

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.,  
Petitioner,  
v.

MOSKOWITZ FAMILY LLC,  
Patent Owner.

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IPR2026-00121  
Patent 11,864,755

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

## **TABLE OF CONTENTS**

|                                                                                                                                                                        |    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| I. INTRODUCTION .....                                                                                                                                                  | 4  |
| II. QUALIFICATIONS.....                                                                                                                                                | 5  |
| III. MATERIALS CONSIDERED.....                                                                                                                                         | 8  |
| IV. LEGAL STANDARDS.....                                                                                                                                               | 10 |
| A. Anticipation .....                                                                                                                                                  | 10 |
| B. Obviousness.....                                                                                                                                                    | 10 |
| C. Claim Construction.....                                                                                                                                             | 12 |
| V. LEVEL OF ORDINARY SKILL IN THE ART. ....                                                                                                                            | 14 |
| VI. BACKGROUND OF THE TECHNOLOGY AND THE '755 PATENT.....                                                                                                              | 16 |
| VII. CLAIM CONSTRUCTION .....                                                                                                                                          | 25 |
| VIII. SUMMARY OF THE ASSERTED REFERENCES.....                                                                                                                          | 26 |
| A. U.S. Patent No. 7,056,343 to Schäfer (Ex. 1001).....                                                                                                                | 27 |
| B. Yeh (Ex. 1008).....                                                                                                                                                 | 30 |
| C. Berry (Ex. 1009).....                                                                                                                                               | 32 |
| D. Suddaby .....                                                                                                                                                       | 35 |
| IX. ANALYSIS OF PETITIONER’S GROUNDS OF UNPATENTABILITY .....                                                                                                          | 36 |
| A. Ground 1: The Claims of the '755 Patent Are Patentable Over Schäfer.....                                                                                            | 36 |
| 1. Schäfer Does Not Disclose a “Turning Mechanism” that Rotates In<br>Response to Rotating of a Tool .....                                                             | 36 |
| 2. Schäfer Does Not Disclose a “Tool-Engagement Surface” .....                                                                                                         | 40 |
| 3. Schäfer Does Not Disclose the Claimed Separate Structures<br>Comprising the Expansion Mechanism.....                                                                | 43 |
| 4. Schäfer Does Not Disclose an “Expansion Mechanism Coupled to<br>the First Opposite Surface and the Second Opposite Surface” as<br>Required by Claims 1 and 12 ..... | 45 |
| 5. Schäfer Does Not Disclose Claim 11’s Turning Mechanism that<br>“Engages Threads of the Threaded Body” .....                                                         | 50 |
| B. Ground 2: Claims 2-6 are Patentable over Schäfer in View of Yeh.....                                                                                                | 52 |

|                                                                                                                                                                                                                                                                                                           |    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| C. Ground 3: Claims 9 and 20 are Patentable over Schäfer in View of Suddaby .....                                                                                                                                                                                                                         | 53 |
| D. Ground 4: Claims 1-4, 8, 10-12, and 17 are Patentable Over Yeh in View of Berry .....                                                                                                                                                                                                                  | 54 |
| 1. Yeh Already Discloses a Complete Actuation System.....                                                                                                                                                                                                                                                 | 55 |
| 2. Yeh Does Not Exhibit the Problems Identified in Other Prior Art References. ....                                                                                                                                                                                                                       | 57 |
| 3. Berry Discloses a Fundamentally Different Implant and Instrument Architecture .....                                                                                                                                                                                                                    | 60 |
| 4. Adapting Berry’s Instrumentation to Yeh’s Device Would Require Substantial Redesign .....                                                                                                                                                                                                              | 64 |
| 5. A POSITA Would Not Have Reasonably Expected the Proposed Combination to Operate Successfully .....                                                                                                                                                                                                     | 68 |
| 6. Yeh in View of Berry Does Not Teach or Suggest a Rotating Gear .....                                                                                                                                                                                                                                   | 72 |
| 7. Yeh in View of Berry Do Not Teach an Expansion Mechanism Comprising the Distinct Tool-Engagement Surface, Threaded Body, and Turning Mechanism Structures Required by Claim 1 or the Expansion Mechanism Comprising the Distinct Tool-Engagement Surface and Rotating Gear Structures of Claim 12..... | 74 |
| 8. Yeh in View of Berry Does Not Teach or Suggest the Claimed Tool-Engagement Surface Required by Claims 1 & 12 .....                                                                                                                                                                                     | 77 |
| E. Ground 5: Claims 5, 6, 18, and 19 are Patentable Over Yeh in View of Berry and Schäfer .....                                                                                                                                                                                                           | 81 |
| F. Ground 6: Claims 9 and 20 are Patentable Over the Combination of Yeh in View of Barry and Suddaby .....                                                                                                                                                                                                | 83 |
| X. CONCLUSION.....                                                                                                                                                                                                                                                                                        | 85 |

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

## **I. INTRODUCTION**

1. I have been retained as an expert witness to provide my independent opinions in regard to the matters at issue in the *inter partes* review of U.S. Patent No. 11,864,755 (the '755 patent") in the IPR2026-00121 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 2032 and is also summarized in Section II below.

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

## **II. QUALIFICATIONS**

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

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

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

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

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

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

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

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

11. I hold multiple patents and have served as an expert witness on approximately a dozen product and patent litigation cases, including several patent cases involving medical implants. My CV, which includes a list of all publications I have authored in the past 10 years is attached as Exhibit 2032.

### **III. MATERIALS CONSIDERED**

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

| <b>Materials Considered</b>                                                          |
|--------------------------------------------------------------------------------------|
| Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,864,755                |
| Ex. 1001, U.S. Patent No. 11,864,755 to Moskowitz et al.                             |
| Ex. 1002, Declaration of Brad Culbert                                                |
| Ex. 1004, File History for U.S. Patent No. 11,864,755                                |
| Ex. 1008, U.S. Patent Application Publication No. 2003/0045877 A1 to Yeh (“Yeh”)     |
| Ex. 1009, U.S. Patent Application Publication No. 2004/0059271 A1 to Berry (“Berry”) |
| Ex. 1010, U.S. Patent No. 7,056,343 to Schäfer et al. (“Schäfer”)                    |
| Ex. 1011, U.S. Patent No. 6,395,034 to Suddaby (“Suddaby”)                           |

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| Ex. 1006, U.S. Patent Application Publication No. 2008/0249569 A1 to Waugh et al. (“Waugh”)                                                                                                             |
| Ex. 1007, U.S. Patent No. 7,077,864 to Byrd et al. (“Byrd”)                                                                                                                                             |
| Ex. 1020, Phulchand Prithvi Raj, Intervertebral Disc: Anatomy-Physiology-Pathophysiology-Treatment, 8(1) PAIN PRACT. 18 (2008)                                                                          |
| Ex. 1031, Daniela Alexandru and William So, Evaluation and Management of Vertebral Compression Fractures, 16(4) PERM J. 46 (2012)                                                                       |
| Ex. 1032, Michael Shulte et al., Vertebral body replacement with a bioglasspolyurethane composite in spine metastases – clinical, radiological and biomechanical results, 9(5) EUR. SPINE J. 437 (2000) |
| Ex. 1033, Issada Thongtrangan et al., Vertebral body replacement with an expandable cage for reconstruction after spinal tumor resection, 15(5) NEUROSURG FOCUS. 1 (2003)                               |
| Ex. 1034, Christian Knop et al., Biomechanical compression tests with a new implant for thoracolumbar vertebral body replacement, 10(1) EUR. SPINE J. 30 (2001)                                         |
| Ex. 1035, U.S. Patent No. 4,657,550 to Daher (“Daher”)                                                                                                                                                  |
| Ex. 1036, U.S. Patent No. 6,752,832 to Neumann (“Neumann”)                                                                                                                                              |
| Ex. 1050, Ortrun Pohler, Unalloyed titanium for implants in bone surgery, 31 INJURY 7 (2000)                                                                                                            |
| Ex. 1051, Amended Complaint, Exhibit J1, Moskowitz Family, LLC v. Medtronic, Inc., No. 0:25-cv-00769 (D. Mass. filed Feb. 28, 2025), Dkt. 27-26.                                                        |
| Ex. 1052 – Memorandum Opinion, <i>Moskowitz Family LLC v. Globus Medical, Inc.</i> , No. 2:20-cv-03271 (E.D.Pa.), Dkt. 143.                                                                             |
| Ex. 1053, Anne Polikeit et al., The importance of the endplate for interbody cages in the lumbar spine, 12(6) EUR. SPINE J. 556 (2003)                                                                  |
| Ex. 2029, June 29, 2026 Claim Construction Order in <i>Moskowitz Family, LLC v. Nuvasive, LLC and Nuvasive Inc.</i> , Case No. 25-711 (D. Del.)                                                         |
| Ex. 2030, July 1, 2026 Deposition Testimony of Brad Culbert                                                                                                                                             |

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

## **IV. LEGAL STANDARDS**

### **A. Anticipation**

14. 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 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.

15. 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.

16. 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**

17. 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.

18. 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.

19. 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.

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

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

### **C. Claim Construction**

21. 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.

22. 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.

23. 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.”

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. I understand that a claim limitation expressed as a “means” for performing a specified function is construed to cover the corresponding structure, material, or acts described in the specification that perform the claimed function, and equivalents thereof. Identifying the corresponding structure requires first determining the claimed function and then identifying the structure disclosed in the specification that a POSITA would understand to perform that function.

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

30. 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 the earliest possible priority date for the '755 patent is April 12, 2005, based on the filing date of provisional application No. 60/670,231. I also understand that the priority chain of the present application includes U.S. non-provisional application no. 11/208,644, filed on August 23, 2005. I understand that Petitioner and its expert have applied a priority date of August 23, 2005 for purposes of its Petition. For purposes of this Declaration, I have been instructed to use August 23, 2005 as the time of the invention, although I understand that the priority date for one or more of the

challenged claims may be as early as April 12, 2005. My analysis and conclusions are the same whether the relevant time period is August 2005 or April 2005.

31. 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.

32. In my opinion, a person of ordinary skill in the art as of the 2005 time period, which I understand to be the '755 patent's earliest possible priority date, 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.

33. I understand that Petitioner has stated that a person of ordinary skill in the art, which Petitioner refers to as a POSITA, “would have a bachelor’s or equivalent degree in Mechanical Engineering or a related discipline (e.g., biomechanics, biomedical or metals and materials engineering), and at least five years of experience.” Pet. 14. 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. 1003 ¶ 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.

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

## **VI. BACKGROUND OF THE TECHNOLOGY AND THE ’755 PATENT**

35. At the time of the invention, expandable intervertebral implants were developed to address competing surgical objectives. A surgeon desired an implant that could be inserted through a relatively small surgical corridor in a compact configuration, yet provide sufficient stability after implantation to restore disc height, maintain alignment of vertebrae, and promote spinal fusion. A POSITA

would have understood that these competing objectives required careful coordination between the implant's structural components and its expansion mechanism.

36. A POSITA also would have understood that expandable spinal implants are mechanical systems. Unlike static fusion cages, expansion occurs only if rotational or other input provided by the surgeon is transmitted through a coordinated series of mechanical components that convert the surgeon's actuation into controlled movement of the implant. Consequently, the relationship between the implant, its expansion mechanism, and the surgical instrument used to actuate that mechanism is a central aspect of expandable implant development and design.

37. The surgical environment further influences implant design. Expandable spinal implants are actuated after insertion while positioned within the confined anatomy of the spine. Because the implant is not directly visible during much of the procedure, the surgeon depends upon predictable mechanical interaction between the surgical instrument and the implant's actuation mechanism. Accordingly, expandable implant systems are generally designed so that the tool reliably interfaces with the implant throughout the expansion procedure.

