

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner

IPR2025-00225
Patent No. 9,730,805

EXPERT DECLARATION OF BRAD CULBERT

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,730,805 to Wensel (“the ’805 Patent”)
1002	Declaration of Technical Expert Brad Culbert
1003	Prosecution History of the ’805 Patent
1004	U.S. Patent 8,172,854 (“Blain”)
1005	U.S. Provisional Application No. 60/950,801 (“Blain-Provisional”)
1006	U.S. Patent No. 7,985,255 (“Bray”)
1007	Excerpts from Webster’s New World College Dictionary (4 th Ed., 1999)
1008	Excerpts from The Oxford American Desk Dictionary (1998)
1009	Excerpts from The American Heritage Dictionary (2 nd College Ed., 1982)
1010	Redline Comparison of Abstracts of Blain and Blain-Provisional
1011	Redline Comparison of Specification of Blain and Blain-Provisional
1012	Redline Comparison of Claims of Blain and Blain-Provisional
1013	Patent Owner’s Infringement Contention Claim Chart for ’805 Patent Against Globus Hendron AI Interbody Spacer
1014	U.S. Patent No. 8,535,353
1015	U.S. Patent No. 5,766,253
1016	U.S. Patent No. 4,790,303 (“Steffee”)
1017	U.S. Patent No. 9,358,127 (“Duffield”)
1018	U.S. Patent No. 7,942,903

IPR2025-00225

U.S. Patent No. 9,730,805

Exhibit No.	Description
1019	U.S. Patent No. 8,075,593
1020	U.S. Patent Application Publication No. 2006/0265076
1021	Spinelogik's Preliminary Identification of Proposed Terms for Construction in <i>Spinelogik, Inc. v. Globus Medical, Inc.</i> , No. 2:23-cv-529-JRG-RSP, served October 30, 2024
1022	Globus's Preliminary Claim Constructions in <i>Spinelogik, Inc. v. Globus Medical, Inc.</i> , No. 2:23-cv-529-JRG-RSP, served October 30, 2024
1023	U.S. Patent No. 7,918,891
1024	U.S. Patent No. 8,328,851
1025	U.S. Patent No. 7,846,210
1026	U.S. Patent No. 8,673,005
1027	U.S. Patent No. 6,923,814
1028	U.S. Patent Application Publication No. US 2007/0270806
1029	U.S. Patent No. 6,613,091
1030	U.S. Patent No. 8,273,127
1031	Globus Marketing Video for Hendron IA Interbody Spacer
1032	U.S. Patent No. 7,662,186
1033	U.S. Patent No. 8,100,955
1034	U.S. Patent No. 7,041,135
1035	U.S. Patent No. 6,447,546
1036	U.S. Patent Application Publication No. US 2009/0112261
1037	U.S. Patent No. 8,105,382

IPR2025-00225

U.S. Patent No. 9,730,805

Exhibit No.	Description
1038	U.S. Patent Publication No. 2005/0085913 (“Fraser”)
1039	<i>Curriculum Vitae</i> of Brad Culbert
1040	Machinery Handbook, 28th Ed. (Excerpts)

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	BACKGROUND AND QUALIFICATIONS.....	1
III.	LEGAL STANDARDS	6
A.	Patentability.....	6
B.	Prior Art.....	11
C.	Anticipation and Obviousness.....	12
D.	Person of Ordinary Skill In The Art.....	17
E.	Claim Construction.....	19
F.	Written Description	21
IV.	BASES FOR OPINIONS	21
V.	OVERVIEW OF THE '805 PATENT AND PROSECUTION HISTORY	22
A.	Overview	22
B.	Prosecution History	27
VI.	LEVEL OF ORDINARY SKILL IN THE ART.....	31
VII.	OPINIONS ON CLAIM CONSTRUCTION.....	33
A.	<i>housing</i> (claims 2-4).....	33
B.	each channel of the fusion member is curved (dependent claims 5, 16)	35
VIII.	OVERVIEW OF PRIOR ART REFERENCES.....	38
A.	Blain	38
B.	Bray	50
C.	Steffee.....	53
IX.	OPINIONS ON PATENTABILITY	56
A.	GROUND 1.....	56
Claim 1		56

Claim 2: “The apparatus of claim 1, wherein the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member.”	77
Claim 3: “The apparatus of claim 2, wherein the retention mechanism comprises at least one retention rod for coupling with the fusion member.”	81
Claim 4: “The apparatus of claim 2, wherein the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism.”	82
Claim 5: “The apparatus of claim 1, wherein each channel of the fusion member is curved.”	82
Claim 6: “The apparatus of claim 1, wherein traversing through the different channel of the fusion member comprises entering the different channel of the fusion member through a corresponding channel of the delivery mechanism.”	84
Claim 11	85
Claim 12: “The fusion device of claim 11, wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member.”	87
Claim 15: “The fusion device of claim 11 further comprising a driving member configured to drive each independent anchoring member through the delivery mechanism.”	90

Claim 16: “The fusion device of claim 11, wherein each channel of the fusion member is curved.”	92
Claim 17: “The fusion device of claim 11, wherein each independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism in order to couple the fusion member to the penetrated vertebral body.”	92
B. GROUND 2	93
Claims 1, 11	93
Claims 5, 16	100
Claim 12	108
The Other Challenged Claims	109
C. GROUND 3	109
X. CONCLUSION	124

I. INTRODUCTION

1. I have been retained as a technical expert by Globus Medical, Inc. (“Globus”) and asked to provide my objective and unbiased opinions concerning U.S. Patent No. 9,730,805 (“the ’805 Patent”). Specifically, I have been asked to provide my opinions on the patentability of the ’805 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 submitted as Exhibit 1039 to this declaration. 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 considerable 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.

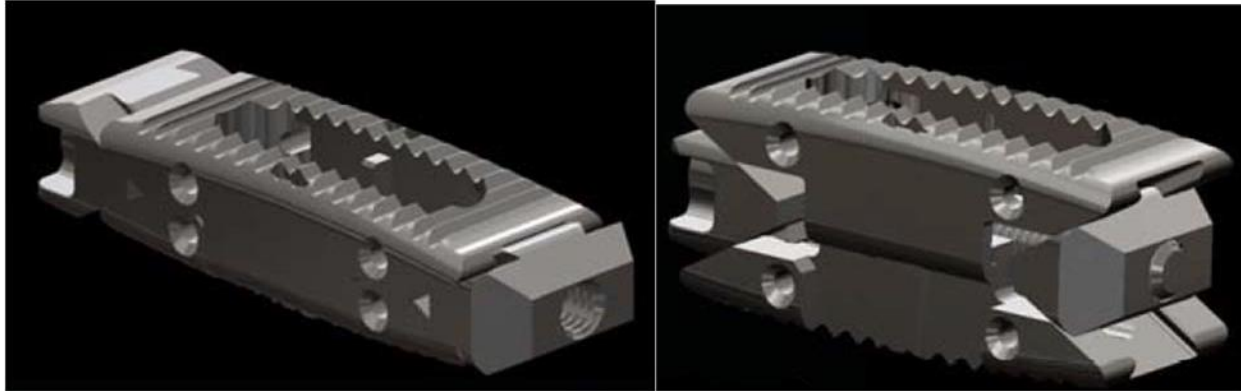
7. In 1996, I accepted a position as an R&D Project Manager at CVD. CVD was a cardiovascular company focused on developing new angioplasty balloons and stents with focal technology. While at CVD, I designed and developed new PTCA catheters and stent delivery systems and participated in the preparation 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 Nos. 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 '805 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 '805 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 '805 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.

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. Anticipation and Obviousness

34. 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.”

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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”).

41. 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.

42. 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).

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

D. Person of Ordinary Skill In The Art

50. 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.

51. 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:

- a. the educational level of the inventor;
- b. the type of problems encountered in the art;
- c. prior art solutions to those problems;
- d. the rapidity with which innovations are made;
- e. the sophistication of the technology; and
- f. the educational level of active workers in the field.

52. 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.

53. 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.

54. 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

55. 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.

56. 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.

57. 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.

58. 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 dictionary definitions and 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.

59. I understand that Spinelogik has filed a lawsuit against Globus in federal court for alleged infringement of the '805 Patent and that, for the purposes of this *inter partes* review, I am permitted to apply any claim construction proposed by Spinelogik in that litigation, regardless of whether I agree with Spinelogik's construction.

60. 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.

F. Written Description

61. I understand that written description support means a specification must reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date based on an objective inquiry into the four corners of the specification. The written description requirement is satisfied when the specification sets forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed. I also understand that the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.

IV. BASES FOR OPINIONS

62. The opinions set forth in this Declaration are my own. In forming the opinions herein, I have considered the exhibits to the Petition for *Inter Partes Review*

filed against the '805 Patent, as well as the additional materials cited in this Declaration. I have also relied on my education, training, and experience.

63. 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. OVERVIEW OF THE '805 PATENT AND PROSECUTION HISTORY

A. Overview

64. The '805 Patent teaches implants for use in spinal fusion and delivery tools for installing these implants. Ex. 1001, 1:20-21. As explained in the Specification, when discs between adjacent vertebral bodies in the spine degenerate, surgical fusion of the vertebrae using spinal implants is often used when conservative treatments fail to treat pain. *Id.*, 1:27-35. Surgical “interbody” fusion involves removing (or “dissecting”) the degenerated disc between two vertebral bodies to replace the disc with a fusion implant. The fusion implant provides stability and support while also facilitating bone growth.

65. In one embodiment described in the Specification, the implant includes a fusion member (e.g., a fusion implant) designed to be positioned between two vertebral bodies, a delivery mechanism, and anchoring members. *Id.*, 6:41-51. The delivery mechanism allows the surgeon to deliver and position the fusion member between adjacent vertebral bodies after the degenerated cartilage has been dissected. *Id.* The anchoring members are what secure the fusion member to the vertebral bodies. *Id.* The delivery mechanism may include a delivery housing, which houses anchoring members, such as needles. *Id.*, 6:62-7:7. The delivery housing and fusion member may contain several channels, each of which align with a channel of the fusion member. *Id.*, 7:39-44. This allows the anchors to be delivered through the fusion member and into the vertebral bodies. *Id.*

66. Figure 1A depicts delivery mechanism 130 coupled to fusion member 120, and anchoring mechanisms 140 inserted into fusion member channels 170 (which are not labeled):

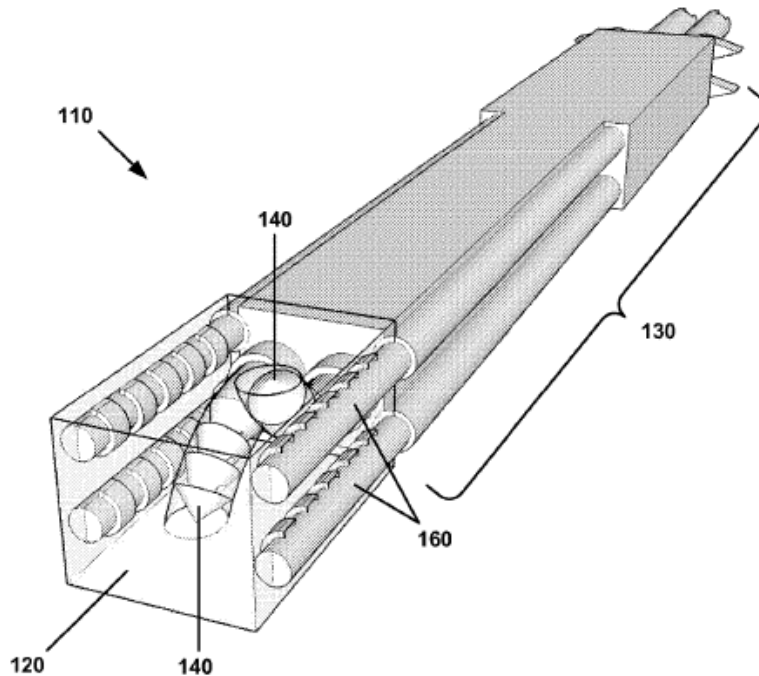


Figure 1A

Id., 9:29-37.

67. After the surgeon delivers and positions the fusion member between the vertebral bodies, he or she can use driving members to push anchoring members through channels in the delivery mechanism and through the corresponding, aligned channels in the fusion member. *Id.*, 2:35-42, 3:26-29. Each anchoring member then penetrates one vertebral body, thereby coupling the fusion member with the vertebral bodies. *Id.*, 2:60-66, 3:10-15. Figure 2 shows the fusion member 120 after it has been positioned between two vertebral bodies 210, 220 and Figure 15 shows two

anchoring members 1410, 1420 after driving members 1430, 1440 have driven them through the channels of fusion member 120:

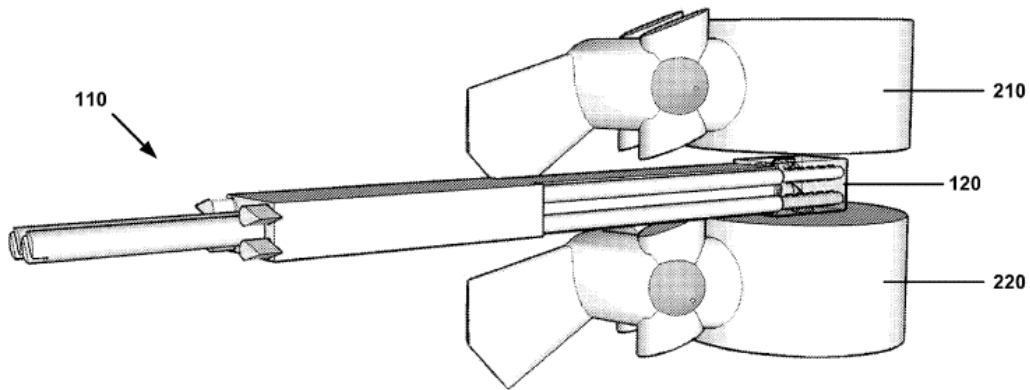


Figure 2

Id., 9:25-27.

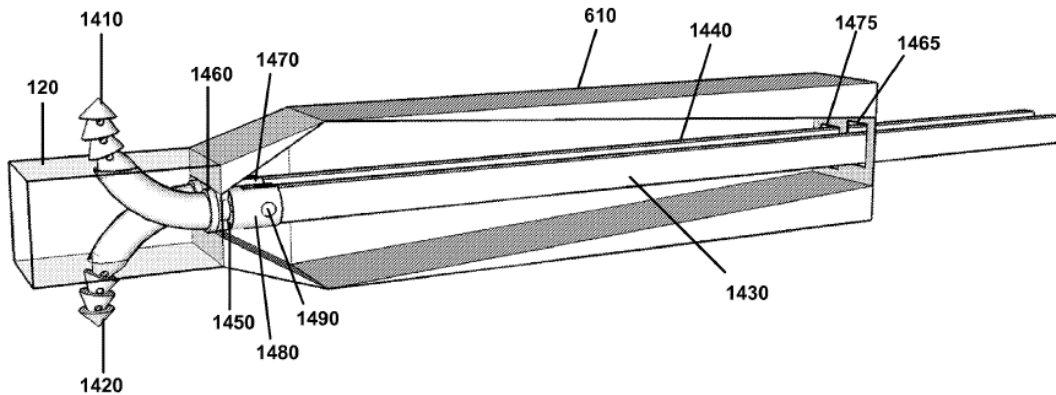


Figure 15

Id., 14:21-30.

68. The delivery mechanism may also include a retention mechanism, whose function is to couple the delivery mechanism to the fusion member for delivery, and decouple the delivery mechanism from the fusion member after delivery. *Id.*, 2:35-39, 2:60-3:39; 7:1-5; 7:22-28. In embodiments that have a retention mechanism, the delivery mechanism may include channels that guide the retention rods of the retention mechanism. *Id.*, 7:1-7. Figure 6 shows retention rods 160 extending through delivery mechanism 130 and to fusion member 120:

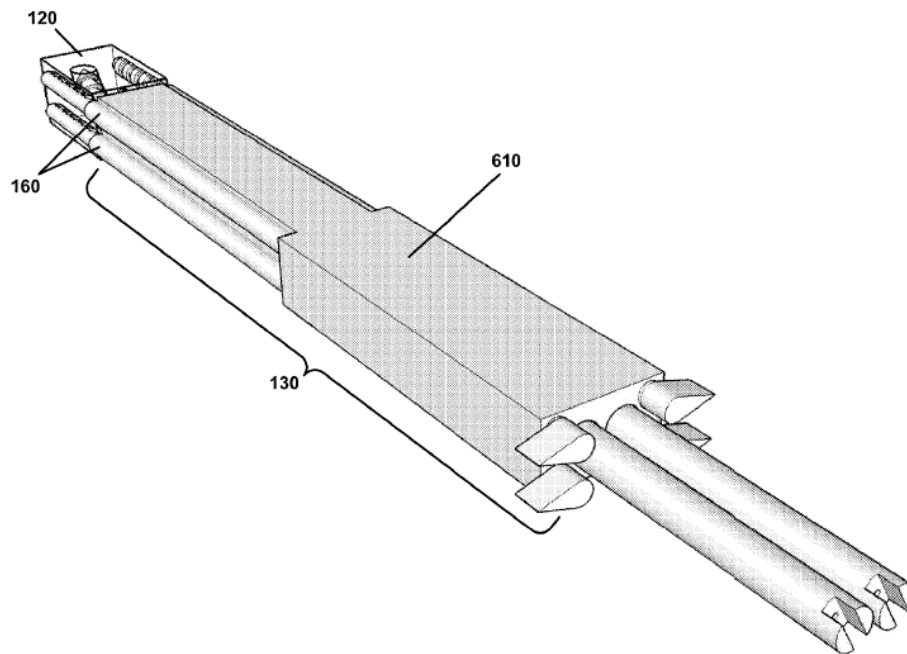


Figure 6

Id., 11:24-32.

69. As shown in Figure 11 below, the retention rods 160 may have retention teeth 910 that mate with retention grooves 510 of the fusion member when the surgeon rotates the rods using handles. *Id.*, 12:51-60. This mechanism is what allows

the retention mechanism to attach and detach from the fusion member, as discussed above. *Id.*

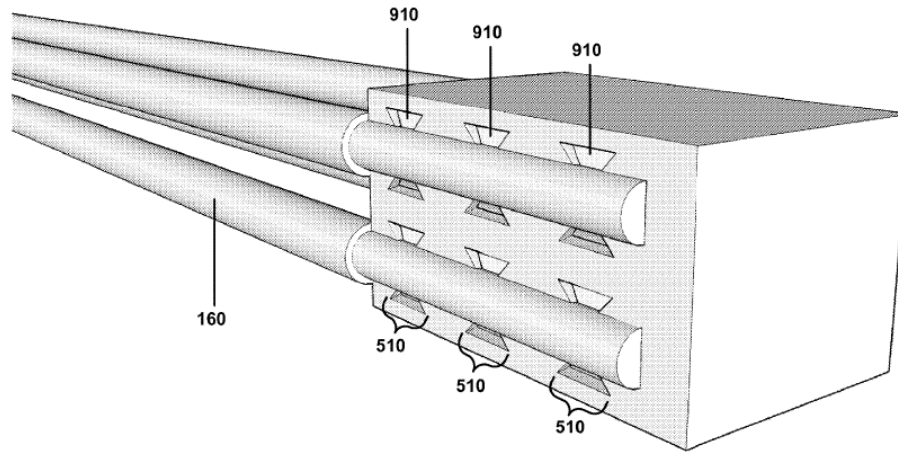


Figure 11

B. Prosecution History

70. In providing my opinions, I have reviewed and considered the prosecution history of the '805 Patent. I understand that during prosecution of the '805 Patent, the Examiner rejected then-pending claims 11-13, 15, 22-27, 29, 31, and 33-36 as anticipated by U.S. Patent No. 9,358,127 ("Duffield"). Ex. 1003, 110-111. Duffield teaches a "stand alone interbody fusion device for implementation in the spine," which is shown in Figure 9 below. Duffield's device is an interbody implant 32 for insertion between two vertebral bodies. Ex. 1017, 1:15-16. As shown below, the implant 32 includes, *inter alia*, plate portion 34 and spacer portion 33. *Id.*, 4:43-48.

