

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDACTA USA, INC., PRECISION SPINE, INC., and LIFE SPINE, LLC

Petitioners,

v.

RSB SPINE, LLC,

Patent Owner.

Case No. IPR2020-00275

Patent No. 9,713,537

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,713,537
CHALLENGING CLAIMS 1, 3-6, 10, 13-15, 18-19, 21-22, 24, 29-30**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	MANDATORY NOTICES	1
A.	Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))	1
B.	Related Matters (37 C.F.R. § 42.8(b)(2)).....	1
C.	Counsel (37 C.F.R. §42.8(b)(3)) and Service Information (37 C.F.R. §42.8(b)(3)-(4)).....	2
III.	CERTIFICATION AND FEES.....	3
IV.	IDENTIFICATION OF CLAIMS AND GROUNDS.....	3
V.	BACKGROUND	5
A.	The '537 Patent	5
B.	Prosecution History	9
1.	Prosecution of the '537 patent	9
2.	Prosecution of the '234 patent	13
3.	Statement pursuant to 35 U.S.C. §325(d)	14
VI.	LEVEL OF ORDINARY SKILL.....	16
VII.	CLAIM CONSTRUCTION	16
	“SCREW RETAINER”	21
	ARGUMENT	22
VIII.	GROUND #1: MICHELSON '045 RENDERS CLAIMS 1, 4-6, 10, 13-14, 21-22, 24, 29 AND 30 OBVIOUS.....	22
A.	Claim 1	26
1.	A bone stabilization plate system comprising:	26
2.	a base plate having a top surface, first and second ends, a bottom surface, and a plurality of bone screw holes,	27
3.	wherein the base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion; and.....	30

4.	a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively;.....	33
5.	wherein the vertebral bones have top surfaces and have side surfaces generally facing each other;	33
6.	wherein a first of the bone screw holes, being configured to receive a first of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the side surface of a first of the vertebral bones;	35
7.	wherein a second of the bone screw holes, being configured to receive a second of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the lip osteophyte of a second of the vertebral bones; and	36
8.	wherein each and every one of the plurality of bone screw holes is configured to receive one of the bone screws angled relative to the base plate and oriented generally in an anterior-posterior direction through at least partially the top surface of the base plate.	40
B.	Claim 4	42
C.	Claim 5	43
D.	Claim 6	44
E.	Claim 10	45
F.	Claim 13	47
G.	Claim 14	48
H.	Claim 21	49
1.	A bone stabilization plate system for anchoring between side surfaces of first and second adjacent vertebral bones, comprising:.....	49

2.	a base plate having a top surface, a first end nearer the first bone comprising a first bone screw hole extending at least partially therethrough and a first bone engaging region fully extending uninterrupted between lateral extents of the first end, a second end nearer the second bone comprising a second bone screw hole extending at least partially therethrough, and a bottom surface, and.....	50
3.	configured to fit primarily between an anterior portion of the first bone's lip osteophyte and an anterior portion of the second bone's lip osteophyte while bearing weight to hold the bones for fusion; and.....	52
4.	a first bone screw configured to secure the base plate to the first bone by insertion through the first bone screw hole and to extend from at least partially the top surface of the base plate to at least partially the side surface of the first bone, and.....	52
5.	a second bone screw configured to secure the base plate to the second bone by insertion through the second bone screw hole and to extend from at least partially the top surface of the base plate to at least partially the side surface of the second bone.....	53
I.	Claim 22	54
J.	Claim 24	55
K.	Claim 29	57
L.	Claim 30	57
M.	Claims 14, 21, and 24.....	58
IX.	GROUND #2: MICHELSON '045 IN VIEW OF BYRD RENDERS CLAIMS 3, 15 AND 18-19 UNPATENTABLE AS OBVIOUS	60
A.	Claim 3	60
B.	Claim 15	62
1.	A bone stabilization plate system comprising:	62
2.	a base plate having a plurality of bone screw holes, a top surface, a generally flat bottom surface and first and second ends	63

3.	for retaining bone graft material between adjacent vertebral bone bodies having top surfaces and having side surfaces generally facing each other,	64
4.	wherein the base plate is configured to fit primarily between anterior portions of the bone bodies' lip osteophytes, without covering significant portions of the top surfaces of the bone bodies,	66
5.	to primarily bear weight, and to permit force transmission between the bone bodies through the bone graft material while holding the bone bodies for fusion; and.....	67
6.	a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into the lip osteophytes,	68
7.	with each of the bone screws being configured to extend from at least partially the top surface of the base plate to at least partially the side surface of one of the bone bodies, such that the base plate is secured.	68
C.	Claim 18	69
D.	Claim 19	70
E.	Reasons and Motivations to Combine Michelson '045 in view of Byrd.....	71
X.	GROUND #3: MICHELSON '045 IN VIEW OF FRASER '106 RENDERS CLAIMS 1 AND 14 UNPATENTABLE AS OBVIOUS	74
A.	Claim 1	74
B.	Claim 14	76
C.	Reasons and Motivations to Combine Michelson '045 in view of Fraser '106	77
1.	A POSITA would have considered both Michelson '045 and Fraser '106 because they are analogous art	78
2.	There is an express motivation to combine Michelson '045 and Fraser '106	81
3.	The combination of Fraser '106 and Michelson '045 would have yielded an improved spinal implant	82

XI.	GROUND #4: MICHELSON '045 IN VIEW OF FRASER '106 AND BYRD RENDERS CLAIM 15 UNPATENTABLE AS OBVIOUS	83
A.	Claim 15	83
B.	Reasons and Motivations to Combine Michelson '045 in view of Fraser '106 and Byrd	85
XII.	CONCLUSION	88
	CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS.....	89
	CERTIFICATE OF SERVICE	90

PETITIONERS' EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
Ex.1001	U.S. Patent No. 6,984,234 to Bray (“the ’234 patent”)
Ex.1002	U.S. Patent No. 9,713,537 to Bray (“the ’537 patent”)
Ex.1003	Patent Prosecution History of the ’234 patent
Ex.1004	Patent Prosecution History of the ’537 patent
Ex.1005	Declaration of Michael Sherman
Ex.1006	International Publication No. WO 2000/066045A1 (“Michelson ’045”)
Ex.1007	U.S. Patent No. 6,432,106 to Fraser (“Fraser ’106”)
Ex.1008	U.S. Patent No. 7,077,864 to Byrd (“Byrd”)
Ex.1009	Proposed Claim Constructions
Ex.1010	U.S. Patent No. 7,112,222 to Fraser (“Fraser ’222”)
Ex.1011	U.S. Patent No. 6,231,610 to Geisler (“Geisler”)
Ex.1012	U.S. Patent No. 6,066,175 to Henderson (“Henderson”)
Ex.1013	U.S. Patent No. 5,800,433 to Benzel (“Benzel”)
Ex.1014	Reserved
Ex. 1015	Reserved
Ex. 1016	Reserved

Petition for *Inter Partes* Review
IPR2020-00275 (U.S. Patent No. 9,713,537)

Ex. 1017	Revised Claim Constructions
Ex. 1018	Reserved
Ex. 1019	Reserved

I. INTRODUCTION

Petitioners request *Inter Partes* Review (“IPR”) of claims 1, 3-6, 10, 13-15, 18-19, 21-22, 24, and 29-30 (the “Challenged Claims”) of U.S. Patent No. 9,713,537 (“the ’537 patent”). The Board should institute an IPR and cancel the Challenged Claims.

II. MANDATORY NOTICES

A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest are Medacta USA, Inc., Precision Spine, Inc., Life Spine, LLC (“Petitioners”) and Xtant Medical Holdings, Inc. (“Xtant”). Xtant is not a petitioner, but Petitioners list Xtant as a real party-in-interest out of an abundance of caution.¹

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The ’537 patent is related to several pending litigations. RSB Spine, LLC (“Patent Owner”) is asserting the ’537 patent and related U.S. Patent No. 6,713,234 (“the ’234 patent”) against Petitioners and other third parties in the following cases.

- *RSB Spine, LLC. v. Life Spine, LLC*, 18-cv-1972 (D. Del.);
- *RSB Spine, LLC. v. Medacta USA, Inc.*, 18-cv-1973 (D. Del.);

¹ Petitioners understand that Xtant objects to being identified as a real party-in-interest, and Xtant does not voluntarily agree to be identified as a real party-in-interest. Petitioners understand that Xtant reserves all rights to challenge its identification as a real party-in-interest.

- *RSB Spine, LLC. v. Precision Spine, Inc.*, 18-cv-1974 (D. Del.);
- *RSB Spine, LLC. v. RTI Surgical, Inc.*, 18-cv-1975 (D. Del.);
- *RSB Spine, LLC. v. Xtant Medical Holdings, Inc.*, 18-cv-1976 (D. Del.); and
- *RSB Spine, LLC. v. DePuy Synthes, Inc.*, 19-cv-1515 (D. Del.).

Petitioners have filed four petitions:

- IPR2020-00274 challenging claims 1-10, 13, 14, 16, 18-20, 22, 24, 25, 28, 29, 31 and 32 of the '234 patent;
- IPR2020-00265 challenging claims 35, 37, and 39 of the '234 patent
- IPR2020-00275 challenging claims 1, 3-6, 10, 13-15, 18-19, 21-22, 24, 29-30 of the '537 patent;
- IPR2020-00264 challenging claims 1, 3-6, 10, 12-15, 18, 19, 21, 22, 24, 29, and 30 of the '537 patent.

Finally, related U.S. patent application no. 15/723,522 is currently pending.

As of the filing of this petition, no other judicial or administrative matters are known to Petitioners that would affect, or be affected by, a decision in an IPR of the '537 patent.

C. Counsel (37 C.F.R. §42.8(b)(3)) and Service Information (37 C.F.R. §42.8(b)(3)-(4))

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Please address all correspondence to lead and back-up counsel as shown above. Petitioner consents to electronic service by e-mail to all of the e-mail addresses provided. For compliance with 37 C.F.R. §42.10(b), a Power of Attorney is also filed concurrently herewith.

III. CERTIFICATION AND FEES

Petitioners certify that the '537 patent is available for IPR and that Petitioners are not barred or estopped from requesting this IPR on the grounds identified herein.

Pursuant to 37 C.F.R. §42.103, Petitioners authorize the USPTO to charge/refund Deposit Account No. 19-0741 for the required fees as well as for any fee deficiencies and credit overpayments.

IV. IDENTIFICATION OF CLAIMS AND GROUNDS

U.S. Pat. Application No. 10/419,652, which issued as the '234 patent, was filed on April 21, 2003. The '537 patent is a continuation-in-part application of the '234 patent. Petitioners treat **April 21, 2003** as the priority date ("Priority Date")

for purposes of this proceeding.

Because the filing date of the application that led to the '234 patent is before the effective date of the AIA, March 16, 2013, the pre-AIA statute applies.

The Grounds in this Petition rely on the following prior art references:

Michelson '045 (Ex. 1006). This application published on **November 9, 2000** as International Publication No. WO 2000/066045A1 ("Michelson '045"). Michelson '045 is prior art to the '537 patent under pre-AIA §102(b) because it was published before the Priority Date.

Fraser '106 (Ex. 1007). U.S. Patent No. 6,432,106 ("Fraser '106") to inventor Robert Fraser issued on **August 13, 2002**. Fraser '106 was filed on **November 24, 1999** and is prior art to the '234 patent under pre-AIA §102(a) and (e) because it published and was filed before the Priority Date.

Byrd (Ex. 1008). U.S. Patent No. 7,077,864 ("Byrd") issued on July 18, 2006. Byrd was filed on **February 5, 2003** and claims priority to provisional application No. 60/356,373 filed **February 12, 2002**. Byrd is prior art to the '537 patent under pre-AIA §102(e) because it was filed before the Priority Date.

Petitioners requests that the Board find each of the Challenged Claims unpatentable based on the following Grounds:

<u>Ground</u>	<u>Statutory Basis and Art Cited</u>	<u>Claims</u>
1	§103 – Obvious over Michelson '045	1, 4-6, 10, 13-14, 21-22, 24, 29-30

2	§103 – Obvious over Michelson '045 in view of Byrd	3, 15 and 18-19
3	§103 – Obvious over Michelson '045 in view of Fraser '106	1 and 14
4	§103 – Obvious over Michelson '045 in view of Fraser '106 and Byrd	15

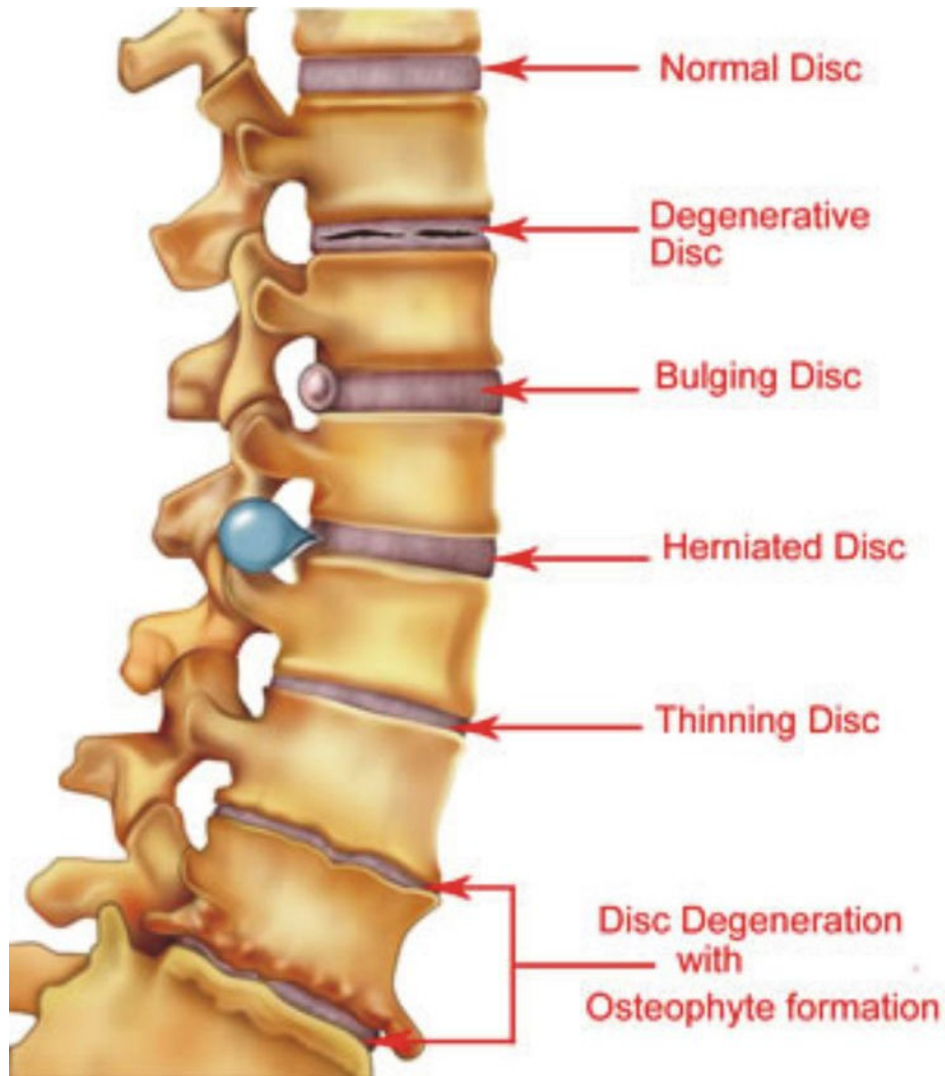
V. BACKGROUND

A. The '537 Patent

The '537 patent is directed “to implant devices for the fixation and support of bone bodies.” Ex.1002, 1:32-33; *id.*, 1:34-36. The '537 patent uses anatomical terms to refer to portions of the implant and/or bones. These terms are described below.

The '537 patent also refers to “vertebral bones,” which are found in the human spine. Ex.1002, 37:65-40:57. The '537 patent explains that “[t]he spinal column comprises a series of vertebrae stacked on top of each other.” Ex.1002, 1:42-43. It further explains “[e]ach vertebra has a cylindrical shaped vertebral body in the anterior portion of the spine with an arch of bone to the posterior which covers the neural structures” and that “[b]etween each vertebral body is an intervertebral disk, a cartilaginous cushion to help absorb impact and dampen compressive forces on the spine.” Ex.1002, 1:45-50. The specification also explains “[v]arious types of problems can affect the structure and function of the spinal column [including]...degenerative conditions of the intervertebral disk....”

Ex.1002, 1:55-59. Depicted below are examples of a healthy spine and degenerative spinal conditions.

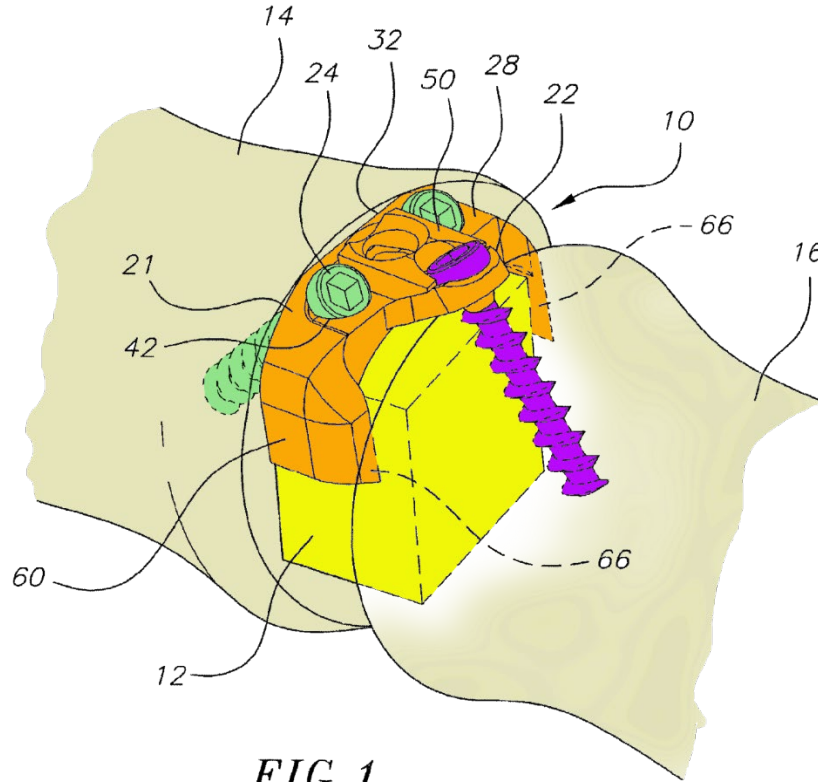


To treat these degenerative conditions, the specification discloses that it was known to fuse adjacent vertebrae together by “removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral bodies together.” Ex.1002, 2:3-6. The specification also discloses it was known that

“fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone.” Ex.1002, 2:7-10. The ’537 patent discloses two prior art implant designs that assist with stabilizing the bones and promoting fusion: a plate attached to the anterior surface of the bones, and an interbody device used with a spacer. Ex.1002, 2:32-59, 3:5-14.