38. The '755 patent generally describes expandable spinal fixation systems that may be inserted in a compact configuration and subsequently expanded after placement between vertebrae. Ex. 1001. The disclosed embodiments are intended

to provide fixation between vertebrae after insertion while reducing reliance on some of the larger fixation constructs available at the time of the invention, such as conventional anterior plating systems and pedicle-screw constructs. As the '755 patent notes, such prior systems had several drawbacks including increased surgical complexity, greater tissue disruption, and other associated complications. Ex. 1001, 1:42-4:61. For example, the patent observes that anterior cervical plating systems may project beyond the vertebral bodies and contact adjacent soft tissue, including the esophagus. *Id.* at 2:45-65.

39. To overcome the drawbacks of the prior art, the disclosed embodiments achieve fixation using an implant positioned within the intervertebral space that expands after insertion. *Id.* at 6:58-7:9. In particular, the '755 invention is directed to a coordinated mechanical system in which opposing shell structures, an expansion mechanism positioned between those shell structures, and a surgical tool are designed to function together to achieve controlled implant expansion after implantation. Ex. 1001, Abstract, Figs. 1-7. The implant can be inserted between vertebrae in a relatively compact configuration to facilitate placement. Once the implant is properly positioned, a surgeon inserts a surgical tool into the implant and applies rotational input. The expansion mechanism receives that rotational input and mechanically converts it into controlled separation of the opposing shell structures,

thereby increasing the implant height and anchoring the implant against the vertebral bodies.

40. In my opinion, a POSITA would understand that the invention is not directed merely to an implant that expands, but rather to an implant having a specific mechanical architecture that is designed to receive rotational input from a surgical tool and convert that input, through the expansion mechanism, into predictable and controlled expansion of the implant after implantation. The specification consistently depicts the expansion mechanism as including multiple cooperating mechanical components that perform different functions. Certain components receive rotational input from the surgical tool. Other components transmit that rotational input. Still other threaded components convert rotational motion into axial movement that expands the implant.

41. For example, in the first embodiment (Figs. 1A-1D), a surgical tool engages a drive screw or pinion positioned within the implant. Rotation of the drive screw or pinion is transmitted through an interposing gear arrangement, which in turn simultaneously drives opposing threaded screw members—one left-handed and one right-handed—in opposite directions. Ex. 1001, Figs. 1A-1D, 5:41-6:7. Prior to actuation, the threaded screw members are contained within the implant body. As rotational input is transmitted through the expansion mechanism, the threaded screw

members advance outwardly in opposite directions to engage the vertebral bodies, thereby providing fixation and stabilizing the spinal segment. *Id.*

42. The patent discloses similar mechanical arrangements in the remaining embodiments, each utilizing separate drive members, gears, and threaded members that cooperate to convert rotational input into controlled expansion through different mechanical implementations. *See, e.g., id.* at Figs. 2A-3E, 6:10-29.

43. The second embodiment (Figs. 2A-2G) implements the same overall expansion concept through a different mechanical arrangement. In this embodiment, rotational input supplied by the surgical tool is transmitted to a central drive pinion 201, which meshes with left and right gears 204 and 205. Those gears independently rotate corresponding left- and right-handed threaded screw members 202 and 203. Ex. 1001, 6:8-20. The specification explains that, in one implementation, one screw member may be nested within the other while the implant is in its closed configuration, such as a relatively narrow solid screw positioned within a wider hollow screw. This nested arrangement permits the implant to maintain a compact insertion profile while providing a greater range of extension after implantation. As with the first embodiment, rotational input supplied by the surgeon is mechanically transferred through multiple cooperating components before producing controlled expansion of the fixation elements.

44. The third embodiment (Figs. 3A-3E) likewise converts rotational input into controlled expansion but utilizes separate drive pinions 301a and 301b that independently actuate opposing screw members. Ex. 1001, 6:21-37. The specification explains that this arrangement allows the opposing fixation members to be adjusted independently while still employing the same basic mechanical principles disclosed in the earlier embodiments. A POSITA would have understood that, although the specific arrangement of gears and pinions differs among the embodiments, each embodiment relies upon separate mechanical components that cooperate to receive rotational input, transmit rotational motion, and convert that motion into controlled movement of threaded fixation members.

45. The specification next describes several implant configurations that incorporate these expandable fixation mechanisms into different spinal stabilization constructs. Figures 4A-4C disclose embodiments in which one or more expandable screw devices extend across the intervertebral disc space. One embodiment positions a single expandable screw anteriorly to function both as a fixation device and as a barrier against anterior migration of an interbody cage. Another embodiment employs three expandable screw devices arranged in a triangulated configuration spanning the anterior and middle spinal columns. Ex. 1001, 6:38-57. The specification explains that this triangular arrangement increases resistance to

subsidence while leaving substantial open space between the fixation members to accommodate bone graft or other osteoinductive material for fusion.

46. Figures 5A-5D illustrate another embodiment in which the expandable fixation mechanism is incorporated into a generally horizontal linear mini-plate. The disclosed plate is formed from upper and lower portions that interdigitate through corresponding alignment pins and recesses. Slots formed in the plate receive expandable fixation screws that are actuated after implantation to engage the vertebral bodies. Ex. 1001, 6:58-7:3. The specification explains that the plate is intended to remain flush with, or recessed relative to, the anterior vertebral surfaces, thereby avoiding the profile associated with conventional anterior plating systems.

47. Figures 6A-6G disclose a triangular mini-plate used in combination with multiple expandable fixation screws, including a posteriorly positioned fixation screw, to provide triangulated stabilization while maintaining a relatively low-profile construct. Ex. 1001, 7:4-9. Figures 6H-6I further disclose a “three-in-one” embodiment in which the triangular plate also functions as an interbody fusion cage capable of receiving bone graft material. In that embodiment, structural features traditionally associated with separate cages, fixation plates, and fixation screws are incorporated into a single implant that is inserted into the intervertebral space and subsequently expanded to secure fixation.

48. The patent also discloses an expandable intervertebral body fusion device (“IBFD”) illustrated in Figures 7A-7B which includes first and second shell structures. The shells include vertebral-engaging spikes, adjustable expansion components, and expandable fixation screws extending from the implant into the vertebral bodies. Ex. 1001, 7:22-8:6. The specification further explains that the interior of the device, together with the surrounding intervertebral space, may be packed with bone graft material or other osteoinductive substances to promote spinal fusion.

49. Independent claims 1 and 12 reflect the mechanical principles reflected in these embodiments, including opposing structural members, an expansion mechanism positioned between those members, and a mechanical interface configured to receive rotational input from a surgical tool, and convert it into controlled expansion of the implant. Claim 1 recites first and second shells having vertebral-engaging surfaces, and an expansion mechanism positioned between the shells and coupled to their opposing surfaces. The expansion mechanism includes a tool-engagement surface and threaded components that translate rotational input into expansion. The claim further requires that rotating the tool about its longitudinal axis while the tool remains engaged with the tool-engagement surface causes rotation of a turning mechanism and expansion of the implant. The shells may include cavities

and circumferentially positioned engagement features, reinforcing fixation at vertebral interfaces.

50. Claim 12 similarly recites an expandable implant having first and second shells with an expansion mechanism positioned between the shells and coupled to their opposing surfaces. Unlike claim 1, claim 12 identifies the expansion mechanism as comprising a tool-engagement surface and at least one rotating gear configured to rotate about an axis passing through the gear. Ex. 1001, claim 12. As in claim 1, the recited expansion mechanism converts rotational input supplied by a surgical tool into controlled movement of the shell structures to expand the implant after insertion. A POSITA would have understood claim 12 to describe the same coordinated mechanical relationship disclosed throughout the specification, in which a surgical tool operatively interfaces with the expansion mechanism and rotational input is transmitted through multiple cooperating mechanical components to achieve controlled expansion of the implant.

51. Collectively, the challenged claims describe a coordinated mechanical system in which distinct structural components cooperate to receive rotational input from a surgical tool and convert that input into controlled expansion of the implant. A POSITA would have understood that this coordinated mechanical operation occurs after the implant has been positioned within the relatively confined space, requiring

the expansion mechanism and tool interface to function reliably within the limited surgical workspace available between vertebral bodies.

## **VII. CLAIM CONSTRUCTION**

52. Aside from the phrase “means for placement of a bone fusion material” in claim 10, which I discuss below, I have applied the plain and ordinary meaning, as understood by a POSITA at the time of the invention of the ’755 patent, to all remaining claim terms in forming my opinions.

53. Petitioner has only identified the one term as requiring construction—the “means for placement of a bone fusion material” in claim 10. I understand that Petitioner contends the phrase “means for placement of a bone fusion material” is subject to 35 U.S.C. § 112, ¶ 6 and identifies the corresponding structure as an elastomeric sheath. Based on my review of the ’755 patent, however, a POSITA would understand the specification to disclose additional structures that perform the recited function of placing bone fusion material. For example, the specification explains that “bone fusion substances are placed/packed or poured, into the inner aspects of the device 700 and its surrounding intervertebral space.” Ex. 1001, 7:52-55. The patent likewise teaches that, after placement of the BDFT mechanism, “the inside of the denuded intervertebral space can then be packed with autologous or allograft bone, BMP, DBX, or similar osteoinductive material,” or that an intervertebral spacer filled with such material may be inserted. Ex. 1001, 3:16-20,

9:35-47. A POSITA would therefore understand the specification to disclose multiple structures that are configured to receive or contain bone fusion material for placement at the surgical site, rather than only an elastomeric sheath. In my opinion, limiting the corresponding structure solely to an elastomeric sheath would exclude other structures expressly identified in the specification as performing the same placement function.

54. Additionally, I have reviewed the recent claim construction order entered in Patent Owner's litigation against NuVasive as well as the Globus memorandum opinion. Exs. 1052, 2029. I understand that those district courts construed certain claim terms of patents related to the '755 patent, including terms that also appear in the claims of the '755 patent. Ex. 2029. I further understand that Petitioner does not contend that any of those claim terms require construction in this proceeding. Thus, I do not offer an opinion as to whether the claim constructions adopted in that order should apply to the '755 patent.

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

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

**A. U.S. Patent No. 7,056,343 to Schäfer (Ex. 1001)**

56. Schäfer describes an expandable intervertebral implant intended to be inserted between adjacent vertebrae in a contracted configuration and expanded after implantation by rotating internal threaded components. Ex. 1010, Abstract.

57. Schäfer explains that earlier expandable implants utilized a threaded sleeve that was rotated using a radially inserted pin or hook wrench. *Id.* at 1:11-23. Because the tool engaged the circumference of the rotating element, the surgeon was required to remove and repeatedly reinsert the tool after only a limited amount of rotation, such as approximately one-quarter turn. *Id.* Schäfer identifies this repeated removal and reinsertion of the tool as a disadvantage, particularly during surgical procedures.

58. Schäfer addresses that problem by relocating the actuator interface from the circumference of a rotating component to the front surfaces of internal drive elements. *Id.* at 1:31- 40. According to the specification, this arrangement permits the surgeon to continue rotating the tool without repeatedly removing and reinserting it during expansion. *Id.* at 2:43-52.