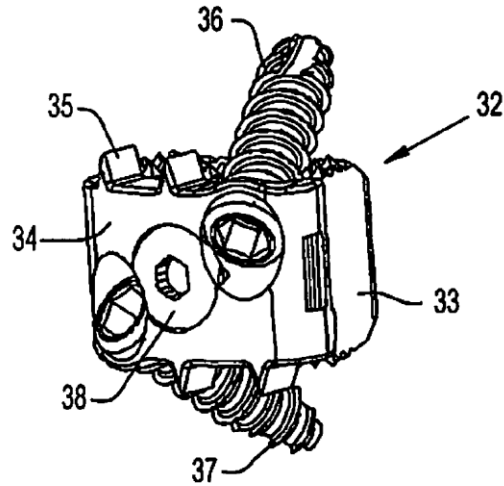
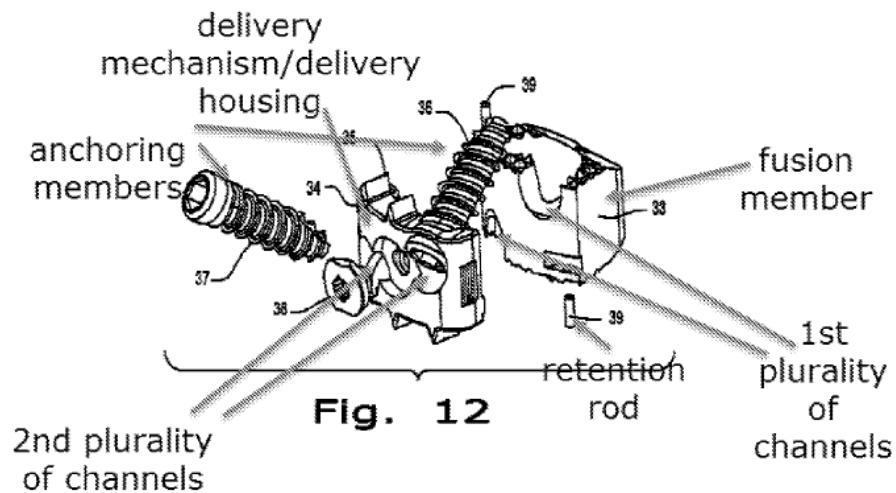


Fig. 9

71. In the rejection, the Examiner identified plate portion 34 of Duffield as the *delivery mechanism* and spacer portion 33 of Duffield as the *fusion member*:¹



Ex. 1003, 111.

¹ Claim language is italicized throughout my Declaration.

72. Thus, the Examiner determined that a portion of the implant 32 itself was the “delivery mechanism,” instead of an actual delivery tool that is required to insert the implant into the patient. Indeed, a POSA would understand that the implant of Duffield must necessarily be delivered and secured between the vertebral bodies using some form of delivery tool. In fact, Duffield teaches that its implant is “attached to an implant holder and drill guide” and then “inserted into the disc space.” Ex. 1017, 4:23-25.

73. According to notes in the file history, in an examiner-initiated interview, the Examiner suggested that the applicant could overcome the rejection based on Duffield if the rejected claims were amended to require that the delivery mechanism extends outside the patient’s body to a medical practitioner. Ex. 1003, 116.

74. After the interview, Applicant amended the claims to require that the *delivery mechanism* extends outside the patient’s body to a medical practitioner as proposed by the Examiner:

I. Applicant's Statement of the Substance of the Interview

Applicant's representative, Matthew Chavez (Reg. No. 68,318), had a telephonic interview with Examiner Hoffman on June 17th, 2016. During the interview, Examiner Hoffman discussed claim language that would overcome prior art such as Duffield, clarifying that the delivery mechanism is an insertion tool that is configured to extend outside of a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies. Applicant agreed to contact the Examiner after reviewing the Final Office Action to discuss a possible Examiner's amendment incorporating that language into the independent claims. Applicant's summary of the substance of the Examiner Interview is being submitted with this response, and is therefore timely. Applicant thanks Examiner Hoffman for the courtesy extended by doing the interview.

Id., 85-93. A Notice of Allowance issued after these amendments. *Id.*, 69-73.

75. It appears, based on the prosecution history, that the Examiner allowed the claims over Duffield because Duffield allegedly did not disclose the *extending outside a patient's body* limitation. This determination was based on the Examiner's identifying one portion of Duffield's implant as the *delivery mechanism*. However, as I later explain and show with the prior art, it was well-known and common for interbody implants to be delivered with delivery tools extended outside a patient's body.

76. I have reviewed the '805 Patent Specification and note that it does not disclose that its delivery mechanism extends outside a patient's body to a medical practitioner. *See generally* Ex. 1001.

VI. LEVEL OF ORDINARY SKILL IN THE ART

77. As discussed above, I understand that multiple factors are considered in determining 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 '805 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.

78. The subject matter of the '805 Patent is directed to an intervertebral fusion device and methods of using the same. Based on the materials I have considered, my own knowledge and experience, and the level of skill required to design and build an intervertebral spinal fusion implant device, it is my opinion 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.

79. My experience and qualifications exceed that of a POSA. Specifically, I have formal education of a Bachelor's of Applied Science in Metals and Materials Engineering degree and substantial professional experience with spinal implant devices, including roughly a decade of experience designing, developing and inventing spinal fusion devices, including expandable interbody fusion devices. Ex. 1039. 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 considerable design and development experience with fusion technologies qualify me as a POSA.

80. 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 '805 Patent, which I understand to be March 27, 2008. However,

I note that my opinions herein would not change even assuming that the level of ordinary skill was determined as of the filing date of the '805 Patent, which is October 18, 2012.

VII. OPINIONS ON CLAIM CONSTRUCTION

A. *housing* (claims 2-4)

81. A POSA would understand a *housing* to be a component that protects, covers, supports, or contains another component. This is consistent with the usage of the term throughout the Specification, as well as its meaning as used in common parlance. For example, numerous dictionaries define *housing* consistent with this understanding. *See, e.g.*, Ex. 1009, 5 (defining “housing” as “[s]omething that **covers, protects, or supports**”); Ex. 1007, 5 (defining “housing” as “a frame, box, etc. **for containing** some part, mechanism etc.”); Ex. 1008, 5 (defining “housing” as “rigid **casing**, esp. for machinery, etc.”).

82. Turning to the Specification, it uses the term *housing* consistent with its commonly understood meaning. For example, Figures 1A and 6 (provided below) of the '805 Patent depict a delivery housing 610. These figures show that the delivery housing has tubular passages and that anchoring members 140 are inserted and driven through these tubular passages and into the fusion member 120:

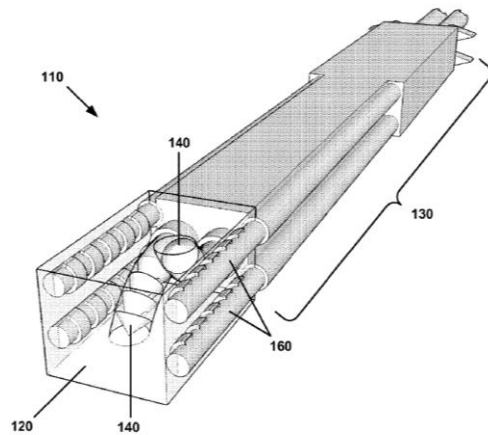


Figure 1A

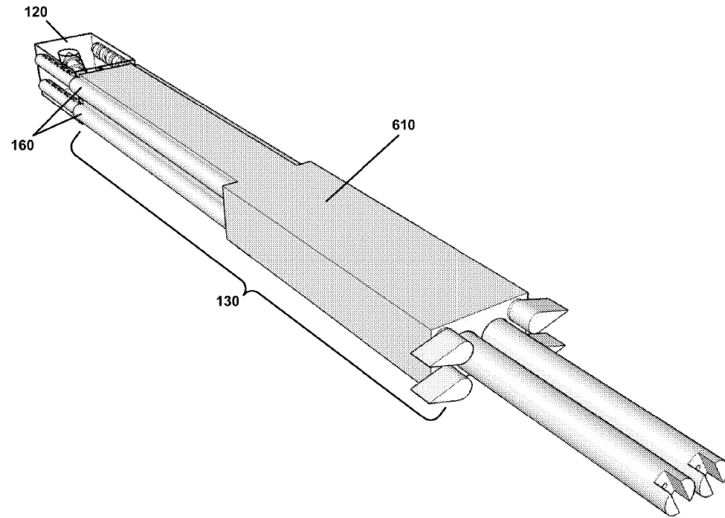


Figure 6

Ex. 1001, 11:24-45.

83. Because the anchoring members are supported, contained, and protected within the delivery housing as they are guided to the implant, a POSA would understand that the delivery housing 610 “houses” the anchoring members 140.² *Id.*, 13:25-27 (teaching that “the delivery housing channels **house** and guide the anchoring mechanism to the proper location in the fusion member.”); Ex. 1001, 2:37 (“a delivery housing that **houses** the anchoring members ...”). Similarly, a POSA would understand that that the delivery housing 610 also “houses” the

² “Anchoring members” are also called “anchoring mechanisms” throughout the Specification. See Ex. 1001, 19:64-66; *id.*, 9:29-37.

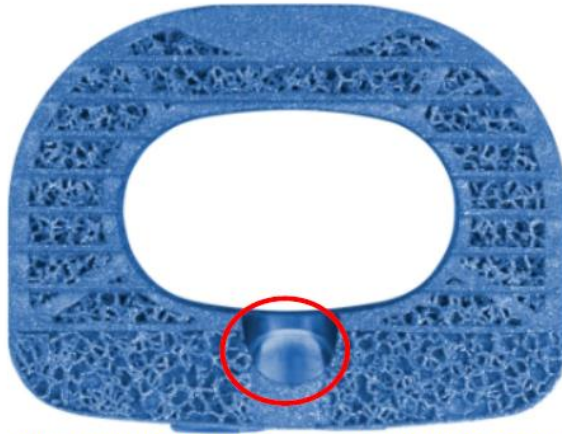
retention rods 160 because the retention rods are supported, contained, and protected within the delivery housing. *Id.*, 7:1-7, 11:27-28.

84. A POSA would thus understand *housing* to have its plain and ordinary meaning—a component (e.g., housing 610) that protects, covers, supports, or contains another component (e.g., an anchoring member 140, retention rods 160).

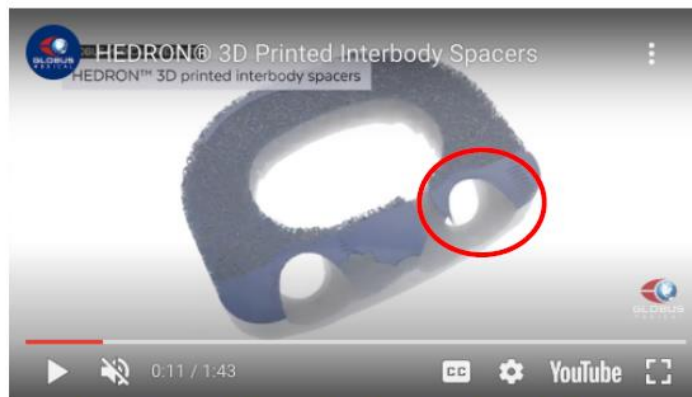
B. each channel of the fusion member is curved (dependent claims 5, 16)

85. I understand that Spinelogik has filed a lawsuit against Globus in federal court for alleged infringement of the '805 Patent. I further understand that Spinelogik has alleged that the anchor openings of Globus's accused interbody implants have *curved* channels. I have reviewed Spinelogik's infringement contentions from that lawsuit, provided below, which refer to a marketing video for one of Globus's accused interbody implants:

5. The apparatus of claim 1, wherein each channel of the fusion member is curved.

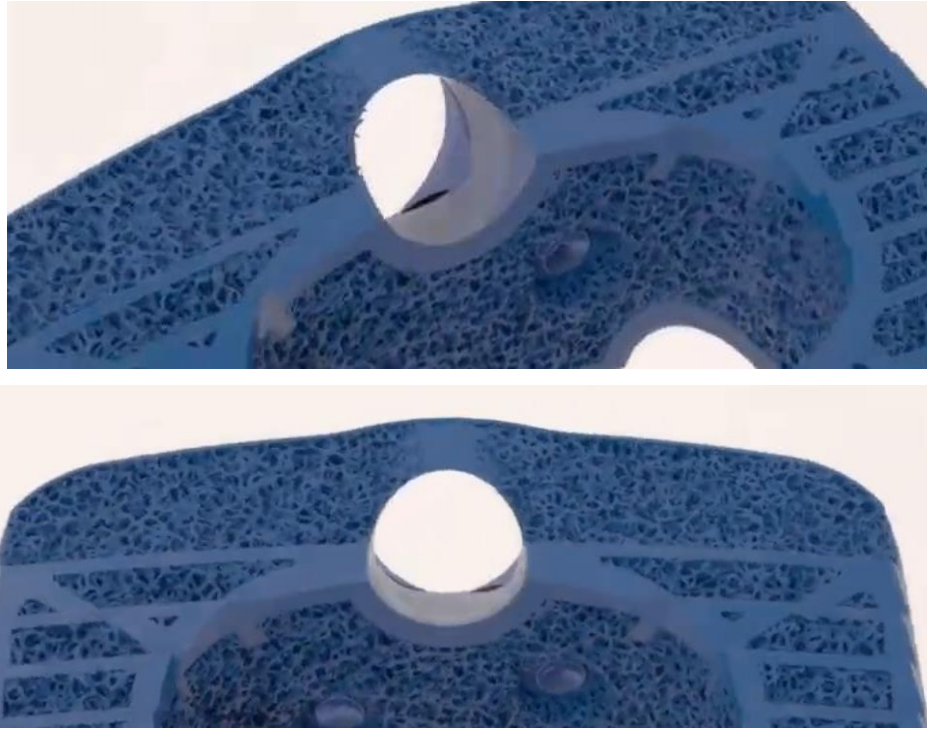


<https://www.globusmedical.com/products/hedron-ia/>



<https://www.globusmedical.com/products/hedron-ia/>

Ex. 1013, 11. A screenshot (below) from about the 23 second mark of the video shows that the accused interbody implants have anchor channels that follow a straight path, not a curved path. Ex. 1031.



86. As seen above, the anchor channels have circular openings on both ends, tubular inner walls, and anchor seats for the anchor heads. Given that Spinelogik accuses these anchor channels of being *curved*, I understand Spinelogik to be applying the term *channel ... is curved* as encompassing any channel having a curvature, regardless of whether the channel follows a curved path, like channels 4610, 4620 from Figures 46 and 47 of the '805 Patent. Ex. 1001, 23:26-31.

87. Based on Spinelogik's application of the term, it appears that a *channel* qualifies as *curved* when it has an: (1) opening with a curvature (e.g., round opening); (2) an inner wall with a curvature (e.g., tubular inner-wall); (3) a radially

inward curvature in the inner wall (e.g., a concave surface that forms a spherical anchor head seat); and/or (4) follows a curved path (e.g., an arc-shaped path).

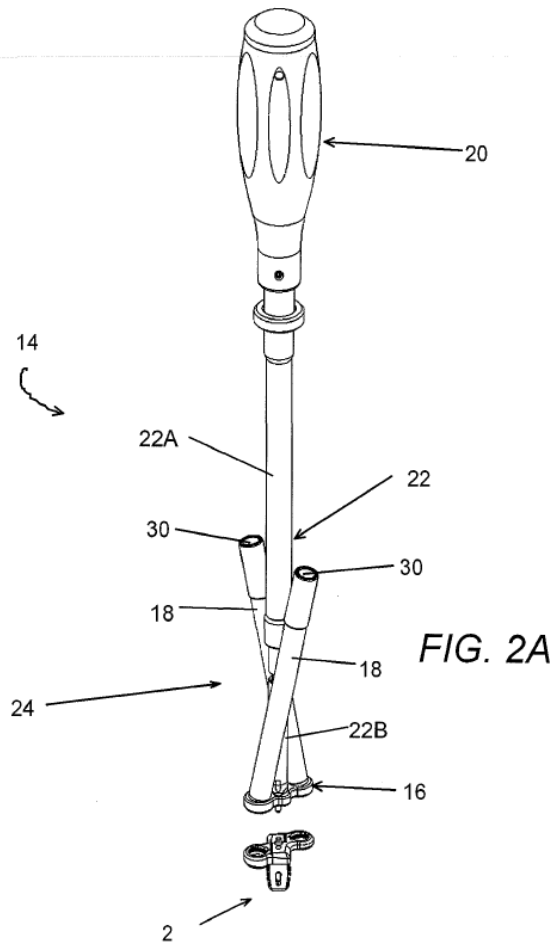
88. For purposes of my Declaration, I have been asked to apply Spinelogik's interpretation of *channel ... is curved* when applying the prior art to the claims. I offer no opinion on the correctness of Spinelogik's construction and have not been asked to offer any opinions on the correctness of that construction.

VIII. OVERVIEW OF PRIOR ART REFERENCES

A. Blain

89. I have been asked to provide my opinion on whether the Blain-Provisional provides adequate written description support for at least one claim of Blain. I first note that the Blain-Provisional is substantively identical to Blain, as evidenced by redline comparisons of the abstract (Ex. 1010), specification (Ex. 1011), and claims (Ex. 1012) of Blain and the Blain-Provisional. The figures are also identical. *Compare* Ex. 1004, Figs. 1-6 *with* Ex. 1005, 25-34. As one might expect then, the Blain-Provisional provides clear support for the claims of Blain. I have provided a table below showing where the Blain-Provisional provides written description support for claims 1 and 22 of Blain:

Blain Claims (Ex. 1004)	Blain-Provisional (Ex. 1005)
1. An instrument guide, comprising:	Instrument guide 14 (Figs. 2A to 2C). <i>See e.g.</i> , ¶¶[0004], [0020].



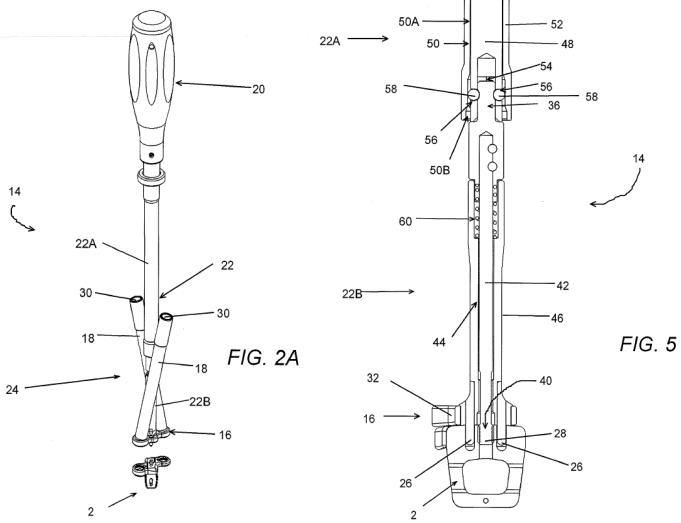
a releasable lock assembly comprising a movable outer tubular member having a lumen, the outer tubular member being movable in the longitudinal direction between a distal configuration and a proximal configuration;

Releasable lock assembly comprising a movable outer tubular member (movable outer shaft 52) having a lumen (proximal tubular lumen 50). *See ¶¶[0006], [0029].*



a shaft having a proximal end and a distal end, wherein the shaft is partially in the lumen of the releasable lock assembly;

A shaft (inner proximal shaft 48) having a proximal end (end closer to handle 20) and a distal end (the end opposite of proximal end), wherein the shaft is partially in the lumen (proximal tubular lumen 50) of the releasable lock assembly. *See* ¶¶[0020], [0038]; *see also* ¶¶[0005]-[0006]. Moreover, when the outer shaft 52 is in the proximal (or retracted)

	configuration (not shown in Fig. 5), the inner proximal shaft 48 protrudes even further outside of the outer shaft 52.
a handle at the proximal end of the shaft;	Handle 20 is at the proximal end of the shaft (inner proximal shaft 48, within shaft 22A). See ¶¶[0004], [0006], [00020], [0029].  FIG. 2A FIG. 5
a device coupler comprising a coupling base with a through lumen and an elongate coupling member comprising a proximal end and a distal end, wherein the distal end is configured with a least one mechanical interfit structure, wherein at least a portion of the elongate coupling member is configured so as to move in the through lumen of the coupling base; and	The Blain-Provisional discloses a “a device coupler comprising a coupling base with a through lumen and an elongate coupling member comprising a proximal end and a distal end, wherein the distal end is configured with a least one mechanical interfit structure, wherein at least a portion of the elongate coupling member is configured so as to move in the through lumen of the coupling base.” ¶[0006]. Figure 5 also depicts a device coupler 16 having a coupling base 32 with a through lumen, through which elongate coupling member (distal inner shaft 42 and engagement

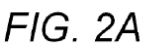
	member 36) passes. ¶¶[0029]-[0030]. The coupling member has a proximal end (the end closer to the handle 20) and a distal end 40, and the distal end 40 is configured with at least one mechanical interfit structure (movable coupling member 28). <i>Id.</i> At least a portion of the elongate coupling member (the portion containing movable coupling member 28) is configured so as to move through the lumen of the coupling base 32. <i>Id.</i>
at least one drill guide member joined to the device coupler;	The Blain-Provisional discloses “at least one drill guide member joined to the means for detachably coupling an implantable device” (¶[0005]) and “at least one drill guide member joined to the device coupler” (¶[0006]). Figures 2A-2C also depict drill guide (guide members/tubes 18) joined to the device coupler 16. See ¶¶[0020], [0035] (“The guide members 18 may comprise any shape suitable for accurately guiding a drilling device or other instrument, or fastener.”).
wherein the releasable lock assembly is configured to releasably lock the proximal end of the elongate coupling member of the device coupler to the distal end of the shaft when the outer tubular member is in a distal configuration.	When the releasable lock assembly is in the “distal configuration” (as shown in Fig. 5) it forces ball bearings 58 into recesses of engagement member 36, thereby releasably locking the proximal end of the elongate coupling member (engagement member 36 and distal inner shaft 42) of the device coupler 16 to the distal end of the shaft (inner proximal shaft 48). See ¶¶[0029]-[0030]; See also ¶¶[0005]-[0006].
22. A method for treating a patient, comprising:	“[A] method for treating a patient is provided.” ¶[0007].

attaching an instrument guide with respect to an implantable device, wherein the instrument guide comprises a detachable handle and at least one instrument guide lumen;	“[A]ttaching an instrument guide with respect to an implantable device, wherein the instrument guide comprises a detachable handle and at least one instrument guide lumen.” ¶[0007]; <i>See also</i> ¶¶[0020]-[0022] (describing instrument guide 14 having detachable handle 20 and at least one instrument guide lumen 18)
inserting the implantable device to an implantation site;	“inserting the implantable device to an implantation site” ¶[0007]; <i>see also</i> ¶¶[0045] (explaining that instrument guide 14 may be attached to implant 2 prior to insertion, so that the instrument guide 14 can be used as the implant delivery tool).
separating the handle from the instrument guide;	“separating the handle from the instrument guide” ¶[0007]; <i>See also</i> ¶[0038] (explaining that the handle 20 is detached after insertion so that it does not interfere with insertion of the fasteners through guide tubes 18).
passing a component through the at least one instrument guide lumen to the implantable device to the implantation site;	“passing a component through the at least one instrument guide lumen to the implantable device to the implantation site.” ¶[0007]; <i>See also</i> ¶[0038] (explaining that, after the implant is in the desired location and the handle has been removed to avoid interference, the fasteners are inserted through guide tubes to the implantation site)
reattaching a handle to the instrument guide; and	“reattaching a handle to the instrument guide.” ¶[0007]. <i>See also</i> ¶[0038] (explaining that the handle 20 is reattached to the instrument guide 14 once the fasteners have been secured).
releasing the instrument guide with respect to the implantable device.	“releasing the instrument guide with respect to the implantable device.” ¶[0007]; <i>See also</i> ¶[0038] (explaining that the instrument guide 14 is detached from the implant once the handle 20 has been reattached)

91. Fig. 1 of Blain illustrates an implant 2 having fastener apertures 4 through which fasteners 6 are inserted to secure the implant 2. *Id.*, 4:26-39.