Despite these disclosures and these prior art devices, the ’537 patent asserts that its claimed device is inventive for four reasons: (1) it is an interbody plate that is integral with a spacer, (2) it is fixed to a lip osteophyte with bone screws, (3) it is implanted between the bones so and does not extend beyond the anterior surface of the bones, and (4) it bears weight to hold the bones while sharing weight with bone graft material for fusion. Ex.1002, 1:32-36; 2:15-62; 4:38-47.

Specifically, Figure 1 of the ’537 patent, reproduced below, depicts one embodiment of the claimed base plate. Ex.1002, 5:63-65. The base plate 20 (orange) retains bone graft material 12 (yellow) between first vertebral body 14 and second vertebral body 16. Ex.1002, 8:46-52. The base plate 20 also includes first bone screw 24 (green) and second bone screw 25 (purple) to retain the base plate between the vertebral bodies 14 and 16.



The '537 Patent, Ex.1002, Fig.1²

This embodiment is also depicted in Figure 3 below, and displays the outwardly-facing top surfaces (blue) and side surfaces (red) of each bone 14, 16. The base plate 20 (orange) is inter-fit between the first bone 14 and second bone 16, and is adjacent to lateral extents of the bone graft material 12 (yellow). The first bone screw 24 (green) and second bone screw 25 (purple) extend into the first and second vertebral bodies, respectively, to retain the base plate between the

² Text annotations in red, various colors added to the drawings, and some figures are rotated, unless otherwise noted.

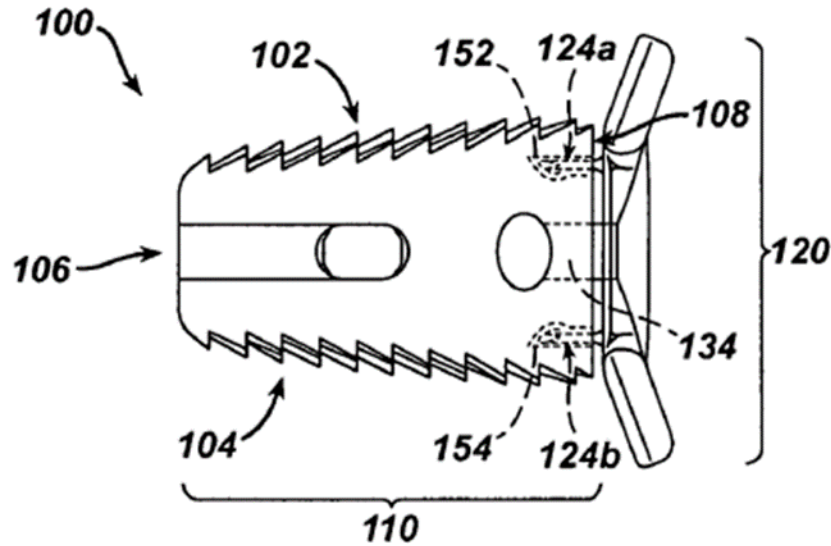


Ex.1002, Fig.3

B. Prosecution History

1. Prosecution of the '537 patent

9



Fraser '222, Ex.1010, Fig.1

On April 7, 2017, the applicant initiated an interview with the Examiner to discuss the March 10, 2017 rejection in view of Fraser '222. In the applicant's summary of the interview, the applicant also emphasized that the pending claims were distinct from Fraser '222 because "the [Fraser '222] **plate 120 is for application onto the anterior side/face of vertebral bones** [and it] was noted that **the plate 120 is not for location between the bones** [as required by the pending claims], and the [Fraser '222] plate has apertures 122a-d that **places all of the bone screws onto the anterior side/face of vertebral bones.**" Ex.1004 at 218 (emphasis added).

On April 27, 2017, the applicant initiated a second interview with the Examiner to discuss potential amendments to the claims. However, during this

interview, the Examiner presented Geisler and Henderson as additional prior art references. To overcome these additional references, the applicant argued that these prior art base plates, like the implant in Fraser '222, cover the top surfaces of the bone, while the claims require the device to sit completely between the bones. Ex.1004 at 204, 218-19.

Depicted below are the Geisler and Henderson implants discussed by the Examiner and Patent Owner.

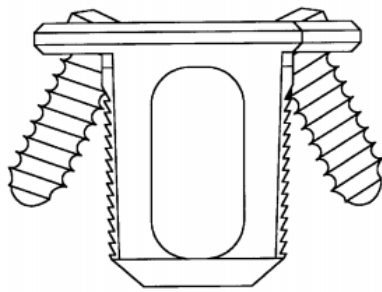


FIG-7

Geisler, Ex. 1011, Fig. 7

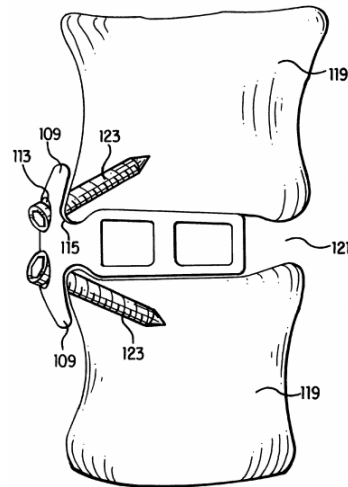


FIG.14

Henderson, Ex. 1012, Fig. 14

On May 11, 2017, the applicant initiated a third interview with the Examiner “to discuss claim 15 and potential amendments, in light of Henderson” and the Examiner summarized that interview by stating:

Applicant’s representative called to discuss claim 15 and potential amendments, in light of Henderson. Proposed amendments would include language similar to “without

covering significant portions of the top surfaces of the bone bodies...” **This language precludes Henderson, as it requires flanges extending from at least the midline of the space out over the osteophyte and nearly to the centerline of the vertebra. This structural difference of the present invention is not considered obvious because of a functionality difference in having a cover extending on the bones.**

Ex.1004 at 208 (emphasis added).

On May 26, 2017, Patent Owner amended the claims, incorporated the previous three Examiner interviews, and argued that Fraser ’222 did not anticipate the claims. Ex.1004, 211-215.

Based on these amendments, the applicant argued that these claims were distinct from Fraser ’222 because the “Fraser [’222], device is a two-part assembly 100” that includes “a fusion cage 110 and a separately applied plate 120.” Ex.1004 at 221.

In short, the applicant argued the Fraser ’222 base plate did not anticipate the amended claims because the Fraser ’222 base plate: (1) did not bear weight from the vertebrae, (2) was attached to the anterior surface the bones, and (3) was a two-part plate and spacer system. Ex.1004 at 222.

In response to these amendments and arguments, the Examiner issued a notice of allowance, and stated the claims were allowable because:

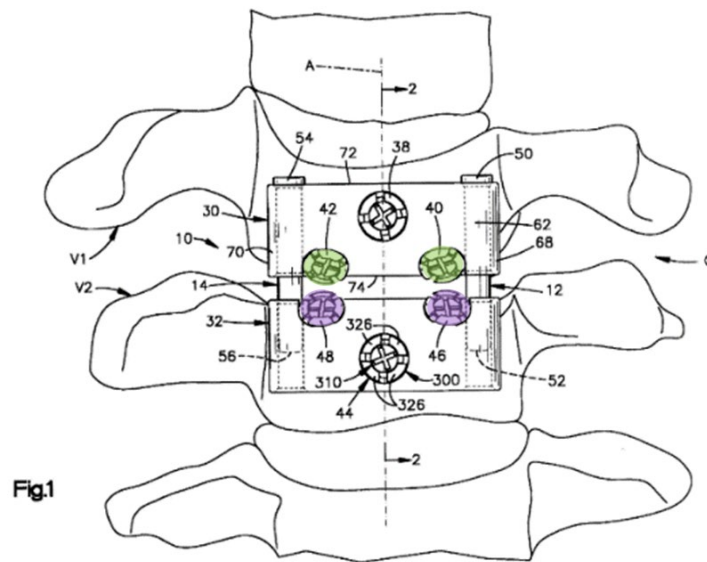
no reference of reasonable combination thereof could be found which disclose or suggest a bone stabilization plate with a base plate **configured to fit primarily between**

anterior portions of adjacent bones' lip osteophytes, wherein first and second bone screw holes extend partially from the top surface of the base plate and opens at least partially toward the side surface of the vertebral bones, as in claim 1.”

Ex.1004 at 233 (emphasis added).

2. Prosecution of the '234 patent

U.S. Patent Application No. 10/419,652, which issued as the '234 patent, was filed on April 21, 2003. The '234 patent is the parent of the '537 patent. On May 24, 2005, the Examiner issued a non-final office action rejecting the claims as anticipated by U.S. Patent No. 5,800,433 (“Benzel”). A depiction of the Benzel device is below.



Benzel, Ex.1013, Fig.1

On August 18, 2005, the Patent Owner argued that Benzel did not disclose a base plate with “a *first end nearer the first bone* and a *second end nearer the*

second bone, where in the base plate has a *first screw hole extending through the first end* and a *second screw hole extending through the second end* . . .” Ex.1003 at 97 (emphasis in original). Instead, Patent Owner argued “the **fasteners 40 and 46 are provided through a middle portion of the plate, not at first and second ends**...as required by claim 1. Ex.1003 at 97-98 (emphasis added).

Thus, according to the Patent Owner, Benzel did not anticipate the claims because the claims require the screw holes to be near the top and bottom portions of the base plate, and those screw holes cannot be near the “middle portion of the plate.”

3. Statement pursuant to 35 U.S.C. §325(d)

Pursuant to 35 U.S.C. §325(d), the Board can deny institution of a trial if the same or substantially the same prior art or arguments were previously presented to the Office. To evaluate this issue, the Board considers the non-exhaustive factors listed in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586 (PTAB Dec. 15, 2017) (Paper 8). Here, the factors do not weight in favor of the Board declining to institute this trial.

First, Michelson ’045 and Fraser ’106, are materially different from the prior art applied during examination, which disclosed devices with screws inserted into the anterior surface of the vertebral bones. *See* Ex.1010 at Abstract, FIGS. 3, and 7-9; Ex.1011 at Abstract, FIGS. 6-8; and Ex.1012 at Abstract, FIGS. 1, 3-5, 9, and

14-15. Patent Owner argued that its claims were different from the previously applied references because its screws enter the side surfaces and lip osteophytes of the bones. However, unlike the previously applied prior art, and like the '537 patent, Michelson '045 and Fraser '106 disclose implants with screws that enter the side surfaces and lip osteophytes of the bones.

Second, Michelson '045 and Fraser '106 are not cumulative of the previously applied prior art because they disclose new screw insertion locations that were not discussed during prosecution.

Third, neither Michelson '045 nor Fraser '106 were mentioned during prosecution of the '537 patent, let alone substantively discussed or used as the basis for a claim rejection. Byrd was not disclosed during prosecution.

While, Michelson '045 and Fraser '106 were applied by a different examiner, evaluating different claims, during prosecution of a related application, that application was directed to a spacer/cage that permits a bone to subside after it was implanted, which is not at issue here.

Fourth, Petitioners are not presenting the same invalidity arguments regarding Michelson '045 and Fraser '106 that were made during the examination of the '537 patent (or were made during prosecution of a related application).

Fifth, the Examiner did not substantively address or use Michelson '045 or Fraser '106 as the basis for a claim rejection.

Finally, Petitioners rely on a new declaration of Mr. Sherman to explain why Michelson '045 and Fraser '106 (unlike the prior art relied on during examination) meet all of the limitations of the Challenged Claims.

In short, the *Becton Dickinson* factors weight in favor instituting this trial.

Even if the Board determines that this petition raises substantially the same prior art or arguments as those previously presented, which it does not, then the Board must still decide whether to exercise its discretion under § 325(d). *Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 8 at 7 (Apr. 3, 2017) (holding that the Board must consider whether petitioners should be given the opportunity to be heard).

VI. LEVEL OF ORDINARY SKILL

A person having ordinary skill in the art (“POSITA”) at the time of the alleged invention would have had at least a Bachelor of Science degree in the field of Mechanical, Biomechanical or Biomedical engineering as well as at least 5-10 years of experience designing and developing orthopedic implants and/or spinal interbody devices. Ex.1005 at ¶22.

VII. CLAIM CONSTRUCTION

In the district court litigation, the parties are engaged in claim construction. On December 2, 2019, Patent Owner, Petitioners, and non-petitioners Xtant and DePuy exchanged their initial list of Proposed Claim Terms for Construction.

Ex.1009; 1017. Patent Owner’s opening claim construction brief is due on February 12, 2020, the final claim construction brief is due on May 20, 2020, and the Markman hearing is scheduled for June 19, 2020. The parties are continuing to negotiate the scope of these proposed constructions. As such, the proposed constructions that the parties may rely on in district court are not finalized.

Petitioners do not believe that any of these disputed constructions are material to intuition of this petition. However, to ensure that the Board is aware of the parties’ current claim construction disputes, the key disputed terms are summarized below.

Base Plate	
Petitioners	Patent Owner
“A fixation plate to stabilize adjacent vertebrae for fusion, which is distinct from bone graft material deployed across a bone graft site and is not used with a load-bearing fusion cage. ”	“A fixation plate to stabilize adjacent vertebrae for fusion and distinct from a spacer and bone graft material deployed across a bone graft site.”

Patent Owner and Petitioners currently agree that a POSITA would understand the term “base plate” to include “a fixation plate to stabilize adjacent vertebrae for fusion” which is “distinct from bone graft material deployed across a bone graft site.” Ex.1009.

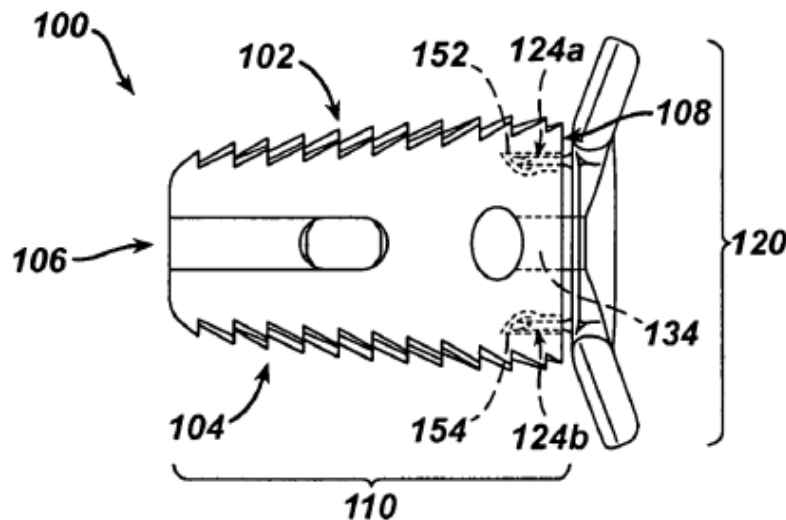
Patent Owner and Petitioners, however, currently disagree about two aspects

of this term. First, whether the base plate can be used with a load-bearing fusion cage, and second whether the base plate is distinct from a spacer.

With respect to the first issue, Patent Owner took the position during prosecution that the claims do not cover implants that use load-bearing spacers. In particular, to overcome Fraser '222, depicted below, Patent Owner distinguished its claims and argued that:

fusion cage 110 is load-bearing between the two vertebral bodies. The plate 120, which is applied after the load-bearing fusion cage 110 is already in place, keeps the load-bearing fusion cage 110 in place. The **plate 120 is applied, again after the load-bearing fusion cage 110 is in place**, to the respective anterior face of each of the two vertebral bodies.

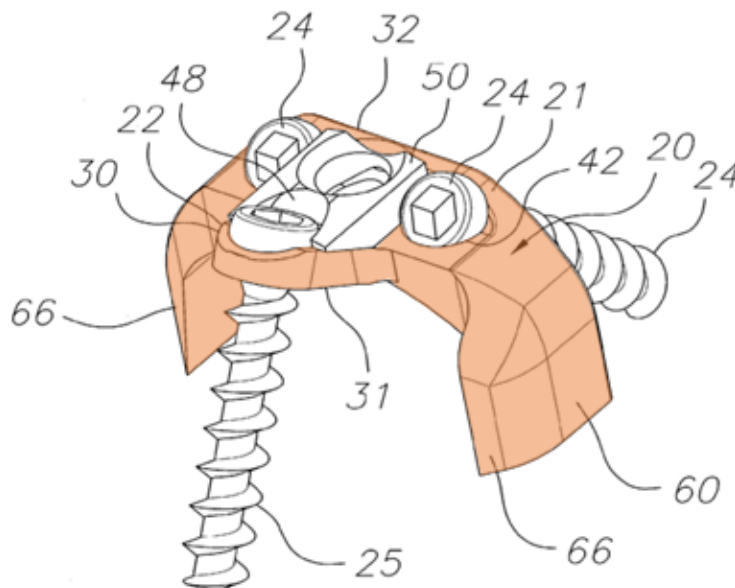
Ex.1004 at 222 (emphasis added).



In response, the Examiner issued a notice of allowance over Fraser '222's two-piece plate and fusion cage implant. Ex.1004 at 232-33. This prosecution history disclaimer is both clear and unambiguous, and, as such, restricts Patent

Owner from now arguing that the claimed base plate can be used with a separate load bearing spacer/cage.

With respect to the second issue, whether the base plate is distinct from a spacer, the intrinsic evidence directly contradicts Patent Owner's proposed construction. The entire disclosure of the '234 patent is directed to a base plate 20 (orange) that includes an integrated spacer 60.



The '234 Patent, Ex.1001, Fig.2

The '537 patent is also directed to a various types of plates, each with an integrated spacer.

Patent Owner's attempt to exclude a spacer in their proposed construction is wrong. The Federal Circuit frequently holds that "a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever,

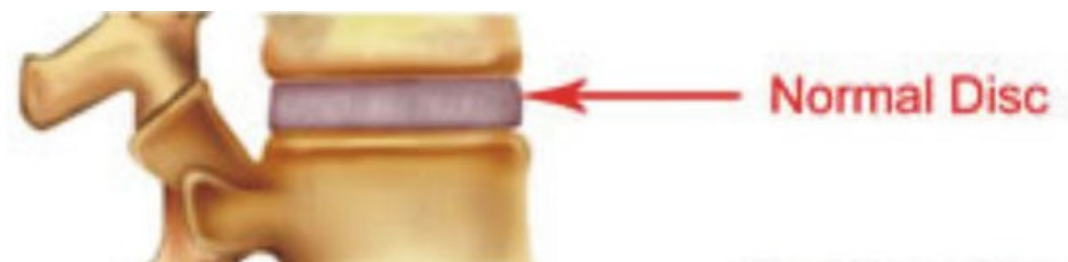
correct.” *See, e.g., On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*,
386 F.3d 1133, 1138 (Fed. Cir. 2004).

For at least these reasons, Petitioners’ proposed construction is correct.

