

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,
v.

MOSKOWITZ FAMILY LLC,
Patent Owner

Case No. IPR2026-00162
Patent No. 12,011,367

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. 12,011,367 (the '367 patent") in the IPR2026-00162 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 2070 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 2070.

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. 12,011,367
Ex. 1001, U.S. Patent No. 12,011,367 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. 12,011,367
Ex. 1004, File History for U.S. Patent No. 12,011,367
Ex. 1006, U.S. Patent Application Publication No. 2008/0249569 A1 to Waugh et al. (“Waugh”)
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. 1024, U.S. Patent No. 9,585,766 to Robinson (“Robinson”)
Ex. 1047, U.S. Patent No. 6,342,074 to Simpson (“Simpson”)
Ex. 1053, U.S. Patent No. 7,846,188 to Moskowitz et al. (“the ’188 patent”)
Ex. 1057, U.S. 9,445,919 to Palmatier (“Palmatier”)
Ex. 1059, Patent Owner’s Infringement Claim Charts, Exhibit K1, <i>Moskowitz Family, LLC v. Medtronic, Inc.</i> , No. 0:25-cv-00769 (D. Mass.), served October 30, 2025.
Ex. 1060, Senthil Eswaran et al., <i>The micro-mechanics of cortical shell removal in the human vertebral body</i> , 31 COMPUT. METHODS APPL. MECH. ENGRG. 3025 (2007)
Ex. 1061, Vivek Palepu et al., <i>Biomechanics of Disc Degeneration</i> , ADV. ORTHOP (2012)
Ex. 1062, Kai-Uwe Lewandrowski, <i>Surgical Technique of Endoscopic Transforaminal Decompression and Fusion with a Threaded Expandable Interbody Fusion Cage and A Report of 24 Cases</i> , 7(2) J. SPINE 1 (2018)
Ex. 1063, Erik Emstad et al., <i>The VariLift(®) Interbody Fusion System: expandable, standalone interbody fusion</i> , 8 MED. DEVICES (AUKL.) 219 (2015)
Ex. 1064, Gstoettner Michaela et al., <i>Footprint mismatch in lumbar total disc arthroplasty</i> , 17(11) EUR. SPINE J. 1470 (2008)
Ex. 1065, Thomas Steffen et al., <i>Cages: designs and concepts</i> , 9 EUR. SPINE J. S89 (2000)
Ex. 1066, Thomas Lowe et al., <i>A Biomechanical Study of Regional Endplate Strength and Cage Morphology as It Relates to Structural Interbody Support</i> , 29(21) SPINE 2389 (2004)
Ex. 2028, Email correspondence between inventors Eric Sugalski, Andy Moskowitz, and David Schoon regarding fusion devices, dated May 5, 2011

Ex. 2029, Email correspondence between inventors Eric Sugalski, Andy Moskowitz, and David Schoon regarding fusion device prototyping, dated May 18, 2011
Ex. 2030, Email correspondence between inventors Eric Sugalski and Andy Moskowitz regarding fusion device 27 revisions, dated May 19, 2011
Ex. 2053, File History for U.S. Provisional Patent Application No. 61/718,707, filed October 25, 2012
Ex. 2057, Email correspondence between inventors Nathan Moskowitz, Andy Moskowitz, and Eric Sugalski regarding maintaining ridges, dated April 17, 2011
Ex. 2068, Transcript of Deposition of Mr. Brad Culbert, July 29, 2026
Ex. 2127, Email correspondence between inventors Eric Sugalski, Andy Moskowitz, and David Schoon regarding wedge fusion device, dated May 3, 2011
Ex. 2156, Email correspondence between inventors Andy Moskowitz and Eric Sugalski regarding CAD drawings, dated April 15, 2011

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 selecting and combining teachings from different embodiments or

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.

D. Conception

32. I understand that conception occurs when the inventors form a definite and permanent understanding of the invention—including each limitation of the claimed subject matter—such that a person of ordinary skill in the art could understand the structure and operation of the invention.

E. Reduction to Practice

33. I understand that an invention may be reduced to practice either actually or constructively. Actual reduction to practice generally involves making and sufficiently testing a physical embodiment of the invention. Constructive reduction to practice occurs when a patent application is filed that adequately describes and enables the invention. A provisional patent application may constitute a constructive reduction to practice even if no physical prototype has yet been completed or tested,

provided that the application demonstrates possession of the invention and enables a person of ordinary skill in the art to make and use it. Where conception occurred before the filing of the application, priority may also require reasonably continuous diligence from shortly before the relevant date through the constructive reduction to practice.

V. LEVEL OF ORDINARY SKILL IN THE ART

34. 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 October 25, 2012 for purposes of its Petition. For purposes of this Declaration, I have been instructed to use the 2011-2012 timeframe, although I understand that ’367 patent claims priority to earlier applications, including Provisional Application No. 60/670,231, filed on April 12, 2005.

35. 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.

36. In my opinion, a person of ordinary skill in the art in the 2011-2012 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.

37. I understand that Petitioner has stated that a person of ordinary skill in the art in the early 2010s “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. 17. 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, ¶ 21. This definition is broader as it would

include people with general engineering experience rather than specialized medical-device or spinal-instrumentation experience or advanced technical training. My opinions below are the same under either definition.

38. 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, and therefore qualified to offer opinions concerning a POSITA.

VI. BACKGROUND OF THE TECHNOLOGY AND THE '367 PATENT

39. The '367 patent describes expandable intervertebral implants intended to restore and maintain spacing between adjacent vertebral bodies, stabilize the treated spinal segment, and facilitate fusion. Ex. 1001 at 3:29–52. The '367 patent claims priority to a number of applications, including provisional application no. 61/718,707 filed on October 25, 2012.

40. The '367 patent refers to its implants as “zero-profile expandable intervertebral spacers,” or “ZP-EIS” devices. These implants are configured for insertion into an intervertebral disc space in a collapsed configuration and subsequent expansion to separate and support the adjacent vertebral bodies. The patent discloses several embodiments that use different expansion mechanisms, including scissor-jack linkages, threaded drive mechanisms, translating wedges, and gear-driven arrangements. Ex. 1001 at 7:1–12:5, Figs. 1A–8G.

41. Figures 6A–6D illustrate an expandable implant having opposing upper and lower bodies and an expansion mechanism positioned between them. *Id.*, Figs. 6A–6D. The bodies extend longitudinally between respective ends and include opposing side portions, exterior vertebral-engagement surfaces, and interior surfaces facing the expansion mechanism. *Id.* The expansion mechanism in Figures 6A–6D includes a longitudinally movable wedge positioned between the upper and lower bodies. *Id.* Rotation of the adjusting structure moves the wedge between different longitudinal positions, causing the bodies to move between compressed and expanded configurations. *Id.* As illustrated, the wedge remains positioned within the axial space defined by the upper and lower bodies during that movement. The bodies are substantially equal in length, and an end portion of one body is configured to fit between the side portions of the opposing body at its corresponding end. *Id.* These features of the Figure 6A–6D embodiment provide support for the body-length, end-positioning, wedge-position, and axial-confinement limitations recited in the challenged claims.

42. The disclosed implants also include cavities or openings configured to receive bone-graft material or other material intended to promote bone growth and fusion. Ex. 1001 at 2:18–31, 4:14–17, 7:26–32, 7:64–8:2, 8:30–32, 8:56–58, 9:20–22, 9:45–47, 9:67–10:3, 11:53–55, Figs. 1A–7D. Following implantation, these regions permit bone growth through or around the implant to facilitate fusion of the

adjacent vertebral bodies. The implant surfaces include ridges or similar engagement features that contact the vertebral endplates and help resist movement of the implant. *Id.* at 7:22–26, 7:60–61, Figs. 1A–2D.

43. The '367 patent also discloses instrumentation for inserting and expanding the ZP-EIS implants. Ex. 1001 at 2:16–17, 2:54–58, 10:9–12:1, Figs. 8A–8G. The disclosed tool engages the implant, permits the surgeon to position it within the intervertebral space, and actuates the implant's expansion mechanism through a rotatable interface. *Id.* In this manner, the implant may be delivered in a compact configuration and expanded after reaching the desired location.

44. Thus, the '367 patent describes a family of intervertebral implants combining expandable body arrangements, vertebral-engagement surfaces, graft-receiving regions, and dedicated insertion and expansion instrumentation. These features allow the implant to be introduced through a relatively compact surgical corridor, expanded to establish the desired spacing between adjacent vertebral bodies, and retained in position to support stabilization and fusion. Ex. 1001 at 11:26–12:27.

VII. CLAIM CONSTRUCTION

45. I have applied the plain and ordinary meaning, as understood by a POSITA at the time of the invention of the '367 patent, to all claim terms in forming my opinions.

VIII. SUMMARY OF THE ASSERTED REFERENCES

46. I have reviewed the Palmatier reference relied upon by Petitioner. First, as I will explain further below, I do not believe that Palmatier is prior art to the '367 Patent. However, because the Petition relies entirely on Palmatier, I summarize the portions that are relevant to my technical opinions regarding the structure, operation, and functionality of the disclosed implant systems.

A. Palmatier – U.S. Patent No. 9,445,919 (Ex. 1057)

47. Palmatier was filed on December 19, 2011. Palmatier describes three principal expandable intervertebral implant designs: implant 40 in Figures 1–16, implant 540 in Figures 17–21, and implant 840 in Figures 22–28. Although Palmatier describes the later implants as similar to earlier embodiments, each uses a different physical arrangement of the piston component, base component, and translating wedge.

48. Implant 40 extends along a longitudinal axis between anterior end 42 and posterior end 44. Ex. 1057 at 6:25–35. Piston component 46 is positioned above base component 48 and is pivotably connected to base component 48 by hinge 50 near their posterior ends. *Id.* at 6:29–39, 8:42–50.

49. Wedge 58 is positioned between piston component 46 and base component 48 and includes two longitudinal rail portions 110, 112. Each rail portion has axially spaced anterior and posterior wedge portions that engage corresponding

inclined portions of piston component 46. *Id.* at 8:56–9:67. Screw 92 translates wedge 58 axially relative to the piston and base components. *Id.* at 8:10-38. As wedge 58 moves anteriorly, its inclined surfaces slide against piston component 46 and pivot that component away from base component 48 about hinge 50. *Id.* at 11:24–40. Translating wedge 58 in the opposite direction permits piston component 46 to pivot back toward the collapsed configuration. *Id.* at 11:46–12:2. In the collapsed configuration, the posterior portions of wedge 58 extend beyond the posterior ends of the piston and base components. *Id.* at 9:62–67, Figs. 1, 5, 8-9, 12, 14-15. Base component 48 has a planar inner surface without any lateral walls or an anterior wall, nose, or housing structure. *Id.* at 7:67–8:4, Figs. 1–16.

50. Implant 540 likewise pivots open about a posterior hinge, but uses different body and wedge designs. Implant 540 extends along longitudinal axis between anterior end 542 and posterior end 544 and includes piston component 546 pivotably connected to base component 548 by hinges 550 at the posterior end of the implant. *Id.* at 15:9–23, 16:34–42. In the collapsed configuration, the longitudinal sides and anterior end of piston component 546 rest above the corresponding structure of base component 548. *Id.*, Fig. 17. Piston component 546 does not nest between base component 548's lateral walls. *Id.*

51. Wedge 558 is positioned between piston component 546 and base component 548 and translates within the inner-surface boundary defined by base

component 548. *Id.* at 15:63–16:3. Rotation of screw 592 translates wedge 558 axially, causing piston component 546 to pivot relative to base component 548 about hinge 550. *Id.* at 16:4–52. Portions of wedge 558 extend beyond the posterior ends of the piston and base components when the implant is collapsed. *Id.* at Figs. 17, 19–20. Although base component 548 has lateral walls, it does not have a raised structure closing its anterior side or an anterior nose corresponding to wedge-shaped anterior end 884 of implant 840. *Id.*, Figs. 17–21.

52. Implant 840 departs from the overlying piston-and-base arrangements of implants 40 and 540. Base component 848 includes longitudinal sidewalls and an anterior nose, which Palmatier calls “wedge shaped anterior end 884.” *Id.* at 18:42–46, Figs. 22–27. Piston component 846 has a narrower anterior region that fits between the longitudinal sidewalls of base component 848 as implant 840 collapses. The anterior end of piston component 846 terminates behind wedge shaped anterior end 884. *Id.*, Figs. 22–27. Thus, base component 848 extends farther anteriorly than piston component 846. The additional length of base component 848 is associated with its wedge shaped anterior end 884 rather than an additional longitudinal extent of the ridged vertebral-engagement surface. *Id.*, Figs. 22–26.

53. Palmatier explains that implant 840 includes a screw 892, that can be rotated to cause it to axially translate wedge 858. *Id.* at 18:42–45. Palmatier further

explains that forces used to introduce or deliver implant 840 are transmitted through the inserter to anterior end 842. *Id.* at 18:48–52. Base component 848, including wedge shaped anterior end 884, is positioned in front of the internal wedge and screw, and Palmatier states that base component 848 “protects wedge 858 and screw 892 as intervertebral implant 840 is inserted into an intervertebral disc space.” *Id.* at 18:45–48. Figures 24–26 depict wedge shaped anterior end 884 in cross-section as solid material positioned anterior to piston component 846, wedge 858, and screw 892. *Id.* Figs. 24–26.

54. Axial movement of wedge 858 controls the separation and collapse of piston component 846 relative to base component 848. *Id.* Figures 24–26 show implant 840 in expanded, partially expanded, and collapsed configurations. In the collapsed configuration of Figure 26, posterior portions of wedge 858 extend beyond the posterior ends of both piston component 846 and base component 848. *Id.* at Fig. 26. Figure 28 separately depicts wedge 858 and shows its longitudinally extending posterior geometry, including the portions partially obscured by screw 892 in the cross-sectional view of Figure 26. *Id.* at Fig. 28.

IX. ANALYSIS OF PALMATIER’S STATUS AS PRIOR ART

55. I understand that Patent Owner contends that it conceived the challenged claims at least as early as May 18, 2011 and constructively reduced the claims to practice in an October 25, 2012 provisional application. I understand that

if Patent Owner proves conception of the claims earlier than Palmatier's filing date of December 19, 2011, and proves that it constructively reduced the claims to practice with reasonable continuous diligence, then Palmatier would not be prior art.

56. I have analyzed the conception evidence as it relates to the claims of the '367 patent below in Appendix A. As shown in Appendix A, the conception evidence illustrates that the inventors had formed a definite and permanent understanding of each limitation of the claimed subject matter by May 18, 2011. In my opinion, a person of ordinary skill in the art would have understood the structure and operation of the claims, which I have detailed further in my chart, with sufficient detail that they could implement the designs through routine engineering and/or prototype fabrication. *See* Appendix A.

57. I have also analyzed the corresponding disclosure of the provisional application as it relates to the claims of the '367 patent below in Appendix B. Each and every element of the challenged claims is adequately described and demonstrates that the inventors were in possession of the claimed invention as of October 25, 2012. Furthermore, the provisional application would have enabled a POSITA to make and use the claimed intervertebral devices. *See* Appendix B.

X. ANALYSIS OF PETITIONER'S GROUND 1: PALMATIER ANTICIPATION AND/OR OBVIOUSNESS

58. In my opinion, Palmatier does not anticipate or render obvious claims 8, 9, and 17-21 of the '367 patent.

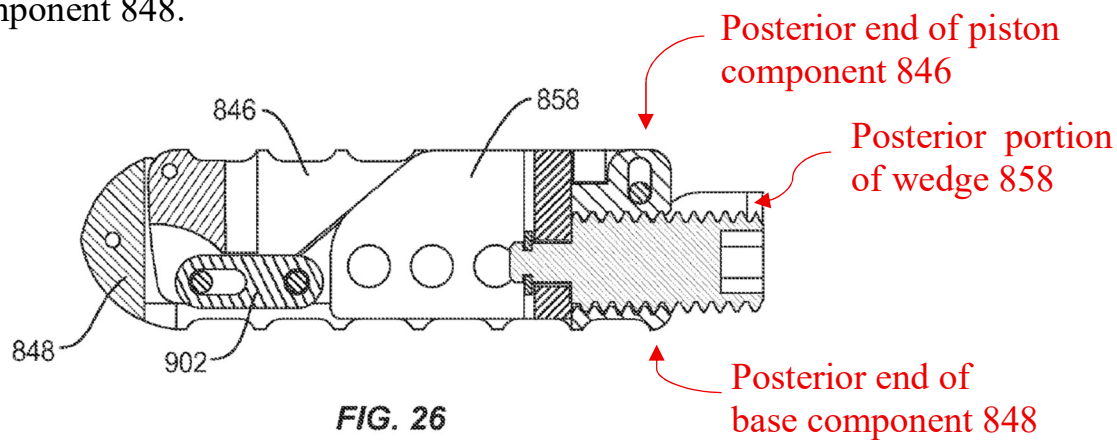
A. Palmatier Fails to Teach or Suggest Independent Claims 8 and 17

59. Independent claims 8 and 17 require that “the wedge remains axially confined within the space defined by the first body and second body” in both compressed and expanded configurations for limitation 8[h] and in first and second wedge positions for limitation 17[k]. Ex. 1001, claims 8, 17. I note that the first wedge position in limitation 17[k] corresponds to a substantially closed configuration of the implant and the second wedge position in limitation 17[k] corresponds to an open configuration of the implant. *Id.*; *see also* Pet. at 39-40, 56.