92. The instrument guide 14 comprises device coupler 16, handle 20 attached to corresponding shaft 22, and guide members/tubes 18, as shown in Figure 2A. *Id.*, 4:55-61.



proximal shaft 22A and distal shaft 22B. *Id.*, 4:59-61. As used here, “proximal”

means the side of the device or instrument that is closer to the physician performing the surgery, and “distal” means the side of the device or instrument furthest from the physician. The distal end of the shaft is coupled to device coupler 16. *Id.*, 4:59-61. The guide members/tubes 18 have proximal openings 30 of a tubular channel leading to distal openings (not shown), which are coupled to corresponding openings (also not shown) in device coupler 16. *Id.*, 8:5-8. Instrument guide is coupled to implant 2 via device coupler 16, and this aligns channels of guide tubes 18 with fastener apertures 4 so that fasteners 6 can be driven through the guide tube channels, device coupler openings, implant apertures 4 and then into the bone of the vertebral bodies. *Id.*, 1:55-57, 5:18-33, 6:1-8.

94. Figures 3A and 6A show the instrument guide 14 attached to implant 2 via device coupler 16. *Id.*, 8:46-54. Once the implant has been delivered between the vertebral bodies, the proximal shaft can be removed so that screw driver 66 can be inserted through guide tubes 18 (as shown in Figure 6A) to drive each anchor into a vertebral body. *Id.*

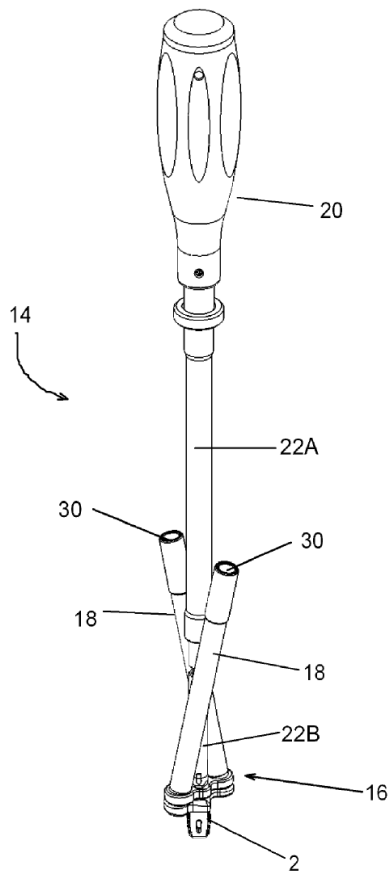


FIG. 3A

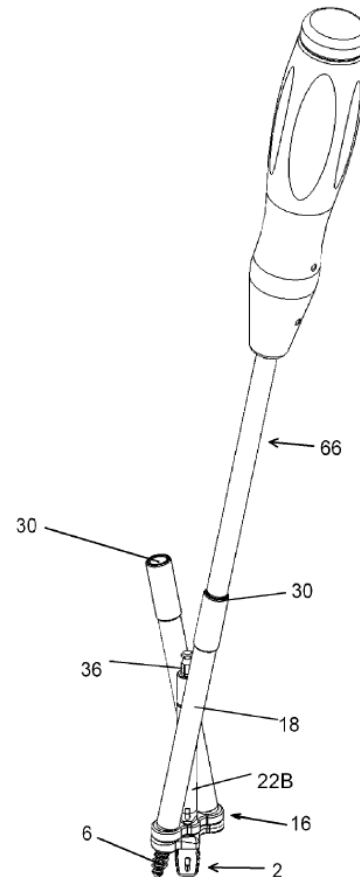
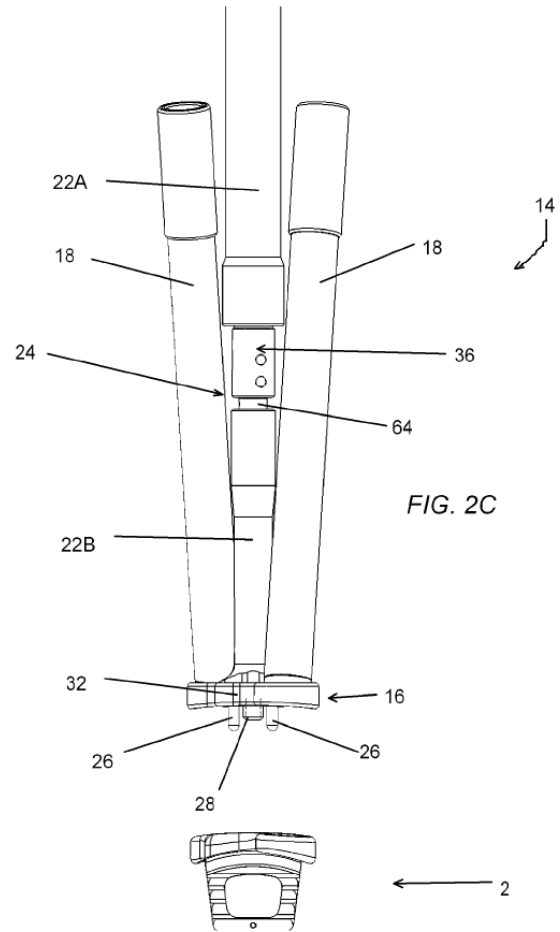
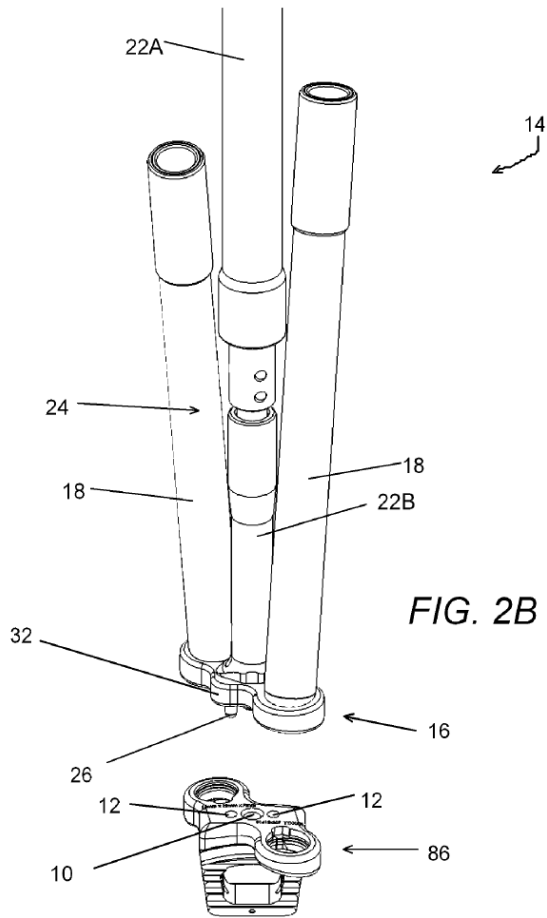


FIG. 6A

95. In reference to Figures 2B and 2C (provided below), the device coupler 16 has two fixed coupling members 26 and one movable coupling member 28, as shown in Figures 2B-2C. *Id.*, 5:19-22. The movable coupling member can detachably engage the coupling opening 10 of the implant 2 via its locking configuration (e.g., via threading or an interlocking fit). *Id.*, 5:44-50. The fixed coupling structures 26 are also inserted into coupling sites 12 on implant 2 to limit rotational movement between implant 2 and instrument guide 14. *Id.*, 6:1-8.



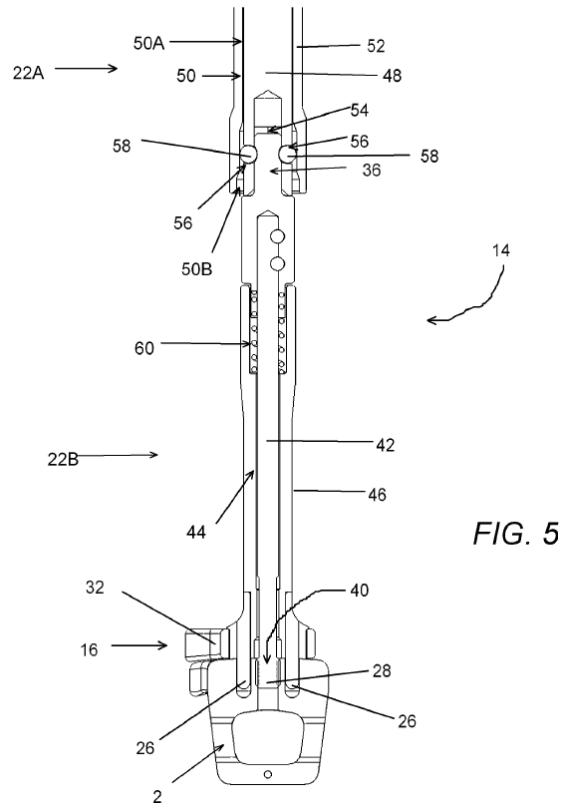


FIG. 5

96. As shown in Figure 2C and 5 (provided above), the movable coupling member 28 is at the distal end of the inner shaft 42, which is itself within a distal tubular lumen 44 of distal outer shaft 46 of distal shaft 22B. *Id.*, 6:47-52. The handle 20 can be manipulated to cause axial translation of the distal engagement member 36, which results in movable coupling member 28 moving axially. *Id.*, 7:11-17. Blain teaches that the movable coupling member 28 may comprise a locking structure comprising “any of a variety of complementary mechanical interfits with the coupled implant, such as a threaded lock, snap-on fitting, or an interlocking fit.” *Id.*, 5:44-57. This locking structure allows instrument guide 14 to be used as a

delivery instrument to deliver and insert the implant 2 between the vertebral bodies, because the instrument guide can be coupled to implant 2 prior to implantation and detached after delivery. *Id.*, 10:4-11.

B. Bray

97. Bray teaches an interbody implant for implanting between two adjacent vertebrae for fixation and support of the vertebrae. Ex. 1006, Abstract. The interbody implant 10 includes base member 20 comprising a primary member 100 with two bone screw holes 140 and a secondary member 110 with bone screw hole 180, as shown in Figures 1, 4 and 5 below. *Id.*, 4:37-40, 7:15-18, 7:40-42.

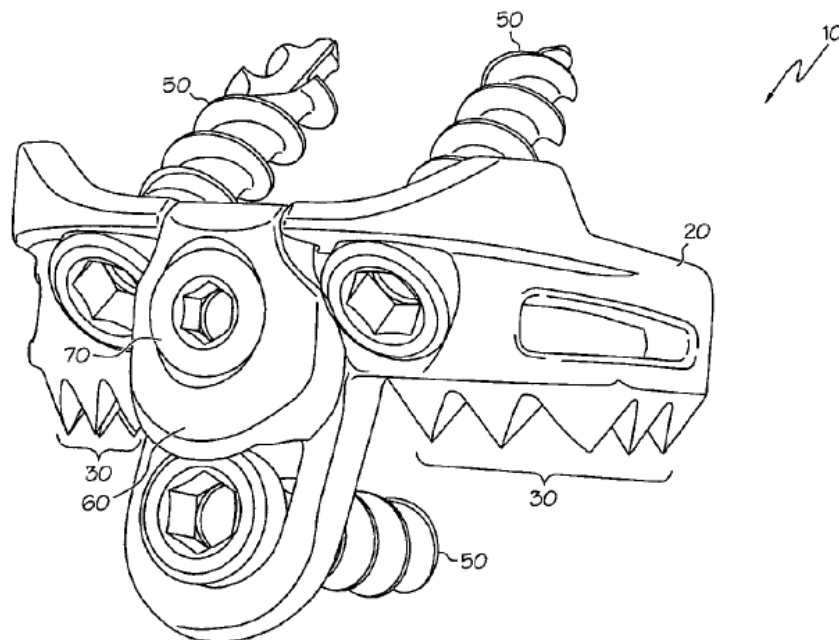


FIG. 1

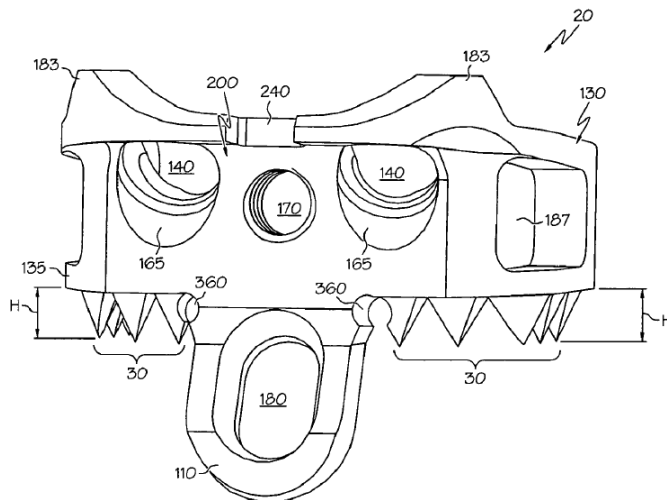


FIG. 4

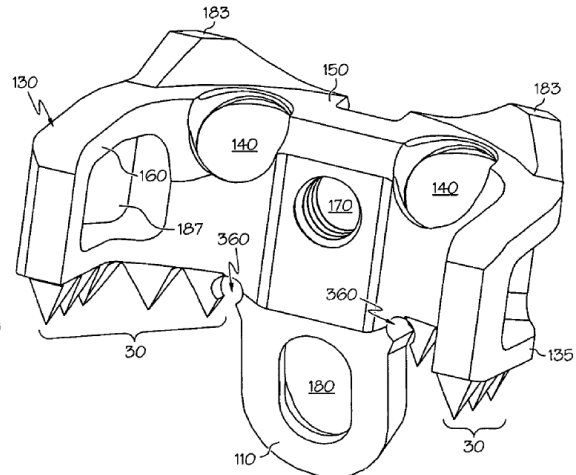


FIG. 5

98. Each screw hole 140 has seat 165 on which the retaining portion of a bone screw rests. Each seat has a concave, spherical shape, and the portion of the screw in contact with each seat has a complementary convex spherical shape. *Id.*, 7:30-36.

99. Bray's implant also includes a restraining feature "for securely covering at least a part of each of the bone fasteners 50 so that the bone fasteners 50 cannot back out from the bone bodies once screwed in through the base member 20 of the device 10." *Id.*, 4:49-57. The restraining feature is depicted in Figure 1 and comprises restraining plate 60 and restraining plate fixing means 70. *Id.* Figures 9 and 10 are front and back perspectives, respectively, of the restraining plate. *Id.*, 3:46-51.

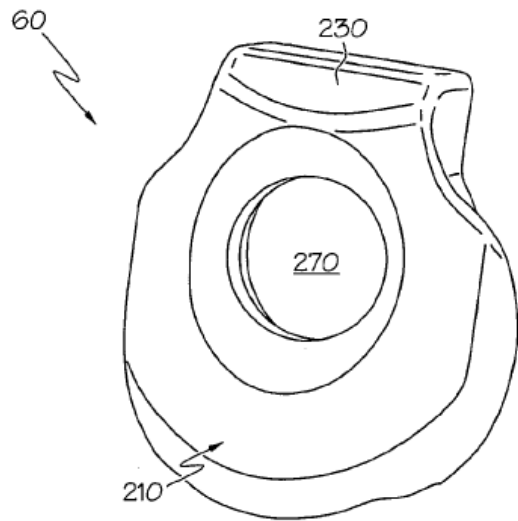


FIG. 9

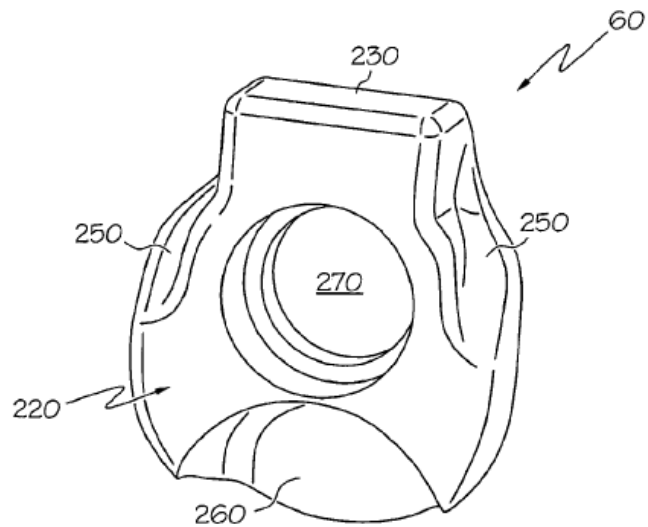


FIG. 10

100. Bray also teaches a guide tool 310 for delivering base member 20 between the vertebral bodies, as seen in Figure 13 below:

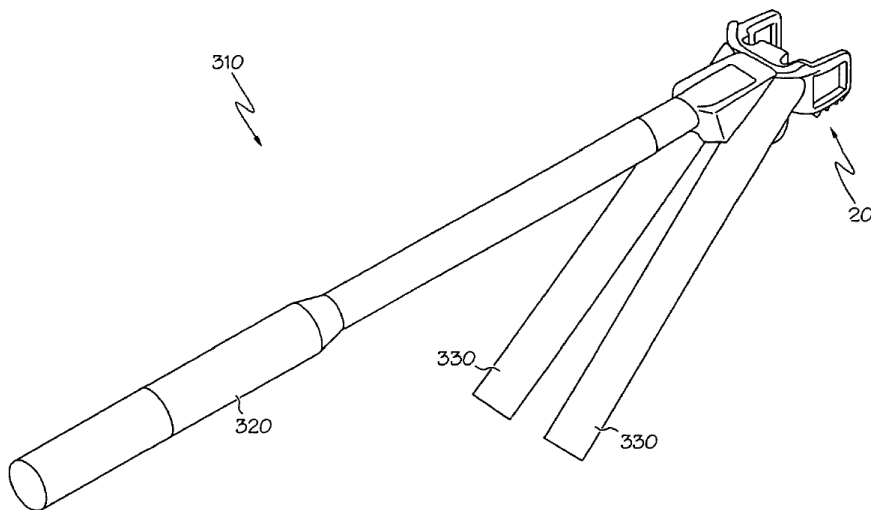


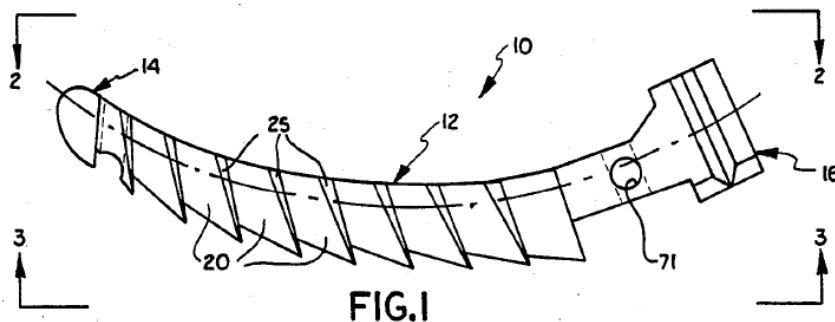
FIG. 13

Id., 9:61-10:14. The guide tool 310 has handle 320 and a pair of guide tubes 330, which the surgeon can drill through and then insert the bone screws 50 through to

anchor the bone screws into the bone. *Id.* The bone screws are not depicted in Figure 13, but are shown in Figure 1.