59. The principal embodiment of Schäfer includes upper and lower outer sleeves 12 and 14 that are positioned coaxially about longitudinal axis 44. *Id.* at 4:37-5:8. Located between the outer sleeves are upper and lower inner sleeves 34 and 36, a supporting ring 18, and locking element 42. *Id.* The inner sleeves are

threaded into the corresponding outer sleeves through mating inside and outside threads, while the locking element joins the opposing inner sleeves and maintains them on the supporting ring. *Id.* at col. 4:55-64, Fig. 3. Set screws 38 may subsequently lock the expanded position by securing the inner sleeves relative to the outer sleeves. *Id.* at 4:53-64.

60. Expansion is accomplished through rotation of the inner sleeves relative to the outer sleeves. Each inner sleeve includes external threads that engage corresponding internal threads formed on the inner circumference of the outer sleeves. As the inner sleeves rotate, the threaded engagement causes the outer sleeves to move axially away from one another, thereby increasing the height of the implant. *Id.* at 1:31-41, 2:42-56.

61. The opposing ends of the inner sleeves rest upon a stationary supporting ring 18. The supporting ring spaces the inner sleeves apart while supporting them during rotation. The specification explains that the supporting ring serves as a bearing surface for the front faces of the inner sleeves and substantially prevents them from tipping while they rotate. *Id.* at 3:3-10.

62. Each inner sleeve includes flange 56 having front-surface bevel teeth 26. *Id.* at 5:18-30. Those bevel teeth form the mechanical drive interface through which rotational input is transmitted to the inner sleeves. The supporting ring includes radial openings 22 that intersect inwardly projecting shoulders 66. *Id.* at

Fig. 8, 5:41-51. The openings permit access to the front faces of the inner sleeves while the shoulders support the inner sleeves during operation.

63. Opening 22 “allows insertion of the tool into the supporting ring and to move it to the front surface of the inner sleeve, on the one hand, and to guide and support the tool, on the other hand.” *Id.* at 2:63-67. The specification further explains that the diameter of each opening is greater than the thickness of the supporting shoulder so that the tool projects beyond the shoulder and reaches the front surface of the inner sleeve. *Id.* at 3:11-25. As a result, portions of bevel teeth 26 project into the inside cross-section of the opening, making the teeth accessible through the opening.

64. After passing through opening 22, the distal end of tool 70 directly mates with bevel teeth 26. The tool itself includes complementary teeth 72, and the specification explains that teeth 72 and teeth 26 together form a bevel gear. *Id.* at Fig. 10, 3:25-35. Rotation of tool 70 therefore rotates the inner sleeves through the bevel gear interface. The specification attributes the ability to rotate the implant continuously without repeated removal of the tool to this bevel gear arrangement rather than to any interaction between the tool and the supporting ring itself.

65. The specification further describes and shows the configuration of the surgical tool used to actuate Schäfer’s implant. *Id.* at 4:25-28, Fig. 10. A POSITA would have understood that this tool was specifically designed to interface with the

implant's disclosed actuation mechanism. Schäfer explains that the tool is "designed in the shape of a rod and [has] a star-shaped cross-section." Ex. 1010, 4:25-28. The specification further states that the distal end of the tool "can be slightly conically tapered similar to a bevel gear" and may be "disposed on a flexible shaft so that the implant can be used and extended even if it is difficult to access the implant." *Id.* at 4:28-33. Schäfer also explains that the tool is configured such that it "can be easily inserted into and turned in the supporting ring." *Id.* at 4:29-30. In my opinion, a POSITA would have understood this disclosure to require sufficient clearance between the tool and the supporting ring to permit insertion and free rotation of the tool through openings 22 until the tool reaches and mates with bevel teeth 26. Such clearance necessarily requires the tool to have an outer diameter smaller than the corresponding opening through which it passes.

**B. Yeh (Ex. 1008)**

66. Yeh describes a spinal column fixation device intended to stabilize spinal segments during treatment. Ex. 1008, Abstract. It is comprised of a central support member extending between a top seat and a bottom seat. *Id.* at ¶ 21.

67. Yeh explains that adjustment of the implant height is accomplished by directly rotating adjustment ring 130. *Id.* at ¶ 21, 26. Specifically, the specification states that "the adjustment of height of the support member is attained by a tool which is inserted into the tool holes 131 to rotate the adjustment ring 130." *Id.* at ¶

26. The disclosed tool therefore acts directly on the adjustment ring and constitutes the actuator used to expand the implant.

68. A POSITA would have understood tool holes 131 to be specifically provided to receive the adjustment tool. Yeh's tool is inserted into the tool holes and, through engagement with the adjustment ring, transmits force directly to the adjustment ring. As the adjustment ring rotates, its threaded engagement with the upper support body 120 causes relative movement between the upper and lower support bodies, thereby changing the height of the implant. The disclosed expansion sequence therefore consists of a straightforward mechanical arrangement in which the surgeon turns the adjustment ring directly using a tool specifically configured to engage tool holes 131.

69. A POSITA would have understood Yeh's adjustment tool and adjustment ring to be designed as corresponding components of a single integrated actuation system. The geometry and location of tool holes 131 determine how the tool interfaces with the adjustment ring and how force is transmitted to the implant. Because the tool operates directly on the adjustment ring, the design of the tool and the design of the adjustment ring are mechanically interdependent.

70. A POSITA likewise would have understood that tools used to actuate expandable spinal implants are ordinarily designed to correspond to the particular actuator interface provided by the implant. The tool disclosed in Yeh is designed to

engage tool holes 131 formed in adjustment ring 130 and to rotate that adjustment ring directly. Nothing in Yeh suggests that the disclosed tool interface is intended to be universal or interchangeable with different implant actuation systems. Nor does Yeh disclose modifying adjustment ring 130 or tool holes 131 to accommodate a different expansion instrument. Instead, Yeh presents the disclosed tool and implant interface as a complete system for adjusting implant height.

71. Separate from the height-adjustment mechanism, Yeh also discloses independent angle-adjustment mechanisms positioned between each seat and the corresponding support body. *Id.* at ¶¶ 29-30. Those mechanisms utilize mating serrated curved surfaces and fastening screws to permit the angular orientation of the top and bottom seats to be adjusted independently of the height-adjustment mechanism. The angle-adjustment mechanisms perform a different function from the adjustment ring and do not participate in expanding the height of the implant.

**C. Berry (Ex. 1009)**

72. Berry discloses an expandable intervertebral implant system together with a specialized expansion apparatus designed to actuate the implant after it has been positioned between vertebrae. Ex. 1013, Abstract. The implant generally includes a central tubular body and opposing upper and lower endplate assemblies that move relative to one another during expansion. *Id.* at 3:55-4:9; Figs. 1-5.

73. The central tubular body functions as the principal rotating component of Berry's expansion mechanism. The opposing endplate assemblies are threadably coupled to the tubular body so that rotation of the tubular body causes the endplate assemblies to translate axially away from one another, thereby increasing the height of the implant. *Id.* at 4:10-29; 5:22-31; Figs. 2-5. A POSITA would understand that Berry converts rotational movement of the tubular body into controlled axial expansion through this threaded relationship.

74. Berry's implant includes a series of circumferential apertures formed around the tubular body. These apertures are not merely access openings; rather, they serve as the implant-side engagement interface for Berry's expansion apparatus. *Id.* at 5:45-57; Figs. 4-5.

75. Berry further discloses a specialized expander apparatus engineered to cooperate with the geometry of Berry's implant. The apparatus includes a handle assembly, an elongated shaft, an internal gear transmission, and an engager positioned at the distal end of the instrument. *Id.* at 6:8-41; Figs. 6-10.

76. Rotational input applied by the surgeon at the handle is transmitted through the shaft to a gear train within the instrument. The gear train rotates the distal engager, which includes radially arranged teeth configured to mate with the circumferential apertures formed on Berry's tubular body. Rotation of the engager thereby causes rotation of the tubular body, which in turn expands the implant by

advancing the opposing endplate assemblies away from one another. *Id.* at 6:8-7:35; Figs. 6-10.

77. Berry also discloses a C-shaped positioning mechanism that partially surrounds the implant while maintaining engagement between the engager and the implant throughout expansion. The positioning mechanism assists in maintaining proper alignment between the instrument and implant and helps prevent disengagement of the toothed engager during operation. *Id.* at 7:36-8:28; Figs. 6-10.

78. The geometry of Berry's instrument and implant are interdependent. The spacing and configuration of the engager teeth correspond to the spacing of the apertures formed in the tubular body, while the gear transmission is configured to rotate the tubular body through that engagement interface. A POSITA would understand that these features cooperate as an integrated actuation system in which the implant-side engagement structure and the surgical instrument are designed to function together.

79. Berry attributes several advantages to this integrated actuation system, including actuation about the implant's longitudinal axis while reducing lateral translation of the surgical instrument during expansion. A POSITA would understand that these advantages arise from the combined operation of Berry's geared transmission, toothed engager, positioning mechanism, and implant-side

engagement geometry, rather than from any individual component viewed in isolation. Ex. 1013, 1:49-67; 6:8-8:28.

**D. Suddaby**

80. Suddaby discloses a structurally simple intervertebral disc endoprosthesis comprising an expandable stent with two opposed convex heads connected by an expandable telescoping mechanism. Ex. 1011, Abstract, 2:28-34. The stent is inserted into the evacuated disc space in a collapsed configuration, expanded to restore disc height, and then surrounded by an injected hardenable material that cures in situ to form the completed prosthesis. *Id.* at 4:31-46. The patent emphasizes that this straightforward structure is simple to implant surgically and easy to manufacture from common materials, avoiding the complexity of prior-art disc replacements. *Id.* at 1:26-28. The specification further explains that the stent itself may be made from titanium, steel, or any other readily available biocompatible material, while the surrounding hardenable component may be formed from bone cement or a variety of injectable synthetic materials, including acrylics, carbonates, plastics, or other materials capable of hardening after injection. *Id.* at 2:64-3:5. Thus, the invention is presented as a simple mechanical construct that can be manufactured using a wide range of conventional materials.

## **IX. ANALYSIS OF PETITIONER’S GROUNDS OF UNPATENTABILITY**

81. Petitioner sets forth six separate grounds in its Petition. Each are addressed below.

### **A. Ground 1: The Claims of the ’755 Patent Are Patentable Over Schäfer**

82. Ground 1 of the Petition alleges that Schäfer anticipated claims 1, 8, 10-12, and 17-19 of the ’755 Patent. In my opinion, the claims are patentable over Schäfer because Schäfer fails to disclose (1) a turning mechanism whose rotation is caused by rotation of the tool, (2) the claimed tool-engagement surface, (3) the distinct structural components recited by the claims, (4) an expansion mechanism coupled to the claimed opposite shell surfaces, and (5) claim 11’s requirement that the turning mechanism engages threads of the threaded body.

#### **1. Schäfer Does Not Disclose a “Turning Mechanism” that Rotates In Response to Rotating of a Tool**

83. Claim 1 of the ’755 patent requires an expansion mechanism including a “turning mechanism” and further requires that the expansion mechanism expands “in response to rotating of a tool engaged with the tool-engagement surface, wherein rotating of the tool causes a rotation of the turning mechanism.” A POSITA would understand the plain meaning of this claim language to require that the turning mechanism itself rotates in response to rotation of the surgical tool. The claim does not describe rotation of only a portion of the turning mechanism or rotation of a separate component associated with the turning mechanism. Because the claim

attributes rotation to the turning mechanism itself, a POSITA would not understand the claim to be satisfied where the identified turning mechanism includes structures that remain stationary while only other portions rotate.

84. I have reviewed Petitioner’s mapping of the “turning mechanism” limitation to Schäfer. Petitioner’s mapping identifies bevel teeth 26 of inner sleeves 34 and 36 together with supporting ring 18 as corresponding to the claimed turning mechanism. In my opinion, a POSITA would not understand supporting ring 18 to function as part of the rotating drive mechanism that actuates expansion of Schäfer’s implant.

