

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner

Patent No. 8,460,385

EXPERT DECLARATION OF BRAD CULBERT

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I. INTRODUCTION

1. I have been retained as a technical expert by Globus Medical, Inc. (“Globus” or “Petitioner”) and asked to provide my objective and unbiased opinions concerning U.S. Patent No. 8,460,385 (“the ’385 Patent”), which Globus is challenging in a Petition for *Inter Partes* Review. Specifically, I have been asked to provide my opinions as to the patentability of certain claims of the ’385 Patent in view of certain prior art references, the state of the art at the time of the claimed invention, and the knowledge of a person of ordinary skill in the art at the time of the claimed inventions.

II. BACKGROUND AND QUALIFICATIONS

2. In forming the opinions expressed in this Declaration, I have considered and relied upon my education, background, and experience. In addition, I have reviewed and relied upon additional materials in preparation of this Declaration, as described below.

3. My experience, qualifications and education are detailed in my curriculum vitae (“CV”), a copy of which is attached as Appendix A to this declaration and which I understand is also being submitted as an exhibit to the Petition. My CV also lists patents and publications on which I am a named author

and identifies parties on behalf of whom I have previously provided expert testimony.

4. I am a medical device engineer with substantial experience designing and developing expandable intervertebral fusion cages for treating damaged and diseased vertebrae. For example, I led the design and development of the Opticage[®] Expandable InterbodyFusion Device, as discussed below.

5. I received a Bachelor's of Applied Science in Metals and Materials Engineering from the University of British Columbia in 1992. I later received a Master's in Business Administration from California State University, Fullerton in 2001.

6. In 1994, I accepted a position as a manufacturing engineer at Vas-Cath Inc. I was later promoted to Angioplasty Product Team Leader. Vas-Cath was a small privately held company focused on developing and distributing dialysis and angioplasty catheters. I led a team of R&D, manufacturing, and quality engineers to improve and maintain the company's angioplasty catheter product lines.

7. In 1996, I accepted a position as an R&D Project Manager at CVD. CVD was a cardiovascular company focused on developing new angioplasty balloons and stents with focal technology. While at CVD, I designed and developed new PTCA catheters and stent delivery systems and participated in the preparation and filing of regulatory documents.

8. In 1998, I accepted a position as Senior R&D Project Manager at Endicor Medical, Inc. Endicor Medical was a small venture backed startup company focused on developing percutaneous thrombectomy and atherectomy systems for cardiovascular and neurovascular applications. I designed and developed a thrombectomy system that cuts larger channels through in-stent restenosis and led project teams to transfer the product to manufacturing.

9. In 2000, I was hired as the first employee at Interventional Spine, Inc. (formerly known as Triage Medical, Inc.). I was initially hired as Director of Engineering but was quickly promoted to Vice President of Research and Development. I was later promoted to Chief Technology Officer. While at Interventional Spine, I oversaw the design and development of a series of percutaneous spine procedures and devices, including the Opticage®. In my various roles, I led, oversaw, and managed employees who also met the definition of a person of ordinary skill in the art and I was actively involved in the development process. For example, as explained below I contributed substantially to the design of the Opticage®.

10. The Opticage® (shown below) is an FDA cleared titanium expandable cage designed for insertion between two damaged or diseased vertebrae. As shown, the cage had large graft windows in the top and bottom to receive bone graft. The

bone graft would promote bone growth through the device after implantation and eventually fuse the patient's vertebrae together.



11. Beginning in 2010, I started my own consulting business focused on medical devices companies. I currently advise medical device companies across a range of disciplines, including product development, regulatory approval, manufacturing, intellectual property procurement, and financing. My consulting work involves consulting on spinal implant technology.

12. For example, Ellipse Technologies hired me as a full-time consultant to help develop magnetic implant technology. The goal for me was to find other indications and designs that could use the magnetic implant for spine procedures, including intervertebral fusion. A summary of my work for this project can be found in U.S. Patent No.'s 10,265,101 and 11,123,107.

13. In addition to my professional experience and education discuss above, I am also listed as an inventor on over 30 U.S. patents relating to devices and methods for treating the spine.

14. Based on my experience, I am very familiar with the spine and vertebrae, when healthy and when diseased, and with the functional requirements of intervertebral repair systems designed to relieve the symptoms of diseased or damaged vertebrae. I am also familiar with and understand the surgical procedures used to implant intervertebral implants.

15. Based on my education and professional experience, I am an expert in the relevant field of the '385 Patent and have been an expert in this field since before the earliest possible priority date (which I understand to be March 27, 2008). I am familiar with how a person having ordinary skill in the art would have understood and used the terminology found in the '385 Patent as of that date.

16. I am being compensated for services provided in this matter at my standard rates. I am also being reimbursed for reasonable expenses, such as travel expenses. My compensation is not contingent on my opinions, on the outcome of any matter, or on any of the technical positions I explain in this declaration. I have no financial interest in Patent Owner or the '385 Patent.

III. LEGAL STANDARDS

17. I am not an attorney. For purposes of this Declaration, I have been informed about certain aspects of the law that are relevant to my opinions, as set forth below.

A. Patentability

18. I understand that for an invention claimed in a patent to be valid and patentable, it must be, among other things, new and not obvious in light of what was known and came before it. That which was known or came before the invention claimed is generally referred to as “prior art.”

19. I understand that there are two ways in which prior art may render a patent claim unpatentable. First, the prior art can be shown to “anticipate” the claim. Second, the prior art can show that the claim was obvious to a person of ordinary skill in the field of the invention at the time the invention was made.

20. I understand that, for a patent claim to be “anticipated” by the prior art, each and every element or requirement of the claim must be found, expressly or inherently, in a single prior art reference. Further, I understand that anticipation requires that the single prior art reference must disclose the elements of the claim arranged or combined in the same way as in the claim.

21. It is my understanding that whether a claimed invention is obvious is a question of law, with underlying factual inquiries that are determined from the perspective of a person of ordinary skill in the art at the time of the claimed invention.

22. It is my understanding that a claimed invention is obvious if the differences between the claimed invention and the prior art are such that the claimed

invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art (a “POSA”).

23. It is my understanding that obviousness requires consideration of the following underlying factual inquiries:

- determining the scope and content of the prior art
- ascertaining the differences between the claimed invention and the prior art;
- resolving the level of ordinary skill in the art; and
- evaluating objective evidence or “secondary considerations” of non-obviousness, such as commercial success, long-felt but unresolved needs, failure of others, industry praise, and unexpected results.

24. It is my understanding that a reference must be analogous art to the claimed invention in order to be properly considered for use in an obviousness inquiry. It is my understanding that a reference is analogous art to the claimed invention if:

- the reference is from the same field of endeavor as the claimed invention (even if it addresses a different problem); or
- the reference is reasonably pertinent to the problem faced by the inventor (even if it is not in the same field of endeavor as the claimed invention).

25. It is my understanding that whether a reference is reasonably pertinent turns on how the problem faced by the inventor is reflected, either explicitly or implicitly, in the specification.

26. It is my understanding that the following are exemplary rationales that may support a conclusion of obviousness:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known techniques to improve a similar method or product in the same way;
- Applying a known technique to a known method or product ready for improvement to yield predictable results;
- Obvious to try – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

27. In addition to the above, I understand that a person of ordinary skill in the art may resort to logic, judgment and common sense available to him or her at the time of the invention to find a claim feature obvious, even if the prior art relied on does not explicitly state or teach that feature. I understand that when common sense is relied on to find a feature obvious, the reasoning for that conclusion must be articulated with sufficient clarity.

28. I also understand that a patent claim is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. An obviousness determination requires finding both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so. I understand that it is important to be careful not to allow hindsight reconstruction of references to produce the claimed invention, without any explanation as to how or why the references would be combined to produce the claimed invention.

29. Regarding “objective evidence” or “secondary considerations,” I understand that for such evidence to be relevant to the obviousness of a claim, there must be a causal relationship (called a “nexus”) between the claim and the evidence. I also understand that such objective evidence may include: commercial success of products covered by the patent claims; long-felt need for the invention; failed

attempts by others to solve the problem addressed by the invention; copying of the invention by others in the field; unexpected results achieved by the invention; praise of the invention; the taking of licenses under the patent by others; expressions of surprise by experts and those skilled in the art at the making or use of the invention; and that the patentee proceeded contrary to the accepted wisdom of the prior art.

30. I understand that a person of ordinary skill is also a person of ordinary creativity. I further understand that the obviousness analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, but instead can take into account “ordinary innovation” that does no more than yield predictable results, which are inferences and creative steps that a person of ordinary skill in the art would be understood to employ.

31. I understand that sometimes it will be necessary to look to interrelated teachings of multiple patents and publications; the effects of demands known to the relevant field or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art. I understand that all these issues may be considered to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

B. Prior Art

32. I understand that for purposes of this proceeding, prior art includes patents and printed publications in or outside the United States before the effective

filing date of the claimed invention. I also understand that prior art includes U.S. patents, published U.S. patent applications, and published international applications (pursuant to the Patent Cooperation Treaty) that themselves have an effective filing date before the effective filing date of the claimed invention, as long as they name another inventor.

33. I also understand that prior art may include any public disclosure, including any products in public use, on sale, or otherwise available to the public, before the effective filing date of the claimed invention. I understand that information that constitutes prior art generally must be information that was publicly disclosed before the effective filing date of the claimed invention. I understand that there may be exceptions to what is prior art but have been instructed that they are not relevant for purposes of my opinions here.

C. Inherency

34. I understand that if a prior art reference does not expressly set forth a particular claim element, the prior art may still disclose that element if it is “inherent” in its disclosure. To establish inherency, it is my understanding that evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. It is my understanding that inherency may not be established by probabilities or possibilities. In other words, it is my understanding

that the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.

35. I understand that under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform a claimed method, then the method will be considered to be anticipated by the prior art device. I also understand that when the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process.

D. Person of Ordinary Skill In The Art

36. I understand that “a person of ordinary skill in the art” or POSA is a hypothetical person who is presumed to have known the relevant art at the time of the invention. I understand that the term “person having ordinary skill in the art” or POSA is sometimes used synonymously. Such a person would necessarily have the capability of understanding any scientific and engineering principles applicable to the pertinent art.

37. I understand that factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the following:

(1) the educational level of the inventor;

(2) the type of problems encountered in the art;

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

38. I understand that a person of ordinary skill in the art is not a real person, but rather is a hypothetical individual having the qualities reflected by the factors above. This hypothetical person has knowledge of all prior art in the relevant field as if it were arranged on a workshop wall and takes from each reference what it would teach to a person of ordinary skill in the art.

39. I understand that a person of ordinary skill in the art is a person of ordinary creativity, not an automaton. In many cases a person of ordinary skill will be able to fit the teachings of multiple prior art references together like pieces of a puzzle.

40. I understand that a person of ordinary skill in the art can collaborate with one or more other persons of ordinary skill in the art for one or more aspects with which the other person may have superior expertise, experience, and/or knowledge.

E. Claim Construction

41. It is my understanding that claim construction, or the interpretation of the claims of a patent, is ultimately a question of law. I have been informed that claim terms are generally presumed to carry their ordinary and customary meaning. However, I understand that a patent applicant is his own lexicographer and is entitled to provide alternate definitions of words in common usage, but if the patent applicant uses a term that is in common usage without providing an alternate definition, then that term should generally be understood as having its common meaning.

42. I understand that a person of ordinary skill in the art is deemed to read a claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent specification and the “file history” of the patent developed during examination by the Patent Office.

43. I understand that the claims, the specification, and the file history are referred to as “intrinsic evidence,” and are to be read as a person of ordinary skill in the art at the time of the invention would have done at the time of the alleged invention.

44. In addition to the intrinsic evidence, I understand that the court or tribunal may also consider other relevant evidence, which is called “extrinsic evidence,” concerning relevant scientific principles, the meaning of technical terms, and the state of the art. Such evidence includes the testimony of expert witnesses.

Although extrinsic evidence may be used to resolve ambiguities that may exist after reviewing the intrinsic evidence, I understand that extrinsic evidence cannot be used to contradict a claim construction that is clear from the intrinsic evidence.

45. I understand that some claims are independent, and that those independent claims are complete by themselves. Other claims refer to these independent claims, or other dependent claims, and are “dependent” on those claims. The dependent claims include all of the limitations of the claims on which they depend.

IV. BASES FOR OPINIONS

46. The opinions set forth in this Declaration are my own. In forming my opinions, I have considered the materials cited herein and my education, training, and experience. These materials include the exhibits to the Petition included in the exhibit listing below:

Exhibit No.	Description
1001	U.S. Patent No. 8,460,385 to Wensel (“the ’385 Patent”)
1003	File History, U.S. Patent Application 12/705,972 (’385 Patent).
1004	U.S. Patent No. 7,942,903 (“Moskowitz”)
1005	U.S. Patent No. 4,790,303 (“Steffee”)
1006	U.S. Patent No. 8,075,593 (“Hess”)

Exhibit No.	Description
1007	U.S. Patent Application Publication US 2006/0030851 (“Bray”)
1008	U.S. Patent Application Publication US 2005/0085913 (“Fraser”)
1009	Excerpts from Webster’s New World College Dictionary (4th Ed., 1999)
1010	Excerpts from The Oxford American Desk Dictionary (1998)
1011	Excerpts from The American Heritage Dictionary (2nd College Ed., 1982)
1012	Infringement Contentions Claim Chart of ’385 Patent
1013	Youtube Video File cited in Patent Owner’s Infringement Contents available at: https://www.globusmedical.com/products/hedron-ia/ downloaded from https://www.youtube.com/watch?v=mfkNhww75N0
1015	U.S. Patent No. 9,980,824
1016	Lumbar Interbody Fusion Techniques <i>Cages, Dowels, and Grafts</i> , ed. Haid, Jr. et al., Quality Medical Publishing, Inc., St. Louis, Missouri 2003.
1017	Advances in Spinal Fusion – Molecular Science, Biomechanics, and Clinical Management, ed. Lewandrowski et al., Marcel Dekker, Inc., New York, New York 2004.
1018	U.S. Patent 8,100,955
1019	U.S. Patent No. 7,662,186
1020	U.S. Patent No. 7,041,135
1021	U.S. Patent Application Publication No. US 2009/0112261
1022	U.S. Patent No. 6,447,546
1023	U.S. Patent 8,172,854
1024	U.S. Patent 8,273,127
1025	Machinery Handbook, 28th Ed. (excerpts)
1026	A Method to Machine a Curved Tunnel with EDM, International Journal of Electrical Machining, No. 7, 2002, Goto et al.

47. My analysis of the materials relating to this matter is ongoing and I will continue to review any new material that is provided to me. This Declaration

represents certain opinions that I have formed to date and the bases for those opinions. I reserve the right to revise, supplement, and/or amend my opinions based on new information presented to me and on my continuing analysis of the materials cited herein or later provided to me.

V. LEVEL OF ORDINARY SKILL IN THE ART

48. As discussed above, I understand that multiple factors may be used to inform the level of ordinary skill in the art. In considering the characteristics of the hypothetical POSA, I have considered the type of problems encountered in the field, the complexity (and lack thereof) of the technology and technological principles used in the invention and in similar devices and methods, the rapidity with which innovations were made, and the education, background, and experience of those actively working in the field, and the level of education necessary to understand the '385 Patent. Finally, I placed myself back in the relevant period of time and considered the state of art and the level of skill of the persons working in the field at the time.

49. The subject matter of the '385 Patent is directed to an intervertebral fusion device and methods of using the same. Based on the materials I have considered (including the prior art cited herein), my own knowledge and experience, and the level of skill required to design and build an intervertebral spinal fusion implant device, I have come to the conclusion that the a POSA would have had a

bachelor's or equivalent degree in mechanical engineering or a related discipline (e.g., biomedical or metals and materials engineering), and at least five years of experience consisting of (a) designing, developing, evaluating and/or using spine devices, (b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and (c) biomechanical and functional loading of orthopedic implants. A person could have qualified as a POSA with some combination of (a) more formal education and less technical experience or (b) less formal education and more technical or professional experience in the listed fields. For example, a POSA could have an advanced degree in the technical disciplines noted above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

50. My experience and qualifications exceed that of a POSA. Specifically, I have formal education as a Bachelor's of Applied Science in Metals and Materials Engineering and substantial professional experience with spinal implant devices, including roughly a decade of experience designing, developing and inventing spinal fusion devices, including expandable spinal fusion device technologies. Additionally, I also have roughly four years of experience studying and reviewing expandable implants, including patents covering such implants, in my capacity as a technical expert in patent disputes. Thus, my education combined with my substantial design and development experience with fusion technologies qualify me as a POSA.

51. All references to a POSA here are made pursuant to the foregoing opinion regarding the level of ordinary skill in the art, as of the earliest possible priority date of the '385 Patent (which I understand to be March 27, 2008).

VI. OPINIONS ON CLAIM CONSTRUCTION

52. Except as discussed below, I have applied the plain and ordinary meaning to a POSA of all claim terms at issue. To the extent I believe an explanation of the plain and ordinary meaning may be helpful, I have provided it where appropriate below.

53. There is at least one term that may require construction based on the prior art in the grounds asserted in the Petition—"curved," and specifically the meaning of this term when modifying the term "channel." Accordingly, I address the meaning of "channel" as used in the '385 Patent (which is its plain and ordinary meaning), and then the construction of "curved."

1. *channel*

54. A POSA would understand the claim term "channel" to refer to a passage through which something moves or is conveyed. This is the plain and ordinary meaning of the term provided in multiple general purpose dictionaries. *See* EX1009 at 4 ("5 a) any means of passage b) a course through which something moves or is transmitted, conveyed, expressed etc."); EX1010 at 3-4 ("4 course in which anything moves; direction"); EX1011 at 4 ("5. A course or passage through

which something may be moved or directed”). This is consistent with the usage of “channel” throughout the specification, which uniformly refers to a passage through which something (e.g., an anchoring member) traverses. Ex. 1001, 9:42-44, 9:53-55, 10:63-66, 11:47-63, 14:25-31, 14:65-67, 16:32-35, 22:51-57, 24:55-67.

55. There are no limitations on the particular dimensions (e.g., length, diameter) required for a passage to qualify as a “channel” provided in the specification. In fact, the specification states that “[o]ther embodiments have channels of different shapes and sizes.” *Id.*, 13:51-52. The specification does explain that in certain embodiments “a circular channel with a constant diameter throughout its entire length can guide the anchoring mechanism” *Id.*, 13:48-51. This indicates to a POSA that such additional requirements are not intrinsic to the term “channel” itself. *See also id.*, 10:10-13 (“Even though the fusion member channels shown in these figures are curved and tubular, one of ordinary skill in the art will know that the channels may be other shapes or configurations”).

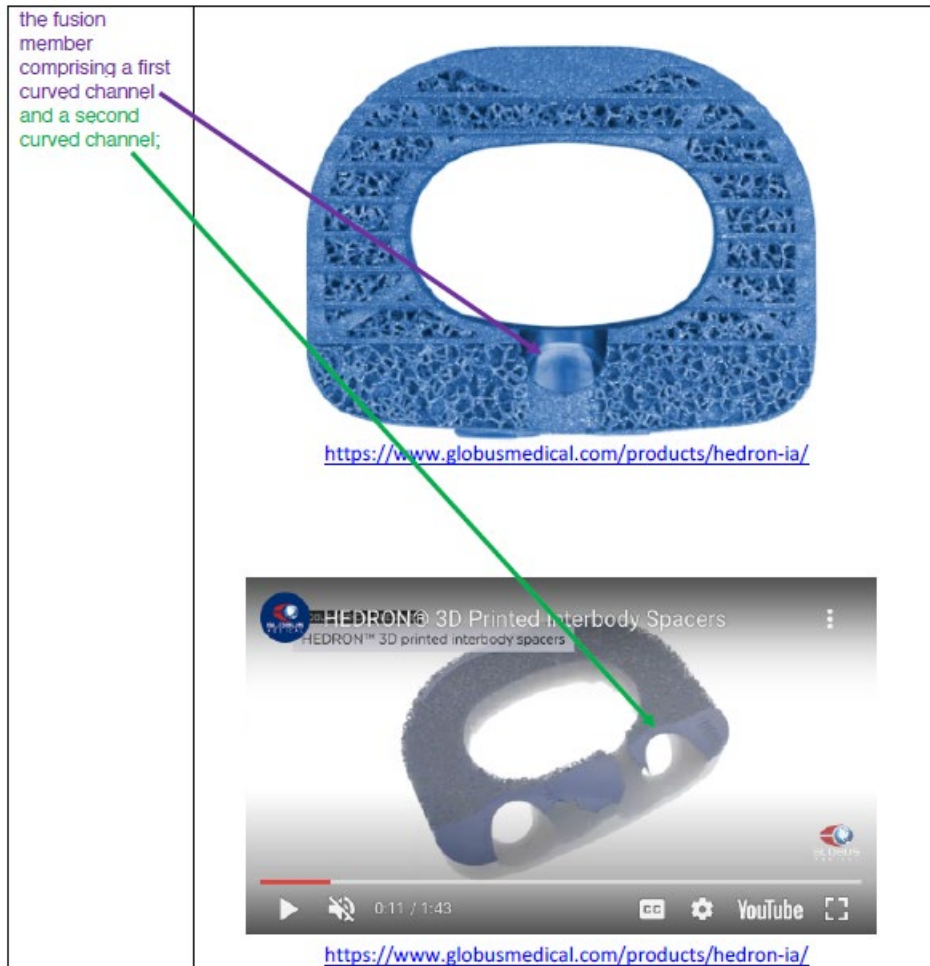
2. *curved* [channel]

56. The specification describes various channels as “curved.” *See* Ex. 1001, 5:40-43 (referring to the “curved tubular channels” of Figs. 30-33); 5:52-54 (referencing the “nonparallel angled curved channels” of Figs. 38-40); 5:65-6:3 (referencing the “curved tubular channels” of Figs. 46A-47); 10:1-14 (discussing Fig. 4 and stating that “[e]ven though the fusion member channels shown in these

figures are curved and tubular, one of ordinary skill in the art will know that the channels may be other shapes or configurations in other embodiments”); 15:31-58 (referencing Fig. 14 and explaining that “[a]s the fusion member channel is curved, the path that the anchoring member travels is also curved. In other words, the anchoring member traverses in a second direction that is curved throughout its advancement through the fusion member channel. Accordingly, from the initial configuration of the anchoring mechanism to its final configuration, the tip of the anchoring member travels in a semi-circular path of movement”); 19:9-14 (“[T]he delivery housing channel of some embodiments can be circular and constant in diameter throughout the entire length of the channel as described above in FIGS. 7A-7C. In some such embodiment, the flexibility of the anchoring member enables the anchoring member to be advanced through the curved channel of the fusion member.”); 23:21-32 (“In FIGS. 35-37, an embodiment of the fusion member 3500 includes two curved semicircular channels 3510 and 3520.”); 23:33-44 (“FIGS. 38-40 depict an alternate embodiment of the fusion member 3800 with curved channels 3810 and 3820 and curved channels 3830 and 3840 extending to inferior and superior faces of the fusion member, respectively.”); 23:66-24:16 (“FIGS. 46A, 46B, and 47 depict an alternate embodiment of the fusion member. ... FIG. 46B illustrates that each of the channels 4610 and 4620 trace circular arcs that are a portion of two conceptual circles which traverse planes that are parallel to each other and non-

parallel to all faces of the fusion member. ... Although this embodiment provides for channels and anchoring members that trace the arcs of conceptual circles, other embodiments provide for alternative curved conceptual shapes (e.g. ellipses, parabolas, etc.); 26:50-54 (“Also, in several of the above-described embodiments, the channels and anchoring members have circular-arc cross-sectional profiles. However, in other embodiments, the channels and anchoring members have alternative curved arc shapes.”). In each case, the curved channel appears to trace, or is described as tracing, an arc of some shape (circle, ellipse, parabola, etc.).

