

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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Case No. IPR2026-00163  
Patent No. 11,376,136

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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. 11,376,136 (the '136 patent") in the IPR2026-00163 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 2040 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 of 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, a device 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.

9. 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.

10. As the founder of, and consultant to, many medical device 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.

11. 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.

12. 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 2040.

### III. MATERIALS CONSIDERED

13. 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. 11,376,136                                                     |
| Ex. 1001, U.S. Patent No. 11,376,136 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. 11,376,136 |
| Ex. 1004, File History for U.S. Patent No. 11,376,136                                                                     |
| Ex. 1006, U.S. Patent Application Publication No. 2008/0249569 A1 to Waugh et al. (“Waugh”)                               |
| Ex. 1012, U.S. Patent Application Publication No. 2006/0253201 A1 to McLuen (“McLuen”)                                    |
| Ex. 1013, U.S. Patent Application Publication No. 2005/0278026 A1 to Gordon et al. (“Gordon”)                             |

|                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ex. 1014, International Publication No. WO 02/062272 to Michelson (“Michelson”)                                                                                             |
| Ex. 1020, Phulchand Prithvi Raj, <i>Intervertebral Disc: Anatomy-Physiology-Pathophysiology-Treatment</i> , 8(1) PAIN PRACT. 18 (2008)                                      |
| Ex. 1021, Fabio Galbusera et al., <i>Ageing and degenerative changes of the intervertebral disc and their impact on spinal flexibility</i> , 23(3) EUR. SPINE J. 324 (2014) |
| Ex. 1022, Dil Patel et al., <i>Interbody options in lumbar fusion</i> , 5(1) J. SPINE SURG. S19 (2019)                                                                      |
| Ex. 1037, Daniel Orr et al., <i>Expandable interbody cages for lumbar spinal fusion: a systematic review</i> , 25(8) SPINE J. 1773 (2025)                                   |
| Ex. 1053, U.S. Patent No. 7,846,188 to Moskowitz et al. (“the ’188 patent”)                                                                                                 |
| Ex. 2038, Transcript of Deposition of Mr. Brad Culbert, July 29, 2026                                                                                                       |
| Ex. 2041, Excerpts of Merriam-Webster’s Collegiate Dictionary, Eleventh Edition, 2003                                                                                       |

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

#### IV. LEGAL STANDARDS

##### A. Anticipation

15. I understand that a claim is unpatentable if it is anticipated by prior art. I understand that anticipation requires that a single prior art reference discloses each and every limitation recited in a claim, either expressly or inherently, as arranged in the claim. I understand that a reference need not expressly spell out all limitations as combined in the claim if a person of skill in the art would at once envisage the combination. However, I also understand that a single prior art reference disclosing multiple distinct teachings that might somehow be combined is not anticipation.

16. I further understand that inherency requires that a claim limitation be necessarily present in, or the natural and inevitable result of, the disclosure of the reference. Inherency cannot be established by mere possibilities or probabilities. The missing limitation must necessarily flow from the reference itself, and not from extrinsic evidence or speculation.

17. I understand that a dependent claim incorporates all the limitations of claims from which it depends. Accordingly, if an independent claim is not anticipated by a prior art reference, a claim that depends from that independent claim likewise cannot be anticipated by that same reference for at least the same reasons.

18. I further understand that, to anticipate, a prior art reference must be sufficiently enabling to allow a POSITA to make and use the claimed invention without undue experimentation.

## **B. Obviousness**

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

### **C. Claim Construction**

24. 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.

25. 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.

26. 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.”

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.**

32. 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 ’136 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.

33. 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.

34. 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.

35. 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

broad 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.

36. 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.

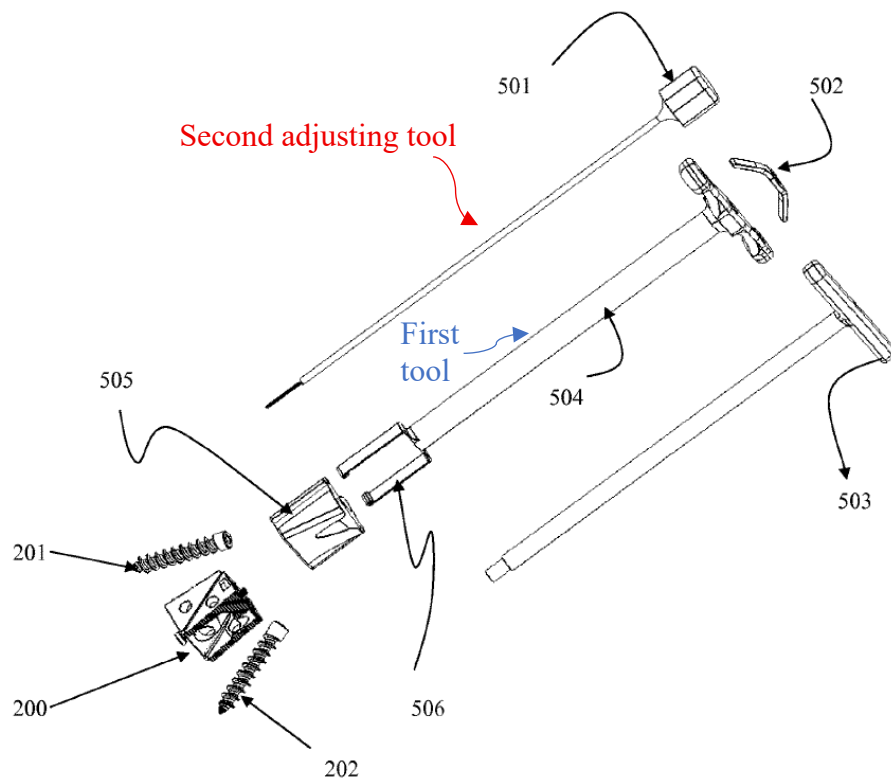
## **VI. BACKGROUND OF THE TECHNOLOGY AND THE '136 PATENT**

37. 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 expansile forces can be applied in a controlled manner without losing the implant's position. The '136 patent discloses a coordinated implant-and-instrumentation system for performing those functions.

38. The '136 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 surgical tool assembly configured both to implant the device and mechanically

expand it once positioned within the patient. Ex. 1001, 2:64-3:10, 7:44-8:15, 8:61-9:17, 10:52-11:22, Fig. 1A-1E, 5A-5G.

39. The patent describes a nested instrumentation architecture comprising at least two 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 adjusting tool, such as an Allen key or similar driver, is receivable through the first tool and engages the implant's expansion mechanism to transmit rotational input for expansion. Ex. 1001, 8:61-9:17, Figs. 5A-5G.



Ex. 1001, Fig. 5C (Annotated).

40. The disclosed instruments cooperate in a telescoping arrangement while remaining separate surgical tools. The first tool aligns and stabilizes the implant and includes a passage for the second adjusting tool, and the second adjusting tool actuates the implant's expansion mechanism. *Id.*

41. The claims reflect this same structural architecture. Independent claim 9 recites a system comprising a tool assembly comprising a first tool having engagement prongs and an adjusting tool passage, and a second adjusting tool with a screw engagement portion and a shaft with a smaller diameter than the adjusting tool passage of the first tool. *Id.*, claim 9. The system further includes an expandable implant including first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool, as well as an adjusting screw in a location that the second adjusting tool can engage upon extending through the adjusting tool passage while the first and second engagement prongs are engaged with the first and second too engagement portions. *Id.* Independent claim 18 recites substantially similar features. *Id.*, claim 18.

42. Dependent claims 10-12, 14-17, and 20 recite additional requirements such as the location of the engagement portions (*id.*, claim 10), angled wedge surfaces to expand the implant (*id.*, claim 11), a plurality of ridges (*id.*, claim 12), a through-hole for placement of bone material (*id.*, claim 14), first and second single

integral implant structures (*id.*, claim 15), substantially straight engagement prongs (*id.*, claim 16), a method of using the system of claim 9 (*id.*, claim 17), and combinations thereof (*id.*, claim 20).

43. 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.

## **VII. CLAIM CONSTRUCTION**

44. I have applied the plain and ordinary meaning, as understood by a POSITA at the time of the invention of the '136 patent, to all claim terms in forming my opinions.

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

45. 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. 2005/0278026 A1 to Gordon (Ex. 1013)**

46. Gordon describes numerous implant embodiments as well as instruments that may be used to insert and expand certain implants. One embodiment relates to implant 304, shown in Figures 15A–15C. Gordon describes

implant 304 as a C-shaped, expandable, articulating implant having an insert 306, expansion member 308, opening 310, and advancing element 312. Expansion member 308 is inserted through opening 310, after which advancing element 312 may be inserted into opening 310 and used to advance expansion member 308 beneath insert 306, as shown in Figures 15B-15C below.

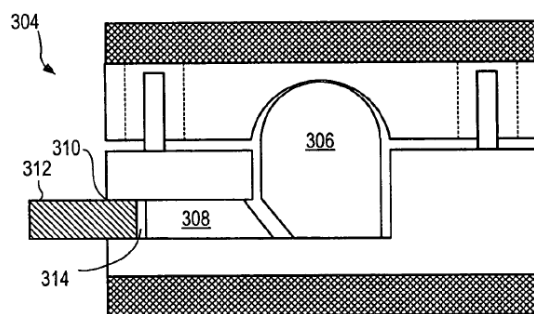


FIG. 15B

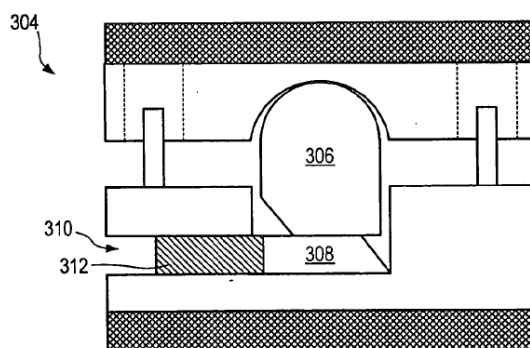


FIG. 15C

Gordon further explains that advancing element 312 may remain in recess 314 to inhibit displacement of expansion member 308 after expansion. Ex. 1013, ¶ 177. Gordon describes a separate embodiment in Figure 16 having, among other things, a smaller expansion member 308. *Id.* at ¶ 178.

47. In another separate embodiment, Gordon describes an implant 484. Implant 484 is expanded in an entirely different way by advancing driver 726 to directly engage an insert 472 in a torsional manner, shown in Figure 24D below.

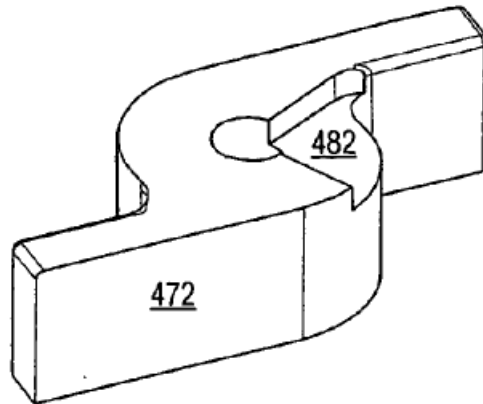


**FIG. 24D**

Advancement of driver head 726 rotates insert 472 to expand implant 484 between the vertebrae, as illustrated in Figures 47A-47B below. *Id.* ¶¶ 238, 248, Figs. 47A-4B.

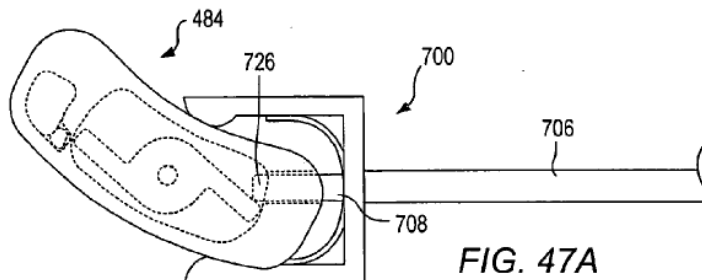


**FIG. 47A**

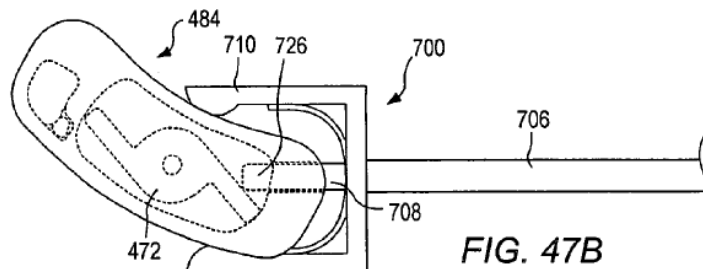
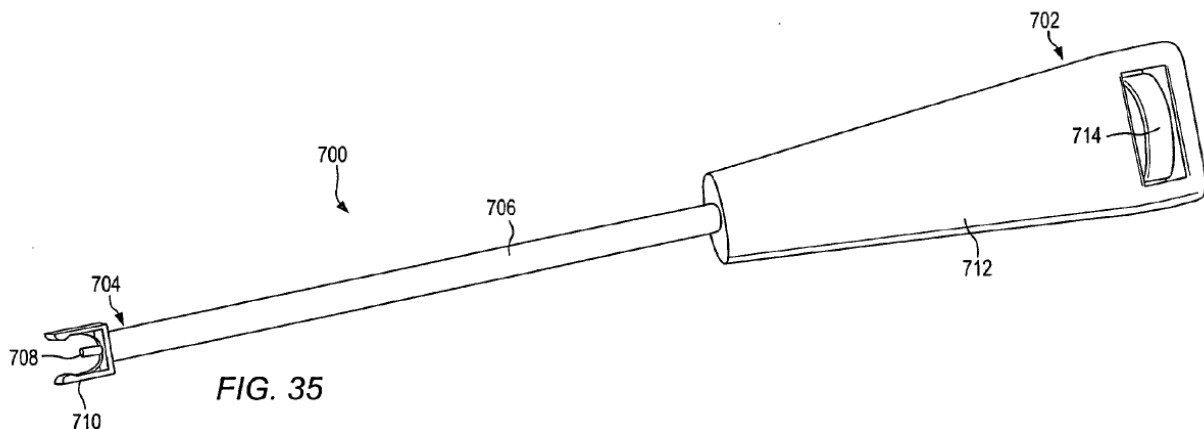


**FIG. 47B**

Rather than advancing an expansion member beneath an insert to expand implant 304, implant 484 relies on direct driver head interaction with a rotatable insert for expansion. *Id.*

48. Gordon also describes an instrument 700 that can be used to hold and expand implant 484. *Id.* at ¶ 227, Figs. 35, 38. Instrument 700 includes a proximal end 702, distal end 704, outer shaft 706, driver 708, holding device 710, and handle 712. Gordon explains that instrument 700 includes a thumbwheel 714 that is coupled to driver 708 by an internal shaft residing inside outer shaft 706 and can be used to rotate driver 708.



49. The thumbwheel 714 resides within a slot 732 located between the grip and end portion of handle 712. *Id.* at ¶¶ 234-235. Instrument 700 includes a holding device 710 at the distal end that is designed to hold implant 484 during insertion between two vertebrae. Holding device 710 includes holding arms 716 coupled to

outer shaft 706 that have lobes 722 at their distal end that are configured to engage complementary recesses 733 on implant 484.

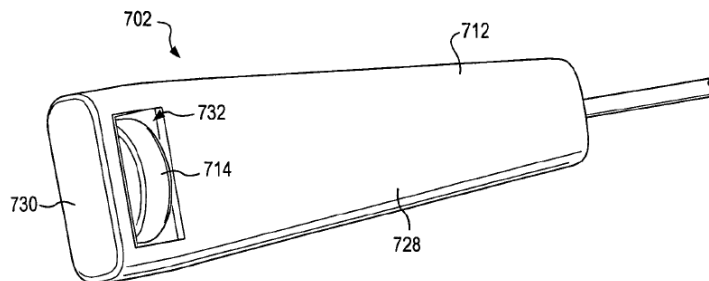


FIG. 37

50. The coupling of thumbwheel 714 to driver 708 mechanically interlocks driver 708 within handle 712 and outer shaft 706 of instrument 700. *Id.* at ¶¶ 229, 233. Gordon does not describe any possibility for driver 708 to be removed from outer shaft 706 or handle 712, and instead describes its thumbwheel-slot mechanism as an internal retention mechanism that provides for rotation while maintaining the assembled relationship between driver 708 and outer shaft 706 and handle 712. A POSITA therefore would have understood outer shaft 706, driver 708, handle 712, and thumbwheel 714 to be cooperating components of a single tool.

51. Gordon gives a knob, lever, and button as alternatives to thumbwheel 714. *Id.* at ¶ 228. A POSITA would have understood these alternatives, like thumbwheel 714, are all examples of mechanisms actuatable with a user's thumb. A POSITA would also have understood Gordon's thumbwheel alternatives to protrude in a similar manner through slot 732.