85. A POSITA would understand from Schäfer that supporting ring 18 functions as a stationary structural support positioned between the upper and lower outer sleeves. Throughout the specification, supporting ring 18 provides structural support for the inner sleeves while maintaining their alignment during operation. Schäfer repeatedly describes the inner sleeves—not the supporting ring—as the components that rotate during expansion. For example, the Abstract explains that “the inside drive element is rotatably driven with respect to the supporting ring.” Likewise, the specification states that the inner sleeves are “rotatably driven with respect to the supporting ring.” Ex. 1010, Abstract; 6:12-14; 7:6-7. A POSITA would understand the phrase “with respect to the supporting ring” to identify the

supporting ring as the stationary reference structure relative to which the rotational movement occurs.

86. A component described as rotating “with respect to” another component indicates relative motion between those components. In Schäfer, the rotating components are the inner sleeves carrying bevel teeth 26, while supporting ring 18 remains fixed relative to the remainder of the implant. The supporting ring therefore serves as the stationary bearing and support structure against which the rotating drive elements operate.

87. As shown in Figure 8, tool 70 can be inserted through opening 22 in supporting ring 18. Shoulder 66 is designed to partially surround the tool as it passes through the supporting ring toward the bevel teeth located on the front faces of the inner sleeves. Ex. 1010, Fig. 8. A POSITA would understand this arrangement to permit the tool to rotate relative to the supporting ring while transmitting torque to the inner sleeves. The supporting ring itself does not rotate during this operation, and any attempt to rotate supporting ring 18 with the tool would be mechanically impeded by the shoulder configuration.

88. One advantage of Schäfer’s disclosed actuation mechanism is that the surgeon may continue rotating the tool without repeatedly removing and reinserting it during expansion. Ex. 1010, col. 3:25-35. That result is achieved because tool 70 rotates relative to the stationary supporting ring while its distal teeth 72 remain

engaged with bevel teeth 26 to turn the inner sleeves. Supporting ring 18 provides a guide for the rotating tool while maintaining access to the operative bevel-gear interface. If supporting ring 18 rotated together with the tool, the tool would no longer rotate within the supporting ring, and the supporting ring could not perform its disclosed guide and access functions during continuous rotation.

89. A POSITA would instead understand the torque transmission sequence in Schäfer to proceed as follows. Tool 70 is inserted through opening 22 of supporting ring 18. The distal teeth 72 of the tool then mate with bevel teeth 26 located on the inner sleeves. Rotation of the tool is transmitted directly through the mating bevel teeth to rotate inner sleeves 34 and 36. The threaded engagement between the inner sleeves and outer sleeves then converts that rotational movement into axial translation of the outer sleeves, thereby expanding the implant. Throughout this sequence, supporting ring 18 remains stationary while the tool and inner sleeves rotate relative to it.

90. In my opinion, a POSITA therefore would not understand supporting ring 18 itself to be part of the rotating drive assembly. The supporting ring performs different mechanical functions, including supporting, spacing, and aligning the rotating components while permitting them to rotate relative to the ring.

91. Because supporting ring 18 does not rotate during actuation, a POSITA would not understand rotation of the surgical tool to cause rotation of any assembly

that includes supporting ring 18 as a component. Instead, rotation of the tool causes the inner sleeves to rotate relative to the supporting ring. In my opinion, these are mechanically different relationships. Accordingly, it is my opinion that Schäfer does not disclose claim 1's "turning mechanism."

## **2. Schäfer Does Not Disclose a "Tool-Engagement Surface"**

92. Claims 1 and 12 recite an expansion mechanism comprising a "tool-engagement surface." The claims further require that the implant expands "in response to rotating of a tool engaged with the tool-engagement surface," and that the tool is rotated about its longitudinal axis "while the tool is engaged with the tool-engagement surface." Ex. 1001, claim 1. In my opinion, a POSITA would understand these limitations to require that the recited tool-engagement surface is a portion of the expansion mechanism that remains mechanically engaged with the surgical tool while the tool is rotated.

93. I have reviewed Petitioner's mapping of Schäfer's supporting ring 18, and more specifically the contours of openings 22, to the claimed "tool-engagement surface." In my opinion, a POSITA would not understand opening 22 to constitute a surface that the surgical tool engages while rotating. The openings do not necessarily mechanically engage the tool during its rotation. Rather, they permit the tool to pass through and rotate freely. Treating the openings as an engagement interface would impede rotation of the tool and is inconsistent with Schäfer's

disclosure that the openings are provided to allow insertion and to guide the tool, and ultimately permit the tool to reach the structures that receive and transmit rotational input, the bevel teeth 26 of inner sleeves 34 and 36.

94. Schäfer consistently attributes only access, insertion, guidance, and support functions to openings 22. Specifically, the specification explains that openings 22 “allow insertion of the tool into the supporting ring,” permit the tool “to move ... to the front surface of the inner sleeve,” and “guide and support the tool.” Ex. 1010, 2:63-67. A POSITA would understand these disclosures as describing openings 22 as passageways through which the tool is introduced into the implant and aligned with the operative drive interface.

95. A POSITA also would understand that substantial frictional or interference contact between tool 70 and the edges of openings 22 would be undesirable. During surgical actuation, the surgeon must be able to rotate the tool smoothly while maintaining tactile feedback regarding the resistance of the implant's expansion mechanism. If openings 22 were intended to serve as an engagement interface while the tool rotates, increased friction between the tool and the supporting ring would increase the torque required to rotate the tool, diminish tactile feedback, increase wear, and interfere with controlled expansion of the implant. Instead, a POSITA would understand openings 22 to provide sufficient clearance to

permit the tool to be inserted and rotated freely until the operative drive interface is reached.

96. This understanding is consistent with Schäfer's description of the surgical tool itself. The specification expressly explains that the actuation tool should be configured so that it "can be easily inserted into and turned in the supporting ring." Ex. 1010, 4:29-30. In my opinion, a POSITA would understand this disclosure to require sufficient clearance between the tool and openings 22 to permit free rotation of the tool within the supporting ring. Such clearance is inconsistent with the contours of openings 22 functioning as the operative structure through which the tool remains engaged during rotation.

97. In my opinion, a POSITA therefore would not identify openings 22 as a tool-engagement surface merely because the tool passes through them or may contact them during insertion or use. Incidental contact between the tool and a guide structure is mechanically different from engagement during rotation of the tool, as required by the claims.

98. I have also reviewed the opinions expressed by Petitioner's expert regarding this limitation. In my opinion, those opinions do not explain, from a mechanical engineering perspective, why a POSITA would equate Schäfer's guide openings with the operative interface with which the tool engages during rotation.

### **3. Schäfer Does Not Disclose the Claimed Separate Structures Comprising the Expansion Mechanism**

99. Claim 1 identifies a tool-engagement surface, a threaded body, and a turning mechanism. A POSITA would understand these components to refer to distinct structures within the expansion mechanism because the claim separately identifies each component and assigns each different structural characteristics and functional relationships.

100. For example, claim 1 describes the threaded body as extending between the first and second shells and having a first end, a second end, and a longitudinal axis. The claim separately requires a tool to engage the tool-engagement surface, and separately requires that rotation of the tool causes rotation of the turning mechanism. A POSITA would recognize that these separately described structures have differing characteristics and relationships and, therefore, each recited component has independent significance.

101. I do not believe Schäfer discloses separate corresponding structures for the recited components of claim 1 in the manner proposed by the Petition. Petitioner's mapping relies upon overlapping portions of the same underlying structures to satisfy multiple separately recited claim elements. Specifically, Petitioner identifies the contours of openings 22 in supporting ring 18 as the claimed tool-engagement surface while also relying upon supporting ring 18 as part of the alleged turning mechanism of claim 1. Likewise, Petitioner identifies inner sleeves

34 and 36 as the claimed threaded body while simultaneously relying upon the bevel teeth formed on those same inner sleeves as another part of the alleged turning mechanism.

102. A POSITA would not understand Schäfer to disclose those structures as separate components in the manner proposed by the Petition. As explained above, Schäfer consistently describes supporting ring 18 as a stationary support structure through which tool 70 is inserted and guided toward the inner sleeves. Once the tool reaches the inner sleeves, the tool teeth 72 directly mate with bevel teeth 26 of the inner sleeves. Rotation of the tool rotates the inner sleeves, whose external threads cooperate with corresponding threads of the outer sleeves to produce axial expansion of the implant. In other words, Schäfer describes one integrated rotating adjustment mechanism centered on the inner sleeves, while supporting ring 18 serves only to admit, guide, and support the tool during insertion.

103. A POSITA would not understand supporting ring 18 to be part of a rotating turning mechanism. Nor would a POSITA understand openings 22 to constitute a separate structure apart from the supporting ring itself. Likewise, a POSITA would not understand the bevel teeth to be structurally separate from the inner sleeves on which they are formed. Rather, the bevel teeth are integral portions of the rotating inner sleeves that receive rotational input from the tool and cooperate with the threaded portions of those same sleeves to expand the implant.

104. In my opinion, Petitioner’s mapping artificially separates and reallocates portions of Schäfer’s disclosed mechanism in order to correspond to the separate claim limitations. The Petition assigns operative significance to openings 22 that Schäfer itself does not attribute to those openings, while simultaneously dividing the inner sleeves into separate alleged threaded-body and turning-mechanism components even though Schäfer discloses those structures as one integrated rotating component. A person of ordinary skill would instead understand Schäfer’s expansion mechanism according to the way Schäfer itself describes its operation.

105. For these reasons, I do not believe a POSITA would conclude that Schäfer discloses the separate structural components recited in claim 1. Instead, Petitioner’s analysis depends upon assigning overlapping portions of Schäfer’s disclosed structures to multiple separately identified claim elements and attributing functions to those structures that Schäfer itself does not describe. In my opinion, that does not accurately reflect how a POSITA would understand Schäfer’s disclosed mechanism.

**4. Schäfer Does Not Disclose an “Expansion Mechanism Coupled to the First Opposite Surface and the Second Opposite Surface” as Required by Claims 1 and 12**

106. I have reviewed Petitioner’s mapping of the limitation requiring “an expansion mechanism . . . coupled to the first opposite surface and the second

opposite surface.” Petitioner’s mapping identifies inner sleeves 34 and 36, supporting ring 18, and locking element 42 as the claimed expansion mechanism, while identifying planar surfaces 16 of upper outer sleeve 12 and lower outer sleeve 14 as the claimed first and second opposite surfaces. In my opinion, a POSITA would not understand Schäfer to disclose that the identified expansion mechanism is coupled to those particular surfaces.

107. A POSITA would understand the claim language to require a structural relationship between the recited expansion mechanism and the specific surfaces identified as the first opposite surface and the second opposite surface. The claims do not simply require that the expansion mechanism be generally coupled to the shells. Rather, they identify particular surfaces of the shells and requires the expansion mechanism to be coupled to those identified surfaces.

108. Figures 1 through 3 of Schäfer illustrate the relevant structural relationships. Inner sleeves 34 and 36 include external threads 50 that engage internal threads 46 formed along the cylindrical interior surfaces of outer sleeves 12 and 14. Ex. 1010, Abstract; Fig. 3; col. 2:15-21; col. 5:8-22. The threaded engagement therefore occurs between the cylindrical threaded portions of the inner and outer sleeves. It does not occur at planar surfaces 16 identified by Petitioner as the claimed opposite surfaces.