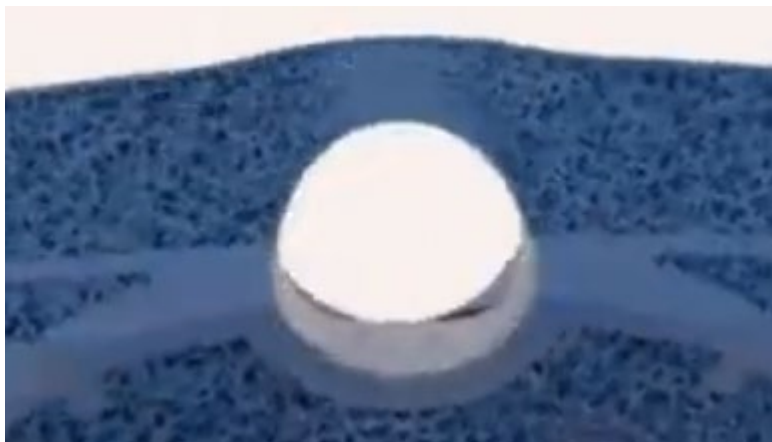
57. However, I understand that the Patent Owner (“Spinelogik”) has asserted in a lawsuit alleging infringement of the ’385 Patent that various channels in Petitioner’s products are “curved” as that term is used in the claims. Thus, I understand that Spinelogik alleges that the anchor openings of Petitioner’s accused implants constitute “curved channels” as recited in claim 1. I have reviewed Spinelogik’s infringement contentions (Ex. 1012). A representative example from Spinelogik’s infringement contentions is shown below:



Ex. 1012, 34.

58. The above example references an embedded Youtube marketing video for one of Globus's accused interbody implants, found on Globus's website (Ex. 1013). A review of that video discloses that the accused product contains an aperture for its anchors comprising a circular opening and tubular channel having straight sides extending from one surface to another, and a seat for the anchor heads, as shown in the screen shots (and magnifications) below:





Ex. 1013 (frames from video at 0:23).

59. The contentions also cite a discussion in Petitioner’s patent, U.S. Patent No. 9,980,824 (Ex. 1015), stating that the channels (bores 26) “may be substantially linear” which “allows bores 26 to receive both linear fastening members and curvilinear fastening members.” Ex. 1012, 5. Figure 4 depicting the bores is reproduced below. Ex. 1015, Fig. 4.

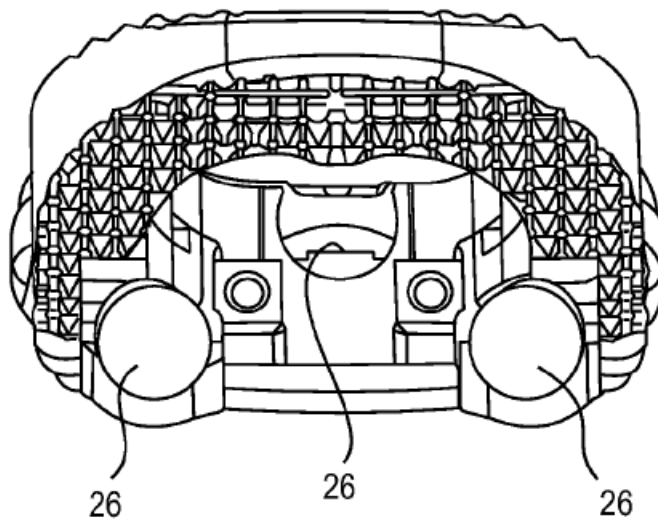


FIG. 4

60. Based on these materials, I understand that Spinelogik is applying “curved” to channels regardless of whether those channels trace an arc of some shape that follow a curved panels (like the channels referred to as “curved” with regard to particular embodiments in the specification previously discussed).

61. Using Spinelogik’s apparent applied construction, a channel may be considered “curved” when it has: (1) an opening with a curvature (e.g., rounded

openings); (2) an inner wall with a curvature (e.g., tube-like wall); and/or (3) a radial curvature in an inner wall (e.g., a concave surface that forms a seat to engage the head of an anchor), or (4) follows a curved path (e.g., an arc-shaped path).

62. For purposes of my declaration, I have been asked to use Spinelogik's applied construction when applying the prior art to the claims. I offer no opinion on the correctness of Spinelogik's construction and have not been asked to offer any opinions on the correctness of that construction.

VII. OPINIONS ON PATENTABILITY

VIII. BACKGROUND

A. Technological Background

63. The fusion of adjacent bone structure is commonly performed to provide for long-term replacement to compensate for degenerative and or deteriorated disorders in bone. In many cases, low back pain can be avoided by preventing relative motion between spinal vertebrae. By fusing the contiguous vertebrae in the lumbar region, lower back pain can be abated. Ex. 1022, 1:11-17.

64. Surgical techniques were known for use in spinal stabilization. Surgical techniques sought to rigidly join the vertebrae that are separated by a degenerated disc. Ideally, the surgery effectively replaced the vertebra-disc-vertebra combination with a single rigid vertebra. Various surgical techniques were developed to approximate this ideal. *Id.*, 1:18-23.

65. Many of the techniques began by partially removing the degenerative disc material. Where the techniques differed is in their strategy for replacing the disc material. Some procedures filled the void left between the contiguous vertebra with bone graft materials. Other techniques relied on the use of an implant acting alone or along with bone graft. *Id.*, 1:24-33.

66. Various types and styles of interbody vertebral implants have been developed. One category included “cages” shaped alternatively as horizontal cylinders, vertical rings, or open boxes (“box cages”) comprised of various materials such as bone, metals, and polymers:

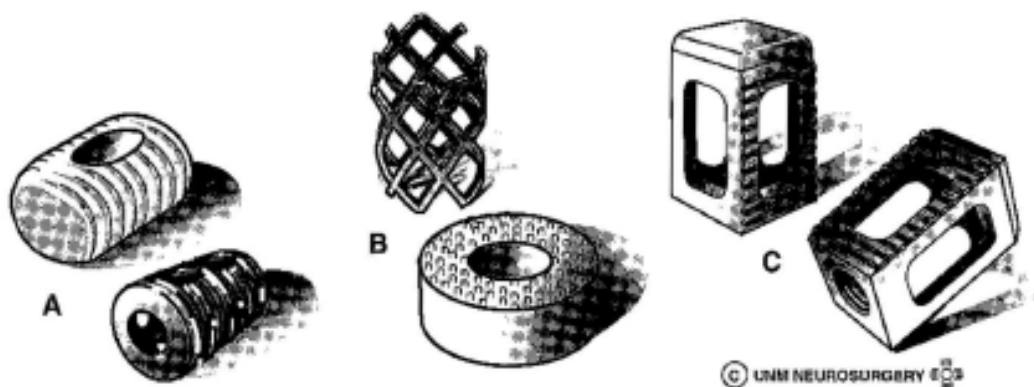


FIGURE 3-2. Current cage designs basically follow the pattern of threaded horizontal cylinders (A), vertical rings (B), or open boxes (C). A variety of materials including bone, metals, and polymers are used in the manufacture of these devices. (Reproduced with permission from the Division of Neurosurgery, University of New Mexico, Albuquerque, New Mexico.)

Ex. 1016 at 8; Ex. 1017 at 9. Eventual fusion of the opposing bone segments results from bone growth into and through the implant.

67. In some cases, the above procedures have failed due to shifting (frequently referred to as migration) of the implant between the adjacent vertebrae during the initial stabilization period (before fusion takes place). Ex. 1022, 1:34-40. Migration as used here refers to the implant moving around in the intervertebral space between the vertebral body endplates—either sagittally (forward/backward), laterally (side-to-side), or some combination of the two. This movement of the implant can lead to discomfort and serious consequences for the patient due to the proximity of nerves and blood vessels in the implanted area. Ex. 1022, 1:34-40. Such migration of the implant is therefore recognized as detrimental to the success of intervertebral fusion procedures, and various solutions have been advanced to prevent or minimize this movement. *See, e.g.*, Ex. 1018, 23:48-50 (explaining that “teeth” on the surface of implant plates may reduce migration of the device out of the intervertebral space); Ex. 1019, 4:61-64 (explaining that “migration of the implant” may be somewhat inhibited using roughened surface topography on the top and bottom surfaces of the implant for “gripping adjacent bone”); Ex. 1020, 13:15-30 (discussing various implant bone screw designs to prevent screw migration, which a POSA would understand to cause migration of the implant); Ex. 1024, 1:31-39 (“One problem with prior art spinal fusion techniques relates to device migration. For example, prior to complete bone fusion, a fusion device may migrate from the desired position. In examples where bone screws are used, the insertion and

tightening of the bone screws tends to cause device migration. Another problem with typical prior art fusion techniques is that fusion devices, or associated plates or fasteners, protrude from the spine, causing discomfort, damage, or danger to surrounding vascular or neurological tissues.”); *id.*, 3:35-46 (explaining that angled ridges formed on the top and bottom ends of the fusion device and help hold the device to the vertebrae endplates to reduce the chance of device migration); *id.*, 4:26-28 (explaining that the fusion device is held in place by a retention device “such that anterior and lateral migration is prevented”).

B. The '385 Patent

68. The '385 Patent describes an intervertebral fusion member as a rectangular shaped or oblong block having one or more channels, for placement between adjacent vertebrae. Ex. 1001, 2:29-45. One or more anchoring members are pushed through the channels and into the vertebrae, to affix the fusion member to the vertebrae. *Id.* Figure 4 is a transparent perspective of the fusion member and channels for its anchoring members, which run in planes that are parallel to one another. *Id.*, 4:39-41, 10:1-14. Figure 35 shows the anchoring members advanced into the vertebrae (not shown) inside the channels, which “traverse cross-sectional planes parallel to one another as well as to the lateral fusion member surfaces.” *Id.*, 5:47-50; 23:21-32.

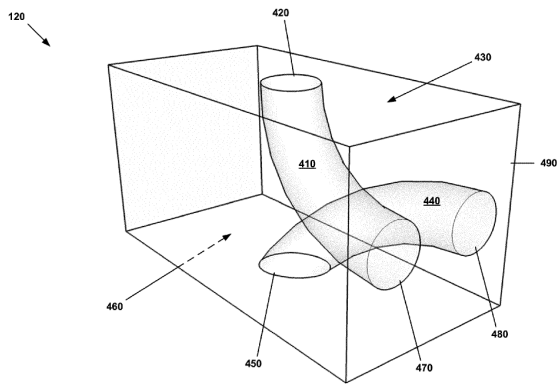


Figure 4

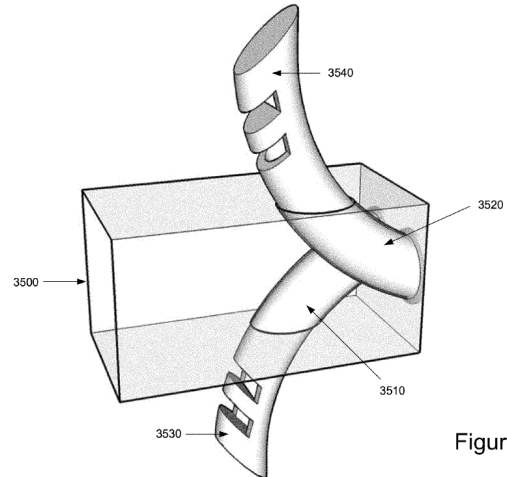


Figure 35

IX. GROUND 1

69. I understand that under Ground 1, Petitioner asserts that the challenged claims are obvious in view of Moskowitz and the general knowledge of a POSA. My opinions with regard to the claims challenged under this ground are set forth below.

A. Brief Description of Moskowitz

70. U.S. Patent No. 7,942,903 (“Moskowitz”, Ex. 1004) teaches an intervertebral device for use in spinal fusion. Ex. 1004, Abstract, 1:20-26. As pictured in Figure 1A below, one embodiment is an expandable “screw box” consisting of two triangular sliding bases (103, 104), penetrated by two threaded bone screws (101, 102) at holes allowing traversal of the screws through internalized drill or screw guides. *Id.*, Abstract, 7:37-41, 7:49-53, 7:65-8:9. The screws traverse through the screw box for screwing into separate vertebral bodies to effect vertebral

fusion. *Id.*, 8:17-19, 10:62-63. The height of the screw box is adjustable by turning a height-adjusting screw connecting the two triangular bases. *Id.*, 7:38-48. Both bases (103, 104) have holes (108) which can optionally be filled with bone graft. *Id.*, 7:57-62.

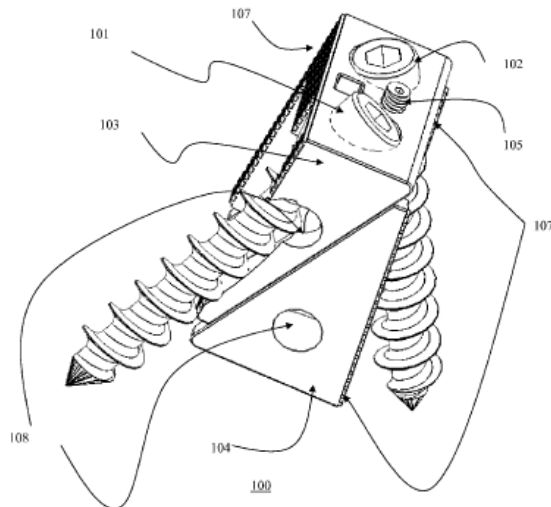


Fig. 1A

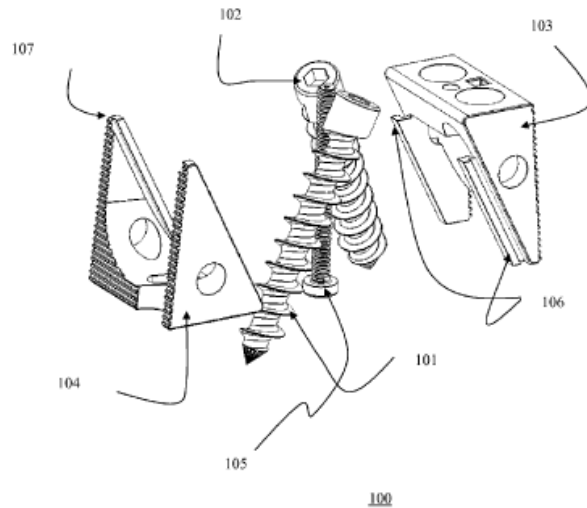


Fig. 1D

B. Independent Claim 1

71. As explained below, Moskowitz either discloses or (when considered with the general knowledge of a POSA) renders obvious all elements of Claim 1. Therefore, Ground 1 renders Claim 1 unpatentable.

Claim 1.0 “A fusion device comprising:”

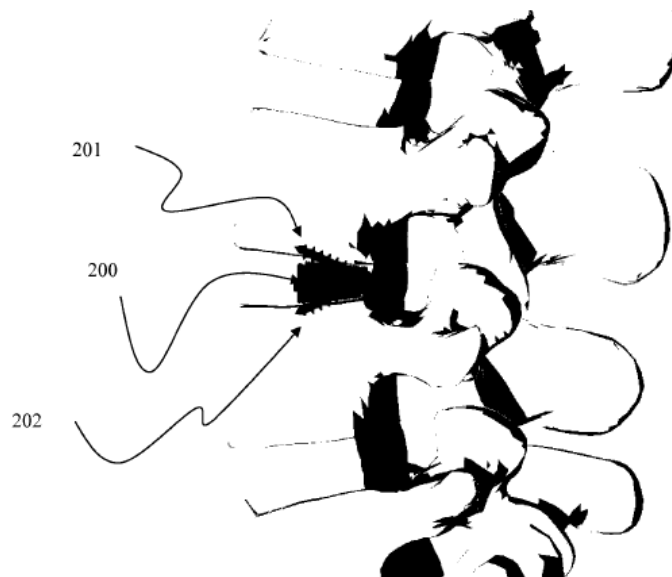
72. Moskowitz describes “a fusion device,” specifically, “[a] self-drilling bone fusion screw apparatus” where “[t]he screw members are screwed into

vertebral bodies in order to fuse the vertebral bodies together.” Ex. 1004, Abstract.

“This device therefore is a flexible fusion device.” *Id.*, 3:66-67.

Claim 1.1 “a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel”

73. Moskowitz’s fusion device is a “screw box” (the claimed “fusion member”) “placed inter-vertebrally,” that is, “between vertebral bodies.” *Id.*, 2:40-51. Fig. 6B shows that the device is “configured to position between first and second vertebral bodies.” The figure “illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws.” Ex. 1004, 9:15-17.



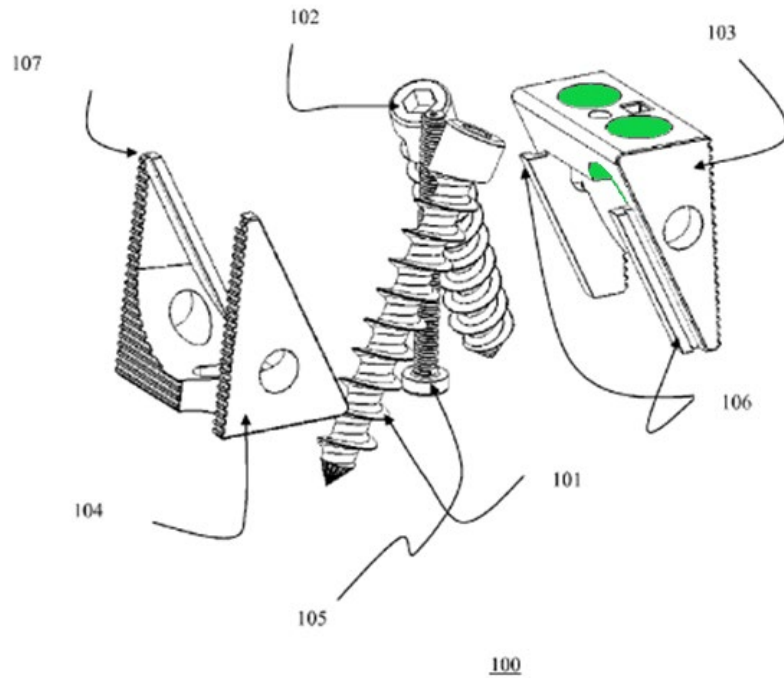


Fig. 1D

75. Moskowitz's embodiment II is shown in a superior perspective in Fig. 2C, again annotated in green to show the location of the channels:

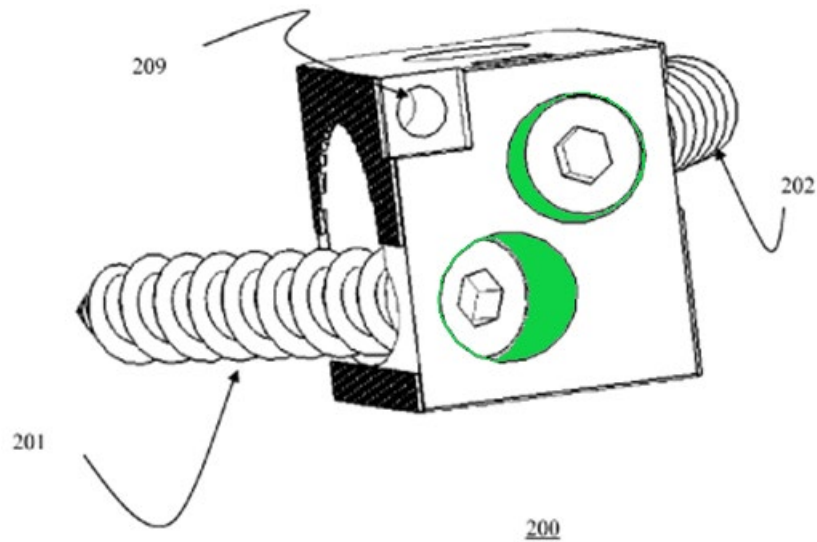


Fig. 2C

76. Using Spinelogik's applied interpretation of a "curved" channel (Section VI.2.), both of the channels are "curved" in at least three ways. First, as shown in Figures 1C and 1D (annotated below), each channel has a rounded proximal opening on the side where the screws are inserted, and a rounded distal opening that the screw protrudes from:

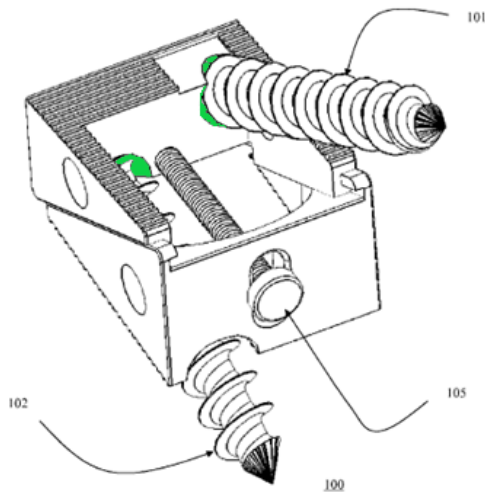


Fig. 1C

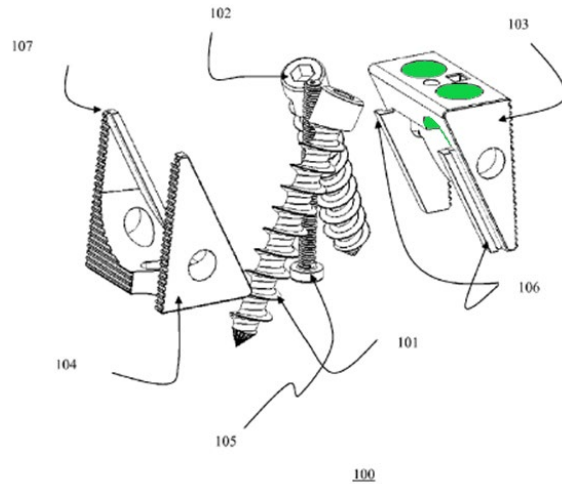


Fig. 1D

The channel openings are round, making each channel “curved.” Second, as also shown in the annotated figures, each channel has a tubular inner wall extending from one opening to the other opening. Because the inner wall is tubular, each *channel* is “curved.” A POSA would understand the channels to necessarily have a tubular inner wall because they circumscribe the inserted screws along the length of the passage through the wall of the triangular sliding base. Ex. 1004, 7:49-52 (“Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100 ... in opposing directions”). Third, each channel is “curved” because the channels necessarily contain an internal curvature (which may be the same as or separate from the beginning of the screw threading) which serves as a recessed seat to engage the bearing surface on the underside of each screw’s head.

