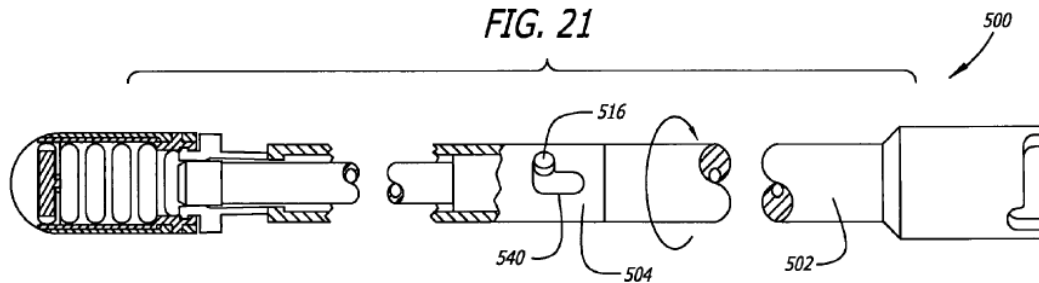
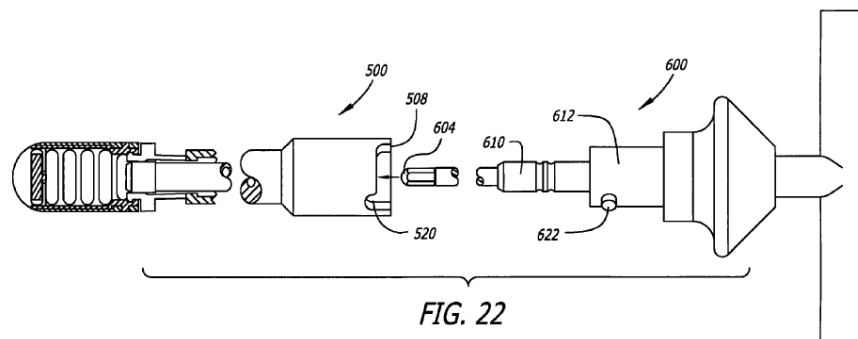


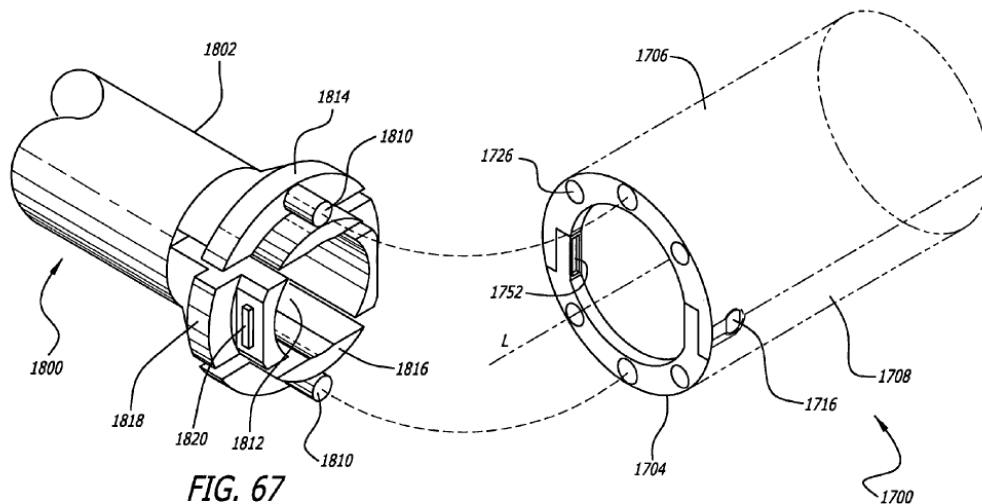
FIG. 20



51. After the implant has been positioned, expander driver 600 is inserted through implant holder 500 to engage the implant's expansion mechanism, as shown in the figure below. *Id.* at 15:28-30, Fig. 22. Rotation of expander driver 600 rotates the expansion mechanism to expand the implant while implant holder 500 remains coupled to the implant. *Id.* at 16:46-55.