C. Steffee

101. Steffee teaches an interbody fusion using bone graft. Ex. 1016, Abstract. In Figure 1, Steffee discloses a rigid bone fastener, such as titanium or steel, comprising “[a]n elongated curved fastener 10” which “includes a shank portion 12” having “a pointed end 14 and at its opposite end has a driving head portion 16.” *Id.*, 2:33-43. As depicted below, barbs 20 project from the shank portion 12. *Id.*



102. Regarding Figure 5, Steffee explains, “[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.*, 2:45-48. A POSA would understand that Steffee’s bone portion 22 is a reference to one vertebral body, bone portion 26 is a reference to an adjacent vertebral body, and that bone graft 24 resides between these two vertebral bodies.

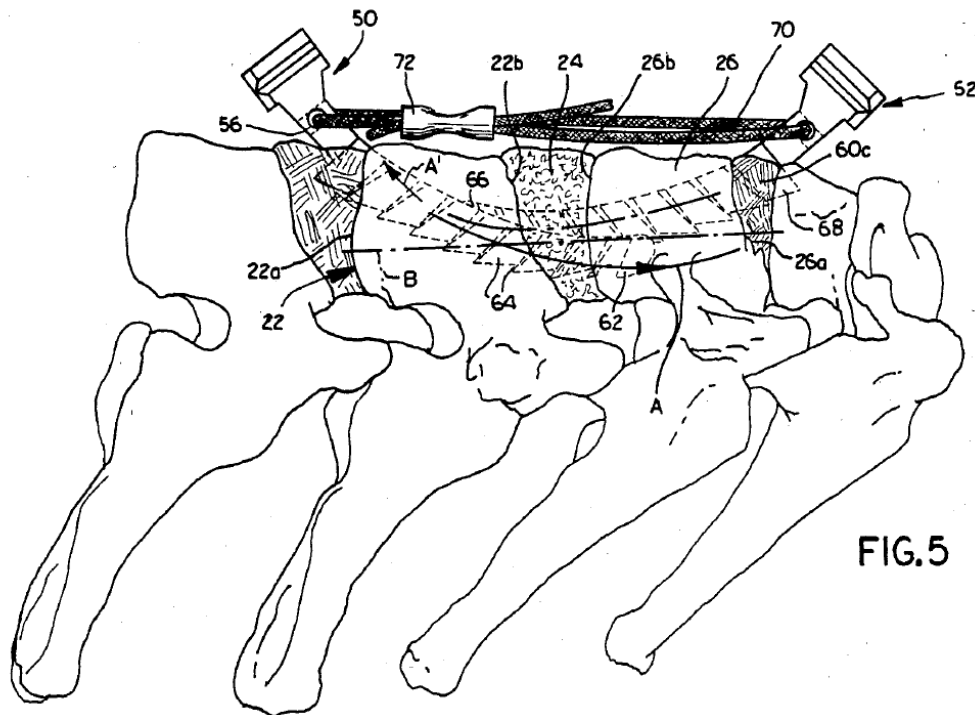


FIG. 5

103. Steffee teaches that it was known that “bone graft contracts as it resorbs.” Ex. 1016, 1:11-14. Resorption is the process by which bone graft material breaks down and is absorbed by the body. While this happens, new naturally forming bone is created by the body. The contraction of bone graft as it resorbs “resulted in difficulties in securing bone graft between spaced apart bone portions which are to be connected by the bone graft.” Ex. 1016, 1:11-14. Steffee also teaches that staples were used to secure bone graft between the vertebral bodies, but as bone graft resorbs, it applies a force that “acts through a moment arm and causes the leg to pivot relative to a portion of the staple base,” causing the staple “to loose (sic) its effectiveness.” *Id.*, 1:14-20. Steffee’s curved fastener avoids this issue. It “extends

104. Steffee discloses an alternative embodiment in Figure 6 (shown below):



105. The fasteners 90, 92 are driven into the side of corresponding vertebral bodies 100, 102, respectively, and curve into the bone graft between those bodies and into the opposing body. Ex. 1016, 4:23-34. Thus, Steffee teaches interbody fusion using bone graft held between the vertebral bodies by rigid curved fasteners. Steffee does not expressly disclose the use of interbody cage implants to provide structural support, like those disclosed in Blain and Bray. However, it was common to pack bone graft in and around such interbody cage implants to facilitate bone fusion of vertebral bodies, which would exhibit the same behavior as the bone fusion that occurs in Steffee. Ex. 1006, 4:31-37; Ex. 1004, 1:32-34.

IX. OPINIONS ON PATENTABILITY

A. Ground 1: Whether Claims 1-6, 11, 12 and 15-17 are Anticipated and/or Obvious Based on Blain.

106. I have been asked to provide my opinions on whether claims 1-6, 11, 12, and 15-17 of the '805 Patent are anticipated by Blain, or, when considered with the general knowledge of a POSA, rendered obvious by it. As explained in detail below, it is my opinion that they are.

Claim 1

1.0 [Preamble] “An apparatus comprising:”

107. Blain discloses the preamble, as will be explained below.

1.1 “a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;”

108. Blain discloses an “interbody fusion implant 2,” which is *a fusion member for positioning between two vertebral bodies*. This is depicted in Figure 1, which is annotated below:

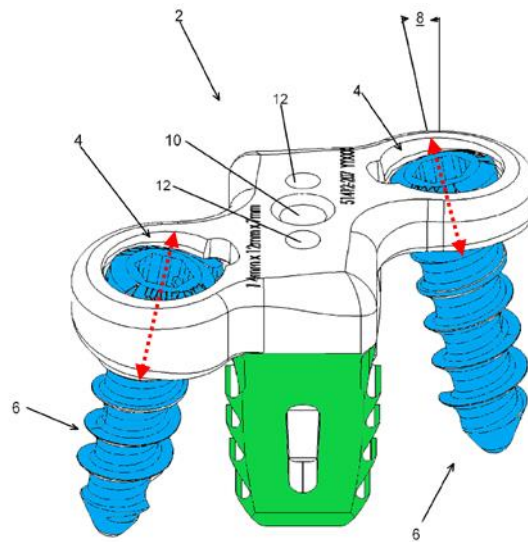


FIG. 1

Ex. 1004, 4:26-28.

109. A POSA would understand that the term “interbody fusion” in “interbody fusion implant” refers to how the implant is designed for insertion between two adjacent vertebral bodies to facilitate fusion. Specifically, “interbody” refers to the fact that the implant is inserted between two adjacent vertebral bodies,

providing structural support and stability. *See, e.g.*, Ex. 1001, 2:19-23 (referring to implant as “**interbody fusion** member” because it is used to fuse two adjacent vertebral bodies); Ex. 1014, 4:12-13 (“Spinal fusion involves removal of the spinal disc and fusing or joining the **two adjacent vertebrae**.”), 4:52-55 (“[i]n **all** interbody surgical approaches” disc (“nuclear material”) is removed and the end plates of the vertebral bodies are decorticated to facility bony fusion); Ex. 1015, 1:32-43; Ex. 1017, 1:13-17)). Blain also refers to this by teaching that spinal fusion “surgery involves removal of the affected disc and fusion of the **adjacent vertebrae**,” which a POSA would understand to refer to fusion between two vertebral bodies (i.e., “interbody” fusion). Ex. 1004, 1:30-34. Thus, a POSA would understand that Blain’s interbody fusion implant is *for positioning between two vertebral bodies*, at least because “interbody” refers to the two adjacent vertebral bodies between which the fusion implant 2 is placed.

110. Referring to Figure 1 above, a POSA would understand that the “cage” portion (green) is the portion inserted in the disc space between two adjacent vertebral bodies. During a fusion procedure, one fastener 6 (blue) would be inserted through implant opening 4 and fastened to one vertebral body. The other fastener 6 (blue) would be inserted into the other opening 4 and fastened to the other vertebral

body. Then fusion would then occur around and through the cage openings, while the implant provides structural support and stability during the recovery process.

111. The interbody implant 2 of Blain further comprises *a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member*. A POSA would understand that a *channel* refers to a passage through which something moves or is conveyed. Ex. 1007, 4; Ex. 1008, 4; Ex. 1009, 4. Notably, the Specification places no limits, such as length or diameter, on the ordinary meaning of channel, and states that different embodiments can have “channels of different shapes and sizes.” Ex. 1001, 13:32-33. Based on this, understanding, as shown in annotated Figure 1 above, there are two channels identified generally by a red-dashed arrow (*a first plurality of channels*). Each channel has an opening 4 on the proximal (top) side (same side) of the implant and an opening on the distal (bottom) side (not visible in Figure 1). Ex, 1004, 4:28-39; *see also* Fig. 2B (showing channels having an opening without fasteners 6 inserted). Each fastener 6 (blue) is inserted through a channel from the proximal side. *Id.*, 8:5-8, 8:17-18.

1.2.1 “a delivery mechanism for delivering the fusion member between the two vertebral bodies,

112. I understand that in the litigation, Spinelogik proposed plain and ordinary meaning for *delivery mechanism*, and Petitioner proposed “insertion tool separate from the driving member.” Ex. 1021; Ex. 1022, 2. Blain discloses this claim limitation under either construction.

113. As shown in Figure 3A (below), instrument guide 14 is a *delivery mechanism for delivering the fusion member between the two vertebral bodies*:

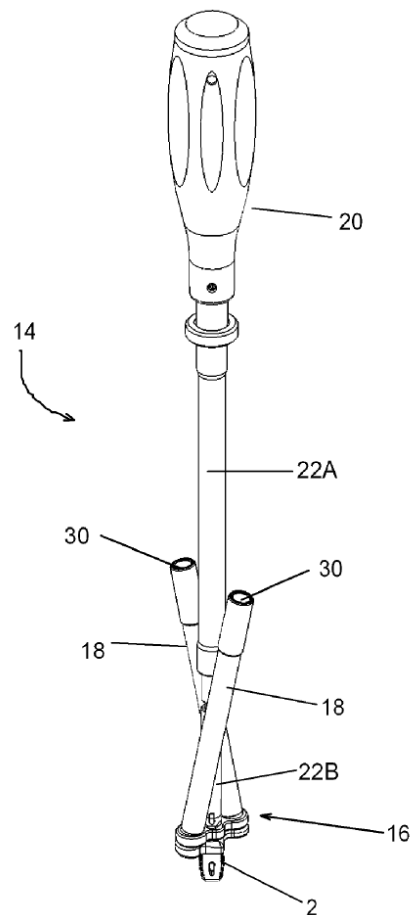


FIG. 3A

114. Blain teaches: “instrument guide 14 comprises one or more guide members 18 and a device coupler 16 with one or more coupling structures 26, 28

engageable to the implant 2.” Ex. 1004, 4:55-58. In one embodiment of Blain, “the instrument guide 14 is attached to the orthopedic device 2 prior to implantation, and the instrument guide 14 is also used *as a delivery instrument* used to insert and fix the orthopedic device 2 to the spine. In this embodiment, only a single attachment and a single detachment step is used to implant the orthopedic device 2, which simplifies the implantation procedure and may reduce the risk of error or injury.” *Id.*, 10:6-13. A POSA would understand that a medical practitioner would use the handle 20 of instrument guide 14 to deliver the attached implant 2 between the vertebral bodies. Screw driver 66, which is the *driving member* as recited in challenged claim 15, is clearly separate from the instrument guide 14 as the screw driver is a separate tool that is later used to drive the bone screws into the vertebral bodies after the implant has been delivered between them by the instrument guide.. Ex. 1004, 8:50-54, Figs. 6A-B (showing screw driver 66 as a separate tool inserted into guide tubes 18). Thus, Blain’s instrument guide 14 is a *delivery mechanism for delivering the fusion member between the vertebral bodies*.

115. Although not required to be shown, I further note that Blain’s *delivery mechanism* has very similar structure for delivering the implant 2 as the delivery mechanism disclosed in the ’805 Patent. Specifically, the ’805 Patent discloses one or more housed rotatable retention rods 160, each having a handle 820 and retention

teeth 910, “male/female structures,” a “clamp,” or “expandable clasps” for attaching and detaching the implant. See *e.g.*, Ex. 1001, 11:60-12:2, 12:7-16, 13:8-24. Similarly, as shown in Figure 5 below, Blain discloses distal inner shaft 42 (housed in distal outer shaft 46 and coupling base 32), distal engagement member 36 (housed in distal outer shaft 46 and movable outer shaft 52), and proximal inner shaft 48 (housed partially in movable outer shaft 52 and distal outer shaft 46), each of which is highlighted yellow. Ex. 1004, 6:47-67.

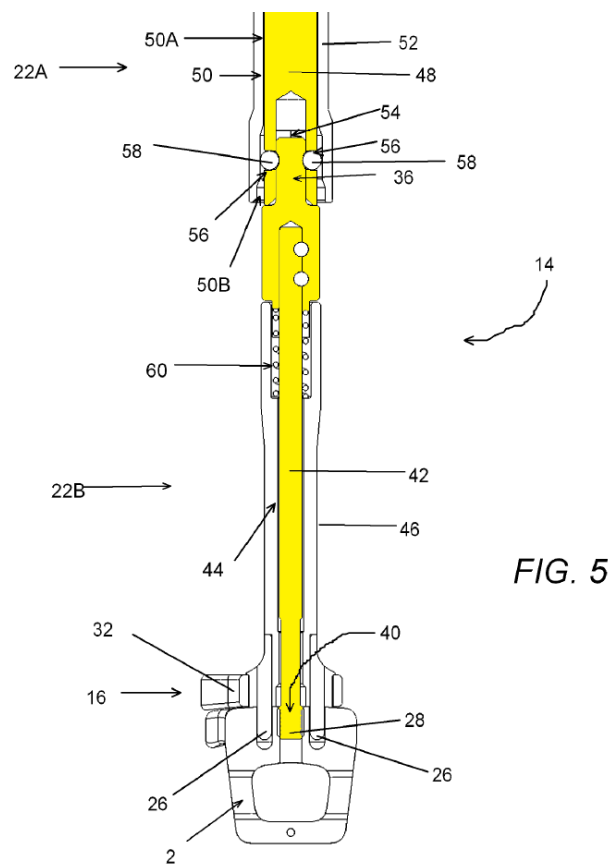


FIG. 5

The combination of these components in Blain mirrors each housed rotatable retention rod 160 disclosed in Figure 10A of the '805 Patent. Ex. 1001, 12:7-11.

FIG. 3A

FIG. 3A

117. Blain's *delivery mechanism* also comprises retention teeth, male/female structures, or a clamp for attaching and detaching to the implant. Blain teaches that the movable coupling member 28 preferably comprises a "locking configuration or structure to detachably engage the implant" and may comprise "any of a variety of

complementary mechanical interfits with the coupled implant, such as threaded lock, snap-on fitting, or an interlocking fit.” Ex. 1004, 5:44-54, 6:28-38. Blain further explains that coupling member 28 may comprise “a hook that engages a recess or pin on the implantable device, or a pivot or clamp member that retain the components by grasping onto the sides of the components.” *Id.*, 6:25-28. Thus, the “interlocking fit” of Blain’s coupling member’s 28 correlates to the retention teeth or male/female structures of the ’805 Patent (such as 910 in Fig. 10B). Similarly, the coupling member’s 28 pivot or clamp member correlates to the clamp of the ’805 Patent.

1.2.2. “the delivery mechanism extending outside a patient’s body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,”

118. Blain does not explicitly state that instrument guide 14 *extend[s] outside a patient’s body to a medical practitioner* as claimed. However, I note again that the Specification of the ’805 Patent does not discuss this claim limitation either. *See generally* Ex. 1001. Regardless, a POSA would understand this limitation to be disclosed by Blain for several reasons.

119. First, the instrument guide 14 of Blain has a handheld handle 20. A POSA would readily understand that the handle was designed so that the physician can manipulate the positioning of the implant from outside the patient’s body and

rotate the inner shaft 48 to attach to, and detach from, the implant 2 once the implant is inserted. Ex. 1004, 4:57-62, 7:11-17, 10:6-13. Specifically, the handle is used not only so the physician can guide and deliver the implant to between the vertebral bodies, but also to reposition the implant as needed and decouple the instrument guide from the implant once the implant has been secured.

120. Many other prior art references show that such handles for spinal fusion implant delivery were specifically designed for this purpose. *See, e.g.*, Ex. 1027, 5:43–56 (explaining that interbody implant insertion tool shaft 15 is “generally cylindrical of a length sufficient to allow the device to span **from the surgical target site to a location sufficiently outside the patient’s body** so the handling feature 14 can be easily accessed by a clinician or a complimentary controlling device.”); Ex. 1029, 9:55–56, 10:45–54 (explaining that implant delivery tool 50 “includes a shaft 91, having a length sufficient to reach into the intradiscal space **from outside the patient.**”); Ex. 1023, 7:6-9, 31-43 (explaining how delivery instrument 20 for interbody implant has a handle 42 and elongate tubular element 28 “of a length sufficient to allow the device to span from the surgical target site to a location sufficiently **outside the patient’s body so the handle 42 and thumbwheel housing 389 can be easily accessed by a clinician**”); Ex. 1026, 7:18-29; Ex. 1024, 15:28-37 (explaining that the elongated shaft 104 of insertion tool 100 for interbody implant

10 is “of a length sufficient to allow the device to span from the surgical target site **to a location sufficiently outside the patient’s body**”); Ex. 1025, 5:8-13; Ex. 1028 ¶¶[0012], [0022]). Indeed, a POSA would understand that if the handle was not designed to be outside the patient’s body, the physician would be required to insert his or her hand into the patient’s body during deployment of the implant between the vertebral bodies, which would significantly impair the ability of the physician to maneuver and position the implant. Thus, a POSA would understand that the handle was designed to be outside the patient’s body.

121. In all my surgical experience prior to March 2008, I have never seen an interbody implant delivery tool that did not extent outside the patient’s body when the implant is between the vertebral bodies. There is simply no reason a physician would want to install or deliver the implant with a delivery tool that is entirely within the patient’s body.

122. A POSA would also understand, based on the dimensions of the implant 2 relative to the dimensions of instrument guide 14, that during surgery at least the handle 20 and part of proximal shaft 22A of the instrument guide 14 would extend outside of the patient’s body through the surgical access channel. A POSA would understand that the implant 2 is sized to fit between two vertebral bodies, and thus, its size would correspond generally to the size of the disc space into which it is

inserted. Even assuming interbody fusion surgery were performed on an extraordinarily large patient, based on the relative dimensions of the implant 2 to the instrument guide 14 and the size of space between vertebral bodies, it would be apparent to a POSA that the shaft 22A and handle 20 would necessarily extend outside the patient's body. Indeed, the instrument guide 14 has a handle 20 and shafts because it is designed to be manipulated by the physician from outside the patient's body, including when the implant is sitting between the vertebral bodies.

123. It also would have been obvious based on common sense and the general knowledge of POSAs to make the length of the shaft of instrument guide 14 sufficiently long so that the physician would not have to stick his or her hand inside the incision location to insert the implant between the vertebra. The various prior art references discussed above (Exhibits 1023 to 1028) show that delivery tools commonly extended outside a patient's body to the physician once the implant was inserted, including for the purpose of allowing the physician to easily access the tool handle and control coupling, for example, via a thumb wheel.

124. It would be common sense to a POSA that the combined length of the shafts of Blain should be long enough for this purpose so that the physician could maneuver and manipulate the delivery tool without having to insert his or her hand into the patient's body to deliver and position the implant. It was obvious that having

to manipulate the positioning of the delivery tool from within the patient's body would significantly hinder the physician's ability to maneuver and manipulate delivery of the implant. A POSA would also know, again based on common sense, that designing the handle to extend outside the patient's body could allow for a smaller incision on the patient, because neither the surgeon's hand nor the instrument guide handle 20 would have to fit inside the incision site. This allows a more minimally invasive procedure, which was highly desirable as evidenced by numerous prior art references. *See, e.g.*, Ex. 1014, 1:35-36; Ex. 1018, 2:26-28; Ex. 1020 ¶ [0008]; Ex. 1037, 2:31-36.