109. From a mechanical engineering perspective, a threaded engagement establishes a structural connection at the threaded interface itself. A POSITA would not ordinarily understand such a threaded connection to establish a structural coupling to every surface located elsewhere on the same component. Rather, the threaded engagement mechanically joins the threaded portions of the sleeves, while planar end surface 16 remains a separate and independent geometric feature of the outer sleeve.

110. Figure 3 further illustrates this distinction. Surface 16 is a planar annular face located at the end of each outer sleeve and oriented generally perpendicular to the threaded interface between the inner and outer sleeves. The inner sleeves do not attach to, engage, or otherwise mechanically connect to these planar faces. Instead, the inner sleeves engage only the internal threaded surfaces extending along the interior circumference of the outer sleeves.

111. A POSITA would further understand that surfaces 16 translate axially together with the outer sleeves during expansion. By contrast, the inner sleeves rotate relative to the outer sleeves while remaining threadably engaged to their interior threaded surfaces. Because surface 16 forms part of the translating outer sleeve rather than the rotating drive mechanism, a POSITA would not understand the threaded engagement between the inner sleeves and outer sleeves to establish a structural coupling to the particular planar surfaces identified by Petitioner.

112. I have also considered Petitioner's alternative theory that the claimed coupling is satisfied because surfaces 16 "rest against" supporting ring 18. In my opinion, a POSITA would not understand the relationship described in Schäfer to constitute a structural coupling.

113. Schäfer explains that surfaces 16 may rest against supporting ring 18 when the implant is in its collapsed configuration. Figure 2 further illustrates that, as the implant expands, outer sleeves 12 and 14 move axially away from supporting ring 18 while the inner sleeves rotate relative to the supporting ring. A POSITA therefore would understand any contact between surfaces 16 and supporting ring 18 to exist only in the fully collapsed configuration and to cease as expansion proceeds.

114. From a mechanical engineering perspective, components that merely rest against one another are not ordinarily understood to be mechanically coupled. Contact between adjacent surfaces does not itself establish a structural connection unless the components are joined in a manner that causes them to function as a mechanically connected assembly. Likewise, temporary contact that exists only in one position of travel would not ordinarily be understood as establishing a continuing structural coupling throughout operation of the mechanism.

115. This distinction is particularly important in Schäfer because supporting ring 18 performs a different mechanical function. As explained elsewhere in my declaration, supporting ring 18 serves as a stationary support structure that supports

and aligns the rotating inner sleeves during operation. The outer sleeves, including surfaces 16, translate axially away from supporting ring 18 as the implant expands. A POSITA therefore would not understand supporting ring 18 to remain structurally coupled to surfaces 16 throughout operation of the expansion mechanism.

116. More generally, a POSITA would distinguish between a component being coupled to another component and a component being coupled to a particular surface of that component. When evaluating whether a structure is coupled to a specifically identified surface, a POSITA would look for a structural connection—either direct or through an identifiable mechanical load path—to that particular surface, rather than merely to another portion of the same component. Accordingly, a threaded connection to the interior of an outer sleeve would not establish that the connected structure is coupled to a separate planar end surface of that outer sleeve.

117. Accordingly, in my opinion, neither of the structural relationships identified by Petitioner establishes that Schäfer discloses an expansion mechanism coupled to the specific opposite surfaces identified in Petitioner's mapping. The threaded engagement occurs between the inner sleeves and the threaded interior of the outer sleeves, while any contact between surfaces 16 and supporting ring 18 is merely positional and exists only in the collapsed configuration. A POSITA therefore would not understand Schäfer to disclose an expansion mechanism coupled to the particular first and second opposite surfaces recited in claim 1.

**5. Schäfer Does Not Disclose Claim 11's Turning Mechanism that "Engages Threads of the Threaded Body"**

118. I have reviewed Petitioner's mapping of claim 11. Petitioner's mapping identifies inner sleeves 34 and 36, together with locking element 42, as the claimed threaded body. Petitioner's mapping further identifies bevel teeth 26 and supporting ring 18 as the claimed turning mechanism. In my opinion, a POSITA would not understand Schäfer to disclose that the identified turning mechanism engages the threads of the identified threaded body.

119. A POSITA would understand one mechanical component to "engage" the threads of another component when separate structures mechanically interface through those threads. In other words, the recited relationship requires a structure identified as the turning mechanism to mechanically interact with the threaded portions of the separately identified threaded body. A POSITA would not understand this relationship to be satisfied merely because a feature located on the threaded body may cause the threaded body to rotate.

120. Schäfer discloses two distinct mechanical interfaces during expansion. First, tool teeth 72 mate with bevel teeth 26 located on the front surfaces of inner sleeves 34 and 36. Ex. 1010, col. 3:21-25; col. 5:45-54. This bevel-gear interface transmits rotational input from the surgical tool to the inner sleeves. Second, external threads 50 formed on the inner sleeves engage internal threads 46 formed on the outer sleeves. Ex. 1010, col. 2:15-21; col. 5:8-22. It is this threaded engagement

between threads 46 and 50 that converts rotational movement into axial expansion of the implant.

121. A POSITA would understand these to be different mechanical interfaces that perform different functions. The bevel-gear interface transmits torque into the rotating inner sleeves. The threaded interface converts rotational motion into axial translation. These interfaces occur at different locations on different structures and involve different forms of mechanical engagement.

122. In Petitioner's mapping, bevel teeth 26 are not separate from the alleged threaded body. Rather, bevel teeth 26 are formed integrally on the ends of the same inner sleeves that Petitioner identifies as the threaded body. Accordingly, Petitioner's mapping does not identify a separate turning mechanism that engages the threads of the threaded body. Instead, it identifies one feature of the alleged threaded body as purportedly engaging another feature of that same component.

123. A POSITA would not ordinarily describe a feature located on a threaded component as engaging the threads of that same component. The bevel teeth neither contact nor mesh with external threads 50. Instead, bevel teeth 26 receive rotational input from tool teeth 72, while threads 50 separately engage internal threads 46 of the outer sleeves. These are distinct mechanical interactions occurring at different portions of the implant.

124. This understanding is confirmed by Schäfer's description of operation. The specification explains that tool teeth 72 mate with bevel teeth 26 to rotate the inner sleeves. Ex. 1010, col. 3:21-25; col. 5:45-54. It separately explains that external threads 50 engage internal threads 46 of the outer sleeves to produce expansion. Ex. 1010, col. 2:15-21; col. 5:8-22. At no point does Schäfer describe bevel teeth 26 as engaging the screw threads formed on the inner sleeves.

125. In my opinion, a POSITA would understand Schäfer to disclose that the only structures engaging external threads 50 during expansion are the corresponding internal threads 46 of outer sleeves 12 and 14. The bevel teeth do not engage those threads, supporting ring 18 does not engage those threads, and neither structure performs the mechanical function of engaging the threaded portions of the inner sleeves.

126. Accordingly, a POSITA would not understand Schäfer to disclose the mechanical relationship recited in claim 11, namely, that the turning mechanism engages the threads of the threaded body. Instead, Schäfer discloses that rotational input is delivered to the bevel teeth, while the threaded engagement responsible for expansion occurs separately between the inner sleeves and the outer sleeves.

**B. Ground 2: Claims 2-6 are Patentable over Schäfer in View of Yeh**

127. I have reviewed Petitioner's Ground 2 with respect to dependent claims 2-6. Petitioner's arguments do not remedy the deficiencies I identified above

with respect to Petitioner's analysis of independent claim 1. Accordingly, my opinions concerning claim 1 apply equally to Ground 2. Additionally, Petitioner's analysis does not address claim 5's additional structural requirement that "the second shell curves continuously around a perimeter of the second shell." For this additional reason, claim 5 is patentable over the combination of Schäfer in view of Yeh.

**C. Ground 3: Claims 9 and 20 are Patentable over Schäfer in View of Suddaby**

128. I have reviewed Petitioner's Ground 3 with respect to dependent claims 9 and 20. Petitioner's arguments do not remedy the deficiencies I identified above with respect to Petitioner's analysis of independent claims 1 and 12. Accordingly, my opinions concerning claims 1 and 12 apply equally to Ground 3.

129. I also do not believe Suddaby provides a technical reason why a person of ordinary skill in the art would have modified Schäfer's implant to use titanium. Suddaby describes a relatively simple telescoping implant intended to be "easy to manufacture from common materials." That design is mechanically much simpler than Schäfer's implant, which employs a more complex expansion mechanism including multiple interacting threaded and rotating components. In my opinion, a person of ordinary skill would not have viewed Suddaby's manufacturing discussion as applicable to Schäfer's substantially different mechanical architecture or as providing a reason to modify Schäfer's device.

130. Likewise, Suddaby does not identify titanium as the material that should be selected for its implant. Rather, it broadly states that the implant may be formed from titanium, steel, or any other suitable biocompatible material. Material selection for an implant is an engineering decision that depends on numerous considerations, including the geometry of the device, the expected loading conditions, the manufacturing process, wear characteristics, and the interaction of the various components. The Petition does not analyze those engineering considerations with respect to Schäfer's implant or explain why a person of ordinary skill would have selected titanium from among Suddaby's disclosed alternatives for use in Schäfer's more complex mechanism. In my opinion, the generalized observation that titanium is a suitable implant material does not provide a technical motivation for that specific material selection.

**D. Ground 4: Claims 1-4, 8, 10-12, and 17 are Patentable Over Yeh in View of Berry**

131. I have reviewed Petitioner's proposed combination of Yeh and Berry and have considered whether, from the perspective of a person of ordinary skill in the art at the time of the alleged invention, the proposed modification would have been technically sensible and reasonably expected to operate successfully. In forming my opinions, I considered the disclosures of Yeh and Berry as a whole, including the structures each reference discloses for actuating implant expansion and the corresponding surgical instrumentation. In my opinion, a POSITA would have

understood that both references disclose complete, but materially different, implant-and-instrument systems. Because those systems employ different actuator architectures, engagement interfaces, torque-transfer mechanisms, and implant geometries, a POSITA would not have regarded Berry's specialized expansion apparatus as a generic surgical tool that could simply replace Yeh's disclosed adjustment arrangement without redesign of the implant-tool interface. My opinions are explained below.

**1. Yeh Already Discloses a Complete Actuation System.**

132. In my opinion, a POSITA would have understood Yeh to disclose a complete and functional height-adjustment system, including both an implant-side actuation mechanism and a corresponding surgical tool interface. Yeh's height-adjustment mechanism includes lower support body 110, upper support body 120, and adjustment ring 130. The specification explains that implant height is adjusted by inserting a tool into tool holes 131 and rotating adjustment ring 130, which produces relative threaded movement between the upper and lower support bodies. Ex. 1008, ¶¶ 21, 26; Figs. 2, 3, 5A-6B.

133. A POSITA would understand from Yeh that the disclosed adjustment mechanism is complete and fully operational. During implantation, a surgical tool is inserted into tool holes 131 and used to apply rotational force to adjustment ring 130. Based on the disclosed tool-hole interface, a POSITA would understand that

the tool would function in the manner of a simple lever, with the tool holes serving as the mechanical contact point through which torque is applied to rotate the adjustment ring. Rotation of adjustment ring 130 produces relative movement between the upper and lower support bodies through the disclosed threaded relationship, thereby increasing or decreasing the height of the implant. Yeh therefore discloses not only an expandable implant, but also the corresponding mechanism by which the implant is actuated during surgery.

134. A POSITA would understand that Yeh's implant, adjustment ring, tool holes, and corresponding surgical instrument were intended to operate together as a coordinated mechanical system. The adjustment ring provides the implant-side engagement interface, while tool holes 131 define how rotational input is introduced into the implant. Those structural features are not independent of one another; rather, they cooperate to provide the disclosed method of implant expansion.