60. The plain and ordinary meaning of “axial confinement” as used in limitations 8[h] and 17[k] is that the wedge does not extend beyond the first body or second body in an axial direction at either end of those components. In its analysis of these limitations, Petitioner identifies Palmatier’s piston component 846 as the claimed first body, base component 848 as the claimed second body, and wedge 858 as the claimed wedge. Pet. at 38, 41. In my opinion, Palmatier does not disclose the required axial confinement because the posterior portions of wedge 858 extend beyond the posterior ends of both piston component 846 and base component 848 when implant 840 is collapsed or partially collapsed, and therefore does not remain axially confined within a space defined by the piston component 846 and base component 848. Ex. 1057, Figs. 25, 26, 28.

61. Palmatier explains that screw 892 axially translates wedge 858 relative to piston component 846 and base component 848. Ex. 1057 at 18:42–45. During expansion, wedge 858 translates towards toward the anterior end of the implant, with its angled surfaces engaging with corresponding surface of the piston, causing the piston to pivot about the hinge to an expended state. *Id.* Figs. 24-26. Palmatier also describes the use of pin structures to cause the piston component 846 to return to a collapsed configuration when the screw is retracted. *Id.* at 18:53–19:11. Thus, Figure 26 depicts the relative axial positions of wedge 858, piston component 846, and base component 848 of implant 840 in the collapsed configuration.

62. Figure 26 is a longitudinal cross-sectional view of collapsed implant 840. Because of the location of the section plane and the overlap of screw 892 with wedge 858, Figure 26 does not depict the entire three-dimensional geometry of wedge 858. It nevertheless shows posterior portions of wedge 858 behind screw 892 and extending beyond the posterior ends of piston component 846 and base component 848.



Ex. 1057, Fig. 26 (annotated).

63. Figure 28 provides a perspective view of wedge 858 apart from the surrounding piston and base components. Palmatier illustrates wedge 858 as a single, unitary component comprising longitudinally extending posterior portions, the same posterior portions that are partially obscured in the cross-sectional view of Figure 26. Comparing the two figures confirms that the structures visible behind screw 892 in Figure 26 are portions of wedge 858.

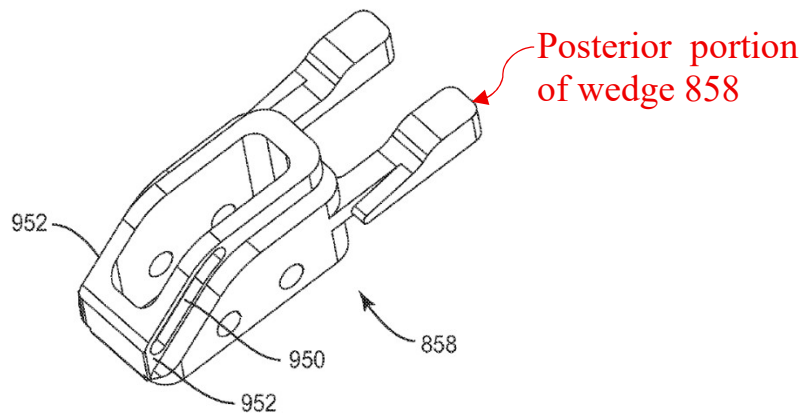


FIG. 28

Id., Fig. 28 (Annotated). It is clear from these figures that when implant 840 is in its collapsed configuration (with the wedge in its first wedge position), posterior portions of wedge 858 extend outside of the space defined by the piston component 846 (which Petitioner maps to the claimed first body) and the base component 848 (which Petitioner maps to the claimed second body). The same is true in the partially collapsed configuration shown in Figure 25. Wedge 858 therefore does not remain axially confined within the space defined by the first body and second body in both

compressed and expanded configurations for limitation 8[h] and in first and second wedge positions for limitation 17[k].

64. I understand that Mr. Culbert agreed that Figure 26 shows wedge 858 “extending beyond the posterior ends of the base and piston in the unexpanded state.” Ex. 2068 at 41:15–20. I understand that he further agreed that wedge 858 continues to extend beyond those ends in the partially expanded state shown in Figure 25. *Id.* at 41:21–42:2. I understand that Mr. Culbert also agreed that, in the collapsed configurations of Palmatier’s implants 40 and 540, their respective wedges extend posteriorly beyond the piston and base components as well. *Id.* at 27:13–29:2, 32:18–33:7. Thus, in all of Palmatier’s implants, the wedge fails to remain in a space defined by first and second bodies of the implant.

65. In my opinion, wedge 858 does not remain axially confined within the space defined by piston component 846 and base component 848 when its posterior portions extend beyond the posterior ends of both components. Because Palmatier explicitly depicts that relationship in the collapsed configuration shown in Figure 26, Palmatier does not disclose the axial confinement required by limitations 8[h] and 17[k] in both recited configurations or wedge positions.

66. Accordingly, it is my opinion that Palmatier fails to anticipate or render obvious independent claims 8 and 17.

B. Palmatier Fails to Teach or Suggest Claims 9, 13, and 21

67. Claims 9 and 13 depend from claim 8. Claim 21 depends from claim 17. Because claims 9, 13, and 21 depend from independent claims that Palmatier fails to anticipate or render obvious, Palmatier necessarily fails to anticipate or render obvious claims 9, 13, and 21 for the same reasons I explained above.

C. Palmatier Fails to Teach or Suggest Claims 18-20

1. Claim 18

68. Claim 18 depends from independent claim 17. Because claim 18 depends from claim 17, Palmatier necessarily fails to anticipate or render obvious claim 18 for the same reasons. Palmatier also fails to anticipate or render obvious claim 18 for the additional reasons I explain below.

a. Palmatier fails to teach or suggest limitation 18[a]: “[t]he expandable intervertebral device of claim 17, wherein a first length of the first body from the first end to the second end is substantially equal to a second length of the second body from the third end to the fourth end.”

69. Petitioner argues that “Palmatier discloses and renders obvious this limitation.” Pet. at 56. To support its allegation of that Palmatier discloses “wherein a first length of the first body from the first end to the second end is substantially equal to a second length of the second body from the third end to the fourth end,” Petitioner points to the length of the bodies for implants 40 and 540, rather than implant 840 which it relies upon for the other claimed features of claims 17 and 18.

Pet. at 43-56. Petitioner does this because implant 840 does not include first and second bodies being substantially equal in length.

70. Implants 40, 540, and 840 are distinct embodiments. First, each implant has a different wedge design. *Compare* Ex. 1057, Figs. 7, 19, 28. Notably, wedge 58 has a single anterior ramp 114 and is dimensioned to fill the entire width of implant 40, whereas wedge 858 has multiple anterior ramps and is dimensioned to be disposed within the implants. *Id.*; *see also id.* Figs. 22-23 (illustrating wedge 858 within implant 840).

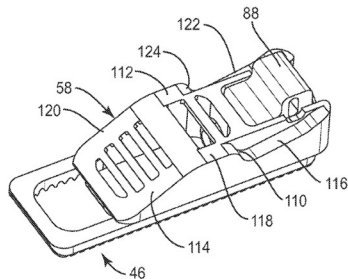


FIG. 7

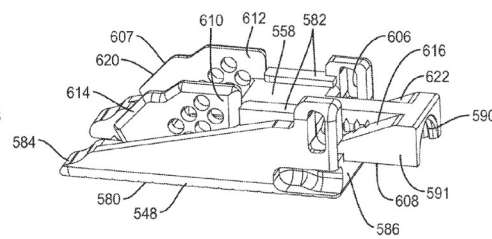


FIG. 19

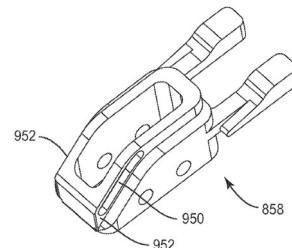


FIG. 28

71. Second, implants 40 and 540 have a top portion that rests on top of a bottom portion, whereas implant 840 has a top portion that nests into its bottom portion. *Compare id.* Figs. 12, 17, 27. For its nesting configuration, Palmatier describes a pin and link/channel connection between wedge and piston, not found in any other embodiment. *Id.* Figs. 24-28.

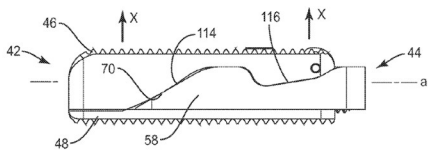


FIG. 12

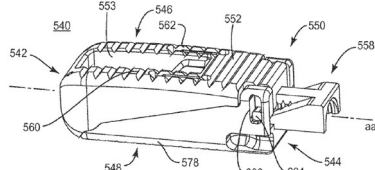


FIG. 17

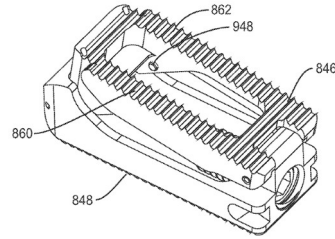


FIG. 27

72. Third, the base component of implant 40 does not include sidewalls, whereas the base components of implant 540 has sidewalls that are tapered so that they decrease in size moving towards the anterior direction, and implant 840 has full sidewalls along its entire sides. Ex. 2068, 23:17-22, 30:22-31:2, 35:24-36:3. As shown by Figure 19, due to the tapering the sidewall of base component 548 effectively terminates at anterior end 584 such that there is no longer a sidewall at the end portion of the anterior end.

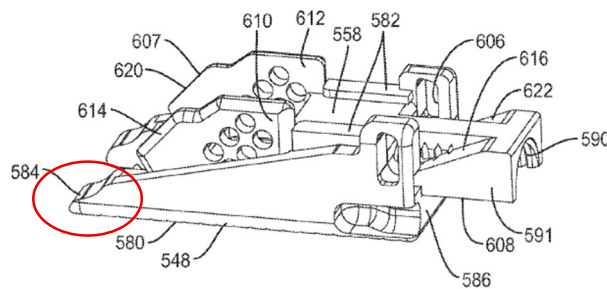


FIG. 19

Ex. 1057, Fig. 19 (Annotated)

73. Fourth, base components 48 and 548 of implants 40 and 540, respectively, do not include an anterior wall or other structure extending upward from their planar inner surfaces, whereas base component 848 of implant 840 includes a wedge-shaped anterior end 884. *Id.* at 24:17-20, 31:24-32:2

74. Fifth, as I explained above, the lengths of the top and bottom portions of implant 840 are not substantially equal in length. Petitioner acknowledges this length difference. Pet at 50 (“In contrast, in implant 840, the base and piston components have different lengths”). This is also shown in Palmatier’s Figure 22.

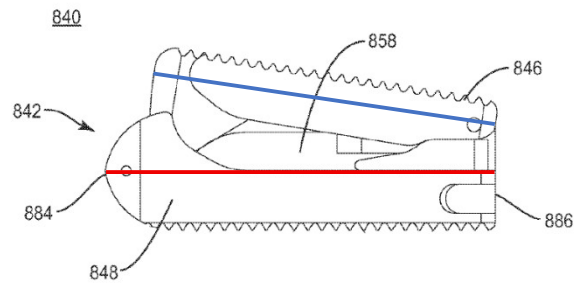


FIG. 22

Id. Fig. 22 (annotated). And even if the lengths of the top and bottom bodies of implant 40 were substantially equal in length, the lengths of the top and bottom bodies of implant 540 are not substantially equal. This is clearly shown in Palmatier’s Figure 17.

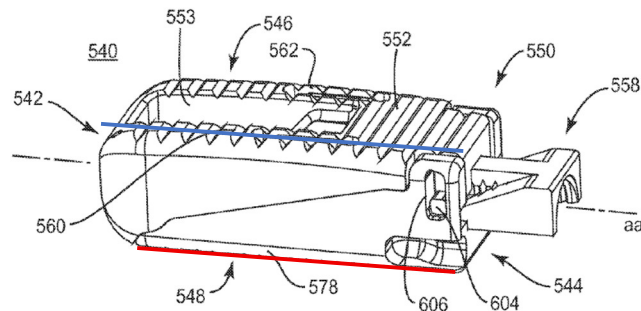
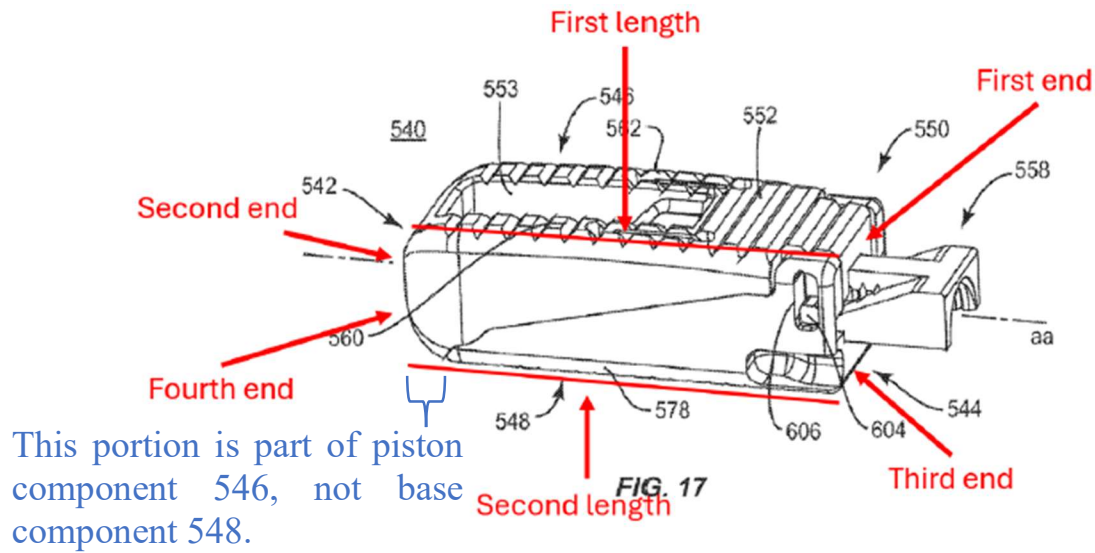


FIG. 17

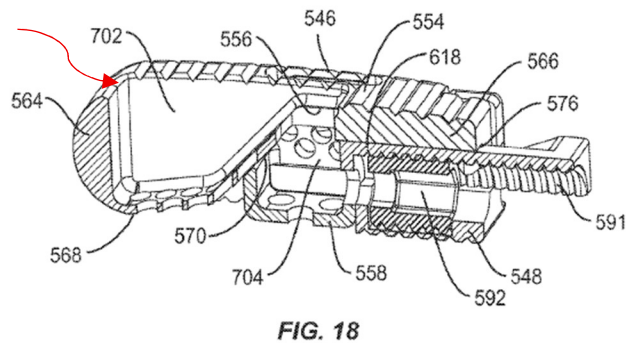
Id. Fig. 17 (annotated). I note that Petitioner draws its line for base component 548 beyond its actual footprint to include part of piston component 546 to allege the two bodies are substantially equal in length.



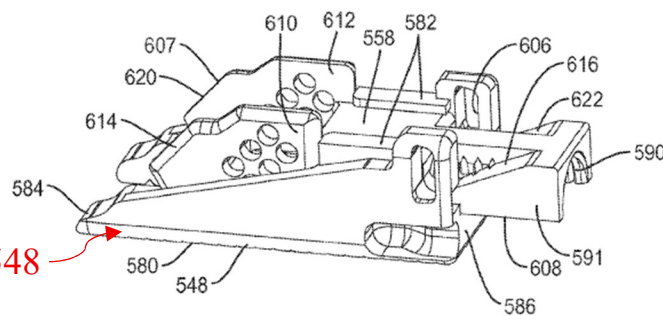
(Ex. 1057, Figs. 3, 17 (annotated).)

Pet. 57 (my annotations are added in blue). Figures 18-19 confirm the respective boundaries of piston component 546 and base component 548.

Piston component 546



Base component 548



Ex. 1057, Figs. 18-19 (Annotated)

75. These key differences make each of implant 40, 540, and 840 distinct embodiments. 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. Palmatier does not disclose the elements of claim 18 (which includes the features of independent claim 17) arranged or combined as they are in the claim.

76. I understand Petitioner does not contend that Palmatier anticipates claim 18. I agree it does not anticipate claim 18 because Petitioner relies on the implant 840 embodiment for claim 17 and then turns to other distinct embodiments for the additional features of claim 18.

77. It is also my opinion that Palmatier does not render claim 18 obvious. For claim 18, Petitioner relies on its obviousness arguments for limitation 17[f]. Pet. 56. Petitioner asserts “a POSITA would have found it obvious to extend the second end of the piston component such that its ends line up like in implants 40 and 540. Pet. 56–57. I disagree. As explained above, Petitioner misidentifies a portion of piston component 546 in Figure 17 to make piston component 546 and base component 548 appear substantially equal in length. But Figure 17 shows those

components are not substantially equal in length. In addition, a POSA would not have been motivated to modify implant 840 in the manner Petitioner proposes. To the contrary, Palmatier's teachings concerning the function of the anterior wedge-shaped end 548 as well as implant 840's structure and operation would have discouraged that modification.

78. Petitioner's statement that implant 840's nesting "arrangement could have been maintained while extending anterior end of the piston component 846 to align with the anterior end of the base component 848" (Pet. at 52) is incorrect. As Figures 24–26 show, piston component 846 moves downward into a collapsed position. But if the piston component 846 was extended in length it could not collapse into the wedge-shaped anterior end 884 because that wedge would mechanically block it from doing so. Accordingly, Petitioner's proposal to extend piston component 846 would render the implant non-functional.