125. It was known to POSAs that during spinal fusion surgeries, physicians used fluoroscopy (an x-ray imaging process) to help guide and insert the implant between the vertebrae. *See* Ex. 1023, 3:3-13; Ex. 1024, 18:7-12; Ex. 1027, 1:48-51. It was understood that if the physician inserted his/her hand into the patient, this would partially obscure the imaging, meaning the physician would essentially be delivering the implant with his or her vision obscured. It was also known that the fluoroscopy causes unwanted radiation exposure, leading to obvious health hazards. This is yet another obvious reason that a physician would not want to insert his or her hand inside the patient's body during this procedure, and that it would have involved nothing more than common sense to design the instrument guide handle to

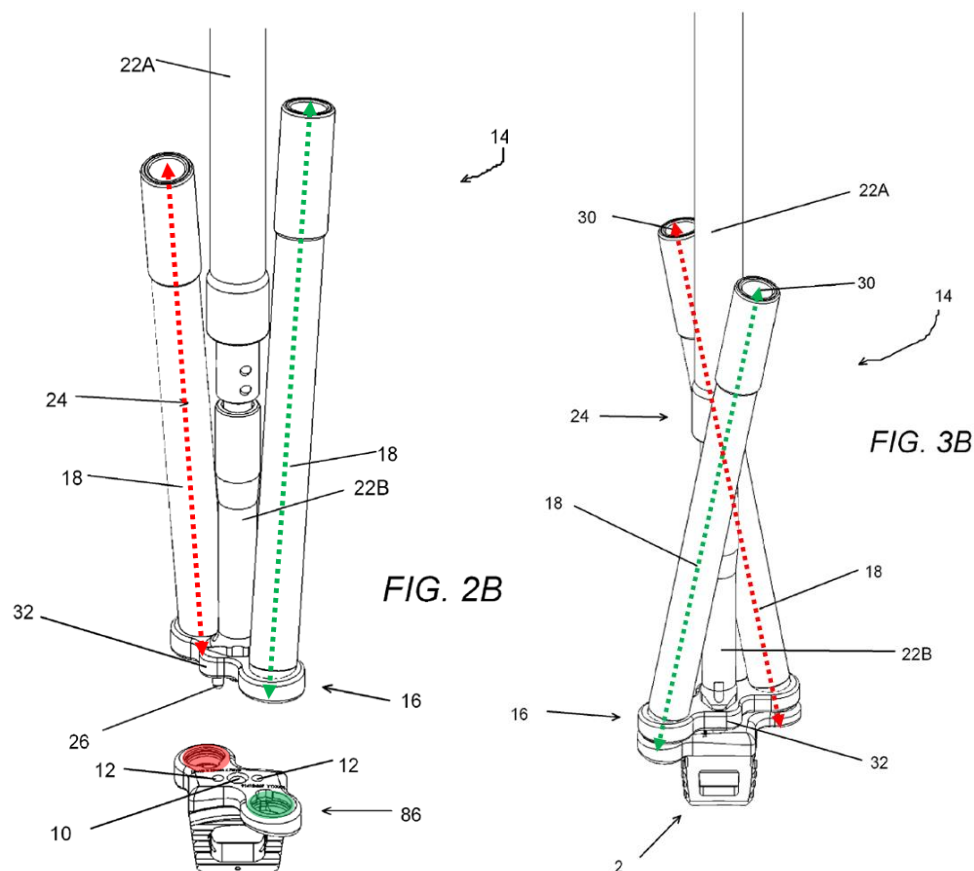
extend outside the patient's body during the entire delivery process, including when the implant is between the vertebral bodies.

126. A POSA would have had a reasonable expectation of success in modifying the instrument guide 14 such that its handle 20 and shaft 22 extend outside the patient's body, because this modification involved nothing more than lengthening the proximal shaft 22A and/or distal shaft 22B. In fact, Blain expressly teaches that "the relative lengths between the proximal shaft 22A and the distal shaft 22B can vary" and the prior art discussed above shows that it was common to have handles long enough that they extend outside the body. Ex. 1004, 5:4-6. A POSA would have found this to be a very rudimentary mechanical design change that would have no effect on the functionality or operation of the instrument guide 14, other than the fact that the handle 20 would extend outside the patient's body during implant delivery, making the procedure easier for the physician.

1.2.3. "the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and"

127. Blain's tubular passages that extend from one end of a respective guide tube 18 to the other end of the guide tube 18 are the instrument guide's 14 *second plurality of channels*. Figures 2B and 3B (annotated below) show the same

embodiment from different perspectives. As seen below, they show one guide tube 18 that has a proximal opening 30 of a channel that extends to the opposing end of the guide tube (as indicated by red-dashed arrow) and to a channel opening (not shown) in device coupler 16. Ex. 1004, 8:5-16. The other guide tube 18 has a proximal opening 30 of a channel that extends to that guide tube's opposing end (as indicated by green-dashed arrow). *Id.*



128. Blain discloses that *each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral*

bodies. As seen above, the guide instrument channel (red-dashed line) aligns with the implant fastener channel (red circle), and the guide instrument channel (green-dashed line) aligns with a different implant fastener channel (green circle). *Id.*, 4:55-58, 5:17-33, 6:1-9. Figure 2B shows the instrument guide 14 before coupling and Figure 3B shows the instrument guide 14 after coupling. *Id.*, 5:17-18, 5:29-33.

129. As discussed in element 1.2.1, alignment exists when the delivery mechanism delivers the fusion member between the two vertebral bodies because the instrument guide 14 is already coupled to the implant 2 when the surgeon inserts the implant between the vertebral bodies. See *id.*, 10:6-13 (“In a preferred embodiment, however, the instrument guide 14 is attached to the orthopedic device 2 prior to implantation, and the instrument guide 14 is also used as a delivery instrument to insert and fix the orthopedic device 2 to the spine. In this preferred embodiment, only a single attachment and a single detachment step is used to implant the orthopedic device 2, which simplifies the implantation procedure and may reduce the risk of error or injury.”).

1.3 “a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) traversing through a different channel of the fusion member, (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body.”

130. Blain teaches *a plurality of independent anchoring members* (bone fasteners 6) *configured to secure the fusion member to the vertebral bodies*. Specifically, Blain explains that “[a]fter the implant 2 is positioned in its desired location and orientation, self-tapping or self-drilling bone fasteners 6 may be inserted into the proximal openings 30 of the guide tubes 18 and **fastened to bone using a screw driver 66.**” *Id.*, 8:50-54. Figures 1 and Figure 6A (partial) are both annotated below to identify the bone fasteners 6 (blue):

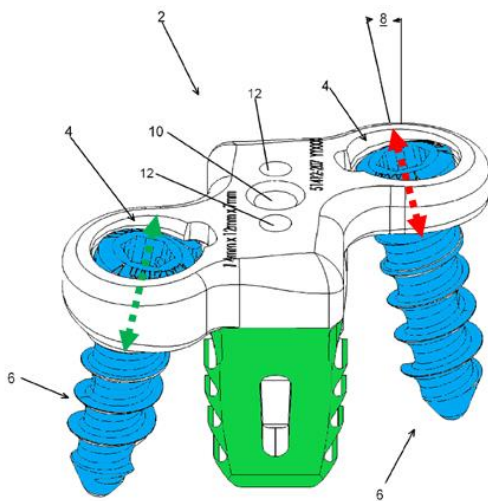


FIG. 1

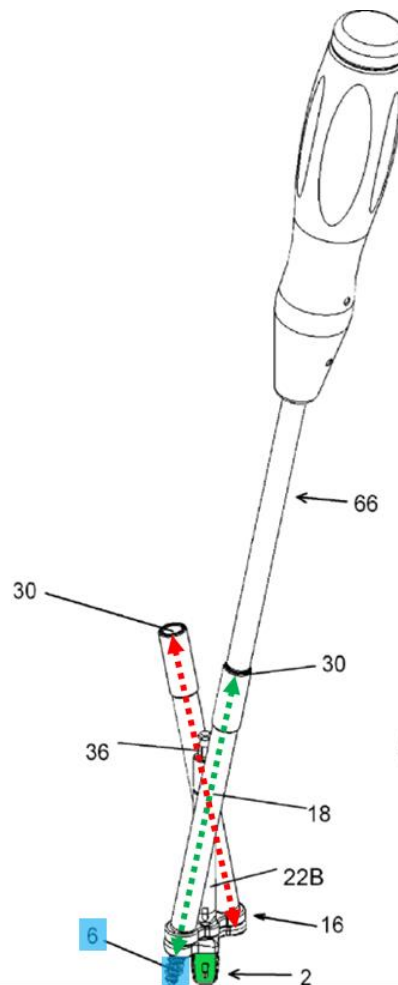


FIG. 6A

131. Figure 6A shows how screw driver 66 goes through guide tube 18 to engage with one fastener 6 so that the fastener can be driven into a vertebral body (i.e., bone). Similarly, the other fastener 6 would be inserted into the other guide member 18 and screw driver 66 used to drive and couple it into to the other vertebral body. *Id.*, 8:46-54.

132. Blain also discloses that *each independent anchoring member is for (i) traversing through a different channel of the fusion member*, where it explains “**bone fasteners 6 may be inserted into the proximal openings 30** of the guide tubes 18 and fastened to bone using a screw driver 66.” *Id.*, 8:46-56. Blain thus teaches that each *anchoring member* (blue fastener 6) is inserted into a *different channel* (red-dashed and green-dashed channel) of implant 2.

133. Blain also discloses that each independent anchoring mechanism is *for (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body*. Blain teaches that the fasteners 6 are “fastened to bone using a screw driver 66,” which is referring to how the fastener is screwed into the vertebral body to secure the fusion implant to and between the vertebral bodies. *Id.*, 8:50-54. Thus, each fastener 6 (anchoring member) penetrates the vertebral bodies and couples and prevents decoupling of the fusion implant from the

vertebral bodies due to the fastener's threaded engagement with its respective vertebral body. The '805 Patent teaches that "variations for the anchoring tip contours prevent the anchoring members from being easily withdrawn from the bone." Ex. 1001, 4:1-4; 8:28-33; 15:53-62; 25:66-26:4. The threading of Blain's fasteners 6 similarly prevents the fasteners from being easily withdrawn from the bone (vertebral body) as described in the '805 Patent.

134. Blain also discloses an anti-rotation mechanism to further *prevent decoupling*. Specifically, Figure 1 of Blain discloses an anti-rotation mechanism (blue) comprising a lobe (blue) on each fastener head and a recess (red) adjacent the threading (pink) of each implant channel, which prevents the fasteners from rotating counter-clockwise to unthread.

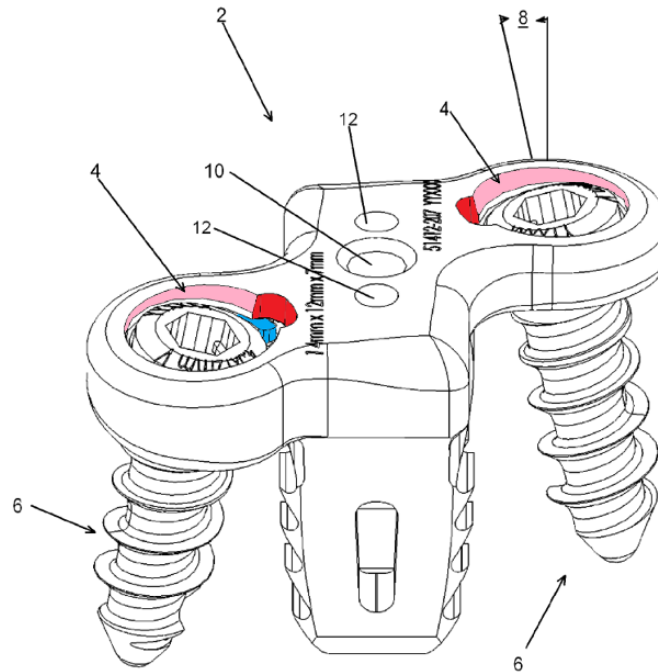
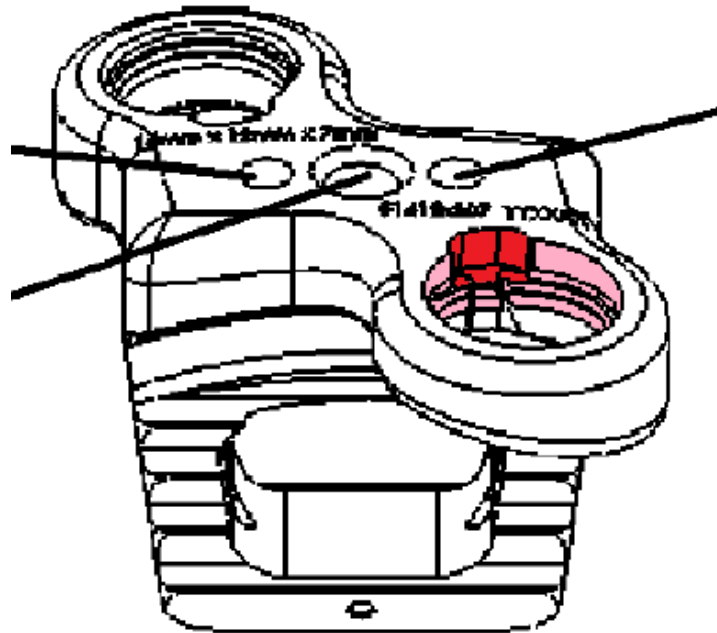


FIG. 1

135. This anti-rotation mechanism is not expressly discussed in Blain. However, a POSA would understand this to be an anti-rotation “locking” feature that prevents the fasteners 6 from unscrewing to unthread from the implant channel and/or vertebral bodies. This unwanted unthreading is referred to “backing out,” because as the screw unthreads it separates from the implant resulting in the head of the screw being spaced apart from the implant. Once backing out begins, there can be unwanted movement of the implant relative to the vertebral bodies.

136. I will briefly explain how this locking feature works. Blain depicts that the anchor channels are threaded, as seen in pink in Figure 2B (partial, annotated below);



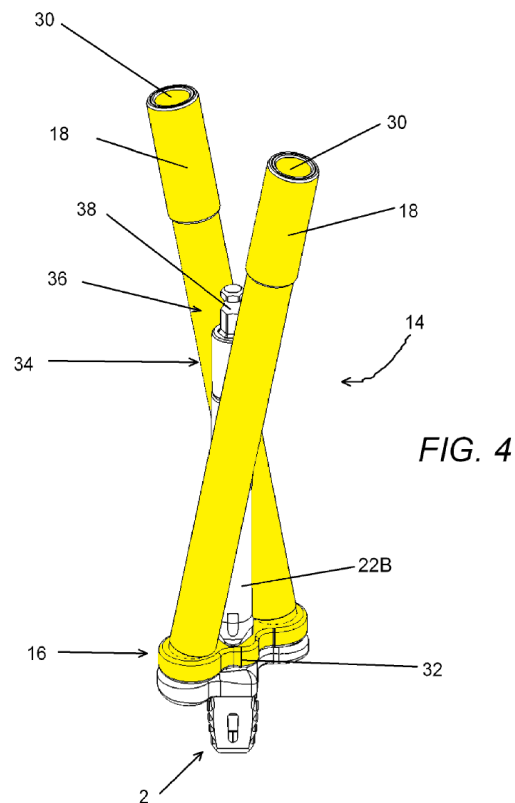
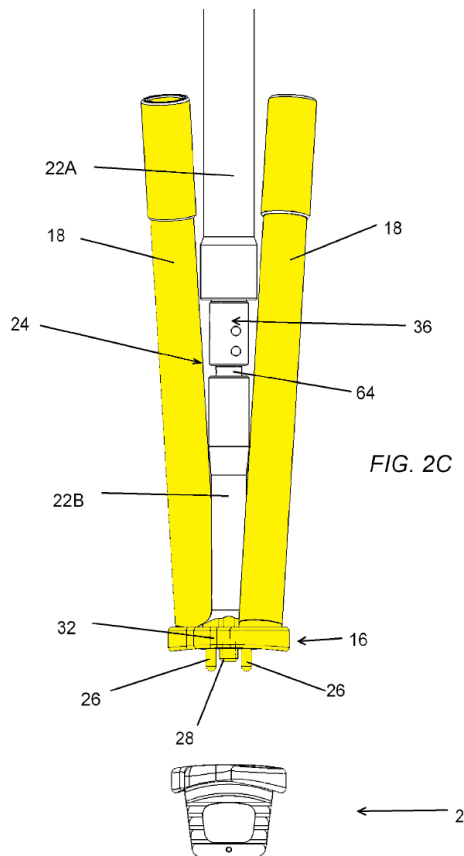
This means that the anchor fasteners 6 of Blain are not only threaded to vertebral bodies—they are also each threaded to the threading of the respective implant channel through which they pass. As the threading of the fastener advances into the vertebral body, the screw head engages the threads in the pink area of the implant channel.

137. As the screw continues to be rotated and the head of the screw moves closer to being fully seated in the channel, the torque required to advance the screw increases. The physician would continue torquing the screw until the lobe (blue) of

the fastener head bottoms out (or “snaps” / “clicks”) into the recess (red area), which indicates that the implant and screw are fully coupled together. The recess (red) then prevents the screw head (fastener 6) from rotating counter-clock wise due to the lobe (blue), which means the screw cannot unscrew from the penetrated bone or implant. The recess (red) also acts as a seat for the screw head, thus preventing the screw head from advancing all the way through the implant. Consequently, the locking feature prevents the screw from unthreading from its vertebral body and the implant channel through which it is inserted. Thus, each fastener 6 is not only threaded to a vertebral body—it is threaded to the respective implant channel through which it passes and is “locked” via the anti-rotation mechanism.

Claim 2: “The apparatus of claim 1, wherein the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member.”

138. Blain’s instrument guide 14 comprises *a delivery housing for guiding each independent anchoring member into the fusion member*. As shown below in Figures 2C and 4, Blain’s instrument guide 14 (*delivery mechanism*) has a device coupler 16 (yellow) that is coupled to two guide tubes 18 (yellow):



Ex. 1004, 8:5-20.

139. Guide tubes 18 constitute a *delivery housing* because they are part of the *delivery mechanism* (instrument guide 14) and house fasteners 6 (*anchoring mechanism*) as they pass through the guide tubes to the device coupler 16 and fusion implant 2. *Id.*, 5:30-33, 8:5-11, 8:48-54.

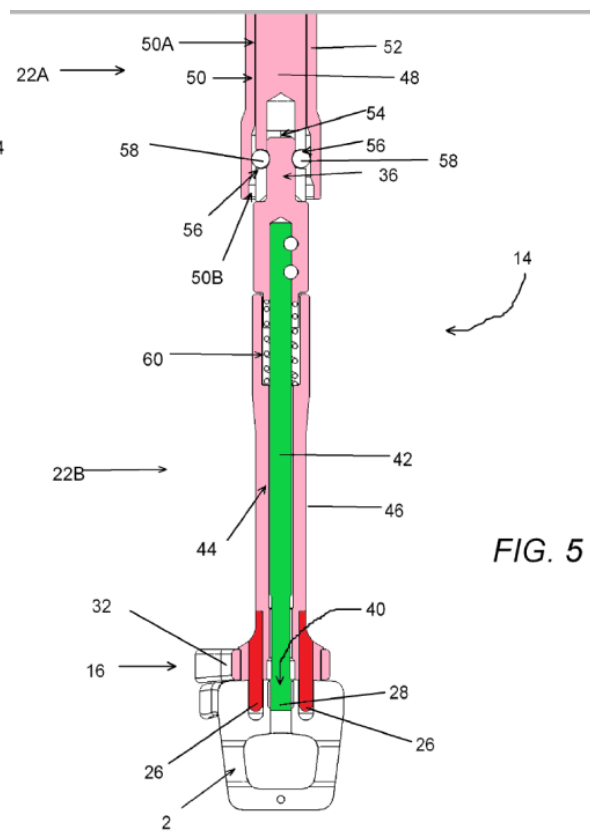
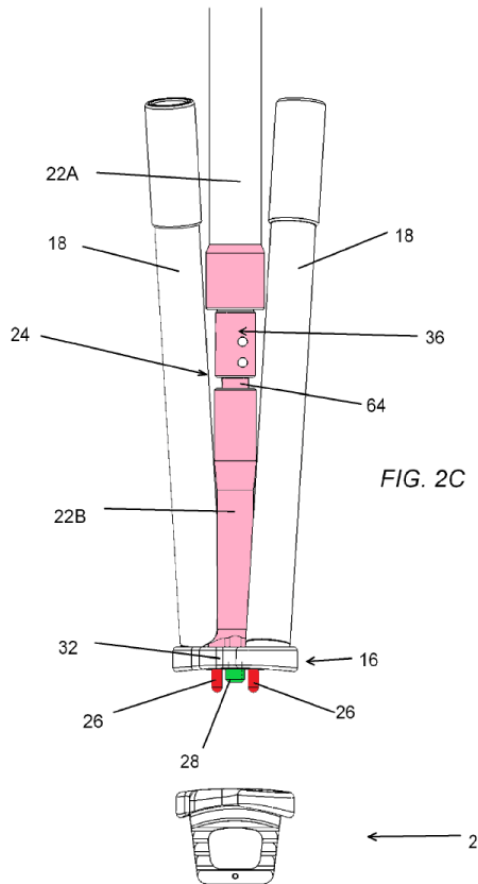
140. The device coupler 16 likewise constitutes a *delivery housing* because it is part of the *delivery mechanism* and houses the fasteners 6 (*anchoring members*) as they pass through the openings in the device coupler on their way to the proximal

openings 4 in the fusion implant 2. *Id.*, 1:52-55, 8:5-11, 8:50-54. Thus, the device coupler is a *delivery housing*.