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

52. 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 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.

53. 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.*

54. To address this concern, McLuen describes an instrument for holding the implant using engagement channels 1522 formed in the implant body, as shown in the figure below. *Id.* at ¶¶ 76, 78.

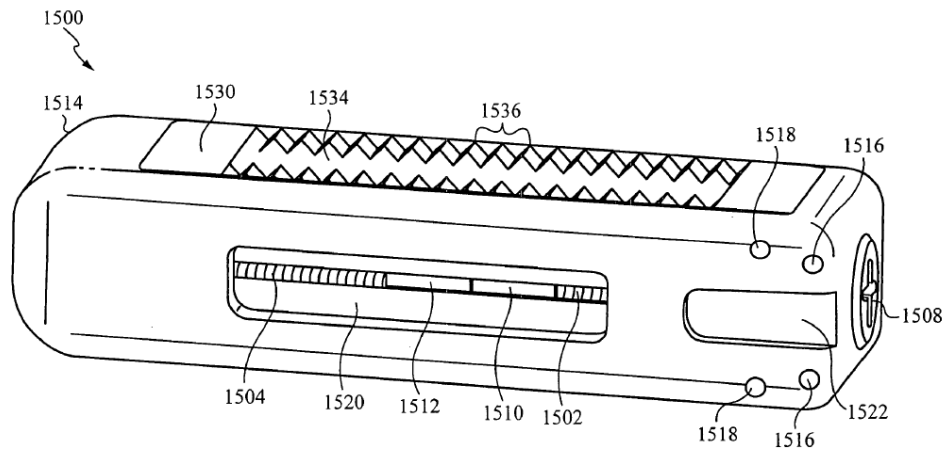


**Fig. 16**

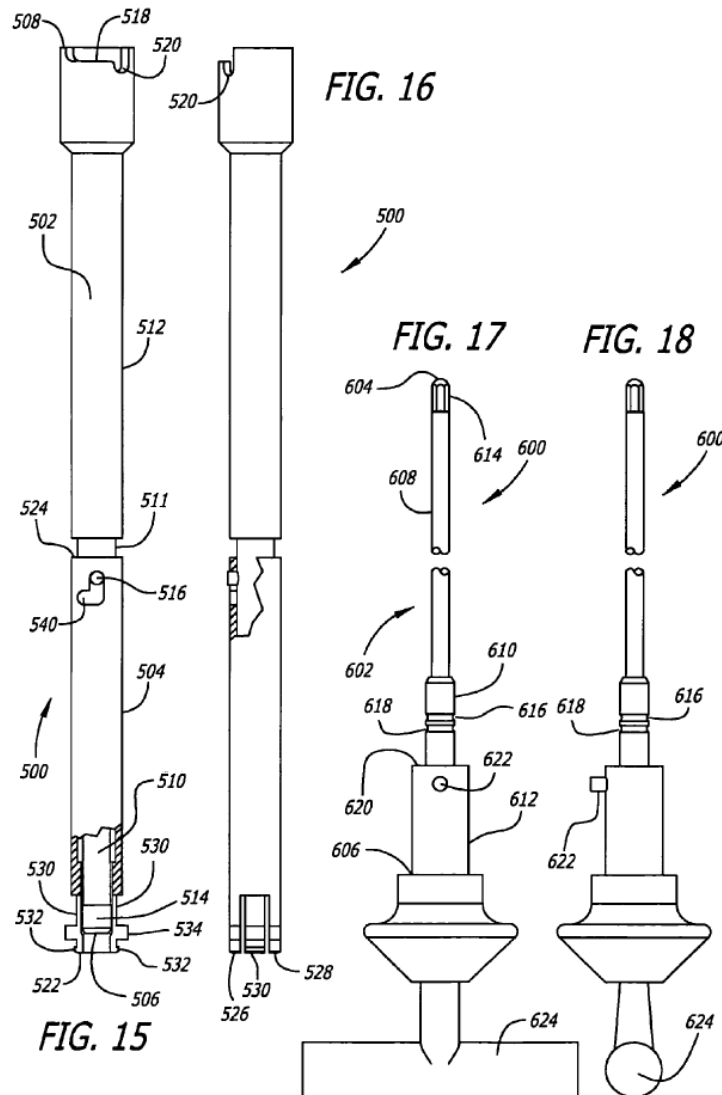
55. The tool has attachments configured to fit within the engagement channels while a screwdriver engages positioning means 1508. *Id.* According to McLuen, the attachments engage the channels to position and stabilize the instrument relative to the implant, helping maintain alignment with positioning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

56. 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.

57. A POSITA would understand that McLuen's disclosed attachment-and-channel interface is designed to 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 coupling for applying rotational coupling torque while permitting straightforward disengagement of the tool after the implant has been positioned and expanded.

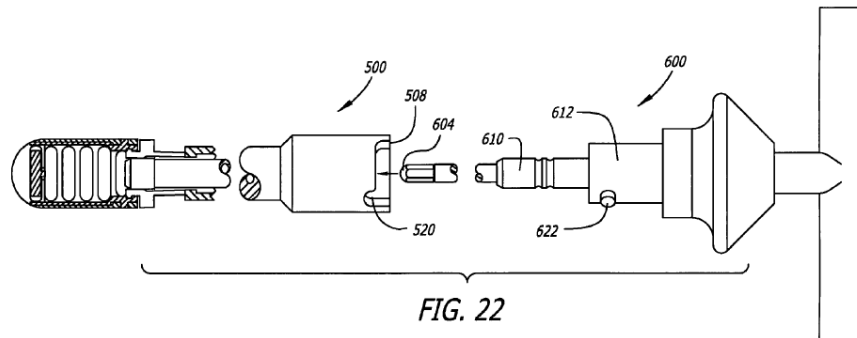
**C. International Publication No. WO 02/062272 to Michelson (Ex. 1014)**

58. Michelson discloses an expandable interbody implant used with an assembly comprising an implant holder 500 and an expander driver 600, shown in the figures below. Ex. 1014,19-20.



*Id.*, Figs. 15-18.

59. Implant holder 500 comprises a shaft 502 positioned within an outer sleeve 504. *Id.* at 12:45-46. The expander driver 600 extends through implant holder 500, 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. *Id.* at 16:46-55.



## IX. ANALYSIS OF PETITIONER'S GROUND 1: GORDON ANTICIPATION AND/OR OBVIOUSNESS

60. In my opinion, Gordon does not anticipate or render obvious claims 9-12, 14-18, and 20 of the '136 patent.

### A. Petitioner Mixes Distinct Embodiments of Gordon to Allege Anticipation.

61. I understand that, for anticipation, the claimed elements must be disclosed in the prior-art reference arranged or combined as they are in the claim. I further understand that it is not sufficient to identify individual claim elements in separate embodiments within the same document and then assemble those elements into a combination that the reference itself does not disclose. Gordon does not disclose the elements of claim 9 or 18 arranged or combined as they are in the claims.

62. Petitioner begins its anticipation analysis of claim 9 by pointing to Gordon's instrument 700 for limitations 9[a]-9[d]. Pet. 16-22. What Petitioner does not do is point to the implant with which Gordon describes instrument 700 is used. Gordon does not describe instrument 700 as a universally applicable tool. Rather,

Gordon describes instrument 700 as being specifically being used with implant 484. Ex. 1013, ¶¶ 237-238, 242, 247-249, Figs. 38-41, 46-47.

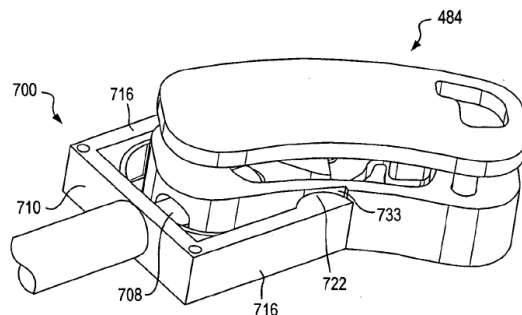


FIG. 38

63. Instead of continuing to rely on that embodiment for limitations 9[e]-9[g] (limitations describing features of an expandable implant), Petitioner instead turns to Gordon's implant 304 embodiment of Figures 15A-15C. Pet. at 23-28. Gordon expressly identifies Figures 15A-15C as depicting implant 304 and describes implant 304 as having insert 306, expansion member 308, opening 310, and advancing element 312. Ex. 1013, ¶ 177. Expansion member 308 is inserted through opening 310, and advancing element 312 is then inserted through opening 310 to advance expansion member 308 beneath insert 306. Gordon further states that advancing element 312 may remain in recess 314 to inhibit dislocation of expansion member 308 after expansion. *Id.*

64. When Petitioner gets to limitations 9[h]-9[j], however, Petitioner turns back to the instrument 700/implant 484 embodiment. Pet. at 29-34. Petitioner thus relies on implant 304 for the claimed expandable spinal implant structures defining

vertebral body engagement surfaces sized and configured to engage vertebral bodies (limitation 9[f]) and the claimed adjusting screw having a screw head and a threaded shaft for expanding the implant in response to turning the adjusting screw (limitation 9[g]), and then turns to implant 484 for the claimed tool engagement portions sized, shaped, and configured for receiving engagement prongs of the first tool (limitation 9[h]) and formed in the sides of the implant (limitation 9[i]) such that the adjusting tool can engage the adjusting screw while the engagement prongs are engaged with the engagement portions of the implant (limitation 9[j]).

65. This is important because limitations 9[h]-9[j] introduce additional features for the implant described in limitations 9[e]-9[g]. But Petitioner relies on two different implants—implant 304 and implant 484—which are distinct embodiments with varying features. The Petition nevertheless relies on these distinct embodiments, because implant 304 and implant 484 are allegedly both “c-shaped.” But Gordon does not describe implant 304 as having holding recesses 733 or interacting with instrument 700. Rather, Gordon’s discussion of recesses 733 are limited to the implant 484 embodiment and specifically only mentioned in paragraph 237.

66. In my opinion, Gordon’s use of the term “c-shaped” does not disclose that these otherwise distinct embodiments share all of the same structural features. Gordon expressly defines “c-shaped” broadly. It states that “‘c-shaped’ implants

generally refer to implants with an arcuate shape,” and explains that some such implants may be only slightly curved, including “banana shaped,” while others may have a substantially greater degree of curvature. Ex. 1013, ¶ 137. Gordon also describes many different implants throughout the specification as c-shaped even though they employ materially different internal structures and expansion mechanisms. For example, Gordon describes c-shaped implants employing screws, non-threaded expansion members, expansion plates, lordotic mechanisms, cam devices, and the expansion-member/advancing-element arrangement of Figures 15A-15C. Gordon thus presents a series of separately identified implant embodiments, sometimes carrying components or concepts across them and other times not. A POSITA therefore would have understood “c-shaped” as describing the general external geometry of an implant, not as a statement that every feature disclosed for one c-shaped implant is necessarily present in every other c-shaped implant.

67. The differences between implants 304 and 484 are important because Gordon does not describe them as interchangeable implementations of the same detailed structure. Implant 304 uses expansion member 308 and advancing element 312 to raise insert 306. Advancing element 312 moves expansion member 308 beneath insert 306, and Gordon contemplates that advancing element 312 may

remain in recess 314 after expansion to inhibit displacement of expansion member 308. Ex. 1013, ¶ 177, Figs. 15B-15C.

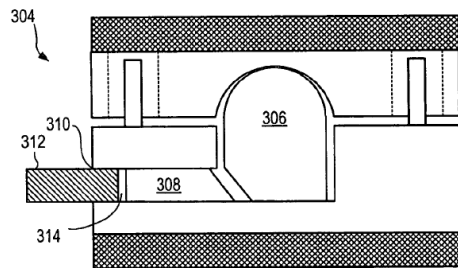


FIG. 15B

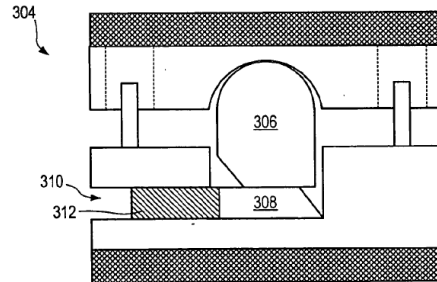


FIG. 15C

68. Gordon describes a different mechanism with implant 484. Gordon describes that a driver is advanced through a tapped through-hole in lower body 488 until it directly engages insert 472. Advancement of driver may then rotate insert 472 to expand implant 484. Ex. 1013, ¶ 248, Figs. 47A-47B.

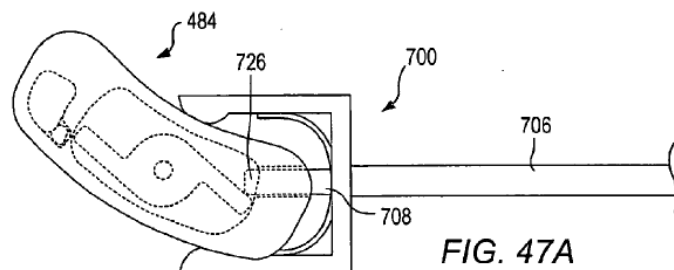


FIG. 47A

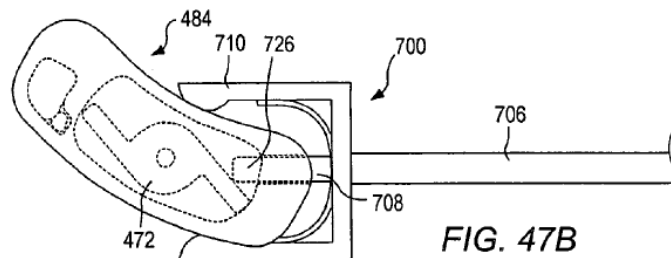


FIG. 47B

Thus, the disclosed expansion arrangement for implant 484 is not the same expansion-member/advancing-element arrangement Gordon describes for implant 304.

69. Those structural differences matter to Petitioner's identification of recesses 733 on implant 484 as satisfying the claimed engagement portions of limitations 9[h]-9[j]. Gordon does not identify where recesses 733 would be positioned on implant 304 relative to opening 310, expansion member 308, advancing element 312, or the other structures of implant 304. Nor does Gordon explain whether recesses configured as shown on implant 484 could simply be incorporated into implant 304 without interfering with the structure or operation of implant 304's different expansion mechanism. Petitioner's analysis does not address those details. Instead, it merely identifies distinct embodiments and alleges a surface-level similarity in pulling features from each of them. Pet. at 29.

70. Gordon itself demonstrates that, when Gordon intended a particular feature to have broad applicability across different implant embodiments, it expressly said so. For example, Gordon expressly states that "the expansion member/advancing element combination may be employed with any of the disclosed implants, including cages." Ex. 1013, ¶ 177. Gordon provides no comparable statement that holding recesses 733 may be incorporated into any disclosed implant,

all c-shaped implants, or implant 304 in particular. That contrast is significant to how a POSITA would read Gordon.

71. The same problem extends to Petitioner's reliance on instrument 700 for limitations 9[a]-9[d] and implant 304 for limitations 9[e]-9[g]. Gordon only discusses instrument 700 for interaction with implant 484. Gordon does not disclose instrument 700 in connection with implant 304. Figure 38 expressly depicts implant 484 held by instrument 700, and Figures 47A-47B again depict implant 484 on instrument 700 before and during expansion. Gordon does not provide a corresponding disclosure of implant 304 coupled to or operated by instrument 700.

72. Gordon does not disclose the combination on which Petitioner's anticipation theory depends: implant 304 modified to include recesses combined with instrument 700. Gordon discloses those features in separate embodiments. I understand that an assembly of separate embodiments does not establish anticipation where the claimed elements are not disclosed arranged or combined in that manner in the reference itself.

73. Because Petitioner's anticipation theory is not based on disclosures of the claimed arrangement of claim 9, independent claim 9 has not been proven anticipated. The same is true for independent claim 18, which has similar features as independent claim 9, as well as each of the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**B. Gordon Fails to Disclose, Teach, or Suggest 9[c] or 18[c].**

74. Claim 9 and 18 both require “a second adjusting tool having a second proximal end and a second distal end.” Claim 9 further requires that “the second adjusting tool includes a second handle positioned at the second proximal end.” Gordon fails to disclose, teach, or suggest these features of claims 9 and 18.

**1. Gordon Fails to Disclose, Teach, or Suggest the Claimed Second Adjusting Tool in Limitations 9[c] and 18[c].**

75. As I explained above, Petitioner’s Ground 1 fails to prove anticipation as it points to one embodiment for the tool limitations of claim 9 (limitations 9[a]-9[d]) and claim 18 (18[a]-18[d]), and points to a different embodiment for implant limitations for claim 9 (limitations 9[e]-9[g]) and claim 18 (limitations 18[e]-18[g]).