77. The internal design of the channel is not shown in the foregoing figures.

This seat appears to be shown in Figure 4C, a portion of which is annotated below:

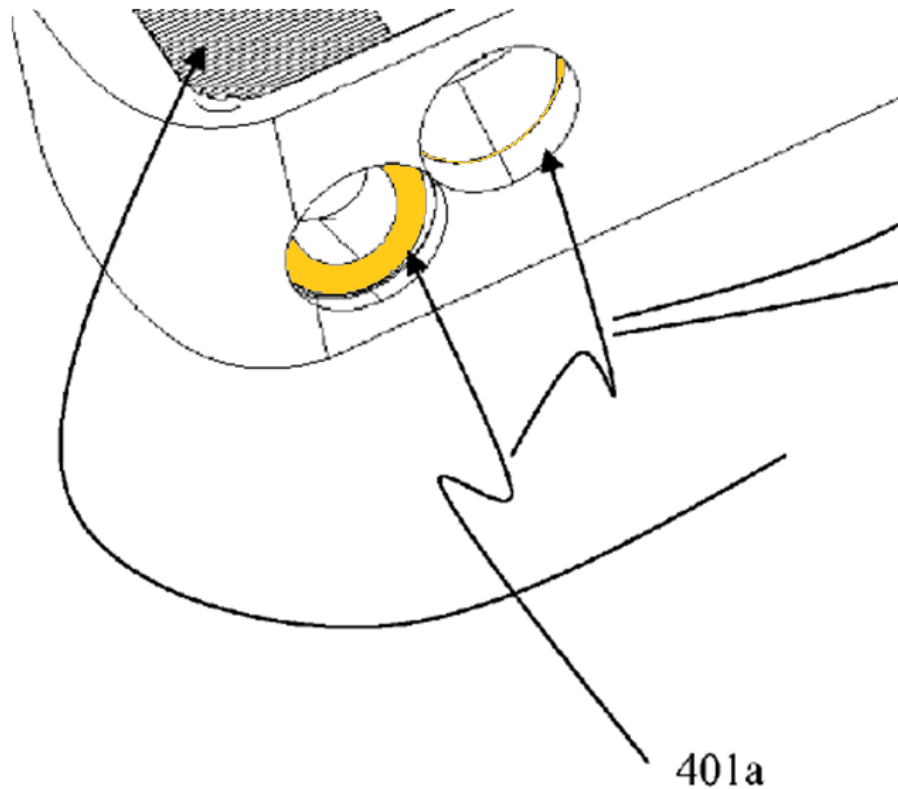
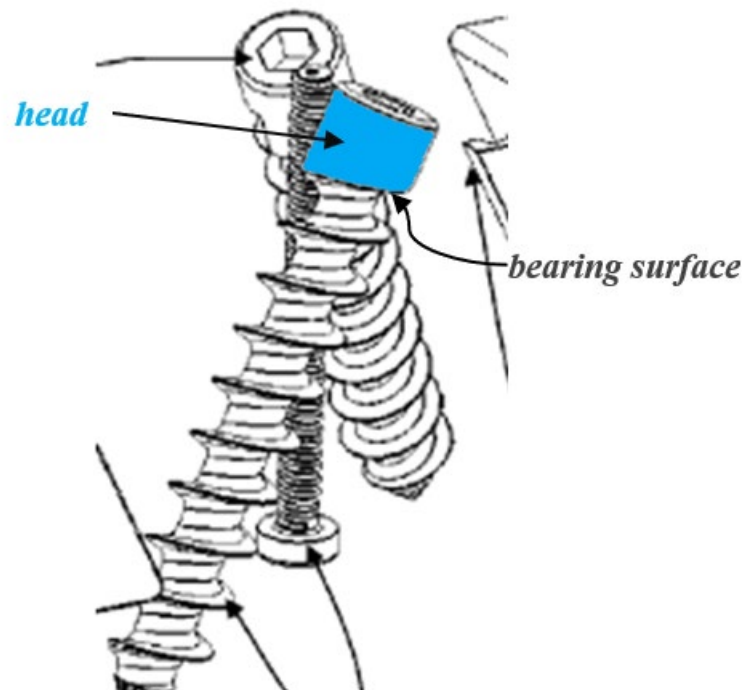


Figure 4C relates to an embodiment using a circumferential cage around two of the screw boxes. Ex. 1004, 6:41-43. The cage itself contains perforations 401a for the placement of the screws. *Id.*, 8:37-38. The figure either discloses or suggests the internal seat of the channels (shown in orange) inside the circumferential cage.

78. Even if Figure 4C did not disclose or suggest an internal seat in each channel, a POSA would understand that such a seat would be necessarily present or at least obvious based on the general knowledge of a POSA. This is because a POSA understood that such a seat is required to retain the screws within each channel via

engagement with the bearing surface on the underside of each screw's head, which is shown in annotated Figure 1D below.



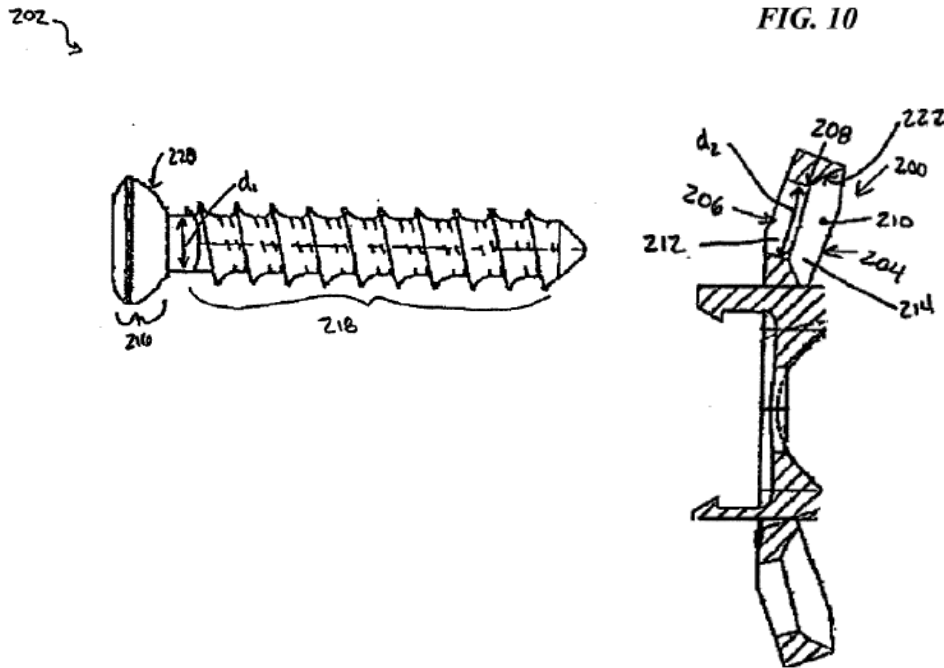
79. As shown, each screw has a pronounced cylindrical head having an underside (the bearing surface) at an angle. The figure suggests that the angle is the same as the screw's threads, although I understand that may not necessarily be the case. A POSA would understand that this underside comprises the bearing surface of the head which will engage an internal seat. That seat could be either the beginning of the threading inside the channel, designed to engage the screw threads, or a separate seat. This engagement between the implant (via the seat) and bearing surface is necessary because this engagement is what actually affixes the screw to

the base. Without such engagement, the screw would not engage with the base but simply pass through it. The screw would therefore be unable to serve its purpose of affixing the device to the vertebral bodies, but would instead only affix the screw to the bone. This would defeat the purpose of the screws (to affix the device to the vertebral bodies), and there would be no need for the pronounced screw head without such seat. The seat also serves as a stop so that, during surgery, the physician will know when the screw is fully advanced. Thus, the angled seat, which engages the screw head, comprises a curvature within the channel, making the channels “curved.”

80. As discussed above, a POSA understood that, to create the engagement between the base and the screw necessary to affix the base to the vertebral bodies, the base must contain a surface such as a seat to engage the bearing surface of the screw heads. This type of design is traditional and well-known for use with screws that are generally referred to as having a “raised countersunk head.” In this design, an internal seat formed in the screw bore engages with the bearing surface on the underside of the screw head, allowing the head to be flush with the surface of the affixed object. *See, e.g.*, Ex. 1025 at 8-10.

81. This type of design is also disclosed in multiple prior art devices designed for intervertebral fusion procedures. For example, U.S. Patent Application Publication US 2005/0085913 (“Fraser”, Ex. 1008) teaches the use of an “inner

lumen 210” (that is, a channel) having “a shape and size adapted to receive the head 216 of a bone screw 202” as shown in Figs. 9 and 10 below. Ex. 1008 [0061], Figs. 9, 10.



Fraser’s screw “includes a head 216 and a threaded shank 218. The head 216 of the bone screw 202 includes a substantially convex, slightly rounded outer surface 220. The first portion 214 of the inner lumen 210 of the aperture 200 has a concave sidewall 222, e.g., a generally spherical recess, to allow the rounded head 216 of the bone screw 202 to seat therein.” *Id.* As explained above, a POSA would understand that the concave sidewall (that is, the seat) both prevents the screw from advancing through the implant and allows the angle of the screw to be slightly adjusted.

82. Such a design is also shown in U.S. Patent Application Publication US 2006/0030851 (“Bray”) (Ex. 1007). In Bray, each bone screw extends through holes 140 (channels), which “are sufficiently large to allow a portion of a respective bone screw to pass therethrough but not large enough to allow a retaining portion of the bone screw through, such as the head of the bone screw.” Ex. 1007 [0047], Figs. 3, 4. Each of the “bone screw holes 140 has a seat 165 on which the retaining portion of a respective bone screw rests. Each seat 165 has a generally concave spherical shape and the surface of the retaining portion of the bone fastener in contact with the seat 165 has a complementary convex spherical configuration.” *Id.*

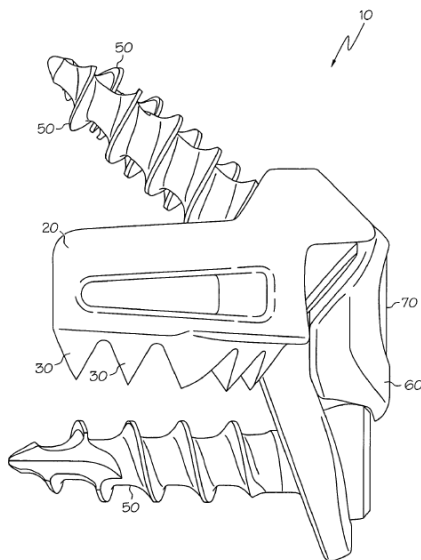


FIG. 3

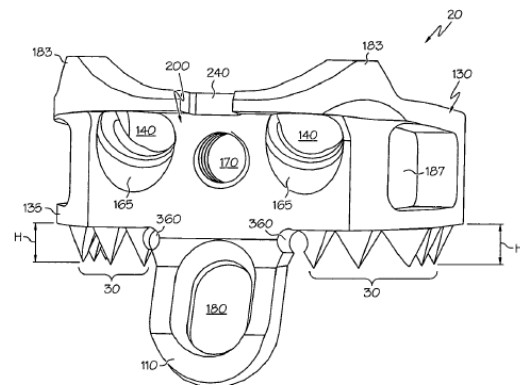


FIG. 4

83. A POSA would have been motivated to include such a seat within his general knowledge (as represented in Bray and/or Fraser) to enable the screw to affix the base to the vertebral bodies. A POSA was also motivated to include such a seat

for the same reasons explained in Bray—to include a channel that allows “a portion of a respective bone screw to pass therethrough but not large enough to allow a retaining portion of the bone screw through, such as the head of the bone screw.” *Id.*; Ex. 1007 [0047]. A POSA understood that such a design engages the bearing surface of the bone screw with the base member such that tightening the screw into the vertebral body affixes the implant itself, and not merely the screw, to the bone. This type of design was desirable because it would firmly attach Moskowitz’s screw box to the superior and inferior vertebral bodies. Such firm attachment was required to provide a stable platform for bone fusion. As discussed in the background discussion above, movement or migration of the implant after implantation was recognized as detrimental to the success of intervertebral fusion procedures. A POSA would have recognized that firmly attaching Moskowitz’s screw box to the superior and inferior vertebral bodies would prevent such migration and therefore would make the intervertebral fusion procedure more likely to succeed.

84. A POSA was also motivated to add concave seats having a radially inward curvature, such as those in Bray and Fraser, because they would allow the screws to pivot on their seats, enabling the screw angle to be adjusted to the desired angle for insertion. Ex. 1007 [0047]; Ex. 1008 [0014]. Using such a seat would also optionally allow for use of a screw having a convex head (to match the concave seat) for a closer fit to the seat, although this modification would simply be a design choice

and would not have been necessary. *Id.* Such a modification provides the additional benefit of allowing the screw angle to be adjusted by pivoting (as expressly discussed by Fraser) so that the anchor can be adjusted to the desired angle for insertion.

85. Additionally, the use of an anchor with a spherical (versus planar) head was an obvious alternative design choice, as was designing the seat to have a complementary shape to provide for close conformity with the screw head. There is no appreciable difference in using a spherical anchor head rather than a planar head, aside from the benefits discussed above.

86. A POSA would have had a reasonable expectation of success in using a seat such as that in Bray and Fraser because such designs were variations on standard screw seat designs for engaging with screw heads to allow the screw to affix the seat-containing component to whatever material the screw was designed to penetrate. *See, e.g.*, Ex. 1025 at 8-10.

87. A POSA also would have had a reasonable expectation of success in including such a seat because such designs had been successfully implemented in similar spinal fusion implants as shown by Bray and Fraser. As in Moskowitz, these prior art implants have bone screw holes configured such that the bone screws extend through the hole at an angle. The bone screw holes in Bray extend through posterior

corners of the device in exactly the same way as in Moskowitz, as shown in posterior views from Moskowitz (Fig. 1C) and Bray (Fig. 5) below.

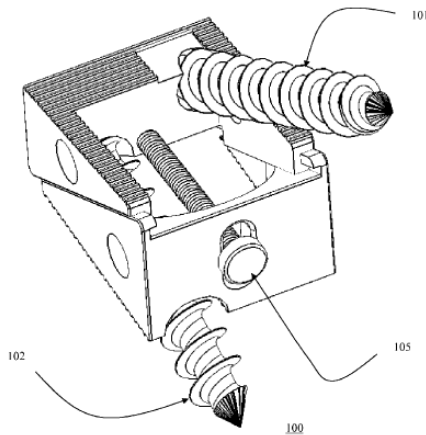


Fig. 1C

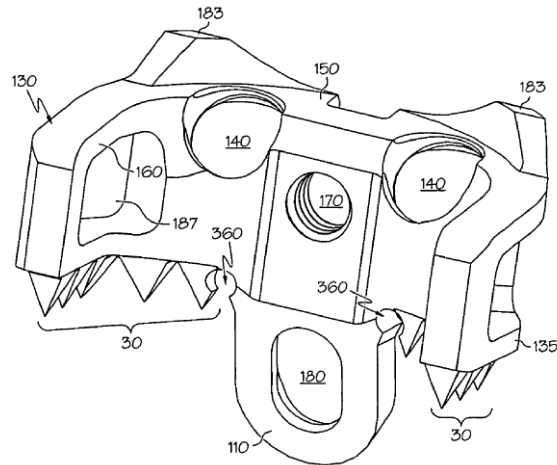


FIG. 5

88. While it is not necessary that the channels contain a seat that has a concave shape to satisfy Spinelogik's applied construction of a "curved" channel, such a concave shape also qualifies to render the channel "curved."

89. A POSA would have also recognized that, if one wanted to provide the benefit of pivotability via a spherical anchor seat, the channel threading of Moskowitz would need to be eliminated and the channel and the head would need to have a slightly larger diameter than the shaft of the anchor, which would provide a certain degree of freedom for the screw to pivot. While eliminating the threading from the channel would eliminate the anchor's ability to directly couple to the implant via threading, the seat would still serve to firmly engage with the bearing

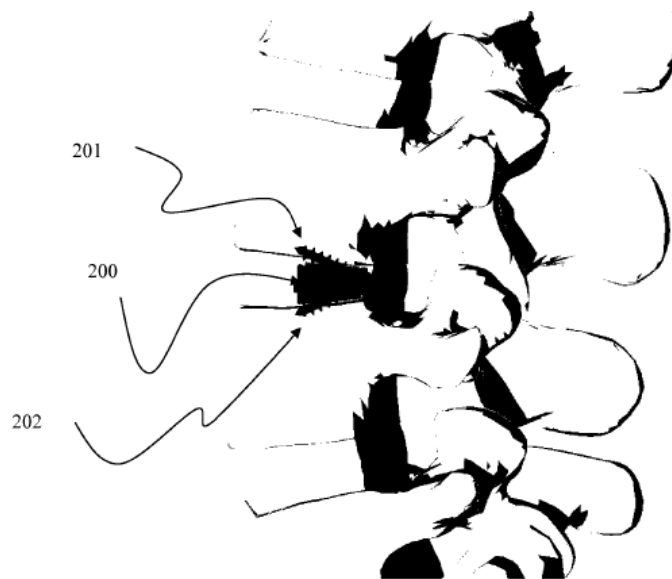
surface of the screw. Again, it is not necessary to add a spherical anchor seat, but a POSA would have recognized that such a seat possessed certain additional benefits as previously discussed.

Claim 1.2 “a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and a second anchoring member configured to insert through the second curved channel and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body,”

90. Moskowitz’s transvertebral screws comprise first and second “anchoring members” as required by the claim. The screws insert into the screw guides through the rounded openings in the box, which are the openings of the first and second “curved channels.” Moskowitz’s screw box “incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.” Ex. 1004, 2:43-51. As illustrated in Figures 1-6, “[t]ransvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-directionally.” *Id.*, 7:49-62. During surgery, “a transvertebral screw is screwed into

the vertebral body via the built-in box screw guides 505.” *Id.*, 10:54-64. Thus, one of Moskowitz’s screws is inserted “partially into the first vertebral body” (which is either the superior or inferior vertebral body) and the other is inserted “partially into the second vertebral body” (which is the other vertebral body not penetrated by the first screw).

91. Moskowitz’ apparatus is described as “a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.” Ex. 1004, 5:11-18. Further, “Figures 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine.” *Id.*, 11:8-9. Fig. 6B provides a “three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.” *Id.*, 9:15-18.



92. As can be seen from Fig. 6B, each anchoring member/screw remains partially within the screw box, while also inserted into a vertebral body. Further, a POSA would have understood that each screw will remain partially within the screw box to provide necessary engagement between the screw and base, as discussed for claim element 1.1 above. Therefore, “a portion of the first anchoring member” (first screw) “remains within the fusion member, in order to couple the fusion member with the first vertebral body,” and a “a portion of the second anchoring member” (second screw) “remains within the fusion member, in order to couple the fusion member with the second vertebral body” as required by the claim.

93. The first screw also “couple[s] the fusion member with the first vertebral body” and the second screw “couple[s] the fusion member with the second vertebral body.” Moskowitz explains that “[i]n all screw-box embodiments, a

rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudal [sic] directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior vertebral body.” Ex. 1004, 3:11-16. The insertion of each screw into the vertebral bodies, while partially remaining in the screw guide, with the screw head engaging the seat in each channel in the base, would be understood as comprising a coupling between the screw box and each vertebral body.

94. Moskowitz also explains that “[t]he screw members are screwed into vertebral bodies in order to fuse the vertebral bodies together.” Ex. 1004 Abstract. “The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the ... screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.” *Id.*, 2:36-39. The intervertebral bone agents, placed in perforations in the screw box to promote bone growth throughout, as well as the superior and inferior oriented screws, fuses the superior and inferior vertebral bodies. *Id.*, 3:39-44, 8:17-18. This bone growth would not be in the optimal location for a successful outcome if the screws did not firmly couple the screw box with the vertebral bodies, because the screw box would be allowed to migrate after initial placement. This movement would either prevent the bone graft material (“intervertebral bone agents”) from integrating appropriately, or

would cause the material to integrate such that the screw box would be out of place, which could lead to detrimental results for the patient.

Claim 1.3 “wherein the first curved channel has a first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member and the second curved channel has a second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member, wherein the first and second cross-sectional planes are parallel to each other.”

95. As shown in the '385 Patent, the referenced cross-sectional planes are planes parallel to the channel's path (and the path taken by the anchor inside the channel) and which bisect the channel. This is shown with regard to Fig. 5B reproduced below. The patent explains that “the cross-sectional view of the two channels 530 that go through the fusion member 120 are parallel to the right and left side of the fusion member 120.” Ex. 1001, 10:63-11:4.