141. The device coupler 16 and guide tubes 18 are each *for guiding each independent anchoring member into the fusion member*, because both provide channels leading to the fastener openings 4 of the implant 2.

142. I understand that in the litigation, both parties have proposed that *retention mechanism for fixedly coupling the deliver housing to the fusion member* should be given its plain and ordinary meaning. Exs. 1021, 1022. Based on the plain and ordinary meaning, the instrument guide 14 (*delivery mechanism*) also comprises *a retention mechanism for fixedly coupling the delivery housing to the fusion member*.

143. Referring to Figures 2C and 5 (annotated below), the instrument guide 14 includes inner shaft 42 (green) that resides in outer shaft 46 (pink) and has coupling members 26 (red) and 28 (at distal end 40 of green shaft 42). Ex. 1004, 6:47-57.



144. The distal end 40 of the distal inner shaft 42 has a movable coupling member 28. *Id.*, 6:50-51. Blain teaches that “coupling member 28 may comprise, for example, any of a variety of complementary mechanical interfits with the coupled implant, such as a **threaded lock, snap-on fitting, or an interlocking fit.**” *Id.*, 5:44-50. This complementary mechanical interfit allows the instrument guide 14 to be coupled to the implant 2 in a “locking configuration...to detachably engage the implant (2)” *Id.* The inter-locking fit between the coupling member 28 and the coupling opening 10 of the implant 2 results in the instrument guide 14 (including the device coupler 12 and guide tubes 18) being fixedly coupled to the fusion implant

2. Thus, Blain's inner shaft 42, and its coupling member 28, qualifies as the claimed *retention mechanism*, because it enables the *delivery housing* (guide tubes and device coupler) to fixedly couple to the implant.

145. Notably, Blain's disclosed *retention mechanism* has very similar structure to the retention mechanism disclosed in the '805 Patent. Specifically, the '805 Patent discloses a retention rod 160 with one or more of retention teeth 910, male/female structures, a clamp, or expandable clasps. Ex. 1001, 2:46-49, 7:8-11, 10:48-57, 12:31-39. Similarly, as explained above, Blain's coupling member 28 is part of a retention rod (inner shaft 42) and has mechanical interfits (e.g., like retention teeth 910 of the '805 Patent) or a clamp member (like the clamp referenced in the '805 Patent) to fixedly couple the delivery housing to the implant.

Claim 3: "The apparatus of claim 2, wherein the retention mechanism comprises at least one retention rod for coupling with the fusion member."

146. As explained with respect to claim 2 above, Blain's *retention mechanism* includes a *retention rod* in the form of green inner shaft 42, which has a distal end 40 with coupling member 28 that couples to the coupling opening 10 of fusion implant 2. The *retention mechanism* also comprises coupling members 26, which are rods used to couple the instrument guide 14 to the implant 2 via coupling openings 12 in the implant. Ex. 1004, 6:1-8 (explaining that fixed coupling structures

26 “serve to limit rotational movement between the implantable device 2 and the instrument guide 14”).

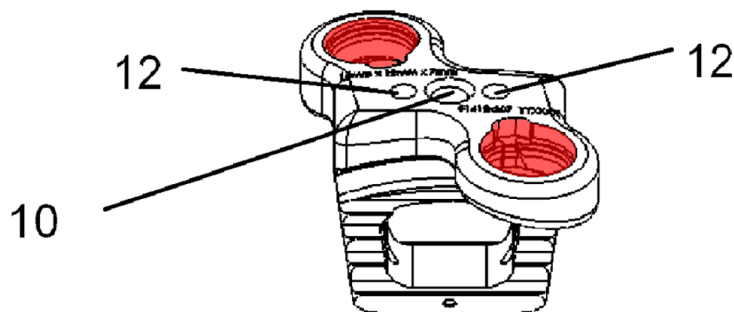
Claim 4: “The apparatus of claim 2, wherein the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism.”

147. My analysis of claim element 1.2.3 shows how coupling the instrument guide 14 (including the device coupler 16 and guide tubes 18) to the implant 2 results in alignment of each channel (red-dashed channel and green dashed-channel) of the instrument guide 14 with a different channel (red circle and green circle, respectively) of the implant 2. In fact, Blain expressly teaches that “[t]he aligned coupling between the instrument guide 14 and implant 2 matches the guide lumens 18 of the instrument guide 14 with the fastener apertures 4 of the implant 2.” Ex. 1004, 5:30-33. A POSA would thus understand that Blain satisfies this element.

Claim 5: “The apparatus of claim 1, wherein each channel of the fusion member is curved.”

148. Based on the interpretation advanced by Spinelogik in the co-pending litigation, Blain discloses that *each of the plurality of first channels is curved*. Each channel of the fusion implant 2 (*fusion member*) is *curved* in two ways.

149. Referring to Figure 2B (partial, annotated below), *each channel* has a rounded proximal opening (red) on the side that a fastener 6 is inserted into and a rounded distal opening (not visible) that the fastener protrudes out of.



Based on Spinelogik's claim interpretation, because these openings are round (e.g., they represent a round cross-section of the channel), the *channels* would be *curved*. Notably, during prosecution of the '805 Patent, the Examiner determined that Duffield's prior art channels were *curved* based solely on their cross-section being circular, which is the same as the channel openings of Blain shown in red above. Ex. 1003, 111-112 ("Each channel of the fusion member is curved (circular curved cross section).") (citing Ex. 1017, Fig. 12).

150. Additionally, *each channel* in Blain has a tube-like inner wall extending from one opening to the other opening. More specifically, each anchor channel has a proximal opening (on the top side of the implant in Figure 2B) and a distal opening on the bottom side of the implant (on the bottom side of the implant in Figure 2B),

with a tube-like passage extending between those openings. Because the inner wall of the passage is tube-like, each *channel* is *curved* under Spinelogik's interpretation.

Claim 6: “The apparatus of claim 1, wherein traversing through the different channel of the fusion member comprises entering the different channel of the fusion member through a corresponding channel of the delivery mechanism.”

151. Figures 2B and 3B (annotated below) show how the channel of the guide member 18 (red-dashed line) aligns with the fastener channel (red circle), and the channel (green-dashed line) aligns with a different fastener channel (green circle). Ex. 1004, 4:55-58, 5:17-33, 6:1-9. Figure 2B shows the instrument guide 14 before it has coupled to implant 2, while Figure 3B shows the instrument guide 14 after coupling to the implant 2:

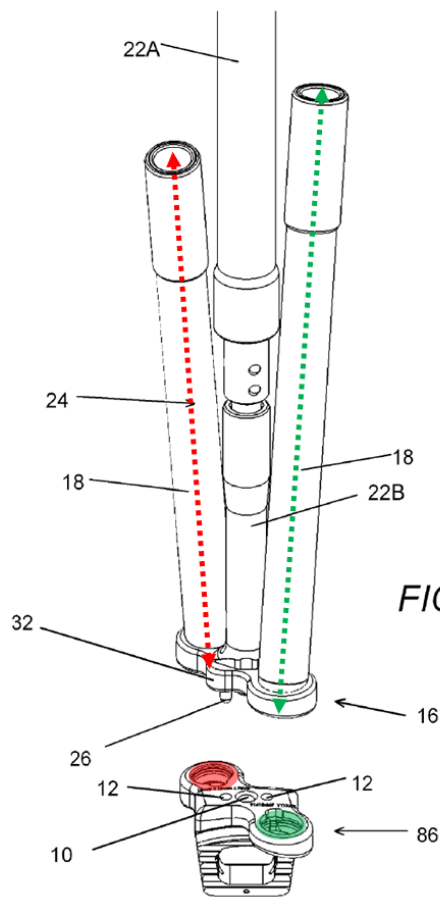


FIG. 2B

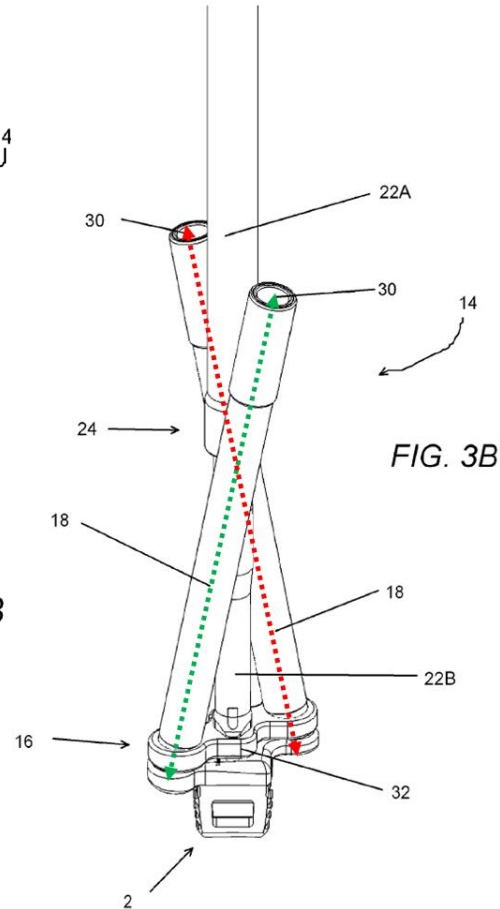


FIG. 3B

Blain teaches that “[a]fter the implant 2 is positioned in its desired location and orientation, self-tapping or self-drilling **bone fasteners 6 may be inserted into the proximal opens 30 of the guide tubes 18** and fastened to bone using a screw driver 66.” *Id.*, 8:50-54. Thus, Blain’s bone fastener 6 (*anchoring member*) traverses through a different channel of the implant through a corresponding channel of guide rod 18 of instrument guide 14 (*delivery mechanism*).

Claim 11

11.0 [Preamble] “A fusion device comprising:”

152. Blain discloses the preamble will be shown below.

11.1 “a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;”

153. See claim element 1.1 above.

11.2.1 “a delivery mechanism for delivering the fusion member between the two vertebral bodies,

154. See claim element 1.2.1 above.

11.2.2. the delivery mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,”

155. See claim element 1.2.2 above.

11.2.3 “the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and”

156. See claim element 1.2.3 above.

11.3 “a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) coupling the fusion member to the vertebral body, and (ii) preventing decoupling of the fusion member from the vertebral body.”

157. This claim element is identical to claim element 1.3, except that this element does not have the limitation of “(i) traversing through a different channel of the fusion member” and “(ii) penetrating into one of the vertebral bodies.” In other words, this claim element is broader than claim element 1.3. The discussion of claim element 1.3 thus demonstrates that claim element 11.3 is satisfied by Blain.

Claim 12: “The fusion device of claim 11, wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member.”

158. As discussed with respect to claim element 1.3 above, Figures 1 and 2B (annotated below) shows Blain’s fasteners 6 threadingly engaging the proximal opening of implant channels 4. Additionally, the proximal openings include recesses (red) that lobes (blue) of the fasteners’ heads seat into once fully threaded into the openings, locking the fasteners to the implant by preventing their counter-clockwise rotation to back out from the implant channel and penetrated bone.

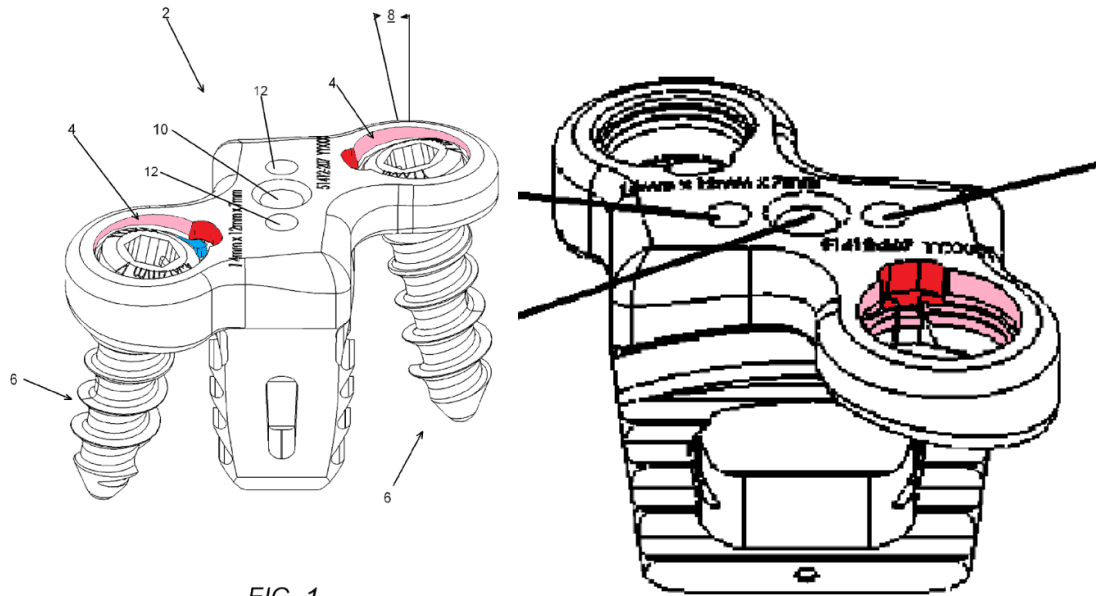
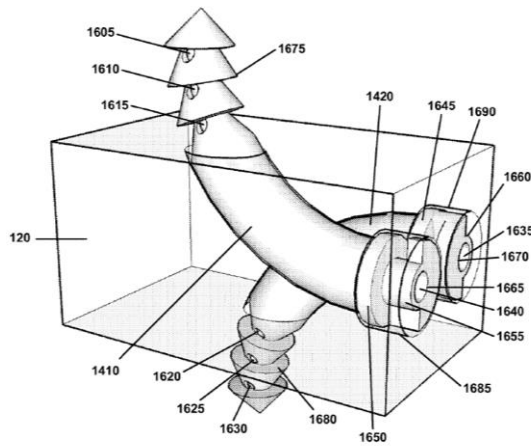
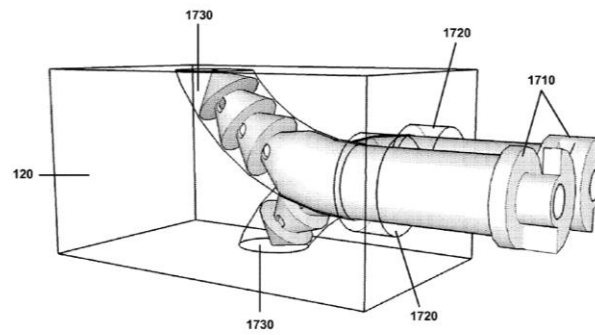


FIG. 1

A POSA would have understood that locking each fastener to the implant after they are fully advanced through the implant channels prevents decoupling.

159. Additionally, the '805 Patent describes “locking” a fusion member and anchoring member together in an embodiment. Referring to Figures 16 and 17 annotated below, flanges 1645-1650 of the anchoring members 1410-1420 fit into recesses 1685-1690 of the fusion member channels “locking **the anchoring members 1410-1420 to the fusion member 120 once the anchoring members are fully advanced through the fusion member’s channels.** FIG. 17 illustrates the flange cavities 1720 at the proximal end of each fusion member channel 1730 that aid in affixing each anchoring member to the fusion member 120 when the anchoring members are fully advanced.” Ex. 1001, 15:63-16:5.

**Figure 16****Figure 17**

160. As depicted above, the anchoring members have surface contours 1675 to assist with retention of the anchoring members within the vertebral bodies. *Id.*, 15:52-62. Thus, the '805 Patent characterizes fitting a head of an anchoring member into a recess of a channel of the fusion implant after the anchors have been coupled to the vertebrae as “locking” the anchoring member and fusion implant together. The '805 Patent does not teach that this “locking” requires any additional mechanism, such as an anti-rotation key or restraining plate that goes over the head of the anchoring member to prevent it from backing out of the channel.

161. Just as the anchoring members of Figures 16 and 17 are “locked” to the implant by fully advancing the surface contours into the vertebral bodies and the having the head of the anchoring members residing in recesses of the fusion implant, the Blain’s *anchoring members* (fasteners 6) are similarly *locked* to the *fusion member* (implant 2) by virtue of their surface contours (threading) being fully

advanced into the vertebral bodies and each anchoring member having a head that fits within a recess of the fusion member.

Claim 15: “The fusion device of claim 11 further comprising a driving member configured to drive each independent anchoring member through the delivery mechanism.”

162. Blain’s screw driver 66 is *a driving member configured to drive each independent anchoring member through the delivery mechanism*. Blain teaches that bone fasteners are “fastened to bone using a **screw driver 66**” in reference to Figures 6A and 6B (below). Ex. 1004, 8:50-54. These figures show the shaft of the screw driver 66 inserted through each of the guide tubes 18 to perform the fastening.

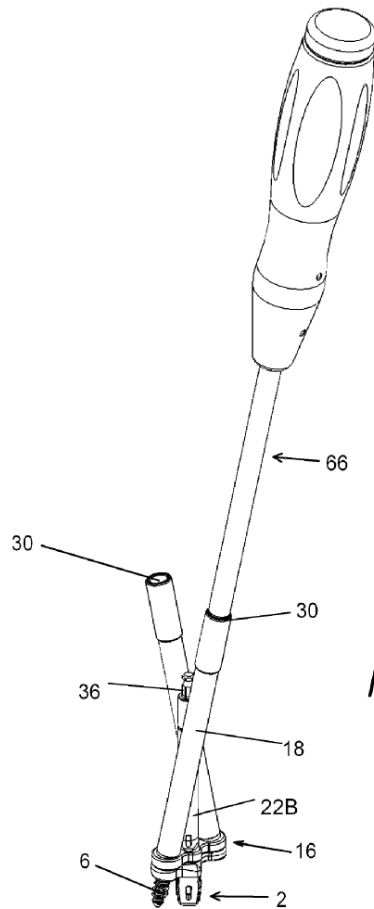


FIG. 6A

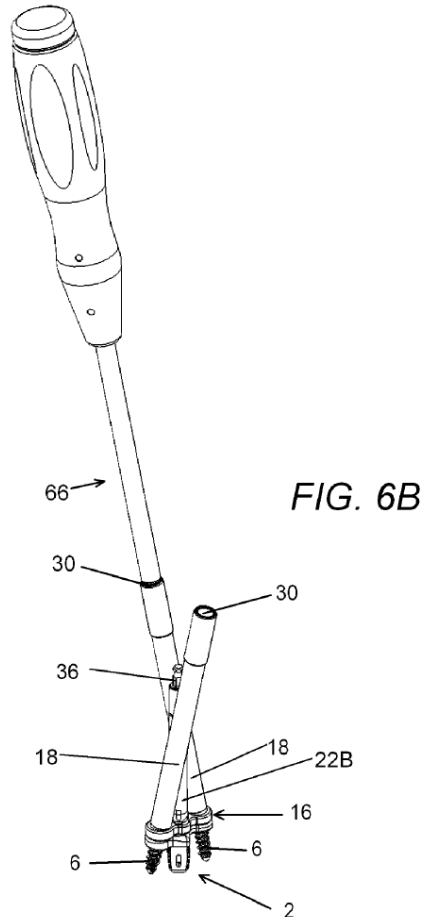


FIG. 6B

163. A POSA would have understood that screw driver 66 is a *driving member* that *drives each independent anchoring member through the delivery mechanism* because it drives each fastener 6 through a guide tube 18 and, when it screws each fastener 6 into the vertebral bodies, each fastener 6 is driven further through its guide tube 18 and through the opening of coupling device 16 of the instrument guide 14 (*delivery mechanism*) as the fastener penetrates further and further into the vertebral body.

Claim 16: “The fusion device of claim 11, wherein each channel of the fusion member is curved.”

164. See above discussion of claim 5.

Claim 17: “The fusion device of claim 11, wherein each independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism in order to couple the fusion member to the penetrated vertebral body.”