76. I understand that Petitioner contends that Gordon discloses the “first tool” and “second adjusting tool” of claims 9 and 18 by ignoring the fixed combination of components within Gordon’s instrument 700. In particular, Petitioner identifies outer shaft 706, holding device 710, and handle 712 collectively as the claimed “first tool,” while identifying driver 708 fixed inside the housing of the first tool as the claimed “second adjusting tool.” A POSITA would not understand Gordon as disclosing two tools because Gordon describes Petitioner’s identified components as integrated within a single instrument 700.

77. Gordon introduces instrument 700 by stating that “a single instrument may be used to perform multiple steps of a spinal procedure. For example, an

instrument may be used to position an implant in an intervertebral space and to actuate an expansion member to expand the implant in the intervertebral space.” Ex. 1013, ¶¶ 226-227. Gordon states that instrument 700 “may include outer shaft 706, driver 708, holding device 710, and handle 712.” *Id.* Thus, Gordon explicitly identifies driver 708, outer shaft 706, holding device 710, and handle 712 as components of the same instrument 700.

78. The physical relationship of the components further demonstrates that the instrument is a single tool. Gordon states that driver 708 is disposed within outer shaft 706 and handle 712, and is coupled to thumbwheel 714 that resides in a slot 732 between a grip portion 728 and an end portion 730. Ex. 1013, ¶¶ 228, 233-234. Gordon explains that handle 712 is shaped so that a user can access enough of thumbwheel 714 to rotate it while the handle protects both thumbwheel 714 and inner shaft 724 from damage. Ex. 1013, ¶¶ 234-235. Thus, the structure Petitioner labels the “second tool” is permanently fixed within the shaft of the instrument.

79. Gordon similarly describes the distal components as functioning together as part of instrument 700. Holding device 710 may hold the implant during insertion, while driver 708 operates within that same instrument to actuate the implant. Ex. 1013, ¶¶ 230, 233. In the Figure 38 embodiment, Gordon states that implant 484 is “held by instrument 700 after driver 708 has been operated to expand the implant.” Gordon then describes holding arms 716 maintaining the implant’s

position during insertion and expansion while driver 708 actuates the implant. *Id.* at ¶¶ 237-238. A POSITA viewing this disclosure would understand that the implant-holding and implant-adjusting functions are performed by coordinated components of one instrument, not by two separately disclosed tools.

80. Driver 708 and/or thumbwheel 714 are not removable from instrument 700. Gordon, however, does describe components of other systems as separable. *Id.* at ¶¶ 241 (“In the embodiment shown in FIG. 39, inserter 738 may be easily separated from outer shaft 706.”), 255 (“The rods may be removable from base member 798.”). Thus, when Gordon wanted to describe separate structures, Gordon did so expressly. The fact that different components of instrument 700 perform different functions does not cause those components to become separately disclosed “first” and “second” tools, especially when Gordon consistently describes all of those structures as parts of the same instrument 700 and they are described and shown as being fixed within the instrument housing.

81. Accordingly, it is my opinion that Gordon fails to disclose, teach, or suggest both of the claimed tools in claims 9 and 18. Because Petitioner relies on Gordon to supply both of the claimed tools of claims 9 and 18, it is my opinion that Ground 1 fails to show that independent claims 9 and 18 are anticipated or obvious. The same is true for the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**2. Gordon Fails to Disclose, Teach, or Suggest the Claimed Handle in Limitation 9[c].**

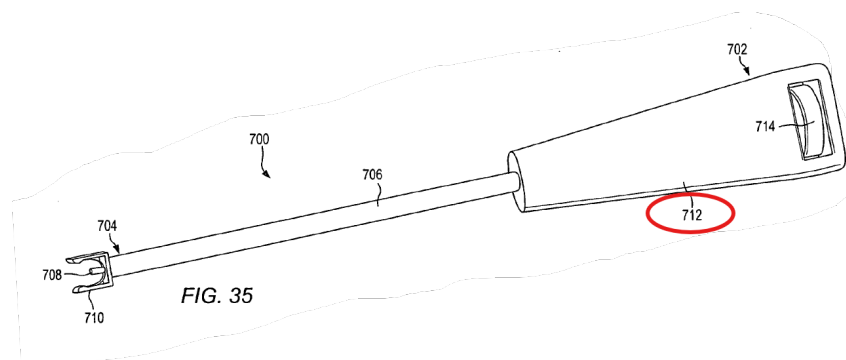
82. Claim 9 requires the second adjusting tool to include, among other things, “a second handle positioned at the second proximal end.” I understand Petitioner has not offered a construction for “handle,” such that it should have its ordinary meaning in this context. Webster’s defines a handle as “a part that is designed esp[ecially] to be grasped by the hand.” Ex. 2041, 565. From a mechanical perspective, whether a component constitutes a handle depends on whether its structure provides for grasping by the hand so that the user can manipulate it with rotational and axial force to use the associated tool.

83. Petitioner identifies Gordon’s driver 708 as the alleged “second adjusting tool” and thumbwheel 714 as the claimed “second handle.” Pet. at 19-20. The Petition states that inner shaft 724 of driver 708 is coupled to thumbwheel 714 and characterizes thumbwheel 714 as a “second handle” positioned at the proximal end of driver 708. *Id.* at 20.

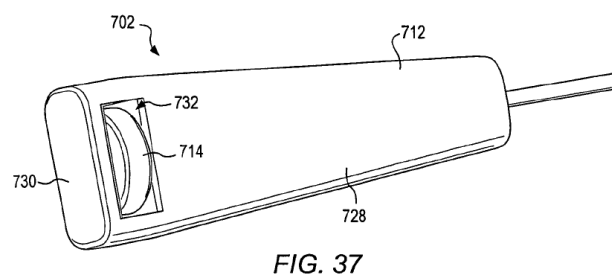
84. Thumbwheel 714 is not a handle. Nor are the alternative “control members” that Gordon identifies, namely, “a knob, a lever, or a button.” *Id.* None of these structures allow the user to grasp the structure with the hand, and apply rotational and axial force like a handle does. A button is actuated by pressing it with a finger. Likewise, Gordon’s constrained thumbwheel is manipulated with the

thumb and/or finger, and a lever or knob within a slot as shown in Gordon would likewise be finger-actuated.

85. Gordon's discussion of handle 712 further indicates that it considered a handle to be a different structure than the thumbwheel and its identified alternatives. In the same instrument in which Gordon identifies thumbwheel 714 as a control member, Gordon identifies a different structure as the "handle." Instrument 700 includes "outer shaft 706, driver 708, holding device 710, and handle 712."



Gordon subsequently describes handle 712 as having a "grip portion 728" and an end portion 730. Ex. 1013, ¶ 234.



Thus, when Gordon describes the structure intended to be gripped by the user, Gordon expressly calls that structure a handle and identifies a grip portion.

86. Gordon also physically distinguishes handle 712 from thumbwheel 714. Gordon states that slot 732 is formed in handle 712 between grip portion 728 and end portion 730, and thumbwheel 714 resides within that slot. Gordon further explains that this arrangement allows a user access to a sufficient portion of thumbwheel 714 to turn the thumbwheel, while handle 712 protects thumbwheel 714 and inner shaft 724 from damage. Ex. 1013, ¶¶ 234-235. In other words, Gordon depicts and describes the thumbwheel/control member as a component that is partially recessed within the structure that Gordon identifies as the handle.

87. Figure 37 is consistent with that description. Handle 712 extends around the proximal portion of instrument 700 and includes grip portion 728. Thumbwheel 714 is positioned within slot 732 so that only a portion of the thumbwheel is exposed for manipulation. A POSITA viewing this arrangement would understand the distinction Gordon draws between the structure intended to be gripped—handle 712—and the control that the user manipulates while using the instrument—thumbwheel 714.

88. Petitioner acknowledges that Gordon calls handle 712 a handle, but nevertheless also characterizes thumbwheel 714 as a second handle because a user's "other hand would hold and operate thumbwheel 714" to rotate driver 708. Pet. at 20-21. Petitioner further relies on Gordon's statement that the control member could alternatively be a knob or lever and contends that those alternatives would also

constitute a second handle. *Id. at 21*. As discussed above, the fact that a user touches or manipulates a nested component does not make that component a handle.

89. Nor would a POSITA equate the ability to rotate thumbwheel 714 with grasping a handle. Many mechanical devices include controls that a user manipulates with the fingers while holding the device by a separate handle. Gordon's instrument 700 is described in precisely that manner: it has a handle 712, including a grip portion 728 and end portion 730, and a separate thumbwheel 714 accessible through slot 732 for controlling driver 708. Gordon's choice of terminology is therefore consistent with the different mechanical functions and manner of interaction of these structures.

90. The Petition's comparison to the '136 patent does not change my opinion. Petitioner argues that Gordon's thumbwheel is consistent with the second handle because the '136 patent, according to Petitioner, depicts an Allen key that "has a knob similar to Gordon's thumbwheel 714 (or a "knob" or "lever" in an alternative embodiment)." Pet. at 21. But as Figures 5A shows, the Allen Key 501 in the '136 patent includes a part by which the Allen Key 501 is picked up, held, grasped with a hand (e.g., a handle), not a constrained, finger-actuated thumbwheel.

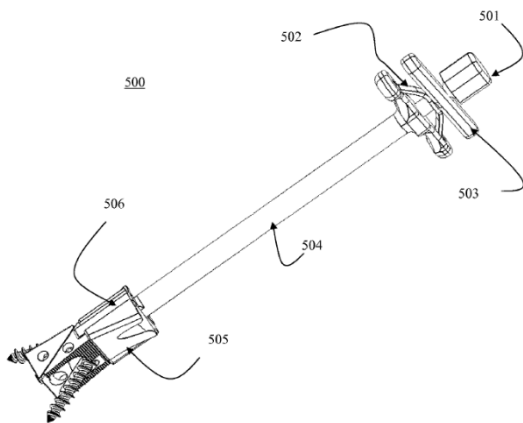


**FIG. 5A**

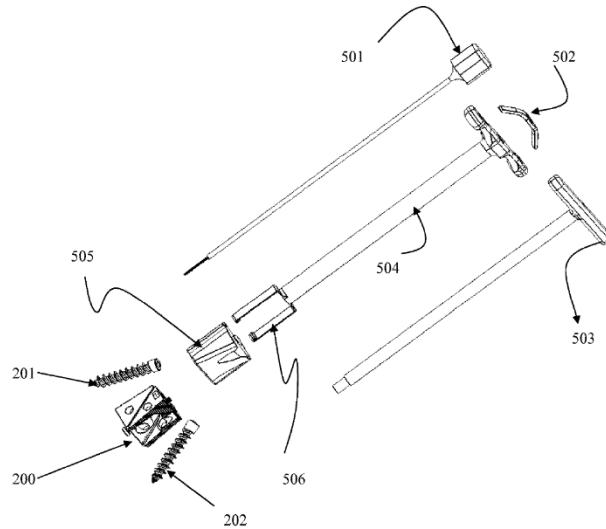


**FIG. 5E**

91. The distinction is further illustrated by Petitioner’s alternative obviousness theory based on Michelson. In that theory, Petitioner relies on Michelson’s T-shaped handle 624, which Petitioner would not have to turn to if Gordon’s thumbwheel 714 disclosed, taught, or suggested a handle. Accordingly, in my opinion, a POSITA would not understand Gordon’s thumbwheel 714 to disclose the claimed “second handle.” Gordon expressly identifies thumbwheel 714 as a control member and identifies a separate component, handle 712 with grip portion 728, as the handle of instrument 700. Gordon’s disclosure of a knob, lever, and button as alternatives to thumbwheel 714 are alternative finger-actuated control, not a component structured to be grasped by the hand.

92. Accordingly, it is my opinion that Gordon fails to disclose, teach, or suggest the claimed second handle in claim 9. It is my opinion, therefore, that

Ground 1 fails to show that independent claim 9 is anticipated or obvious. The same is true for the claims depending from claim 9 (e.g., claims 10-12, and 14-17).

**C. Gordon Fails to Disclose, Teach, or Suggest 9[h] or 18[h].**

93. Claim 9 further requires that “the expandable spinal implant defines first and second tool engagement portions sized, shaped, and configured for receiving the first and second engagement prongs of the first tool.” Claim 18 includes substantially similar requirements. Pet. at 29, 49.

94. As I explained above, Petitioner’s Ground 1 fails to prove anticipation as it points to different implant embodiments (implant 304 and implant 484) to satisfy the implant limitations of claim 9 (limitations 9[e]-9[j]) and claim 18 (limitations 18[e]-18[j]).

95. I understand that Petitioner alternatively contends that, even if Gordon does not disclose implant 304 with the claimed first and second tool engagement portions, a POSITA would have modified implant 304 to include holding recesses 733 like those disclosed on implant 484. Pet. at 30. Petitioner states that a POSITA would have been motivated to make this modification “in order to allow Gordon’s c-shaped implant 304 to be inserted and expanded using a tool such as instrument 700.” Petitioner further asserts that a POSITA would have had a reasonable expectation of success because implants 304 and 484 are both c-shaped and expandable and because driver head 726 may engage a set screw.

96. This analysis does not account for the different surrounding structures and internal operating mechanisms of the two implants or the modifications that would actually be necessary to make instrument 700 operate with implant 304.

97. Gordon describes holding recesses 733 located on both sides of lower body 488 of implant 484 that are shaped to engage with lobes 722 of holding arms 716. Ex. 1013, ¶¶ 231, 237. That engagement maintains the implant's position during insertion and expansion and places implant 484 in the appropriate alignment for engagement with the driver used to expand the implant. Gordon further states that the location of recesses 733 may be selected according to the surgical approach and "the location of an expansion member of the implant." Ex. 1013, ¶ 237. Thus, Gordon itself recognizes that the proper location of the holding recesses depends on other structural and functional aspects of the particular implant.

98. Petitioner does not perform that analysis for implant 304. Gordon describes implant 304 as having insert 306, expansion member 308, opening 310, and advancing element 312. Expansion member 308 is inserted through opening 310, and advancing element 312 is thereafter inserted through that opening to advance expansion member 308 beneath insert 306. Advancing element 312 may remain in recess 314 after expansion. Ex. 1013, ¶ 177. Petitioner does not identify the location of opening 310 on the implant, the location of expansion member 308,

or where recesses 733 would be added to the implant relative to the opening and expansion member.

99. That omission is significant from a mechanical standpoint. To achieve Petitioner's proposed objective, it would not be sufficient merely to cut two recesses somewhere into the sides of implant 304. The recesses would have to be positioned and dimensioned so that lobes 722 of holding arms 716 could simultaneously engage implant 304 while driver 708 is aligned with advancing element 312. Accordingly, the geometry of the recesses determines the position and orientation in which the holding arms constrain the implant relative to the axis of driver 708. For instrument 700 to function as Petitioner proposes, that constrained position would have to place driver head 726 in the proper alignment with advancing element 312.

100. Gordon does not establish that the locations of recesses 733 on implant 484 would provide that alignment if transferred to implant 304. To the contrary, Gordon expressly teaches that the recess location for implant 484 is selected in view of, among other things, "the location of an expansion member of the implant." Yet Petitioner does not analyze the location of implant 304's expansion mechanism relative to the proposed recesses. Instead, Petitioner assumes that recesses arranged for implant 484 can be transferred to implant 304 and that instrument 700 will automatically align with advancing element 312.

101. Implants 304 and 484 use different techniques to expand the implant. Implant 304 employs expansion member 308, which is introduced through opening 310 and advanced beneath insert 306 by advancing element 312. By contrast, when Gordon describes instrument 700 operating implant 484 in Figures 47A–47D, driver head 726 is advanced through a tapped through-hole in lower body 488 until the tip of driver head 726 engages insert 472; continued advancement of driver head 726 causes insert 472 to rotate, which, in turns, causes an upper portion of implant 484 to expand upward. Ex. 1013, ¶¶ 238, 248. Thus, instrument 700 interacts with implant 484 through an arrangement different from the expansion-member/advancing-element arrangement disclosed for implant 304.

102. Petitioner’s reliance on the fact that advancing element 312 may be a “set screw” does not resolve these mechanical differences. Gordon states generally that driver head 726 may take various forms and, in some embodiments, may engage a set screw in an implant. Petitioner reasons from this disclosure that instrument 700 is therefore compatible with implant 304 because advancing element 312 may also be a set screw. But compatibility requires more than having a driver capable of engaging a particular type of screw head. The driver head must be able to reach that screw head along the required axis while holding arms 716 are engaged with the implant and holding that implant in the proper alignment for insertion into the intervertebral disc space. Petitioner’s analysis does not address whether placing

recesses 733 on implant 304 would position instrument 700 so that driver 708 could actually reach and properly engage advancing element 312 while holding the implant in the proper orientation.