52. Michelson also discloses an alternative embodiment which it describes as having an implant holder “adapted so that the side extensions may be forced toward one another to lock the implant to the implant holder.” Ex. 1014, 15:8-13. That embodiment is shown in Figure 67:



53. In this embodiment, implant 1700 includes opposed slots 1752 formed along the interior surface of trailing end 1704. *Id.* at 25:37-42. The opposed slots 1752 are configured to lockably receive corresponding flanges 1820 of implant holder 1800. *Id.*

54. Implant holder 1800 comprises a shaft 1802 having a distal end 1804 with an implant engagement area 1808. *Id.* at 25:43-50. Implant engagement area 1808 includes a central bore 1812, upper and lower extensions 1814 and 1816 surrounding the bore, and opposed side extensions 1818. *Id.* Each side extension 1818 includes a flange 1820 configured to cooperatively engage a slot 1752 of implant 1700 when the holder is in a locked configuration. *Id.* at 25:47-50.

55. During use, the side extensions 1818 are temporarily compressed inward to move flanges 1820 into alignment with slots 1752 on the inside of implant 1700 and then released, causing the flanges to rebound outwardly, lockably engage

the slots, and secure implant holder 1800 to the implant. *Id.* at 25:51-54. An expander driver, such as the driver described with respect to Figure 55, is then inserted through bore 1812 to engage and actuate the implant's expansion mechanism. *Id.* at 25:54-58. As implant 1700 expands, the height of trailing end 1704 decreases as upper and lower members 1706 and 1708 articulate about pivot point 1716. *Id.* at 25:59-61. To accommodate this change in geometry while maintaining engagement with the implant, upper and lower extensions 1814 and 1816 move inwardly toward the longitudinal axis of implant holder 1800, allowing the holder to remain lockably engaged throughout expansion. *Id.* at 25:64-67.

## **IX. ANALYSIS OF PETITIONER'S GROUND I: MCLUEN IN VIEW OF MICHELSON**

56. In my opinion, McLuen and Michelson do not render claims 16 and 19 of the '797 patent obvious.

### **A. A POSITA Would Not Have Been Motivated to Combine McLuen and Michelson.**

#### **1. McLuen already discloses a complete system, including the necessary instrumentation to surgically implant its device.**

57. I do not agree with Petitioner's or Mr. Culbert's opinion that a POSITA would have been motivated to replace McLuen's disclosed instrumentation with Michelson's tools, including in order to prevent tool slippage during implant expansion. Pet. 24. In my opinion, McLuen already discloses a complete

implantation system, including the implant and the necessary instrumentation to surgically implant the device.

58. McLuen describes a screw driver used to turn the positioning means 1508 to secure the bone fusion device 1500 in place. Ex. 1012 ¶¶ 76. McLuen additionally recognizes the possibility of its disclosed screwdriver slipping out of place and expressly discloses a solution to address that issue:

Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

*Id.*

59. A POSITA would have understood from this disclosure what type of tool McLuen contemplates, even though the tool itself is not illustrated. McLuen expressly states that the tool includes “attachments that fit within the channels 1522 to secure the tool ... in place.” Ex. 1012, ¶¶ 76-77. This describes a straightforward keyed engagement interface in which one or more projecting features on the tool are dimensioned and positioned to fit within corresponding channels 1522 formed in the implant 1500. The particular geometry of the engagement features and handle could be selected as a matter of ordinary engineering design so long as the tool cooperates with channels 1522 and also allows the transmission of torque to the positioning means.

60. McLuen further does not identify any inadequacies with its disclosed instrumentation. Instead, it consistently describes its disclosed tool and channels 1522 as sufficient in addressing slippage while securing the device in place. Ex. 1012 ¶¶ 76 (“Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone’s spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.”); 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.”).

61. Because McLuen already discloses the instrumentation required for its device, a POSITA would have no reason to look elsewhere, including to Michelson for use of its complex tool which is based on an entirely different implant design and would require extensive redesign in order to be compatible with McLuen’s implant, as discussed further below.

**2. A POSITA would not have reasonably expected Michelson’s disclosed tool to function with McLuen’s disclosed implant**

62. A POSITA would not have reasonably expected Michelson’s disclosed tool to function with McLuen’s disclosed implant because the references employ fundamentally different expansion interfaces and different implant-retention mechanisms. As disclosed, the two systems are not mechanically compatible.