“lip osteophyte” / “lip osteophite”	
Petitioners	Patent Owner
“bony outgrowth at the anterior corner of the bone and is structurally the strongest part of the bone”	“the lip of the vertebral body that is structurally the strongest part of the bone”

Patent Owner and Petitioners currently agree that a POSITA would understand the term “lip osteophyte” is a lip located the corner of the bone.
Ex.1009.

The parties, however, currently disagree about whether a lip osteophyte is a bony growth that projects away from the bone, as proposed by Petitioners. As discussed in Section V.A, a healthy bone does not have any lip osteophytes. However, as depicted below, when a disc degrades a POSITA would understand that lip osteophytes can form on the bones and that they extend away from the bone. Ex.1005 at ¶26.





For at least these reasons, Petitioners’ proposed construction is correct.

“screw retainer”	
Petitioners	Patent Owner
Function: “preventing at least one of the bone screws from backing out” Structure: “A single retaining plate and set screw, multiple retaining plates with set screws that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws.”	Plain and ordinary meaning

This term is governed by 112 ¶ 6. A POSITA would understand that the function is “preventing at least one of the bone screws from backing out,” and a POSITA would understand that the structures described in the specification for performing this specified function is a “single retaining plate and set screw, multiple retaining plates with set screws that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws.” Ex.1005 ¶55. However, as discussed below, the prior art references

disclose this element under either construction.

ARGUMENT

As shown below, the Challenged Claims of the '537 patent are unpatentable in view of the prior art references discussed herein. Each ground and the supporting reasons for the unpatentability of each Challenged Claim are discussed below.

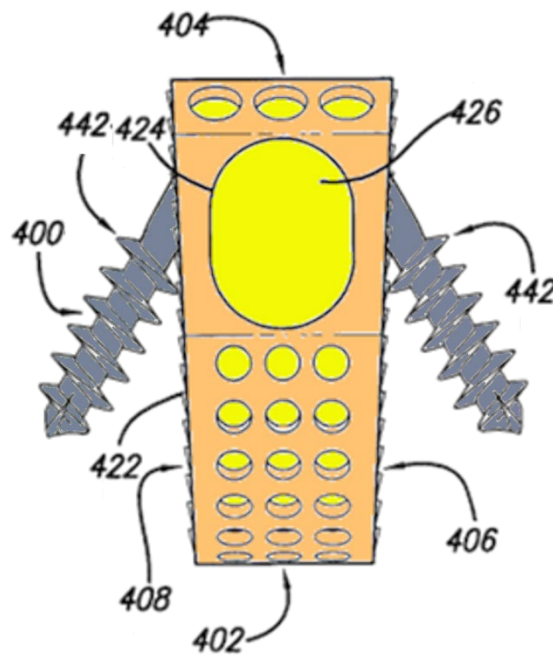
VIII. GROUND #1: MICHELSON '045 RENDERS CLAIMS 1, 4-6, 10, 13-14, 21-22, 24, 29 AND 30 OBVIOUS

For the reasons stated below, claims 1, 4-6, 10, 13-14, 21-22, 24 and 29-30 of the '537 patent are rendered obvious under 35 U.S.C. §103 by Michelson '045 and the knowledge of a POSITA.

Michelson '045 discloses a variety of improved interbody spinal fusion implants. Ex.1006 at 2 (“[t]he present invention relates generally to interbody spinal fusion implants.”). Specifically, Michelson '045 discloses that “[i]n order to perform anterior interbody spinal fusion, a significant amount of disc material is removed from the interspace to be fused” and then “the disc space is filled with an implant, which generally includes bone or bone in combination with a reinforcing structure, such as an artificial (other than bone) interbody spinal fusion implant.” *Id.* at 3. Michelson '045 also discloses that “interbody implants [are] adapted for placement within a disc space of the human spine between adjacent vertebral bodies, which implants have surfaces for contacting each of the adjacent vertebral

bodies.” *Id.* at 3. In short, an interbody spinal fusion implant replicates the size, shape, and location of spinal disc material. Ex.1005 at ¶65.

With respect to this petition, the primary embodiment in this ground is Michelson '045's implant 400, which is the interbody implant depicted below:

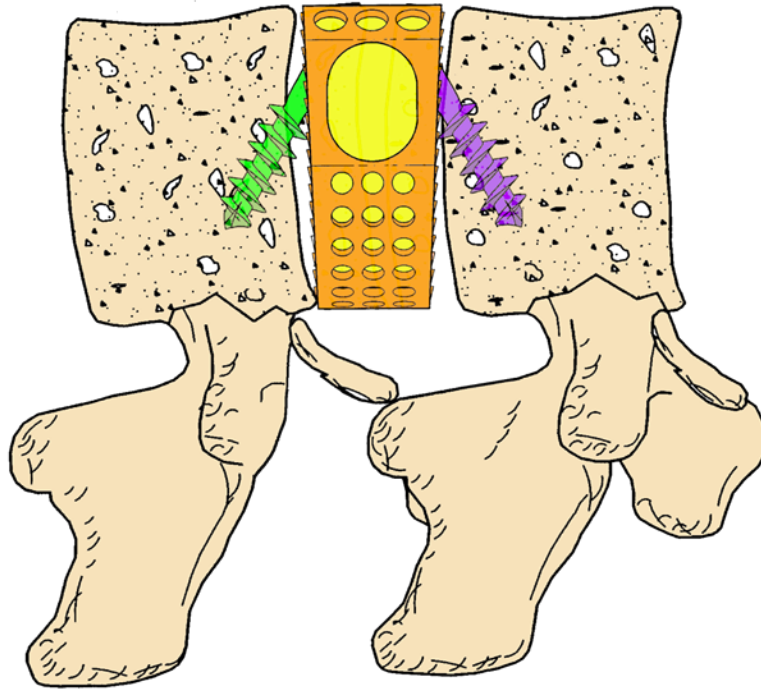


Michelson '045, Ex.1006, Fig.24³

Just like all interbody implants, Michelson '045 discloses that implant 400 “functionally substitutes for the anterior longitudinal ligament at the level to be fused, **without protruding from the spine.**” *Id.*

Mr. Sherman depicts implant 400 between two bones in the image below:

³ Annotations and color added to the drawings throughout, unless otherwise noted.



Michelson '045, Ex.1006, Fig.24 (depicted between two bones)

Following the style used in the '234 patent, Mr. Sherman also depicts implant 400 between two “box” style vertebral bones, and orients the anterior surfaces of implant 400 and the bones as the top of the image. The implant disclosed in the '234 patent and the Michelson '045 implant 400 are depicted below:

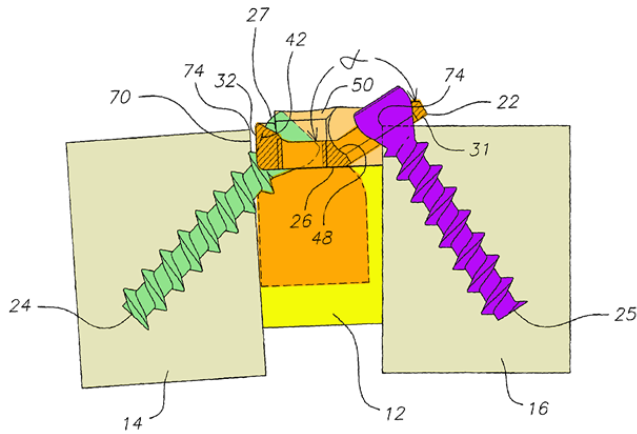
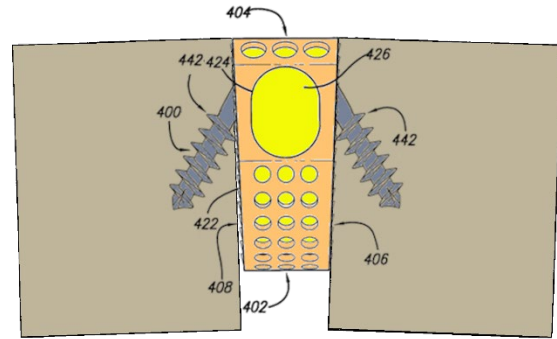


FIG. 3



'234 patent, Ex.1001, Fig.3

**Michelson '045, Ex.1006, Fig.24
 (depicted between bones)**

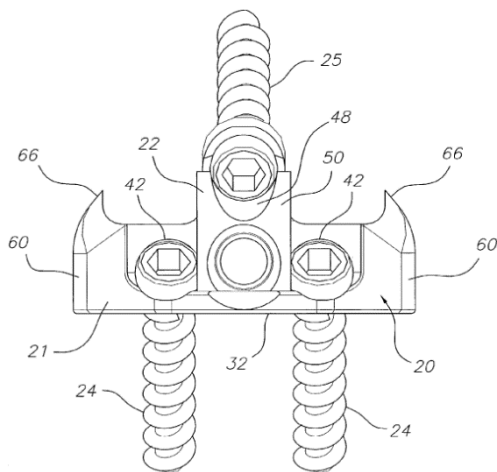
Although this is only one example of how implant 400 would be placed between two bones (*e.g.*, it could be placed in a more/less anterior position depending on the shape and condition of the bones, and the screws could be inserted at different angles) it is generally representative of how implant 400 would be placed in the spine. Ex.1005 at ¶70.

A. Claim 1

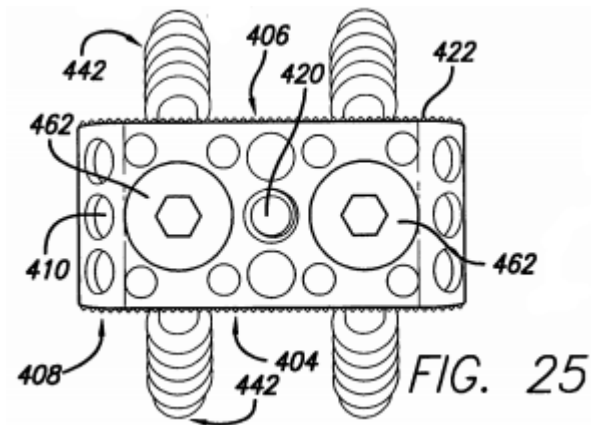
1. A bone stabilization plate system comprising:

The preamble is not a limitation of the claim because it does not breath life or meaning into the claim. *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012) (“as a general rule preamble language is not treated as limiting.”). Nonetheless, as shown below, Michelson ’045 discloses this limitation. Ex.1005 at ¶71.

As shown in the side-by-side comparison figures below, Michelson ’045 discloses the bone stabilization plate system recited by the ’537 patent. In particular, Michelson ’045 teaches “[t]he present invention relates generally to **interbody spinal fusion implants.**” Ex. 1006 at 2.



'537 patent, Ex.1002, Fig. 4



Michelson '045, Ex. 1006, Fig. 25

As such, Michelson ’045 discloses this limitation.

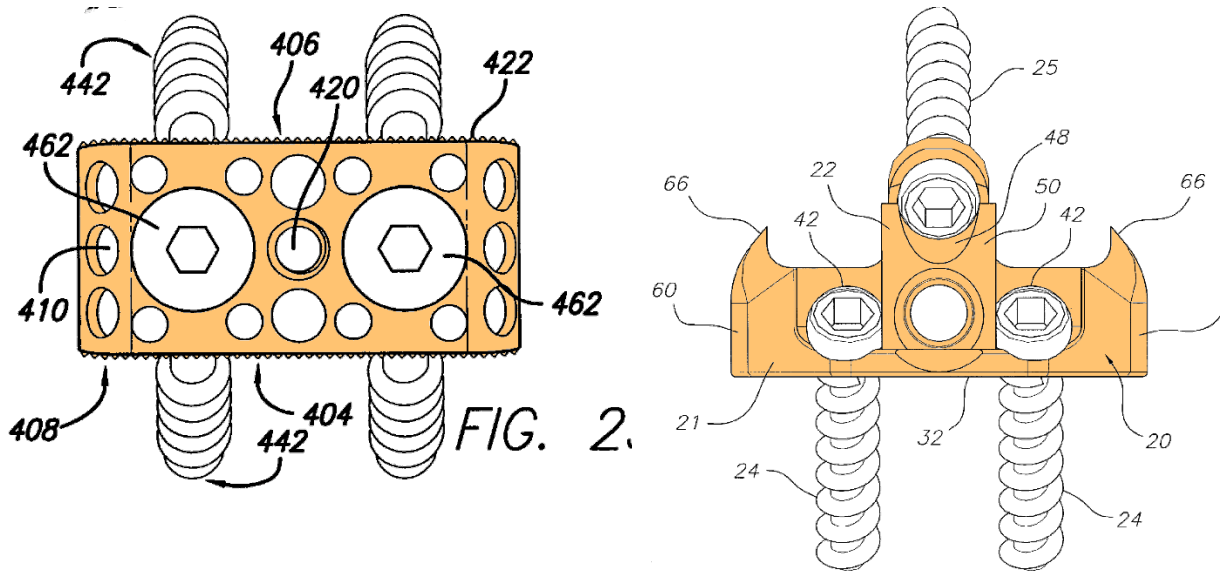
2. a base plate having a top surface, first and second ends, a bottom surface, and a plurality of bone screw holes,

This limitation includes three features: (1) a base plate, (2) a base plate with a top, bottom, and two ends, and (3) a base plate with bone screw holes.

Michelson '045 discloses this limitation and each of these features. Ex.1005 at ¶75.

As discussed in Section VII, the term “base plate” means “a fixation plate to stabilize adjacent vertebrae for fusion, which is distinct from bone graft material deployed across a bone graft site and **is not used with a load-bearing fusion cage.**”

As shown in the side-by-side comparison figures below, like the '537 patent, Michelson '045 discloses a fixation plate 400 to stabilize adjacent vertebrae for fusion. *See, for example*, Ex. 1006 at Fig. 25; Ex.1005 at ¶77



'537 patent, Ex.1002, Fig.4

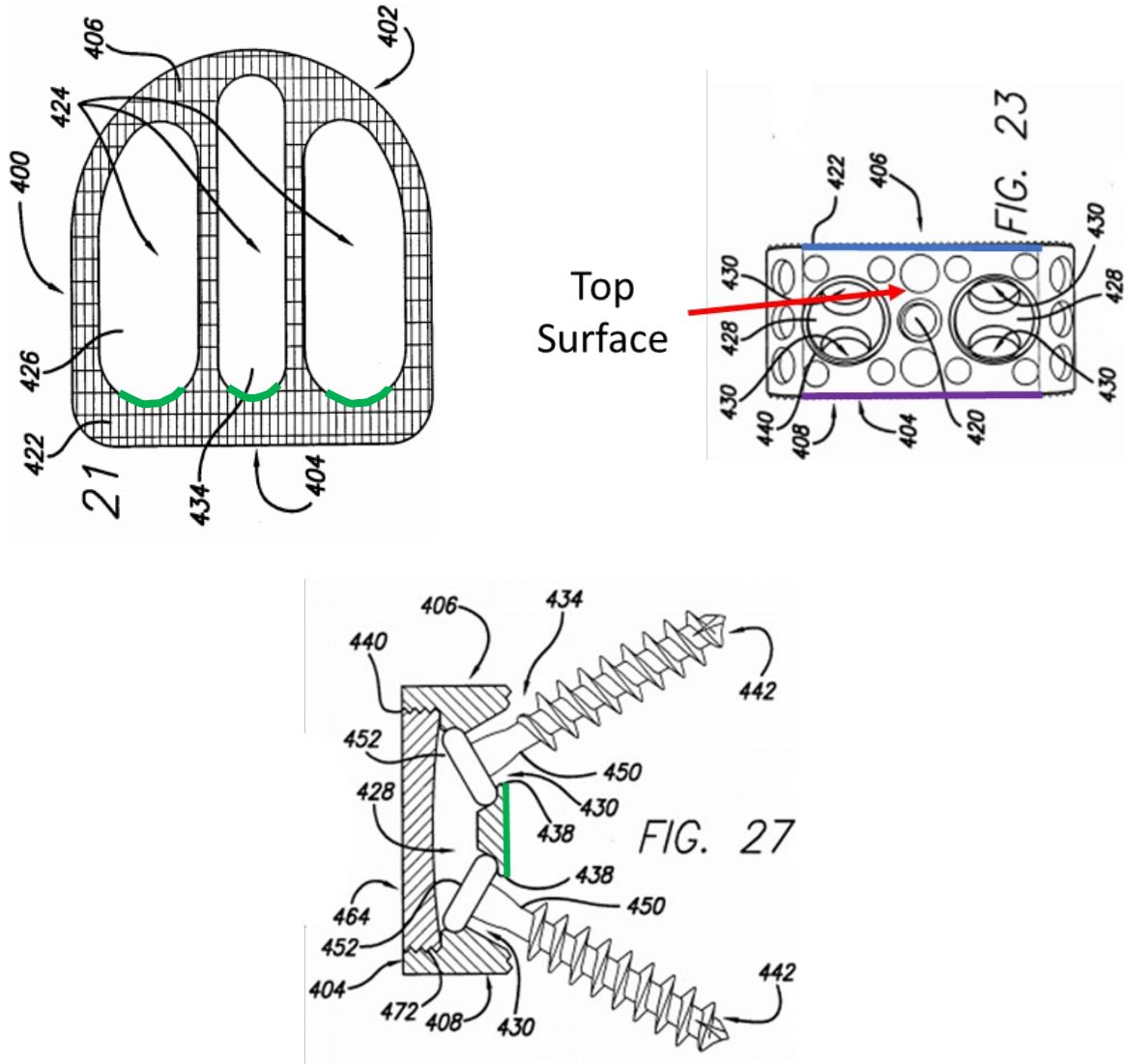
Michelson '045, Ex. 1006, Fig. 25

Michelson '045 further teaches its implant is distinct from bone graft material deployed across a bone graft site. Rather, Michelson '045 teaches the implants include openings for insertion of separate bone graft material. Ex. 1006 at 9.

Finally, Michelson '045 teaches its implant is integrated with a load-bearing fusion cage, and is not used with a separate load-bearing fusion cage or spacer. Ex. 1006 at. FIGS. 10-11, 46D, and 50-53, at pgs. 4, 13, and 22. As shown in the comparison above, like the '537 patent, Michelson '045 utilizes a single component implant without the need for a separate load-bearing fusion cage. Therefore, Michelson '045 discloses a **base plate**.

With respect to the second feature, a base plate with a top, bottom, and two ends, Michelson '045 discloses each of these aspects of the base plate, as depicted

in the figures below. Specifically, the base plate having a top surface (annotated in red), first (blue) and second ends (purple), and a bottom surface (green) are identified in figures 21, 23 and 27 below.