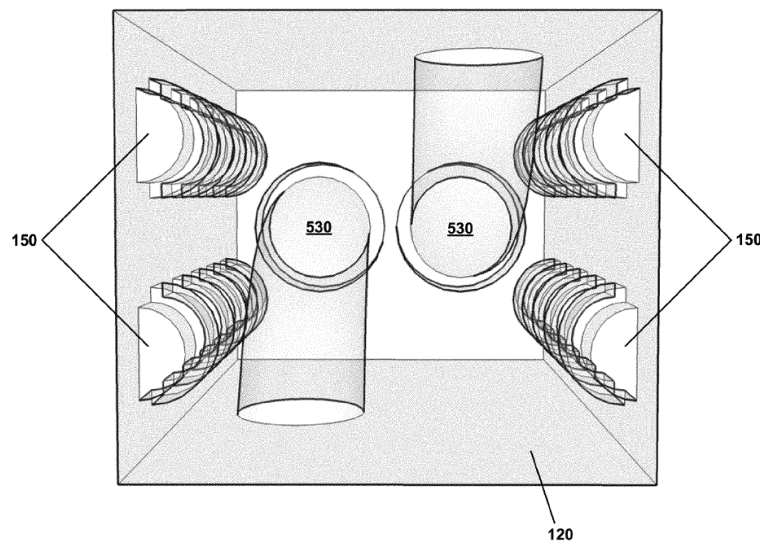
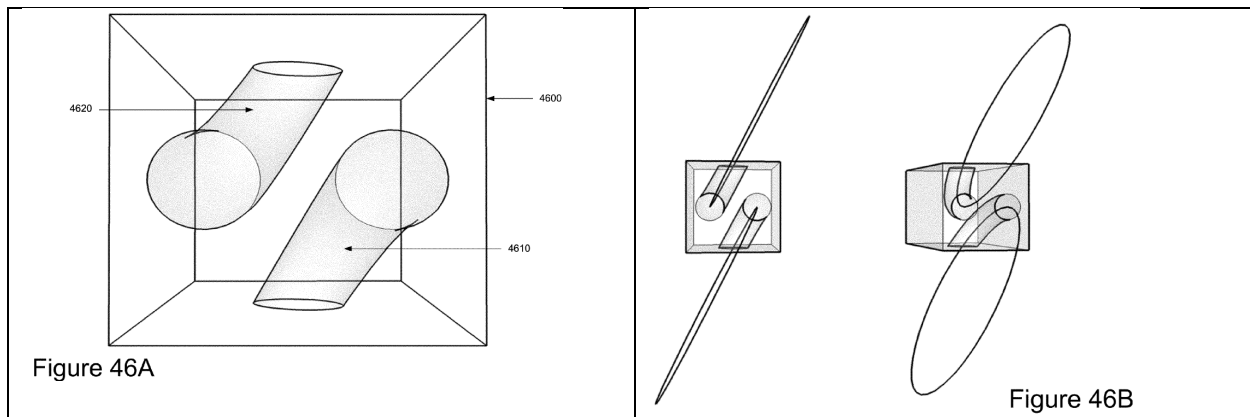


Figure 5B

96. The location of the cross sectional planes is also explained with reference to Figs. 46A and 46B, which show a fusion member having “channels that run in parallel planes with respect to each other but are nonparallel to the adjacent faces of the fusion block member.” *Id.*, 5:65-6:3. These figures are reproduced below:



See also *id.*, 23:66-24:16 (“Channels 4610 and 4620 traverse in parallel cross-sectional planes with respect to each other but are non-parallel with respect to the faces of the fusion member. FIG. 46B illustrates that each of the channels 4610 and 4620 trace circular arcs that are a portion of two conceptual circles which traverse planes that are parallel to each other and non-parallel to all faces of the fusion member.”).

97. Like the described cross-sectional planes, Moskowitz’s curved channels each have a “cross-sectional plane along” each channel’s path, that is “traversed by” each “channel through the fusion member.” This is best seen in Figure

1C, annotated below to include the cross-sectional planes, but a POSA would understand each of Moskowitz's figures to show these same planes.

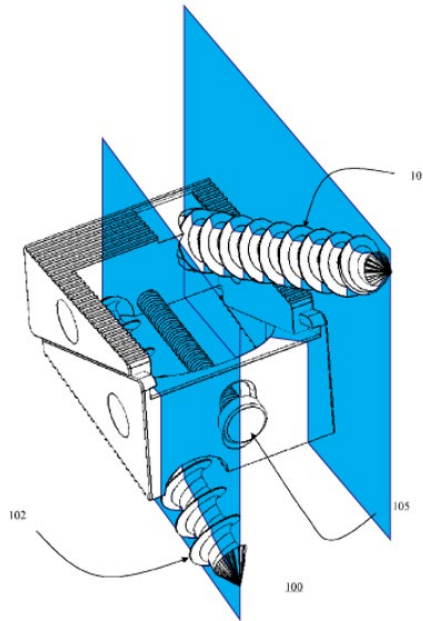


Fig. 1C

As can be seen, both the “first and second cross-sectional planes are parallel to each other” as required by the claim. Further, a POSA would have understood that the channels have these cross-sectional planes not only based on Moskowitz's figures, but from its description explaining that the body of each screw member is “laterally aligned with the box,” indicating that the channels along which the screws run are parallel to the box's sides. Ex. 1004, 5:11-18.

C. Claim 2: “The fusion device of claim 1, wherein the first and second cross-sectional planes are parallel to at least one surface of the fusion member.”

98. In Moskowitz, the identified “first and second cross-sectional planes are parallel to at least one surface of the fusion member” as required by Claim 2. The planes are parallel to at least the surface(s) on one side of the screw box, which is shown in yellow in the annotated figure below.

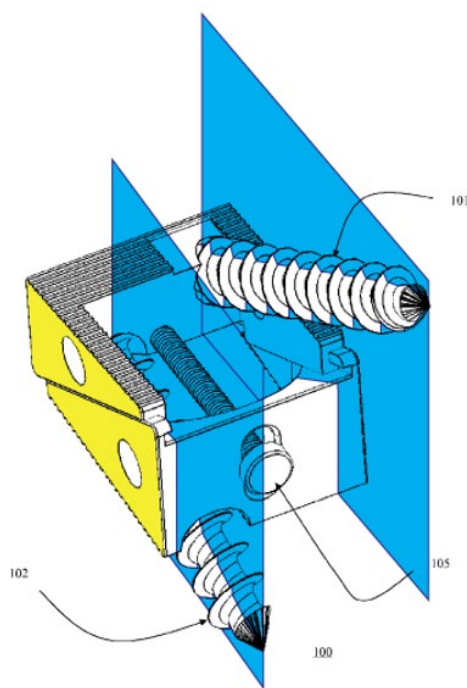


Fig. 1C

D. Claim 3: “The fusion device of claim 1, wherein neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member.”

99. Claim 3 requires that neither the first or the second cross-sectional planes required by claim 1 (element 1.3) be parallel to at least one surface of the

100. In Moskowitz, at least one surface of the fusion member is not parallel to the channels' planes. This surface is shown in yellow in the annotated Figure 1C below. Thus, Moskowitz discloses that "neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member."



E. Claim 4: “The fusion device of claim 1,”

Claim 4.1 “wherein the first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member,”

101. Moskowitz’s Figure 1B illustrates a superior perspective of its embodiment IA, while Figure 1C provides an inferior perspective. Ex. 1004, 6:22-26. As shown in annotated 1B below, the first curved channel (right) opens to at least two surfaces: the proximal surface (yellow) and a second top surface (pink). The second curved channel (Fig. 1B, left) also opens to the proximal surface (yellow). As shown in Fig. 1C, this channel (now on the right) also opens to an additional, bottom surface (orange).

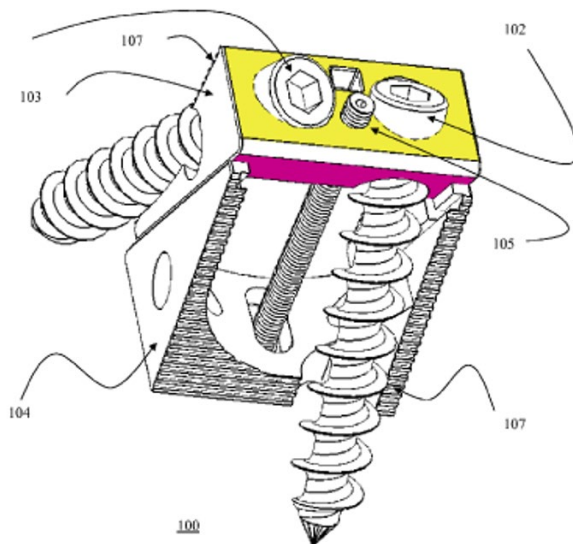


Fig. 1B

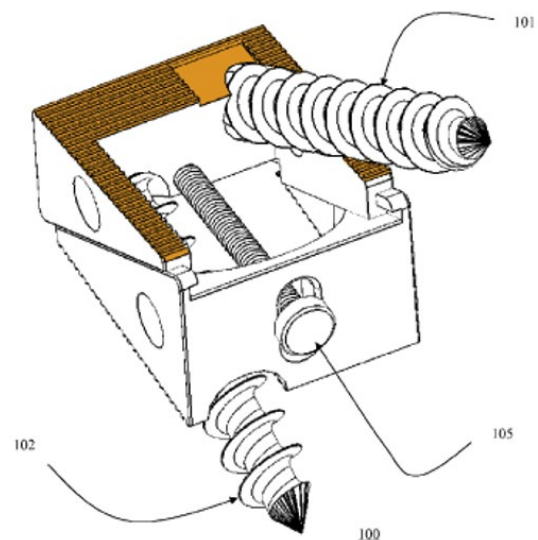


Fig. 1C

102. Thus, both curved channels open to at least two surfaces of the fusion member—a first (yellow) surface for both channels, and different second surfaces (pink or orange). This meets the claim language requiring “wherein the first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member.”

Claim 4.2 “wherein the first cross-sectional plane is not parallel to either of the two surfaces to which the first curved channel opens and the second cross-sectional plane is not parallel to either of the two surfaces to which the second curved channel opens.”

103. As shown in the annotated figures below, neither of the first or second cross-sectional planes are parallel to any of the surfaces to which any of the curved channels open. The cross-sectional planes are instead perpendicular to each of the surfaces to which the channels open.

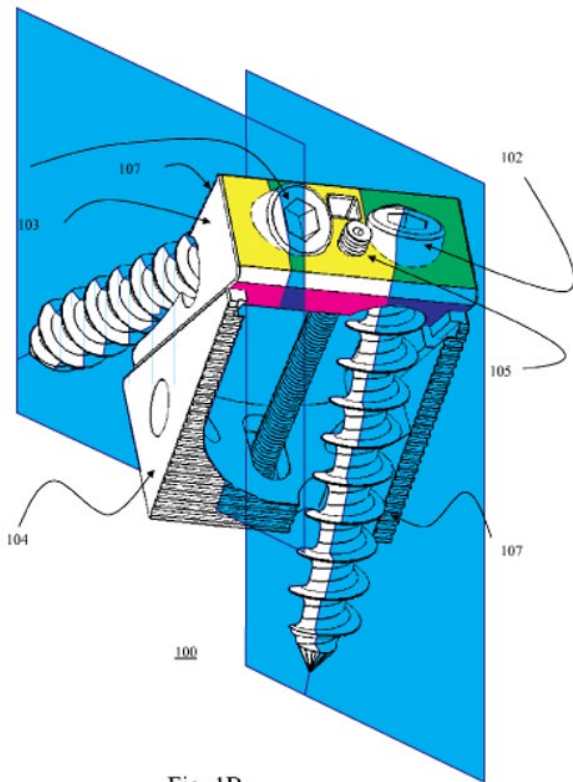


Fig. 1B

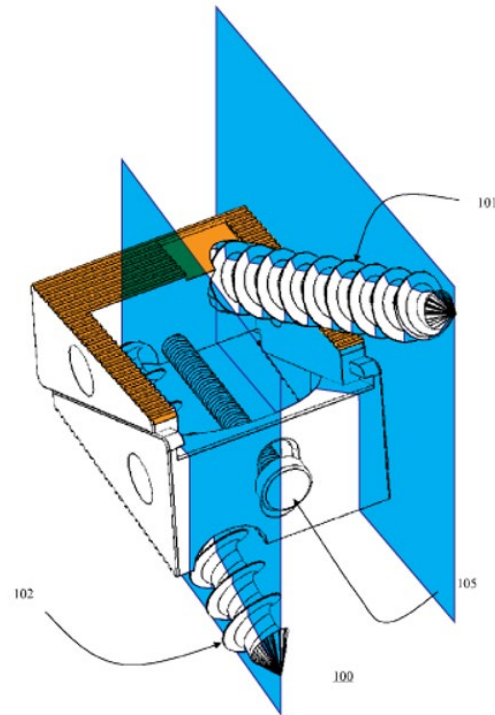


Fig. 1C

F. Claim 5: “The fusion device of claim 1,”

5.1 “wherein the first and second curved channels open to a first surface of the fusion member but the first curved channel traverses to a second surface of the fusion member and the second curved channel traverses to a third surface of the fusion member;”

104. As shown for claim 4, the first and second curved channel each open to a first surface—the proximal (yellow) surface through which the screws enter the box. The first curved channel opens to a second surface—the top (pink) surface, while the second curved channel opens to a third surface—the bottom (orange) surface. In other words, the first curved channel opens to the top of the screw box, and the screw in that channel engages the superior vertebral body, while the second

curved channel opens to the bottom, and the screw in that channel engages the inferior vertebral body. *Id.* This is the same arrangement described in the '385 Patent as shown in, for example, Fig. 16, reproduced below. Thus, Moskowitz discloses this limitation.

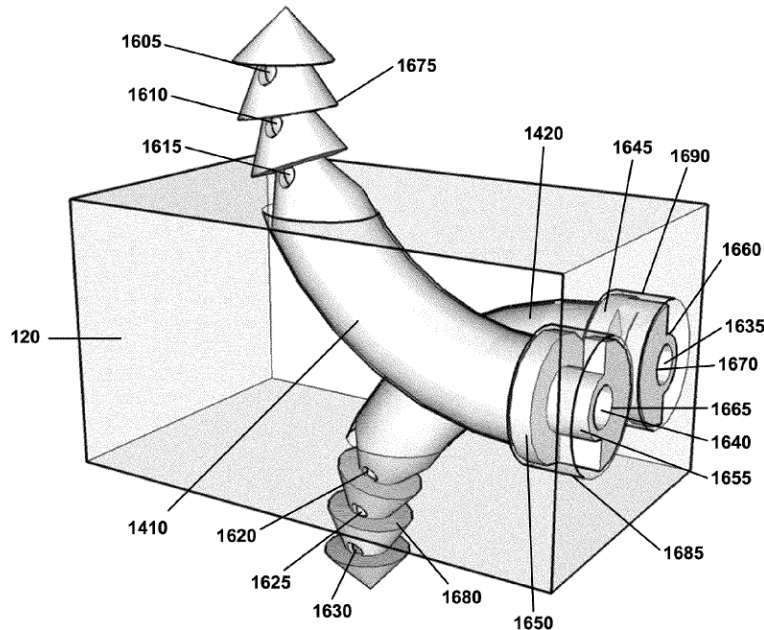


Figure 16

5.2 “wherein the traversal of the first and second curved channels through the fusion member allows (i) the first anchoring member to enter the first surface of the fusion member but exit the second surface of the fusion member at a first desired location on the second surface of the fusion member and (ii) the second anchoring member to enter the first surface of the fusion member but exit the third surface of the fusion member at a second desired location on the second surface without hindering the first anchoring member's insertion through the fusion member.”

105. As an initial matter with respect to this claim element, I note that the claim requires the second anchoring member to “exit the third surface ... at a second

desired location on the **second** surface.” This appears to be a logical impossibility. I have also not found any teaching in the ’385 Patent referencing such a configuration. For purposes of analysis here, I have been instructed to consider this claim as instead requiring that the second anchoring member “exit the third surface of the fusion member at a second desired location on the **third** surface”

106. As shown for Claim 4, the first and second anchoring members each enter their respective channels at the proximal opening of the respective channel into the screw box. Each anchoring member also exits their respective surfaces. The claim states that this must be “at a [first or second] desired location.” Of course, the exact location at which the screw exits the screw guide is fixed by the design of Moskowitz. Thus, those exit locations would be considered the locations desired by the designers of the Moskowitz device.

107. In addition, because the channels are parallel, the screws would travel through them in parallel paths. These paths never intersect, so a POSA would understand that each screw enters and exits its respective screw guide without hindering the insertion of the other screw through the fusion member. Accordingly, Moskowitz discloses all limitations of Claim 5.

G. Claim 7 “The fusion device of claim 1,”

7.1 “wherein each anchoring member is configured to couple to a driving member,”

108. Moskowitz teaches that a positioning tool 500a and driver assembly 550 are used for “impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone.” Ex. 1004, 8:63-9:1. These components are shown in Figure. 5H reproduced below.

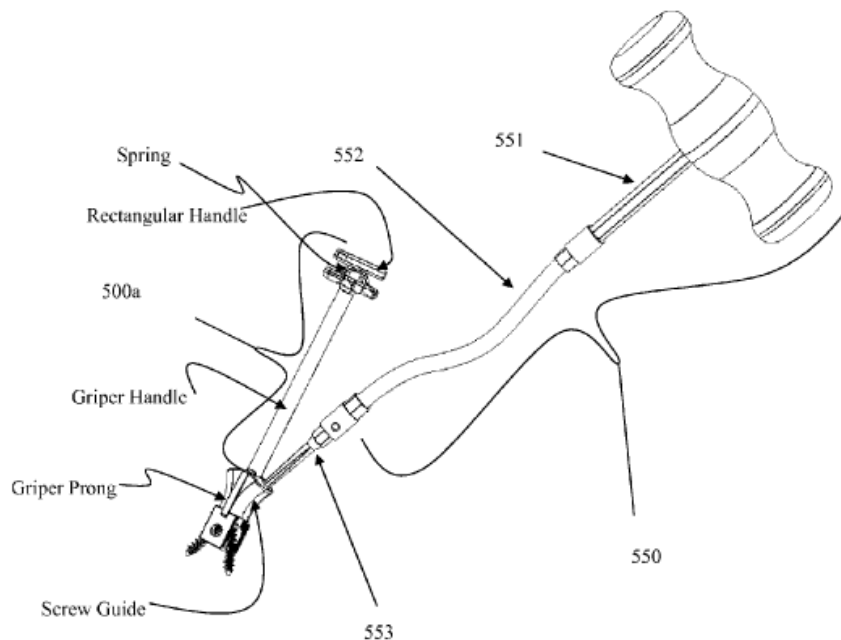


FIG. 5H

109. Moskowitz explains that the positioning tool 500a has a handle which “serves to position the screw box within the intervertebral space, and screws 201, 202 within the screw box.” *Id.*, 9:4-8. Once the screw box is placed in position, “a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built-in box screw guides 505. For difficult angles, an angled screw driver can be employed.” *Id.*, 10:60-64.

110. From this description, a POSA would have understood that the positioning tool 500a and driver assembly 550 comprise a driving member. The positioning tool is coupled with the screws to position them in place, and the driver assembly is coupled with the screws when it engages to turn them to screw into the vertebral bodies. Therefore, “each anchoring member is configured to couple to a driving member” as required by the claim limitation.

7.2 “wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.”

111. As discussed for element 7.1, the purpose of the driver assembly is to screw the transvertebral screws into the vertebral bodies. The driving member is therefore “configured to drive the anchoring member into the corresponding vertebral body.”

112. The positioning tool and driver assembly are also configured to decouple from the screws once the screws are satisfactorily engaged with the superior and inferior vertebral bodies. This is apparent from the description, as well as from Figs. 6A and 6B which illustrate “the process of insertion and final placement of the construct into the lumbar spine.” Ex. 1004, 11:8-10. Neither figure shows the driver assembly engaged with the screw box, showing that the assembly is ultimately decoupled with the anchoring member. This is as would be expected—the standard procedure for implantation of an intervertebral implant would require, after placement of the device and screw insertion, that the surgeon remove the positioning tool and driver assembly before closing. These devices are plainly for use during surgery but are not designed to remain within the human body. Thus, a POSA would have understood that Moskowitz’s placement tool and driver assembly are necessarily decoupled from the transvertebral screws.

113. Therefore, Moskowitz discloses all limitations of Claim 7.

H. Claim 9: “The fusion device of claim 1,”

9.1 “wherein each channel of the fusion member has an opening on a surface of the fusion member and the opening has a recess,”

114. The ’385 Patent describes certain embodiments (e.g., Fig. 16) having a recess to accommodate a flange at the base of each anchoring member. Ex. 1001, 9:53-67, 21:17-27. The specification describes certain recesses as “a recess of increased diameter.” *Id.* However, the claim does not contain a similar limitation.

Thus, based on the plain language of the claim and the specification, I do not understand that the claimed recess must have a diameter larger than the rest of the channel.

115. As discussed for element 1.2 above, each channel has a proximal opening on the surface of the screw box. As explained for that element, a POSA understood that each channel also contained a seat inside the channel, or that the inclusion of such a seat was obvious. *See* Claim 1.2. A POSA would understand that the portion of the channel between the proximal opening and the seat would be recessed from the opening itself. This recess matches the language of the claim limitation.

9.2 “wherein each anchoring member has a base that fits within the recess of the channel associated with the anchoring member in order to maintain the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body.”

116. Moskowitz’s Fig. 1D shows that each transvertebral screw has a base or head, annotated in blue below.

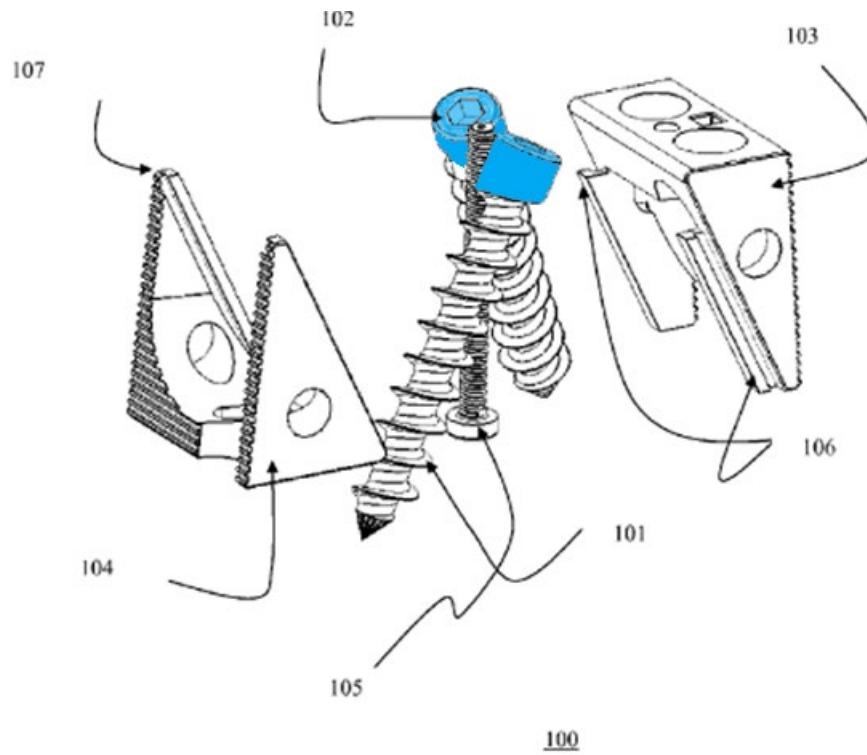
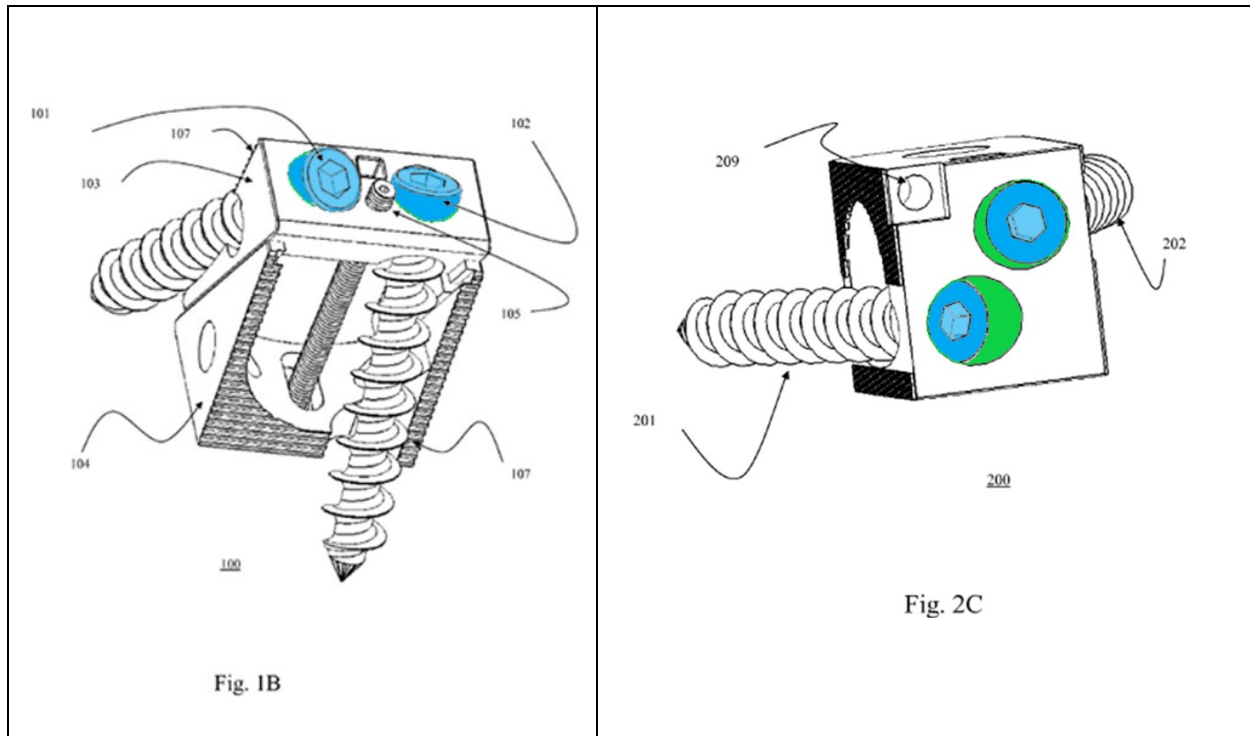


Fig. 1D

117. The base or head fits within the cylindrical recess (green in annotated Figs. 1B and 2C below) inside the proximal surface of the screw box.