103. In addition, Petitioner fails to account for the impact of adding recesses 733 on the mechanical integrity of implant 304. An intervertebral implant is a load-bearing structure positioned between vertebral bodies. Forming recesses in the exterior walls removes material from those walls and changes their local geometry. Such geometrical discontinuities always produce localized stress concentrations. The significance of those effects depends on the depth, shape, and position of the recesses relative to the load-bearing portions and internal structures of the implant. Gordon does not provide dimensions or a location for recesses 733 on implant 304 because Gordon does not disclose such recesses on implant 304 in the first place.

104. Those concerns are particularly relevant to the Figure 15 embodiment because implant 304 contains internal structures associated with insert 306 and expansion member 308. Gordon depicts insert 306 as substantially round in Fig. 15A and explains that expansion member 308 is advanced into position below it during expansion. Ex. 1013, ¶ 177, Figs. 15A-15C.

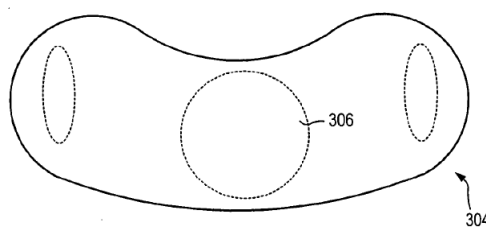


FIG. 15A

A POSITA considering removal of material from the exterior sides of this implant would therefore need to consider the relationship between the proposed recesses and the portions of the implant surrounding and supporting these internal structures. In my opinion, placing recesses in or near regions experiencing stresses associated with supporting and expanding around insert 306 could increase localized stresses and potentially reduce the implant's resistance to deformation or failure. The Petition does not address this issue.

105. This is not merely a question of whether a POSITA knew how to form a recess in an implant. The proposed recesses must perform the particular function relied upon by Petitioner: they must be sized, shaped, and positioned to receive lobes 722 on opposite holding arms 716; permit those arms to securely maintain the implant during insertion and expansion; properly orient implant 304 relative to instrument 700; allow driver 708 to reach and engage advancing element 312; avoid interfering with the operation of expansion member 308; and preserve adequate structural integrity of the implant, which is essential to its function.

106. Petitioner's stated motivation does not address these considerations. Petitioner essentially reasons that adding recesses 733 would be desirable because doing so would permit implant 304 to be used with instrument 700. But that assumes the very technical compatibility that must be established. The Petition does not explain where a POSITA would place the recesses on implant 304, how they would

be dimensioned, whether that placement would align advancing element 312 with driver 708, or how the recesses would coexist with implant 304's expansion mechanism and load-bearing structure.

107. I also do not agree that the fact that implants 304 and 484 are both described as c-shaped provides a sufficient technical reason for transferring recesses 733 between them. As discussed above, Gordon uses "c-shaped" broadly to describe implants having an arcuate geometry, including implants ranging from slightly curved or "banana shaped" to implants having greater curvature. The term does not define the implants' internal expansion mechanisms, wall geometry and discontinuities, tool interface, or location of their expansion members. Thus, any shared c-shaped classification—which captures a broad range of intervertebral implants given the geometry of the vertebrae—does not tell a POSITA where recesses 733 could be placed on implant 304 or whether the resulting structure would operate successfully with instrument 700.

108. Looking at Fig. 15B, advancing element 312 extends significantly outward beyond implant 304. Yet in all illustrations involving instrument 700, driver 708 is disposed within an opening in a respective implant while holding arms are engaged with recesses. Ex. 1013, Figs. 38, 41, 46, 47A-D. If driver 708 were to engage advancing element 312 while it is external to implant 304, it is not clear that holding arms could even engage implant 304 even if recesses were added thereto.

109. Petitioner's reasonable-expectation-of-success analysis suffers from the same problem. Petitioner states that success would have been reasonably expected because Gordon shows recesses 733 on the "similar" c-shaped implant 484 and because driver head 726 may engage a set screw. Those observations establish that recesses 733 work in the particular implant 484 configuration disclosed by Gordon. They do not establish that recesses 733 could be incorporated into the materially different structure of implant 304 in a location that simultaneously permits engagement by holding arms 716 and proper alignment and operation of driver 708 with advancing element 312, while maintaining the implant in a proper orientation for insertion. A POSITA would have had to determine not only where the recesses should be located relative to the implant structure, but also how the resulting tool/implant interface would accommodate the sequence required to introduce expansion member 308 and advancing element 312, align driver 708 with advancing element 312, and operate the expansion mechanism after the implant had been positioned. Petitioner does not address these aspects of the proposed combination.

110. Gordon's disclosure regarding recess location underscores what is missing from Petitioner's analysis. Gordon does not prescribe one universal location for holding recesses. It states that their location may be selected according to the surgical approach and the location of the expansion member. A POSITA therefore would understand from Gordon that adapting this holding arrangement to a different

implant requires consideration of the geometry and expansion mechanism of that particular implant. Petitioner and its expert do not undertake that analysis for implant 304.

111. Accordingly, in my opinion, Petitioner has not provided a sufficient technical basis for concluding either that a POSITA would have been motivated to modify implant 304 in the particular manner required by claim 9 or that a POSITA would have reasonably expected that modification to succeed. Petitioner's proposal identifies a desired endpoint—implant 304 provided with recesses that permit it to be held and expanded by instrument 700—but does not explain the critical engineering necessary to reach that endpoint. In particular, it does not address the location and dimensions of the proposed recesses, their relationship to implant 304's distinct expansion mechanism, the alignment required between driver 708 and advancing element 312, whether the implant could be held at the proper orientation during each of insertion and expansion with the proposed arrangement, or the effect of removing material from implant 304 on the implant's structural integrity. In my opinion, the similarities identified by Petitioner do not resolve those unanswered technical issues.

112. Because independent claim 18 shares the same features as independent claim 9, it is my opinion that Gordon fails to render independent claims 9 and 18

anticipated or obvious. The same is true for the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**D. Gordon Fails to Disclose, Teach, or Suggest 9[i] or 18[j].**

113. Claim 9 further requires that “the first tool engagement portion is formed in [a] first side surface of the expandable spinal implant and the second tool engagement portion is formed in a second side surface of the expandable spinal implant.” Claim 18 includes substantially similar requirements. Pet. at 49.

114. As I explained above, Petitioner’s Ground 1 fails to prove anticipation as it points to different implant embodiments (implant 304 and implant 484) to satisfy the implant limitations of claim 9 (limitations 9[e]-9[j]) and claim 18 (limitations 18[e]-18[j]).

115. Petitioner relies on the same proposed modification discussed above, asserting that a POSITA would have modified implant 304 to include the side recesses 733 disclosed for implant 484. For this limitation, Petitioner points to Figure 38 and Gordon’s statement that lobes 722 engage holding recesses 733 “on either side of lower body 488.” In my opinion, I do not agree with Petitioner’s explanation for why a POSITA modifying implant 304 would have selected its first and second side surfaces as the locations for the proposed engagement portions.

116. In the Figure 38 embodiment, recesses 733 cooperate with holding arms 716 to maintain implant 484 during insertion and expansion and to place that

particular implant in the appropriate alignment relative to the holding instrument. Petitioner relies on those functions as its reason for transferring recesses 733 to implant 304. But identifying a desire to hold implant 304 during insertion and expansion does not explain why a POSITA would necessarily implement that function by cutting engagement recesses into the two side surfaces of implant 304. As discussed above, the location of any such engagement features would have to be considered in view of implant 304's particular geometry, internal structures, expansion mechanism, and the required alignment between the implant and the instrument.

117. Gordon itself confirms that side engagement is not the only arrangement contemplated for holding an expandable implant. Figure 46, illustrated below, shows an “alternate embodiment of a holding device” for implant 484.

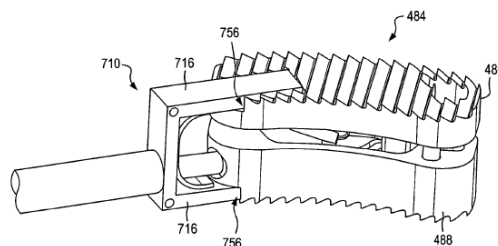


FIG. 46

In that embodiment, Gordon states that holding device 710 “may engage a top surface of implant 484.” Ex. 1013, ¶ 247. Gordon provides notches 756 that permit the outer surfaces of holding arms 716 to remain flush with the outer surfaces of upper body 486 and lower body 488 during insertion. Thus, Gordon expressly

teaches alternative arrangements in which the holding device engages structures other than opposing side-surface recesses.

118. These alternatives are significant to a POSITA because they demonstrate that the desired function identified by Petitioner—securely holding an implant during insertion and expansion—does not itself dictate the location of the engagement portions. Gordon discloses one arrangement involving recesses 733 on either side of lower body 488 and another arrangement in which holding device 710 engages a top surface of the same implant 484. Gordon therefore provides multiple approaches for interfacing a holding device with an expandable implant. Nothing about Gordon’s general objective of holding an implant during insertion and expansion establishes that a POSITA applying that objective to implant 304 would select the particular side-surface arrangement required by claim 9.

119. The Petition does not address these alternatives or explain why the Figure 38 side-recess arrangement would be selected for implant 304 rather than another arrangement. Instead, Petitioner concludes that because Gordon shows side recesses 733 on implant 484, a POSITA would have been motivated to include “recesses 733 on the sides” of implant 304. In my opinion, that reasoning assumes the location required by the claim rather than providing a technical reason for selecting it. The fact that one Gordon implant employs side recesses does not establish that side surfaces would be the appropriate locations for engagement

features on a different implant having the different structure and expansion mechanism explained above—particularly where Gordon itself expressly teaches other engagement locations.

120. The structural considerations discussed above further bear on this limitation. Forming engagement portions in the first and second side surfaces of implant 304 would require removing or otherwise modifying material at those particular locations. A POSITA would have considered the depth and geometry necessary for the engagement portions to receive the corresponding holding arms, the amount of material remaining in the side structures, the proximity of those features to implant 304's internal components, and the stresses imposed on the implant during insertion and expansion. The Petition does not analyze the side-wall geometry of implant 304 or explain why opposing side surfaces provide suitable locations for recesses having the size and shape necessary to engage instrument 700.

121. Nor does Petitioner's reliance on the alleged general overarching similarity between implants 304 and 484 answer that question. Petitioner notes that both implants are c-shaped and expandable. But those general characteristics do not establish that their side surfaces have the same geometry, structural requirements, or relationship to their respective expansion mechanisms. As Gordon's Figure 46 embodiment demonstrates, even for implant 484 itself, Gordon contemplates a holding arrangement that engages the implant from the top rather than through the

side recesses of Figure 38. A POSITA therefore would not understand Gordon's disclosure of side recesses 733 as establishing side-surface engagement as an inherent or necessary feature of a c-shaped expandable implant.

122. Accordingly, I do not believe Petitioner has demonstrated a motivation for a POSITA to add first and second tool engagement portions in the first and second side surfaces of implant 304 as required by claim 9.

123. Because independent claim 18 shares substantially similar features as independent claim 9, it is my opinion that Gordon fails to render independent claims 9 and 18 anticipated or obvious. The same is true for the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**E. Gordon Fails to Disclose, Teach, or Suggest 9[j] or 18[i].**

124. Claim 9 further requires that "the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement portions of the expandable spinal implant." Claim 18 includes substantially similar requirements. Pet. at 49.

125. As I explained above, Petitioner's Ground 1 fails to prove anticipation as it points to different implant embodiments (implant 304 and implant 484) to

satisfy the implant limitations of claim 9 (limitations 9[e]-9[j]) and claim 18 (limitations 18[e]-18[j]).

126. In my opinion, this limitation requires more than identifying an adjusting screw, an adjusting tool, and engagement portions somewhere in Gordon. The relative locations of those structures must provide for simultaneous engagement. In particular, when the first tool is engaged with the implant through its two engagement prongs, that engagement must position the adjusting-tool passage such that the second adjusting tool extending through that passage is aligned with and able to engage the screw head.

127. Petitioner again relies on different Gordon embodiments to arrive at this arrangement. For the claimed adjusting screw, Petitioner relies on advancing element 312 of implant 304. Gordon describes implant 304 in Figures 15A–15C and states that expansion member 308 may be inserted through opening 310, followed by advancing element 312, which advances expansion member 308 beneath insert 306. Ex. 1013, ¶ 177. Gordon states that advancing element 312 may be a set screw. For the claimed first tool, engagement prongs, tool engagement portions, adjusting-tool passage, and second adjusting tool, however, Petitioner relies on instrument 700 and the recesses 733 disclosed in connection with the separate implant 484 embodiment. Petitioner's argument for this limitation relies on Figure 38 and then

simply states that this disclosure “equally applies to the use of instrument 700 with implant 304.” Pet. at 34.

128. I disagree that Gordon teaches or suggests that arrangement. As discussed above, Gordon does not disclose recesses 733 on implant 304, much less disclose implant 304 engaged by holding arms 716 of instrument 700. The Petition proposes adding recesses 733 to implant 304 because instrument 700 uses those recesses to establish the position of implant 484 relative to the instrument. But once the locations of those recesses are selected, they necessarily establish the position and orientation of implant 304 relative to holding device 710 and, consequently, relative to driver 708 passing through outer shaft 706. Petitioner does not identify where the proposed recesses would be located on implant 304 or demonstrate that engagement at those locations would place driver 708 on an axis that intersects and properly engages the head of advancing element 312.

129. This is not a relationship that a POSITA would simply assume. Gordon itself recognizes that the location from which an implant’s expansion mechanism is accessed can vary depending on the particular implant and surgical approach. For example, for implant 318 of Figure 17, Gordon explains that advancing element 322 may engage expansion member 320 from a side of the implant and compares accessing the expansion member from the longer side with accessing it from a shorter end. Ex. 1013, ¶ 179. Similarly, for implant 422, Gordon expressly states

that advancing element 394 may be positioned on a side, such as the posterior side, in some embodiments, or “on an end” of the implant in other embodiments. *Id.* at ¶ 197. Thus, Gordon recognizes that the location from which the expansion mechanism is accessed varies among implant configurations.

130. The instrument 700/implant 484 embodiment further demonstrates the importance of this geometry. Gordon describes driver head 726 as being advanced into a tapped through hole in lower body 488 until the tip of driver head 726 engages insert 472. Holding device 710 simultaneously maintains implant 484 in a fixed position while driver 708 actuates that expansion mechanism. Ex. 1013, ¶ 248. In that embodiment, therefore, the location of the opening in implant 484, the position at which holding device 710 engages implant 484, and the axis of driver 708 are coordinated so that the driver can reach the particular expansion mechanism of implant 484.

131. Petitioner performs no comparable analysis for implant 304. Implant 304 does not use implant 484’s expansion mechanism. Implant 304 instead employs expansion member 308, advancing element 312, insert 306, and opening 310. Advancing element 312 acts on expansion member 308 to move expansion member 308 beneath insert 306. By contrast, in the Figure 47 embodiment of implant 484, driver head 726 is advanced through the tapped opening until its distal tip engages insert 472, and advancement of the driver head rotates insert 472 to expand the

implant. The fact that both mechanisms may involve rotational actuation does not establish that they have the same access location, actuation axis, or geometric relationship to the structures by which the implant is held.

132. Petitioner’s statement that driver head 726 “may engage a set screw” likewise does not supply the missing geometry. Petitioner reasons that this statement “demonstrates compatibility” with implant 304 because advancing element 312 may also be a set screw. Pet. at 31. But the ability of a driver head to engage a particular type of screw does not establish that the driver will be positioned to engage with that screw when the implant is secured to the instrument. Claim 9 requires both conditions simultaneously: driver 708 must extend through the alleged adjusting-tool passage and engage advancing element 312 while holding arms 716 remain engaged with the proposed engagement portions on implant 304. Whether that can occur depends on the relative positions, orientations, and geometries of opening 310, advancing element 312, the proposed recesses, holding arms 716, outer shaft 706, and driver 708. Petitioner does not analyze those relationships.

133. Gordon’s alternative holding arrangements further underscore the problem. As discussed above, Gordon does not teach a single fixed relationship between holding device 710 and an implant. Figure 46 describes an alternate embodiment in which holding device 710 engages a top surface of implant 484, rather than the side-recess arrangement on which Petitioner relies. Thus, Gordon

itself varies the manner in which the holding device engages the implant. Changing that engagement necessarily changes the geometric relationship that must be considered between the holding structure, implant, and expansion mechanism. Petitioner provides no explanation why its proposed placement of recesses 733 on implant 304 would establish the particular relationship necessary to align driver 708 with advancing element 312. Petitioner notably does not identify where the recesses would be if added to implant 304.

134. The sequence in which Gordon describes assembling and expanding implant 304 presents an additional issue that Petitioner does not address. Gordon states that expansion member 308 “may be inserted through opening 310” and that advancing element 312 “may be inserted in opening 310 following insertion of expansion member 308.” Ex. 1013 ¶ 177. Advancing element 312 then advances expansion member 308 beneath insert 306.