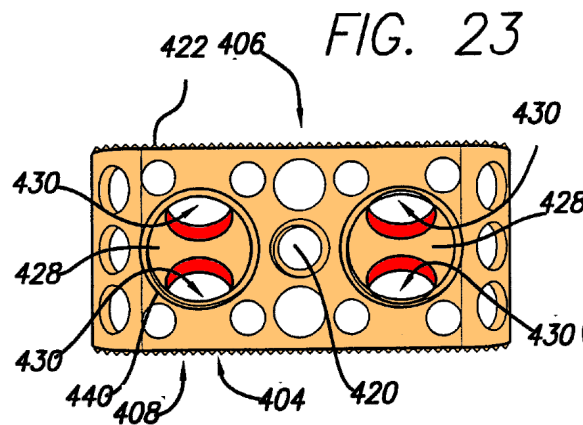


Michelson '045, Ex. 1006, Figs. 21, 23 and 27

Finally, with respect to the third feature, a base plate with bone screw holes, Michelson '045 teaches “[t]he implants of the present invention differ from all

prior art implants in that they are adapted to receive through their trailing ends at least a **pair of appropriately sized opposed bone screws** that can be directed at an appropriate angle, at least one each, into each of the adjacent vertebral bodies adjacent the disc space to be fused.” Ex. 1006 at 9; *see* Ex.1005 at ¶79.

The base plate having a plurality of bone screw holes 430 are identified below.



Michelson '045, Ex. 1006, Fig. 23

Therefore, as described above, Michelson '045 discloses this limitation.

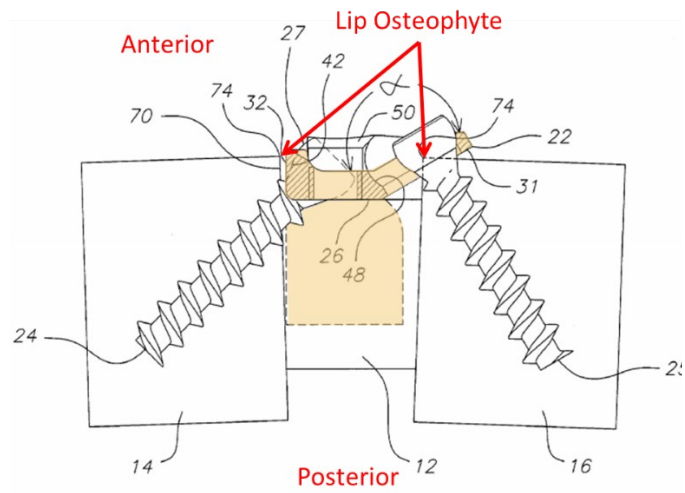
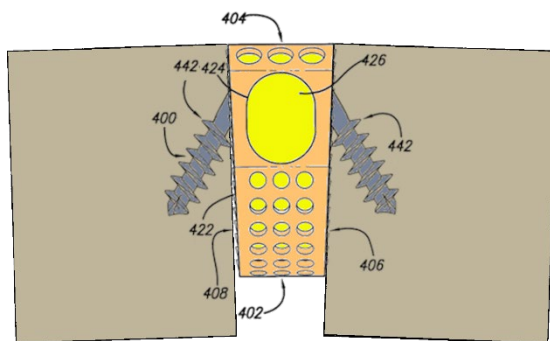
3. **wherein the base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion; and**

This limitation includes three features: (1) a base plate configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes, (2) a base plate that bears weight in conjunction with the bone graft material and,

and (3) a base plate that holds the vertebral bones for fusion. Michelson '045 discloses this limitation and each of these features. Ex.1005 at ¶82.

With respect to the first feature, a base plate implanted between the bones' lip osteophytes, as discussed above in Section VII.B., incorporated here, "lip osteophytes" means "**bony outgrowth at the anterior corner of the bone and is structurally the strongest part of the bone**".

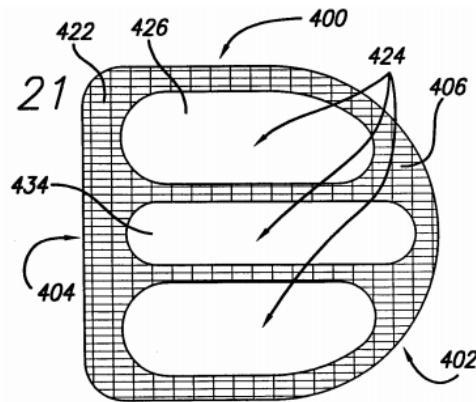
To the extent the embodiment depicted in figure 3 of the '537 patent discloses this limitation, so does Michelson '045. As shown by the side-by-side figures below, like the '537 patent, Michelson '045 discloses a base plate (orange) configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes:



'537 patent, Ex.1002, Fig. 3

Michelson '045, Ex.1006,
Fig.24 (depicted between bones)

With respect to the second feature, a base plate that bears weight in conjunction with the bone graft material, Michelson '045 teaches “[t]he present invention relates generally to **interbody spinal fusion implants.**” Ex.1006 at 2; Fig. 21 (below).



Michelson '045, Ex. 1006, Fig. 21

A POSITA would understand that when the implant 400 engages the surfaces of the vertebrae, the first and second bone bodies would be in direct contact and share the weight with the bone graft material. Ex.1005 at ¶88.

Michelson '045 discloses “increasing and more evenly distributing the compressive loads across the fusion site.” Ex.1006 at 6. As such, a POSITA would understand that Michelson '045 discloses that the first and second bone bodies engage the bone graft material and bear the weight. Ex.1005 at ¶88.

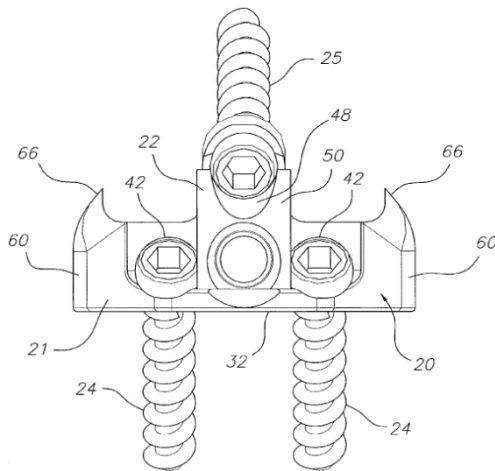
With respect to the third feature, a base plate that holds the bones, Michelson '045 teaches that “[b]one screws 442 further serve to **pull the vertebral bodies to**

upper and lower implant surfaces 406 and 408 so as to increase the compressive load thereon and mitigate against a loss of that compressive load.” Ex.1006 at 20.

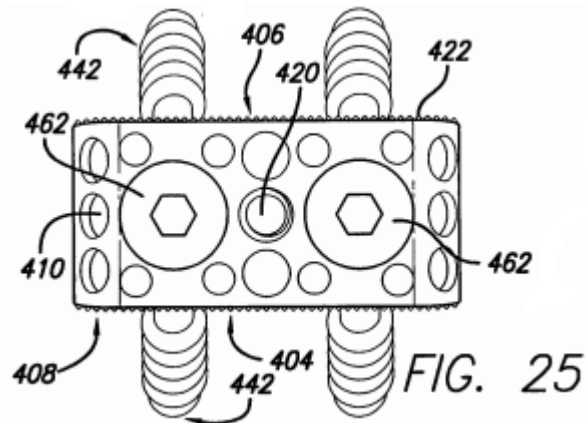
Therefore, as described above, Michelson '045 discloses this limitation.

4. a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively;

As shown by the side-by-side figures below, like the '537 patent, Michelson '045 discloses “a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively.” Ex.1005 at ¶91.



'537 patent, Ex.1002, Fig. 4



Michelson '045, Ex. 1006, Fig. 25

Therefore, Michelson '045 discloses this limitation.

5. wherein the vertebral bones have top surfaces and have side surfaces generally facing each other;

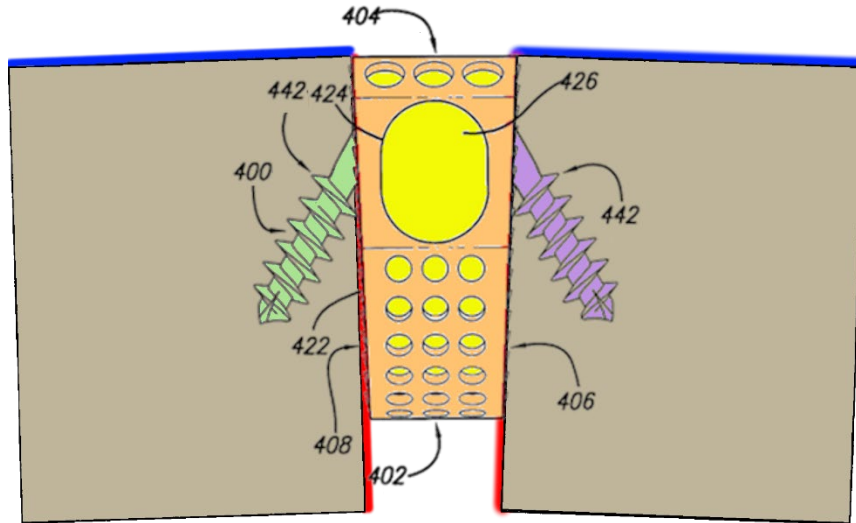
As an initial matter, this limitation merely describes the natural

configuration of a vertebral bone. The '537 patent specification explains that

“[t]he spinal column comprises **a series of vertebrae stacked on top of each other**” and “[e]ach vertebra has a cylindrical shaped vertebral body in the anterior portion of the spine with an arch of bone to the posterior which covers the neural structures.” Ex.1002 at 1:42-43, 45-48.

Additionally, Michelson '045 discloses this limitation. Michelson '045 is directed toward “implants to be **placed within a human spine**, at least in part, within **a disc space between adjacent vertebral bodies**, for the purpose of fusing together those two adjacent vertebral bodies across the intermediate disc space.” Ex.1006 at 9.

For example, Michelson '045 discloses two adjacent vertebral bodies having outwardly facing surfaces (identified in blue) and each vertebral body having a side surface (identified in red) facing toward the side surface of the other vertebral body (fig. 24 below). Ex.1005 at 97.

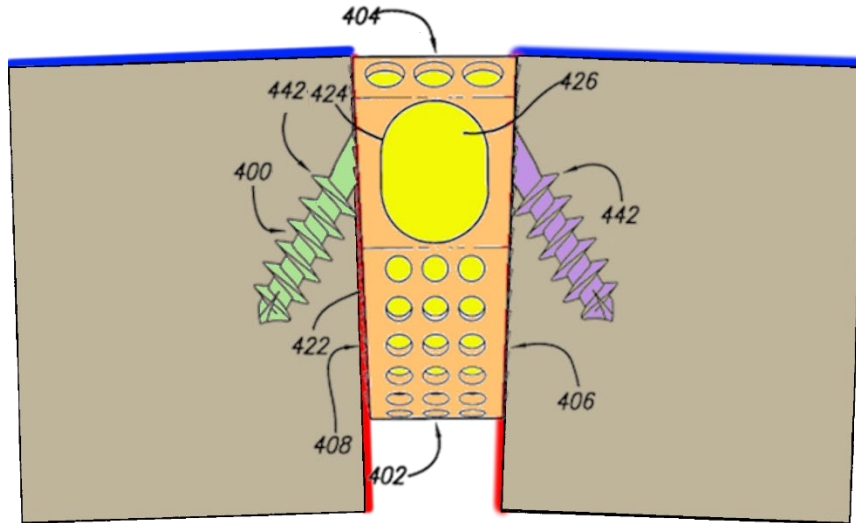


Michelson '045, Ex.1006, Fig.24 (depicted between bones)

Therefore, Michelson '045 discloses this limitation.

- 6. wherein a first of the bone screw holes, being configured to receive a first of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the side surface of a first of the vertebral bones;**

As shown by the figure below, like the '537 patent, Michelson '045 discloses “wherein a first of the bone screw holes, being configured to receive a first of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the side surface of a first of the vertebral bones.” The first of the bone screws are shown below in green and the side surface of the first vertebral bone is shown in red.



Michelson '045, Ex.1006, Fig.24 (depicted between bones)

Therefore, Michelson '045 discloses this limitation.

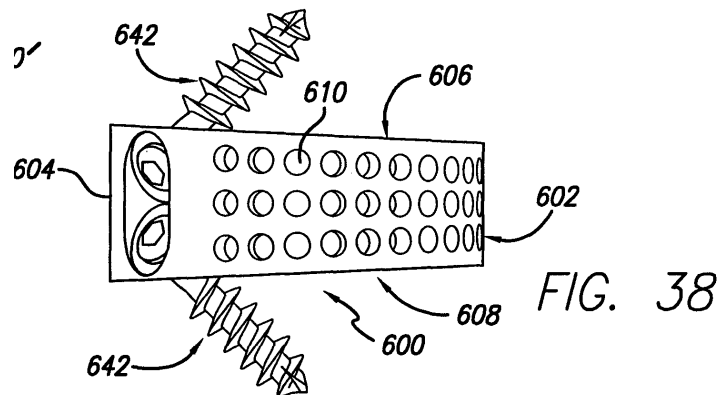
7. **wherein a second of the bone screw holes, being configured to receive a second of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the lip osteophyte of a second of the vertebral bones; and**

Michelson '045 discloses this limitation. As discussed above in Section VII.B., incorporated here, “lip osteophytes” means “bony outgrowth at the anterior corner of the bone and is structurally the strongest part of the bone.” Ex.1005 at ¶54.

As noted in the prior limitation, Michelson '045 discloses a screw hole with a wide range of screw insertion angles. This disclosure also includes a screw hole that opens toward the lip osteophyte of the bone. Ex.1006 at 17; *see also* Ex.1006 at claims 5 and 101. The disclosed angle ranges from between 25° and 75° from

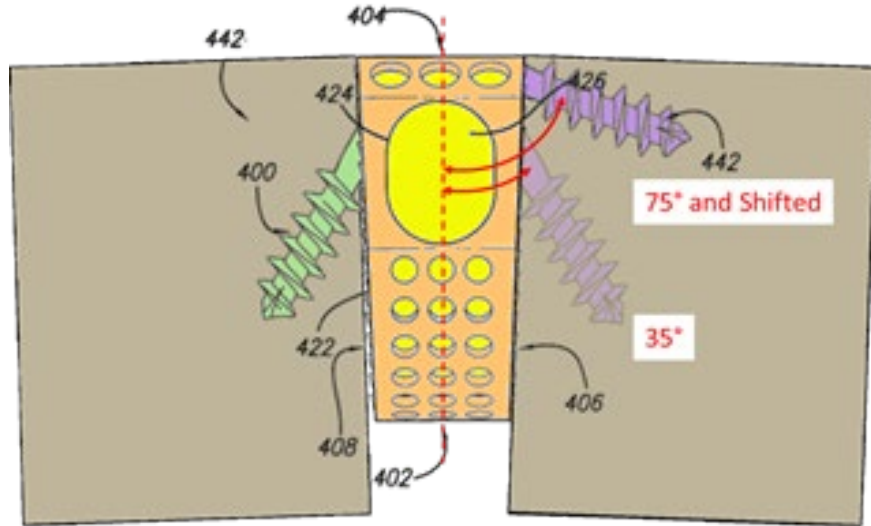
the mid-longitudinal axis of the implant, or from between 15° and 65° from the top surface.

Further, Michelson '045 teaches a wide range of locations for the screw hole in the base plate. For example, in implant 600, Michelson '045 discloses that the holes can be in the middle of the plate, or at the edges of the plate as depicted below.



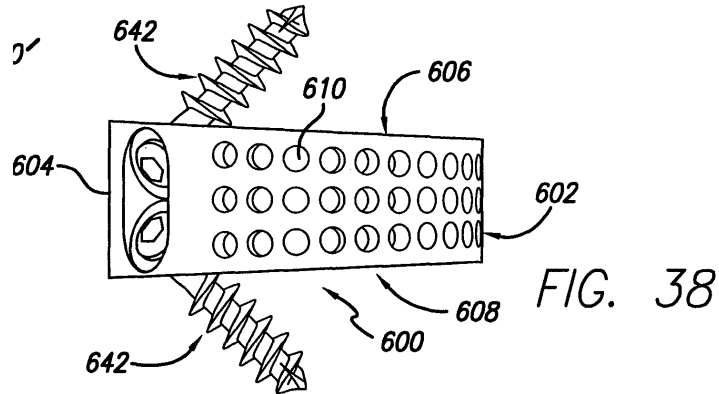
Michelson '045, Ex.1006, Fig.38

Below is an image of implant 400 (figure 24) with a screw hole and screw angled at 75° from the midline of the base plate, and with the bone screw hole shifted toward the edge of the base plate (as taught by implant 600). The second bone screw hole opens at least partially toward the lip osteophyte of a second of the vertebral bones:



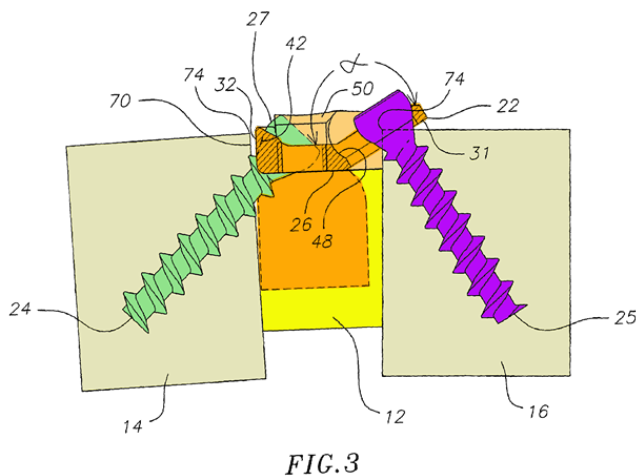
Michelson '045, Ex.1006, Fig.24 (depicted between bones)

It would have been obvious to a POSITA to shift the position of the screw as shown in Figure 38 below to the respective superior and inferior sides of the implant, in order to achieve a wider range of implant options into the bones and to accommodate the 75° angle. Ex.1005 at ¶107. Further, it would have been obvious to a POSITA to perform routine experimentation and optimization to choose the most suitable screw hole location and angle for each hole based on any clinical considerations. *Id.*

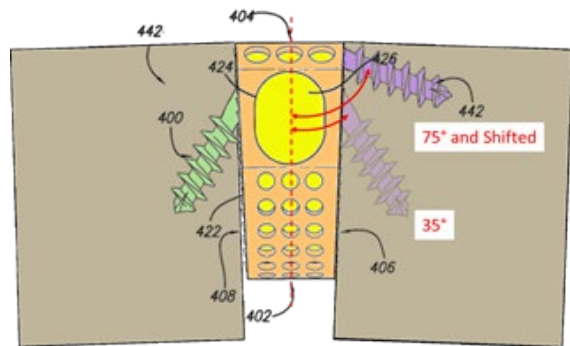


Michelson '045, Ex.1006, Fig.38

As shown by the side-by-side figures below, like the '537 patent Michelson '045 discloses “wherein a second of the bone screw holes, being configured to receive a second of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the lip osteophyte of a second of the vertebral bones.” The second bone screw is shown in purple.



'537 patent, Ex.1002, Fig. 3



**Michelson '045, Ex.1006, Fig.24
 (depicted between bones)**

Therefore, Michelson '045 discloses this limitation.

8. wherein each and every one of the plurality of bone screw holes is configured to receive one of the bone screws angled relative to the base plate and oriented generally in an anterior-posterior direction through at least partially the top surface of the base plate.