As discussed for element 1.2, a POSA would have understood that the channel includes a seat which is engaged by the base or head of the screw, which retains the screw in the screw box as it is being turned and advanced into the vertebral body. *See* Claim 1.2 above. The base or head of the screw is retained within the recess (as explained for element 9.1, the portion of the channel between the proximal surface and the seat). Fig. 6B shows that the screw is maintained at least partially within the screw box while the screw is inserted into the vertebral body:

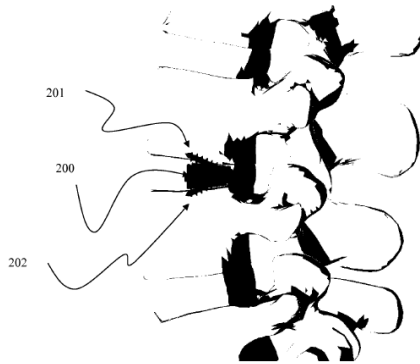


Fig. 6B

118. Thus, in Moskowitz, “each anchoring member has a base that fits within the recess of the channel associated with the anchoring member in order to maintain the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body.”

X. GROUND 2

119. I understand that under Ground 2, Petitioner asserts that the challenged claims are obvious in view of Hess and the general knowledge of a POSA. My opinions with regard to the claims challenged under this ground are set forth below.

A. Brief Description of Hess

120. U.S. Patent No. 8,075,593 (“Hess”, Ex. 1006) teaches an implant (10) having an upper shell (12a) and lower shell (12b). Ex. 1006, Abstract, 6:59-61.

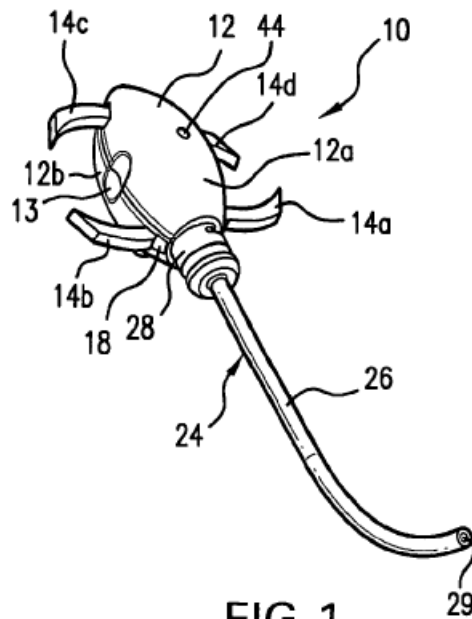


FIG. 1

The implant's interior cavity contains curved guide tracks (19) for four locking wings (14a-14d) that move from a stowed to deployed position. *Id.*, 7:18-22, 7:26-31, 8:5-19. When deployed, the wings extend out of their respective openings (46a-46d) and fixate into the surrounding bone, locking the implant into place. *Id.*, 7:38-45, 7:56-58. The implant is depicted with wings in the stowed (Fig. 10A) and deployed (Fig. 10B) positions. *Id.*, 5:53-58.

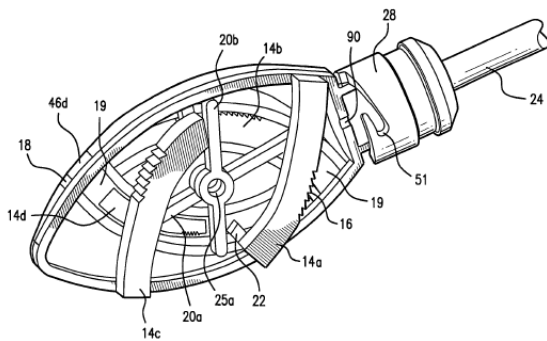


FIG. 10A

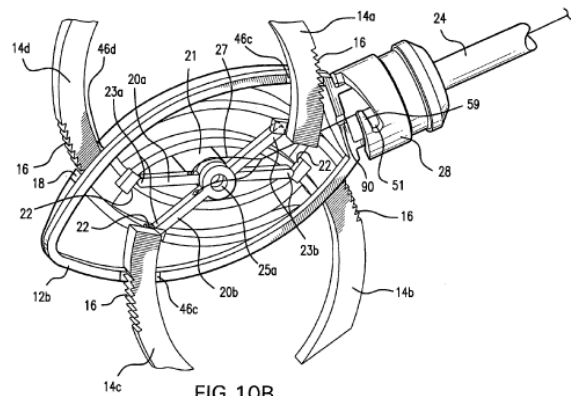
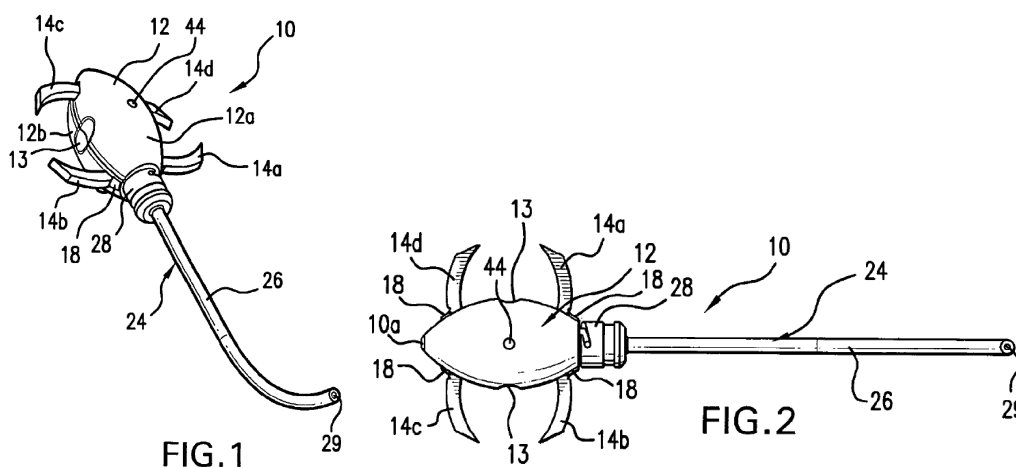


FIG. 10B

B. Independent Claim 1

Claim 1.0 “A fusion device comprising:”

121. Hess explains that its “[i]mplant ... is particularly well adapted for use in performing minimally invasive surgical procedures for treating spinal stenosis, including, for example, interspinous process decompression (IPD).” Ex. 1006, 6:45-48. Hess’s device is thus “directed to a spinal implant used primarily for interspinous process decompression procedures that can be percutaneously introduced into the interspinous space.” Ex. 1006, 2:3-6. Figures 1 and 2 of Hess depict an interspinous implant 10 that “can be used ... as an adjunct to spinal fusion procedures.” Ex. 1006, 6:43-52; *id.*, Abstract (“A spinal implant for treating lumbar spinal stenosis or as an adjunct to spinal fusion.”).



Hess’s implant 10, shown in Figures 1 and 2 reproduced above, possesses “locking wings” (14a-14d above) which are “adapted and configured to engage adjacent

vertebral portions of the spinous process.” *Id.*, 7:18-20.

122. A POSA would have understood that Hess, although primarily directed at an interspinous implant, was also suitable and desirable for use as an intervertebral spinal implant with only minimal modifications. This is because Hess was designed to stabilize two parts of the spine—the spinous processes of adjacent vertebrae. Hess was designed to be inserted through an access channel with its anchors extending into a plane perpendicular to the implant’s length. Ex. 1006, 9:48-10:32. An intervertebral fusion implant is similarly inserted through an access channel and designed to stabilize the vertebral bodies until they fuse. Further, Hess—like intervertebral implants—was designed for permanent implantation. Ex. 1006, 13:30-45.

123. A POSA was also motivated to use Hess as an intervertebral implant because its curved locking wings provided known advantages over straight anchors. It was well understood that loosening or migration of an intervertebral implant post-surgery must be prevented, so that the implant remains in a fixed position to stabilize the vertebrae and to support fusion between the vertebrae. *See* Section VIII.A. Such loosening or migration is caused by lateral and/or sagittal forces which are exerted on the implant and the anchors attaching it to the vertebrae as the spine moves. For the implant to move, it must move sagittally (forward or backward) or laterally (side-

to-side) (or some combination of the two). That is, parallel to the plane of the vertebral body endplates.

124. A POSA understood that, to prevent loosening and/or migration of the interbody implant, the anchor members used to secure the implant device to the vertebrae should ideally be as perpendicular to the interbody device as possible when inserted into the vertebral body. Anchors inserted at other angles allow a larger moment arm to act on the anchors, applying greater lateral force to the anchor and implant and urging it to move laterally. *See* Ex. 1005, 1:17-20. When anchors are inserted perpendicular to the vertebral body, the moment arm acting on the anchors is as small as possible, meaning that the applied forces must act along the longitudinal axis of the anchor (straight up or down). Such forces do not tend to cause lateral or sagittal movement of the implant. Thus, anchors inserted perpendicular to the vertebral body require the greatest force (relative to other insertion angles) to pull the anchor from the bone post-surgery while the vertebrae fuse. This is also explained further with regard to Steffee (Ex. 1005), discussed in Ground 3 below. *See* Section XI.B.

125. However, a truly perpendicular approach using a straight anchor is not practically feasible because there is insufficient space between the vertebrae and through the implant to drive an anchor during surgery. The access channels for anchoring members are linear to the implant (generally, from front to back).

Therefore, the anchors must be inserted in this direction. Using a curved anchor—one that curves upwards or downwards—allows the anchor (which is inserted linearly, generally from the back to the front) to penetrate the adjacent vertebrae as close to perpendicular to the implant as possible. Therefore, a POSA would have recognized that curved anchors, such as those in Hess and Steffee, would minimize lateral and sagittal movement of the implant. *See* Section XI.B. below. Thus, a POSA understood that Hess, with minimal modifications, was suitable and desirable for use as an intervertebral fusion device to stabilize the vertebrae for fusion.

126. The only changes required to modify Hess for use as an intervertebral implant would be to modify the dimensions of Hess's shell, which was "dimensioned and configured for placement between the spinous processes," (Ex. 1006, 7:3-4) for use instead as an intervertebral implant. This would have been considered routine for a POSA, as Hess itself explains that the "bullet" shape shown in its figures could easily be modified for "many other variations" for the purpose of "match[ing] the profile of the adjacent bone when deployed." Ex. 1006, 7:7-13. Thus, this modification would have entailed merely modifying the external dimensions such that the implant formed, for example, a rectangular box (having optional external ridges) to interface with the superior and inferior vertebrae. This was a common design for intervertebral implants, generally referred to as a "box cage," since well before the time of the invention, as discussed in Section VIII.A. above. *See, e.g.,* Ex.

1016 at 8; Ex. 1017 at 9. This change would enable the implant to serve as a stable interbody platform to support the vertebrae during the fusion process. If necessary, the implant's design could be modified to increase strength as well. A POSA would understand that the implant shell must be able to withstand the expected forces for an intervertebral implant, and would make such modifications as needed. Such a modification would entail simply modifying (thickening) the wall thickness of the implant shell or using stronger materials. This type of change was well within the skill of a POSA and could reasonably be expected to be successful based on prior art designs such as those referenced above.

127. Optionally, a POSA could also have created perforations in the implant device to allow for the interpenetration of artificial bone graft material, to promote fusion (bone growth) between the two vertebrae in and not merely around the implant. The use of such perforations for enabling fusion using such bone graft material was also within the general knowledge of a POSA when constructing intervertebral fusion devices. *See, e.g.*, Ex. 1007, 4:31-37; Ex. 1023, 1:31-34. This modification is optional, as not all such fusion devices possessed such perforations to allow graft material to penetrate the device's internal cavities.

128. A POSA would have had a reasonable expectation of success in modifying the dimensions of Hess's device and in using it as an intervertebral implant. First, Hess itself teaches that modifying its shape and dimensions was

expected, as explained above. That is, Hess's particular shape was merely a design choice. Second, the internal components of Hess's device do not require its bullet shape (as noted by Hess itself), but could be easily contained in a rectangular box suitable for use as an intervertebral implant. The changes to the internal components required would have been recognized as simple, straightforward mechanical changes well within the skills of a POSA. Accordingly, a POSA would have considered it obvious to modify Hess's device for use as an intervertebral fusion device.

Claim 1.1 “a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel”

129. As discussed above, it was obvious to modify Hess's device to function as an intervertebral fusion apparatus. As an intervertebral device, it would be “configured to position between first and second vertebral bodies,” that is, two adjacent vertebrae.

130. Hess's implant possessed four internal curved guide tracks (each one a “channel” as used in the claim) for its four locking wings:

During deployment of the implant 10, the locking wings 14a-14d are stowed within the shell 12 of the implant 10, as best seen in FIGS. 10A and 11, forming a streamlined structure. As best seen in FIGS. 4, 5A, 5B, 6A, 6B, 10A and 10B, **two curved guide tracks 19** formed within the shell portions 12a, 12b accommodate the wings 14a-14d in the stowed position.

Ex. 1006, 7:26-29. The location of the curved guide tracks corresponding to wings 14b and 14d are shown in green in annotated Figures 10A and 10B below. *Id.* Figs. 10A, 10B; *see also* Figs. 6A, 6B. I note that in these figures, primarily in Fig. 10A, the precise overlap between the guide tracks (19) and the locking wings (14b and 14d) is difficult to discern at some points, because the locking wings reside inside the channels and their dimensions (primarily 14d in Fig. 10A) are not drawn to scale. A POSA would understand that these drawings are not engineering drawings and are only intended to provide a general illustration of the device, which they effectively do. Despite any shortcomings in the drawings, the location of the channels is as generally depicted in the annotated figures.

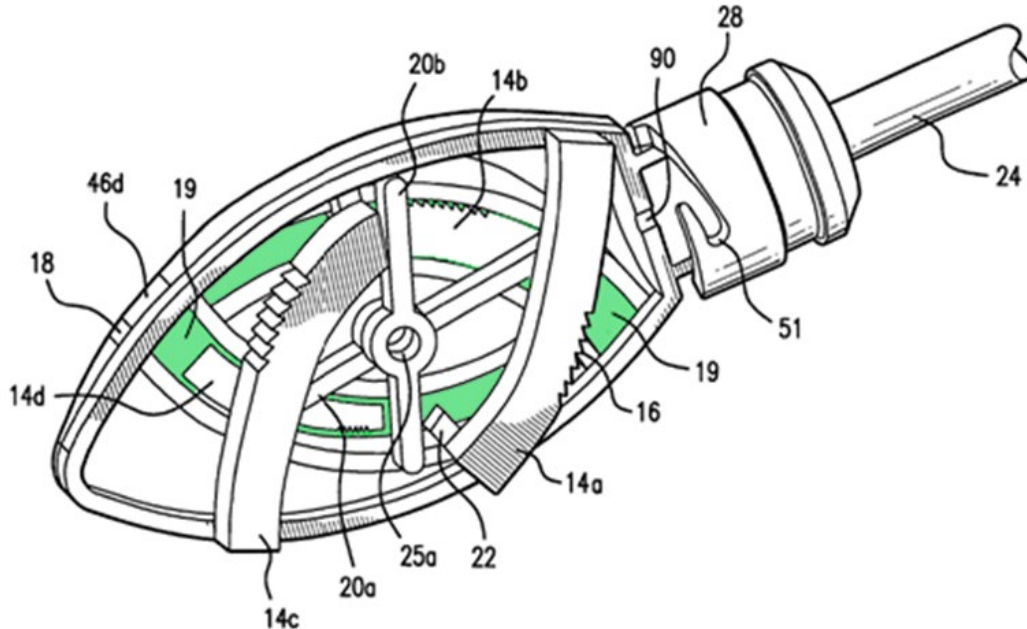
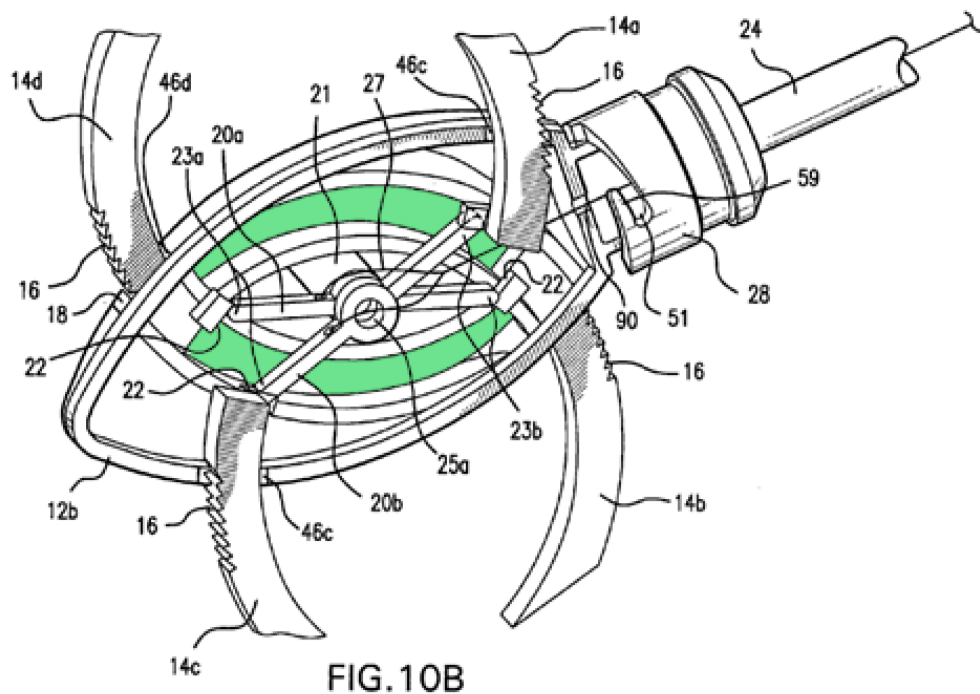


FIG. 10A



131. Hess has four internal guide tracks, with one pair of tracks located in one half of the shell and the other pair in the other half. In the figures above, the guide tracks for locking wings 14a and 14c are in the half of the shell that is not depicted, while the guide tracks for locking wings 14b and 14d are in the depicted half of the shell. The guide tracks for each pair are identical. Locking wings 14a and 14d deploy upward, to engage the vertebral body above the device, while locking wings 14b and 14c deploy downward to engage the vertebral body below the device. Thus, either of the guide tracks for locking wings 14a or 14d would qualify as the claimed “first curved channel.” If the first channel is that for wing 14a, the second

channel would be the guide track for wing 14*b*. If the first channel is that for wing 14*d*, the second channel would be the guide track for wing 14*c*.