135. Petitioner’s proposed use of instrument 700 with implant 304 ignores how implant 304 is structured and expanded. Expansion member 308 and/or advancing element 312 cannot be introduced through opening 310 after implant 304 has been positioned because instrument 700—which contains the driver and thumbwheel fixed inside, would obstruct introduction of those structures. A POSITA would need an unobstructed access path through opening 310 while the implant is at the surgical site. Petitioner does not explain how that would occur while holding

arms 716 of instrument 700 are simultaneously engaged with the newly added recesses on implant 304. And Petitioner expressly states that “if the tool used to hold and deliver the implant is pulled out after the implant is delivered at a target site, then it would have been difficult to find the screw and insert the screw driver into the screw.” Pet. at 56.

136. Alternatively, if Petitioner's proposed combination assumes that expansion member 308 and advancing element 312 are already installed in implant 304 before instrument 700 inserts the implant, that assumption does not eliminate the alignment issue. Petitioner did not explain where the recesses are positioned so that engagement of holding arms 716 with those recesses places driver 708 in the proper position and orientation, and has the correct geometry, to pass through outer shaft 706 and engage the head of advancing element 312.

137. Notably, advancing element 312 of implant 304 is illustrated as extending outside of implant 304 before expansion, such that without modifications to instrument 700, driver 708 would not be able to simultaneously engage advancing element 312 as well as any recesses added to implant 304. Indeed, Gordon's instrument 700 has a trident-like design, with driver 708 between holding arms 716. In every figure illustrating Gordon's instrument-implant interaction, Gordon shows that when holding arms are engaged with the implant, driver 708 is disposed within a corresponding implant opening. Ex. 1013, Figs. Figs. 38, 41, 46-47D. Unlike the

implants illustrated for use with instrument 700 (e.g., implant 484), however, implant 304 includes both expansion member 308 and advancing element 312 within its implant opening 310, causing advancing element to extend outside of implant 304 before expansion. Petitioner does not consider advancing element's external positioning, nor the impact that position would have on instrument 700's design. In Petitioner's proposed arrangement, driver 708 would engage implant 304's expansion mechanism in a significantly different position than that shown in all of the illustrations of instrument 700 with other implants (e.g., externally rather than internally). Accordingly, the illustrated arrangement of holding arms 716 and driver 708 in all of Gordon's Figures would not work with implant 304, and Petitioner fails to identify any modifications a POSITA would have been motivated to make.

138. Finally, Petitioner's theory for this limitation depends on the modification discussed above—adding the alleged first and second tool engagement portions to implant 304 in the first place. Gordon does not disclose implant 304 as having recesses 733 or any other engagement portions configured to receive holding arms 716. Thus, before the claimed simultaneous relationship could even be considered, implant 304 would first have to be modified to include those engagement portions and their locations selected. For the reasons discussed above, Petitioner has not adequately explained why a POSITA would make that modification, where the engagement portions would be placed, or why a POSITA would reasonably expect

the resulting arrangement to position instrument 700 so that driver 708 could engage advancing element 312 in the manner required by claim 9.

139. Because independent claim 18 shares the same features as independent claim 9, it is my opinion that Gordon fails to render independent claims 9 and 18 anticipated or obvious. The same is true for the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**F. Gordon Fails to Disclose, Teach, or Suggest Claim 10.**

140. Claim 10 depends from claim 9 and further requires that “the expandable spinal implant comprises an implant proximal end and an implant distal end, wherein the first and second tool engagement portions are formed as recessed surfaces and positioned at or near the implant proximal end, and wherein the screw head of the adjusting screw is accessible at the implant proximal end from a proximal direction.” Petitioner relies principally on Figure 38 and concludes that Gordon discloses these limitations. Pet. at 35. In my opinion, Figure 38 does not support that conclusion.

141. First, as I explained above, Gordon does not disclose recesses 733 on implant 304, the implant Petitioner relies upon for the adjusting screw and other implant limitations of claim 9. Recesses 733 are disclosed with different implant 484. Petitioner's claim 10 theory therefore again combines features from separate embodiments and does not establish anticipation.

142. Second, Figure 38 does not disclose the claimed screw head accessible from the proximal direction. Implant 484 does not use the adjusting-screw arrangement Petitioner identifies for implant 304. Gordon instead explains that driver 708 advances through lower body 488 and directly engages insert 472, causing insert 472 to rotate and expand implant 484. Ex. 1013 ¶ 248, Figs. 47A–47B. Thus, the structure Petitioner labels in Figure 38 as the claimed screw head is actually driver 708, not the head of an adjusting screw positioned within implant 484. Petitioner therefore identifies no adjusting-screw head in the Figure 38 embodiment that is accessible at the proximal end as claim 10 requires.

143. Third, Figure 38 does not show recesses 733 “at or near” the proximal end of implant 484. As illustrated in the annotated Figure 38 below, the recesses are positioned substantially inward from the proximal end of implant 484, between the implant’s proximal and distal ends. Gordon does not characterize those illustrated recesses as being at or near the proximal end, and Petitioner offers no analysis explaining why their depicted location satisfies that requirement. Merely labeling Figure 38 with the claim language does not establish the claimed spatial relationship. In my opinion, therefore, Gordon does not disclose, teach, or suggest claim 10 in the manner asserted by Petitioner.

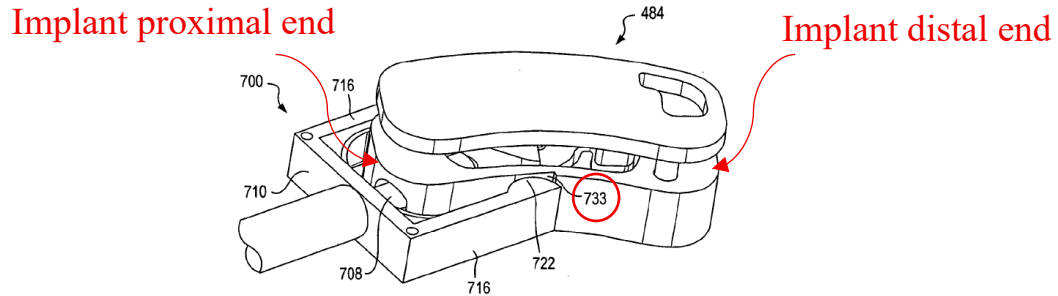


FIG. 38

### G. Gordon Fails to Disclose, Teach, or Suggest Claim 12.

144. Claim 12 depends from claim 9 and further requires that “the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein some of the ridges are positioned on the first vertebral body engagement surface at a distal end of the first vertebral body engagement surface.” Petitioner contends that Gordon discloses this limitation based on a combination of Gordon's general discussion of endplate-engaging surface features in paragraph 138 and the separate implant 422 embodiment shown in Figure 21A. In my opinion, Gordon does not disclose the claimed arrangement in the implant 304 embodiment on which Petitioner relies for claim 9, and Petitioner does not provide a sufficient technical basis for combining those separate disclosures.

145. As discussed above, Petitioner's claim 9 theory relies principally on implant 304 of Figures 15A–15C as the claimed expandable spinal implant of limitations 9[a]-9[d]. Claim 12, however, adds a further requirement concerning the location of ridges on the first vertebral body engagement surface—specifically, that

some of those ridges be positioned at a distal end of that surface. Gordon does not describe or depict implant 304 as having that particular ridge arrangement.

146. Petitioner first relies on Gordon’s paragraph 138, which states generally that “implants described herein may include features not necessarily depicted in each figure” and that, in some embodiments, an endplate-engaging surface “may have regularly or irregularly spaced protrusions of uniform or various shapes and sizes” to facilitate retention between vertebrae. Gordon gives “teeth or ridges” as examples of such protrusions. Ex. 1013, ¶ 138. That passage, however, does not state that implant 304 includes ridges, much less that ridges on implant 304 extend to the distal end of the first vertebral body engagement surface as required by claim 12.

147. To supply those requirements, Petitioner turns to Figure 21A, which concerns a different embodiment—implant 422. Ex. 1013, ¶ 196, Fig. 21A. Petitioner relies on the Figure 21A depiction to contend that Gordon’s ridges extend from the distal to the proximal end of the engagement surfaces. Thus, Petitioner’s claim 12 theory again combines features from separate Gordon embodiments.

148. As I explained above, I understand that for anticipation the elements of the claim must be disclosed together in the reference arranged as in the claim, and that separate embodiments cannot simply be assembled because they appear in the same document. In my opinion, Gordon does not anticipate claim 12 for that reason. Paragraph 138’s general statement that an endplate-engaging surface may include

teeth or ridges does not itself disclose the claimed distal-end placement, while the particular arrangement Petitioner relies upon for that placement appears in the distinct implant 422 embodiment of Figure 21A.

149. I also understand that combining features from separate embodiments for an obviousness theory requires the Petitioner to identify a reason why a POSITA would have made the proposed combination and show that the POSITA would have had a reasonable expectation that the resulting combination would be successful. Petitioner does not provide that analysis for claim 12. It states only that placing ridges at the distal and proximal ends would serve Gordon's general purpose of facilitating retention of the implant between vertebrae, and then points to Figure 21A as an example. That does not explain why a POSITA starting with implant 304 would have selected the particular ridge distribution shown for implant 422.

150. Gordon's paragraph 138 actually emphasizes the range of possible surface configurations rather than a particular one. Gordon permits regularly or irregularly spaced protrusions, of uniform or different shapes and sizes, and identifies teeth or ridges merely as examples. A POSITA reading that disclosure would therefore understand that many surface-feature arrangements could be used to promote retention. The general objective of improving retention does not itself lead to the particular claimed arrangement in which some of the ridges are positioned at the distal end of the first vertebral body engagement surface.

151. The Figure 21A embodiment likewise does not provide a reason to transfer its surface arrangement to implant 304. Implant 422 has a different construction and expansion mechanism from implant 304. Nor does Petitioner analyze whether the precise positioning of ridges at the distal end of implant 304 would affect other design considerations. Surface features on an intervertebral implant may affect insertion forces, resistance to migration, interaction with vertebral endplates, and the ability to position the implant during implantation. Gordon itself permits a range of spacing, shapes, and sizes for those features. Petitioner does not explain why a POSITA would have chosen to extend ridges specifically to the distal end of implant 304's engagement surface rather than employing another configuration within the alternatives Gordon describes.

152. In my opinion, Petitioner's reasoning therefore identifies the claimed structure and then, through hindsight, selects features from different portions of Gordon to reach it. Gordon's general statement that implants may have teeth or ridges does not disclose where those ridges must be located. Figure 21A shows a particular distribution of teeth on a different implant, implant 422. Petitioner does not identify a teaching in Gordon that connects that Figure 21A arrangement to implant 304, nor does it provide a technical reason why a POSITA would have modified implant 304 to adopt that arrangement with a reasonable expectation of success.

153. Accordingly, in my opinion, Gordon does not disclose, teach, or suggest claim 12 in the manner asserted by Petitioner. The anticipation theory relies on combining separate Gordon embodiments, and the obviousness theory does not provide a sufficient motivation to make that particular combination or explain why a POSITA would have expected the specific distal-end ridge arrangement of claim 12 to result from modifying implant 304.

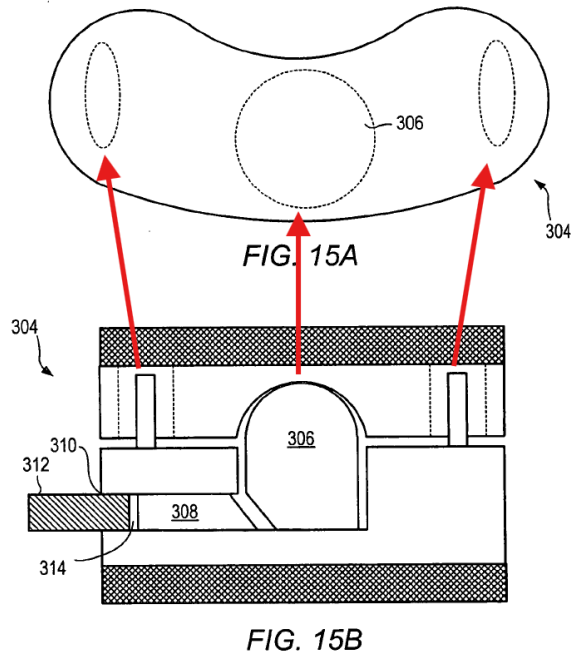
#### **H. Gordon Fails to Disclose, Teach, or Suggest Claim 14.**

154. Claim 14 depends from claim 9 and further requires that “the first and second expandable spinal implant structures each include a through-hole sized to allow for placement of bone material into the expandable spinal implant for fusion.” Petitioner identifies the two dashed elliptical features shown in Figure 15A as alleged through-holes in the upper structure of implant 304 and then reasons that corresponding through-holes would also have been provided in the lower structure. Pet. 39-40. In my opinion, Gordon does not support that interpretation of Figure 15A, nor does Petitioner provide a sufficient technical basis for modifying implant 304 to arrive at the claimed arrangement.

155. First, Gordon never identifies the dashed elliptical features in Figure 15A as openings, much less through-holes for placement of bone material. Gordon does not assign reference numbers to the dashed ellipses in Figure 15A or otherwise describe them as bone-graft openings. Rather, paragraph 177 describes Figure 15A

simply as a top view of implant 304 with insert 306 and notes that a portion of insert 306 may be substantially round.

156. The manner in which Gordon draws Figure 15A is also inconsistent with Petitioner's characterization of the dashed ellipses as openings extending through the top surface. The alleged openings are depicted entirely with dashed lines, rather than solid lines that would be used to identify actual edges or through-holes in the top surface. Gordon uses the dashed lines to identify regions where there are cutouts beneath the solid surface of implant 304. This is shown by the dashed lines for the round insert 306 in Figure 15A, which is located below the top surface. The dashed ovals on the sides of the top surface correspond to cutouts for guides that hold the upper implant body in place before and after extension. Thus, as is typical in engineering drawings, Figure 15A uses dashed lines to depict structures that are located beneath or otherwise obscured by the visible upper surface.



A POSITA would not understand the dashed elliptical outline to indicate that the upper surface contains an opening extending through that surface.

157. Figures 15B and 15C further undermine Petitioner's interpretation. Gordon expressly identifies those figures as side cross-sectional views of implant 304 before and after expansion. In those cross-sectional views, the uppermost vertebral-body-facing surface is shown extending continuously across the top of the implant; Gordon does not depict a passage extending from that top surface through the upper implant structure at the locations corresponding to the dashed ellipses of Figure 15A. See Ex. 1013, Figs. 15B–15C. In my opinion, if the dashed ellipses in Figure 15A represented through-holes extending through the top surface in the manner asserted by Petitioner, one would expect that feature to be reflected in the

cross-sectional depiction. It is not. Petitioner's argument is therefore not supported by Gordon's description of implant 304.

158. Petitioner's theory regarding the second expandable implant structure is still further removed from Gordon's actual disclosure. Because Petitioner first assumes that Figure 15A shows bone-graft openings in the upper structure, and then it asserts that a POSITA would have understood that "similar openings would be provided on the bottom body" and that these openings would extend through the top and bottom surfaces into hollow portions of the implant. But the premise of that reasoning—the existence of the alleged openings in the upper structure of implant 304—is not established. Gordon does not depict or describe corresponding through-holes in the lower structure of implant 304 either.

159. Petitioner also relies on Gordon's paragraph 138, which states generally that "members of an implant may include one or more openings to accommodate packing of bone graft material and/or to allow for bone ingrowth." Ex. 1013, ¶ 138. That general statement does not change the structure of implant 304. Nor does it disclose the more specific arrangement required by claim 14: a through-hole in each of the first and second expandable implant structures, with each through-hole sized to allow placement of bone material into the implant.

160. Petitioner additionally cites paragraph 196, but that paragraph relate to implant 422, not implant 304. Gordon does not state that those openings are features

of implant 304. Nor does Gordon state that the openings of implant 422 should be transferred to implant 304. Petitioner's reliance on that disclosure therefore again requires taking a feature disclosed for one implant embodiment and adding it to the different implant 304 embodiment.

161. I understand that when an obviousness theory combines features from separate embodiments, there must be a reason why a POSITA would have made the proposed combination and a reasonable expectation that the resulting combination would succeed. Petitioner does not provide such an analysis for claim 14. Petitioner identifies Gordon's general desire to permit bone grafting or bone ingrowth and then assumes that implant 304 would therefore include the particular pair of through-holes required by the claim. But the Petition does not explain why a POSITA would modify both expandable structures of implant 304 to include through-holes, where those holes would be located, or how they would be incorporated into implant 304's existing structure.

162. Those considerations are particularly important for implant 304 because its interior is already occupied by structures necessary to its expansion mechanism. Adding through-holes extending from the vertebral engagement surfaces into the implant would require selecting locations that do not interfere with those internal structures or their movement during expansion. Petitioner does not address where such openings could be located on implant 304 (besides incorrectly

identifying through-holes that do not exist in implant 304) or how they could extend through both expandable structures while preserving the disclosed expansion arrangement.