Michelson '045 discloses this limitation. As shown by the side-by-side figures below, like the '537 patent, Michelson '045 discloses “wherein each and every one of the plurality of bone screw holes is configured to receive one of the bone screws angled relative to the base plate and oriented generally in an anterior-posterior direction through at least partially the top surface of the base plate.”

Ex.1005 at ¶110.

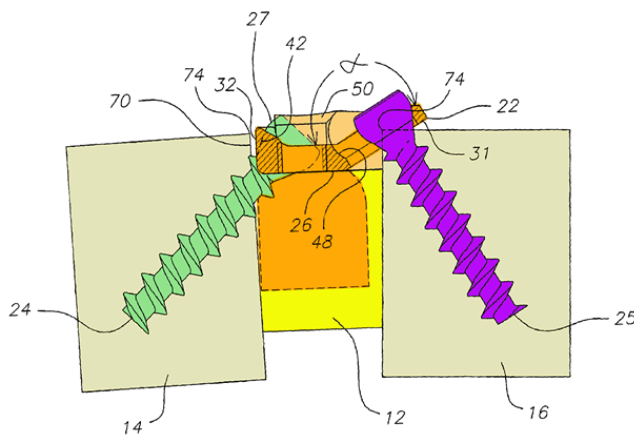
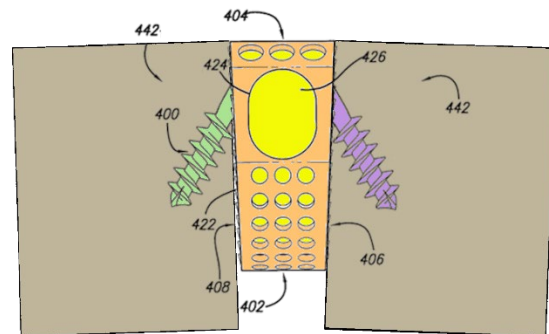


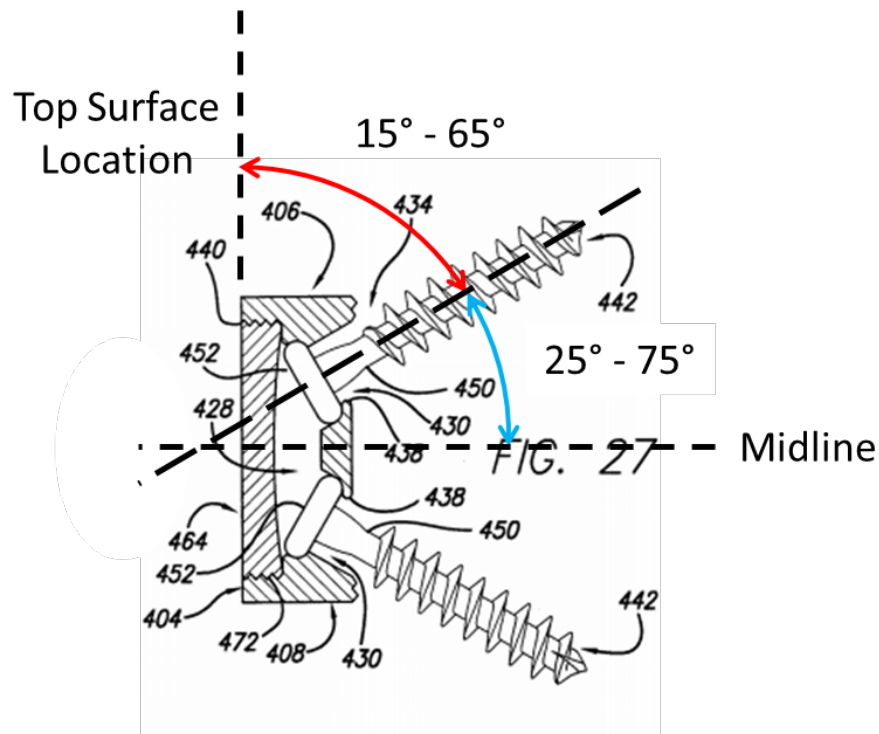
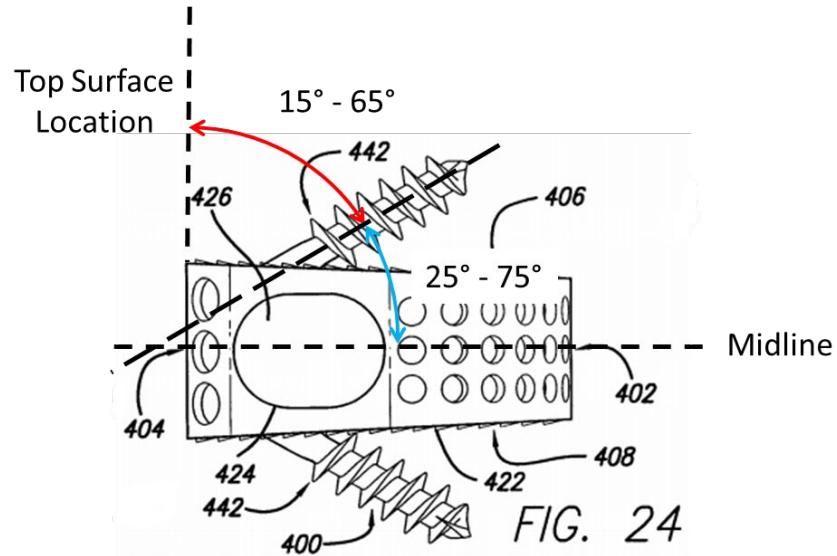
FIG.3

'537 patent, Ex.1002, Fig. 4



Michelson '045, Ex. 1006, Fig. 25

As shown in figures 24 and 27 below, Michelson '045 teaches the base plate includes bone screws extending at between a 15° and 65° angle relative to the top surface of the bone, inserted in an anterior-posterior direction.



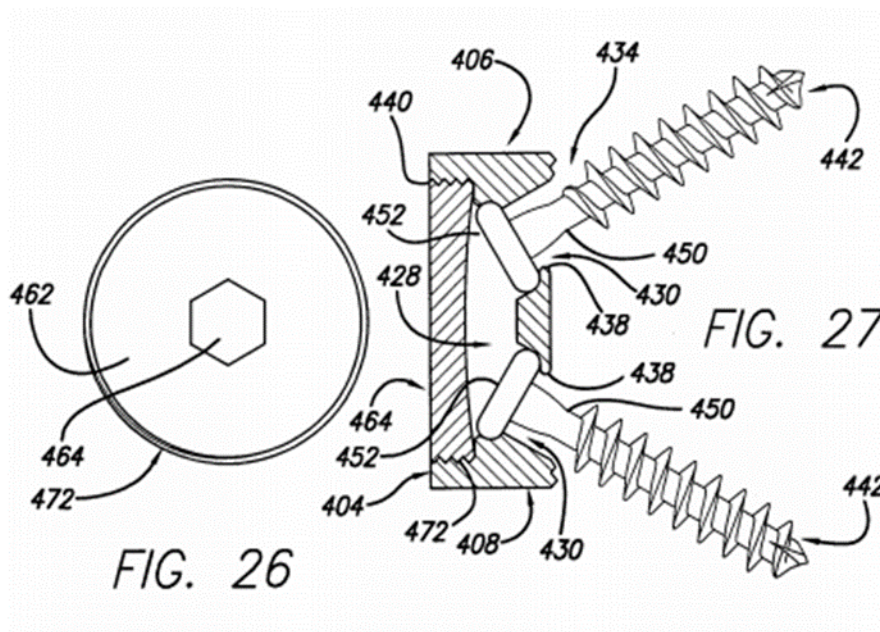
Michelson '045, Ex. 1006, Figs. 24 and 27

Therefore, Michelson '045 discloses each and every element recited by independent claim 1 of the '537 patent.

B. Claim 4

Claim 4 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 4 further recites “**wherein the system further comprises a screw retainer configured to prevent at least one of the plurality of bone screws from backing out.**” Michelson '045 discloses this claim. Ex.1005 at ¶¶114-115.

As shown in figures 26 and 27 below, Michelson '045 teaches the base plate includes a lock 462 that covers part of the first and second bone screws to prevent them from backing out.



Michelson '045, Ex. 1006, Figs. 26 and 27

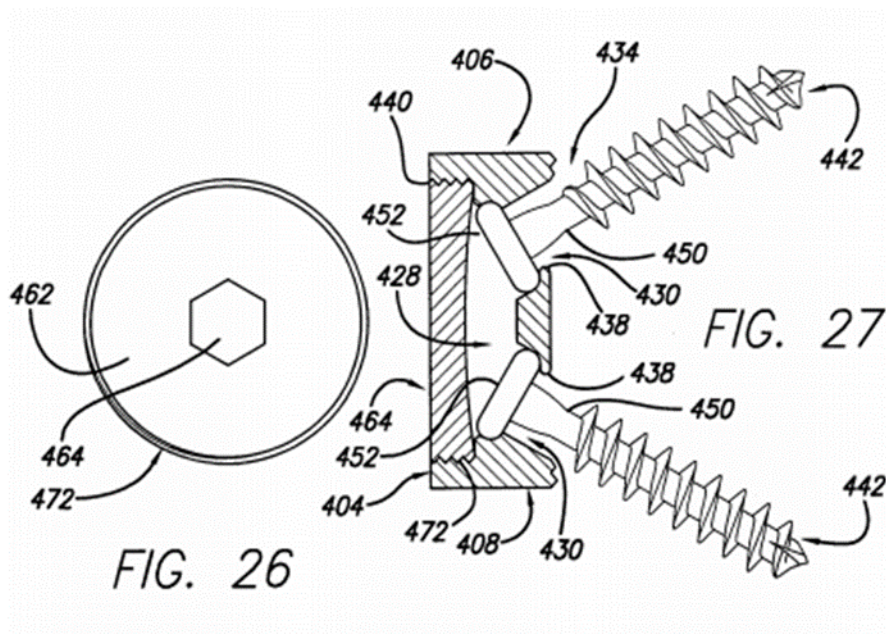
Therefore, Michelson '045 discloses this claim.

C. **Claim 5**

Claim 5 depends from claim 4, which depends from independent claim 1.

All the limitations of claims 1 and 4, discussed above and incorporated here, are disclosed by Michelson '045. Claim 5 further recites “**wherein the screw retainer is a plate or a screw.**” Michelson '045 discloses this claim. Ex.1005 at ¶118.

As shown in figures 26 and 27 below, Michelson '045 teaches the base plate includes a lock 462 that covers part of the first and second bone screws to prevent them from backing out. Michelson '045 discloses that the lock 462 “takes the form of a disc with a threaded side wall 472, capable of threadably engaging threads 472 with common hold 428.” Ex.1006 at 18.



Michelson '045, Ex. 1006, Figs. 26 and 27

Therefore, Michelson '045 discloses this claim.

D. Claim 6

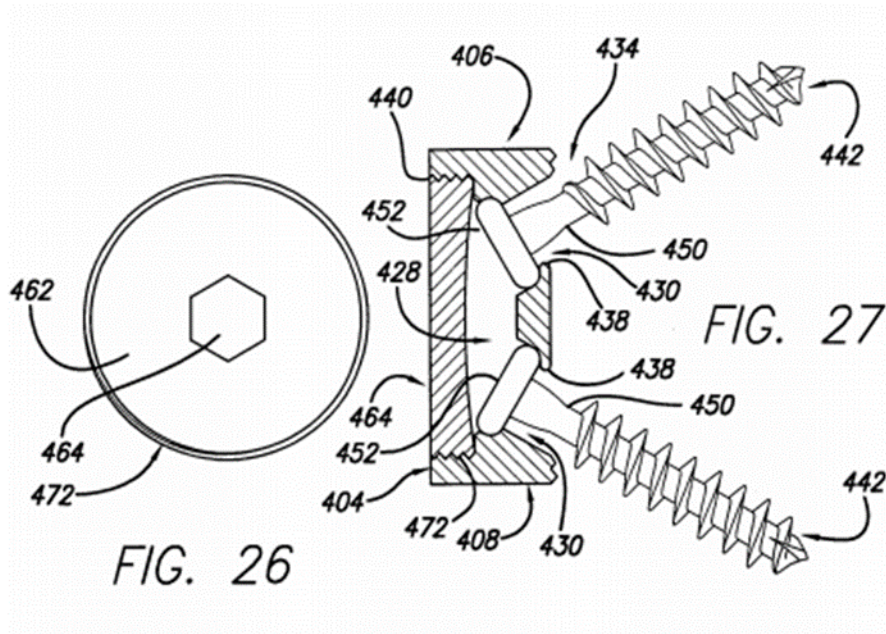
Claim 6 depends from claim 4, which depends from independent claim 1.

All the limitations of claims 1 and 4, discussed above and incorporated here, are disclosed by Michelson '045. Claim 6 further recites “**wherein the top surface of the base plate is configured to have a recessed region and the screw retainer is configured to sit in the recessed region of the base plate.**” Michelson '045 discloses this claim. Ex.1005 at ¶¶121-22.

Michelson '045 teaches “trailing end 404 of **implant 400 is adapted** to receive a total of four bone screws 442 deployed in upwardly and downwardly projecting opposed pairs, and **further to receive into common holes 440 threaded lock members 462, preventing screws 442 from backing out.**”

Ex.1006 at 18. In particular, Michelson '045 teaches “**lock 462 takes the form of a disc with a threaded side wall 472**, capable of threadably engaging threads 472 within common hole 428.” *Id.*

As shown in figures 26 and 27 below, Michelson '045 teaches the top surface of the base plate is configured to have a recessed region 428 and the screw retainer (lock 462) is configured to sit in the recessed region 428 of the base plate.



Michelson '045, Ex. 1006, Figs. 26 and 27

Therefore, Michelson '045 discloses this claim.

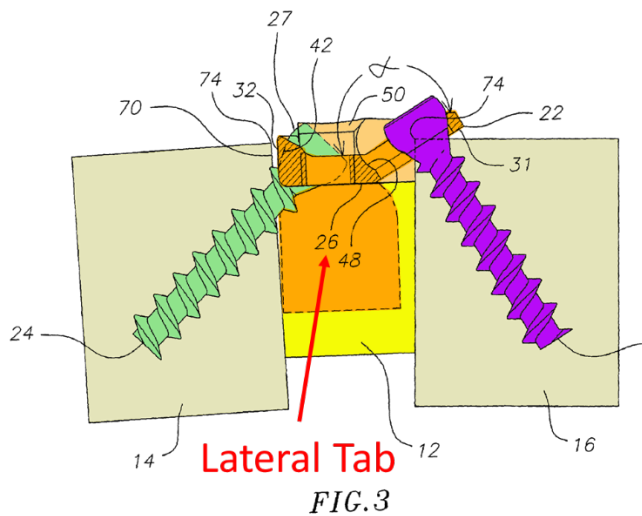
E. Claim 10

Claim 10 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 10 further recites “The system as set forth in claim 1, wherein the **base plate** includes **two lateral tabs** configured to fit between the lip osteophytes of the vertebral bones and extending from opposite ends of the bottom surface of the base plate in a direction generally transverse to the vertebral bones.”

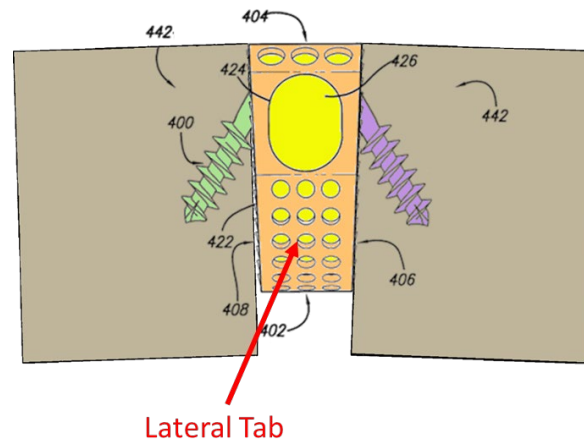
Michelson '045 discloses this limitation. Ex.1005 at ¶125. As discussed above in Section VII, incorporated here, “lip osteophytes” means “bony outgrowth

at the anterior corner of the bone and is structurally the strongest part of the bone.” Ex.1005 at ¶56.

As shown by the side-by-side figures below, like the '537 patent, Michelson '045 discloses that the base plate includes two lateral tabs configured to fit between the lip osteophytes of the vertebral bones and extending from the bottom surface of the base plate in a direction generally transverse to the vertebral bones:

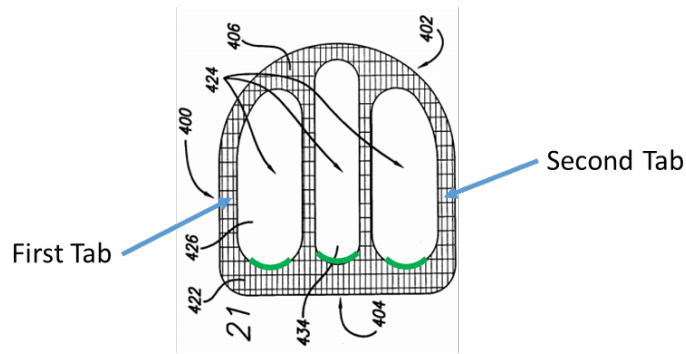


'537 patent, Ex.1002, Fig. 3



Michelson '045, Ex. 1006, Fig. 24

As further shown in annotated figure 21 below, Michelson '045 discloses first and second tabs extending from the bottom surface (green) of the base plate:



Michelson '045, Ex. 1006, Fig. 21

Therefore, Michelson '045 discloses this limitation.

F. Claim 13

Claim 13 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 13 further recites “wherein the **top surface of the base plate** coincides with or generally matches an **outer diameter of the anterior cortex of the vertebral bones.**” Michelson '045 discloses this limitation. Ex.1005 at ¶131-32.

Michelson '045 teaches against affixing any spinal implant hardware anteriorly to the vertebral bodies adjacent the disc space to be fused. In particular, Michelson '045 teaches that “[t]hose skilled in the art have shown great reluctance to utilize such hardware because of **the potential for the hardware to impinge on vital body structures**, such as the aorta, vena cava, or great iliac vessels” and because such placement “**could cause sudden death.**” Ex.1006 at 4.

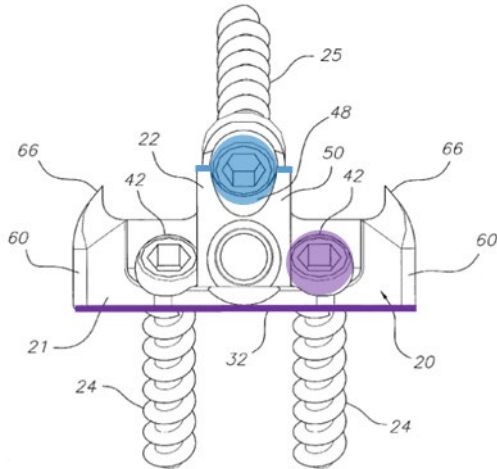
Therefore, Michelson '045 is directed to “an implant that is resistant to dislodgment and functionally substitutes for the anterior longitudinal ligament at the level to be fused, **without protruding from the spine.**” *Id.*

Therefore, Michelson '045 discloses this claim.