63. For example, I disagree with Petitioner's and Mr. Culbert's opinion that a POSITA would have shaped Michelson's tip 14 like a screw driver so it can expand McLuen's implant. Pet. 25; Ex. 1002 ¶ 68. Michelson's tool includes a hex-shaped tip 614 to cooperate with expander 120 of Michelson's implant. Ex. 1014, 13:30-32; 10:54-56; Fig. 8. A POSITA would not have modified Michelson's expander driver by replacing its disclosed hexagonal driver tip with a Phillips-type driver based on McLuen. Doing so would reduce the reliability of Michelson's disclosed instrumentation. A hexagonal drive provides six substantially parallel bearing surfaces that distribute torque over a relatively large contact area and resist cam-out during rotation. By contrast, a Phillips drive relies on tapered, inclined drive surfaces that provide progressively less engagement toward the tip and are more susceptible to cam-out or partial disengagement under increasing torque, imperfect alignment, or less forward pressure. For that reason, a hexagonal interface generally provides more reliable torque transmission than a Phillips interface in applications requiring repeated or controlled rotational actuation.

64. McLuen itself reflects this engineering tradeoff. Although McLuen employs a Phillips-head screwdriver to actuate its Phillips-head positioning means 1508, it also expressly recognizes that "screw drivers unfortunately have the ability to slip out of place" and addresses that concern by providing channels 1522 and corresponding tool attachments that secure the tool during actuation. Ex. 1012, ¶¶

76-77, Fig. 16. Accordingly, it supplements its Phillips interface with additional anti-slippage features to compensate for the possibility of slippage.

65. By contrast, Michelson employs a hexagonal drive interface that inherently provides robust torque transmission through complementary hexagonal engagement surfaces. Ex. 1014, 13:30-31, 22:60-61. A POSITA would not have viewed McLuen as suggesting that Michelson's hexagonal interface should be replaced with a Phillips interface, because doing so would sacrifice one of the advantages of Michelson's disclosed design while providing no identified technical benefit. In my opinion, a POSITA would have understood McLuen and Michelson to reflect different engineering choices, not a teaching that Michelson's hexagonal drive could be replaced with McLuen's Phillips-head arrangement.

66. Additionally, Petitioner's proposed combination assumes that Michelson's implant holder could simply engage McLuen's channels 1522, but neither reference suggests such an interface. McLuen discloses channels 1522 as elongated recesses disposed on the implant exterior intended to cooperate with corresponding tool attachments to reduce slippage during expansion. Ex. 1012 ¶¶ 76-78, Figs. 15-16. Michelson, by contrast, does not disclose engagement with recessed channels on an exterior of its implant. Instead, Michelson's holder retains the implant by moving side extensions outward so that flanges are received into complementary internal retention slots 126 formed within the implant. Ex. 1014,

14:65-15:13. The two engagement mechanisms operate according to different mechanical principles and require different engineering for reliable retention.

67. As shown in Fig. 1, Michelson provides slots 126 in the interior of its implant for its implant holder to engage. Ex. 1014, Fig. 1. A POSITA would have understood that Michelson designed such internal engagement because its implant is intended to pivotably expand along an external pivot point 116. *Id.* Michelson's internal engagement allows upper member 106 to rotate freely while its implant holder 500 remains engaged. A POSITA would have understood that Michelson's implant holder cannot engage its implant with an external engagement because such engagement would interfere with Michelson's pivoting expansion hinge mechanism.

68. Nothing in McLuen suggests that its implant includes interior slots or other complementary structures capable of receiving structures similar to Michelson's outwardly projecting flanges. The Petition likewise does not identify any such structure. A recessed elongated channel on the device exterior does not provide a positive locking interface for an outwardly projecting flange. Without complementary retention geometry, Michelson's flanges would have no identified structure within McLuen's channels to engage or lock against during implant manipulation or expansion.

69. McLuen also does not describe its anti-slippage feature as resulting from engagement comparable to Michelson's flange-retention mechanism. Rather,

McLuen explains that the channels cooperate with tool attachments to reduce slippage between the surgical instrument and the implant during expansion. Ex. 1012, ¶¶ 76, 78. A POSITA would understand that such anti-slippage can be achieved through frictional engagement or compressive contact between complementary tool features and the channel surfaces. McLuen does not describe an interference-based locking mechanism in which projecting flanges are received within corresponding retention slots or recesses.