135. Nothing in Yeh suggests that its disclosed adjustment arrangement is incomplete, deficient, or in need of replacement. Yeh does not identify any reliability concern, manufacturing difficulty, surgical-access limitation, or operational shortcoming associated with its disclosed adjustment mechanism. Nor does Yeh suggest replacing its disclosed instrument with a different type of expansion apparatus.

136. A POSITA ordinarily would not replace a disclosed implant-specific actuation system absent some identified engineering advantage or recognized deficiency in the existing design. Where, as in Yeh, the reference already discloses a complete mechanism for actuating implant expansion, a POSITA would first look to the disclosed adjustment arrangement itself rather than assume that an entirely different implant-specific instrument should be substituted.

137. Accordingly, a POSITA would have understood Yeh to disclose a complete implant actuation system comprising both the implant-side adjustment mechanism and the corresponding surgical instrument designed to operate that mechanism. In my opinion, the existence of this complete adjustment architecture is an important consideration when evaluating whether a POSITA would have had any technical reason to replace Yeh's disclosed instrumentation with the materially different implant-specific expansion apparatus disclosed in Berry.

## **2. Yeh Does Not Exhibit the Problems Identified in Other Prior Art References.**

138. The Petition asserts that a POSITA would have been motivated to use Berry's expander apparatus 50 with Yeh's spinal column fixation device "because of the benefits that Berry's expander apparatus 50 provides," including attempting to "avoid surgical complications by minimally disturbing the surgical site." Pet., 68-69. Mr. Culbert's testimony mirrors that argument. Ex. 1002, ¶ 57. The Petition cites Schäfer and Berry as supporting this supposed motivation. Pet. 69.

139. A POSITA would not assume that criticisms directed to other implant systems, such as Berry and Schäfer, necessarily apply to Yeh. Whether a surgical instrument requires repeated reinsertion, excessive lateral movement, or increased surgical exposure depends upon the geometry of the particular implant and tool interface. Those characteristics cannot be attributed to Yeh without analyzing Yeh's disclosed structure.

140. Yeh's disclosed structure differs significantly from the systems discussed in Schäfer and Berry. As a result, a POSITA would not assume that the advantages or disadvantages associated with the tools used in those different systems necessarily apply to Yeh's implant.

141. For example, Petitioner asserts that a POSITA would have been motivated to replace Yeh's disclosed actuation arrangement because surgical tools requiring repeated reinsertion after a quarter turn or substantial lateral translation are difficult to use in many surgical procedures based on Berry and Schäfer's disclosures. Pet., 69. In my opinion, a POSITA would not attribute those characteristics to Yeh's disclosed adjustment mechanism because Yeh neither describes nor depicts such limitations.

142. Yeh discloses a different actuator geometry than the systems discussed in Schäfer and Berry. As illustrated in Figures 2, 3, 5A-5B, and 6A-6B of Yeh, upper support body 120 is divided into four support legs 121 separated by four

corresponding gaps. Adjustment ring 130 is positioned beneath those support legs and includes tool holes 131 through which the surgeon applies rotational input to adjust the implant height. Ex. 1008, ¶¶ 21, 26; Figs. 2-3, 5A-5B, 6A-6B.

143. A POSITA would understand from Yeh's disclosed structure that only adjustment ring 130 rotates during adjustment, while upper support body 120 translates axially relative to the lower support body. The disclosed geometry indicates that the support legs remain stationary with respect to the upper support body while the adjustment ring rotates beneath them.

144. A POSITA also would understand the interrupted threaded portions 122 and the corresponding gaps between support legs 121 to provide clearance for operation of Yeh's adjustment tool. Because Yeh's tool is inserted into tool holes 131, Yeh's tool's tip can extend into the gapped portions of Yeh's upper support body 120 so that it may freely move as torque is applied to Yeh's tool handle. Due to Yeh's configuration, Yeh's tool tip would move in the opposite direction as the tool's handle during its rotation. The disclosed gaps provide sufficient clearance through which the tool can access tool holes 131 and apply rotational input to adjustment ring 130 while permitting axial translation of the upper support body. If the tool were positioned within a threaded region of the upper support body, rather than a gapped portion, the tool would mechanically interfere with the axial movement of the upper support body and could damage or obstruct the threaded interface while

the threaded region translated. If the depth of the tool hole was itself sufficient to provide surface area for tool leverage, Yeh would not require gaps, and its entire upper body 120 would be threaded.

145. The geometry illustrated in Yeh further indicates that the available angular movement of the tool is limited by the spacing between adjacent support legs. Once the tool contacts one of the support legs, further rotation in that position is prevented until the tool is repositioned. Consequently, a POSITA would not expect Yeh's tool to undergo the large lateral displacement or quarter-turn sweep described in Berry and Schäfer. Rather, Yeh's disclosed geometry would permit only a relatively small angular movement of the tool between adjacent support legs (e.g., less than an eighth of a turn due to the four gaps and four support legs) before repositioning would be required.

146. The geometry illustrated in Yeh therefore differs from the implant configurations discussed elsewhere in the prior art and would not lead a POSITA to assume that Yeh suffers from the same limitations associated with tools requiring substantial lateral movement or repeated quarter-turn reinsertion, such as an enlarged wound or increased labor and time.

### **3. Berry Discloses a Fundamentally Different Implant and Instrument Architecture**

147. In my opinion, a POSITA would understand that Berry implements expansion through a substantially different mechanical architecture than Yeh.

Although both references generally relate to expandable spinal implants, Berry does not simply disclose a different surgical tool or a universal driver. Rather, Berry discloses a different actuator system in which the implant geometry, implant-side engagement interface, transmission mechanism, and surgical instrumentation are engineered to function together as an integrated mechanism.

148. A POSITA would understand that, as a matter of accepted engineering practice, expandable spinal implants and their corresponding instrumentation are ordinarily designed together or, at a minimum, with the intended implant-side engagement interface of the other component in mind. The geometry of the implant determines how torque is introduced into the implant and transmitted through the expansion mechanism, while the design of the surgical instrument is correspondingly developed to cooperate with that geometry. Conversely, the implant geometry is developed with the intended mode of actuation and corresponding instrumentation in mind. A POSITA therefore would not view the implant and the expansion tool as independent or interchangeable components, but rather as parts of a coordinated mechanical system.

149. Berry's implant includes a central tubular body positioned between opposing endplate assemblies. Unlike Yeh, where adjustment is accomplished by rotating adjustment ring 130, Berry expands by rotating the central tubular body itself. The opposing endplate assemblies are threadably coupled to the tubular body

so that rotation of the tubular body causes the endplate assemblies to translate axially away from one another, thereby increasing the height of the implant. Ex. 1013, col. 3:55-4:29; Figs. 1-5.

150. Berry likewise employs a substantially different implant-side engagement interface. Rather than using tool holes formed in an adjustment ring like Yeh, Berry provides numerous sets of circumferentially spaced apertures formed around the tubular body. Those apertures are specifically configured to cooperate with Berry's expander apparatus and serve as the point through which rotational input is introduced into the implant. Ex. 1013, col. 5:45-57; Figs. 4-5.

151. Berry's expander apparatus is itself engineered around that implant geometry. The apparatus includes a handle, elongated shaft, gear transmission, and a C-shaped engager carrying teeth configured to mate with the apertures formed in Berry's tubular body. Rotational input applied by the surgeon is transmitted through the gear train to the toothed engager, which rotates the tubular body through this specialized engagement interface. Ex. 1013, col. 6:8-7:35; Figs. 6-10.

152. Berry further discloses a C-shaped positioning member that partially surrounds the implant during expansion. A POSITA would understand that this positioning structure cooperates with the engager to maintain alignment between the instrument and the rotating tubular body while helping prevent disengagement throughout the expansion procedure. Berry explains that this coordinated

arrangement minimizes lateral movement of the instrument while maintaining continuous engagement with the implant during actuation. Ex. 1013, col. 6:46-8:28.

153. Berry's disclosed expansion system is therefore defined by the coordinated interaction of several interdependent components. Torque is transmitted sequentially through the handle, shaft, gear transmission, toothed engager, implant-side apertures, and rotating tubular body before ultimately producing axial movement of the endplate assemblies. A POSITA would understand that each interface along this torque-transfer path is specifically designed to cooperate with the adjacent component. The geometry of the tubular body determines the spacing of the engagement apertures. Those apertures correspond to the geometry of the toothed engager. The engager is driven through Berry's internal gear transmission. Together, those components transmit rotational input to the rotating tubular body, which then expands the implant through its threaded connection with the opposing endplate assemblies. A POSITA would understand that each of these components is designed to cooperate with the others as part of a single mechanical system.

154. Berry's disclosed advantages likewise arise from this integrated architecture rather than from the expansion instrument alone. For example, Berry attributes reduced lateral movement and longitudinal-axis actuation to the combined operation of the geared transmission, the toothed engager, the C-shaped positioning structure, the circumferential apertures formed in the tubular body, and the rotating

tubular body itself. A POSITA would therefore understand that those characteristics result from the coordinated design of the implant and its corresponding instrumentation, not simply from substituting a different surgical tool.

155. Accordingly, in my opinion, a POSITA would not understand Berry to disclose a generic expansion instrument capable of operating a variety of expandable implants. Rather, Berry discloses a fundamentally different implant-and-instrument architecture in which the implant geometry, implant-side engagement interface, transmission mechanism, and surgical instrumentation are specifically engineered to function together. That architecture differs materially from the adjustment mechanism disclosed in Yeh and would not have been viewed by a POSITA as simply another tool for actuating Yeh's implant.

#### **4. Adapting Berry's Instrumentation to Yeh's Device Would Require Substantial Redesign**

156. I disagree with the Petition's conclusion that Berry's expander apparatus could be used with Yeh's implant with "little to no modifications." In my opinion, the Petition does not provide the engineering analysis that a person of ordinary skill in the art would have required before concluding that Berry's implant-specific expansion tool could be adapted to Yeh's materially different adjustment mechanism.

157. Berry's expander apparatus is not a universal driver. As discussed above, it is designed to cooperate with Berry's own implant geometry and actuator

interface. In Berry, the tool engages the implant through structures specifically configured to interact with Berry's tubular body and its associated engagement features. Yeh, by contrast, uses a different adjustment architecture built around adjustment ring 130 and tool holes 131. Those differences matter because the way torque is introduced into the implant, how the tool remains engaged, and how the implant expands all depend on the particular geometry of the tool-implant interface.

158. The Petition does not explain how Berry's C-shaped engager would physically engage Yeh's adjustment ring. It does not analyze whether Yeh's tool holes 131 are positioned, sized, shaped, or spaced to cooperate with Berry's engagement mechanism. Nor does it address whether the pitch, circumferential spacing, or axial position of Yeh's tool holes correspond in any meaningful way to Berry's actuator interface. These are not minor details. They determine whether the tool can engage the implant at all and whether it can remain properly engaged while torque is applied – the foundations of tool-implant compatibility.

159. The Petition also fails to explain how Berry's tool would transmit torque to Yeh's adjustment ring. In Berry, torque is transmitted through Berry's integrated engagement architecture, which is designed for Berry's rotating tubular body. Yeh uses a separate adjustment ring with a single circumferential row of tool holes. A person of ordinary skill would have understood that transferring Berry's torque path to Yeh would require analysis of tooth reach, hole pitch, engagement

depth, torque reaction, axial stability, and clearance around the ring. The Petition does not address any of those issues.