165. The discussion of claim 6 above explains how Blain discloses that *each independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism.*

166. Additionally, as explained in claim element 1.3, Blain teaches that **“fasteners 6 may be inserted into the proximal opens 30 of the guide tubes 18 and fastened to bone using a screw driver 66.”** Ex. 1004, 8:50-54. Specifically, each fastener 6 (*anchoring member*) is thus inserted into a respective guide tube 18 of the instrument guide 14 (*delivery mechanism*) *in order to couple the fusion implant 2 (fusion member) to the penetrated vertebral body.* It is the threads of fastener 6 that engage the bone of the vertebral body and the head of fastener 6 tightly engaged with the seat of the anchor channel that creates the coupling of the fusion member to the penetrated vertebral body.

B. Ground 2: Whether Claims 1-6, 11, 12 and 15-17 are Obvious Based on Blain and Bray.

167. It is my opinion that it would have been obvious to modify the implant of Blain to incorporate Bray's: (1) restraining plate; and (2) a spherical anchor head and anchor seat. My opinions with regard to the claims challenged under this ground are set forth below and incorporate by reference the analysis and explanation discussed in Ground 1.

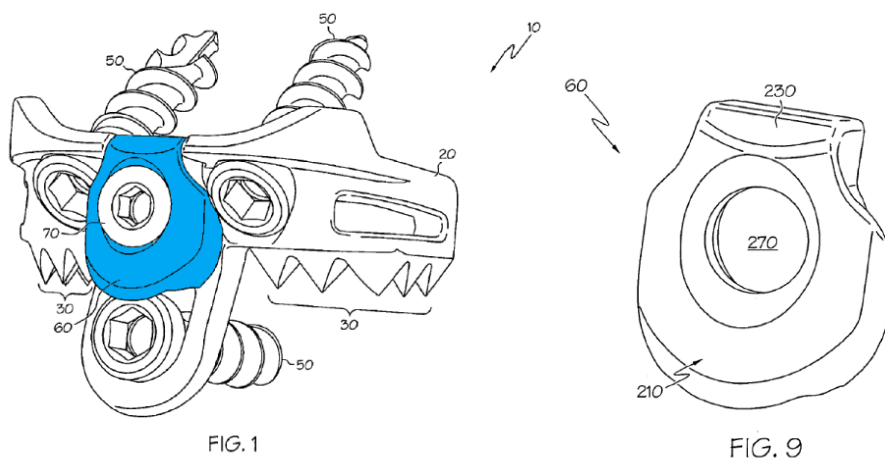
168. Blain and Bray are both directed toward interbody fusion implants and delivery tools for delivering and securing such implants between vertebral bodies. *See supra* Sections VIII.A and VIII.B. Additionally, they are both reasonably pertinent to the problem faced by the inventor of the '805 Patent, namely problems that arise with effectively and efficiently delivering fusion implants and their associated anchors between vertebral bodies. *Id.* Thus, Blain and Bray are from the same field of endeavor and are analogous art.

Claims 1, 11

169. Claims 1.3 and 11.3 recite the element of *preventing decoupling of the fusion member from the penetrated vertebral body*. A POSA would have found it obvious to modify Blain's implant to substitute the restraining feature taught in Bray

for the anti-rotation mechanism of Blain, which would provide an improved mechanism for preventing backing out.

170. Bray teaches a restraining feature so that its bone fasteners 50 “cannot back out from the bone bodies once screwed in” through the implant 10. Ex. 1006, 4:49-57. Bray’s restraining feature is a restraining plate 60 (blue) as depicted in Figure 1 (annotated) and 9:



171. The restraining plate 60 is fixed in place with a restraining member fastener 70, which can be a screw. *Id.*, 9:2-6. Thus, Bray teaches using a restraining plate 60 to “lock” its anchors 50 to the implant, which helps prevent decoupling of the fusion member from the penetrated vertebral body. More specifically, the restraining plate 60 prevents the fasteners 50 from backing out from the implant, which in turn helps prevent the implant from moving or backing out from the vertebral bodies.

172. A POSA would have found it obvious to use Bray's anti-backout mechanism—i.e., a restraining plate that overlays the anchor heads to prevent them backing out—as a simple, yet improved, alternative to the anti-rotation-mechanism of Blain. POSAs recognized and understood that overlay-type “locking” mechanisms, such as that taught by Bray, were well-known and common in the art for this precise reason. *See e.g.*, Ex. 1030, 4:43-53 (describing interbody implant having an “anti-backout mechanism” comprising a “set screw 50” that overlays part of the bone screws 16 to prevent them from backing out); Ex. 1017, 4:62-5:13 (describing interbody implant having “anti-backout mechanism 38” in form of screw overlaying bone screws 36 and 37). As discussed above, Bray itself expressly teaches that the restraining plate prevents backing out. Ex. 1006, 4:49–57. A POSA would have understood that the restraining plate would prevent the fasteners 6 backing out from the implant, because the restraining plate overlays the head of the anchors to prevent them from backing out from the implant under any scenario. In contrast, the anti-rotation mechanism of Blain only prevents backing out due to reverse rotation.

173. A POSA would have also understood Blain's anti-rotation mechanism to be more complex to machine and somewhat more complex in practice to effectuate, as it requires the interaction of multiple specifically designed parts (lobe,

recess, channel threading) and a somewhat precise degree of threaded engagement to “lock” the lobe into the recess to prevent anti-rotation. The retaining plate, on the other hand, is easily coupled to the implant after the implant is secured to the vertebral bodies, working effectively and simply. A POSA would have understood that if Bray’s restraining plate were incorporated into Blain’s implant, the anti-rotation mechanism and internal channel threads of Blain would not be needed because the restraining plate alone would prevent the anchors from backing out from the implant by overlaying the anchor heads. This would allow for the elimination of the anti-rotation mechanism and internal channel threads of Blain—namely the lobe on the anchor head, the recess in the anchor channels, and the threading in the anchor channels. Replacing Blain’s anti-rotation mechanism with Bray’s anti-backout restraining plate would thus reduce the complexity of machining the implant by allowing for the elimination of these features and provide a more reliable and robust anti-backout mechanism.

174. A POSA would have also recognized Bray’s restraining plate to be an improvement over Blain’s anti-rotation mechanism because the plate can simply be removed to allow for the anchors to be unthreaded to remove or reposition the implant (if necessary). In contrast, once Bray’s anchors are advanced such that the anchor head lobe is fully engaged with the anti-locking recess, it would be more

difficult to unthread the anchors if the implant needs to be removed or repositioned.

A POSA would understand this to be a disadvantage compared to Bray's restraining plate, which can easily be removed if needed. A POSA would understand that the reason many of the other cited references use restraining plates or screws is because that is an established, effective way of preventing backing out with implants. *See e.g., See e.g., Ex. 1030, 4:43-53* (describing interbody implant having an "anti-backout mechanism" comprising a "set screw 50" that overlays part of the bone screws 16 to prevent them from backing out); *Ex. 1017, 4:62-5:13* (describing interbody implant having "anti-backout mechanism 38" in form of screw overlaying bone screws 36 and 37). A POSA would have thus found it obvious to use a restraining plate, such as Bray's, because it was known to be effective and simple alternative.

175. A POSA would have had an additional motivation to use the restraining plate of Bray to retain anti-backout/locking functionality when Blain's implant relies on impact driven curved anchors, as proposed in the combination of Ground 3. A POSA understood that the anti-rotation mechanism of Blain would not work with an impact driven anchor (e.g., an unthreaded anchor that is driven using a surgical hammer), which is proposed as a substitute for Blain's fastener screws in Ground 3. This is because an impact driven anchor does not rely on rotation to couple or

decouple, and so an anti-rotation mechanism would not prevent decoupling of such an anchor. Consequently, a POSA would have had an additional motivation to use the restraining plate of Bray to retain anti-backout/locking functionality when Blain's implant relies on impact driven curved anchors, as proposed in the combination of Ground 3.

176. Incorporating the restraining plate of Bray into Blain would have involved nothing more than applying a known technique (preventing an anchor from backing out of an implant using a restraining plate) to improve a similar device (e.g., Blain's implant). Blain's implant is a "base" device and Bray discloses a comparable device that is improved via its use of a restraining plate. A POSA would have readily understood that the same improvement (the restraining plate) could have been applied to the Blain implant in the same way, leading to the entirely predictable result of an anchor head that is prevented from backing by the plate.

177. A POSA had a reasonable expectation of success in making this modification. Referring to Figure 1 and Figure 2B (annotated below) of Blain, the modification simply required: (1) eliminating the anchor head lobe (blue), anchor channel threading (pink), and channel recess (red), while maintaining a seat for the

anchor head to rest on;³ and (2) taking the restraining plate 60 of Bray and modifying it to conform to the shape of the proximal side of Blain's implant 2, such that at least part of the plate overlaps with the proximal openings 4 to prevent the fasteners 6 from backing out.

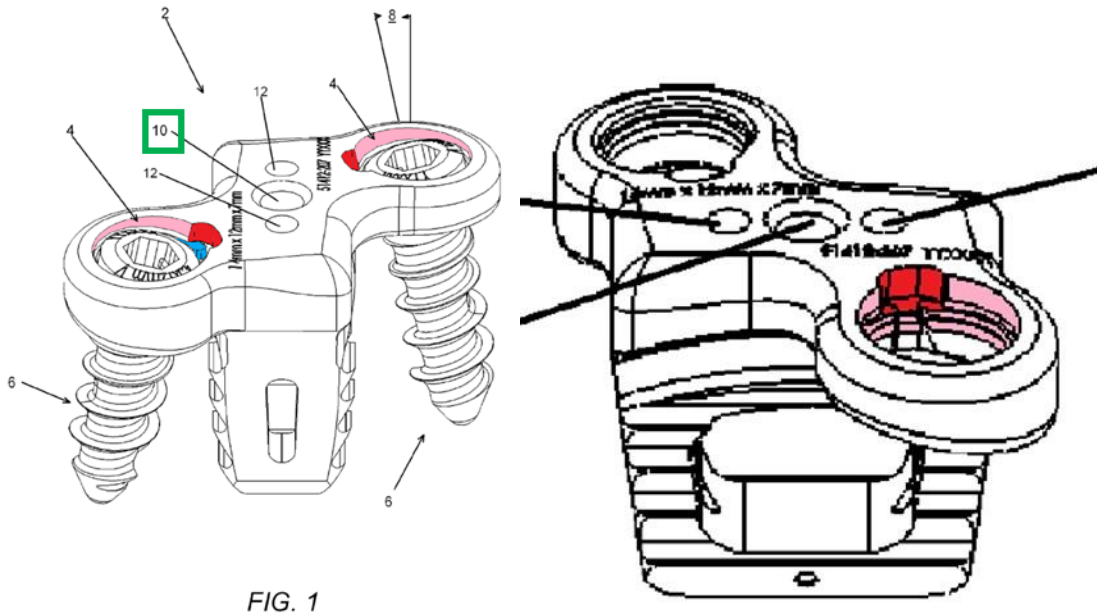


FIG. 1

178. As shown in Figure 1, Blain's implant already has a coupling opening 10 that may be threaded so that the coupling member 28 of the instrument guide 14 can be fixedly coupled to the fusion implant 2. Ex. 1004, 5:57-67. A POSA would have understood that the coupling opening 10 could also be used for threading a

³ As discussed with respect to claims 5 and 16 in Ground 2, it would have been obvious to further modify Blain to incorporate the convex anchor head and concave anchor seat of Bray into Blain's implant, thereby providing a seat to support the anchor head.

restraining member fastener (e.g., screw) after the delivery guide 14 is removed.

This is similar to how the restraining plate 60 of Bray is coupled to its implant using a restraining screw 70.

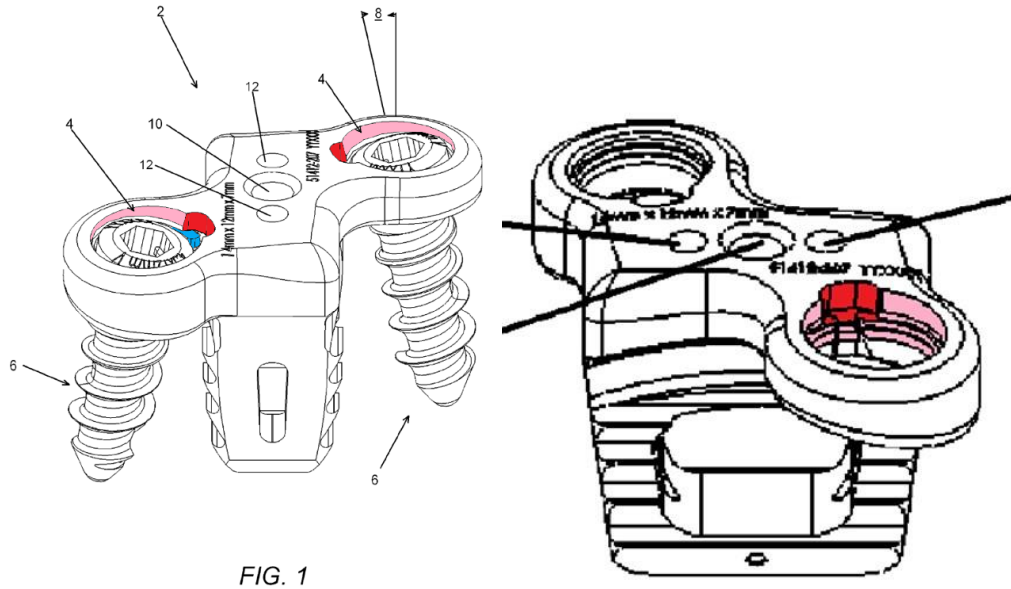
Claims 5, 16

179. Claims 5 and 16 require that *each channel of the fusion member is curved*. It would have been obvious to a POSA to modify the anchor channels 4 of Blain's implant to have spherical seats for the heads of Blain's anchors to sit in, as is taught in Bray. Modifying Blain's anchor channels to include a spherical anchor head and corresponding spherical seat, as taught by Bray, would result in channels that not only have circular openings and tube-like walls, but also radially inward curvatures that form a concave, spherical anchor head seat for the anchor head.

180. 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. 1040, 8-10. POSAs understood that, without a surface

such as a lip or seat to engage the bearing surface of the screw heads, an anchoring screw would not affix the implant to the bone.

181. Blain does not explicitly discuss its anchor seats, which are obscured by the head of the anchors 6 in several of Blain's figures. However, Figure 1B (annotated below) appears to show that the recess (red) and/or threading (pink) is used as a seat upon which the anchor head sits. As I previously explained, it would have been obvious to modify Blain to incorporate the restraining plate of Bray, which would result in the anchor lobe (blue), recess (red) and thread (pink) being removed.



182. A POSA would readily understand that the head of the anchors 6 must rest on a seat when the anchors are fully advanced as depicted in Figure 1 of Blain (below):

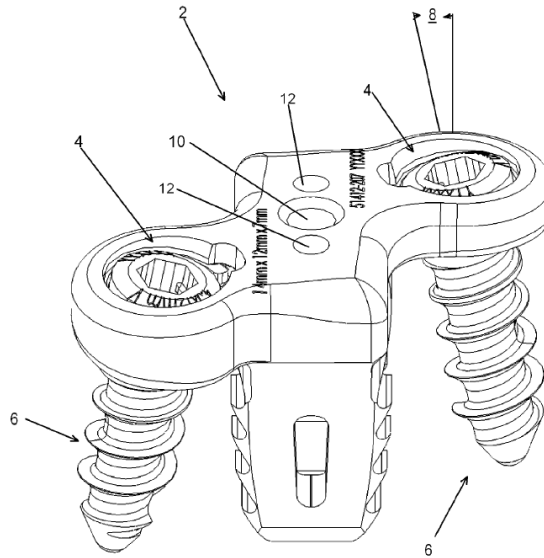
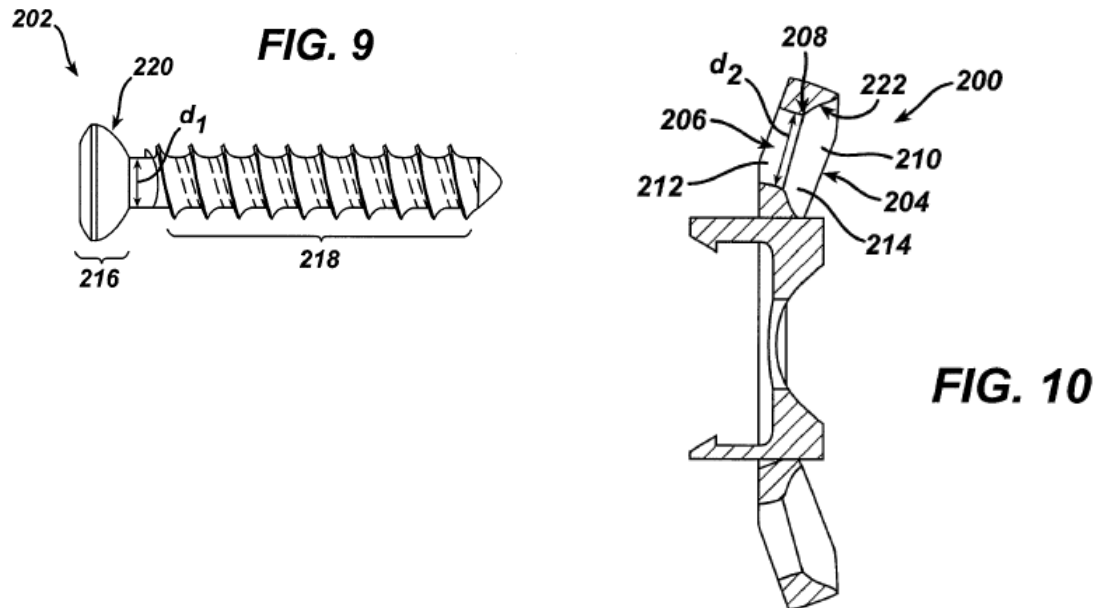


FIG. 1

A POSA would have thus would have been motivated to incorporate the concave anchor seat and convex anchor head of Bray into Blain to provide a bearing surface for the anchor head.

183. The use of a lip or seat was also the well-known mechanism by which screws and other fasteners affix implants to bone, as evidenced by prior art implants. For example, Fraser teaches an inner lumen 210 (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. 1038 ¶[0061], Figs. 9, 10.



184. 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.* Elaborating, Fraser explains that the “generally spherical recess [is] formed in the plate for *rotatably seating* a head of a bone screw.” *Id.* ¶[0014]. Thus, POSAs readily understood that these seats prevent

the screw from advancing through the implant while also allowing the bone penetration angle of the screw to be slightly adjusted.

185. Similarly, as shown in Figures 3 and 5 of Bray (reproduced below), 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. 1006, 7:24-30. Additionally, “[E]ach of the first 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.*, 7:30-37. Blain teaches that this pivotability provides the benefit of allowing “the interbody [implant] to migrate and self-center after it has been implanted.” *Id.*, 10:51-55.

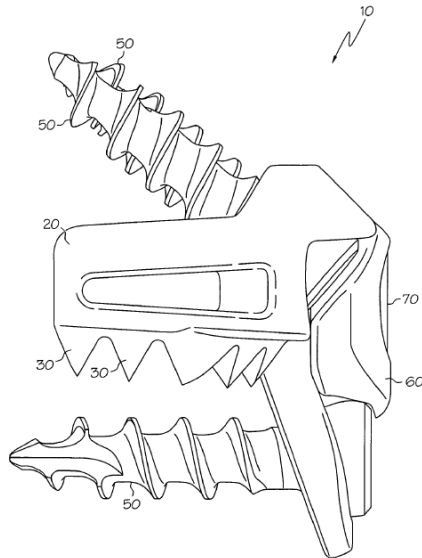


FIG. 3

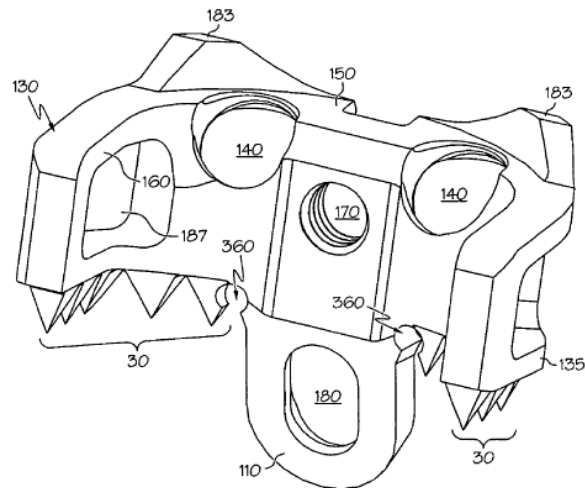


FIG. 5

186. POSAs would have been motivated to modify the proximal openings 4 of Blain to include a concave spherical seat and modify the heads of fasteners 6 to have a complementary convex shape, so that the “bone screws are free to pivot on the seats” as expressly taught by Bray. This would provide several benefits that would have been apparent to a POSA. For one, it would allow the angle of the fastener screws to be toggled by pivoting (as explained in Fraser) so that the anchor can be adjusted to a desired penetration angle into the vertebral body by the physician. Second, the proposed modifications would allow “the interbody [implant] to migrate and self-center after it has been implanted,” as expressly taught by Bray. A POSA would understand that self-centering allows the implant to naturally move to its optimal position between the vertebral bodies, improving long term recovery

and structural support. Third, the proposed modifications would also ensure that the anchor heads has a bearing surface to engage and that the anchor head cannot advance all the way through their respective anchor channels while providing close conformity between the shape of the anchor head and anchor seat.