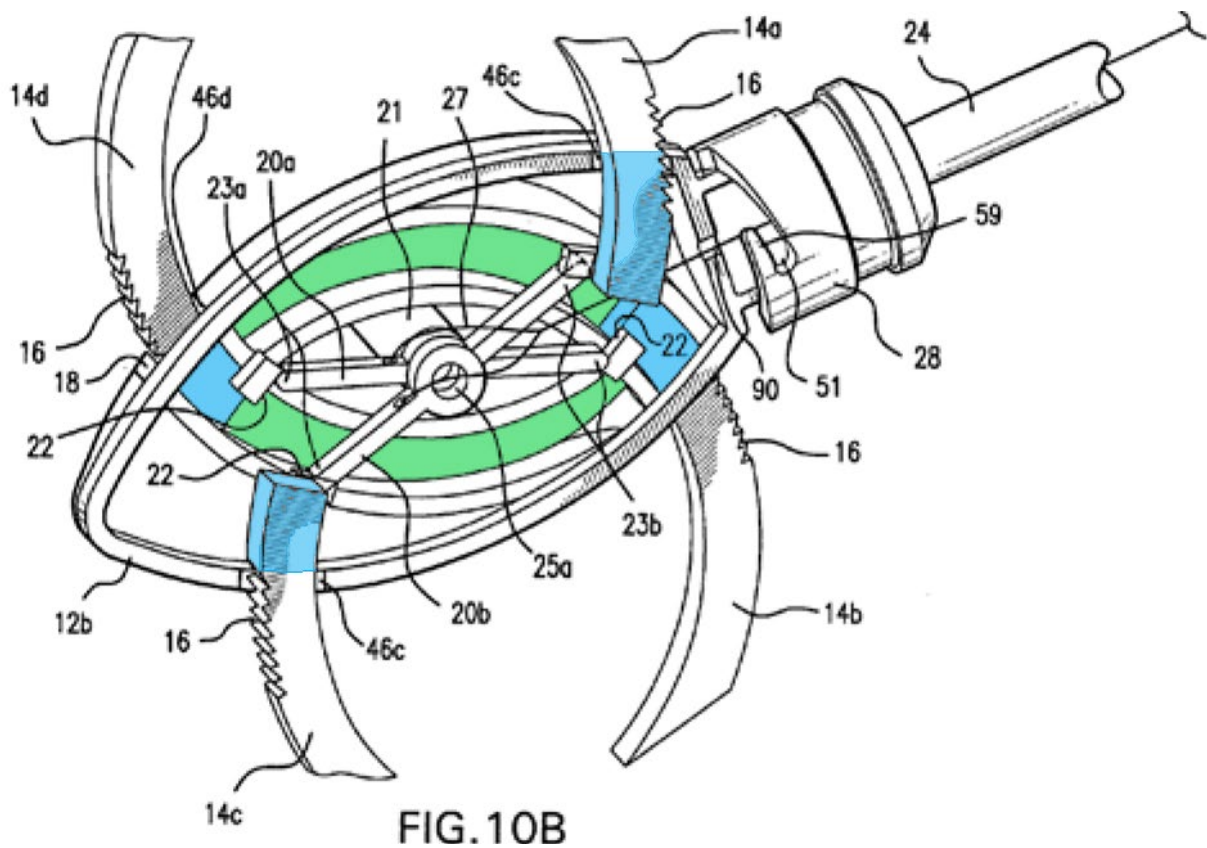
Claim 1.2 “a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and a second anchoring member configured to insert through the second curved channel and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body,”

132. Hess’s device “includes a body portion having an interior cavity, a plurality of locking wings adapted and configured to move between a stowed position retracted within the interior cavity of the body portion and a deployed position extended from the interior cavity of the body portion, and means for moving the plurality of locking wings from the stowed position to the deployed position.” Ex. 1006, 2:6-13. The locking wings are deployed “to engage the spinous processes of adjacent vertebrae.” *Id.*, 2:25-26. In the modified device, the locking wings would engage the vertebral bodies themselves.

133. The main shell of the device “houses four deployable ratcheting locking wings 14*a*-14*d* adapted and configured to engage adjacent vertebral portions of the spinous process. The shell 12 has four openings 46*a*-46*d* that allow the locking wings 14*a*-14*d* to extend outward from the shell 12.” *Id.*, 7:21-22. Hess explains that “[a]dvantageously, once the wings 14*a*-14*d* are deployed to fixate the spinous

processes, migration of the implant 10 is prevented.” *Id.*, 7:43-45. Further, the tips of the locking wings “can be sharp to create penetration of the spinous processes” “so that the edge that forms a point on opposing claws so that the opposing wings could penetrate deeper or through the spinous process bones.” *Id.*, 13:30-36.

134. As shown in annotated Figure 10B below, at least a portion (blue) of the locking wings also remains within the shell in the deployed position.



Id., 5:56-58, Fig. 10B.

135. As modified, a POSA understood that Hess’s locking wings would engage and at least partially penetrate the superior and inferior adjacent vertebrae

instead of the spinous processes. This would serve to couple the shell with each of the vertebral bodies.

136. Thus, as modified Hess discloses “a first anchoring member” (e.g., either locking wings 14*a* or 14*d*) “configured to insert through the first curved channel” (the guide tracks corresponding to either locking wing 14*a* or 14*d*) guide tracks 19 formed in the shell) “and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body.”

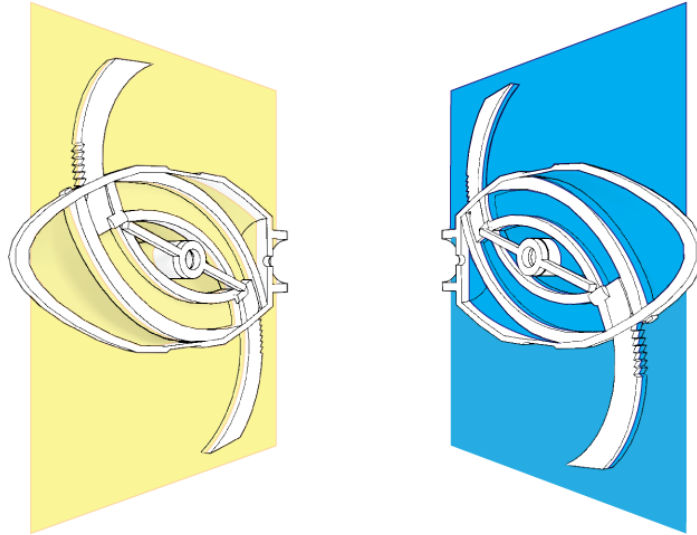
137. One of the other locking wings comprises the second anchoring member. Thus, if the first anchoring member is locking wing 14*a*, the second anchoring member would be 14*b*. If the first anchoring member is 14*d*, the second locking wing would be 14*c*. Therefore, locking wing 14*b* or 14*c* qualifies as the claimed “second anchoring member configured to insert through the second curved channel” (the guide track corresponding to the chosen locking wing 14*b* or 14*c*) “and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body.”

Claim 1.3 “wherein the first curved channel has a first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member and the second curved channel has a second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member, wherein the first and second cross-sectional planes are parallel to each other.”

138. Two of Hess’s anchors (e.g., locking wings 14a, 14c or alternatively locking wings 14b, 14d), which travel through the curved guide tracks, are explicitly disclosed as each “located on first parallel, spaced apart geometric planes that extend on a first side of a centerline of the shell,” while the other pair “are located on second parallel, spaced apart geometric planes that extend on a second side of the centerline of the shell.” Ex. 1006, 3:31-35. Thus, as explained with reference to Figure 3, “in a deployed position, locking wing 14b resides in a deployment plane that is parallel to the deployment plane of locking wing 14c. Similarly, locking wing 14a resides in a plane that is parallel to the deployment plane of locking wing 14d. It follows that, locking wings 14a and 14c reside in a common deployment plane, and locking wings 14b and 14d reside in a common deployment plane.” *Id.*, 7:46-58.

139. Because each of the wings travels through a corresponding guide track, each guide track likewise occupies the same parallel deployment planes as its corresponding locking wing. Thus, for example, the guide track for either locking wing 14a or 14d has a “first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member,” while the guide track for

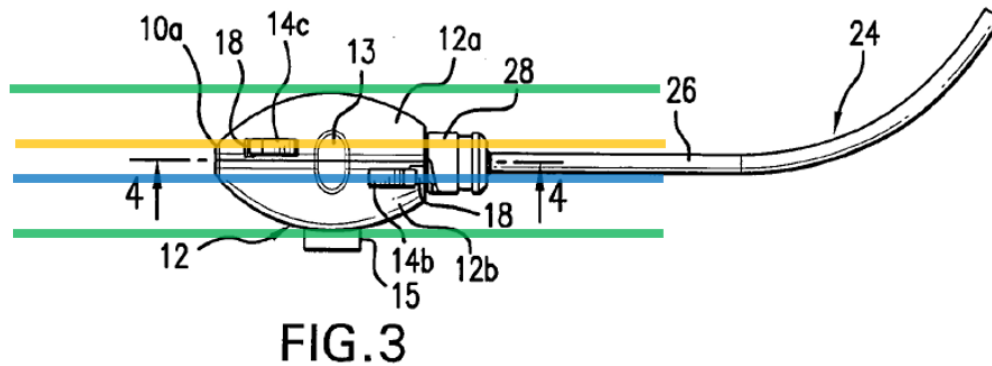
141. As Figure 10B only shows one side of the shell, a 3D rendering of the planes on both sides of the shell is provided below. The planes would have been understood to be parallel to one another after assembly of the shell.



C. Claim 2: “The fusion device of claim 1, wherein the first and second cross-sectional planes are parallel to at least one surface of the fusion member.”

142. The planes of Hess’s guide tracks are parallel to the sides of its shell. When viewed as in annotated Figure 3 below, these surfaces appear at the top and

bottom of the device.¹ This is shown in annotated Figure 3 below, where the plane tangent to those surfaces is noted in green. That is, the plane of the guide tracks (yellow or blue) is parallel to the planes of the sides of the shell (green):

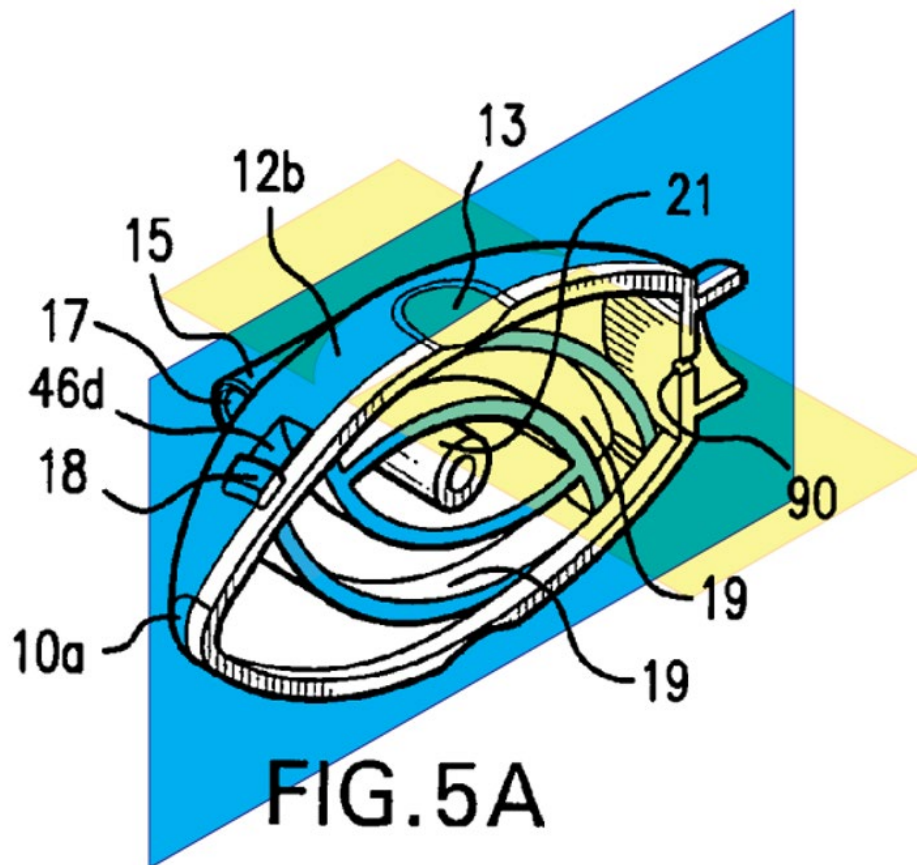


143. Further, as modified, Hess’s shape would be a rectangular shape suitable for use as an intervertebral fusion apparatus, as previously discussed. Thus, the planes of each of the guide tracks would be parallel with the straight sides (the top and bottom in Figure 3) of the implant. *Id.* Thus, Hess discloses that “the first and second cross-sectional planes are parallel to at least one surface of the fusion member.”

¹ I note that although this is stated to be a “side elevational” view in Hess (Ex. 1006, 5:6-7), a POSA would have understood it to be showing the top or bottom of the device as deployed. This is because the locking wings would deploy upwards or downwards to engage the adjacent vertebrae, not out to the side.

D. Claim 3: “The fusion device of claim 1, wherein neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member.”

144. Hess’s shell has opposing depressions 13 on the top or bottom of the implant to match the profile of the adjacent bone when deployed. Ex. 1006, 7:11-13. In annotated Figure 5A below, the surface containing these depressions is shown in yellow. As can be seen, it is perpendicular to the plane (blue) of the curved guide tracks.



145. As modified, Hess's shell would be a rectangular box suitable for use as an intervertebral fusion implant as previously discussed. Thus, the guide tracks would be perpendicular to the top and bottom of the implant (when positioned as it would be placed between vertebrae) in the modified implant as well. Therefore, as required by the claim "neither of the first and second cross-sectional planes" (blue) "is parallel to at least one surface of the fusion member" (the top or bottom surface as deployed, shown in blue above).

E. Claim 7 "The fusion device of claim 1,"

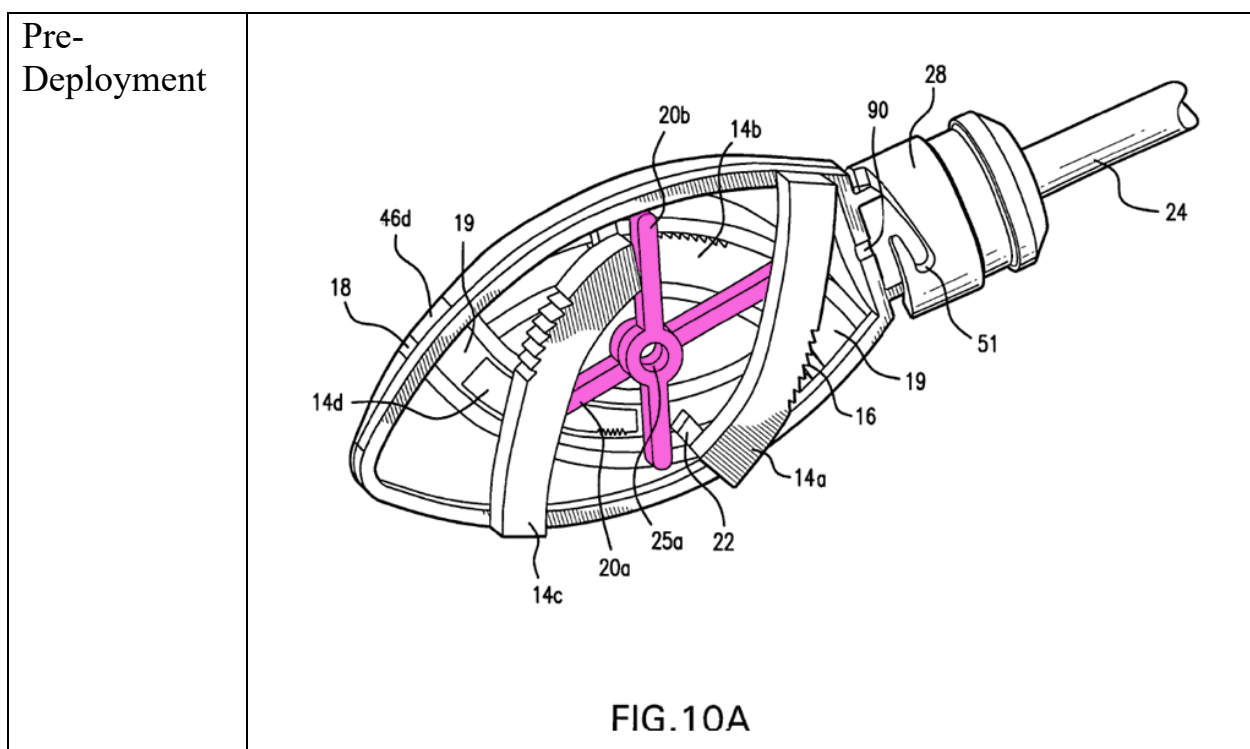
7.1 "wherein each anchoring member is configured to couple to a driving member,"

146. Hess's locking wings are deployed when a "locking wheel" causes them to move. The locking wheels are actuated by a deployment cable, controlled by the surgeon:

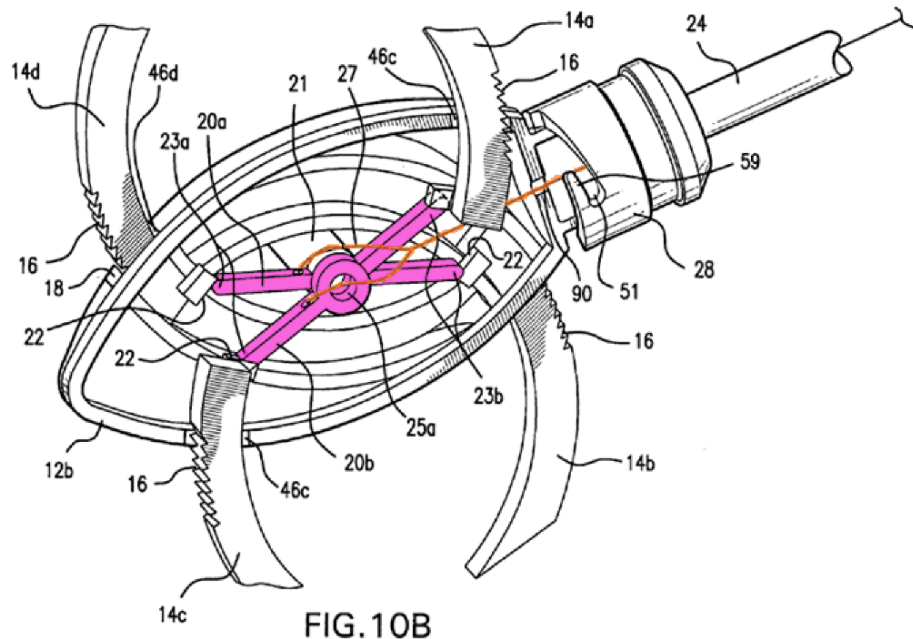
A pair of coaxial locking wheels rotatably mount in the shell to selectively exert a force against each locking wing to move the locking wings from the stowed to the deployed position and a deployment cable couples to the wheels to actuate rotation of the wheels.

Ex. 1006, 3:24-28. As shown with reference to Figs. 10a and 10b (partially annotated below), Hess explains that during surgery, the implant (10) is held in position by the surgeon using placement tools (not shown—see Fig. 20) and one or more deployment cables (27) (orange) are pulled to actuate the locking wings (14a-14d).

Id., 11:55-12:4. A distal end of the cable(s) is attached to an opening (41) in the coaxial locking wheels (20a, 20b) (pink) so that as the cable is pulled, the locking wheels rotate about the central hub (21). *Id.* Fig. 10A details the position before deployment, while 10B illustrates after deployment. *Id.*, 5:53-58, 10:53-58. The ends (23a, 23b) of the locking wheels push against surfaces (22) of the locking wings, causing them to slide outward in their guide tracks (19). Upon deployment, the locking wings engage the adjacent bone. Ex. 1006, 8:5-19, 11:55-12:4. After deployment, the cable maybe be disengaged or cut. *Id.*, 8:18-19.



Post-
Deployment



147. Hess's deployment cable(s) 27 actuates rotation of the locking wheels, which in turn move the locking wings through their guide tracks and cause them to deploy and engage the adjacent bone (as modified, the vertebral bodies). The deployment cables qualify as the claimed "driving member." Each of the locking wings is "configured to couple" to the deployment cable, indirectly via the locking wheels. Therefore, in Hess "each anchoring member" (a locking wing) "is configured to couple to a driving member" (the deployment cables).

7.2 “wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.”

148. As explained for element 7.1, deployment cable 27 (the claimed “driving member”) is configured to drive each locking wing (“anchoring member”) from its stowed to deployed position, at which point they are driven into the superior and inferior vertebral bodies. *See* Claim 7.1 above; Ex. 1006, 13:30-36 (explaining that the locking wing tips penetrate the adjacent bones). After deployment, the cable may be disengaged or cut. Ex. 1006, 8:18-19, 8:50-56. In either case, the cable (or a part of the cable, which may also be considered the driving member) is either completely or partially decoupled from the locking wings. The operation of the cable would not change in the modified version of Hess, except that (as explained for Claim 1) the locking wings will engage the vertebral bodies and not the spinous processes. Therefore, in Hess the deployment cable qualifies as a “driving member configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.”

F. Claim 9: “The fusion device of claim 1,”

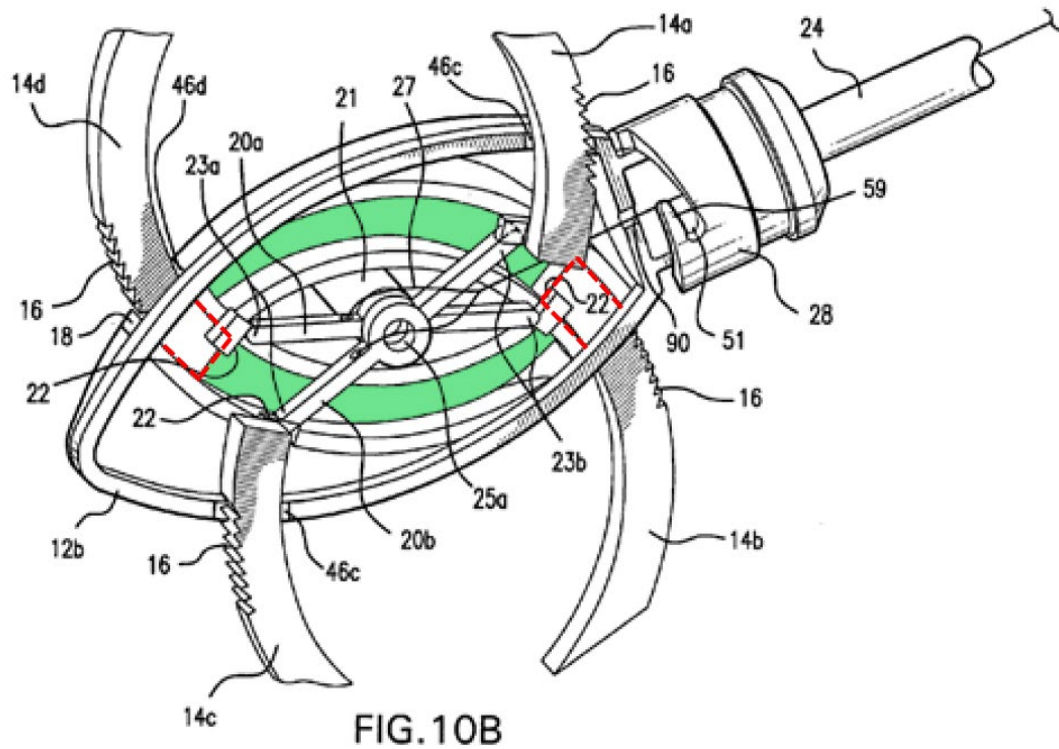
9.1 “wherein each channel of the fusion member has an opening on a surface of the fusion member and the opening has a recess,”

149. Hess teaches at least two ways in which its guide tracks have a recess in their openings onto the surface of its shell.

150. First, Hess's device includes openings in the shell for its guide tracks for deployment of the locking wings. Hess explains that the shell has "upper and lower shell portions defining four interior grooves that terminate in openings in the shell." Ex. 1006, 3:13-18. As shown in Fig. 10B below, each opening possesses a "recess" (depicted with red dashed lines) into the fusion member along the length of the channel. As required by the claim limitation, "each channel" possesses "an opening on a surface of the fusion member" at openings 46a-46d in the shell and "the opening has a recess."