163. Petitioner's assertion concerning the bottom structure illustrates this deficiency. Petitioner reasons that because fusion with both adjacent vertebrae is desirable, "similar openings" would be provided on the bottom body. But a general desire for fusion does not identify the particular structure required by claim 14. Gordon describes other means for facilitating integration with the vertebral bodies, including osteoconductive scaffolding on implant surfaces, which Petitioner relies on as the claimed engagement surfaces of claims 9 and 18. Paragraph 138 itself lists osteoconductive scaffolding separately from openings as another means to "enhance integration of the implant in a patient's spine." Ex. 1013, ¶ 138. Thus, Gordon does not teach that a through-hole in each expandable body is necessary to achieve fusion or vertebral integration.

164. Petitioner's further assertion that its assumed openings would extend through the top and bottom surfaces to an internal cavity likewise does not provide the missing motivation. That argument addresses what the dimensions or extent of an opening might be after assuming the opening exists. It does not explain why a POSITA would first modify implant 304 to include an opening in each expandable structure. Nor does Gordon's statement that openings in some embodiments may

accommodate bone graft material establish that such openings necessarily extend entirely through the particular expandable structures of implant 304.

165. Additionally, in my opinion a POSITA would not have included both through-holes sized to allow for placement of bone material as well as osteoconductive scaffolding, which Gordon illustrates as cross-hatched surfaces in Figs. 15B-15C. Although Gordon does not label the cross-hatched surfaces on the tops and bottom of implant 304 in Figures 15B-15C, Gordon does label similarly located cross-hatched surfaces as item 110 in other Figures. Ex. 1013, Figs. 2A-2B, 9B-9E, 10A, 12A-12B. Gordon describes item 110 as osteoconductive scaffolding, which is a “mesh structure” through which “[v]ertebral bone from a patient’s spine may grow.” *Id.* at ¶ 146. Not only is osteoconductive scaffolding an alternative for through-holes, but its application as a layer “coupled” to the bodies of an implant (*id.*) would also block any through-holes that might exist in the implant bodies. Figs. 15B-15C show no corresponding openings in implant 304 that would correspond to through-holes, but even if they were there (they are not), the osteoconductive scaffolding would prevent the placement of bone material therein.

166. Accordingly, in my opinion, Gordon does not disclose, teach, or suggest claim 14 in the manner asserted by Petitioner. Gordon’s general references to openings in other embodiments do not supply a technical reason for making those

particular modifications to implant 304 or establish a reasonable expectation that the resulting configuration would operate successfully.

167. It is my opinion that Gordon fails to render claim 14 anticipated or obvious.

**I. Gordon Fails to Disclose, Teach, or Suggest Claim 15.**

168. Claim 15 depends from claim 9 and further requires that “the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.” Petitioner contends that Gordon discloses this limitation because the upper and lower expandable structures shown in Figure 15B are allegedly “discrete and unitary,” and further cites Gordon’s statement that a “body” may be of unitary construction. In my opinion, that argument is inconsistent with Petitioner’s own mapping of the “expandable spinal implant structures” and their vertebral body engagement surfaces for claim 9.

169. For claim 9, which requires expandable spinal implant structures defining vertebral body engagement surfaces, Petitioner identifies the upper and lower expandable portions of implant 304 as the claimed first and second expandable spinal implant structures and the osteoconductive scaffolding shown on those structures in Figures 15B-15C as providing the claimed first and second vertebral body engagement surfaces. Specifically, Petitioner states that the first and second

expandable structures are provided with “osteoconductive scaffolding” for securing the implant against the bony endplates of the adjacent vertebral bodies and, on that basis, concludes that those structures define the claimed vertebral body engagement surfaces. Pet. at 25-26.

170. Gordon, however, describes osteoconductive scaffolding as a structure that is coupled to an implant body or member. In paragraph 146, Gordon states that superior surface 106 of upper body 102 and inferior surface 108 of lower body 104 may “include (e.g., be coupled to) Osteoconductive Scaffolding 110.” Ex. 1013, ¶¶ 146, 165-166, 176, Figs. 2A-2B, 9B-9E, 10A, 12A-12B. Thus, Gordon distinguishes the upper or lower body from the osteoconductive scaffolding that is coupled to its surface. A POSITA would understand this repeated use of “coupled to” as describing the scaffolding and the body as distinct components attached to one another, rather than as a single integral structure.

171. This distinction matters because claim 15 does not merely require that some portion of the first expandable spinal implant structure be unitary. It requires the first expandable spinal implant structure to be a first single integral structure and the second expandable spinal implant structure to be a second single integral structure. But claim 9 and 18 require that the expandable spinal implant structures *define* the engagement surfaces. Accordingly, the engagement surfaces are part of the expandable spinal implant structures.

172. Under Petitioner's claim 9 mapping, however, Gordon's osteoconductive scaffolding (which Petitioner identifies as the claimed engagement surfaces) are separate structures from Gordon's implant bodies (which Petitioner identifies as the claimed expandable spinal implant structures) that are coupled together. In my opinion, separate bodies and scaffolding that are coupled together do not constitute a "single integral structure."

173. Gordon's disclosure elsewhere also confirms that it distinguishes between a component that is merely coupled to another component and one that forms an integral part of it. For example, Gordon states that cam portion 298 may be "coupled to" elongated member 290 in some embodiments, while in other embodiments cam portion 298 may "form an integral part of elongated member 290." Ex. 1013, ¶ 175. Gordon therefore uses "coupled to" and "integral part" to describe different structural relationships. That distinction reinforces my understanding that Gordon's disclosure of scaffolding "coupled to" an implant body does not disclose the scaffolding as integral with that body. Petitioner does not address this inconsistency. Petitioner does not explain how a structure comprising a body together with a separately coupled osteoconductive scaffolding satisfies claim 15's requirement that the expandable spinal implant structure, which defines the engagement surfaces, be a "single integral structure."

174. In my opinion, Gordon therefore does not disclose claim 15 under Petitioner's mapping. I understand that Petitioner does not present a separate obviousness rationale for claim 15. Petitioner's discussion states only that Gordon "discloses this limitation" and relies on Figures 15B–15C and paragraph 145. Accordingly, Petitioner does not identify a reason why a POSITA would have modified Gordon's coupled scaffolding/body arrangement to form a single integral structure or explain why such a modification would have been expected to succeed.

175. It is my opinion that Gordon fails to render claim 15 anticipated or obvious.

**J. Gordon Fails to Disclose, Teach, or Suggest Claim 17.**

176. Claim 17 recites a method of using the system of claim 9 and requires, among other steps, "extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant." Petitioner contends that Gordon discloses or suggests this step based on its assertion that driver 708 constitutes the claimed "second adjusting tool" and that it extends through outer shaft 706, which Petitioner characterizes as part of the first tool. In my opinion, Gordon does not disclose the claimed method step of extending a second adjusting tool through a first tool.

177. As I explained above, Petitioner's Ground 1 fails to prove anticipation as it points to one embodiment for the tool limitations of claim 9 (limitations 9[a]-

9[d]), and points to a different embodiment for implant limitations for claim 9 (limitations 9[e]-9[g]).

178. Additionally, as discussed above, Gordon describes instrument 700 as a single instrument having outer shaft 706, driver 708, holding device 710, and handle 712. Gordon expressly states that “a single instrument may be used to perform multiple steps of a spinal procedure,” including positioning an implant and actuating an expansion member, and immediately thereafter introduces instrument 700 as an instrument “for use in installing and expanding an implant.” Ex. 1013, ¶¶ 226-227. Thus, driver 708 is described as a component of instrument 700, not as a separate tool that is subsequently introduced through another tool.

179. Gordon’s description of driver 708 further confirms that it is a single instrument. Gordon states that inner shaft 724 of driver 708 is coupled with thumbwheel 714. Ex. 1013, ¶ 233. Gordon further explains that thumbwheel 714 resides in slot 732 formed within handle 712. Ex. 1013, ¶ 234. This arrangement means that driver 708 and thumbwheel are fixed inside instrument 700, rather than a separate adjusting tool that can be inserted through the instrument during use. Gordon never describes a surgical step in which driver 708 is removed, separately handled, or extended through outer shaft 706 during use.

180. This understanding is supported by Petitioner’s expert. I understand that Mr. Culbert testified: “The way I read Gordon, Ex. 1013, [thumbwheel] 714 is

part of [driver] 708.” Ex. 2038 at 39:3-4. That testimony is consistent with Gordon’s disclosure that thumbwheel 714 is coupled to driver 708 and positioned within slot 732 of handle 712. Thus, the structure Petitioner identifies as the alleged second adjusting tool is not disclosed as a separate tool that can be independently introduced through the remainder of instrument 700.

181. Petitioner's reliance on Gordon’s statement that driver 708 “translates along its axis” does not establish the claimed step. Gordon states that, in one embodiment, thumbwheel 714 may be threadably coupled to driver 708 such that rotation of thumbwheel 714 causes driver 708 to translate axially. Ex. 1013, ¶ 229. Axial translation of a driver already residing within instrument 700 is different from extending a second adjusting tool through a first tool. The former describes extension of a portion of an internal component of an instrument; the latter recites a method step involving one tool being extended through another tool.

182. Petitioner therefore treats a preassembled structural relationship as though it disclosed the claimed act of assembly or insertion. Gordon may show driver 708 located within outer shaft 706 and capable of moving axially within instrument 700, but Gordon does not describe a user performing an act of introducing driver 708 through outer shaft 706 during use of the system (e.g., during a surgical procedure).

183. This distinction is especially important because claim 17 is a method claim. It is not enough that one component happens to reside within another component in Gordon's completed instrument. The claimed method requires the step of "extending the second adjusting tool through the first tool to engage the adjusting screw." Petitioner identifies no disclosure in Gordon of that act being performed with driver 708 and instrument 700.

184. Nor does Gordon disclose the claimed act in connection with implant 304. As discussed above, Gordon does not disclose instrument 700 being used with implant 304 and does not disclose the holding arms of instrument 700 engaging recesses on implant 304. Instrument 700 is expressly shown operating with implant 484. Gordon states that lobes 722 of holding arms 716 engage holding recesses 733 of implant 484 and maintain that implant in position during insertion and expansion. Accordingly, Gordon does not disclose a method in which the alleged first tool is engaged with implant 304 while a separately identifiable second adjusting tool is then extended through that first tool to engage advancing element 312.

185. Petitioner's theory therefore again depends on multiple unstated modifications. It assumes first that selected components of instrument 700 constitute a separate "first tool," notwithstanding Gordon's description of instrument 700 as a single instrument. It then treats driver 708, another component of that same instrument, as a separate "second adjusting tool." Finally, it assumes a method step

in which that alleged second tool is extended through the alleged first tool, even though Gordon identifies driver 708 as being part of instrument 700 and controlled by thumbwheel 714 fixedly residing within handle 712.

186. In my opinion, a POSITA would not understand Gordon's disclosure of an internal driver fixed inside and moving within instrument 700 as teaching the claimed act of extending one tool through another. Gordon describes the operation of a single integrated instrument, not the sequential use of a first tool followed by insertion of a separate second adjusting tool through it. Accordingly, Gordon does not disclose, teach, or suggest the "extending the second adjusting tool through the first tool" step required by claim 17.

187. It is my opinion that Gordon fails to render claim 17 anticipated or obvious.

**K. Gordon Fails to Disclose, Teach, or Suggest Claim 20.**

188. Claim 20 depends from claim 18, and suffers from the same issues I identified with respect to claim 18. Claim 20 adds a number of further structural and functional requirements, including the location of the tool engagement portions and adjusting screw at the proximal end of the implant, ridges at or near the distal end, first and second angled wedge surfaces, openings extending through the engagement surfaces to a cavity sized to receive bone material, first and second expandable spinal implant structures that are each single integral structures, and a particular

relationship among the engagement extensions, tool engagement portions, and second adjusting tool. Petitioner does not identify a single embodiment in Gordon that includes this claimed combination. Instead, its analysis of claim 20 repeatedly refers back to different portions of its analysis addressing different claims and different Gordon embodiments. For example, Petitioner relies on its analysis of limitation 9[j] for the second adjusting tool engaging the adjusting screw, claim 10 for the engagement portions positions at or near the implant proximal end, claim 12 for the ridges, claim 14 for the openings and cavity, claim 15 for the single-integral-structure limitation, and claim 16 for the configuration of the engagement extensions.

189. In my opinion, this approach highlights the fundamental problem with Petitioner's anticipation theory. Gordon contains numerous different implant and instrument embodiments, each having different structures, expansion mechanisms, surface features, and tool interfaces. Petitioner treats those disclosures as though they were a collection of interchangeable parts from which the limitations of claim 20 can be selected. But a POSITA would not read Gordon that way. Features disclosed for one embodiment are not automatically features of another embodiment simply because both appear in the same reference. Moving features between embodiments requires non trivial engineering work not discussed by the Petitioner.

190. The problem begins with the underlying implant. As discussed above, Petitioner primarily relies on implant 304 of Figures 15A–15C for the expandable implant and expansion mechanism. Gordon describes that implant as having insert 306, expansion member 308, opening 310, and advancing element 312. Petitioner then supplements that embodiment with features taken from other disclosures in an attempt to arrive at a combination that satisfies additional claim limitations.

191. First, Petitioner combines implant 304 with instrument 700, but Gordon describes instrument 700 in connection with the different implant 484 embodiment.

192. Second, Petitioner relies on a different implant to identify support for the claimed ridge arrangement. For limitation [20.b], Petitioner does not identify ridges on implant 304 extending to the distal end. Instead, it expressly relies on its claim 12 analysis. As discussed above with respect to claim 12, the particular distal-end ridge arrangement on which Petitioner relies comes from the separate Figure 21A implant 422 embodiment. Gordon’s general statement that implant surfaces may include teeth or ridges does not disclose that particular arrangement on implant 304. Thus, Petitioner relies on a different implant embodiment to provide the claimed ridge arrangement.

193. Third, Petitioner turns back to implant 304 for limitation [20.d], but incorrectly identifies features that are not present in that embodiment. Limitation [20.d] requires “first and second openings extending through the first and second

engagement surfaces to a cavity within the expandable spinal implant, the cavity sized to receive bone material.” Petitioner relies on its analysis for claim 14, but as discussed above, Gordon does not identify the dashed elliptical features in Figure 15A as bone-graft openings and the cross-sectional Figures 15B–15C do not show the alleged through-holes. Petitioner’s claim 20 analysis therefore carries forward the same unsupported assumption and then adds the further assumption that the alleged openings communicate with an internal cavity sized to receive bone material.

194. Fourth, Petitioner relies on different embodiments to satisfy the requirement of limitation [20.a] that the tool engagement portions of the implant be positioned at or near its proximal end and the adjusting screw’s tool engagement feature be accessible from the proximal direction so that the second adjusting tool engages the screw at that end. Petitioner relies on its analyses of the screw alignment limitation of claim 9 and the recessed engagement portions of claim 10. Those theories themselves depend on combining instrument 700 and recesses 733 from the implant 484 embodiment with advancing element 312 and the expansion mechanism of implant 304.

195. As discussed above, that combination leaves important technical relationships unresolved. Gordon does not disclose recesses 733 on implant 304, does not disclose where such recesses would be positioned relative to opening 310 and advancing element 312, and does not show that engagement of holding arms

716 with any proposed recesses on implant 304 would align driver 708 with advancing element 312.

196. Petitioner also misunderstands the structure of implant 304. Limitation [20.e] requires “the first expandable spinal implant structure is a first single integral structure and the second expandable spinal implant structure is a second single integral structure.” Petitioner relies on its analysis for claim 15. As discussed above, Petitioner’s analysis for claim 15 relies on Gordon’s osteoconductive scaffolding as the vertebral body engagement surfaces while Gordon describes such scaffolding as being a separate component “coupled to” the implant bodies. Accordingly, the engagement surfaces Petitioner identifies are not an integral part of the same implant body that Petitioner relies upon.

197. Claim 20 therefore illustrates a fundamental problem with Petitioner’s approach to Gordon. Petitioner does not explain how an implant disclosed in Gordon satisfies the claimed combination. Rather, the analysis picks and chooses from Gordon’s different disclosures to locate individual features that resemble individual claim limitations: implant 304 for one group of structures, implant 484 and instrument 700 for tool-engagement features, implant 422 for a particular ridge arrangement, general statements regarding bone-graft openings for another feature, and still other Gordon disclosures to support allegedly unitary bodies or surface

structures. The resulting configuration is Petitioner's assembly of selected Gordon features, not a configuration Gordon actually describes and discloses.

198. As I explained above, I understand anticipation requires the claimed elements to be disclosed together, arranged or combined as in the claim. In my opinion, Gordon does not disclose an embodiment having the complete arrangement required by claim 20.