187. Moreover, implementing an anchor with a spherical head and corresponding spherical seat (rather than a planar head with corresponding planar seat), was an obvious, alternative design choice. A POSA would have recognized that there is no appreciable difference between using a spherical anchor head and seat instead of a planar head and seat, except for the benefits previously discussed. Consequently, a POSA would have found it obvious to select anchors with a spherical head and designing the implant to having complementary anchor seats, as a simple alternative choice to planar anchor heads and seats.

188. A POSA would have also understood that modifying Blain to incorporate a convex anchor head and concave seat (as taught by Bray) was nothing more than combining known prior art elements according to known methods to yield entirely predictable results. The use of convex anchor heads and concave seats was known, as evidenced by Bray and Fraser. Methods of machining such heads and seats was also well-known using simple machining principles. A convex anchor head and concave seat perform the same function when incorporated into Blain as they do

as-is in Bray. Consequently, a POSA easily could have made this modification and the results of doing so were entirely predictable.

189. A POSA had a reasonable expectation of success in using Bray's anchor head and seat because this design was the standard screw seat design for engaging with screw heads to allow the screw to affix the seat-containing component to whatever material the screw was penetrating. Moreover, a POSA had a reasonable expectation of success in using such a seat or lip, because such designs had been successfully implemented in similar spinal fusion implants, as evidenced by Bray and Fraser. Bray's bone screw holes extended through the implant in the very similar way as in Blain, and minimal modifications would be required to machine an anchor with a spherical head and a corresponding spherical anchor seat. A POSA would recognize that minor dimension changes may be required so that the anti-rotation mechanism operates using a concave lip or seat, although as previously explained it would have also been obvious to modify Blain to use Bray's restraining plate instead of Blain's anti-rotation mechanism and threaded anchor channels, in which case the anti-rotation recess, anchor head lobe and internal threaded anchor channels could be eliminated.

190. A POSA would have also recognized that providing the benefit of pivotability via a spherical anchor seat would require eliminating the threading of

Blain's anchor channels and machining the channels with a slightly larger diameter than the shaft of the anchor, which would provide a certain degree of freedom for the screw shaft to pivot. While this could affect the effectiveness of Blain's "as is" anti-rotation locking feature, Ground 2 also proposes substituting Bray's anti-backout locking plate for Blain's anti-rotation mechanism (as discussed with regards to Claims 1 and 11 in Ground 2 above). Bray's anti-backout locking plate does not require a threaded channel, and thus would not be impacted by eliminating the threading in the anchor channels of Blain's implant.

Claim 12

191. Claim 12 recites *preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member*. As explained with respect to claims 1 and 11 in Ground 2, it would have been obvious to modify Blain to include the Bray's restraining plate as an alternative to it. The restraining plate prevents the fasteners 6 of Blain from backing out of (or separating from) the fusion implant 2. Thus, the restraining plate *locks* each fastener 6 (*independent anchoring member*) to the fusion implant 2 (*fusion member*). Moreover, Bray explicitly teaches that the restraining plate 60 is fixed into place after the bone screws 50 have been "inserted into the bone screw holes 140 and the

bone screw slot 180” and threaded to the vertebral bodies. Ex. 1006, 10:35-50. This means that the *locking* occurs *once the anchoring member is fully advanced through the channel of the fusion member*.

The Other Challenged Claims

As explained in Ground 1, claims 2-4, 6, 15 and 17 are disclosed by Blain. *See supra* Section IX.A. Thus, those claims are also met by Blain as modified by Bray.

C. Ground 3: Whether Claims 5 and 16 are Obvious Based on Blain (With or Without Bray) Further in View of Steffee.

192. It is my opinion that it would have been obvious to modify Blain (with or without the modifications based on Bray) to incorporate a curved anchor as taught by Steffee to minimize post-surgery migration of the implant and anchors. My opinions with regard to the claims challenged under this ground are set forth below and incorporate by reference my opinions in Grounds 1 and 2.

193. Steffee is from the same field of endeavor as the '805 Patent, which includes “surgical procedures for spinal fusion and stabilization.” Ex. 1001, 1:19-21. Steffee relates to “a fastener for securing bone graft between a pair of bone portions.” Ex. 1016, 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 VIII.C. 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. 1016, 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, 1:49-67; Ex. 1033, 1:35-38), and together with implants (Ex. 1018, 3:39-44; Ex. 1032, 2:65-3:3). Thus, Steffee is from the same field of endeavor as the '805 Patent.

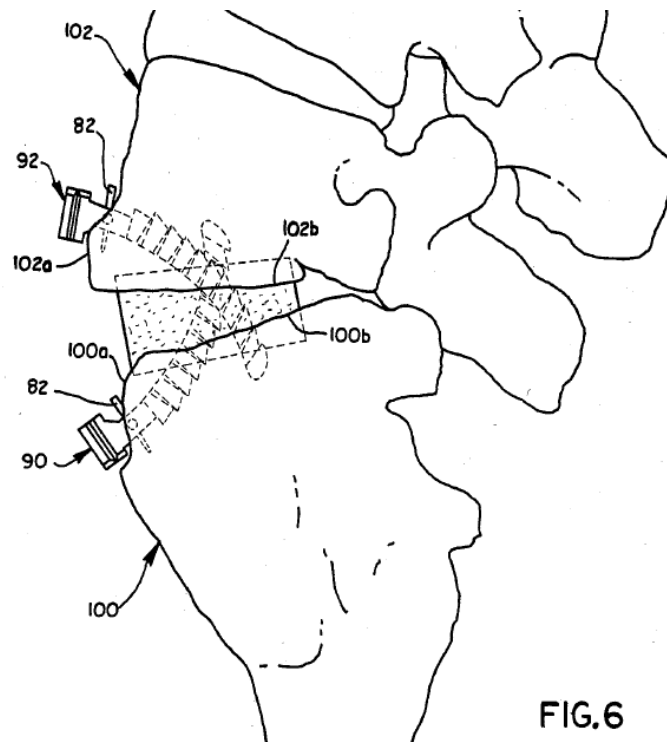
194. Steffee is also reasonably pertinent to a problem facing the inventor of the '805 Patent—improving the reliability of fusion “between unstable vertebral segments” to “avoid the considerable medical and economic impact of failed spinal fusions.” Ex. 1001, 2:1-5. As previously explained, a POSA understood that one reason spinal fusions failed was due to migration of the implant during the initial stabilization period. See Ex. 1033, 23:48-50 (explaining that “teeth” on the surface of implant plates may reduce migration of the device out of the intervertebral space); Ex. 1032, 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. 1034, 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. 1030, 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”).

195. 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. 1016, 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.

196. 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):



197. 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.

198. 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 straight 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.

199. A POSA would have found it obvious to modify Blain to incorporate Steffee's rigid curved anchors in order to prevent migration of the implant anchors which can lead to the anchors and implant backing out of from the vertebral bodies. This modification would also require modifying Blain's implant anchor channels and guide tubes to be slightly curved to accommodate the curvature of Steffee's rigid curved anchors.

200. Steffee explains that migration results in bone graft staples coming out. *Supra* Section VIII.C. In reference to Figure 6 of Steffee (below), migration is inhibited because each anchor is curved such that it traverses the vertebral body at an angle quasi-perpendicular to the angle upon which it entered the bone (e.g., the "entry angle"). For example, anchor 92 exits body 102 (adjacent 102b) at an angle quasi-perpendicular to the angle at which the anchor entered that body (adjacent 102a):

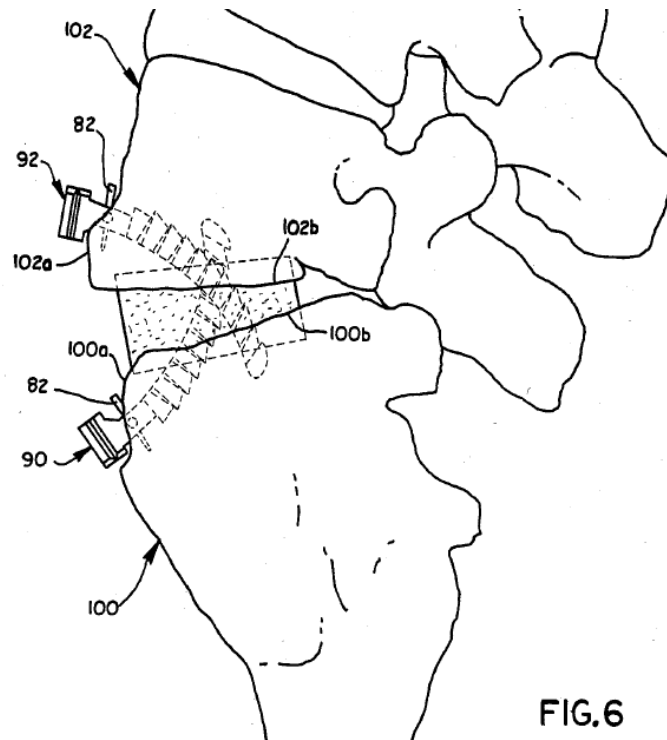


FIG. 6

This inhibits lateral (or sagittal) migration ordinarily caused by side-to-side movement, because the path of the anchor is non-linear and because the anchor path is quasi-perpendicular to the forces that cause sagittal (or lateral) movement. In other words, if the anchors were straight—a side-to-side force along the shaft of the anchors more easily results in migration of the anchors and implant than if the anchors are curved in a direction quasi-perpendicular to those forces.

201. While Steffee addresses migration relating to staples used to affix bone graft between vertebral bodies, migration was a well-known and understood problem with interbody implants with anchors as well. *See e.g.*, Ex. 1034, 13:17–30; Ex. 1030, 1:31–39; Ex. 1032, 4:61–64; Ex. 1033, 23:48–50. For an interbody implant to

move, it must either go forwards/backwards and/or side-to-side. In other words, the implant moves parallel to the plane (sagittal) of the vertebral body endplates.⁴ A POSA would have readily recognized and appreciated that, just as the curved anchor of Steffee inhibits migration that causes staples to come out, a curved anchor would provide the same benefit of inhibiting migration that causes straight implant anchors (like Bray's) to come out or loosen. For example, POSAs understood that using a curved anchor (as in Steffee) would allow for the anchor to be inserted relatively laterally through the side of the vertebral body, while also allowing the anchor to curve through the bone in a direction quasi-perpendicular to the sagittal forces that cause migration, reducing the effect of those forces on the anchors and implant.

202. POSAs understood that straight fasteners (e.g., the prior art staples discussed in Steffee and Blain's screws) follow a linear (or straight) path. This means that such fasteners were more susceptible to the migration forces described in Steffee, which sometimes leads to the fastener pulling out from the bone. Accordingly, a POSA was motivated to use a curved anchor such as that disclosed in Steffee, because it would allow the anchor to traverse the vertebral body in a

⁴ Subsidence of the implant into the vertebral bodies is another problem that can cause slight movement, but this is not relevant to the migration problem being discussed.

quasi-perpendicular (or non-linear) path relative to the entry angle of the anchor into the vertebral body and the forces that cause unwanted sagittal movement. The non-linear path of the anchor would minimize the lateral forces acting on the anchor and the implant, therefore minimizing lateral movement (or mitigation) of the implant.

203. A POSA would have also recognized that having two curved fasteners that curve in non-identical directions (as taught by Steffee), would further resist migration. In order for the implant to move with opposing curved anchors that are coupled with the implant, the force to move the implant away from one of the anchors would be directly against the other anchor and vice versa, Thus, making it very difficult for the implant to migrate. In addition to this benefit, POSAs understood that anchor screws could strip (e.g., due to over-torquing), but rigid barbed anchors such as those in Steffee do not have that risk. This is because such barbs are pushed into the vertebral body and stopped when the anchor head hits the implant. . When screws hit the implant head, the threads still want to advance in the bone if it is continued to be turned which results in the threads stripping in the bone. Consequently, a POSA would view curved barbed anchors as providing this additional advantage over threaded anchors, even though screws may be slightly easier to drive in compared to barbed anchors.

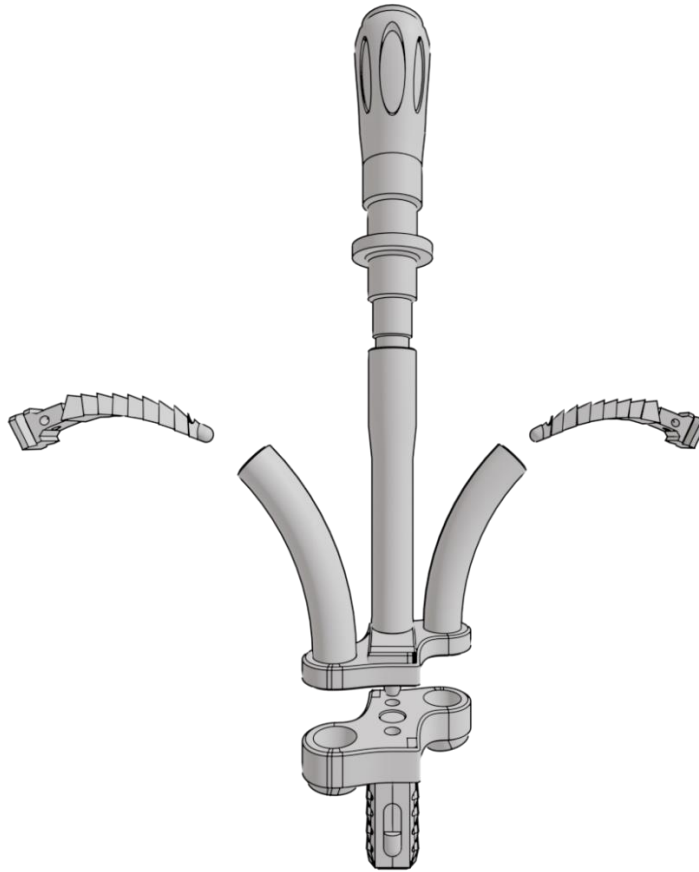
204. Steffee also teaches that its curved fastener is “simple yet extremely effective” for interbody fusion. Ex. 1016, 2:29-33. A POSA would understand this to be an express teaching, motivation, or suggestion to use such anchors with interbody implants used for fusion, particularly given that the same or similar forces are present during interbody fusion regardless of whether an implant is used. A POSA would have found it obvious to try using the rigid curved anchor of Steffee with the implant of Blain (with or without Bray), based on Steffee’s express teaching that the anchor is “extremely effective” and “simple.”

205. A POSA also understood that the shape of the implant channels should match the shape of the anchor shaft to facilitate guiding the anchors into the vertebral bodies, as the curved anchors are rigid and cannot deform to conform to anchor channels that follow a straight path. Consequently, a POSA would have been motivated to modify Blain to rely on rigid curved anchors (as taught by Steffee), and to further modify Blain’s guide tubes and channels to have curved shape that corresponds to the shape of the curved anchors.

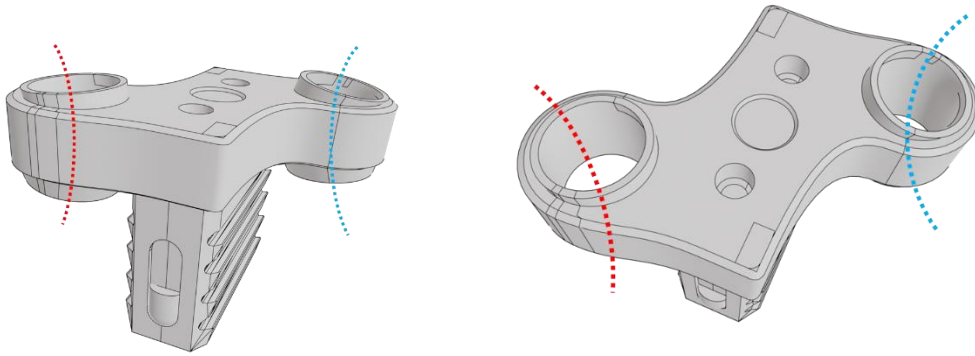
206. A POSA would have recognized that the use of curved anchors was suitable for use with an implant device such as that shown in Blain. Indeed, the use of curved anchors with spinal implants was not novel. *Id.* (citing Ex. 1035, 2:57–61; Ex. 1019, 7:14–25). A POSA understood that modifying Blain to incorporate a

curved anchor would have required simply replacing the anchoring screws 6 of Blain with curved barbed anchors similar to those of Steffee and modifying the fastener channels (of implant 2) and guide tube 18 channels (of guide instrument 14) to have shapes complementary to the curved anchors, such that the fastener channels are curved. In fact, Blain teaches that its guide tubes 18 “may have a tubular or trough-like configuration and may be linear or **non-linear**” and further that “non-linear guide members may facilitate access to difficult anatomical sites.” Ex. 1004, 8:8–16; Ex. 1005 ¶[0035]. Thus, Blain contemplates and suggests using guide tubes with curved channels, and POSAs understood that the anchor channels of the implant 2 and guide tubes 18 should be at least slightly curved to accommodate the curvature of the anchors. It was understood that curved channels would have been necessary to ensure that the rigid anchors did not become stuck or trapped when attempting to drive them through the screw/drill guides during surgery. It was also understood that curved channels would also make it easier to drive the anchors to the desired location by reducing the amount of friction between the anchors and inner-wall of the channels.

207. Petitioner provides figures below showing how simple modifying Blain’s implant and guide instrument would be:



The above figure depicts the instrument guide, implant, and fasteners of Blain as modified as proposed based on Steffee. The below figures depict the implant at various angles, and show that the anchor channels (red-dashed, blue dashed lines) are slightly curved to accommodate the shape of the curved anchor.



208. I have also had a conceptual mock-up created based on Figure 6 of Steffee (as shown below), to generally show how the Blain-Steffee implant would be situated between the vertebral bodies:

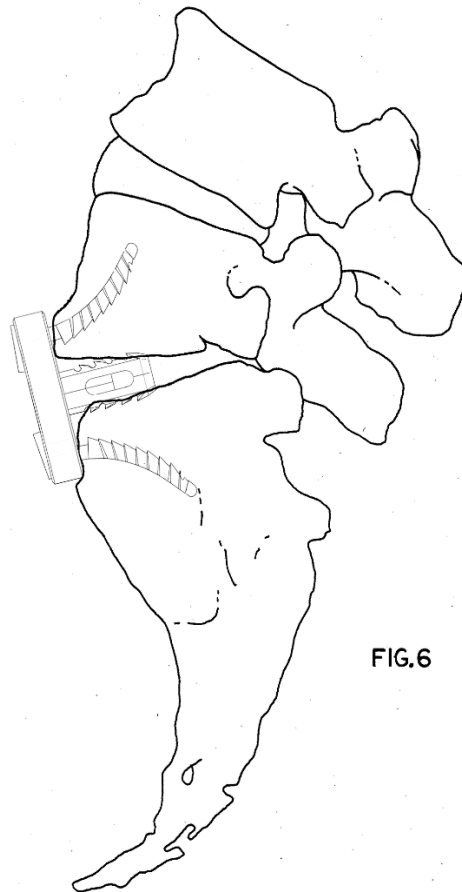


FIG.6

209. POSAs understood and found it obvious that, once these minor modifications are made, an impact driving tool (e.g., surgical hammer) would be used to drive the barbed anchors into their respective vertebral bodies as taught by Steffee. Ex. 1016, 3:4–13. Blain itself teaches, “other [driving] tools are known in the art and may be used with the non-linear guide members.” Ex. 1004, 8:14–16. Impact driving tools for anchors were common, and hammers were a commonly used such tool, as demonstrated by Steffee. Ex. 1036 ¶[0142] (discussing the use of impactor 160 and slap hammer 164 so that the bone anchor can be “driven into the bone path 76”); Ex. 1004, 8:13-16 (explaining that “[n]on-linear or flexible drills, screw drivers and other tools are known in the art and may be used with the non-linear guide members”). Thus, impact tools for use with anchors deployed through non-linear channels was known in the art and a POSA would have readily understood that such tools could be used to drive the curved anchors through Blain’s modified implant and instrument guide.

210. A POSA would have had a reasonable expectation of success in making these proposed modifications, which would only entail modifying Blain’s anchors to be curved and barbed and modifying the contours of the guide tubes and fusion member channels to fit the concave surface of Steffee’s fasteners along the curved path taken by the fastener. This would require only the use of basic machining

IPR2025-00225

U.S. Patent No. 9,730,805

principles well known to a POSA. In this obvious combination, the implant of Blain as modified by Steffee comprises channels that follow a curved path (like the “curved channels” discussed in the ’805 Patent) to accommodate the curved anchors.

X. CONCLUSION

211. 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