160. In my opinion, a person of ordinary skill would not have assumed that Berry's tool could simply be placed around Yeh's implant and used successfully. Berry's C-shaped engager may surround Berry's tubular body, but that alone would not prevent the tool from moving or pivoting vertically relative to the implant. Such movement could misalign Berry's engagement teeth with Yeh's tool holes. That concern is especially important because Yeh's adjustment ring provides only a single circumferential row of tool holes, whereas Berry's tubular body includes multiple vertically spaced rows of apertures. A small vertical displacement that might still permit engagement in Berry could prevent engagement entirely in Yeh.

161. The Petition also does not analyze whether Berry's stabilizing features would be compatible with Yeh's implant. Berry includes structural features that cooperate with Berry's tubular body to maintain alignment while torque is transmitted. Yeh's architecture is different because it uses an adjustment ring positioned relative to upper and lower support bodies. A person of ordinary skill would have needed to determine whether Berry's stabilizing components could be used without interfering with Yeh's translating upper support body, adjustment ring, or surrounding implant structures. The Petition does not provide that analysis.

162. Nor does the Petition identify what modifications would actually be made. It does not specify whether Berry's engager would be resized, reshaped, repositioned, or otherwise redesigned. It does not identify any changes to the engagement teeth, the curvature of the C-shaped engager, the axial location of the engagement structure, the handle orientation, or any stabilizing components. Without identifying the proposed modifications, one cannot evaluate whether the modified tool would preserve Berry's alleged advantages or allow Yeh to operate as intended.

163. In my opinion, the Petition's statement that "little to no modifications would be needed" is conclusory. The Petition appears to rely on overarching geometric similarities: Berry's tubular body includes apertures, Yeh's adjustment ring includes openings, and Yeh's implant is generally cylindrical. Those observations do not establish mechanical compatibility. They do not show that Berry's implant-specific actuator interface would engage Yeh's adjustment ring, remain aligned during use, transmit torque without slipping or disengaging, or avoid interference with Yeh's expansion mechanism.

164. A person of ordinary skill would have recognized that adapting Berry's specialized tool to Yeh would require a detailed engineering assessment. That assessment would include at least the geometry of the engagement interface, the axial and circumferential alignment of the tool teeth and Yeh's tool holes, the

clearance between the tool and Yeh's implant components, the stability of the tool during rotation, the torque path into the adjustment ring, and whether the tool could remain engaged throughout expansion. The Petition does not undertake that analysis.

165. For these reasons, I do not agree that the Petition establishes that Berry's expander apparatus could be successfully adapted for use with Yeh's implant. The Petition identifies a desired result, but it does not explain how that result would be achieved. In my opinion, the Petition assumes compatibility between two materially different actuator interfaces without demonstrating it through engineering analysis. A person of ordinary skill would not have simply assumed that Berry's tool could be used with Yeh's implant with "little to no modifications."

#### **5. A POSITA Would Not Have Reasonably Expected the Proposed Combination to Operate Successfully**

166. Even assuming that a person of ordinary skill in the art would have desired to use Berry's expander apparatus with Yeh's implant, I do not believe such a person would have reasonably expected the resulting system to function successfully based on the analysis presented in the Petition. Before concluding that a specialized surgical instrument developed for one implant could successfully actuate another implant employing a materially different adjustment mechanism, a person of ordinary skill would have analyzed whether the modified system would

reliably operate under the conditions encountered during surgery. The Petition does not perform that analysis.

167. In particular, the Petition does not explain why a person of ordinary skill would have expected Berry's engagement mechanism to reliably engage Yeh's adjustment ring throughout the expansion procedure. Successful operation depends upon repeated and reliable engagement between the tool and the implant while torque is transmitted to the rotating component. Whether that engagement can be achieved depends upon numerous engineering considerations, including the geometry of the mating components, the stability of the tool during use, the alignment of the engagement features, and the ability of the instrument to remain engaged while rotational forces are applied. The Petition does not analyze any of those considerations.

168. The Petition likewise provides no basis for concluding that Berry's engagement mechanism would maintain proper alignment with Yeh's adjustment ring during use. In my opinion, maintaining alignment is a fundamental engineering requirement for functionality whenever torque is transmitted through relatively small engagement features. Even relatively small amounts of axial, radial, or angular movement can reduce engagement between the tool and implant, increase localized loading, promote slippage, or cause the instrument to disengage altogether. Because Berry and Yeh employ different engagement architectures, a person of

ordinary skill would not have assumed that the alignment characteristics of Berry's system would automatically carry over to Yeh's implant.

169. My opinion is reinforced by the deposition testimony of Petitioner's expert. Mr. Culbert acknowledged that successful engagement between a toothed instrument and corresponding implant features requires guidance to properly align the tool before torque can be transmitted. Ex. 2030 at 91-93. He testified that attempting to locate the engagement features without such guidance would require keeping a long, slender instrument "perfectly straight," something he did not believe was physically possible under normal surgical conditions. He further explained that the guidance structure assists the tool so that the engagement teeth "mate nicely" with the corresponding implant features. I agree that proper guidance and alignment are important engineering considerations in systems of this type.

170. Those principles expose a significant deficiency in the proposed Yeh-Berry combination. The Petition does not identify any structure that would provide comparable guidance between Berry's specialized engagement mechanism and Yeh's adjustment ring. Nor does it explain how Berry's tool would consistently locate and engage Yeh's single circumferential row of tool holes before torque transmission begins. In contrast, Berry's own implant includes multiple vertically spaced rows of apertures that provide substantially greater opportunity for engagement despite minor positional variation. Yeh's adjustment ring provides no

comparable redundancy. Consequently, successful engagement in the proposed combination would require considerably greater positioning accuracy than Berry's own system, yet the Petition never explains why or how a person of ordinary skill would have expected that level of precision to be achieved.

171. Nor does the Petition evaluate whether the proposed combination would reliably remain engaged after torque transmission begins. As rotational forces are applied, reaction forces are generated at the interface between the engagement teeth and the implant. Whether those forces can be accommodated without disengagement, excessive wear, binding, or slippage depends upon the geometry of the engagement interface and the structures maintaining alignment between the tool and implant. Those issues are especially important where, as here, the proposed combination substitutes an actuator interface developed for one implant architecture into a different implant architecture. The Petition provides no engineering analysis addressing these issues.

172. The Petition also provides no basis for concluding that the proposed modifications would preserve Yeh's intended operation. Berry's expander apparatus was designed to cooperate with Berry's own implant geometry and stabilizing structures while transmitting torque to Berry's rotating tubular body. Yeh employs a different expansion architecture centered on adjustment ring 130 and cooperating support bodies. In my opinion, a person of ordinary skill would have evaluated

whether adapting Berry's engagement mechanism would interfere with Yeh's intended expansion kinematics, affect the stability of the instrument during adjustment, or otherwise alter the operation of Yeh's implant. The Petition does not undertake any such analysis.

173. Ultimately, the Petition assumes that because Berry's tool and Yeh's implant each generally relate to expandable spinal implants, Berry's specialized actuator interface could simply be adapted with little or no modification and would function successfully. That is not how a person of ordinary skill would approach the engineering problem of implants and surgical instruments. Before expecting success, such a person would have analyzed whether the modified instrument would reliably engage Yeh's adjustment ring, maintain alignment throughout the expansion procedure, transmit torque without slippage or disengagement, and preserve Yeh's intended mechanical operation. Because the Petition does not address those issues, I do not believe it establishes that a person of ordinary skill would have had a reasonable expectation that the proposed Yeh-Berry combination would function successfully.

#### **6. Yeh in View of Berry Does Not Teach or Suggest a Rotating Gear**

174. I have reviewed Petitioner's analysis concerning the "rotating gear" limitation of claims 8 and 12. In my opinion, Petitioner's analysis is conclusory and does not provide the technical explanation that a person of ordinary skill in the art

would require before concluding that Yeh's adjustment ring 130 is the claimed rotating gear. Other than simply labeling adjustment ring 130 as "the gear," the Petition does not explain why a POSITA would understand a threaded adjustment ring to be a gear, nor does it identify any engineering characteristics of adjustment ring 130 that would support such a conclusion.

175. A POSITA would not understand Yeh's adjustment ring 130 to be a gear, based on the plain and ordinary meaning of the term. A threaded adjustment ring and gear are different mechanical components that operate according to different mechanical principles. A threaded adjustment ring functions as a threaded member that converts rotational motion into axial movement through mating screw threads. A gear, by contrast, transmits rotational motion through meshing teeth that engage another gear, pinion, or other toothed member. Simply because both components rotate does not make a threaded adjustment ring a gear. Accordingly, a POSITA would not have understood Yeh's adjustment ring 130 to be a "rotating gear" based solely on its ability to rotate.

176. That understanding is consistent with the intrinsic record of the '755 Patent. The specification consistently distinguishes gears from threaded bodies and screws, describing gears as separate mechanical elements that transmit rotational motion to the threaded expansion components. For example, the '755 Patent explains that the disclosed bidirectional fixation mechanism employs "one or two

pinions which then turns one or two central gears which in turn simultaneously controls expansile movement of right and-left-handed bi-directional screws.” Ex. 1001, 3:8-12. Likewise, every embodiment depicts gears as distinct toothed members that mechanically engage other gears or pinions, while the threaded bodies remain separate structural elements. *See, e.g.,* Ex. 1001, 5:49-60, 6:10-13, 6:21-29, Figs. 1C-1D, 2C, 2F, 3C-3E. Nothing in the patent suggests that the term “gear” was intended to encompass any rotating threaded component or adjustment ring. Nor do Patent Owner’s arguments during prosecution of the ’755 Patent. *See e.g.,* Ex. 1004 at 249 (“Biedermann's threaded spindle 15 (the alleged rotating gear) engages with a threaded bore 55 of the wedge members, but is not “at least one rotating gear”), 250 (“Daher’s buttressing means 1 (the alleged rotating gear) comprises connecting piece 5 and buttressing elements 8 and 9 which are threaded, but are not “at least one rotating gear”).

177. For these reasons, I do not agree that a person of ordinary skill in the art would recognize Yeh’s adjustment ring 130 as the claimed “rotating gear.” In my opinion, Petitioner’s unsupported relabeling of Yeh’s threaded adjustment ring as a gear does not constitute the type of technical analysis that would demonstrate that claims 8 and 12 would have been obvious to a person of ordinary skill in the art.

**7. Yeh in View of Berry Do Not Teach an Expansion Mechanism Comprising the Distinct Tool-Engagement Surface, Threaded Body, and Turning Mechanism Structures Required by Claim 1 or the Expansion Mechanism Comprising the Distinct Tool-**

## **Engagement Surface and Rotating Gear Structures of Claim 12**

178. As discussed previously in my declaration, a POSITA would understand claims 1 and 12 to recite separate structural components within the claimed expansion mechanism. Claim 1 separately recites an expansion mechanism comprising a tool-engagement surface, a threaded body, and a turning mechanism. Claim 12 similarly recites an expansion mechanism comprising a tool-engagement surface and at least one rotating gear. Based on the claim language, a POSITA would understand those separately recited components to correspond to separate structures within the expansion mechanism.

179. Petitioner's mapping does not identify separate corresponding structures. Instead, Petitioner identifies upper support body 120, lower support body 110, and adjustment ring 130 collectively as the claimed expansion mechanism, while relying on overlapping portions of adjustment ring 130 to satisfy multiple separately recited claim components. Specifically, Petitioner identifies tool holes 131, which are formed in adjustment ring 130, as the claimed tool-engagement surface. At the same time, Petitioner identifies adjustment ring 130 itself as the claimed turning mechanism of claim 1 and as the claimed rotating gear of claim 12. Petitioner further identifies the threaded engagement between threaded teeth 122 and 132 as the claimed threaded body of claim 1. Tool holes 131 are not a separate

structural component apart from adjustment ring 130. They are simply openings formed in that same rotating adjustment ring.