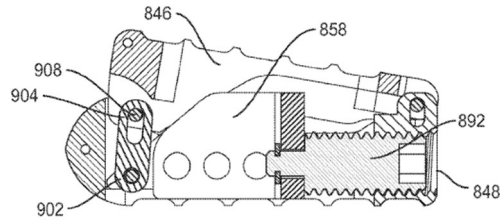


FIG. 24

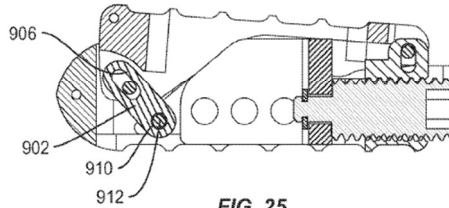


FIG. 25

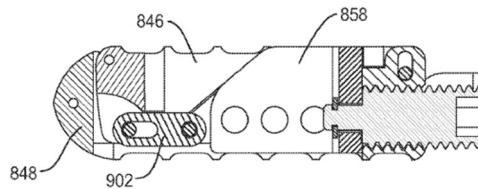


FIG. 26

79. Petitioner provides no explanation to address this conflict created by its own proposed piston component extension. Petitioner's reliance on implants 40 and 540 does not resolve these problems. Those embodiments have different designs. They lack implant 840's wedge-shaped anterior end 884, the nesting arrangement between the piston and base components, and have different sidewalls on both the piston and base component. The fact that components of implant 40 may terminate at approximately the same longitudinal position does not establish that piston component 846 of implant 840 could be extended while preserving implant 840's protective anterior structure, nesting arrangement, and collapsibility. Petitioner's

citation to Palmatier’s general statement that “various modifications may be made” likewise does not explain how the particular proposed modification could be implemented successfully.

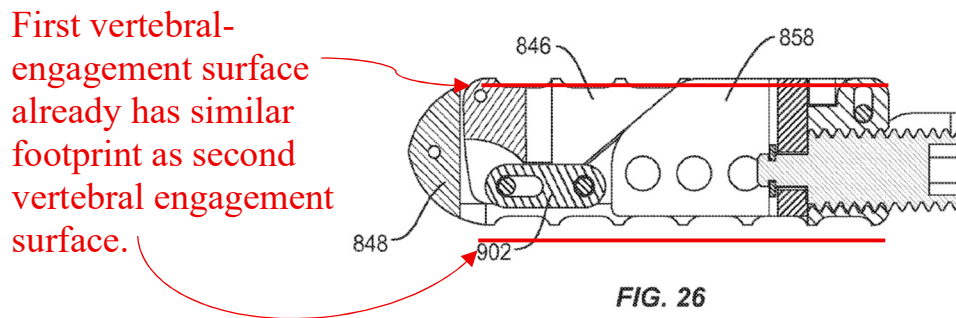
80. Petitioner’s proposed extension cannot be made while preserving the illustrated structure and operation of implant 840. The details illustrated in Figures 24–26 reinforce this conclusion. Wedge-shaped anterior end 884 is illustrated with cross-hatching. A POSITA would have understood that cross-hatching to indicate a solid material rather than an open space into which piston component 846 could extend. A POSITA would have understood that this prevents the extension of piston component 846. Doing so would require removing or redesigning the solid wedge-shaped anterior end 884, and likely the anterior end of piston component 846—not merely making piston component 846 longer as Petitioner proposes.

81. A POSITA would not have been motivated to remove or redesign a portion of the wedge-shaped anterior end 884. Palmatier explains that the forces used to introduce or deliver implant 840 are transmitted to its anterior end. Ex. 1057, 18:48–52. As such, Palmatier explains that base component 848 and wedge shaped anterior end 884 “protect[] wedge 858 and screw 892 as intervertebral implant 840 is inserted into an intervertebral disc space.” *Id.* at 18:45–48. A POSITA would have understood from these disclosures and from Figures 22–26 that wedge-shaped anterior end 884 forms a protective structure for implant 840’s internal components.

A POSITA would also appreciate that wedge shaped anterior end 884 would protect patient tissue during insertion. Petitioner's proposed extension, therefore, would trade structural integrity to merely extend the piston component's footprint. A POSITA would not have made that trade.

82. Removing material from wedge-shaped anterior end 884 would reduce the structural integrity of the very structure Palmatier uses to protect wedge 858 and screw 892 during insertion. Palmatier teaches the importance of retaining a protective anterior structure, not removing portions of that structure to lengthen piston component 846. Petitioner does not identify whether or what material would be removed, propose a replacement structure, or explain how a modified anterior end would continue to protect wedge 858 and screw 892 and withstand insertion forces.

83. I also disagree with Petitioner's argument that increasing the "footprint" of piston component 846 would have motivated Petitioner's proposed modification. Pet. at 50–51; Ex. 1002 ¶ 54. Petitioner assumes that because piston component 846 is shorter than base component 848, it necessarily provides a smaller vertebral-engagement footprint. Figures 22 and 23 show otherwise. Although base component 848 extends farther in the anterior direction, that is due to wedge-shaped anterior end 884 for protection. The vertebral-engagement surfaces of piston component 846 and base component 848 have substantially the same footprint.



Ex. 1057, Fig. 26 (annotated). The additional length of base component 848 is attributable to wedge-shaped anterior end 884, which does not provide a corresponding additional ridged vertebral-engagement surface.

84. A POSITA therefore would not have understood the different overall lengths of piston component 846 and base component 848 to mean that implant 840 had materially different upper and lower vertebral-engagement footprints. A POSA would therefore understand that extending piston component 846 to the anterior extremity of base component 848 would achieve the opposite result of what Petitioner proposes, by yielding a device in which the upper vertebral engagement surface is longer than the lower vertebral engagement surface. Implant 840 already provides corresponding upper and lower vertebral-engagement surfaces while using the additional anterior length of base component 848 for a different purpose: forming the wedge-shaped structure that protects wedge 858 and screw 892 during insertion.

Ex. 1057, 18:45–52.

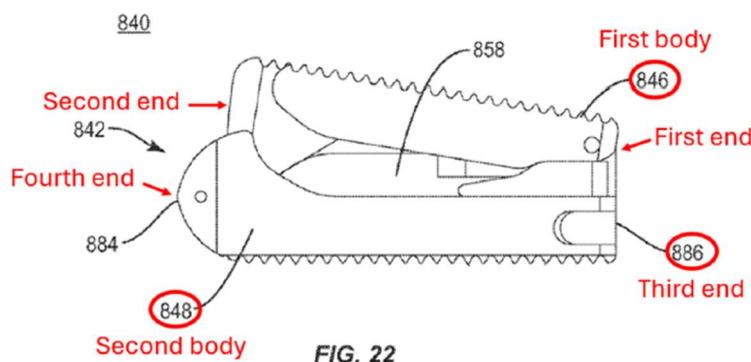
85. I do not dispute that implant footprint can affect biomechanical stability and subsidence. But that general consideration would not have motivated a POSITA to extend one component into space occupied by another component, particularly where the existing vertebral-engagement surfaces already have substantially corresponding footprints. An implant designer would consider footprint together with the implant's geometry, structural integrity, insertion characteristics, and ability to expand and collapse. Petitioner does not explain why a POSITA would sacrifice or redesign the protective anterior structure of implant 840 to obtain an alleged footprint benefit that implant 840's illustrated vertebral-engagement surfaces already provide.

86. For these reasons, a POSITA would not have been motivated to extend piston component 846 as Petitioner proposes. A POSITA also would not have reasonably expected to maintain implant 840's existing arrangement without further redesigning wedge-shaped anterior end 884 and addressing the resulting effects on structural integrity, protection of wedge 858 and screw 892, insertion-force transmission, and collapse of the implant. Petitioner and Mr. Culbert do not address any of those necessary changes or their consequences.

87. Without Petitioner's modification, which a POSITA would not have been motivated to pursue and would not have had a reasonable expectation of success in pursuing, Palmatier fails to teach or suggest limitation 18[a].

- b. Palmatier fails to teach or suggest limitation 18[b]: “wherein the second end portion of the first body is smaller than the fourth end portion of the second body such that the second end portion of the first body is positionable between the third and fourth side portions of the second body at the fourth end of the second body.”*

88. In my opinion, Palmatier does not teach or suggest limitation 18[b]. Petitioner identifies piston component 846 as the claimed first body, base component 848 as the claimed second body, and Palmatier’s wedge-shaped anterior end 884 as the claimed fourth end. Pet. at 23 (“implant 840 includes a piston component 846, which is a ‘first body,’”), 30 (“Palmatier’s implant 840 includes a base component 848, which is a ‘second body.’ ... Palmatier’s base component 848 extends from a posterior end 886, *i.e.*, ‘a third end,’ to an anterior end 884, *i.e.*, ‘a fourth end.’”), 45 (Petitioner labeling the ends of the first and second bodies of Palmatier’s implant 840).



Pet. 45. But Palmatier does not disclose that the portion of piston component 846 identified as the claimed second end portion is positionable between the portions of

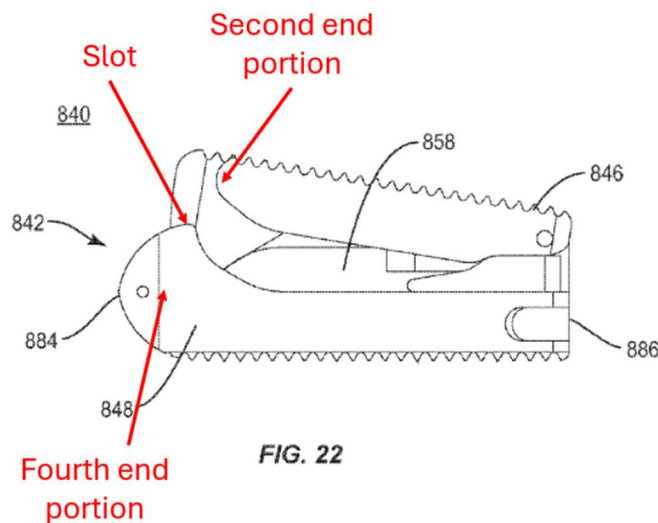
base component 848 identified as the claimed side portions at wedge-shaped anterior end 884. Instead, Figures 22–26 consistently show piston component 846 terminating short of wedge-shaped anterior end 884.

89. Petitioner does not address that spatial deficiency. It asserts that the “anterior end portion” of base component 848 has an opening or slot that receives the anterior end portion of piston component 846. Pet. at 56-57. But claim 18 does not merely require the claimed second end portion to be positioned somewhere within the claimed fourth end portion. It requires the claimed second end portion to be positionable between the claimed side portions “at the fourth end of the second body.”

90. Claims 17 and 18 separately recite a “fourth end” and a “fourth end portion.” I understand that when a claim refers to different terms, those terms are understood to have different meanings. In my opinion, Petitioner cannot satisfy the more specific “at the fourth end” requirement merely by identifying alleged nesting somewhere within the broader region that it labels the fourth end portion.

91. Petitioner’s own mapping confirms the deficiency. Petitioner maps wedge-shaped anterior end 884 to the claimed fourth end. Pet. at 30. Yet its analysis of limitation 18[b] does not identify any portion of piston component 846 positioned at wedge-shaped anterior end 884. Petitioner instead labels a broader region as the claimed fourth end portion and states that an alleged slot within that region receives

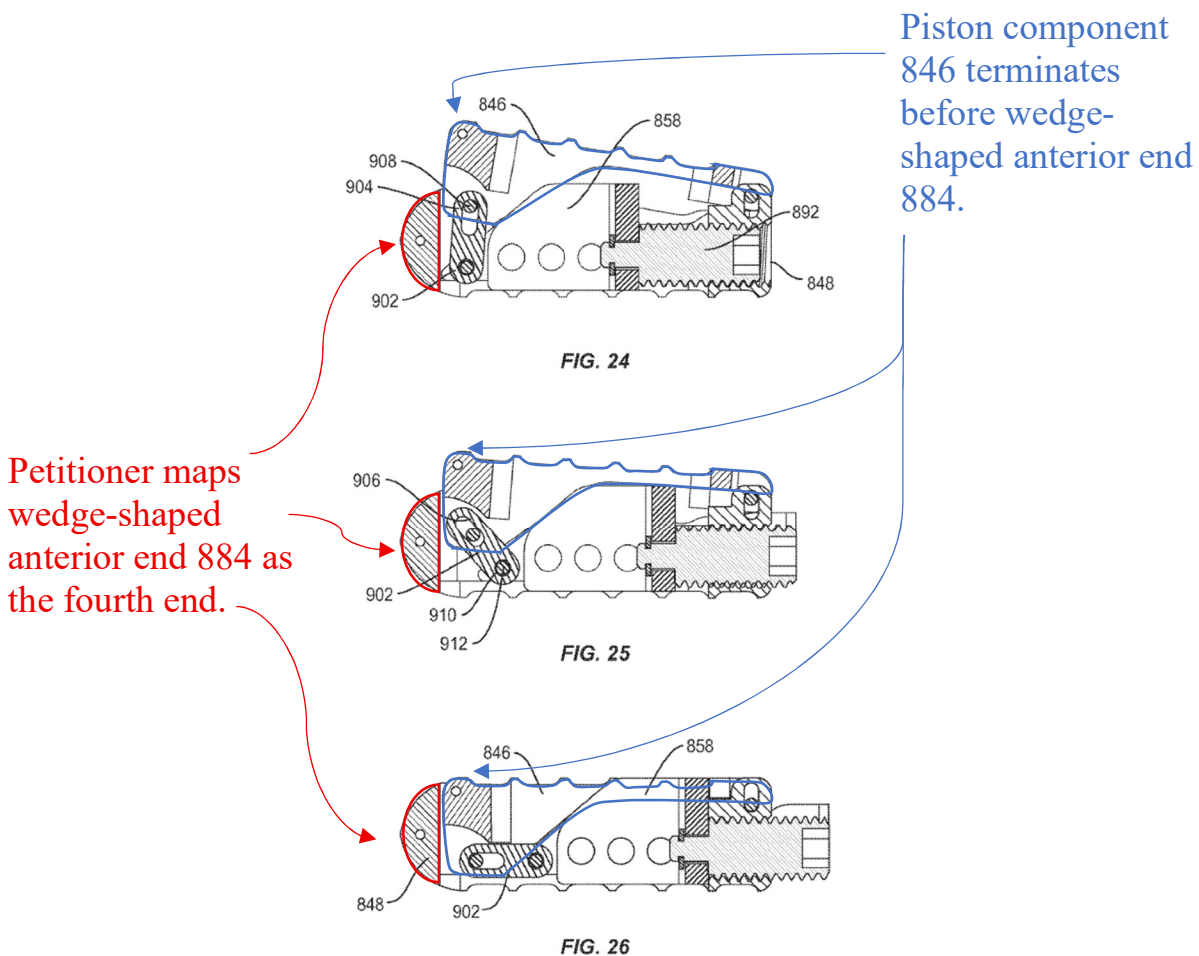
part of piston component 846, as illustrated in Petitioner’s annotation of Palmatier’s Figure 22 reproduced below. Pet. at 58 (referring to Palmatier’s “slot in the fourth end *portion* of the bottom housing that receives the second end portion of the top housing.”); 59 (annotating Palmatier’s Figures 22 and 23 with the label “Fourth end *portion*.”).



Pet. at 59. That does not establish that the anterior end of Palmatier’s piston component 846 (mapped to the claimed second end portion) is positionable between the side portions at the wedge-shaped anterior end 884 (mapped to the claimed fourth end).

92. Palmatier’s disclosure confirms this distinction. In each of Palmatier’s figures illustrating implant 840, piston component 846 stops short of wedge-shaped anterior end 884. Ex. 1057, Figs. 22-27. The same relationship appears even more clearly in the cross-sectional views of Figures 24–26. Palmatier illustrates wedge-

shaped anterior end 884 in cross hatching, which a POSITA would have understood to mean solid material intersected by the cutting plane. In each figure, the cross-hatched structure of wedge-shaped anterior end 884 remains visible and unobstructed by piston component 846. Piston component 846 terminates before (to the right of) wedge-shaped anterior end 884 in both the expanded and compressed configurations.



Ex. 1057, Figs. 24-26 (annotated). Thus, although part of piston component 846 may lie between *portions of base component 848*, Palmatier does not show that any

portion of the piston component 846 is positionable between portions of the base component 848 *at the anterior end 884*.

93. As I explained above, the solid nature of wedge-shaped anterior end 884 would prevent such positioning. Not only does Palmatier illustrate wedge-shaped anterior end 884 with solid cross-hatching in its Figures, Palmatier also describes wedge-shaped anterior end 884 requires structural integrity in order to “protect[] wedge 858 and screw 892 as intervertebral implant 840 is inserted into an intervertebral disc space.” Ex. 1057 at 18:45-48. Indeed, Palmatier further explains that forces used to introduce or deliver implant 840 are transmitted “to an anterior end 842” of the implant. *Id.* at 18:48-52.

94. Petitioner’s separate proposal for limitation 18[a] further confirms the deficiency. For that limitation, Petitioner proposes “extend[ing] the second end of the piston component such that its ends line up like in implants 40 and 540.” Pet. at 56–57. That proposed modification confirms that piston component 846 does not extend to wedge-shaped anterior end 884. Notably, Petitioner does not propose any modifications for its mapping of limitation 18[b]. Petitioner therefore has not established anticipation or articulated an obviousness theory supplying the missing arrangement.

95. Even if Petitioner’s proposed modification for limitation 18[a] were applied to limitation 18[b]—which Petitioner does not suggest—it would not

produce the claimed arrangement. For limitation 18[a], Petitioner proposes extending the anterior end of piston component 846 until it lines up with wedge-shaped anterior end 884. Pet. at 56–57. But, as explained above, Petitioner ignores that the solid wedge-shaped anterior end 884 occupies the space into which piston component 846 would have to extend. Extending piston component 846 as proposed would therefore create interference with wedge-shaped anterior end 884 and prevent piston component 846 from moving into Palmatier’s collapsed configuration. Accommodating the proposed extension would require removing or redesigning wedge-shaped anterior end 884, a redesign that Petitioner does not propose. As I explained above, the structural integrity of wedge-shaped anterior end 884 is important to withstand forces introduced during delivery. Removing material in anterior end 884 is not an arbitrary modification, as it would decrease the structural integrity that Palmatier explains is necessary. Thus, applying Petitioner’s limitation 18[a] theory does not cure the deficiency for limitation 18[b].