70. A POSITA would not view Michelson's holder as operating through the same type of pinching, grasping, or frictional engagement that McLuen requires. Michelson expressly teaches that the holder is inserted into the implant and that the side extensions are subsequently driven outward so the flanges engage internal retention features of the implant. Ex. 1014, 12:55-64, 13:7-19, 15:1-8. The holder does not grasp or engage the outside of the implant via opposed arms around it. Instead, retention is achieved by internal expansion of the holder within complementary locking structures formed on the inside of the implant.

71. In my opinion, a POSITA would not have expected Michelson's disclosed holder to engage McLuen's channels 1522 without substantial redesign of one or both systems, as discussed further below. These would not be routine or simple modifications but would instead require the substitution of an entirely different implant-retention mechanism. Because neither reference identifies

complementary engagement geometry between Michelson's flanges and McLuen's channels, and because the references employ fundamentally different retention mechanisms, I do not believe a POSITA would have reasonably expected Michelson's holder to provide the secure engagement necessary to implant and expand McLuen's device as proposed in the Petition.

### **3. The Proposed Combination Would Require Extensive Redesign**

72. The Petition does not explain how a POSITA would modify Michelson's instrumentation so that it would function with McLuen's implant. Although Petitioner and its expert, Mr. Culbert, characterize any required changes as "minor alterations," I disagree. In my opinion, the proposed combination would require replacing Michelson's disclosed implant-retention mechanism with a substantially redesigned holder incorporating a different engagement architecture and different operating principles that would require extensive testing, analysis, and regulatory analysis. Based on the extensive redesign required, no POSITA would look to combine Michelson with McLuen.

73. For example, Mr. Culbert opines that a POSITA "would have modified the side extensions 530 of outer sleeve 504 such that they would have engaged McLuen's channels 1522 and correspondingly modified the distal portion of shaft 502 ... such that it would lock the side extensions ... e.g., through dovetail joints." Ex. 1002 ¶ 71. He does not identify any disclosure in Michelson or McLuen

describing such a mechanism or explain what specific structural modifications would permit the proposed engagement and locking. Instead, he concludes, without engineering analysis, that the required changes would have been routine. *Id.*

74. In my opinion, Mr. Culbert's analysis is based on an incorrect reading of Michelson. He principally relies on Michelson's statement that "the side extensions may be forced toward one another to lock the implant to the implant holder." Ex. 1014, 15:8-13. That passage, however, does not describe implant holder 500 shown in Figure 19, which Mr. Culbert proposes to modify. Rather, it describes the separate embodiment illustrated in Figure 67, which includes a different implant (1700), a different implant holder (1800), and a different locking mechanism. Implant 1700 includes opposed locking slots 1752 specifically configured to receive flanges 1820 carried on inwardly compressible, and outwardly rebounding side extensions of holder 1800. Ex. 1014, 25:32-66. In this instance the actual locking mechanism is not caused by the inward motion but rather the outward expansion similar to the earlier embodiment.

75. Thus, not only is Michelson's disclosure of inwardly movable side extensions is tied to a different holder operating with a different implant specifically designed with complementary locking slots, but also this different holder maintains interior engagement to continue to allow implant 1700 to pivotably expand. McLuen does not disclose interior engagement with locking slots. Instead, McLuen discloses

external channels 1522 that receive tool attachments to reduce slippage while actuating the positioning means. Ex. 1012 ¶ 77.

76. Because Michelson only describes interior engagement and because McLuen does not disclose comparable interior engagement with locking slots, neither of the references teaches or suggests modifying Michelson's holder 500 in a way such that its side extensions would be able to engage McLuen's outer channels 1522. Instead, Michelson's teachings would dissuade a POSITA from such a modification, because it would no longer be operable with Michelson's expandable implant. Each of Michelson's embodiments disclose internal engagement between its implant and implant holder to enable its implants to pivotably expand.

77. Implementing Mr. Culbert's proposal would therefore require substantially redesigning Michelson's holder 500 in a way that is not taught or suggested by either reference. At a minimum, the redesign would require modifying the side extensions to engage an entirely different implant geometry, changing the operating relationship between the shaft and side extensions, and creating a new engagement interface that is not disclosed in either Michelson embodiment and, as a result, would no longer work with either embodiment.