199. Petitioner's obviousness theory does not cure the problem. When multiple features from different embodiments are combined, a POSITA still would need a technical reason to make the particular combination and a reasonable expectation that the resulting device would operate successfully. Here, the proposed features are not independent decorative additions. The recess locations affect an implant's structural integrity, how and in what orientation the implant is held, and how the driver aligns with the adjusting screw; the implant's internal expansion mechanism constrains available space and access; through-holes and a cavity alter the structure through which loads are transmitted; surface ridges and/or osteoconductive scaffolding affect the vertebral-contacting surfaces; and the requirement for single integral expandable structures constrains how those engagement surfaces can be constructed. Petitioner does not analyze the interaction of these modifications as a whole.

200. That omission is significant because modifying one aspect of implant 304 can impact other features. For example, forming engagement recesses in the side surfaces and forming through-holes extending from the vertebral engagement surfaces both removes or alters material from the implant structure. Those changes would have to coexist with insert 306, expansion member 308, advancing element 312, and opening 310, while also preserving the geometry necessary for instrument engagement and expansion. Likewise, configuring tool-engagement structures at the proximal end requires consideration of the location, orientation, and geometries of numerous components of the expansion mechanism for implant 304. The Petition provides no integrated technical analysis showing how the proposed claim 20 device would actually be constructed, or assess the impact of changes to the implant or tools on the performance of the device and its use in operation.

201. Gordon itself demonstrates that its inventors knew how to state when a feature was intended to apply broadly across embodiments. By contrast, Gordon does not provide an analogous teaching that implant 304 should simultaneously incorporate the side recesses of implant 484, the distal-end surface arrangement relied upon from implant 422, the bone-graft openings disclosed in other contexts, and all of the additional structures required by claim 20.

202. In my opinion, a POSITA would not understand Gordon to disclose, teach, or suggest the resulting collection of features as the integrated implant and

tool system required by claim 20. It is my opinion that Gordon fails to render claim 20 anticipated or obvious.

**X. ANALYSIS OF PETITIONER’S GROUND 2: MCLUEN IN VIEW OF GORDON**

203. For Ground 2, Petitioner combines McLuen’s implant with Gordon’s instrument 700. Petitioner proposes this combination primarily because McLuen does not provide illustrations of “its complete tool assembly for securing and expanding the implant.” Pet. at 54. In my opinion, a lack of illustration of a described tool is not a motivation to seek a different tool. And even if a lack of illustration would motivate a POSITA to seek a different tool, Petitioner provides no motivation that a POSITA would have selected Gordon’s tool rather than some other tool. But even if the combination were proper, it fails to render claims 9-12, 14-18, and 20 obvious.

**A. A POSITA Would Not Have Been Motivated to Combine McLuen’s Implant with Gordon’s Tool.**

**1. McLuen already discloses the necessary instrumentation to implant and expand its device.**

204. 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 Gordon’s tool. Pet. 54-57. In my opinion, McLuen already discloses the instrumentation and corresponding tool-to-implant interfaces to surgically implant the device and prevent screwdriver slippage.

205. McLuen describes a screwdriver 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.*

206. A POSITA would have understood from this disclosure what type of tool McLuen contemplates (even though the tool itself is not illustrated): the screw driver and attachments are operated together in order to maintain alignment and tension to prevent slippage. McLuen expressly states that the tool includes “attachments that fit within the channels 1522 to secure the tool ... in place.” Ex. 1012, ¶¶ 76-77.

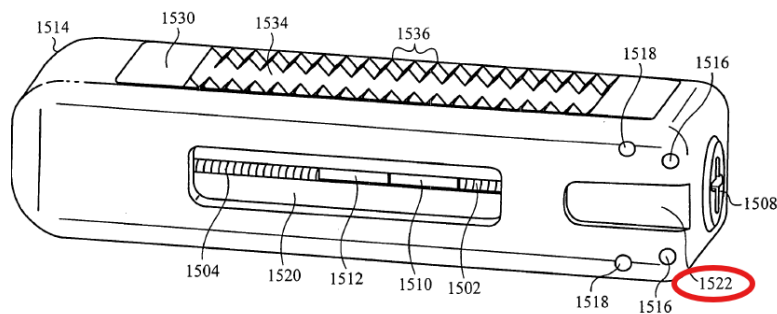


**Fig. 16**

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.

207. Petitioner does not identify any inadequacies with McLuen's tools and implant structures. Instead, McLuen describes its tool and channels 1522 as specifically designed to avoid 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.").

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

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

209. A POSITA would not have reasonably expected Gordon's disclosed tool to function with McLuen's disclosed implant because the two systems are not mechanically compatible.

210. For example, I disagree with Petitioner's and Mr. Culbert's opinion that Gordon's holding device includes arms shaped such that they would engage McLuen's channels. Pet. 57; Ex. 1002 ¶ 73. 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. Gordon, by contrast, includes lobes 722 that extend from Gordon's holding arms 716 that are configured to "engage complementary surfaces (e.g., notches, grooves) on an implant or spacer." Ex. 1013, ¶ 231, Figs. 35-36, 38-45, 47-49. Gordon explains that, when implant 484 is coupled to holding device 710, lobes 722 on holding arms 716 engage holding recesses 733 on either side of lower body 488. Gordon further states that engagement of lobes 722 within those recesses helps maintain the implant's position during insertion and expansion and places implant 484 in a desired alignment for engagement with the expansion tool. Thus, Gordon does not merely disclose two arms contacting the sides of an implant. It discloses a complementary lobe-and-recess interface that mechanically locates the implant relative to instrument 700.

211. McLuen's channels 1522 are not notches, grooves, or recesses complementary to Gordon's lobes 722, nor do channels 1522 include any surfaces that would be considered complementary to Gordon's lobes 722. And Petitioner proposes no modification to McLuen's channels to include any such complementary surfaces. Rather, Petitioner suggests that the holding arms 716 with lobes 722 (as illustrated in Petitioner's annotated Fig. 36) are shaped to engage McLuen's channels. Pet. at 57. They are not. Gordon's holding arms 716 would not fit into McLuen's channels 1522. Rather, at most, the projecting lobes 722 at the distal portions of the arms could potentially enter those channels. The remaining portions of holding arms 716 would not contact implant 1500. Thus, instead of the complementary engagement between lobes 722 and correspondingly shaped recesses 733 disclosed by Gordon, Petitioner's proposed combination would provide contact between the tips of lobes and minimal portions of the walls defining McLuen's channels.

212. In my opinion, that difference would materially affect the security of the tool/implant interface. A larger and more conforming engagement surface provides greater ability to resist translation and rotation of an implant relative to the instrument. By contrast, a small, incidental area of contact between a projecting lobe and an elongated channel provides less constraint and permits greater opportunity for relative motion, particularly under torque. Gordon itself associates the

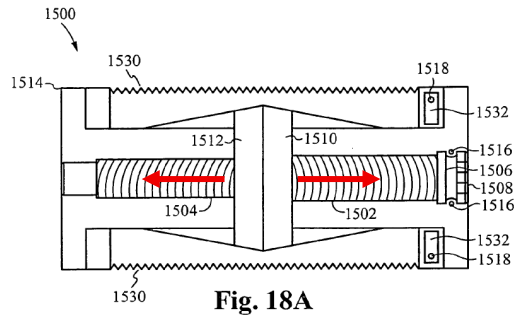
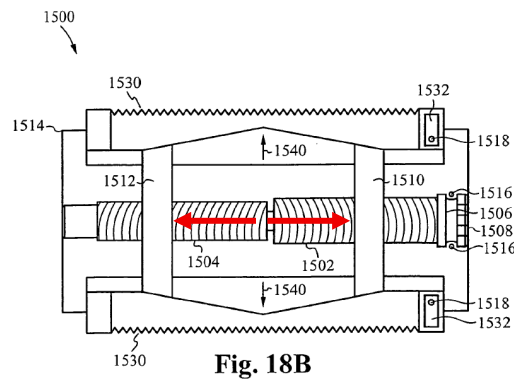
engagement of lobes 722 in recesses 733 with maintaining implant position and establishing the desired alignment for expansion. Petitioner ignores these considerations.

213. The difference in implant geometry further complicates the proposed combination. Gordon's instrument 700 is disclosed with c-shaped implant 484, and Gordon explains that recesses 733 are positioned so that engagement by holding arms 716 places that implant in the appropriate alignment for the expansion tool. McLuen's implant 1500, by contrast, has an elongated rectangular frame 1514, side channels 1522, tabs 1530, and a central positioning means 1508 formed by two oppositely threaded screws and associated extending blocks. Petitioner disregards the spacing, depth, or longitudinal position of channels 1522 in proposing a POSITA would simply swap out the McLuen tool designed to interface with those channels and screws in favor of Gordon's holding arms 716 and lobes 722 that are designed for holding and engaging with a different implant having recesses.

214. Petitioner also does not identify any modification to Gordon's holding arms or lobes that would be required to make them properly fit McLuen's channels. Instead, it asserts that holding arms 716 are "shaped such that they would engage channels 1522" and concludes that there would have been a reasonable expectation of success. That conclusion skips the necessary engineering analysis. A POSITA would need to consider at least the width and depth of channels 1522, the dimensions

and contour of lobes 722, the spacing between opposing holding arms 716, the amount of engagement needed to resist insertion and expansion loads, and the alignment of driver 708 with positioning means 1508. Petitioner does not address those considerations.

215. Petitioner also ignores the differences in the mechanics by which the McLuen implant and the Gordon 484 implant expand. McLuen's implant involves a rotational actuator that does not translate axially during expansion. McLuen explains that positioning means 1508 comprises oppositely threaded screws 1502 and 1504 coupled to extending blocks 1510 and 1512. When positioning means 1508 is turned, the extending blocks travel outwardly along those screws and push tabs 1530 outward. McLuen further states that positioning means 1508 is "held in place but permitted to turn" by pins 1516 engaging retaining groove 1506. Ex. 1012, ¶ 77. This is further illustrated in Figures 18A-18B, as shown below. As positioning means 1508 rotates, blocks 1510 and 1512 translate axially, not positioning means 1508.



Thus, the expansion operation depends upon rotation of positioning means 1508 while its axial position relative to frame 1514 remains fixed.

216. Gordon does not disclose driver 708 operating implant 304, yet Petitioner relies on instrument 700 to engage advancing element 312. Pet. at 34. A driver that advances element 312 must advance axially with element 312 as it advances through opening 310 and pushes expansion member 308 into insert 306 of the implant. But McLuen's positioning means 1508 is restrained to prevent axial displacement so that it rotates in place.

217. Accordingly, the axial motion needed for driver 708 to work with implant 304 of Gordon is incompatible with the expansion mechanism of the McLuen implant, and would cause the holding arms of the Gordon holder to slide

off channels 1522 while the entire holder assembly moves away from the implant, rather than remain stationary as intended.

218. McLuen's channels 1522 are specifically provided to prevent the tool from slipping while positioning means 1508 is turned. McLuen explains that the channels receive attachments of a tool to secure that tool in place during rotation of positioning means 1508. Ex. 1012, ¶ 76. Yet Petitioner's proposed substitution introduces a driver mechanism that generates axial movement—and therefore axial loading at the driver/screw interface—even though McLuen's positioning means is deliberately structured to prevent axial movement. Pet. at 56-57 (referencing its Ground 1 discussion of Gordon and referring to Gordon's "advancing" driver head). Petitioner ignores these differences when suggesting a POSITA would be motivated to use the holder of Gordon with the implant of McLuen.

219. This further undermines Petitioner's asserted reasonable expectation of success. It is not enough to observe that Gordon has a driver capable of engaging a screw head and that McLuen has a screw head that must be rotated. The operating motions of the two systems must be compatible. Here, McLuen expressly restrains positioning means 1508 against axial motion while Gordon's embodiment relied upon by Petitioner deliberately converts rotation of thumbwheel 714 into axial translation of driver 708. Petitioner does not address that mismatch or explain how instrument 700 could preserve secure engagement between holding arms 716 and

channels 1522 while applying the required rotational input to McLuen's axially fixed positioning means with Gordon's advancing driver.

220. Accordingly, a POSA would not be motivated to swap out the holder described by McLuen in favor of Gordon's instrument 700.

**B. McLuen in view of Gordon Fails to Teach or Suggest 9[c] or 18[c].**

221. For its McLuen-Gordon combination, Petitioner relies on its analysis of Gordon in Ground 1 for the tool limitations. Pet. at 58. But as I explained above, Gordon fails to disclose, teach, or suggest the claimed second adjusting tool as required by limitations 9[c] and 18[c], and additionally fails to disclose the second handle as required by limitation 9[c]. Because Petitioner incorporates its Ground 1 failures in Ground 2, it is my opinion that Ground 2 fails to show that independent claims 9 and 18 are unpatentable for the same reasons I explained above. The same is true for all claims that depend from claims 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**C. McLuen in view of Gordon Fails to Teach or Suggest 9[h]-9[i] or 18[h] and 18[j].**

222. As I explained above, a POSITA would not have been motivated to combine, and there would be no reasonable expectation of success in combining, Gordon's holding arms 716 and lobes 722 with McLuen's channels 1522. That same incompatibility also means that the proposed McLuen-Gordon combination does not teach or suggest the requirement of claims 9 and 18 that the tool engagement portions

be “sized, shaped, and configured for” (a) receiving the first and second engagement prongs (claim 9), or (b) engaging with the gripper (claim 18).

223. Gordon describes a particular relationship between holding arms 716, lobes 722, and implant 484. Gordon states that “[l]obes 722 on holding arms 716 may engage complementary surfaces (e.g., notches, grooves) on an implant or spacer.” Ex. 1013, ¶ 231. Lobes 722 engage the holding recesses 733 of implant 484.

224. Gordon’s figures depict lobes 722 with a rounded or arcuate profile. *See* Ex. 1013, Figs. 35-36, 38-45, 47-49. McLuen’s straight, elongated channels 1522 are not complementary to Gordon’s lobes 722 or appropriate for use with such lobes. Ex. 1012, Figs. 15-16. The claims do not merely require that an engagement prong be capable of making some contact with an implant feature. They require tool engagement portions that are “sized, shaped, and configured for receiving” the engagement prongs.

225. Petitioner’s analysis does not address the geometric mismatch. It states that McLuen has channels 1522 and that Gordon has lobes 722, and then concludes that Gordon’s lobes could engage McLuen’s channels “just like Gordon’s implant.” But Gordon’s implant does not merely provide an arbitrary channel. It provides holding recesses 733 specifically engaged by lobes 722, and Gordon characterizes

the relevant implant surfaces as complementary to those lobes. McLuen's straight-sided channels lack such a complementary shape.

226. A POSITA would have therefore recognized that these interfaces are not appropriate for use together, and Petitioner does not identify any modifications to satisfy limitations 9[h] and 18[h]. Accordingly, even apart from the broader reasons discussed above why a POSITA would not have combined Gordon's holding device with McLuen's implant, the proposed combination fails to establish the particular "sized, shaped, and configured" for receiving/engaging relationship required by limitations 9[h], 9[i], 18[h], and 18[j]. For these additional reasons, I believe Ground 2 fails to render independent claims 9 and 18 unpatentable. The same is true for the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**D. McLuen in View of Gordon Fails to Teach or Suggest 9[j] or 18[i].**

227. Limitations 9[j] and 18[i] require the adjusting screw to be positioned such that the second adjusting tool can extend through the adjusting-tool passage of the first tool and engage the screw head while the engagement prongs of the first tool are engaged with the tool engagement portions of the implant. Petitioner contends that this limitation is satisfied by combining McLuen's implant 1500 with Gordon's instrument 700. I disagree.

228. As discussed above, Gordon's instrument 700 is designed around the geometry, insertion trajectory, and operating mechanism of Gordon's implant 484, not McLuen's implant 1500. Petitioner nevertheless assumes that Gordon's holding arms 716 are able to be placed in McLuen's channels 1522, and that this will result in driver 708 being positioned and oriented to engage the head of positioning means 1508. The Petition provides no dimensional or geometric analysis supporting that assumption. It does not compare the spacing and position of holding arms 716 relative to driver 708 with the spacing and position of channels 1522 relative to positioning means 1508. Nor does it identify any disclosure in either reference establishing that engagement of Gordon's holding arms with McLuen's channels would place driver 708 on the axis and distance necessary to engage positioning means 1508.

229. Once Gordon's holding arms are engaged with the implant, their engagement fixes the position and orientation of instrument 700 relative to the implant. Driver 708, in turn, occupies a predetermined position relative to those holding arms. McLuen's positioning means 1508 similarly occupies a predetermined location within implant 1500 relative to channels 1522. Thus, for Petitioner's proposed combination to satisfy the claim, those two sets of geometric relationships must correspond: engagement of arms 716 (via lobes 722) with channels 1522 must place driver 708 in the correct position, orientation, and distance

to engage the head of positioning means 1508. Petitioner does not show that they do.