96. Accordingly, it is my opinion that Palmatier fails to anticipate or render obvious claim 18.

2. Claims 19 and 20

97. Claim 19 depends from claim 18. Claim 20 depends from claim 19. Because both claim 19 and 20 ultimately depend from claim 18 and because, as I explained above, Palmatier fails to anticipate or render obvious claim 18, Palmatier

necessarily fails to anticipate or render obvious claims 19 and 20 for the same reasons I explained above.

XI. CONCLUSION

98. In view of my explanations above, it is my opinion that Palmatier is not prior art. And, even if Palmatier is prior art, Petitioner has not shown that claims 18-20 of the '367 Patent are unpatentable.

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

100. I declare that all statements made herein of my knowledge are true and correct. I also declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 35 U.S.C. § 1001.

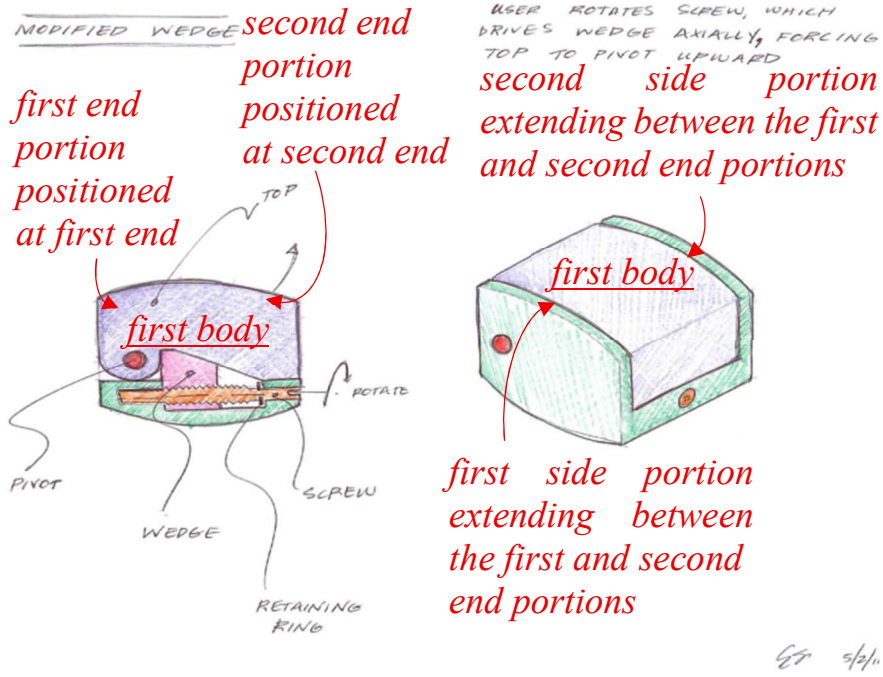
101. I declare under the penalty of perjury that the foregoing is true and correct.

Executed on: August 31, 2026

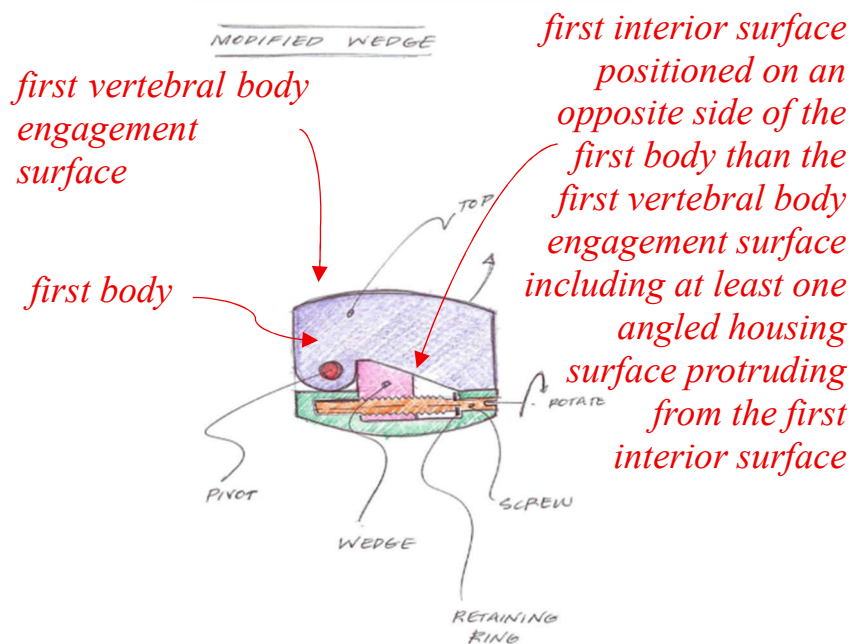


Ken Gall, Ph. D.

XII. APPENDIX A

Claims	Conception Evidence
Claim 8	
8[a]-8[b]: An expandable intervertebral device comprising: a first body extending from a first end to a second end, wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions,	 Ex. 2127 at 10 (Annotated)
	The May 3, 2011 engineering drawings (Ex. 2127) illustrate an expandable intervertebral device having a purple shaded top body (the claimed first body) extending from a first end to a second end. The first and second ends have first and second end portions, respectively. The first body further has first and second side portions extending between the first and second end portions. The intervertebral device depicted above expands by way of a wedge with a screw threaded therethrough. Rotation of the screw would drive wedge axially from a first position to a second position. The contact of the wedge on an interior surface of the first body as it axially translates would cause the second end of the first body to pivot upward about a pin.

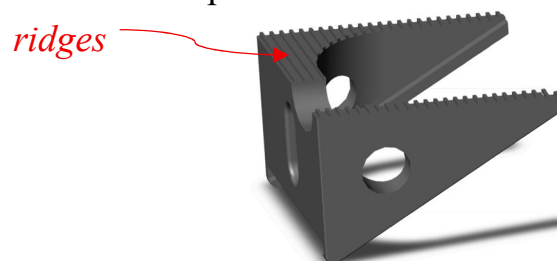
8[c]: wherein the first body has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface comprising a plurality of ridges for interfacing with a vertebral body surface, the first interior surface includes at least one angled housing surface protruding from the first interior surface;



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that the first body's top surface is a vertebral body engagement surface. Opposite the vertebral body engagement surface is an interior surface that includes an angled housing surface protruding therefrom.

Although not illustrated in the May 3, 2011 engineering drawings, the inventors indicated at least as early as April 15, 2011 that a vertebral engagement feature like ridges was needed "to help engage bone." Ex. 2156 at 7, 15, 17; Ex. 2057; Ex. 2029 at 3, 5–7. The inventors included a CAD drawing showing such ridges on the vertebral engagement surface of an implant.



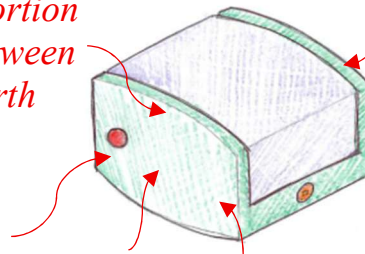
Ex. 2156 at 7 (Annotated)

	And in response to an email attaching the May 3, 2011 engineering drawings, the inventors discussed how “[r]idges will also be placed on the top and bottom surfaces of the fusion wedges to maintain grip while inserted into spinal region.” Ex. 2028 at 2. During the relevant timeframe, ridges were a conventional and well-understood means of increasing engagement with rough or natural surfaces, including adjacent vertebral endplates. A POSITA would have thus understood the vertebral surfaces to have included the discussed ridges on the top and bottom surfaces “to maintain grip.” The absence of explicit illustration of the ridges in an engineering sketch would not have prevented a POSITA from understanding that the inventors contemplated inclusion of a plurality of ridges in the identified vertebral-engagement surfaces. Accordingly, the discussion to include ridges provided sufficient technical direction without requiring explicit illustration. Thus, the contemporaneous record establishes that the inventors had decided to place ridges on the top and bottom vertebral-engagement surfaces of its implant designs circulated on May 3, 2011.
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8[d]: a second body extending from a third end to a fourth end, wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions,

*fourth side portion
extending between
third and fourth
end portions*

*third end
portion
positioned
at third end*



*third side
portion
extending
between third
and fourth end
portions*

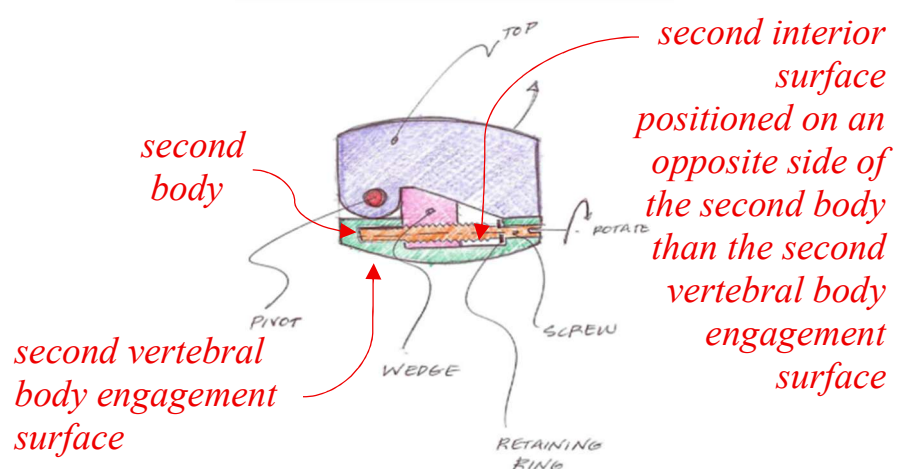
*fourth end portion
positioned at fourth end*

*second
body*

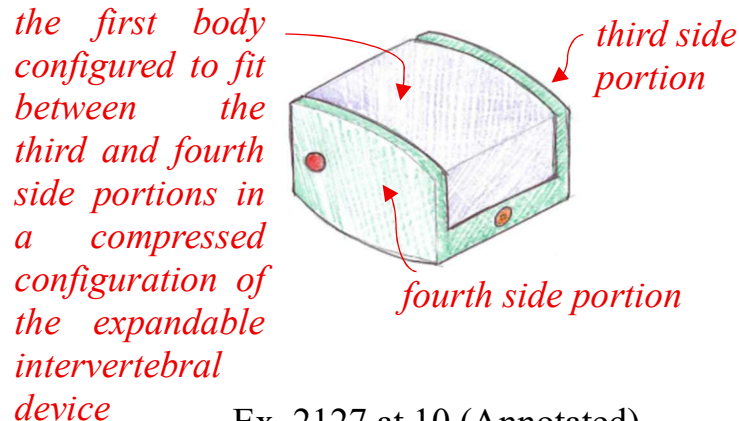
Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate the implant comprising a green shaded bottom body (the claimed second body) extending from a third end to a fourth end. The third and fourth ends have third and fourth end portions, respectively. The bottom body also has third and fourth side portions that extend between the third and fourth end portions.

8[e]: wherein the second body has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface, the first body configured to fit between the third and fourth side portions in a compressed configuration of the expandable intervertebral device; and



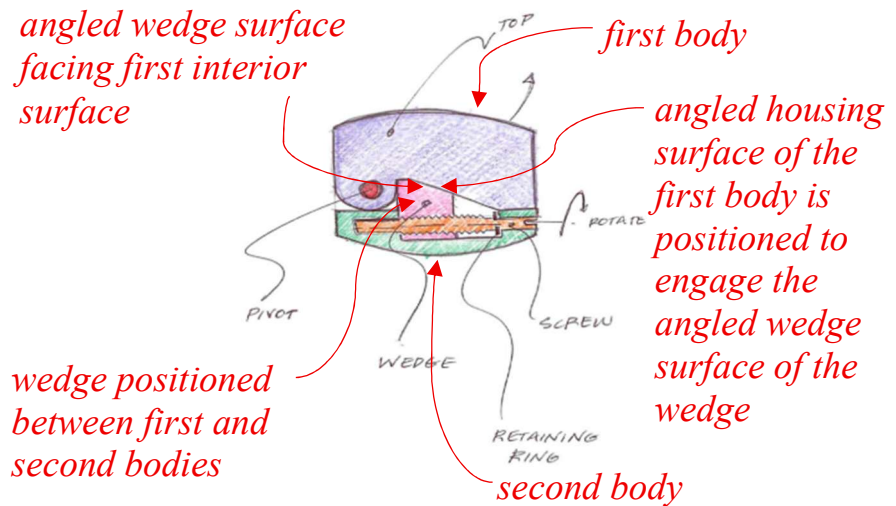
Ex. 2127 at 10 (Annotated)



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that the second body has a vertebral body engagement surface like the first body (but on the bottom) as well as an interior surface on the opposite side of the second body. The engineering drawings also illustrate how the first body (purple) is configured to fit between the third and fourth side portions of the second body (green) in the collapsed configuration.

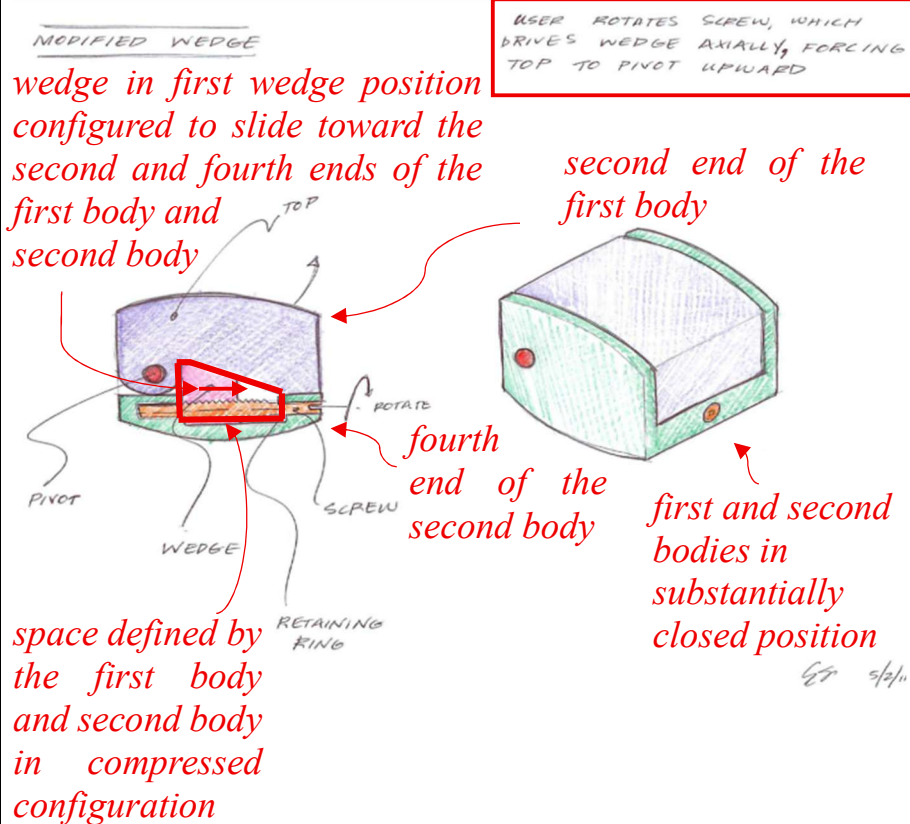
8[f]: a wedge having an angled wedge surface, wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body and the at least one angled housing surface of the first body is positioned to engage the angled wedge surface of the wedge,



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate a wedge (pink) positioned between the first and second bodies. The wedge has an angled surface that is illustrated as facing and engaging the angled housing surface of the interior surface of the first body.

8[g]: wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position in which the first body and the second body are in a substantially closed position to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first body to move the first body relative to the second body from a compressed configuration to an expanded configuration without moving the second body,



Ex. 2127 at 10 (Annotated)

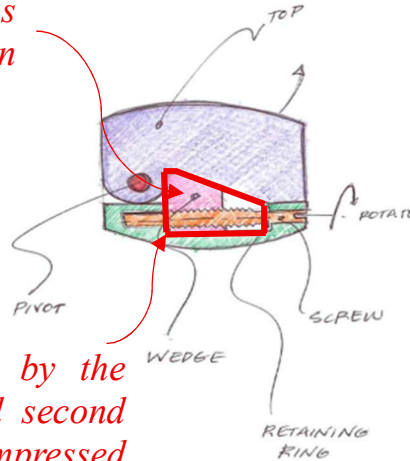
The May 3, 2011 engineering drawings (Ex. 2127) illustrate that the top and bottom bodies define a space in which the wedge is configured to be axially driven toward the second end of the first body and the fourth end of the second body.

While the drawing illustrates the implant is in its compressed (substantially closed) configuration with the wedge in a first position, the upper right corner of the drawing indicates that rotation of a screw drives the wedge axially from the first wedge position to a second wedge position, which in turn forces the top to pivot (via the pin) upwardly and away from the bottom. Because only the top body pivots, a POSITA would have understood that the pivoting would move the implant from the compressed configuration to an expanded configuration without moving the bottom body.