151. Further, each opening possesses a "pawl structure" formed adjacent each opening. *Id.* A "pawl" generally refers to a curved bar or lever that engages the teeth of a ratchet. Hess describes its pawl structure as engaging ratchet teeth on the locking wings to lock them in position. *Id.*, 3:18-23; *see also id.*, 7:33-38. The pawl structure (18) is depicted in Hess as extending from the interior surface of each channel and adjacent the recess formed by the openings (46a-46d) of each channel in the shell, as shown in Figures 5B and 10B below. Although Hess does not depict the pawl structures in detail, based on its descriptions a POSA would have understood that each pawl structure is a protrusion from the wall of the opening into the channel to engage the ratchet teeth on each wing. This protrusion narrows the diameter of the channel at that point. Therefore, there is a recess formed by the pawl on at least one side of the pawl's protrusion, relative to that narrow diameter. Thus,

the recess is created by returning from the narrowed diameter back to the original diameter of the guide track or channel. This would also qualify as the claimed recess, in addition to the recess formed by the end of each channel next to the opening.



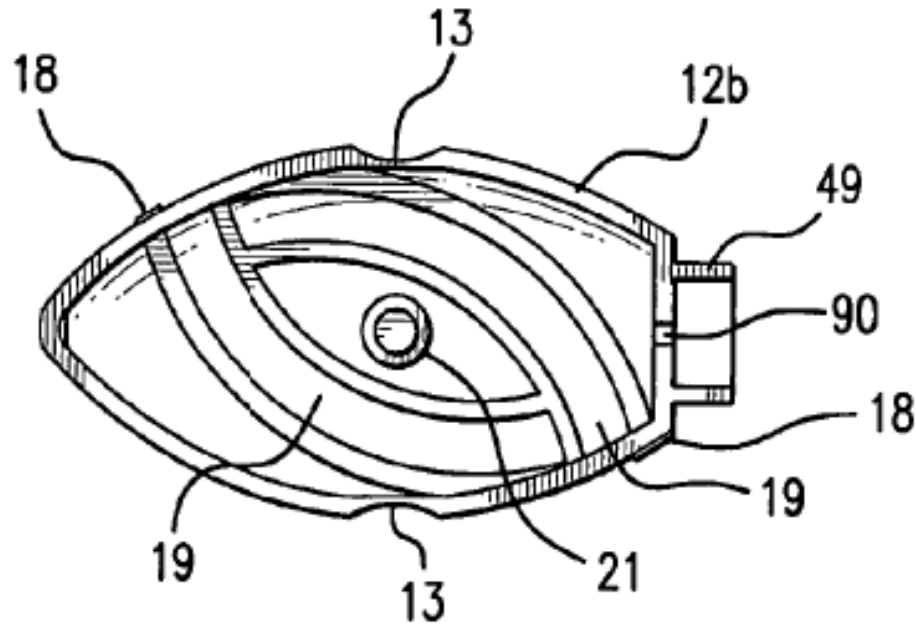
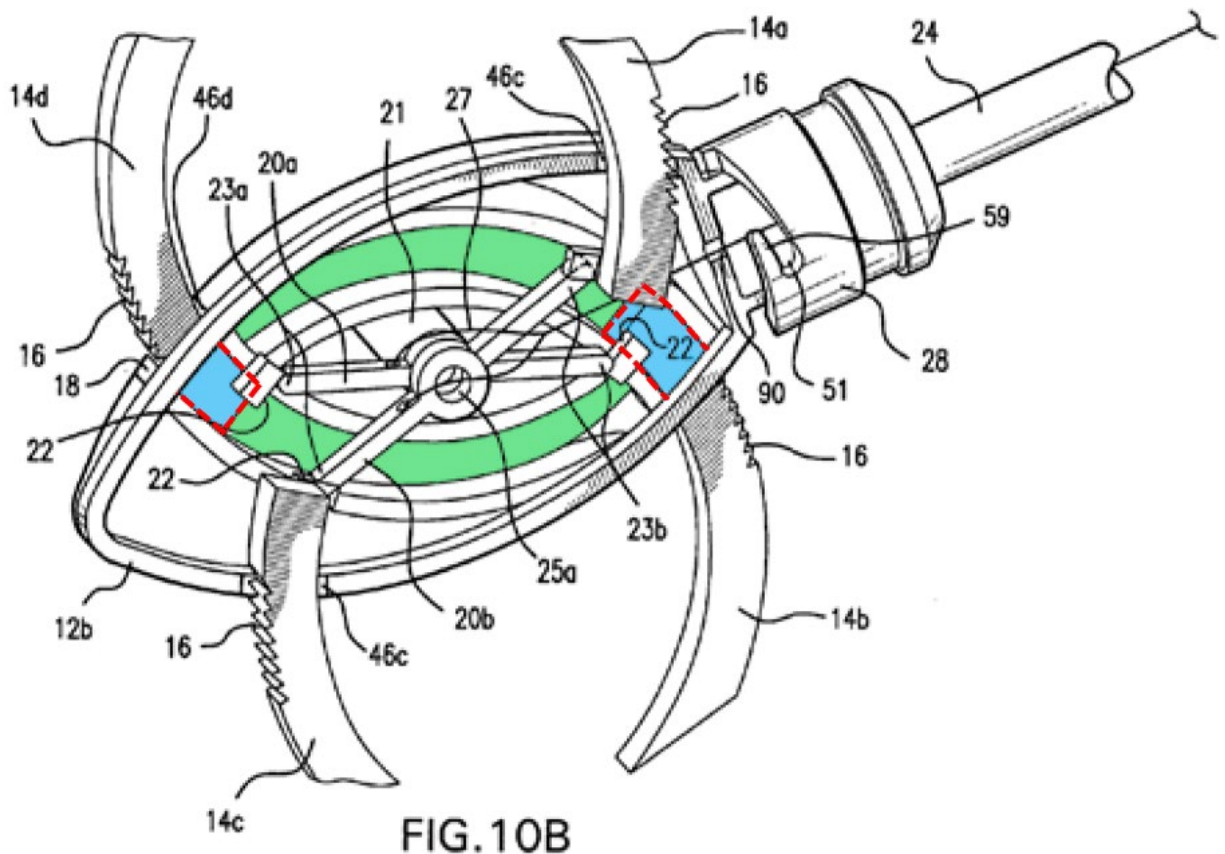


FIG. 5B

9.2 “wherein each anchoring member has a base that fits within the recess of the channel associated with the anchoring member in order to maintain the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body.”

152. Hess’s locking wings (“anchoring members”) each have a base portion that remains inside the shell, within the internal recess below the opening for each of the guide tracks (“channels”). Annotated Fig. 10B below highlights the base portion of the locking wings in blue and the channels in green. As can be seen, at least a portion of each locking wing remains inside the shell, occupying a portion of the channel (the “recess,” red-dashed lines) while the tips of the locking wings penetrate the vertebral bodies.



153. Thus, each anchoring member “has a base that fits within the recess of the channel associated with the anchoring member that maintain(s) the anchoring member at least partially in the fusion member, while the anchoring member is inserted into the vertebral body.” This operation would not change in the modified version of Hess for use as an intervertebral fusion device. Further, at least one groove in the ratchet teeth on each locking wing is engaged by the pawl structure, meaning that the adjacent teeth would fit into the relative recess formed on each side of the tooth. *Id.* This also meets the limitation, as each locking wing (“anchoring member”) has a base (portion having ratchet teeth) “that fits within” the pawl’s “recess” (which

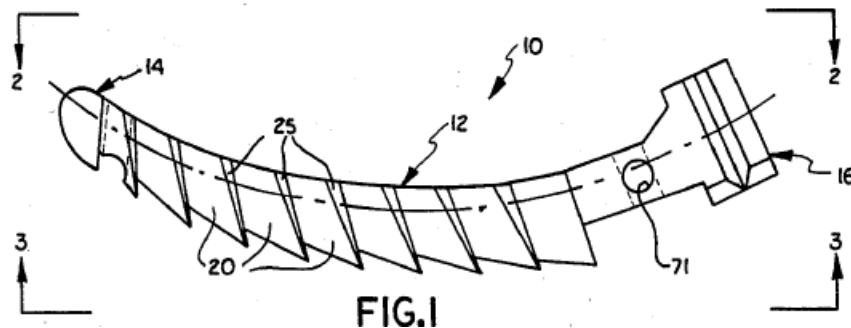
is in the channel), with the engagement between pawl, recess, and ratchet teeth “maintain[ing] the anchoring member at least partially in the fusion member.”

XI. GROUND 3

154. I understand that under Ground 3, Petitioner asserts that the challenged claims are obvious in view of the combination of Moskowitz and Steffee (“Moskowitz-Steffee”). My opinions with regard to the claims challenged under this ground are set forth below.

A. Brief Description of Steffee

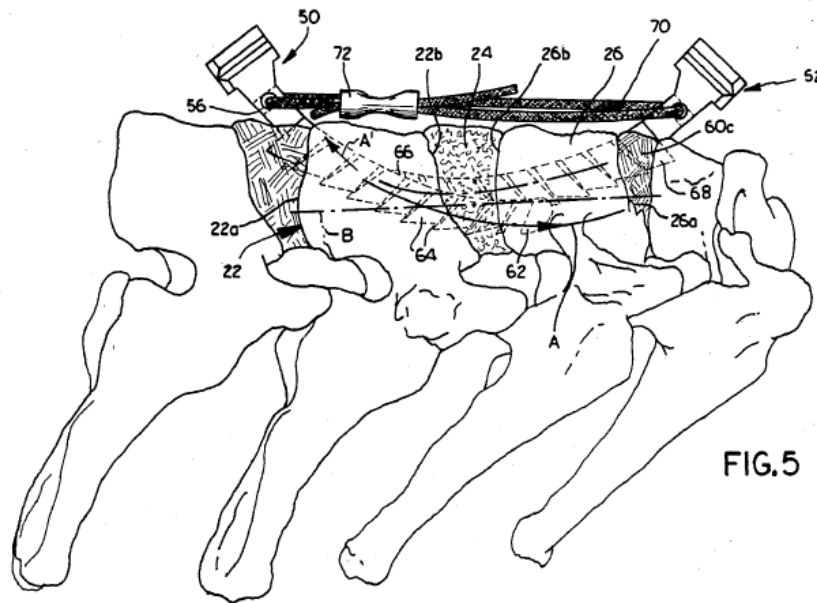
155. U.S. Patent No. 4,790,303 (“Steffee”, Ex. 1005) teaches a curved, elongated fastener for use in securing bone graft between bone portions. Ex. 1005, Abstract.



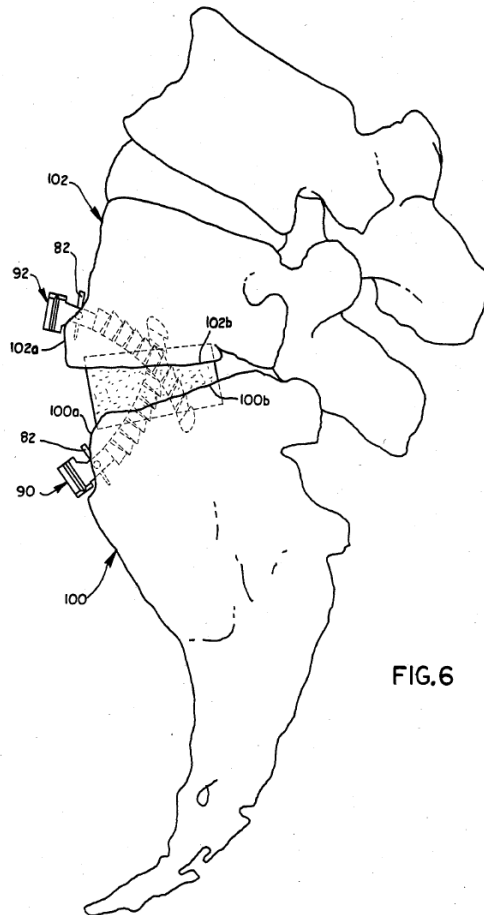
Each fastener has a shank portion (12) with a driving head (16), pointed end (14), and barbs (20) which prevent the fastener from backing out. *Id.*, 2:33-38, 2:61-68. Figure 5 shows two fasteners (50, 52) securing bone graft (24) to adjacent vertebrae (22, 26). *Id.*, 3:16-19. Although not explicitly described as depicting vertebrae, a

POSA would have understood that Figure 5 shows Steffee's fasteners as inserted through the adjacent vertebrae to secure the bone graft material 24. Specifically, a POSA would understand that bone portion 22 is one vertebral body and bone portion 26 is an adjacent vertebral body, and that the bone graft 24 resides between those adjacent bodies.

156. Steffee explains that “[a]s the fastener 10 is driven into the bone portion [22], due to its curved configuration, it progresses along a curved path A through the bone graft 24 and into bone portion 26.” *Id.* at 2:45-48.



157. In another embodiment (Fig. 6, below), each fastener (90, 92) is driven into the side of a corresponding vertebral body (100, 102) and curves into bone graft between those bodies and into the opposing body. Ex. 1005, 4:23-34.



158. Based on the foregoing, a POSA would understand that Steffee discloses interbody fusion using bone graft held by curved fasteners. Although Steffee does not discuss the use of intervertebral implants, bone graft was commonly packed in and around such implants to facilitate vertebral fusion. *See, e.g.*, Ex. 1004, 3:39-44; Ex. 1007, 4:31-37; Ex. 1023, 1:31-34.

B. Whether it was obvious to combine Moskowitz with Steffee.

159. A POSA was motivated to use Steffee's curved anchors with Moskowitz's screw box to minimize potential migration of the screw box after implantation. As discussed in the technology background above, such migration was

well known to detrimentally affect the success of intervertebral fusion procedures. *See* Section VIII.A. This motivation is further explained in Section XI.B.2. below.

160. This modification would entail modifying Moskowitz's screw box to include channels having a curved path, to accommodate the curved anchors. *Id.* A POSA had a reasonable expectation of success in making this modification because it would require the use of known machining techniques to modify the existing screw/drill guides (which would be done when manufacturing the device, not necessarily as a retroactive modification). For example, electrical discharge machining (EDM) uses electrical discharges in the fabrication process. It is typically used for materials which are difficult to machine using other techniques, such as titanium alloys like those often employed in intervertebral devices. Techniques for successfully employing EDM to machine curved channels were known prior to the claimed invention. *See, e.g.,* Ex. 1026.

161. The modification would further entail the use of both curved anchors and curved channels. As discussed further below, both had already been shown to be successful and desirable for use in spinal implants.

162. This combination would possess all elements of the challenged claims. *See* Sections XI.C.-XI.I. below.

1. Steffee is Analogous to the Claimed Invention.

163. Steffee is from the same field of endeavor as the '385 Patent, which includes “surgical procedures for spinal fusion and stabilization.” Ex. 1001, 1:29-30. Steffee relates to “a fastener for securing bone graft between a pair of bone portions.” Ex. 1005, 1:6-9. This relates to surgical fusion procedures because bone graft material was commonly used in spinal fusion procedures as discussed above. *See* Section XI.A. Although Steffee does not reference spinal fusion in its text, Steffee explicitly discloses using its invention in a spinal fusion procedure based on at least Figures 5 and 6, which depict the use of Steffee’s fasteners with bone graft material placed between two vertebral bodies. Ex. 1005, 3:14-38, 4:23-34, Figs. 5-6. Further, Steffee explicitly references “fibrocartilaginous disk 60b” in discussing its Figs. 4 and 5, which a POSA would have understood a referring to a disc between two vertebrae. *Id.*, 3:14-38. Such bone graft material was used both without implants (Ex. 1001, 1:58-61; Ex. 1018, 1:35-38), and together with implants (Ex. 1004, 3:39-44; Ex. 1019, 2:65-3:3). Thus, Steffee is from the same field of endeavor as the '385 Patent.

164. Steffee is also reasonably pertinent to a problem facing the inventor of the '385 Patent—improving the reliability of fusion “between unstable vertebral segments” to “avoid the considerable medical and economic impact of failed spinal fusions.” Ex. 1001, 2:10-13. As previously explained, a POSA understood that one

reason spinal fusions failed was due to migration of the implant during the initial stabilization period. *See* Section VIII.A. above; *see also* Ex. 1018, 23:48-50 (explaining that “teeth” on the surface of implant plates may reduce migration of the device out of the intervertebral space); Ex. 1019, 4:61-64 (explaining that “migration of the implant” may be somewhat inhibited using roughened surface topography on the top and bottom surfaces of the implant for “gripping adjacent bone”); Ex. 1020, 13:15-30 (discussing various implant bone screw designs to prevent screw migration, which a POSA would understand to cause migration of the implant); Ex. 1024, 1:31-39 (“One problem with prior art spinal fusion techniques relates to device migration. For example, prior to complete bone fusion, a fusion device may migrate from the desired position. In examples where bone screws are used, the insertion and tightening of the bone screws tends to cause device migration. Another problem with typical prior art fusion techniques is that fusion devices, or associated plates or fasteners, protrude from the spine, causing discomfort, damage, or danger to surrounding vascular or neurological tissues.”); *id.*, 3:35-46 (explaining that angled ridges formed on the top and bottom ends of the fusion device and help hold the device to the vertebrae endplates to reduce the chance of device migration); *id.*, 4:26-28 (explaining that the fusion device is held in place by a retention device “such that anterior and lateral migration is prevented”).

165. A POSA also understood that at least one reason such migration occurred was due to forces acting on the implant, including through its anchors or fasteners attached to the vertebrae. Steffee explains that it was known that bone graft contracts as it resorbs (that is, as the bone graft material breaks down and forms the substrate for new bone growth). Ex. 1005, 1:11. This “has resulted in difficulties in securing bone graft between spaced apart bone portions which are to be connected by the bone graft.” *Id.*, 1:12-14. Further, as the bone graft resorbs, it applies a force to the straight legs of the prior art staples that were used to secure bone graft between bone portions prior to Steffee’s invention. *Id.*, 1:16-17. “The force acts through a moment arm and causes the leg to pivot relative to a portion of the staple base,” causing the staple to [lose] its effectiveness.” *Id.*, 1:17-20.

166. Steffee solved this problem via curved anchors that traverse the vertebral bodies at a near-perpendicular entry angle. For example, in Fig. 6 (below), anchor 92 enters the bone graft, as well as both vertebral bodies 100 and 102, at an angle nearly perpendicular to their surfaces (100b, 102a). *See* Ex. 1005, 4:23-34.

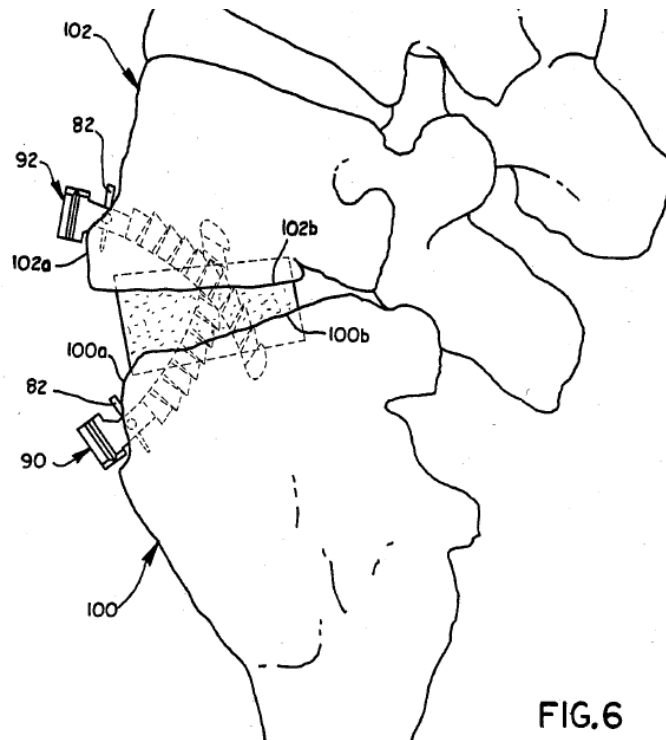


FIG. 6

167. Steffee explains that its curved fastener:

extends through the bone graft in a direction along a line extending through the bone graft and bone portions and along which the bone graft resorbs. Thus, the force applied to the shank by the bone graft as it resorbs acts generally along the longitudinal extent of the shank. Thus, the force does not act through a moment arm nor does it have a detrimental effect on the fastener.

Id., 1:29-36.

168. Thus, a POSA would have understood that Steffee's curved fasteners would not be exposed to the same forces (acting through a moment arm) that tended to cause prior art fasteners to lose effectiveness. This meant the forces acting on the

anchor that tend to cause sagittal and lateral movement, and thus migration of the implant, would be lower than they would be for straight fasteners inserted at a flatter angle. Accordingly, Steffee would have been considered as reasonably pertinent to the problem facing the inventor—increasing the reliability and success rate of spinal fusion procedures—because it related to minimizing the forces causing migration of spinal fusion implants, which was detrimental to the success of spinal fusion procedures.

2. A POSA was motivated to combine Moskowitz and Steffee.

169. A POSA was motivated to use Steffee's curved anchors with Moskowitz's screw box to lower the forces (acting through Moskowitz's existing screws) that tended to cause migration of fusion implants. As discussed above, it was desirable to avoid migration of the implant, thereby increasing the chances of a successful spinal fusion. A POSA understood that this migration was caused by forces acting on the implant to move in the space between the vertebrae, including forces acting on the screws inserted into the vertebral bodies and surrounding bone graft material, which would thereby act on the fusion member engaged with each screw. As discussed above, Steffee taught that forces tending to cause sagittal or lateral movement of the fastener (and thereby any attached implant) can be minimized or eliminated by using a curved fastener that increases the entry angle of the fastener to near-perpendicular. Because this decreases or eliminates the moment

arm acting on the fastener as explained in Steffee, a POSA understood that the use of curved fastener would inhibit migration of the implant by decreasing the forces applied to the fastener and fusion member (in comparison with a straight anchor entering at a flatter angle). The curved anchor would cause the force applied to the anchor by the bone graft as it resorbs to act “generally along the longitudinal extent” of the anchor member, and therefore not “through a moment arm” so as to avoid having “a detrimental effect on the fastener.” *Id.*; Ex. 1005, 1:31-36. Thus, a POSA was motivated to use Steffee’s curved anchors with Moskowitz’s screw box to allow a more perpendicular insertion of the anchor into a vertebral body.

170. A POSA would also have been motivated to use Steffee’s anchors with Moskowitz to form a more secure engagement between the screw box and the vertebrae. Moskowitz’s anchors are threaded screws. *See* Section IX.. A POSA understood that such screws (like all screws) could strip (e.g., due to misalignment or over-torquing), which would reduce the stability of engagement between the fusion member and vertebrae. Because the fasteners in Steffee do not contain threads, and further contained barbs to prevent the fastener from backing out (Ex. 1005, 2:61-68), such fasteners would not be subject to such stripping. Therefore, a POSA would have been motivated to use curved fasteners, like those in Steffee, having barbs to eliminate the risk of stripping inherent when using Moskowitz’s screws.