230. Further, as I explained above, McLuen's positioning means 1508 does not axially translate when rotated—it remains stationary relative to implant 1500. Rotation causes extending blocks 1510 and 1512 to travel inwardly or outwardly along screws 1502 and 1504 while positioning means 1508 just spins at a fixed location. Petitioner's application of Gordon's instrument 700 with implant 304, by contrast, requires operation of thumbwheel 714 to cause the axial displacement of the head of driver 708 so that it can extend into the implant and cause the wedge of expansion member 308 to push up the bottom of insert 306 and cause the implant to expand.

231. Petitioner's proposed McLuen-Gordon combination places the two functions of Gordon's instrument in mechanical opposition. Holding arms 716 need to remain engaged with channels 1522 so that implant 1500 remains secured while positioning means 1508 is rotated. At the same time, Gordon's driver needs to engage McLuen's fixed positioning means. But because Gordon's driver advances axially, its axial movement would tend to withdraw holding arms 716 from channels 1522. This is particularly relevant to limitations 9[j] and 18[i] because the claims expressly require engagement with the adjusting screw to occur while the engagement prongs of the holder remain engaged with the implant.

232. Because engagement of Gordon's axially translating driver would disengage Gordon's holding arms, it is my opinion that McLuen in view of Gordon fails to teach or suggest limitations 9[j] or 18[i]. Thus, Ground 2 fails to render independent claims 9 and 18 unpatentable. The same is true for the claims depending from either claim 9 or 18 (e.g., claims 10-12, 14-17, and 20).

**E. McLuen in View of Gordon Fails to Teach or Suggest Claim 17**

233. As I explained above, claim 17 recites a method of using the system of claim 9 and requires, among other things, "extending the second adjusting tool through the first tool to engage the adjusting screw of the expandable spinal implant." As I explained above with respect to Ground 1, Gordon does not disclose a method step in which a separate second adjusting tool is extended through a first tool. Gordon instead describes driver 708 as a component already incorporated within instrument 700.

234. Petitioner does not suggest that McLuen cures that deficiency. Accordingly, for the reasons explained above with respect to claim 17 in Ground 1, it is my opinion that McLuen in view of Gordon fails to teach or suggest claim 17.

**XI. ANALYSIS OF PETITIONER'S GROUND 3: GORDON IN VIEW OF MICHELSON.**

235. For Ground 3, Petitioner combines Michelson's driver with Gordon's instrument 700. Pet. at 79-85. But Petitioner provides no motivation for a POSITA to remove the driver integrated into Gordon's instrument for "installing and

expanding an implant” (Ex. 1013, ¶¶ 226-227) and replace it with Michelson’s separate driver, which is designed to be used with a different instrument assembly with different implants. Petitioner also does not explain why a POSITA would have reasonably expected Michelson’s driver to function within Gordon’s materially different holder after being removed from Michelson’s coordinated tool assembly. And even if the combination were proper, it fails to render claims 9-12 and 14-17 obvious for the reasons discussed above.

**A. A POSITA Would Not Have Been Motivated to Combine Michelson’s Driver with Gordon’s Tool.**

236. Petitioner’s proposed combination is not simply the substitution of one known driver for another in an otherwise unchanged system. As discussed above, Petitioner’s theory based on Gordon in Ground 1 already selects implant 304 as the implant, adds holding recesses 733 disclosed for the different implant 484, and then proposes using instrument 700—also disclosed in connection with implant 484—to hold and expand the modified implant 304. Ground 3 adds more selections and adaptations: Petitioner retains selected portions of Gordon’s instrument 700, but purports to replace Gordon’s integrated driver 708 and thumbwheel 714 with Michelson’s separate expander driver 600, which—if adopted—would require additional adaptations.

237. Gordon’s disclosed preference for a single integrated instrument undercuts Petitioner’s asserted motivation to replace its integrated driver with

Michelson's separate driver. Ex. 1013, ¶ 226 ("a single instrument may be used to perform multiple steps of a spinal procedure."). Gordon then introduces instrument 700 as such an instrument "for use in installing and expanding an implant." Ex. 1013, ¶¶ 226-227. Gordon's driver 708 and thumbwheel 714 are incorporated into that instrument to provide the expansion function. Thus, Gordon teaches a single, integrated instrument to perform both implantation and expansion.

238. A POSITA would recognize practical advantages to that integrated configuration. Driver 708 is maintained within instrument 700, and thumbwheel 714 is coupled to driver 708 and partially resides within slot 732 of handle 712. Gordon explains that handle 712 protects thumbwheel 714 and inner shaft 724 from damage while still permitting the user to access and operate thumbwheel 714. As discussed above, the arrangement establishes and maintains the relationship between the driver, outer shaft, holding device, and control member. Petitioner does not identify a technical problem with that integrated configuration that would have caused a POSITA to discard it for Michelson's separately insertable driver and redesign Gordon's instrument to receive that driver.

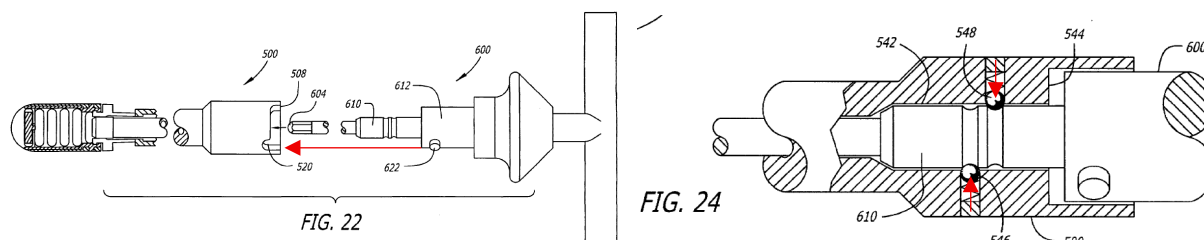
239. Michelson, moreover, does not merely disclose a separate driver that can be transplanted into any implant holder. Michelson discloses a coordinated system comprising implant holder 500, expander driver 600, and implant 100. Michelson's implant holder includes shaft 502 and provides a locking mechanism

that secures the implant to the holder. Expander driver 600 is introduced through the proximal end of shaft 502 and advanced through implant holder 500. Ex. 1014 at 24, Figs. 22-24. Implant holder 500 includes spring locks 546, 548 to engage driver detents 616, 618. *Id.* Thus, Michelson's driver, holder, and implant were designed as cooperating parts.

240. This makes Petitioner's selection of only Michelson's driver particularly unexplained. Petitioner itself identifies Michelson's secure locking mechanism for holding the implant as an advantage of Michelson, but ignores that advantage by suggesting a POSITA would select only Michelson's driver. Pet. at 82. Petitioner does not explain why the POSITA would take Michelson's driver but reject Michelson's holder, the very component that is designed to receive driver 600 and securely retain the implant during insertion and manipulation. Moreover, substituting only Michelson's driver into Gordon's holder would not obtain the secure implant-holding benefit that Petitioner identifies as a reason for looking to Michelson. Petitioner instead retains Gordon's holding arms 716 and lobes 722—structures Gordon does not disclose for use with implant 304—and combines those structures with Michelson's driver. Petitioner's stated reason for looking to Michelson—its secure connection between the implant and holder—points toward using Michelson's complete holder/driver system rather than selecting only driver 600.

241. Petitioner also fails to explain why a POSITA would discard Gordon's integrated driver in favor of the Michelson driver component. Gordon already provides driver 708 and thumbwheel 714 as integrated components of instrument 700 for performing the expansion operation. Thus, there were at least two available tool architectures before Petitioner's proposed combination: Gordon's integrated instrument 700 and Michelson's coordinated implant holder 500 and separately insertable expander driver 600. Petitioner's proposal selects a portion of Gordon's integrated tool and Michelson's driver without identifying a technical deficiency that would have led a POSITA to that particular hybrid or explaining why a POSITA would have expected that hybrid to function successfully.

242. The proposed substitution also sacrifices aspects of Gordon's integrated arrangement. In Gordon, thumbwheel 714 is coupled to driver 708 and retained within slot 732 of handle 712. The driver therefore occupies a defined relationship with the surrounding instrument, which Gordon implements for protection. Ex. 1013, ¶ 235. Michelson's driver 600, by contrast, is designed to be introduced into and advanced through Michelson's shaft 502. Because of this, Michelson provides specific structures that control the relationship between those components: interlocking peg 622 which coordinates with receiving slot 520 and spring locks 546, 548 engage with detents 616 and 618 of implant holder engagement portion 610 cooperate to fix the driver relative to the holder. Ex. 1014, 24, Figs. 22, 24.



243. These components of Michelson's driver (e.g., pegs, detents, or other driver/holder interfaces) would not cooperate with Gordon's instrument. Petitioner identifies no features in Gordon that would interact with the components of Michelson's driver to maintain the appropriate axial position and alignment relative to the implant during insertion and expansion.

244. That omission is significant because Michelson teaches the need for mechanisms establishing and controlling the relationship of the driver with the holder. Michelson does not place a loose shaft through a random hollow implant holder. Its driver is advanced to a defined depth and then lockably engages structures specifically provided in implant holder 500. *Id.* Petitioner's proposal ignores these structures Michelson provides to control and stabilize the driver.

245. Petitioner's treatment of the proximal handle arrangement similarly ignores the divergent structures of the implant holders. Michelson's T-shaped handle is designed to extend proximally beyond Michelson's implant holder. Gordon deliberately uses a different configuration: a thumbwheel 714 fixed within slot 732 of handle 712. Nothing in Gordon suggests that its thumbwheel 714 should instead project proximally beyond handle 712.

246. Nor would Gordon's disclosure of a knob as an alternative to thumbwheel 714 lead to Petitioner's configuration. As discussed above, Gordon identifies a knob, lever, or button as alternatives to thumbwheel 714, but does not explain different configurations for these alternatives. Gordon does not teach or suggest that alternatives to thumbwheel 714 require conversion of the driver into an externally extending separate insertable tool with a proximal T-handle. A POSITA would understand these alternatives to also reside within slot 732. Gordon provides no teaching that replacing thumbwheel 714 requires abandoning its integrated location within handle 712 or extending the control structure outside instrument 700. Substituting one type of integrated and constrained control member for another is not the same modification as converting Gordon's integrated driver into Michelson's separately insertable driver with a proximal T-handle.

247. Petitioner's proposed combination also reflects the same selection problem discussed with respect to Gordon's implant embodiments. Petitioner assumes that a POSITA would begin with implant 304, import the recesses for engaging with the holding device 710 Gordon identifies for implant 484, retain selected portions of Gordon's instrument 700, discard Gordon's driver and thumbwheel, reconfigure Gordon's proximal handle to permit insertion of Michelson's driver, and then import Michelson's expander driver while rejecting Michelson's implant and implant holder. Gordon's implant embodiments differ

structurally and functionally, and Michelson discloses yet another different expandable implant designed to operate with its holder and driver assembly. Petitioner does not provide a technical reason why a POSITA confronted with those alternatives would select the components necessary to construct Petitioner's proposed combination. Instead, it appears Petitioner has suggested these changes through hindsight in an attempt to arrive at the claimed invention.

248. In my opinion, this is particularly problematic because the stated advantages of the references point toward their respective systems, not Petitioner's hybrid. Gordon emphasizes the advantage of a single instrument capable of positioning and expanding an implant. Michelson provides a coordinated holder and driver with complementary positioning and control structures designed to control the driver, as well as a holder designed to secure and manipulate Michelson's implant. Petitioner's combination departs from both approaches: it removes the integrated driver from Gordon's single instrument while declining to use the holder and locking structures Michelson designed to accompany its separate driver.

249. The proposed substitution also does not remedy the other deficiencies of Gordon discussed in Ground 1. Replacing driver 708 and thumbwheel 714 with Michelson's expander driver 600 does not disclose recesses 733 on implant 304, does not provide a reason to place engagement portions on the claimed side surfaces, does not establish the required alignment between the modified holder and

advancing element 312, and does not supply the other missing implant features discussed above for the dependent claims. Those deficiencies remain even if Michelson's driver is substituted for Gordon's driver.

250. Finally, Petitioner proposes modifying Michelson's tip 614 to be shaped like a screwdriver. Pet. at 84. But in making this proposed modification, Petitioner contradicts its prior statement that "[a]ccording to McLuen, one skilled in the art would have recognized that '[s]crew drivers unfortunately have the ability to slip out of place'." Pet. at 55. In my opinion, a POSITA would not simply assume that a proposed screw-head configuration could be substituted without considering its ability to remain securely engaged while torque is applied. Petitioner's analysis does not provide that consideration and its conclusion is contradictory to its earlier conclusions. Michelson discloses tip 614 as preferably hex-shaped and configured to engage opening 130 of Michelson's expander 120. Ex. 1014 at 20–21. Petitioner does not identify the precise tool-engagement geometry of Gordon's advancing element 312, the resulting geometry of modified tip 614, or how the modified tip would remain aligned and engaged after driver 600 is removed from Michelson's holder and inserted through Gordon's reconfigured instrument. Petitioner also does not evaluate that additional modification as part of the complete system it proposes.

251. Accordingly, in my opinion, Petitioner has not shown that a POSITA would have been motivated to replace Gordon's integrated driver 708 and

thumbwheel 714 with Michelson's expander driver 600 or would have had a reasonable expectation of success in doing so. Gordon expressly designed instrument 700 as a single instrument for performing both implantation and expansion, while Michelson designed expander driver 600 as part of a different coordinated holder-and-driver system having its own driver-positioning and locking structures for a different implant structure. Petitioner's proposed combination selectively retains Gordon's holding components, discards Gordon's integrated driver, imports Michelson's separate driver, and discards Michelson's corresponding holder and locking mechanism and implant. The references themselves do not provide a technical reason for that particular selection of components.

252. It is therefore my opinion that a POSITA would not have been motivated to combine Michelson with Gordon as suggested by Petitioner, and would not have had a reasonable expectation of success in doing so.

**B. Gordon in view of Michelson Fail to Teach or Suggest 9[c], 9[h]-9[j], and claims 12, 14-15, and 17**

**1. Limitation 9[c]**

253. For the reasons explained above regarding Petitioner's proposed substitution of Michelson's expander driver 600 for Gordon's integrated driver/thumbwheel arrangement, Petitioner has not shown that a POSITA would have been motivated to modify Gordon to provide the second adjusting tool and second proximal handle required by limitation 9[c], or would have reasonably

expected that modification to succeed, and for this additional reason Petitioner has failed to demonstrate the obviousness of claim 9.

## **2. Claim 17**

254. For the reasons explained above regarding Petitioner's proposed substitution of Michelson's expander driver 600 for Gordon's integrated driver/thumbwheel arrangement, Petitioner has not shown that a POSITA would have been motivated to modify Gordon so as to involve the step of extending a second adjusting tool through the first tool as required by claim 17 or would have reasonably expected Michelson's driver to perform that step through Gordon's materially different instrument. For this additional reason Petitioner has failed to demonstrate the obviousness of claim 17.

## **3. Limitations 9[h]-9[j] and claims 10, 12, and 14-15**

255. Petitioner relies on Michelson only to resolve the deficiencies of Gordon with respect to limitation 9[c] and claim 17. Accordingly, my opinions regarding the deficiencies of Gordon set forth in Ground 1 with respect to all other elements apply equally to the challenged claims of Ground 3. In my opinion, Gordon in view of Michelson fails to render claims 9-12 and 14-17 unpatentable.

## **XII. ANALYSIS OF PETITIONER'S GROUND 4: MCLUEN IN VIEW OF GORDON AND MICHELSON.**

256. For Ground 4, Petitioner seeks to replace Gordon's tool from the combination set forth in Ground 2, with the modified tool from the Gordon-

Michelson combination set forth in Ground 3. Petitioner does not provide any analysis for this new combination, and merely concludes “the Gordon-Michelson tool assembly would have functioned similarly to the Gordon tool assembly for engaging McLuen’s implant.” Pet. at 86. Petitioner fails to identify any reason that would have motivated a POSITA to pursue this combination and fails to provide an articulated reasonable expectation of success. Once again, I believe the proposed combination involving McLuen’s implant, a modified version of Gordon’s holder designed for a different implant structure, and a modified version of Michelson’s driver tool designed for use with a different implant holder and implant is the product of hindsight in which Petitioner looked for different claim elements in the prior art without a rational explanation for why a POSITA would pick and choose the various teachings of the different references. Not only does Petitioner fail to identify a motivation for its proposed combination, but its proposed combination also fails to resolve the issues I identified in Grounds 2 and 3 above.

257. Accordingly, it is my opinion that McLuen in view of Gordon and Michelson fails to teach or suggest claims 9-12 and 14-17.

### **XIII. CONCLUSION**

258. In view of my explanations above, it is my opinion that Petitioner has not shown that any of claims 9-12, 14-18, and 20 of the ’136 Patent are unpatentable.

259. 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.

260. 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.

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

Executed on: August 21, 2026

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Ken Gall, Ph. D.