8[h]: whereby the wedge remains axially confined within the space defined by the first body and second body in the compressed and expanded configurations.

wedge remains confined within space

space defined by the first body and second body in compressed configuration



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that wedge is axially confined within the space defined by the first body and the second body due to the wedge having the threaded screw disposed therethrough. Furthermore, the second body illustrates walls on either side of the space that prevents the wedge from axially translating beyond the space. Although only the compressed configuration is shown in the engineering drawing, a POSITA would have understood from the walls and the threaded screw that the wedge remains within the space in the expanded configuration as well as the compressed configuration, although the space would increase slightly in size due to the pivoting of the first body away from the second body in the expanded configuration.

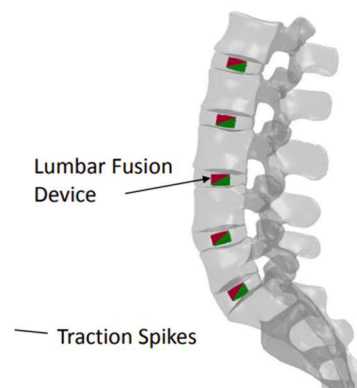
Because each and every element of claim 8 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 8 such that a person of ordinary skill in the art could understand its structure and operation.

Claim 9:

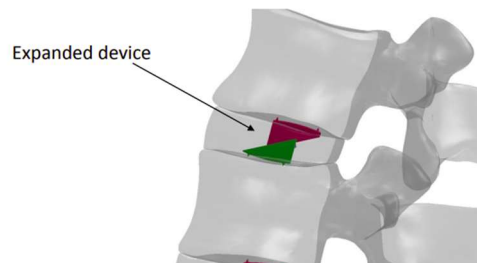
The expandable intervertebral device of claim 8, wherein in the expanded configuration of the expandable intervertebral device the plurality of ridges on the first vertebral body engagement surface are configured to be in contact with the vertebral body surface.

As I explained above for limitation 8[c], the May 3, 2011 engineering drawings and inventor emails indicate the inventors had conceived ridges on the vertebral body engagement surfaces of the expandable intervertebral device of claim 8. *See* limitation 8[c].

The inventors' May 3, 2011 powerpoint (which included the May 3, 2011 engineering drawings) also discussed and showed implants for placement between vertebrae of a human patient in compressed and expanded configurations. Ex. 2127, p. 2, 6.



Ex. 2127, p. 2



Ex. 2127, p. 6

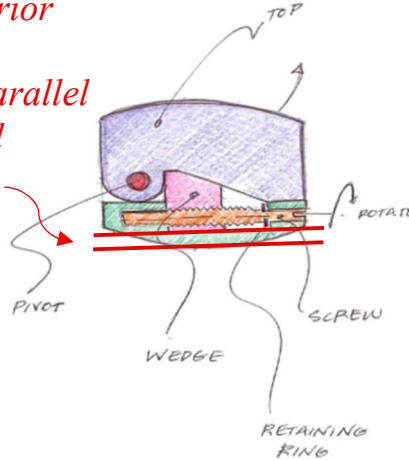
The inventors' May 5, 2011 email also discusses maintaining "grip when inserted into spinal region." Ex. 2028, p. 1. A POSITA would have understood based on these images and emails that the inventors conceived that, in the expanded configuration of the expandable intervertebral device, the plurality of ridges on the first vertebral body engagement surface would be configured to be in contact with the vertebral body surface.

	Because each and every element of claim 9 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 9 such that a person of ordinary skill in the art could understand its structure and operation.
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Claim 13

The expandable intervertebral device of claim 8 wherein the second interior surface is substantially parallel with the second vertebral body engagement surface such that the wedge is configured to move along a path parallel to the second vertebral body engagement surface when the wedge slides within the space against the second interior surface.

the second interior surface is substantially parallel with the second vertebral body engagement surface



Ex. 2127 at 10 (Annotated)

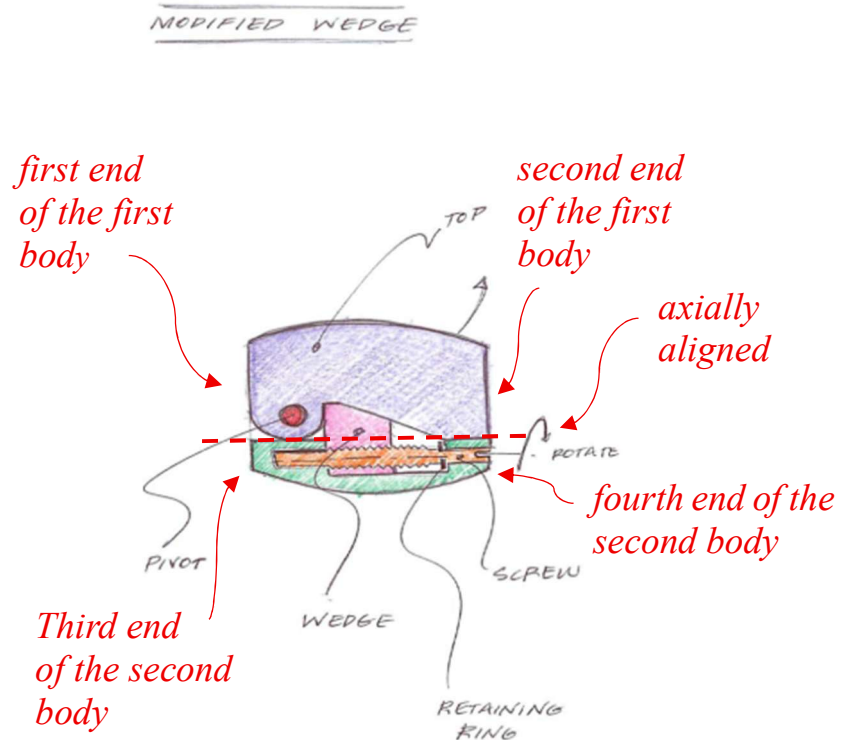
The May 3, 2011 engineering drawings illustrate that the second interior surface is substantially parallel with the second vertebral body engagement surface. Both surfaces extend in the same general longitudinal direction from the third end toward the fourth end. Although the bottom surface has a gradual arcuate contour, “substantially parallel” does not require the surfaces to be perfectly planar, identically shaped, or exactly equidistant at every point. The arcuate contour reflects the exterior surface’s intended anatomical interface with a vertebral body or disc, whereas the interior surface is flat to guide and support movement of the wedge. Viewed as a whole, the bottom surface remains aligned with—and does not extend at a materially different angle from—the interior surface. A POSITA therefore would regard the surfaces as substantially parallel notwithstanding the bottom surface’s modest anatomical curvature.

Because each and every element of claim 13 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 13 such that a person of ordinary skill in the art could understand its structure and operation.

Claim 17	
17[a]-17[c]: An expandable intervertebral device comprising: a first body extending from a first end to a second end wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first body has a first vertebral body engagement surface having a first plurality of ridges formed therein and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface;	<i>See limitations 8[a]-8[c].</i>

17[d]-17[e]: a second body extending from a third end to a fourth end wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second body has a second vertebral body engagement surface having a second plurality of ridges formed therein and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface,	<i>See limitations 8[c]-8[e].</i>
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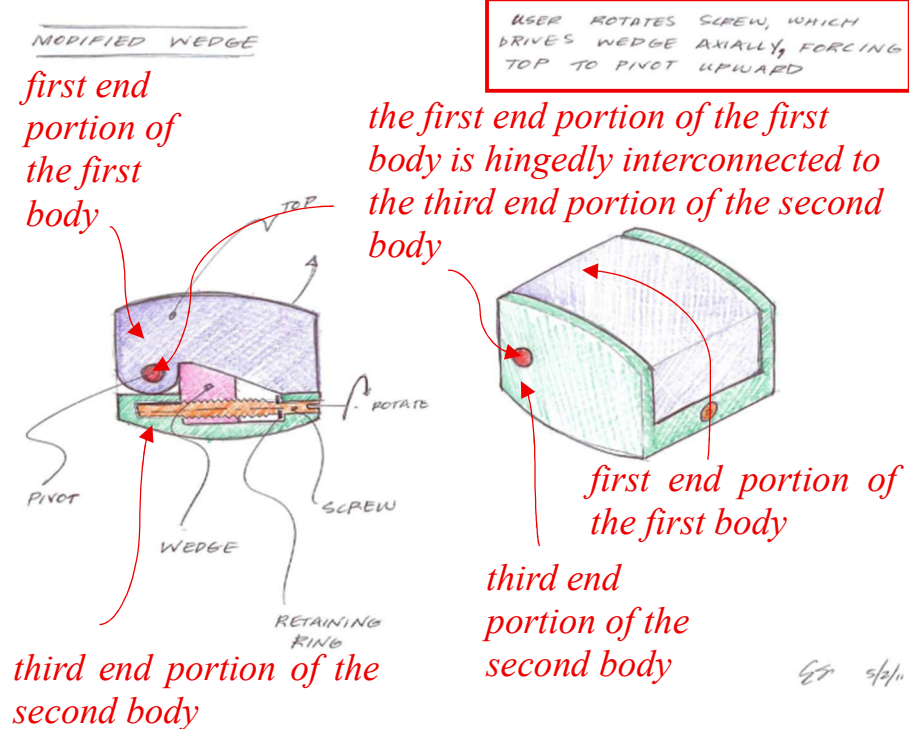
17[f]: wherein the first body is aligned with the second body such that the first end of the first body is axially aligned with the third end of the second body and the second end of the first body is axially aligned with the fourth end of the second body,



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that the respective ends of the first and second body are aligned along the longitudinal axis of the implant, such that the first end of the first body is axially aligned with the third end of the second body and the second end of the first body is axially aligned with the fourth end of the second body.

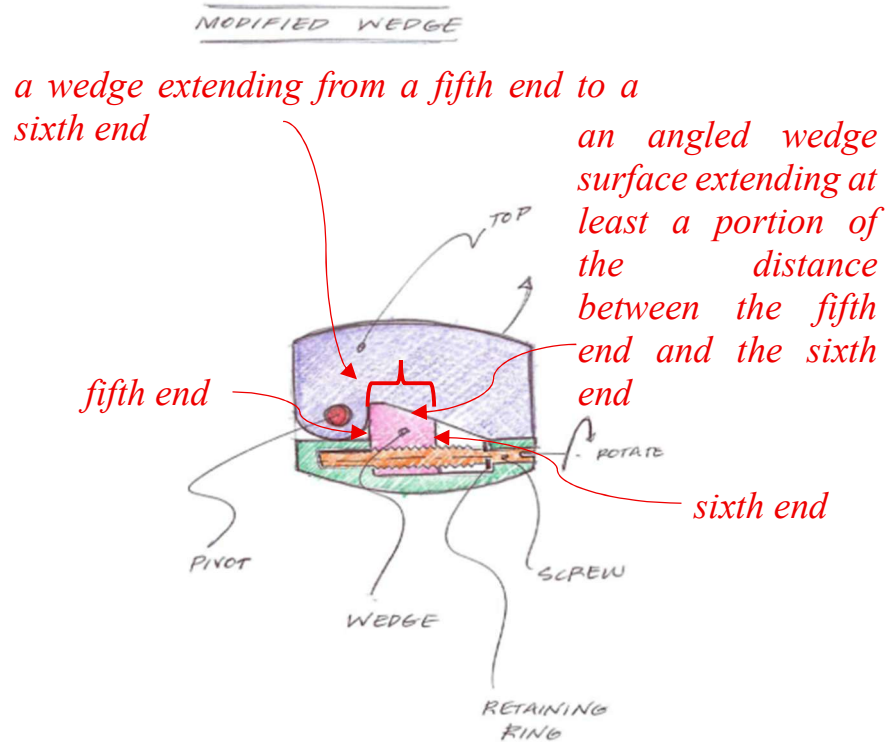
17[g]: wherein the first end portion of the first body and the third end portion of the second body are hingedly interconnected such that the first body can pivot with respect to the second body so as to move the second end portion of the first body away from the fourth end portion of the second body; and



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that the first end portion of the first body is hingedly attached to the third end portion of the third body via one or more pins. P are shown in both the perspective view as well as the cross section view detailing the interconnection between the first and second bodies. As I explained above, the engineering drawings included textual explanation that the top body pivots upward and away from the bottom body. Because the second end portion of the first body is opposite the first end portion of the first body, and because the fourth end portion of the second body is opposite the third end portion of the second body, a POSITA would understand that the second end portion of the first body moves upward and away from the fourth end portion of the second body during expansion.

17[h] a wedge extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end,



Ex. 2127 at 10 (Annotated)

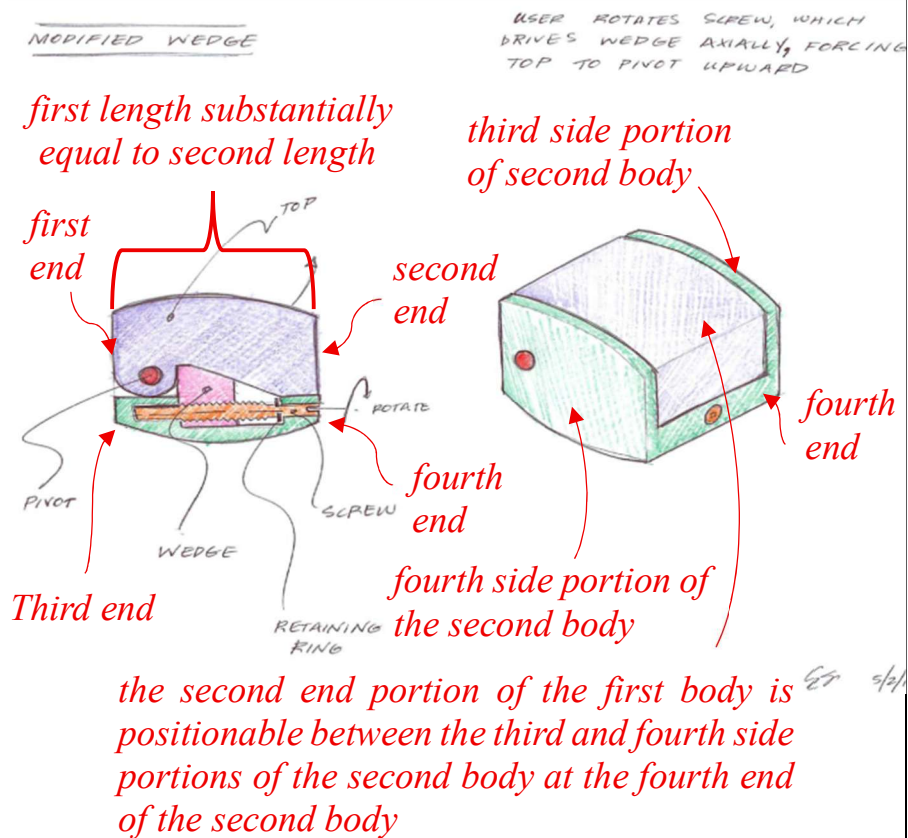
The May 3, 2011 engineering drawings illustrate that the wedge extends from a fifth end to a sixth end, with a portion of that distance including the angled wedge surface. See also limitation 8[f].

17[i]-17[k]: wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body, wherein the first interior surface of the first body has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position that allows the first body and second body to pivot to a position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of	<i>See</i> limitations 8[f]-8[h]. Because each and every element of claim 17 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 17 such that a person of ordinary skill in the art could understand its structure and operation.
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the first body to hingedly open the first body with respect to the second body whereby the wedge remains axially confined within the space defined by the first body and second body in the first and second wedge positions.	
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Claim 18

The expandable intervertebral device of claim 17 wherein a first length of the first body from the first end to the second end is substantially equal to a second length of the second body from the third end to the fourth end and wherein the second end portion of the first body is smaller than the fourth end portion of the second body such that the second end portion of the first body is positionable between the third and fourth side portions of the second body at the fourth end of the second body.



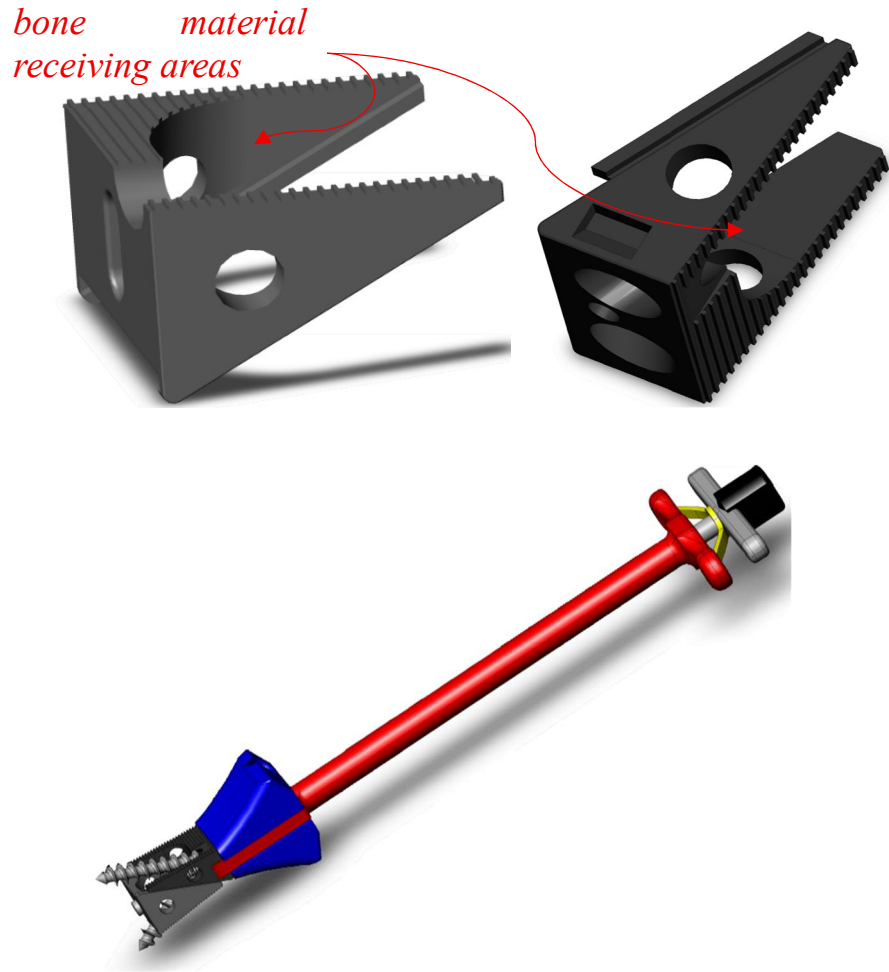
Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that the top and bottom bodies have substantially equal lengths. The engineering drawings also illustrate how the second end portion of the top body is smaller than the fourth end portion of the bottom body, such that the top body nests (e.g., is positionable) between the third and fourth side portions of the bottom body at the fourth end.