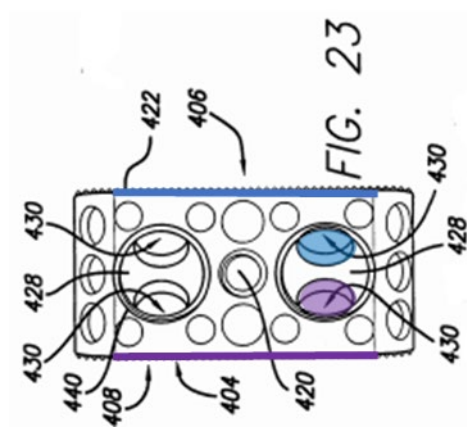
G. Claim 14

Claim 14 depends from independent claim 1. All the limitations of claim 1, discussed above and incorporated here, are disclosed by Michelson '045. Claim 14 further recites “wherein each of the **plurality of bone screw holes** extends at least partially through the first or second end, the first end comprising a first bone engaging region fully extending uninterrupted between lateral extents of the first end, and the second end comprising a second bone engaging region fully extending uninterrupted between lateral extents of the second end.” Michelson '045 discloses this limitation. Ex.1005 at ¶¶136-37.

As shown in the side-by-side comparison figures below, like the '537 patent, Michelson '045 discloses each of the plurality of bone screw holes extends at least partially through the first (blue) or second end (purple). The comparison also shows that Michelson '045 teaches the first end comprising a first bone engaging region (blue) fully extending uninterrupted between lateral extents of the first end, and the second end comprising a second bone engaging region (purple) fully extending uninterrupted between lateral extents of the second end.



'537 patent, Ex.1002, Fig. 4



Michelson '045, Ex. 1006, Fig. 23

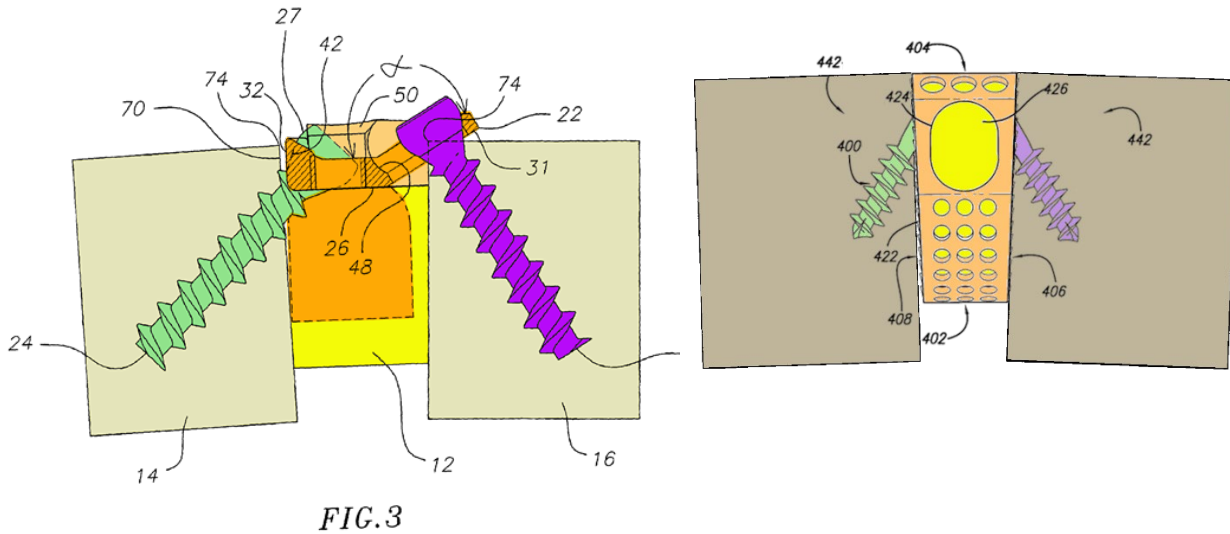
Therefore, Michelson '045 discloses this limitation.

H. Claim 21

1. **A bone stabilization plate system for anchoring between side surfaces of first and second adjacent vertebral bones, comprising:**

As explained in Section VIII.A.1 above, to the extent the preamble is limiting, Michelson '045 discloses a bone stabilization plate system recited by the '537 patent. In particular, Michelson '045 teaches "[t]he present invention relates generally to **interbody spinal fusion implants.**" Ex.1006 at 2. Ex.1005 at ¶142.

As shown in the side-by-side comparison figures below, Michelson '045 discloses the bone stabilization plate system anchors between side surfaces of first and second adjacent vertebral bones as recited by the '537 patent.



'537 patent, Ex.1002, Fig. 3

Michelson '045, Ex.1006, Fig.24
(depicted between bones)

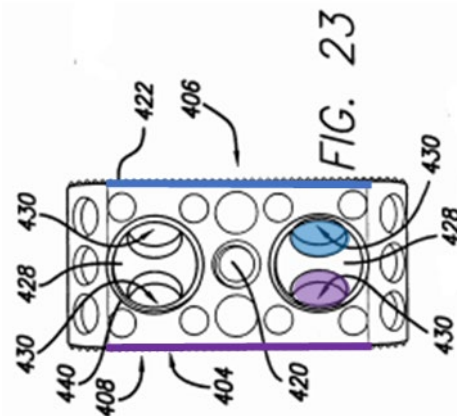
As such, Michelson '045 this limitation.

2. a base plate having a top surface, a first end nearer the first bone comprising a first bone screw hole extending at least partially therethrough and a first bone engaging region fully extending uninterrupted between lateral extents of the first end, a second end nearer the second bone comprising a second bone screw hole extending at least partially therethrough, and a bottom surface, and

This limitation includes four features: (1) a base plate, (2) a base plate with a first end nearer the first bone, a second end nearer the second bone, and a bottom surface, (3) an uninterrupted bone engaging region, and (4) first and second holes extending through the first and second ends. Michelson '045 discloses this limitation and each of these features. Ex.1005 at ¶145.

With respect to the base plate, as explained in Section VIII.A.2 above, Michelson '045 discloses a base plate.

Regarding the second feature, a base plate with a first end nearer the first bone, a second end nearer the second bone, and a bottom surface, as explained in Section VIII.A.2 above, Michelson '045 discloses this feature. A depiction of the Michelson '045 base plate with a first end (blue) nearer the first bone and a second end (purple) nearer the second bone is in figure 23 below. Ex. 1005 at ¶¶146-47.



Michelson '045, Ex.1006, Fig. 23

Regarding the third feature, an uninterrupted bone engaging region, Michelson '045 discloses this feature as explained in Section VIII.G.

Finally, regarding the last feature, first and second holes extending through the first and second ends, as explained in Section VIII.G, Michelson '045 discloses this feature.

Therefore, Michelson '045 discloses this limitation.

3. **configured to fit primarily between an anterior portion of the first bone's lip osteophyte and an anterior portion of the second bone's lip osteophyte while bearing weight to hold the bones for fusion; and**

This limitation includes two features: (1) a base plate implanted between the bones' lip osteophytes, (2) a base plate that bears weight and holds the bones for fusion. Michelson '045 discloses this limitation and each of these features.

Ex.1005 at ¶150.

Both features are disclosed by Michelson '045 as discussed above in Section VIII.A.3.

Therefore, Michelson '045 discloses this limitation.

4. **a first bone screw configured to secure the base plate to the first bone by insertion through the first bone screw hole and to extend from at least partially the top surface of the base plate to at least partially the side surface of the first bone, and**

This limitation includes two features: (1) a bone screw that extends from the top surface of the base plate to the side surface of the bone, and (2) the bone screw configured to secure the base plate to the bone. Michelson '045 discloses this limitation and each of these features. Ex.1005 at ¶156.

Regarding the first feature, Michelson '045 teaches a first bone screw configured to extend from at least partially the top surface of the base plate to at least partially the side surface of the first bone, as explained in Section VIII.A.6.

Regarding the second feature, the first bone screw configured to secure the

base plate to the first bone, Michelson '045 further discloses this feature.

Specifically, Michelson '045 teaches “[t]he implants of the present invention differ from all prior art implants in that **they are adapted to receive through their trailing ends at least a pair of appropriately sized opposed bone screws that can be directed at an appropriate angle**, at least one each, **into each of the adjacent vertebral bodies adjacent the disc space** to be fused” Ex.1006 at 9.

Therefore, Michelson '045 discloses this limitation.

5. **a second bone screw configured to secure the base plate to the second bone by insertion through the second bone screw hole and to extend from at least partially the top surface of the base plate to at least partially the side surface of the second bone.**

This limitation includes two features: (1) a bone screw that extends from the top surface of the base plate to the side surface of the second bone, and (2) the bone screw configured to secure the base plate to the bone. Michelson '045 discloses this limitation and both features. Ex.1005 at ¶160.

Regarding the first feature, Michelson '045 teaches a second bone screw configured to extend from at least partially the top surface of the base plate to at least partially the side surface of the second bone, as explained in Section VIII.A.7.

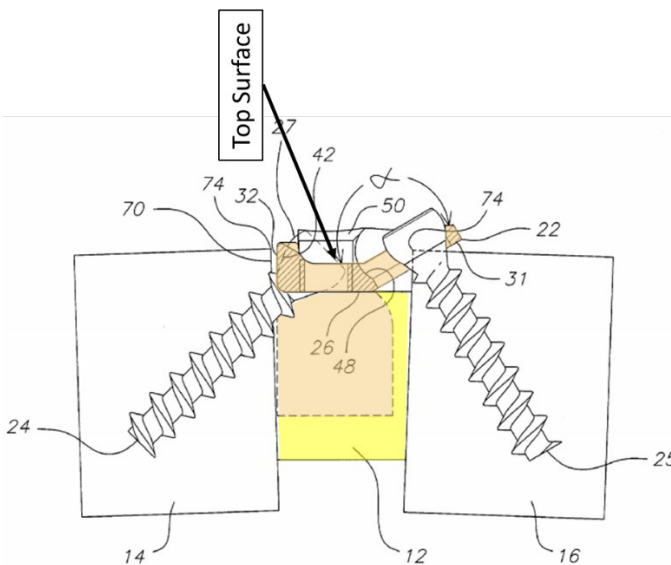
Regarding the second feature, Michelson '045 discloses the second bone screw configured to secure the base plate to the second bone. Ex.1006 at 9, 18. Therefore, Michelson '045 discloses this limitation and claim 21.

I. Claim 22

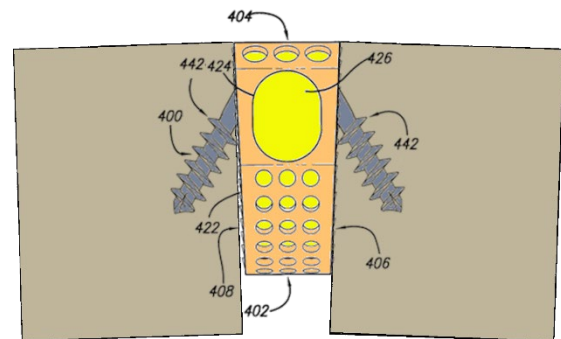
Claim 22 depends from independent claim 21. All the limitations of claim 21, discussed above and incorporated here, are disclosed by Michelson '045.

Claim 22 further recites “wherein the **entire top surface of the base plate** is configured to be an **anterior boundary** of a bone graft site.” Michelson '045 discloses this limitation. Ex.1005 at ¶¶165-66.

As shown in the side-by-side comparison figures below, like the '537 patent, Michelson '045 discloses the top surface of the base plate (orange) is configured to be an anterior boundary of a bone graft site (yellow).



'537 patent, Ex.1002, Fig. 3



Michelson '045, Ex.1006, Fig.24
(depicted between bones)

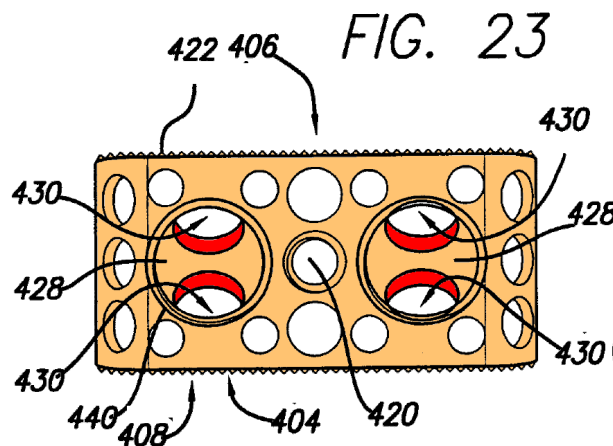
Therefore, Michelson '045 discloses this claim.

J. Claim 24

Claim 24 depends from independent claim 21. All the limitations of claim 21, discussed above and incorporated here, are disclosed by Michelson '045.

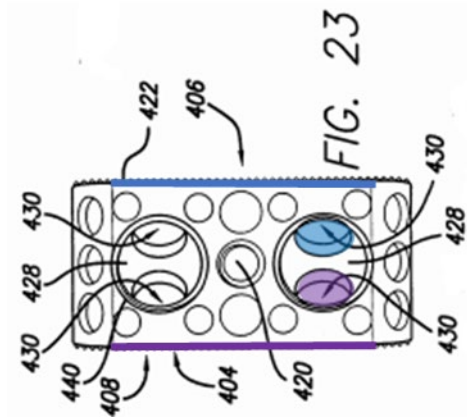
Claim 24 further recites “wherein the **base plate** has **more than two bone screw holes**, a first one of the bone screw holes extends partially through both the bottom surface and the first end, and a second one of the bone screw holes extends partially through both the bottom surface and the second end.” Michelson '045 discloses this limitation. Ex.1005 at ¶¶169-70.

Michelson '045 teaches the base plate has more than two bone screw holes as shown in figure 23 below.

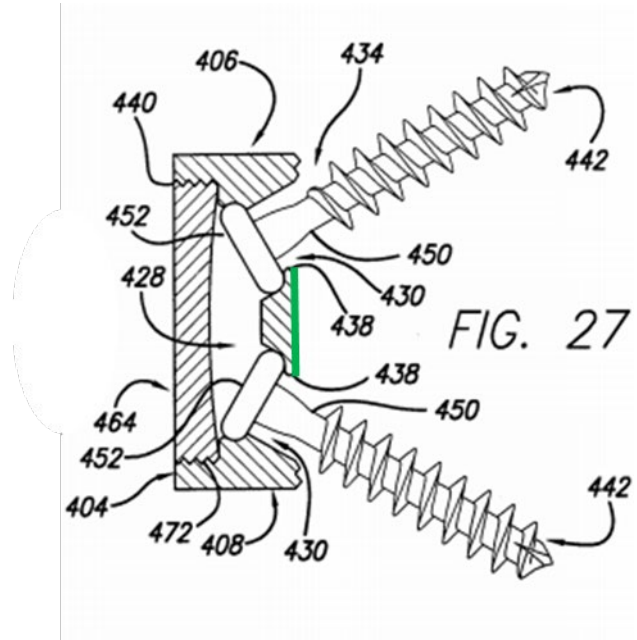


Michelson '045, Ex. 1006, Fig. 23

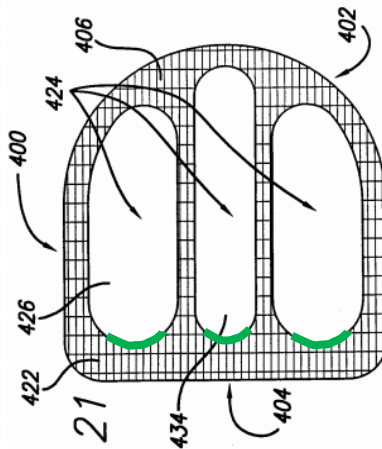
As shown in figures 21, 23 and 27 below, Michelson '045 teaches a first one of the bone screw holes extends partially through both the bottom surface (green) and the first end (blue), and a second one of the bone screw holes extends partially through both the bottom surface (green) and the second end (purple).



Michelson '045, Ex. 1006, Fig. 23



Michelson '045, Ex. 1006, Fig. 27



Michelson '045, Ex. 1006, Fig. 21

Therefore, Michelson '045 discloses this claim.

K. Claim 29

Claim 29 depends from independent claim 21. All the limitations of claim 21, discussed above and incorporated here, are disclosed by Michelson '045.

Claim 29 further recites “wherein the **base plate** has **more than two bone screw holes**, and each and every one of the bone screw holes is configured to receive a bone screw **angled** relative to the base plate and **oriented generally in an anterior-posterior direction** through the top surface of the base plate. Michelson '045 discloses this limitation. Ex.1005 at ¶174.

As explained in Section VIII.J, Michelson '045 discloses the base plate has more than two bone screw holes.

As explained in Section VIII.A.8, Michelson '045 discloses each and every one of the bone screw holes is configured to receive a bone screw angled relative to the base plate and oriented generally in an anterior-posterior direction through the top surface of the base plate.

Therefore, Michelson '045 discloses this claim.

L. Claim 30

Claim 30 depends from independent claim 21. All the limitations of claim 21, discussed above and incorporated here, are disclosed by Michelson '045.

Claim 30 further recites “wherein the system further comprises **a screw retainer**

configured to prevent at least one of the first and second bone screws from backing out.” Michelson ’045 discloses this limitation. Ex.1005 at ¶¶179-80.

As explained in Section VIII.B, Michelson ’045 discloses a screw retainer configured to prevent at least one of the first and second bone screws from backing out.

Therefore, Michelson ’045 discloses this claim.

M. Claims 14, 21, and 24

Claims 14, 21, and 24 do not require the claimed first and second ends be limited to the upper and lower corners of the base plate. However, in the event that the Board determines that the claimed first end and second end only comprises the corner of the base plate, it would have been obvious to a POSITA to adjust the location of the Michelson ’045 bone screws found in implant 400 to the upper and lower edges of the base plate. Ex.1005 at ¶¶183-84.

Michelson ’045 discloses the remainder of the claim limitations of claims 14, 21, and 24, as set forth in Ground 1, and incorporated here. As mentioned above, Michelson ’045 discloses screw holes at the first and second ends of the top surface of the baseplate. A POSITA would, however, recognize there are significant advantages to locating the bone screw holes at the upper and lower edges of the top surface of the baseplate. Ex.1005 at ¶186.