180. Yeh consistently describes adjustment ring 130 as a single rotating adjustment component. During operation, a surgical tool is inserted into tool holes 131 and applies torque directly to adjustment ring 130. Rotation of adjustment ring 130 causes threaded teeth 132 to cooperate with threaded teeth 122 on upper support body 120, thereby translating the upper support body relative to the lower support body and expanding the implant. A POSITA therefore would understand adjustment ring 130 to be one integrated rotating component that receives rotational input from the surgical tool and converts that rotation into implant expansion. The tool holes 131 are simply openings formed in that same adjustment ring through which the tool applies rotational input; they are not disclosed as a separate structural component independent of the adjustment ring itself. Accordingly, a POSITA would not have understood Yeh to disclose separate structures corresponding to both the claimed tool-engagement surface and the separately recited turning mechanism of claim 1 or the separately recited rotating gear of claim 12.

181. In my opinion, Petitioner's mapping artificially separates and reallocates portions of Yeh's disclosed adjustment mechanism in order to correspond to the separately recited claim limitations. Rather than identifying separate structures corresponding to the separate components recited in claims 1 and 12, the

Petition repeatedly assigns multiple claim limitations to overlapping portions of the same adjustment ring while treating integral features of that ring as though they were separate structural components. A person of ordinary skill would instead understand Yeh's expansion mechanism according to the way Yeh itself describes its operation—as a single rotating adjustment ring that receives rotational input through tool holes 131 and expands the implant through its threaded engagement with the upper support body.

182. Accordingly, I do not believe the proposed Yeh-Berry combination discloses the distinct structural components recited in claims 1 and 12. In my opinion, Petitioner's mapping depends on assigning overlapping portions of the same adjustment ring to multiple separately recited claim elements rather than identifying separate corresponding structures within Yeh's disclosed expansion mechanism. That is not how a person of ordinary skill would understand Yeh's mechanism to be configured or to operate.

**8. Yeh in View of Berry Does Not Teach or Suggest the Claimed Tool-Engagement Surface Required by Claims 1 & 12**

183. Claims 1 and 12 list several requirements associated with the claimed "tool-engagement surface." The expansion mechanism must include a tool-engagement surface, the claimed tool must be engaged with the tool-engagement surface while the tool is rotated about its longitudinal axis, and the tool-engagement

surface must be “positioned and configured to be engaged by the tool extending along a direction of insertion.”

184. I have reviewed Petitioner's mapping of the claimed “tool-engagement surface” to the contours of Yeh’s tool holes 131. The Petition does not clearly identify what physical structure constitutes the alleged tool-engagement surface. It is unclear whether Petitioner contends that the claimed surface consists of the collective contours of all of the tool holes, the contour of a single tool hole, or variably changing contours of multiple tool holes (e.g., whichever contour happens to be contacted by Berry’s engagement tooth at a particular moment during rotation). Each interpretation presents different mechanical consequences, and in my opinion none is technically consistent with the operation required by the claims.

185. If Petitioner contends that the alleged tool-engagement surface consists of the collective contours of all of Yeh’s tool holes, a POSITA would not have understood that a collection of separate, discontinuous contours to constitute a single surface. Each tool hole defines its own individual boundary, separated circumferentially from adjacent holes by solid portions of the adjustment ring. A person of ordinary skill ordinarily would not describe multiple spatially separated hole contours as a tool-engagement surface. More importantly, even assuming Berry’s tool could be redesigned to work with Yeh’s device (which I address above), Berry’s tool would never simultaneously engage all of those contours. During

operation, Berry's teeth contact only one, or at most two, tool holes at any given time, while the remaining holes would not touch the tool. Therefore, Berry's tool would never be engaged, nor remain engaged with, the tool-engagement surface during the tool's operation.

186. Whether two structures remain "engaged" depends upon the continuity of their mechanical interaction throughout the operation being performed. When a tool is described as remaining engaged with an identified surface while it rotates, a person of ordinary skill would understand that the same identified surface continues to mechanically cooperate with the tool throughout that rotational movement. A person of ordinary skill would not understand that requirement to be satisfied by a series of separate, independent structures that are contacted only momentarily in succession. Consequently, even if the collective contours of Yeh's tool holes were considered together, Berry's tool would not remain engaged with that collective surface throughout rotation because, at any given time, it contacts only isolated portions of the alleged surface.

187. Alternatively, if the alleged tool-engagement surface is limited to the contour of a single tool hole, the proposed combination likewise does not satisfy the claimed engagement relationship. Again assuming Berry's tool could be redesigned to work with Yeh's device, as Berry's mechanism rotates, successive teeth would advance circumferentially around Yeh's adjustment ring and contact successive tool

holes. Thus, any individual tool hole would be in contact with a tooth only briefly before the tooth would advance to the next opening. Mechanically, the tool would repeatedly disengage from one tool hole and re-engage another rather than remaining engaged with any particular tool while it rotates. A POSITA would not understand this to meet the claims' requirement of a tool-engagement surface, including one with which the claimed tool remains engaged with the tool-engagement surface while the tool is rotated about its longitudinal axis, as well as "be engaged by the tool extending along a direction of insertion."

188. The remaining possibility is that Petitioner asserts that the alleged tool-engagement surface changes throughout operation, becoming whichever tool hole happens to be engaged by Berry's engagement tooth at a particular instant. However, that does not identify one physical engagement surface. Rather, it identifies a succession of different tool holes that are contacted at different times as the adjustment ring rotates. Because the identity of the structure contacting the tool would continuously change during operation, there is no single identified surface that remains engaged throughout rotation, which does not meet the claims' requirements.

189. The geometry of Yeh's adjustment ring further supports this conclusion. Each tool hole is separated from adjacent holes by solid material and functions as an independent localized structural feature. The individual hole contours do not

combine to form one continuous engagement surface. Instead, Yeh's tool holes provide multiple discrete surfaces that—if used with Berry's tool—would be contacted sequentially as Berry's teeth progress around the ring. Accordingly, a person of ordinary skill would not regard the collective contours of Yeh's tool holes as one persistent engagement surface.

190. Neither the Petition nor its expert analyze these engineering principles. Instead, it simply labels the contours of Yeh's tool holes as the claimed tool-engagement surface without considering the implication of such a label, including how the mechanical engagement changes as Berry's engagement teeth progress from one tool hole to the next during operation. Regardless of whether Petitioner's mapping is interpreted as encompassing all of Yeh's tool holes, a single tool hole, or whichever tool hole happens to be engaged at a given moment, the proposed Yeh-Berry combination does not disclose one identified tool-engagement surface that remains engaged by the tool throughout the claimed rotational actuation. Instead, it relies on a continuously changing sequence of separate engagement events involving different tool holes, which is mechanically different from the engagement relationship recited in the challenged claims.

**E. Ground 5: Claims 5, 6, 18, and 19 are Patentable Over Yeh in View of Berry and Schäfer**

191. I have reviewed Petitioner's proposed combination of Yeh, Berry, and Schäfer with respect to claims 5, 6, 18, and 19. Assuming for purposes of my

analysis that a person of ordinary skill had already modified Yeh to incorporate Berry's specialized expansion tool, I do not believe the Petition provides a technical reason why a POSITA would have further modify the resulting implant to incorporate Schäfer's shell configuration.

192. The external shell geometry of an expandable spinal implant is not an isolated design feature that can be considered independently from the implant's expansion architecture. The shell geometry must be compatible with the underlying expansion mechanism, the manner in which expansion forces are introduced into the implant, the relative motion of the implant components during expansion, and the associated instrumentation used to implant and actuate the device. Without considering these factors an implant expansion mechanism could prove unreliable or incompatible with a specific surrounding structure. Consequently, a person of ordinary skill would not simply transplant shell features from one expandable implant to another without evaluating how those features interact with the remainder of the implant system.

193. That consideration is particularly important here because Schäfer employs a materially different expansion architecture than Yeh. Yeh expands through rotation of an adjustment ring, whereas Schäfer employs a stationary supporting ring and rotating inner sleeves that cooperate with threaded components to produce expansion. Because the shell structures in each implant are designed

around different underlying expansion mechanisms, a POSITA would not have assumed that Schäfer's shell geometry could simply be incorporated into the already-modified Yeh-Berry combination while preserving the intended operation of the implant. A person of ordinary skill would have expected to evaluate how the proposed shell configuration interacts with the expansion mechanism, internal components, and surgical instrumentation before concluding that such a modification would be appropriate.

194. The Petition does not perform that engineering analysis. Instead, it merely states that incorporating Schäfer's shell geometry would not hinder the operation of Yeh's implant. In my opinion, that observation does not explain why a person of ordinary skill would have selected Schäfer's shell configuration in the first place. Nor does it address whether the proposed shell configuration is mechanically compatible with the already-modified Yeh-Berry system or whether it would preserve the intended operation of that system. Accordingly, I do not believe the Petition provides a technical basis from which a person of ordinary skill would have been motivated to make the additional modifications proposed in Ground 5.

**F. Ground 6: Claims 9 and 20 are Patentable Over the Combination of Yeh in View of Barry and Suddaby**

195. I have reviewed Petitioner's proposed combination of Yeh, Berry, and Suddaby with respect to Ground 6. The addition of Suddaby does not remedy the deficiencies I identified regarding the proposed Yeh-Berry combination. Moreover,

although titanium was a well-known material for spinal implants at the relevant time, the Petition does not explain why a POSITA would have looked specifically to Suddaby to further modify the already-proposed Yeh-Berry combination. General knowledge that titanium possesses desirable properties, such as strength, corrosion resistance, and biocompatibility, does not provide a technical reason to incorporate Suddaby's teachings into that combination.

196. Likewise, Suddaby's statement that its implant is easy to manufacture from "common materials" does not, in my opinion, provide a technical motivation for the proposed modification. That statement does not attribute any manufacturing advantage specifically to titanium, nor does it suggest that titanium should be incorporated into Yeh's implant or the proposed Yeh-Berry combination for the same reasons. A person of ordinary skill would have understood that material selection depends on the design, geometry, loading conditions, manufacturing process, and intended performance of the particular implant being developed. The Petition does not analyze any of those engineering considerations or explain why Suddaby's disclosure would have led a person of ordinary skill to select titanium for the already-modified Yeh-Berry device.

197. Accordingly, I do not believe the Petition provides a technical basis for looking to Suddaby as part of the proposed combination. Instead, the Petition identifies titanium as a generally known implant material and then cites Suddaby

because it discloses titanium. In my opinion, that does not explain why a person of ordinary skill would have selected Suddaby or expected its disclosure to contribute anything beyond the general knowledge already attributed to such a person.

## **X. CONCLUSION**

198. In my opinion, claims 1-6, 8-12, and 17-20 of the '755 Patent are (1) not anticipated by Schäfer and (2) are not rendered obvious by Schäfer-Suddaby, Yeh-Berry, Yeh-Berry-Schäfer, or Yeh-Berry-Suddaby. Accordingly, it is my opinion that claims 1-6, 8-12, and 17-20 of the '755 Patent are all patentable.

199. 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.

200. 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.

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

Executed on: July 20<sup>th</sup> 2026

A handwritten signature in blue ink, appearing to read "Ken Gall".

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Ken Gall, Ph. D.