Because each and every element of claim 18 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 18 such that a person of ordinary skill in the art could understand its structure and operation.

Claim 19:

The expandable intervertebral device of claim 18 wherein the first body defines a first bone material receiving area between the first and second end portions and the first and second side portions, and the second body defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, and wherein the first bone material receiving area is coupled to the second bone material receiving area when the wedge is in the second wedge position.



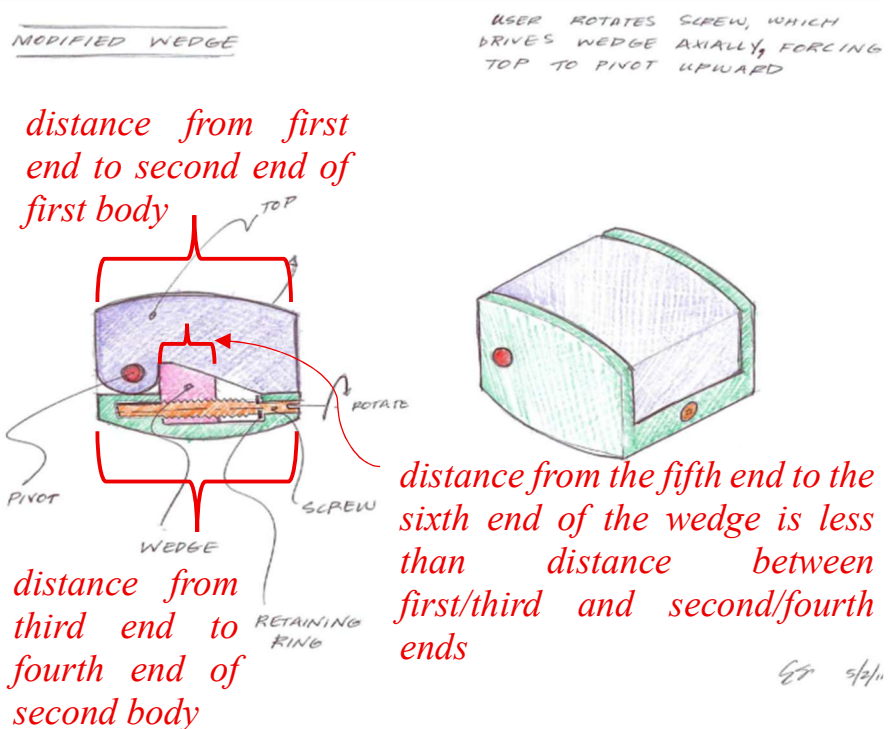
Ex. 2156 at 7, 15, 17 (Annotated)

The April 15, 2011 CAD drawings illustrate bone material receiving areas in top and bottom bodies of an implant within the respective ends and sides of each body. When the top and bottom bodies are connected together (as also shown in the CAD drawings), the two bone material receiving areas would be coupled together. The inventors made clear in their May 18-19, 2011 emails that a “central cavity which can be filled with bone” was in the original design and was important in order “to fuse with the vertebrae above and below thus establishing a biological bridge.” Ex. 2030, p. 2. When Mr. Sugalski circulated e-drawings that did not include these features, Dr. Moskowitz immediately responded about their necessity, indicating that otherwise the device would be rendered “useless.” *Id.*

	A POSITA would have understood from these images and correspondence that the inventors had a definite and permanent understanding that the inventor's implants would include bone material receiving areas in each implant body that would be coupled together to form a central cavity to form a biological bridge between vertebrae above and below the implant. Because each and every element of claim 19 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 19 such that a person of ordinary skill in the art could understand its structure and operation.
Claim 20	

Claim 20:

The expandable intervertebral device of claim 19 wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first body and is less than a distance from the third end to the fourth end of the second body.



Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings illustrate that the wedge is smaller than the top and bottom bodies of the implant.

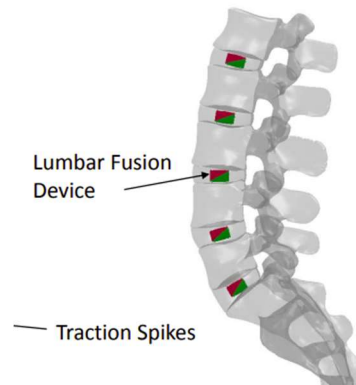
Because each and every element of claim 20 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 20 such that a person of ordinary skill in the art could understand its structure and operation.

Claim 21

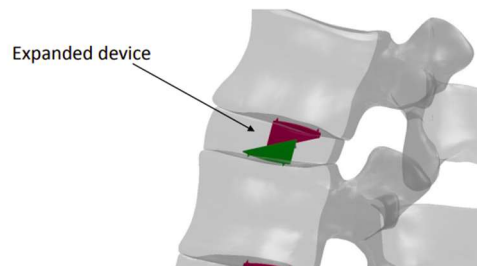
Claim 21:

A method of operating the expandable intervertebral device of claim 17, the method comprising: inserting the expandable intervertebral device in a target surgical location between two vertebrae of a human patient; and

The inventors' May 3, 2011 powerpoint (which included the May 3, 2011 engineering drawings) discuss and show implants for placement between vertebrae of a human patient. Ex. 2127, p. 2, 6.



Ex. 2127, p. 2



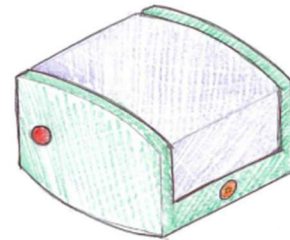
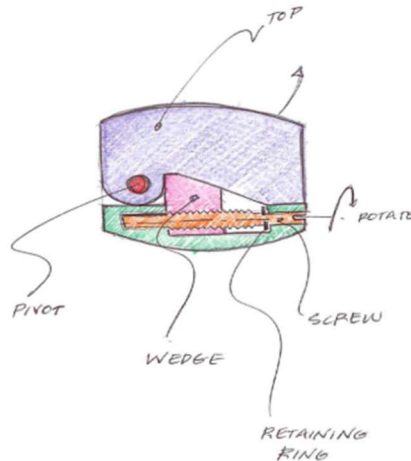
Ex. 2127, p. 6

The inventors' May 5, 2011 email also discusses maintaining "grip when inserted into spinal region." Ex. 2028, p. 1. A POSITA would have understood based on these images that the inventors conceived of inserting their implants into a human patient between two vertebrae.

turning a rotation screw to actuate a movement of the wedge to pivot the first body away from the second body while the device is positioned between the vertebrae of the human patient.

MODIFIED WEDGE

USER ROTATES SCREW, WHICH
DRIVES WEDGE AXIALLY, FORCING
TOP TO PIVOT UPWARD



GT 5/2/11

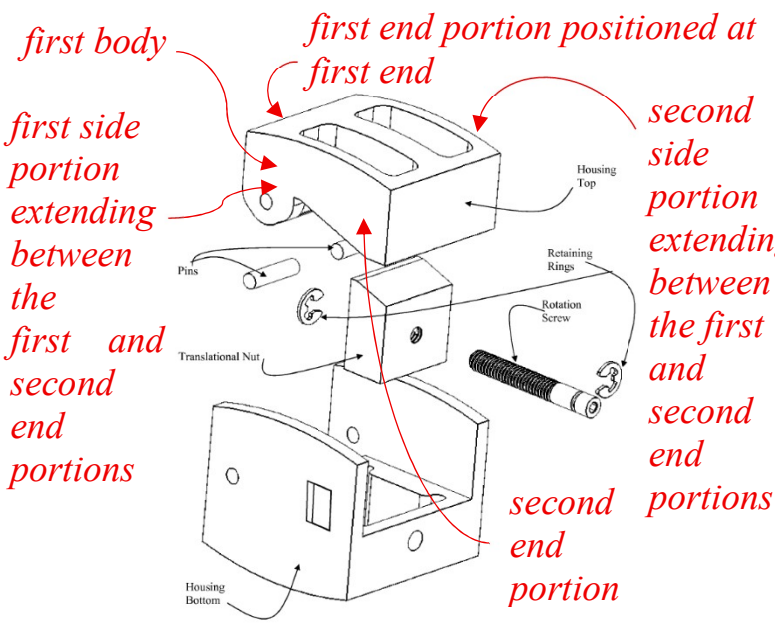
Ex. 2127 at 10 (Annotated)

The May 3, 2011 engineering drawings describe in the upper right corner of the annotated image above that a “user rotates screw, which drives wedge axially, forcing top to pivot upward.” A POSITA would have understood that once the illustrated device was positioned between vertebrae, as discussed above, rotation of the screw drives the wedge to pivot the upper body away from the second body to expand the implant in place.

Because each and every element of claim 21 was illustrated or discussed by the inventors by May 18, 2011, it is my opinion that the inventors had formed a definite and permanent understanding of claim 21 such that a person of ordinary skill in the art could understand its structure and operation.

XIII. APPENDIX B

Claims	U.S. Provisional App. No. 61/718,707 Support:
Claim 8	
8[a]-8[b]: An expandable intervertebral device comprising: a first body extending from a first end to a second end, wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions,	The October 25, 2012 provisional application formalized the May 2011 engineering drawings and features the inventors conceived as discussed above, thereby showing the inventors constructively reduced those concepts to practice through a provisional patent application filing. For example, Figures 6A-6D depict various renderings of the implant shown in the engineering drawings I referenced above in Appendix A. Ex. 2053, Figs. 6A-6D. Figures 6A-6C illustrate that implant in its compressed configuration (Figure 6A), a partially open configuration (Figure 6B), and a fully expanded configuration (Figure 6C). <i>Id.</i> at Figs. 6A-6C. Figure 6D illustrates an exploded view to show the internal mechanics in three-dimensions. <i>Id.</i> Fig. 6D. These figures ultimately formed Figures 6A-6D in the '367 patent, with numerals replacing the explanatory text found in the provisional figures. Ex. 1001, Figs. 6A-6D. Thus, the provisional figures fully support the corresponding figures in the '367 Patent. At least Figure 6D from the October 2012 provisional application illustrates the intervertebral device from the May 2011 engineering drawings comprising a top body (the claimed first body) extending from a first end to a second end. The first and second ends have first and second end portions, respectively. The first body further has first and second side portions extending between the first and second end portions. The intervertebral device depicted below expands by way of a wedge with a screw threaded therethrough. Rotation of the screw drives wedge axially from a first position to a second position. The contact of the wedge on an interior surface of the first body as it axially translates would cause the second end of the

	first body to pivot upward about one or more pins.  Fig. 6D Ex. 2053, Fig. 6D (annotated).
8[c]: wherein the first body has a first vertebral body engagement surface and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface, the first vertebral body engagement surface comprising a plurality of ridges for interfacing with a vertebral body surface, the first interior surface includes at least one angled housing surface protruding from the first interior surface;	At least Figure 6D from the October 2012 provisional application illustrates that the first body's top surface is a vertebral body engagement surface. Opposite the vertebral body engagement surface is an interior surface that includes an angled housing surface protruding therefrom.

*first vertebral body
engagement
surface comprising a
plurality of
ridges for
interfacing with
a vertebral
body surface*

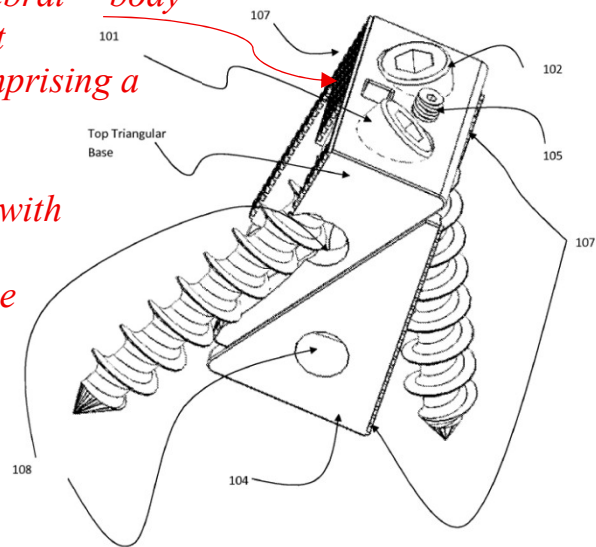


Fig. 1A

Ex. 2053, Fig. 1A (Annotated). The provisional specification also describes how the disclosed implant bodies include ridged external surfaces configured to engage the vertebral bodies. E.g., Ex. 2053, ¶¶ 23, 26 (“The external edges of the housing pieces in contact with vertebral body surfaces include ridges.”).

8[d]: a second body extending from a third end to a fourth end, wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions,

Figure 6D of the provisional illustrates the bottom body (the second body) has third and fourth ends with third and fourth end portions. The bottom body also has third and fourth side portions between the third and fourth end portions.

third end portion positioned at third end

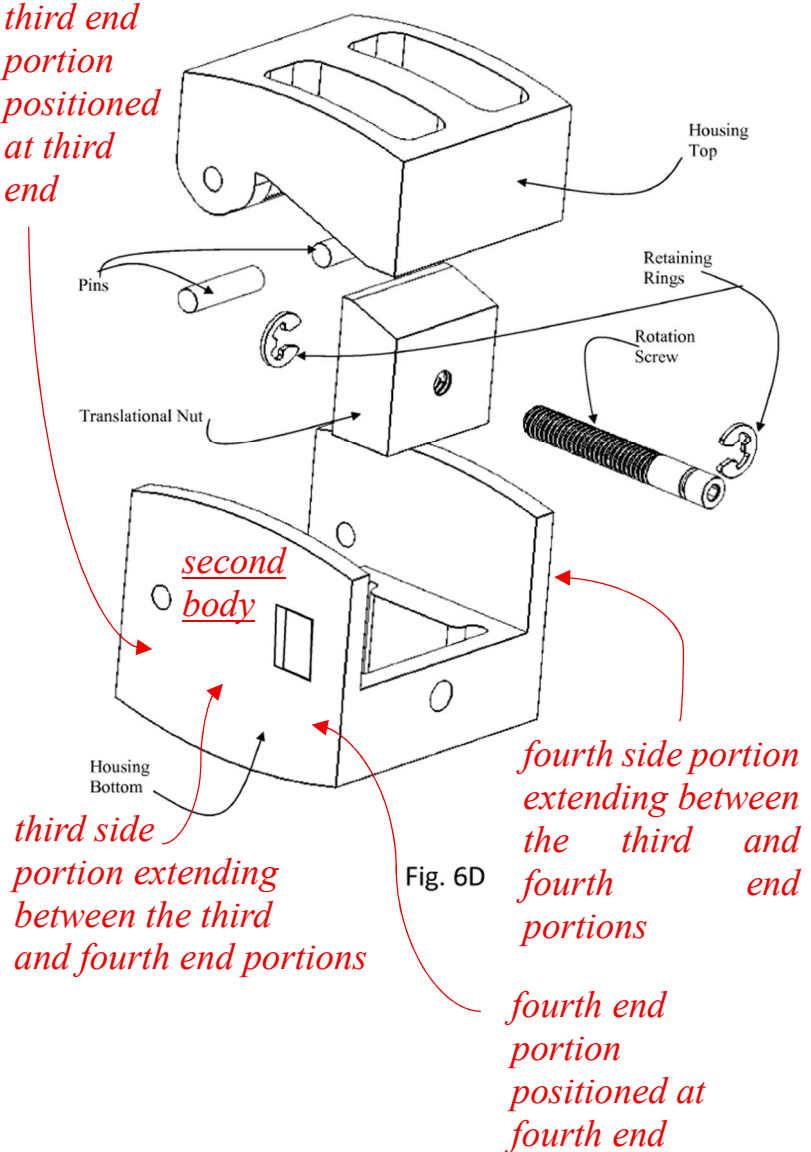
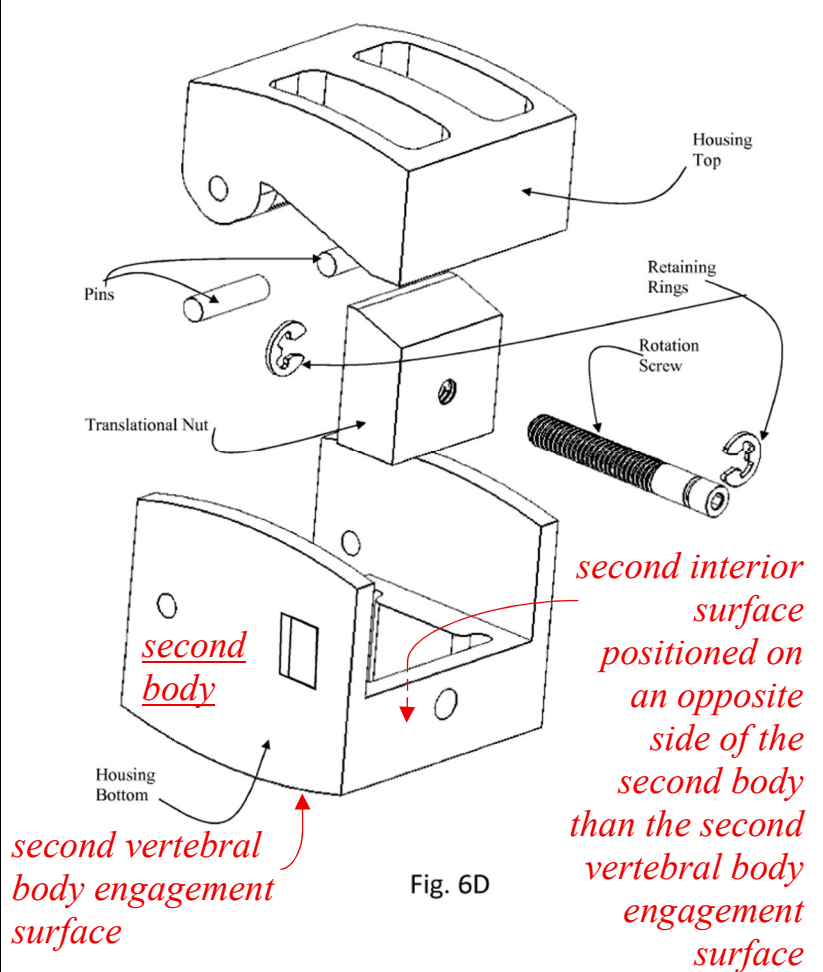