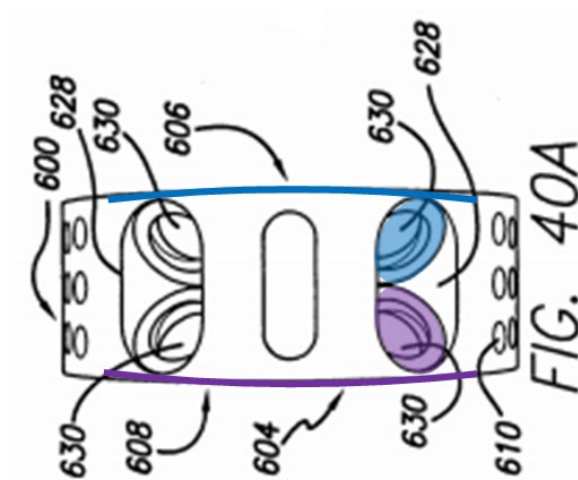
In addition, a POSITA would understand that locating the screw holes at the

first and second ends would provide a wider footprint for screw insertion. *Id.*

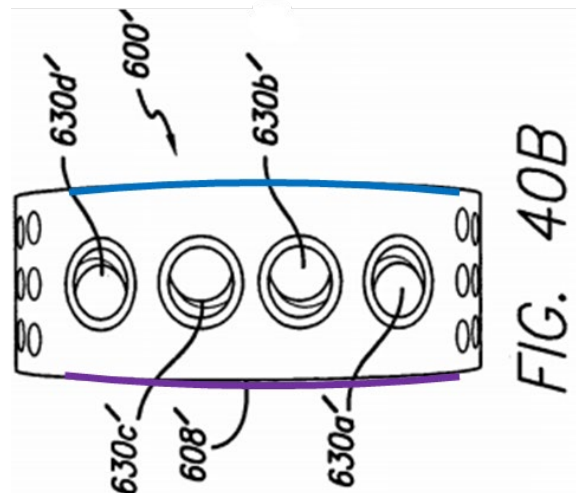
Screw holes located at the first and second ends also allow the bone screws to enter into the bones as close to the anterior portion of the bone as possible. *Id.*

In fact, Michelson '045 teaches that this design could be easily implemented, for example, as disclosed by implant 600. Ex.1006 at 22-23.

As shown in figure 40A and 40B below, Michelson '045 teaches two alternative embodiments, one with the bone screws located at the first and second ends and another with the bone screws all in the middle.



Michelson '045, Ex. 1006, Fig. 40A



Michelson '045, Ex. 1006, Fig. 40B

These physical modifications would be well within a POSITA's skill (and a POSITA would have more than a reasonable expectation of success) as they would only require moving the screw holes to the edges of the implant and a slight adjustment to the trajectories. Ex.1005 at ¶¶187-188.

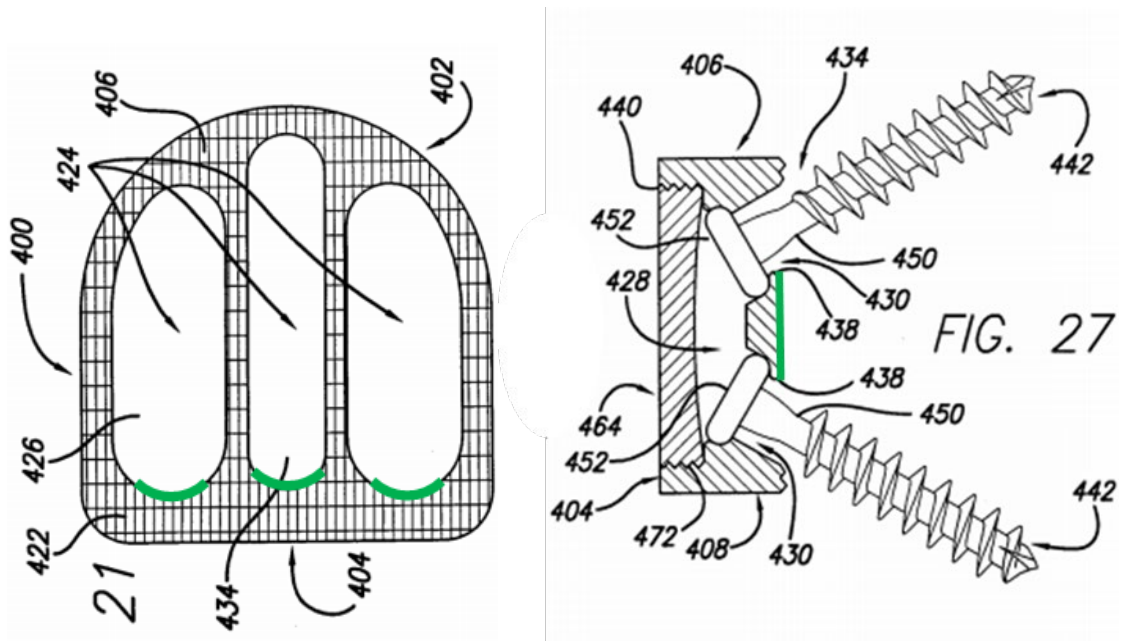
Therefore, Michelson '045 renders claims 14, 21, and 24 obvious.

IX. GROUND #2: MICHELSON '045 IN VIEW OF BYRD RENDERS CLAIMS 3, 15 AND 18-19 UNPATENTABLE AS OBVIOUS

For the reasons stated below, at least claims 3, 15 and 18-19 of the '537 patent are rendered obvious under 35 U.S.C. §103 by Michelson '045 in view of Byrd.

A. Claim 3

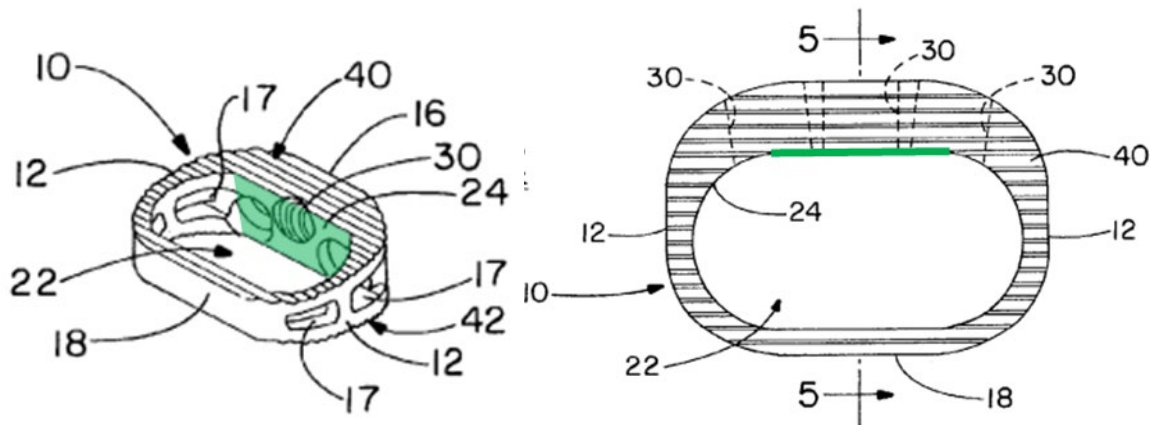
Claim 3 depends from independent claim 1. All the limitations of claim 1, discussed above in Ground 1 and incorporated here, are disclosed by Michelson '045. Ex.1005 at ¶¶191-192. Claim 3 further recites “wherein the **bottom surface of the base plate is generally flat.**” As shown in figures 21 and 27, Michelson '045 teaches a bottom surface (green) of the base plate.



Michelson '045, Ex. 1006, Figs. 21 and 27

Claim 3 does not require that the bottom surface be completely or perfectly flat, just that it be “generally flat.” In the event the Board determines that the bottom surface of the Michelson ’045 implant is not generally flat, it would have been an obvious matter of design choice for a POSITA to modify the bottom surface of Michelson ’045 to be generally flat in view of the disclosures of Byrd and the insignificance of the bottom surface’s shape, as stated in the ’537 patent specification. Ex.1005 at ¶194.

Byrd teaches a base plate having a generally flat bottom surface. Ex.1005 at ¶195. Byrd’s generally flat bottom surface (green) is shown below in figures 1 and 2:



Byrd, Ex. 1008, Figs. 1 and 2

Like the ’537 patent, Byrd teaches that the center opening defined in part by Byrd’s bottom surface sits against bone graft. *Compare* Ex.1007 at 5:40-42 (“The center opening is for the inclusion of a suitable bone graft material used to promote fusion.”) *with* Ex.1002 at 8:49-52 (“[t]he base plate 20 has a bottom surface 26 that

contacts the bone graft 12.)

It would have been an obvious matter of design choice for a POSITA to modify the bottom surface of Michelson '045 to be generally flat in view of the disclosures of Byrd and the insignificance of the bottom surface's shape, as stated in the '537 patent specification. Ex.1005 at ¶196. In short, the '537 patent teaches that the shape of this surface is not important and that any known and typical shape would be suitable. Therefore, making the shape of the bottom surface generally flat is an obvious matter of design choice.

This is consistent with the Board's reasoning in *Ex parte Spangler*, where the specification does not support the criticality of a claimed element, variations of such elements are an obvious matter of design choice. Appeal No. 2018-003800 (Feb. 20, 2019) ("The relative sizes and particular locations of the tabs . . . are not critical to Appellants' invention . . . the relative sizes and particular locations of the tabs along the second side of the featherseal are an obvious matter of design choice . . .").

Therefore, Michelson '045 in view of Byrd discloses this claim limitation.

B. Claim 15

1. A bone stabilization plate system comprising:

As explained in Section VIII.A.1 in Ground 1 above, to the extent the preamble is limiting, Michelson '045 discloses a bone stabilization plate system

recited by the '537 patent. Ex.1006 at 2; Ex.1005 at ¶200.

Therefore, Michelson '045 in view of Byrd discloses this claim limitation.

2. a base plate having a plurality of bone screw holes, a top surface, a generally flat bottom surface and first and second ends

This limitation includes three features: (1) a base plate, (2) a base plate with bone screw holes, and (3) a base plate with a top, a generally flat bottom surface, and two ends. Michelson '045 discloses this limitation and each of these features. Ex.1005 at ¶202.

Regarding the first feature, a base plate, as explained in Section VIII.A.2 in Ground 1 above, Michelson '045 discloses a base plate.

Regarding the second feature, a base plate with bone screw holes, as explained in Section VIII.A.2 in Ground 1 above, Michelson '045 discloses this feature.

Regarding the third feature, a base plate with a top, a generally flat bottom surface, and two ends, Michelson '045 in view of Byrd, discloses this limitation. As explained in Section VIII.A.2 in Ground 1 above, Michelson '045 teaches a base plate with a top, a bottom, and two ends. As further explained in Section IIX.A above, Michelson '045 in view of Byrd discloses a base plate further having a generally flat bottom surface as recited by the '537 patent.

Therefore, as described above, Michelson '045 in view of Byrd discloses a

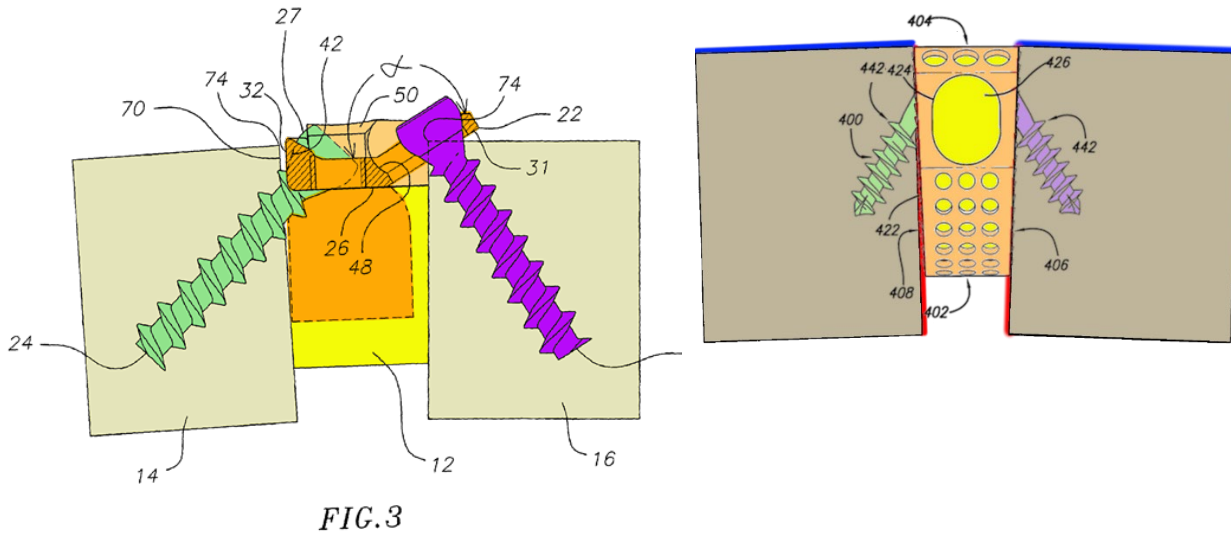
base plate having a plurality of bone screw holes, a top surface, a generally flat bottom surface and first and second ends.

3. for retaining bone graft material between adjacent vertebral bone bodies having top surfaces and having side surfaces generally facing each other,

This limitation includes two features: (1) a base plate for retaining bone graft material between adjacent vertebral bone bodies and (2) vertebral bone bodies having top surfaces and having side surfaces generally facing each other.

Michelson '045 in view of Byrd discloses both these features. Ex.1005 at ¶207.

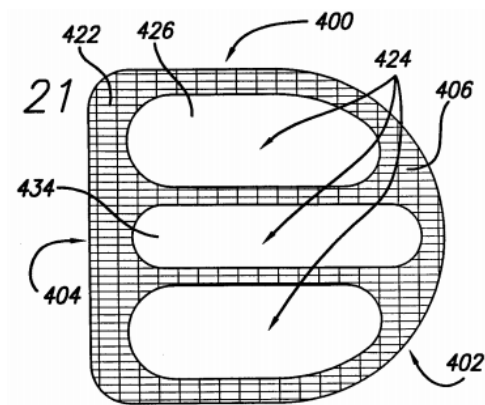
Regarding the first feature, a base plate for retaining bone graft material between adjacent vertebral bone bodies, Michelson '045 discloses this feature. As shown in the side-by-side comparison figures below, like the '537 patent, Michelson '045 discloses the base plate (orange) retains bone graft material (yellow) between the adjacent vertebral bone bodies.



'537 patent, Ex.1002, Fig. 3

Michelson '045, Ex.1006, Fig.24
(depicted between bones)

As shown in Figure 21 below, Michelson '045 discloses “[b]oth leading end 402 and trailing end 404 of implant 400 **are highly perforate** to allow for vascular access to hollow interior 426 of implant 400, and **to allow for the growth of bone therethrough.**” Ex.1006 at 16. Michelson '045 further teaches “these openings are considered highly desirable.” Ex.1006 at 16.



Michelson '045, Ex. 1006, Fig. 21

Regarding the second feature, vertebral bone bodies having top surfaces and having side surfaces generally facing each other, as explained in Section VIII.A.5 in Ground 1 above, Michelson '045 teaches this feature.

Therefore, Michelson '045 in view of Byrd discloses this claim limitation.

- 4. wherein the base plate is configured to fit primarily between anterior portions of the bone bodies' lip osteophytes, without covering significant portions of the top surfaces of the bone bodies,**

This limitation includes two features: (1) a base plate configured to fit primarily between anterior portions of the bone bodies' lip osteophytes and (2) a base plate not covering significant portions of the top surfaces of the bone bodies. Michelson '045 discloses this limitation and each of these features. Ex.1005 at ¶214.

Regarding the first feature, a base plate is configured to fit primarily between anterior portions of the bone bodies' lip osteophytes, as explained in Section VIII.A.3 in Ground 1 above, Michelson '045 discloses this feature.

Regarding the second feature, a base plate not covering significant portions of the top surfaces of the bone bodies, Michelson '045 also teaches this feature. Michelson '045 teaches against affixing any spinal implant hardware to the top surfaces of the bone bodies adjacent the disc space to be fused. Ex.1006 at 4.

Therefore, Michelson '045 is directed to “an implant that is resistant to dislodgment and functionally substitutes for the anterior longitudinal ligament at

the level to be fused, **without protruding from the spine.**” *Id.* See Ex.1005 at ¶¶215-217.

Therefore, Michelson ’045 in view of Byrd discloses this claim limitation.

5. to primarily bear weight, and to permit force transmission between the bone bodies through the bone graft material while holding the bone bodies for fusion; and

This limitation includes two features: (1) a base plate that primarily bears weight and permits force transmission between the bones through the bone graft material, and (2) a base plate that holds the bones for fusion. Michelson ’045 discloses this limitation and both these features. Ex.1005 at ¶218.

With respect to the first feature, as explained in Section VIII.A.3 in Ground 1 above, Michelson ’045 discloses the base plate is configured to bear weight, and to permit force transmission between the bone bodies through the bone graft material while holding the bone bodies for fusion.

Michelson ’045 further teaches that the base plate is configured to primarily bear weight. See Ex.1006 at 18.

With respect to the second feature, a base plate that holds the bones for fusion, as explained in Section VIII.A.3 in Ground 1 above, Michelson ’045 discloses this feature.

Therefore, Michelson ’045 in view of Byrd discloses this claim limitation.

6. a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into the lip osteophytes,

This limitation includes two features: (1) a plurality of bone screws configured for insertion through the plurality of bone screw holes, and (2) the bone screws configured to anchor primarily into the lip osteophytes. Michelson '045 discloses each of these features. Ex.1005 at ¶221.

Regarding the first feature, as explained in Section VIII.A.4 in Ground 1 above, Michelson '045 discloses a plurality of bone screws configured for insertion through the plurality of bone screw holes.

As to the second feature, the bone screws configured to anchor primarily into the lip osteophytes, as explained in Section VIII.A.7 in Ground 1 above, Michelson '045 discloses a bone screw hole, being configured to receive a bone screw, opens at least partially toward the lip osteophyte of a vertebral bone.

Michelson '045 further teaches that the bone screws, when entered through said holes, anchor primarily into the lip osteophyte. Ex.1005 at ¶224.

Therefore, Michelson '045 in view of Byrd discloses this claim limitation.

7. with each of the bone screws being configured to extend from at least partially the top surface of the base plate to at least partially the side surface of one of the bone bodies, such that the base plate is secured.

This limitation includes two features: (1) bone screws extending from the top surface of the base plate to the side surface of the bone, and (2) the bone

screws securing the base plate. Michelson '045 in view of Byrd discloses both these features. Ex.1005 at ¶226.

Regarding the first feature, as explained in Sections VIII.A.6 and VIII.A.7 in Ground 1 above, Michelson '045 discloses each of the bone screws being configured to extend from at least partially the top surface of the base plate to at least partially the side surface of one of the bone bodies.

Regarding the second feature, the bone screws securing the base plate, Michelson '045 further teaches the base plate is secured because of the bone screws. Michelson '045 discloses that the screws “may be rigidly locked to the implant.” Ex.1006 at 27.

Therefore, Michelson '045 in view of Byrd discloses this claim limitation.

In summary, as described above, Michelson '045 in view of Byrd discloses each and every element recited by independent claim 15 of the '537 patent.