78. During his deposition, Mr. Culbert proposed additional modifications not described in his declaration. Ex. 2029 at 79:1-20. Specifically, he proposed enlarging Michelson's side extensions so that they extend around the exterior of

McLuen's implant before reaching inward to engage channels 1522. *Id.* at 79:2-6. He also proposed replacing Michelson's disclosed mechanism with a new dovetail arrangement that would pull the side extensions inward. *Id.* at 9-23.

79. In my opinion, these are not routine design modifications. Michelson's side extensions are designed to fit within and engage the interior of Michelson's implant. Enlarging those extensions to surround the exterior of McLuen's implant would alter the holder's overall profile, the spacing and flexibility of the side extensions, and their relationship to the implant. Mr. Culbert provides no engineering analysis demonstrating that such a holder could fit within the available surgical corridor while maintaining sufficient strength and flexibility to operate reliably. Nor does Mr. Culbert acknowledge how such modifications would drastically change the principle of operation of Michelson's implant holder and render Michelson's implant holder inoperable for its intended purpose of holding Michelson's implant as it pivotably expands.

80. The proposed dovetail arrangement likewise represents a substantial redesign and fundamental difference in retention mechanics rather than a minor modification. Michelson's disclosed stops and distal shaft structure would be replaced with an entirely new sliding-joint mechanism. Developing such a mechanism would require determining appropriate geometry, tolerances, travel, load-bearing capacity, and release characteristics while avoiding binding and

excessive stress concentrations. None of these engineering considerations are addressed in the Petition or Mr. Culbert's declaration.

81. Notably, Mr. Culbert's proposed redesign is also inconsistent with McLuen's stated design objectives and advantages. McLuen explains that, when the extending blocks are retracted, the implant forms a compact assembly suitable for minimally invasive arthroscopic insertion, thereby reducing incision size, tissue retraction, and patient trauma. Ex. 1012 ¶¶ 39, 74. Enlarging Michelson's holder so that it surrounds the exterior of McLuen's implant would necessarily increase the radial profile of the instrument-implant assembly during insertion. A POSITA would have understood that such an enlarged assembly is directly contrary to McLuen's objective of maintaining a compact construct for insertion through a small surgical corridor. I understand that Mr. Culbert has previously stated "[a] POSITA would have been motivated to minimize trauma to the patient" and "reduc[e] the size of a patient's wound." Ex. 2034 at ¶¶ 57-58. Mr. Culbert's own statements are at odds with his proposed redesign of Michelson's holder.

82. Nor do the additional references cited by Mr. Culbert remedy these deficiencies. At most, they demonstrate that implant holders employing external arms or prongs were generally known. They do not teach converting Michelson's internally engaging holder into the externally engaging holder proposed by Mr. Culbert while preserving its remaining functionality. Nor do they teach adapting

Michelson's holder to engage McLuen's straight channels using the newly proposed angled dovetail mechanism.

83. Finally, McLuen describes channels 1522 as receiving tool attachments that secure the actuation tool against slippage during rotation. It does not describe those channels as load-bearing retention features for an implant holder wrapped around the exterior of the implant. Mr. Culbert's proposal therefore depends upon numerous additional assumptions concerning the dimensions, orientation, strength, and function of McLuen's channels that are not disclosed in either reference. In my opinion, the proposed combination represents a substantial redesign of Michelson's holder rather than the type of routine engineering modification that a POSITA would have undertaken.

84. Petitioner's proposed redesign also raises substantial questions regarding the architecture of Michelson's implant holder itself. Petitioner's obviousness theory maps the challenged claims' first and second tools to two components of Michelson's implant holder—outer sleeve 504 and shaft 502—while mapping the third tool to expander driver 600. Michelson's holder, however, is specifically designed as a two-component single tool assembly in which axial movement of shaft 502 relative to outer sleeve 504 actuates the disclosed side extensions. Mr. Culbert proposes replacing that mechanism with externally positioned prongs and a new dovetail arrangement, but neither the Petition nor Mr.