Fig. 6D

Ex. 2053, Fig. 6D (Annotated)

8[e]: wherein the second body has a second vertebral body engagement surface and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface, the first body configured to fit between the third and fourth side portions in a compressed configuration of the expandable intervertebral device; and



Ex. 2053, Fig. 6D (Annotated)

Figure 6D also illustrates that the second body has a vertebral body engagement surface like the first body (but on the bottom) as well as an interior surface on the opposite side of the second body. At least Figure 6A illustrates how the first body is configured to fit between the third and fourth side portions of the second body in the collapsed configuration.

the first body configured to fit between the third and fourth side portions in a compressed configuration of the expandable intervertebral device

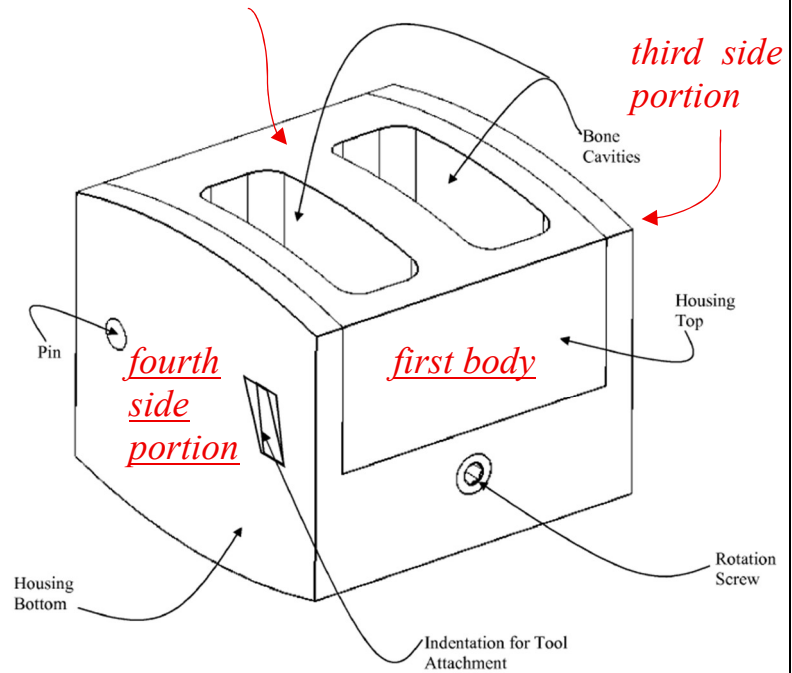


Fig. 6A

Ex. 2053, Fig. 6A (Annotated)

8[f]: a wedge having an angled wedge surface, wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body and the at least one angled housing surface of the first body is positioned to engage the angled wedge surface of the wedge,

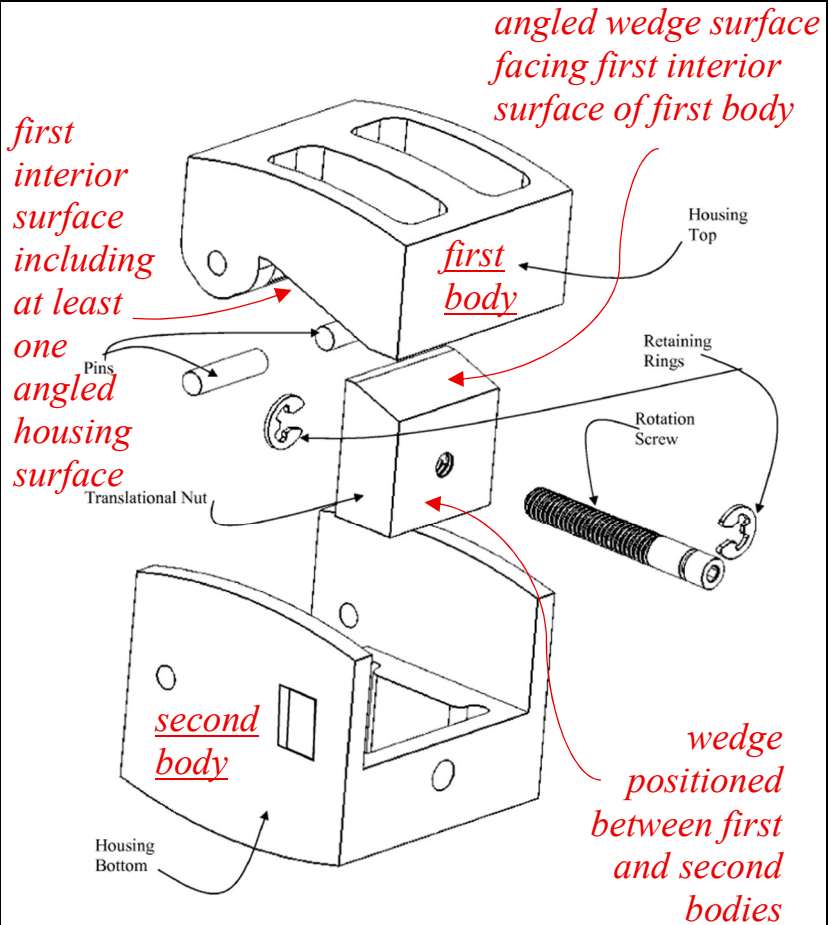


Fig. 6D

Ex. 2053, Fig. 6D (Annotated)

Figure 6D also illustrates the wedge positioned between the first and second bodies. The wedge has an angled surface that is illustrated as facing the angled housing surface of the interior surface of the first body, with the angled housing surface being positioned to engage the angled wedge surface when the components in the exploded view of Figure 6D are combined.

8[g]: wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position in which the first body and the second body are in a substantially closed position to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first body to move the first body relative to the second body from a compressed configuration to an expanded configuration without moving the second body,

Figures 6A-6C illustrate that the top and bottom bodies define a space in which the wedge is configured to be axially driven toward the second end of the first body and the fourth end of the second body. Figure 6A is annotated below to illustrate where a POSITA would understand the first wedge to be located when the bodies are in the substantially closed position. Figure 6C is annotated below to illustrate where a POSITA would understand the second wedge to be located when the top body is moved relative to the bottom body in the expanded configuration (without the bottom body moving). The wedge remains within the space during its axial translation.

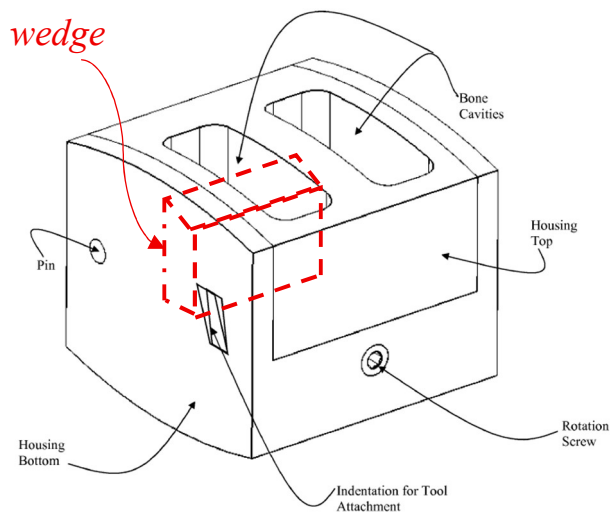
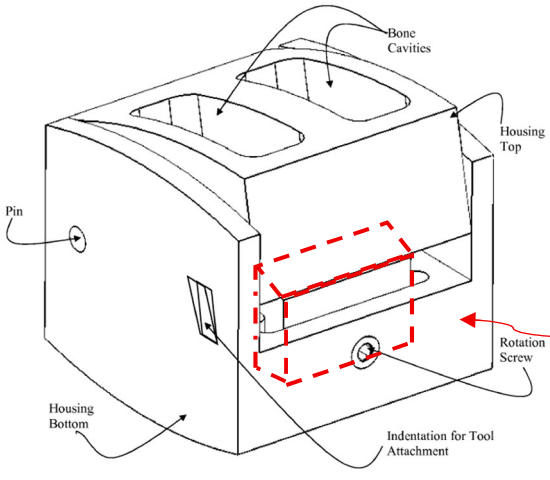


Fig. 6A

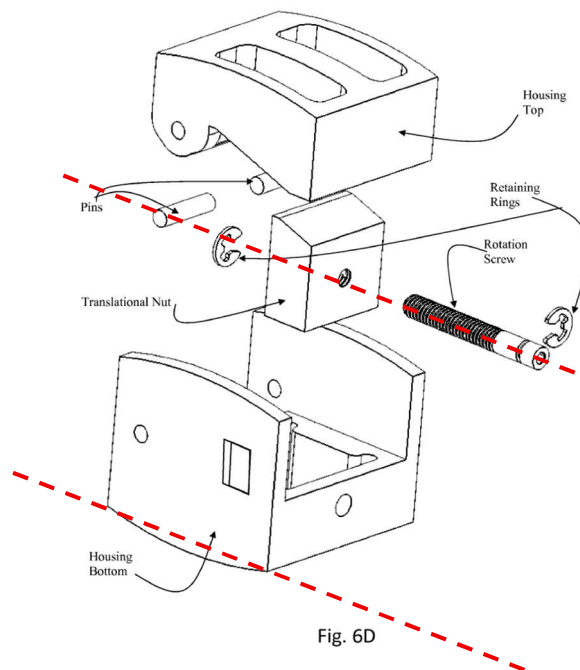
	 Fig. 6C Ex. 2053, Figs. 6A, 6C (Annotated); <i>see also id.</i> ¶¶ 34–35.
8[h]: whereby the wedge remains axially confined within the space defined by the first body and second body in the compressed and expanded configurations.	As I illustrated above for limitation 8[g], a POSITA would understand the wedge remains axially confined within the space defined by the top and bottom bodies in both the compressed and expanded configurations. <i>See</i> limitation 8[g]. Because each and every element of claim 8 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 8 and enabled a person of ordinary skill in the art to make and use it.
Claim 9	

The expandable intervertebral device of claim 8, wherein in the expanded configuration of the expandable intervertebral device the plurality of ridges on the first vertebral body engagement surface are configured to be in contact with the vertebral body surface.	The October 25, 2012 provisional application includes the same disclosures as the May 2011 engineering drawings and inventor emails regarding ridges, thereby showing the inventors constructively reduced those concepts to practice through the provisional filing. For example, the inventors illustrated the ridges in Figures 1A-2D as well as described ridges “in contact with vertebral body surfaces.” Ex. 2053 ¶¶ 23, 26, Figs. 1A-2D. Because these implants were expandable, a POSITA would have understood the ridges would be in contact with the vertebral body surfaces when in the expanded configuration. Ex. 2053 ¶¶ 4, 10, 19. <i>See also</i> Appendix B, limitation 8[c]. Because each and every element of claim 9 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 9 and enabled a person of ordinary skill in the art to make and use it.
Claim 13	

Claim 13:

The expandable intervertebral device of claim 8 wherein the second interior surface is substantially parallel with the second vertebral body engagement surface such that the wedge is configured to move along a path parallel to the second vertebral body engagement surface when the wedge slides within the space against the second interior surface.

The October 25, 2012 provisional application includes the same disclosures as the May 3, 2011 engineering drawings, thereby showing the inventors constructively reduced those drawings to practice through the provisional filing. For example, Figure 6D illustrates how the wedge would be threaded therethrough and would therefore traverse a defined path substantially parallel with the second vertebral body engagement surface. Although not expressly illustrated, a POSITA would have understood that the second interior surface would have to have a substantially parallel surface to allow the wedge, which has a flat bottom, to traverse without interference in a manner I illustrated in the annotated Figures 6A and 6C for limitation 8[g] above.

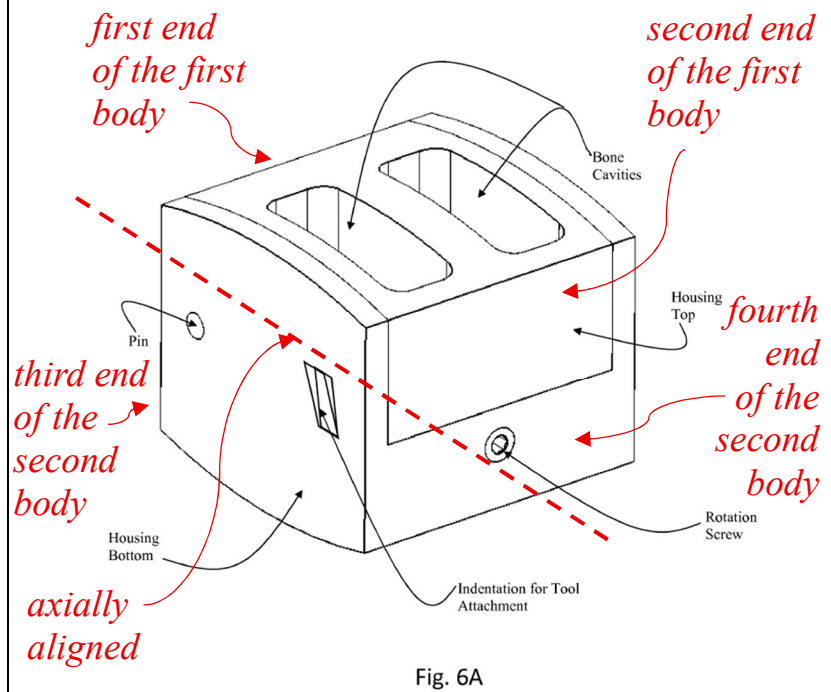


As I explained above, although the bottom surface has a gradual arcuate contour, “substantially parallel” does not require the surfaces to be perfectly planar, identically shaped, or exactly equidistant at every point. The arcuate contour reflects the exterior surface’s intended anatomical interface with a vertebral body or disc. That being said, the bottom surface remains aligned with—and does not extend at

	a materially different angle from—the path of the wedge and thus the interior surface. A POSITA therefore would regard the surfaces as substantially parallel notwithstanding the bottom surface’s modest anatomical curvature. Because each and every element of claim 13 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 13 and enabled a person of ordinary skill in the art to make and use it.
Claim 17	
17[a]-17[c]: An expandable intervertebral device comprising: a first body extending from a first end to a second end wherein the first body has first and second end portions positioned at the first and second ends, respectively, and has first and second side portions extending between the first and second end portions, wherein the first body has a first vertebral body engagement surface having a first plurality of ridges formed therein and has a first interior surface positioned on an opposite side of the first body than the first vertebral body engagement surface;	<i>See limitations 8[a]-8[c].</i>

17[d]-17[e]: a second body extending from a third end to a fourth end wherein the second body has third and fourth end portions positioned at the third and fourth ends, respectively, and has third and fourth side portions extending between the third and fourth end portions, wherein the second body has a second vertebral body engagement surface having a second plurality of ridges formed therein and has a second interior surface positioned on an opposite side of the second body than the second vertebral body engagement surface,	<i>See limitations 8[c]-8[e].</i>
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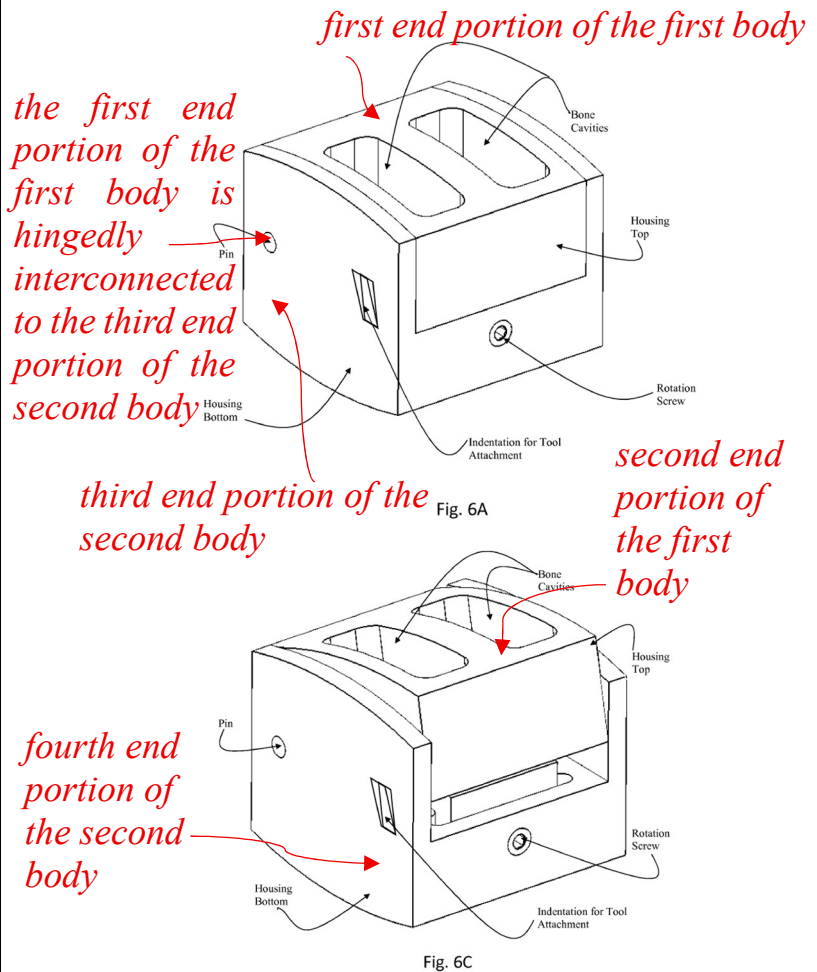
17[f]: wherein the first body is aligned with the second body such that the first end of the first body is axially aligned with the third end of the second body and the second end of the first body is axially aligned with the fourth end of the second body,



Ex. 2053, Fig. 6D (Annotated)

Figure 6D further illustrates that the respective ends of the first and second body are aligned along the longitudinal axis of the implant, such that the first end of the first body is axially aligned with the third end of the second body and the second end of the first body is axially aligned with the fourth end of the second body.