171. Using the curved anchors with the screw box would have required modifying Moskowitz's existing screw or drill guides to accommodate the curved anchors. This would have entailed adding at least some curvature to the channels complementing the curvature of the anchors. This would have been done to ensure that the anchors did not become stuck or trapped when attempting to drive them through the screw/drill guides during surgery. As should be readily apparent, when inserting a rigid curved object such as a rod or anchor into a straight channel, the object will become stuck and unable to pass through if the channel has sufficient length. To ensure this would not occur during surgery, a POSA would have modified Moskowitz's existing screw/drill guides to have a curved path complementary to the curvature of Steffee's anchors.

3. A POSA had a reasonable expectation of success.

172. Making the contemplated modifications to Moskowitz's screw box would have generally required replacing Moskowitz's transvertebral screws with curved fasteners like those disclosed in Steffee, and modifying Moskowitz's screw/drill guides to have a size and curvature complementary to Steffee's anchors. A POSA also would have recognized that, because the fasteners require impact for insertion (as opposed to turning as for a screw), that an impact driving tool would be required in place of Moskowitz's screwdriver. Steffee itself teaches the use of such a tool. Ex. 1005, 3:1-13 (referencing driving tool 38 in Fig. 7).

173. A POSA had a reasonable expectation of success in modifying Moskowitz's implant to utilize anchors like those in Steffee. First, modifying Moskowitz's screw/drill guides to accommodate and complement Steffee's anchors was a matter of using machining techniques well known to a POSA, such as EDM as discussed above. Second, the use of curved anchors in spinal implants was already well known. As discussed for Ground 2 above, Hess taught the use of such curved anchors (passing through curved channels) for an interspinous implant. *See* Section X.B.. Curved anchors had also been successfully applied in intervertebral implants. *See* Ex. 1022, 4:15-29 (referencing tangs 220), Figs. 1, 9. Finally, the use of tools for impacting intervertebral implants and their anchors was well known. *See* Ex. 1004, 9:3-11 (explaining that positioning tool 500a can be used to impact the screw box itself by "tapping the handle with a mallet"); *see also* Ex. 1021 [0142]; Ex. 1023, 8:14-16. Therefore, a POSA had a reasonable expectation of success in combining Moskowitz and Steffee.

C. Independent Claim 1

Claim 1.0 "A fusion device comprising:"

174. Moskowitz discloses an intervertebral "fusion device" as explained for Ground 1. *See* Section IX.B., Claim 1.0. Moskowitz-Steffee's modified device is also an intervertebral fusion device.

Claim 1.1 “a fusion member configured to position between first and second vertebral bodies, the fusion member comprising a first curved channel and a second curved channel”

175. In Moskowitz-Steffee, Moskowitz’s screw box (as modified) is a “fusion member configured to position between first and second vertebral bodies,” for the same reasons discussed for Ground 1 above. *See* Section IX.B, Claim 1.1.

176. As explained above, it was obvious to use a curved channel, similar to those in Hess, to accommodate the use of a curved anchor, as disclosed in Steffee. A POSA would have found it obvious to modify Moskowitz’s screw box to include “a first curved channel and a second curved channel” to accommodate and conform to Steffee’s curved anchors as previously explained. *See* Section XI.B. Thus, the modified screw box of Moskowitz-Steffee discloses this claim limitation.

Claim 1.2 “a first anchoring member configured to insert through the first curved channel and partially into the first vertebral body while a portion of the first anchoring member remains within the fusion member, in order to couple the fusion member with the first vertebral body; and a second anchoring member configured to insert through the second curved channel and partially into the second vertebral body while a portion of the second anchoring member remains within the fusion member, in order to couple the fusion member with the second vertebral body,”

177. The shank of Steffee’s curved fastener has a driving head portion 16, similar to the head of Moskowitz’s transvertebral screws, which comprises the widest part of the fastener. Ex. 1005, 2:35-37; 2:55-61, Fig. 1; Ex. 1004, Fig. 1D. The head portion couples with a driving tool for driving the fastener into the bone.

Ex. 1005, 3:1-6, 4:35-42. Steffee's head portion remains outside of and is not driven into the bone. *See* Ex. 1005, Figs. 4-6.

178. In Moskowitz-Steffee, a POSA would have maintained this functionality just as in both Moskowitz and Steffee, such that at least this head portion would remain inside the screw box. This is because a POSA understood that the bearing surface of the head portion must be securely engaged with the implant after implantation; otherwise, the implant will not be secured to the vertebral bodies but will tend to move laterally or sagittally (or both) to the extent any "play" between the fastener head and implant exists. This would not be desirable for the reasons discussed in Section VIII.A. (discussing implant migration). Further, a POSA would have recognized that if the fastener heads did not remain in the implant and engaged with a seat located in the screw/drill guide, but simply passed through the implant, they would not affix the implant to the vertebrae. *See* Section IX.B. Claim 1.1.² By ensuring that the head portion contacts a seat inside the implant, "a portion [the head] of the first anchoring member [a fastener] remains within the fusion member [the screw box] in order to couple the screw box with the first vertebral body." *Id.* Of

² Even if it is assumed that Moskowitz does not explicitly disclose the use of such a seat, it would have been considered obvious for the same reasons discussed for Ground 1. *See* Section IX.B. Claim 1.1.

course, because there are two fasteners inserted through two curved channels in the combination, as in both Moskowitz and Steffee, Moskowitz-Steffee also possesses a second anchoring member configured just as the first.

Claim 1.3 “wherein the first curved channel has a first cross-sectional plane along a first path that is traversed by the first curved channel through the fusion member and the second curved channel has a second cross-sectional plane along a second path that is traversed by the second curved channel through the fusion member, wherein the first and second cross-sectional planes are parallel to each other.”

179. A POSA would have maintained the same cross-sectional planes in Moskowitz-Steffee as disclosed in Moskowitz itself, which are parallel. *See* Section IX.B., Claim 1.3. Steffee also teaches or suggests that its anchors are inserted parallel to one another. Ex. 1005, Fig. 4. Accordingly, Moskowitz-Steffee discloses that the cross-sectional planes traversed by the first and second curved channels are parallel.

D. Claim 2: “The fusion device of claim 1, wherein the first and second cross-sectional planes are parallel to at least one surface of the fusion member.”

180. The relative alignment of the channels and fasteners in Moskowitz-Steffee will be the same as Moskowitz itself. Thus, for the same reasons explained for Ground 1, Moskowitz-Steffee discloses that the “first and second cross-sectional planes are parallel to at least one surface of the fusion member.” *See* Section IX.C.

E. Claim 3: “The fusion device of claim 1, wherein neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member.”

181. As mentioned above, the relative alignment of the channels and fasteners in Moskowitz-Steffee is the same as Moskowitz itself. Therefore, Moskowitz-Steffee discloses that “neither of the first and second cross-sectional planes is parallel to at least one surface of the fusion member” for the same reasons discussed for Ground 1. Section IX.D..

F. Claim 4: “The fusion device of claim 1, wherein the first curved channel opens to at least two surfaces of the fusion member and the second curved channel opens to at least two surfaces of the fusion member, wherein the first cross-sectional plane is not parallel to either of the two surfaces to which the first curved channel opens and the second cross-sectional plane is not parallel to either of the two surfaces to which the second curved channel opens.”

182. The channels in Moskowitz-Steffee will open to the same surfaces of the fusion member as in Moskowitz itself, with only the internal curvature of the channels being changed. Therefore, Moskowitz-Steffee discloses all limitations of Claim 4 for the same reasons explained for Ground 1. *See* Section IX.E.

- G. Claim 5: “The fusion device of claim 1, wherein the first and second curved channels open to a first surface of the fusion member but the first curved channel traverses to a second surface of the fusion member and the second curved channel traverses to a third surface of the fusion member; “wherein the traversal of the first and second curved channels through the fusion member allows (i) the first anchoring member to enter the first surface of the fusion member but exit the second surface of the fusion member at a first desired location on the second surface of the fusion member and (ii) the second anchoring member to enter the first surface of the fusion member but exit the third surface of the fusion member at a second desired location on the second surface without hindering the first anchoring member's insertion through the fusion member.”**

183. The channels in the proposed combination would open to the same surfaces of the fusion member as in Moskowitz itself. Moskowitz-Steffee therefore discloses the limitations of Claim 5.1 for the same reasons explained for Ground 1. *See* Section IX.F. Claim 5.1. As both fasteners remain in their respective channels, a POSA would have known that the second anchor would exit its respective surface without hindering the first anchor's insertion through the fusion member, as explained for Ground 1. *See* Section IX.F. Claim 5.2.

- H. Claim 7 “The fusion device of claim 1, wherein each anchoring member is configured to couple to a driving member, wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.”**

184. Unlike Moskowitz's screws which are inserted by turning via a positioning tool containing a screw driver (*see* Section IX.F), Steffee's fasteners are

inserted with a driving tool. The head 16 of Steffee's curved fasteners each include grooves "adapted to receive gripping jaws ... of a driving tool" which "holds and drives the fastener 10 into the bone portions ... and bone graft." Ex. 1005, 3:2-6.

185. While the two anchors are inserted differently, a POSA would have modified Moskowitz's positioning tools to accommodate a gripping and driving design such as that disclosed in Steffee to use Steffee's curved fasteners. This modification would of course not be a retroactive change to Moskowitz's existing configuration, but a design change occurring prior to manufacture. Such tools were well known as previously discussed (*see* Section XI.B.3.), and a POSA would therefore have expected them to be easily adapted for use with Moskowitz's apparatus. These devices are quite simple mechanically, and serve the basic function of holding the implant in place while driving the anchoring members. Therefore, a POSA would have reasonably expected that a driving tool similar to that disclosed in Steffee would have been readily adapted for use with Moskowitz's screw box in the proposed combination, especially because there were no reasons to expect any issues in making such a modification. Accordingly, Moskowitz-Steffee discloses that each "anchoring member [fastener] is configured to couple to a driving member, wherein the driving member is configured to drive the anchoring member into the corresponding vertebral body." Further, as in Moskowitz, a POSA would have understood the driving member would be removed after implantation. *See* Section

IX.G. Claim 7.2. Thus, the combination also discloses that its driving member “decouples from the anchoring member” as required by the claim.

- I. Claim 9: “The fusion device of claim 1, wherein each channel of the fusion member has an opening on a surface of the fusion member and the opening has a recess, wherein each anchoring member has a base that fits within the recess of the channel associated with the anchoring member in order to maintain the anchoring member at least partially in the fusion member while the anchoring member is inserted into the vertebral body.”**

186. As in Moskowitz, each channel in Moskowitz-Steffee has an opening on the surface of the fusion member having a recess, and the head portion 16 of Steffee’s fasteners would fit in the channels’ recesses. *See* element 1.2 above; *see also* Section IX.H. Accordingly, Moskowitz-Steffee discloses all limitations of Claim 9.

XII. CONCLUSION

187. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and 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 Section 1001 of Title 18 of the United States Code. I further declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: November 21, 2024



Brad Culbert

APPENDIX A

Brad Culbert
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PROFESSIONAL EXPERIENCE

Consultant, April 2010 - Current

Offering expert witness and consulting services to medical device companies.

- Confidential Company 2
 - Currently serving as an expert witness for 2 IPR cases before the PTAB.
 - Will be producing a declaration report for each.
- Confidential Company 1
 - Currently serving as an expert witness for an IPR case before the PTAB.
 - Will be producing a declaration report
- Walk Vascular/Abbott
 - Consulted for 21 months post-acquisition to assist in the manufacturing and technology transfer to their Temecula, CA facility.
- Globus Medical
 - Served as an expert witness in 7 IPR proceedings before the PTAB.
 - Activities involved producing declaration reports for each IPR and depositions for each.
- Aegis Spine
 - Serving as an expert witness for a trial case.
 - Activities involved producing a declaration report and then subsequently deposed.
 - Case settled prior to going to trial.
- Spinal Elements
 - Served as an expert witness in a PGR proceeding before the PTAB.
 - Activities involved producing a declaration report and then subsequently deposed.
- Incuvate, LLC
 - Manage patent portfolio for the various incubator companies (Irvine Neurovascular, Vesatek, Orpheus and Walk Vascular - prior to acquisition by Abbott)
 - Developed new products for peripheral, cardiovascular, neurovascular and spine procedures for the various incubator companies.
 - Obtained 510k and CE Mark on all products developed.
 - Revised design control procedures along with a new quality system for the company to simplify product development.
 - Managed day to day operations (excluding sales & marketing) for all the incubator companies listed above.
 - Performed the role of VP R&D at Walk Vascular which was subsequently sold to Abbott on Sept 1, 2021.
- Intersect Partners
 - Market evaluation and plan of two new neurovascular devices (flow diverter system and aspiration catheter)
 - Designed and prototyped a self-expanding covered stent and delivery system for flow diversion around neurovascular aneurysms
 - IP assessment (FTO) and patentability strategy for the new devices
 - Developed project plans for the above devices
- Ellipse Technologies (Acquired by Nuvasive)
 - Researched market opportunities for adjustable magnet technology in large spine markets

- Invented new products with adjustable magnet technologies for spinal applications (patents pending)
- Designed and prototyped adjustable pedicle screw system
- Wrote and implemented new design control procedures
- Developed new surgical instrumentation for the adjustable limb lengthening system
- Led a team to design and develop an external magnetic control system (electrical mechanical) to remotely adjust implanted magnets for limb lengthening
- Ceterix Orthopaedics (Acquired by Stryker)
 - Participated in raising Series A financing
 - Researched and setup an OEM design and manufacturing company for its continuous suturing device for rotator cuff repair
 - Developed new meniscus repair suturing device from concept to working prototype (patent pending)
- Basin Medical
 - Developed business plan
 - Designed and prototyped tension measuring device for urinary stress incontinence
 - Co-invented new tension device for prolapse repair (patent pending)

**CTO & Vice President R&D, Interventional Spine, Inc., May 2000 – March 2010
Irvine, CA (Acquired by Depuy Synthes)**

First employee – hired as Director of Engineering, promoted to VP R&D (2001) and CTO (2006)

Triage Medical focused on orthopedic trauma products for small bones and hip fractures. Interventional Spine products applied the core technologies from Triage Medical and developed a series of percutaneous spine procedures. The company was venture backed and had revenue of \$1MM per month.

- Built and managed an R&D team that took several products from concept to market
- Invented and developed the PercuDyn motion preservation system (IDE underway in the US and currently being sold OUS)
- Invented and developed a new percutaneous access port for spine and other orthopedic applications (currently being used worldwide on all Interventional Spine surgeries for all products)
- Developed and launched the Perpos posterior stabilization system (>\$8MM in sales in 2009)
- Submitted the pre-IDE for PercuDyn system and responsible for the biomechanical section of the IDE that was approved by the FDA in 2008
- Performed extensive surgeon training on all products throughout the world
- Developed five orthopedic trauma product lines from concept to market
- Assisted in forming a scientific advisory board of leading surgeons
- Created and implemented the quality system and establishment registration with FDA, European Notified Body and State FDB
- Prepared all 510(k) and CE Mark submissions (first 6 years)
- Participated in venture capital presentations to raise \$40MM in financing over three rounds
- Wrote significant portions of the business plans for the financing.
- Built and maintained the IP portfolio - currently hold 20 spine/trauma patents and over 35 pending
- Co-authored 18 published papers and/or abstracts

**Sr. R/D Project Manager, EndiCOR Medical, Inc. (Acquired by EV3), Aug. 1998 - May 2000
San Clemente, CA**

Endicor Medical was a small venture backed startup company focused on developing percutaneous thrombectomy and atherectomy systems for cardiovascular and neurovascular applications.

- Designed, prototyped and proved animal safety and efficacy of a new version of the X-Sizer thrombectomy system that cuts larger channels through in-stent restenosis (patent issued)
- Developed animal models to satisfy FDA requirements of the safety and efficacy of the X-Sizer

thrombectomy system

- Designed, tested and optimized several different cutters for the X-Sizer
- Developed unique test methods to evaluate the performance of the X-Sizer in-vitro
- Designed a new cutting mechanism for a neuro application of the X-Sizer (patent issued)
- Coordinated and attended clinical evaluations of products subsequent to animal safety and efficacy testing
- Led project teams for the above products to transfer to manufacturing

R/D Project Manager, CVD (Now Endologix), Sept 1996 - Aug 1998

Irvine, CA

CVD was a cardiovascular company focused on developing new angioplasty balloons and stents with focal technology. The focal technology was licensed to Guidant Corporation in 1998.

- Designed and transferred to production new PTCA catheters (Guardian OTW, Arc II)
- Designed and transferred to production stent delivery system (Synthesis SDS)
- Performed sterilization validation for the Synthesis SDS
- Performed aging studies for many different products
- Coordinated biocompatibility testing for all the above projects
- Prepared and submitted PMA supplements (Guardian, Arc II)
- Assisted the regulatory department in the preparation and submission of CE Mark dossiers

**Angioplasty Product Team Leader, Vas-Cath Inc, (Acquired by C.R. Bard), Oct 1994 - Sept 1996
Mississauga, Ontario, Canada**

Vas-Cath was a small privately held company focused on developing and distributing dialysis and angioplasty catheters. They had the number 1 or 2 market share of the angioplasty balloon in all countries in Europe.

- Led a multi-functional team of R&D, manufacturing and quality engineers to continuously improve and maintain the angioplasty catheter product lines
- Designed and validated several new balloon molds and tubing
- Designed apparatus to increase balloon blowing productivity by 40%
- Designed fixtures and performed IQ/OQ and process validations (welders, draw down machines, flaring fixtures, etc.)
- Implemented material change for all balloons on the angioplasty product lines increasing balloon productivity (+50%), burst pressure (+20%) and scratch resistance (+30%)
- Designed single unit packaging for angioplasty catheters
- Performed test method validations for product testing
- Coordinated internal and external efforts to efficiently launch the angioplasty product line into the U.S.

**Manufacturing/Project Engineer, Camco Inc. (A division of General Electric), Oct 1992 - Oct 1994
Hamilton, Ontario, Canada**

Camco was the largest major appliance manufacturer in Canada.

- Developed an efficient process to incorporate a sub-assembly line onto a main refrigeration line using just-in-time strategy that resulted in an annual company savings of \$300,000
- Successfully coordinated and implemented a \$500,000 project that introduced a new product to market
- Led a team to implement predictable manufacturing to several key processes of the plant to conform to ISO 9000
- Designed work and test stations for the refrigeration assembly line
- Developed, redesigned and tested polyurethane foam molds and fixtures for new refrigeration product

EDUCATION

2001, MBA from California State University, Fullerton

1992, BAsC. in Metals and Materials Engineering from University of British Columbia

List of US Patents:

US8105382B2 Intervertebral implant
US8568481B2 Intervertebral implant
US10390963B2 Intervertebral implant
US10398566B2 Intervertebral implant
US10583015B2 Intervertebral implant
US11273050B2 Intervertebral implant
US11432942B2 Intervertebral implant
US11497618B2 Intervertebral implant
US10265101B2 Adjustable magnetic devices and methods of using same
US11123107B2 Adjustable magnetic devices and methods of using same
US6951561B2 Spinal stabilization device
US7648523B2 Method and apparatus for spinal stabilization
US9028533B2 Method and apparatus for spinal stabilization
US9226758B2 Method and apparatus for spinal stabilization
US9445826B2 Method and apparatus for spinal stabilization
US9962189B2 Method and apparatus for spinal stabilization
US10639074B2 Method and apparatus for spinal stabilization
US10667844B2 Method and apparatus for spinal stabilization
US8945190B2 Method and apparatus for spinal fixation
US9101411B2 Method and apparatus for spinal fixation
US9387313B2 Telescopic Percutaneous Tissue Dilation Systems and Related Methods
US10293147B2 Telescopic percutaneous tissue dilation systems and related methods
US8551094B2 Distal bone anchors for bone fixation with secondary compression
US7326211B2 Deployment tool for distal bone anchors with secondary compression
US7686807B2 Tool for bone fixation device
US6890333B2 Method and apparatus for bone fixation with secondary compression
US8715284B2 Method and apparatus for bone fixation with secondary compression
US9408648B2 Method and apparatus for bone fixation with secondary compression

US10349991B2 Method and apparatus for bone fixation with secondary compression

US7070601B2 Locking plate for bone anchors

US7175625B2 Soft tissue anchor and method of using same

US6648890B2 Bone fixation system with radially extendable anchor

US6632224B2 Bone fixation system

US7008428B2 Bone fixation system

US6942668B2 Proximal anchors for bone fixation system

US9861354B2 Meniscus repair

US11013510B2 Meniscus repair

US10758222B2 Meniscus repair

US8579926B2 Plaque removal device with rotatable cutting element

US7842055B2 Neuro thrombectomy catheter

US7235088B2 Neuro thrombectomy catheter

US6482217B1 Neuro thrombectomy catheter

US11490909B2 Systems and methods for removal of blood and thrombotic material

US10716583B2 Systems and methods for removal of blood and thrombotic material

US11490909B2 Systems and methods for removal of blood and thrombotic material

US9883877B2 Systems and methods for removal of blood and thrombotic material

US10716583 Systems and methods for removal of blood and thrombotic material

US10492805B2 Systems and methods for thrombolysis and delivery of an agent

US11510689B2 Systems and methods for thrombolysis and delivery of an agent

US10492805B2 Systems and methods for thrombolysis and delivery of an agent

US10716583B2 Systems and methods for thrombolysis and delivery of an agent

US10561440B2 Systems and methods for manipulating medical devices

US11497507B2 Systems and methods for closing portions of body tissue

US9248221B2 Aspiration monitoring system and method

US9895473B2 Aspiration monitoring system and method

US10603415B2 Aspiration monitoring system and method

US10702292B2 Aspiration monitoring system and method

US10226263B2 Aspiration monitoring system and method

US11051832B2 Aspiration monitoring system and method

US9433427B2 Systems and methods for management of thrombosis

US9913936B2 Systems and methods for management of thrombosis

US10192230B2 Systems and methods for management of thrombosis

US10922704B2 Systems and methods for management of thrombosis

US11540847 Systems and methods for management of thrombosis

US10716880B2 Systems and methods for aspiration and monitoring

List of Publications:

Mechanical characteristics of the new BONE-LOK bi-cortical internal fixation device

- November 2003
- [The Journal of foot and ankle surgery: official publication of the American College of Foot and Ankle Surgeons](#) 42(6):344-9

DOI:[10.1053/j.jfas.2003.09.003](https://doi.org/10.1053/j.jfas.2003.09.003)

Mechanical and structural characteristics of the new BONE-LOK cortical-cancellous internal fixation device

- February 2003
- [The Journal of foot and ankle surgery: official publication of the American College of Foot and Ankle Surgeons](#) 42(1):15-20

DOI:[10.1053/jfas.2003.50000](https://doi.org/10.1053/jfas.2003.50000)