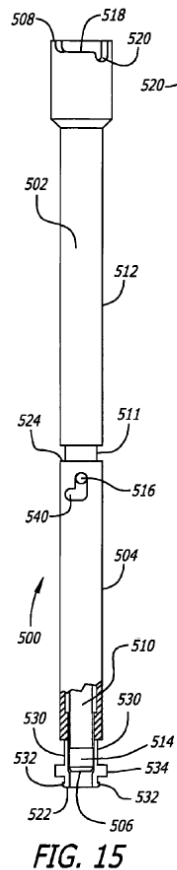
Culbert's declaration explains how shaft 502 and outer sleeve 504 would continue to be required after those modifications and whether, after modification, they would still be considered "tools" under Petitioner's broad and incorrect understanding of the term. A POSITA would have understood that redesigning the holder's engagement mechanism necessarily affects the interaction between shaft 502 and outer sleeve 504, yet no engineering analysis is provided demonstrating that the modified holder would retain Michelson's disclosed two-component architecture while performing the proposed function.

**B. Michelson Does Not Teach or Suggest Three Tools**

85. Claim 16 requires a "first tool," "second tool," and "third adjusting tool." Petitioner relies on Michelson to satisfy these three tool limitations. Pet. 29-41. Specifically, Petitioner identifies Michelson's expander driver 600 as the claimed third adjusting tool and separately maps the outer sleeve 504 and shaft 502—both components of Michelson's implant holder 500—to the claimed first tool and a second tool, respectively. Pet. 29, 33.

86. In my opinion, a POSITA would understand Michelson as disclosing two instruments that are used during implantation: implant holder 500 and expander driver 600. Implant holder 500 comprises shaft 502 and outer sleeve 504. Ex. 1014, 12:43-46. I would understand shaft 502 and outer sleeve 504 to be structural components of a single implant holder rather than separate surgical tools.

87. Michelson describes shaft 502 and outer sleeve 504 as being mechanically interconnected. Shaft 502 includes outwardly extending peg 516 that is received within L-shaped slot 540 of outer sleeve 504. Ex. 1014, 12:64-67; Fig. 15:



Ex. 1012, Fig. 15. The intended operation of implant holder 500 is dependent upon this structural connection. The peg-and-slot arrangement constrains the relative movement of the two components and permits shaft 502 to move only within the travel allowed by slot 540. Michelson further explains that shaft 502 is rotated relative to outer sleeve 504 to move peg 516 between locked and unlocked positions

within L-shaped slot 540. *Id.* at 15:14-21; 17:63-18:2. A POSITA would recognize this as an integrated mechanical assembly in which the shaft and sleeve are permanently connected.

88. During use, shaft 502 is advanced within outer sleeve 504 until shoulder 514 contacts ramp portions 538 of side extensions 530, forcing those side extensions outward so that flanges 532 engage with inward facing slots in implant 100. *Id.* at 15:1-8. When shaft 502 is subsequently retracted, the side extensions rebound inward, releasing flanges 532 from the inward facing slots and allowing implant holder 500 to disengage from the implant. *Id.* at 17:65-18:2. The engagement and release of the implant therefore result from the coordinated interaction of shaft 502 and outer sleeve 504. Michelson never describes shaft 502 as being separable from outer sleeve 504. For example, Michelson does not describe peg 516 as being a spring lock, despite identifying such mechanisms elsewhere. Rather, Michelson describes peg 516 as an extension of shaft 502 itself. Ex. 1014, 12:64-67. Based on Michelson's disclosures, a POSITA would have understood that shaft 502 and outer sleeve 504 could not be separated without breaking one or both components.

89. In my opinion, a POSITA would not regard shaft 502 as a separate surgical tool merely because it is movable relative to outer sleeve 504 within the same tool. Michelson consistently describes these components as together forming implant holder 500, not as separate instruments. I also understand that Mr. Culbert

has identified Michelson's implant holder 500 as a "first tool ... that securely holds an expandable spinal implant in place at a desired implant site while a second tool (expander driver 600) passes through the first tool and engages the implant for adjusting its height" in another proceeding. Ex. 2032 at 80; Ex. 2033 at ¶ 90.

90. This understanding is reinforced by Michelson's description of the remaining instrumentation. In addition to implant holder 500, Michelson separately discloses expander driver 600, which is inserted through implant holder 500 to actuate the implant's expansion mechanism after the implant holder has secured the implant. Ex. 1014, 13:20-44, 15:28-30. Thus, Michelson distinguishes between implant holder 500 as one instrument and expander driver 600 as a second, separate instrument. Petitioner and Mr. Culbert agree with this in other proceedings. Ex. 2032 at 80; Ex. 2033 at ¶ 90. Michelson does not distinguish shaft 502 and outer sleeve 504 as separate tools.