17[g]: wherein the first end portion of the first body and the third end portion of the second body are hingedly interconnected such that the first body can pivot with respect to the second body so as to move the second end portion of the first body away from the fourth end portion of the second body; and



Ex. 2053, Figs. 6A, 6C (Annotated)

Figures 6A and 6C further illustrate that the first end portion of the first body is hingedly attached to the third end portion of the third body via one or more pins. Pins are shown in both the perspective view as well as Figure 6D's exploded view, thereby detailing the interconnection between the first and second bodies. Figure 6C specifically illustrates that the second end of the first body pivots upward and away from the fourth end of the second body.

17[h]: a wedge extending from a fifth end to a sixth end and having an angled wedge surface extending along at least a portion of a distance between the fifth end and the sixth end,

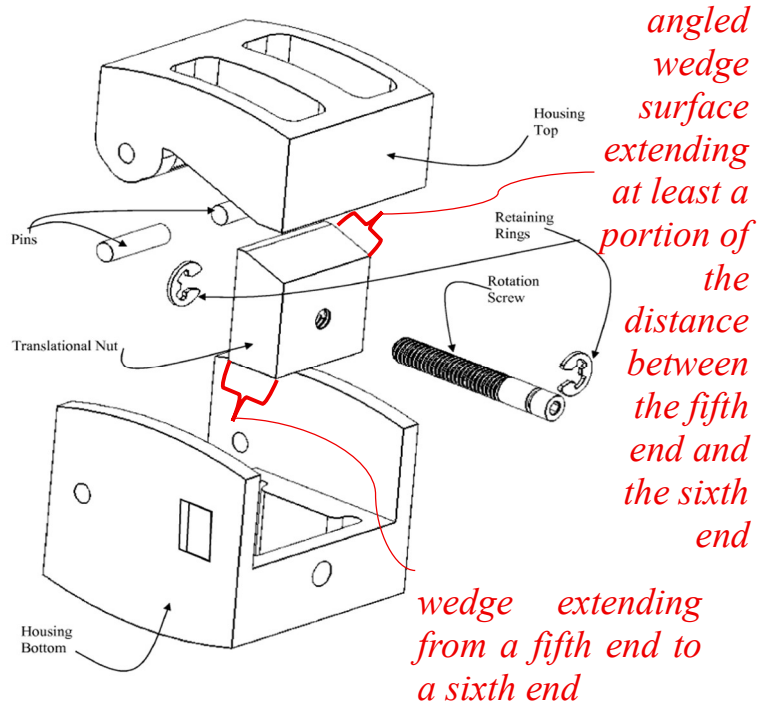


Fig. 6D

Ex. 2053, Fig. 6D (Annotated)

Figure 6D illustrates that the wedge extends from a fifth end to a sixth end, with a portion of that distance including the angled wedge surface. See also limitation 8[f].

17[i]-17[k]: wherein the wedge is positioned between the first body and the second body with the angled wedge surface facing the first interior surface of the first body, wherein the first interior surface of the first body has an angled housing surface shaped to engage the angled wedge surface of the wedge, wherein the wedge is configured to slide within a space defined by the first body and second body in a direction toward the second and fourth ends of the first body and second body from a first wedge position that allows the first body and second body to pivot to a position that is substantially closed to a second wedge position whereby the angled wedge surface presses against the first interior surface of the first body to hingedly open the first body with respect to the second body whereby the wedge remains axially confined within the space defined by the first body and second body in the first and second wedge positions	<i>See limitations 8[f]-8[h].</i> Because each and every element of claim 17 was illustrated or described in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 17 and enabled a person of ordinary skill in the art to make and use it.
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Claim 18

The expandable intervertebral device of claim 17 wherein a first length of the first body from the first end to the second end is substantially equal to a second length of the second body from the third end to the fourth end and wherein the second end portion of the first body is smaller than the fourth end portion of the second body such that the second end portion of the first body is positionable between the third and fourth side portions of the second body at the fourth end of the second body.

The October 25, 2012 provisional application includes the same disclosures as the May 3, 2011 engineering drawings, thereby showing the inventors constructively reduced those concepts to practice through the provisional filing. For example, Figure 6A illustrates that the first and second bodies are substantially equal in length. Figure 6A further illustrates that the second end portion of the first body nests (e.g., is positionable) between the third and fourth side portions of the second body at the fourth end.

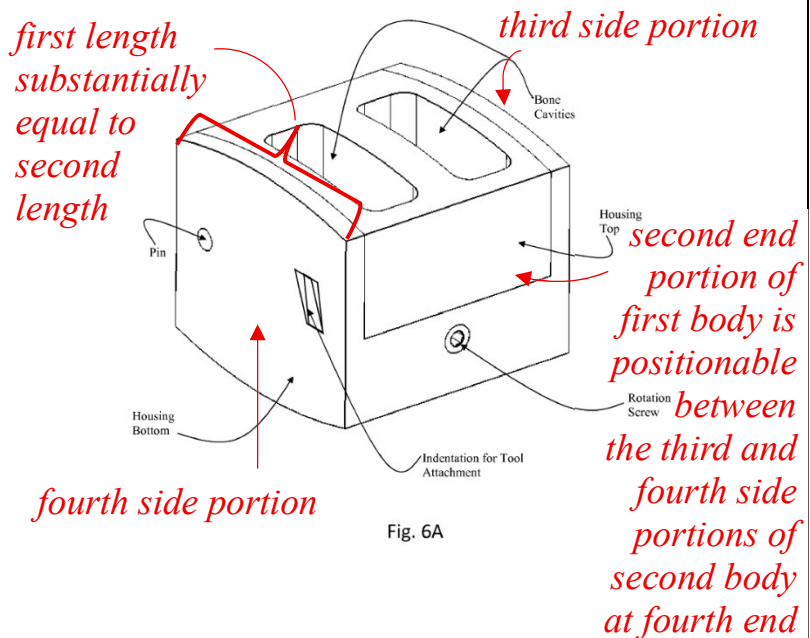


Fig. 6A

Ex. 2053, Fig. 6A (Annotated)

Because each and every element of claim 18 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 18 and enabled a person of ordinary skill in the art to make and use it.

Claim 19

Claim 19:

The expandable intervertebral device of claim 18 wherein the first body defines a first bone material receiving area between the first and second end portions and the first and second side portions, and the second body defines a second bone material receiving area between the third and fourth end portions and the third and fourth side portions, and wherein the first bone material receiving area is coupled to the second bone material receiving area when the wedge is in the second wedge position.

The October 25, 2012 provisional application includes the same disclosures as the April 15, 2011 CAD drawings and May 18-19, 2011 inventor emails, thereby showing the inventors constructively reduced those concepts to practice through the provisional filing. For example, Figures 6A-6D illustrate first bone receiving areas in the first body between its end and side portions. Ex. 2053, Figs. 6A-6D.

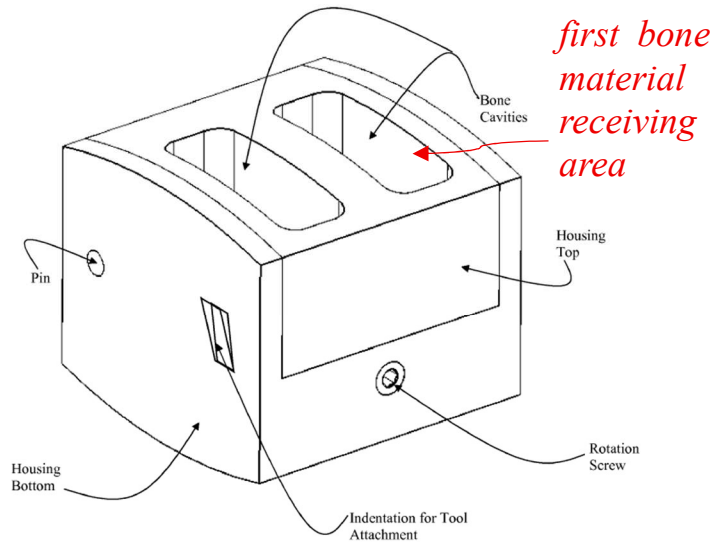


Fig. 6A

Ex. 2053, Fig. 6A (Annotated)

Figures 6D illustrates a second bone material receiving area between the end and side portions of the second body.

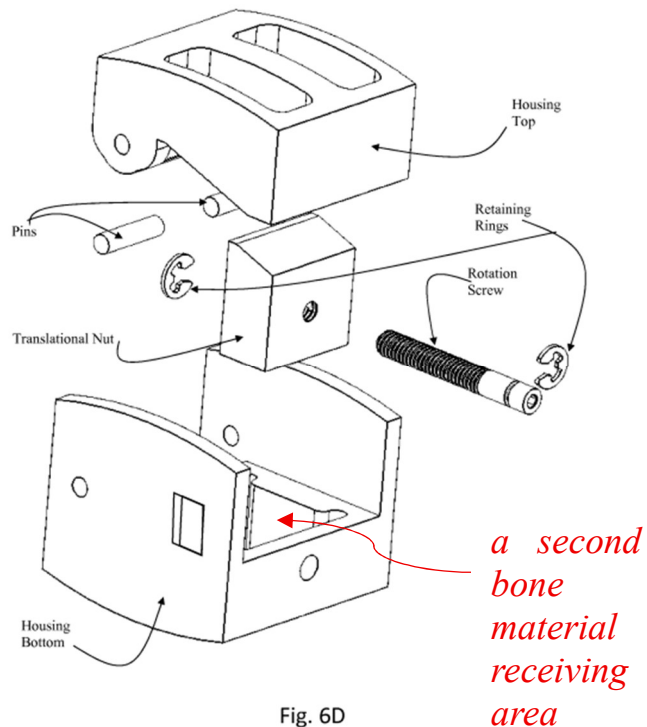


Fig. 6D

Ex. 2053, Fig. 6D (Annotated)

Additionally, from Figures 6C-6D, a POSITA would have understood that the area around the wedge allows the first bone receiving area to couple to the second bone material receiving area when the wedge is the second position (expanded).

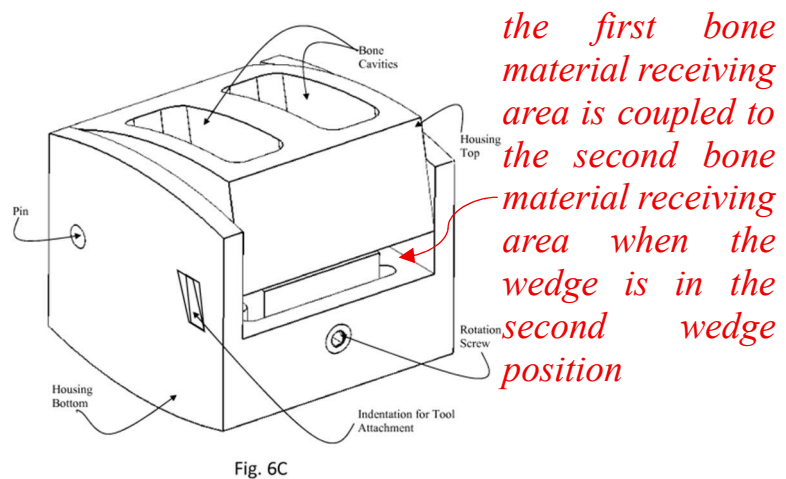


Fig. 6C

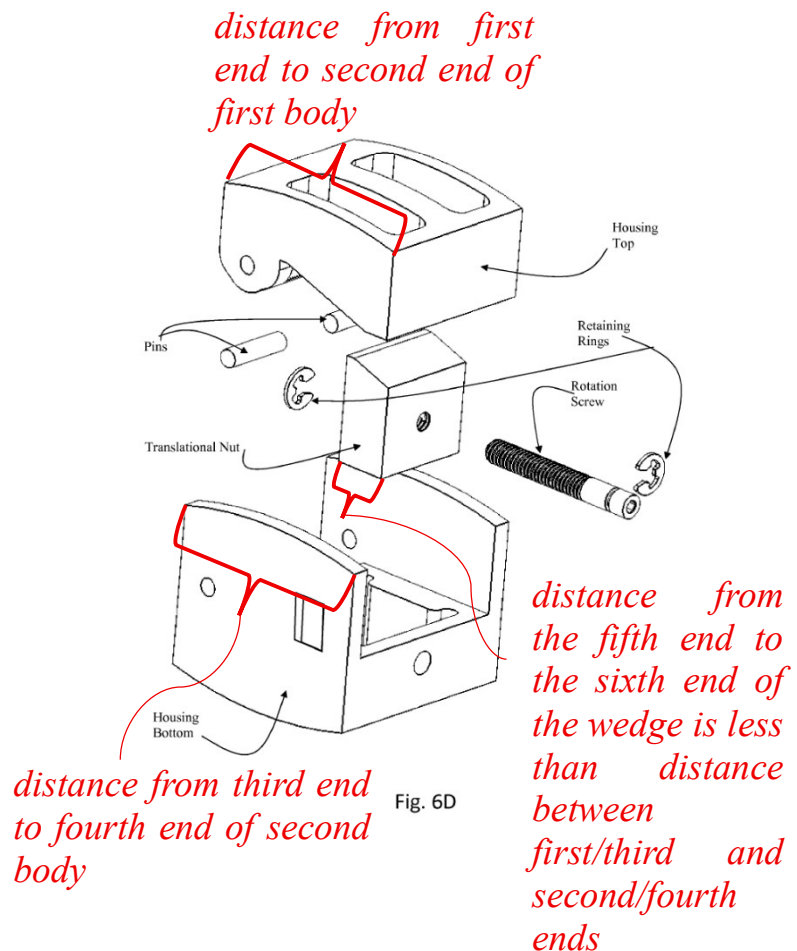
Ex. 2053, Fig. 6C (Annotated)

	Because each and every element of claim 19 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 19 and enabled a person of ordinary skill in the art to make and use it.
Claim 20	

Claim 20:

The expandable intervertebral device of claim 19 wherein a distance from the fifth end to the sixth end of the wedge is less than a distance from the first end to the second end of the first body and is less than a distance from the third end to the fourth end of the second body.

The October 25, 2012 provisional application includes the same disclosures as the May 3, 2011 engineering drawings, thereby showing the inventors constructively reduced those concepts to practice through the provisional filing. For example, Figure 6D illustrates how the dimensions of the wedge are less than those of the first and second bodies.



Ex. 2053, Fig. 6D (Annotated)

Because each and every element of claim 20 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the

	invention of claim 20 and enabled a person of ordinary skill in the art to make and use it.
Claim 21	
A method of operating the expandable intervertebral device of claim 17, the method comprising: inserting the expandable intervertebral device in a target surgical location between two vertebrae of a human patient; and	The October 25, 2012 provisional application includes the same disclosures as the May 3, 2011 engineering drawings, thereby showing the inventors constructively reduced those concepts to practice through the provisional filing. For example, the provisional explains that “[f]or embodiments III–VII the ZP-EIS device is inserted into the disc space ... Once in the disc space the rotation screw is turned by rotating the Allen key of the tool expanding the device to the desirable disc height achieving the desirable intervertebral distraction deemed necessary for the individual patient and disc space.” Ex. 2053 ¶ 46. The ’367 patent shares this same disclosure. Ex. 1001, 11:32-12:1.
turning a rotation screw to actuate a movement of the wedge to pivot the first body away from the second body while the device is positioned between the vertebrae of the human patient.	As I explained above, the provisional states that “[o]nce in the disc space the rotation screw is turned by rotating the Allen key of the tool expanding the device to the desirable disc height achieving the desirable intervertebral distraction deemed necessary for the individual patient and disc space.” Ex. 2053 ¶ 46. And as I explained above, Figures 6A-6C illustrate how the first body pivots away from the second body. Because each and every element of claim 21 was illustrated and described by the inventors in the October 25, 2012 provisional application, it is my opinion that the provisional application constitutes a constructive reduction to practice because it demonstrates that the inventors had possession of the invention of claim 21 and enabled a person of ordinary skill in the art to use the device of claim 17 according to the method of claim 21.