91. I also note that the embodiment of Figure 67, on which Mr. Culbert relies elsewhere in his declaration, likewise describes a different implant holder (1800), not separate holder components corresponding to shaft 502 and outer sleeve 504. Thus, Michelson consistently describes implant holders as integrated instruments, even though their internal configurations differ between embodiments. Nothing in Michelson suggests that the internal components of those holders would themselves be understood as separate surgical tools.

92. Based on Michelson's disclosure, a POSITA would therefore have understood the reference to disclose two surgical tools: implant holder 500 and expander driver 600. A POSITA would not have understood shaft 502 and outer sleeve 504 to constitute separate tools because they are mechanically interdependent components of a single implant holder assembly that cannot be separated from one another without breaking.

**C. Michelson Does Not Teach or Suggest the Claimed Engagement Prongs**

93. As explained above, a POSITA would understand claim 16's "engagement prongs" to mean "protruding members located on opposite sides of the first tool and configured to engage corresponding tool engagement indentations on opposite lateral sides of the of the exterior of the expandable intervertebral fusion device."

94. I have considered Petitioner's contention that Michelson teaches the "first and second engagement prongs" recited in claim 16. Pet. 21-30. In my opinion, a POSITA would not have understood Michelson to disclose or suggest the claimed engagement prongs. Rather, Michelson retains its implant using an internally expanding flange-locking mechanism that operates in the opposite manner as the prong-and-indentation engagement relationship recited in claim 16.

95. In the embodiment of Figures 15-19, implant holder 500 is first inserted into the interior of implant 100 while flanges 532 are not engaged with slots 126.

Shaft 502 is then advanced so that side extensions 530 expand outwardly, causing flanges 532 to engage the interior-facing slots. Ex. 1014, 15:1-21. Likewise, in the Figure 67 embodiment, the side extensions are compressed toward one another during insertion and then resiliently rebound outwardly so that flanges 1820 engage opposed slots 1752, which are located on the interior surface of trailing end 1704. *Id.* at 25:35-67. Although Michelson states that the side extensions may be temporarily forced toward one another, *id.* at 15:8-13, retention is ultimately achieved because the flanges expand outwardly after insertion into the implant. In both embodiments, the holder locks itself to the implant from within through an internally expanding flange mechanism.

96. A POSITA would not regard Michelson's flanges as the claimed engagement prongs. The claimed engagement prongs are protruding members configured to mate with corresponding tool engagement indentations located on opposite sides of the implant. Michelson's flanges are not disclosed as such. Rather, they are locking features of an expandable internal retention mechanism that achieve fixation only after the holder has been inserted into the implant and the flanges have expanded outwardly into internal slots. In my opinion, these are different engagement architectures that operate according to different mechanical principles.

97. In my opinion, this distinction is reinforced by Petitioner's own analysis. Rather than relying exclusively on Michelson's side extensions and flanges

as corresponding to the claimed engagement prongs, Petitioner cites additional references (Allen, Gordon, and Lim) as showing that engagement prongs were generally known. A POSITA would understand those references to disclose different engagement architectures, not merely insignificant variations of Michelson's holder. Petitioner's reliance on those additional references is therefore consistent with my opinion that Michelson itself does not disclose or suggest the claimed engagement prong structure.

## **X. CONCLUSION**

98. Because a POSITA would not have been motivated to combine McLuen and Michelson, would not have expected a reasonable expectation of success in the proposed combination, and because the proposed combination still fails to teach or suggest multiple features of claim 16, it is my opinion that Petitioner has not shown that claim 16 is obvious. Petitioner has also not shown that claim 19 is obvious for the same reasons due to claim 19's dependency on claim 16. Accordingly, it is my opinion that claims 16 and 19 of the '797 Patent are all patentable.

99. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination. If cross-examination is required of me, I will appear for cross-

examination at a mutually agreeable time and date within the United States during the time allotted for cross-examination.

100. I declare that all statements made herein of my knowledge are true and correct. I also declare 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 35 U.S.C. § 1001.

101. I declare under the penalty of perjury that the foregoing is true and correct.

Executed on: August 3<sup>th</sup> 2026

A handwritten signature in blue ink that reads "Ken Gall".

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Ken Gall, Ph. D.