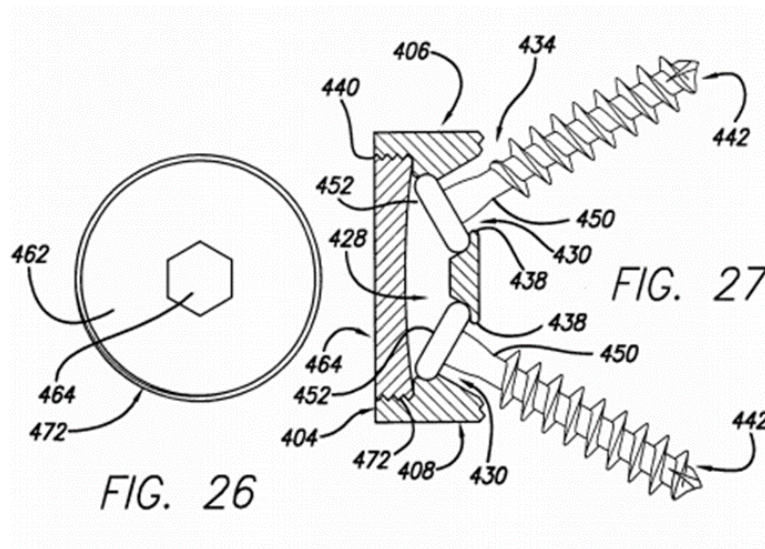
C. Claim 18

Claim 18 depends from independent claim 15. All the limitations of claim 15, discussed above and incorporated here, are disclosed by Michelson '045 in view of Byrd. Claim 18 further recites “wherein the top surface of the base plate is configured to have a recessed region, and the system further comprises a screw retainer in said recessed region configured to prevent one or more of the bone screws from backing out.” Michelson '045 in view of Byrd discloses this

limitation. Ex.1005 at ¶¶230-231.

As explained in Section VIII.D in Ground 1 above, Michelson '045 discloses the top surface of the base plate is configured to have a recessed region and the screw retainer is configured to sit in the recessed region of the base plate.

Michelson '045 teaches the screw retainer is configured to prevent one or more of the bone screws from backing out. Ex.1005 at ¶232. As shown in figures 26 and 27 below, Michelson '045 teaches the base plate includes a lock 462 that covers part of the first and second bone screws to prevent them from backing out.



Michelson '045, Ex. 1006, Figs. 26 and 27

Therefore, Michelson '045 in view of Byrd discloses this limitation.

D. Claim 19

Claim 19 depends from independent claim 15. All the limitations of claim 15, discussed above and incorporated here, are disclosed by Michelson '045 in

view of Byrd. Claim 19 further recites “wherein each and every one of the plurality of bone screw holes is configured to receive a bone screw angled relative to the base plate and oriented generally in an anterior-posterior direction.”

Michelson '045 in view of Byrd discloses this limitation. Ex.1005 at ¶¶234-235.

As explained in Section VIII.A.8 in Ground 1 above, Michelson '045 discloses each and every one of the plurality of bone screw holes is configured to receive a bone screw angled relative to the base plate and oriented generally in an anterior-posterior direction.

Therefore, Michelson '045 in view of Byrd discloses this claim limitation.

E. Reasons and Motivations to Combine Michelson '045 in view of Byrd

As Mr. Sherman explains in his declaration, a POSITA would have been motivated to combine Michelson '045 and Byrd for several reasons. *See* Ex.1005 at ¶238.

A POSITA would be motivated to modify the Michelson '045 base plate in view of Byrd so that the bottom surface that contacts the bone graft is generally flat. A POSITA would have been motivated to make this modification for at least the following reasons.

A POSITA would have appreciated that Michelson '045 and Byrd are analogous to the '537 patent. Indeed, all three are squarely within the same field of endeavor. Here, the '537 patent defines its “Technical Field” as “implant devices

for the fixation and support of bone bodies” Ex.1002 at 1:32-33. To treat degenerative conditions, the ’537 patent discloses that it was well known to fuse the adjacent vertebrae together by “removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral bodies together.” Ex.1002 at 2:3-6.

Just like the ’537 patent, Michelson ’045 and Byrd are directed to a spinal implant device for fixation and support of vertebrae. Ex.1006 at Abstract (“An apparatus including an interbody spinal fusing implant (100) . . . to permit for the growth of bone from vertebral body to adjacent vertebral body through the implant.”), at 2 (“The present invention relates generally to interbody spinal fusion implants . . . for spacing apart and aligning those vertebral bodies and for allowing for the growth of bone in continuity from vertebral body to adjacent vertebral body through said implant.”); Ex.1008 at Abstract (“A vertebral cage is provided for use in preserving the space between adjacent vertebral during the process of spinal fusion.”), at 2:26-28 (“an object of the invention to provide for relative stability of the adjacent vertebrae to facilitate spinal fusion.”).

Michelson ’045 and Byrd also disclose that it is preferable for spinal implants to include openings to contain bone growth material and promote fusion through the implant itself. Ex.1006 at 9 (“It is desirable that each of these opposed

surfaces has at least one opening . . . to allow for the growth of bone from vertebral body to adjacent vertebral body through said implant. . . those openings and those hollows can preferably be filled with fusion promoting substances . . .”); Ex.1008 at 5:29-42 (“The cage is hollow with a center opening 22 defined by a smooth continuous interior surface 24 . . . center opening is for the inclusion of a suitable bone graft material used to promote fusion.”).

Because Michelson ’045 and Byrd disclose intervertebral implants that include openings for bone graft material to promote fusion through the implant, Byrd is analogous and in the same field of endeavor as the ’537 patent and Michelson ’045. Therefore, Michelson ’045 and Byrd are analogous art and would have been considered by a POSITA attempting to solve the problem identified in the ’537 patent. Ex.1005 at ¶241.

Furthermore, a POSITA would be motivated to combine Michelson ’045 and Byrd. A POSITA would have appreciated that an implant with flat interior sides would be easier and cheaper to manufacture. Ex.1005 at ¶242. Therefore, replacing the curved bottom surface disclosed by Michelson ’045 with the flat bottom surface taught by Byrd would be a simple substitution of one known element for another to obtain an improved and predictable result. *Id.*

The physical combination of Michelson ’045 with Byrd would also be simple for a POSITA. The combination would give the POSITA a reasonable

expectation of success because the only modification required to Michelson '045 would be to alter the design of the interior opening of the implant. The bottom surface disclosed by Michelson '045 could be easily modified with the more cost-effective flat design disclosed by Byrd with a reasonable expectation of success.

As such, it would have been obvious for a POSITA to modify Michelson '045 to include the flat bottom surface taught by Byrd, thereby rendering claims 3, 15 and 18-19 unpatentable as obvious.

**X. GROUND #3: MICHELSON '045 IN VIEW OF FRASER '106
RENDERS CLAIMS 1 AND 14 UNPATENTABLE AS OBVIOUS**

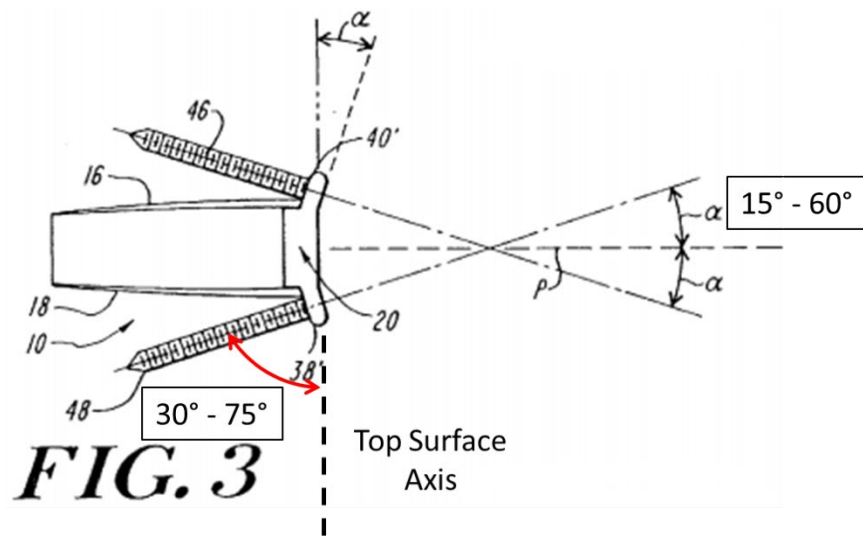
For the reasons stated below, at least claims 1 and 14 of the '537 patent are rendered obvious under 35 U.S.C. §103 by Michelson '045 in view of Fraser '106.

A. Claim 1

Michelson '045 discloses the remainder of the claim limitations of claim 1 as set forth in Ground 1 and are incorporated here. Claim 1 recites, in part, “wherein a **second of the bone screw holes**, being configured to receive a second of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward the lip osteophyte of a second of the vertebral bones.” To the extent this limitation is not disclosed by Michelson '045 alone, Michelson '045 in view of Fraser '106 discloses this claim. Ex.1005 at ¶245.

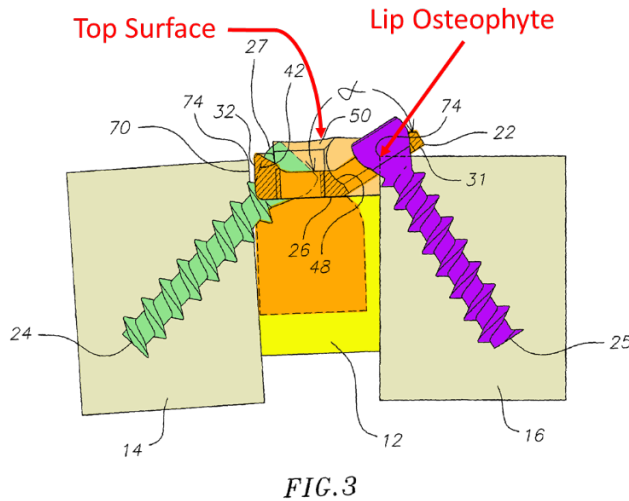
Fraser '106 discloses a second bone screw hole that opens at least partially from the top surface of the base plate and opens at least partially toward the lip

osteophyte of a second of the vertebral bones. Ex.1005 at ¶246. With respect to the top surface of the base plate, the disclosed angle ranges from 30° to 75°.

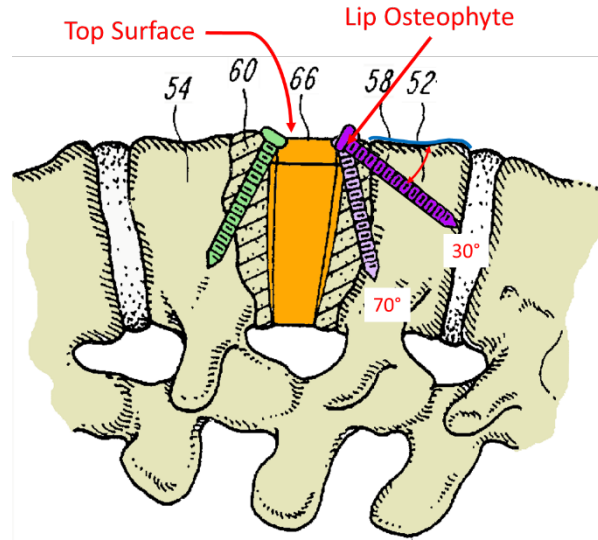


Fraser '106, Ex. 1007, Fig. 3

As shown by the side-by-side figures below, when angled at 30° with respect to the top surface, Fraser '106 discloses a second of the bone screw holes, being configured to receive a second of the bone screws (purple), extends at least partially from the top surface of the base plate (orange) and opens at least partially toward the lip osteophyte of a second of the vertebral bones like the '537 patent discloses.



'537 patent, Ex.1002, Fig. 3



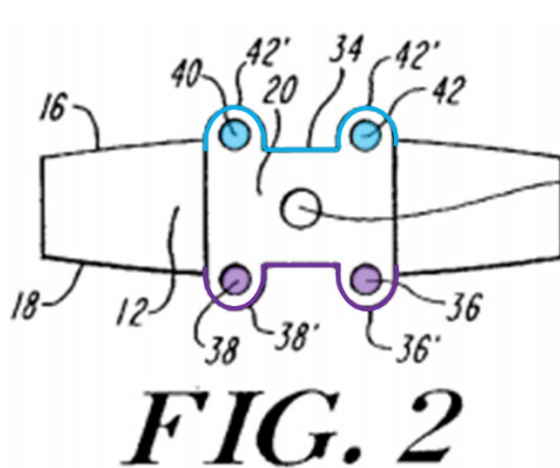
Fraser '106, Ex. 1007, Fig. 8

Therefore, Michelson '045 in view of Fraser '106 discloses this claim limitation.

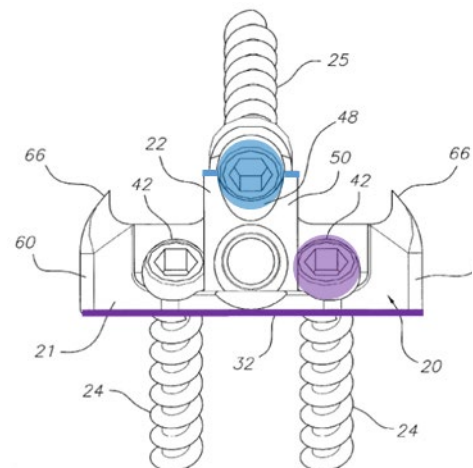
B. Claim 14

Claim 14 depends from independent claim 1. All the limitations of claim 1, discussed above in Ground 1 and incorporated here, are disclosed by Michelson '045. Claim 14 further recites “wherein each of the plurality of bone screw holes extends at least partially through the first or second end, the first end comprising a first bone engaging region fully extending uninterrupted between lateral extents of the first end, and the second end comprising a second bone engaging region fully extending uninterrupted between lateral extents of the second end.” To the extent this limitation is not disclosed by Michelson '045 alone, Michelson '045 in view of Fraser '106 discloses this claim. Ex.1005 at ¶250.

As shown in the side-by-side comparison figures below, like the '537 patent, Fraser '106 discloses each of the plurality of bone screw holes extends at least partially through the first (blue) or second end (purple). The comparison also shows that Fraser '106 teaches the first end comprising a first bone engaging region (blue) fully extending uninterrupted between lateral extents of the first end, and the second end comprising a second bone engaging region (purple) fully extending uninterrupted between lateral extents of the second end.



Fraser '106, Ex. 1007, Fig. 2



'537 patent, Ex.1002, Fig. 4

Therefore, Michelson '045 in view of Fraser '106 discloses this claim.

C. **Reasons and Motivations to Combine Michelson '045 in view of Fraser '106**

As Mr. Sherman explains in his declaration, a POSITA would have been motivated to combine Fraser '106 and Michelson '045 for several reasons. *See* Ex.1005 at ¶254.

1. A POSITA would have considered both Michelson '045 and Fraser '106 because they are analogous art

Fraser '106 and Michelson '045 are both analogous art to the alleged invention claimed in the '537 patent. Here, the '537 patent defines its “Technical Field” as “implant devices for the fixation and support of bone bodies” Ex.1002 at 1:32-33. The '537 patent explains that “[v]arious types of problems can affect the structure and function of the spinal column [including] . . . degenerative conditions of the intervertebral disk or the articulating joints, traumatic disruption of the disk, bone or ligaments supporting the spine, tumor or infection.” Ex.1002 at 1:55-59. To treat these degenerative conditions, the '537 patent discloses that it was well known to fuse the adjacent vertebrae together by “removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral bodies together.” Ex.1002 at 2:3-6. In addition, the '537 patent discloses that it was well known that “fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone.” Ex.1002 at 2:7-10. The '537 patent explains “[t]he bone stabilization plate system includes a plurality of bone screws configured to fit in respective bone screw holes in the base plate to secure the base plate.” Ex.1002 at Abstract.

Just like the '537 patent, Michelson '045 discloses a spinal intervertebral

implant device for fixation and support of vertebrae. Ex. 1006 at Abstract (“An apparatus including an interbody spinal fusing implant . . . to permit for the growth of bone from vertebral body to adjacent vertebral body through the implant.”), at 2 (“The present invention relates generally to interbody spinal fusion implants . . . for spacing apart and aligning those vertebral bodies and for allowing for the growth of bone in continuity from vertebral body to adjacent vertebral body through said implant.”)

Michelson '045 also discloses the use of bone screws to secure the implant and stabilize vertebrae to be fused. Ex.1006 at 9 (“The implants of the present invention . . . are adapted to receive through their trailing ends at least a pair of appropriately sized opposed bone screws that can be directed at an appropriate angle, at least one each, into each of the adjacent vertebral bodies adjacent the disc space to be fused.”). Michelson '045, like the '537 patent, further teaches the use of locks to prevent the bone screws from backing out. *Compare* Ex.1002 at 2:46-49 (“insecure locking of the screw to the plate resulting in screw back out, or inadequate fixation strength and resultant collapse of the graft and angulation of the spine.”) *with* Ex. 1006 at 9 (“the screws are adapted to receive locks to lock the screws to the implants to prevent the backing out of the bone screws from the implants.”)

Fraser '106 is likewise analogous to the '537 patent. Fraser '106 is directed

to a spinal implant device for fixation and support of vertebrae. *See* Ex.1007 at Abstract (“A spinal fixation assembly”), 1:36-38 (“The present invention improves upon known spinal fusion devices, especially those devices intended for an anterior approach to the spine.”). Therefore, Fraser ’106 is squarely in the same field of endeavor as the ’537 patent. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (explaining prior art is analogous where “the art is from the same field of endeavor, regardless of the problem addressed”).

Fraser ’106 is also in the same field of endeavor as (and thus analogous to) the ’537 patent because Fraser ’106 discloses the use of bone screws to secure the implant and stabilize vertebrae to be fused. *See* Ex.1007 at 1:40-42 (“The plate is configured to receive, retain and orient bone screws, thereby holding the fusion cage and adjacent vertebral bodies in a stable relationship to promote fusion.”).

Because Fraser ’106 discloses an intervertebral implant that uses bone screws to secure the implant and stabilize vertebrae to be fused, Fraser ’106 is analogous and in the same field of endeavor as the ’537 patent and Michelson ’045. Therefore, Fraser ’106 and Michelson ’045 are analogous art and would have been considered by a POSITA attempting to solve the problem identified in the ’537 patent. Ex.1005 at ¶¶255-259.

In sum, Fraser ’106 and Michelson ’045 are not only in the same field of endeavor as the ’537 patent, but also specifically address the very problem the ’537

patent purports to solve. *Id.* at ¶260. Therefore, Fraser '106 and Michelson '045 are analogous art and would have been considered by a POSITA attempting to solve the problem identified in the '537 patent.

2. There is an express motivation to combine Michelson '045 and Fraser '106

Michelson '045 provides an express motivation for the combination with Fraser '106 because Michelson '045 teaches that its improved spinal implant designs may be used in other spinal implant devices. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (finding a reference that suggested use of shapes other than those expressly described provided a motivation for a POSITA to combine its teaching with other references disclosing other shapes); *In re Gartside*, 203 F.3d 1305, 1321 (Fed. Cir. 2000) (finding patents' disclosure of "low residence times" to prevent undesired effects provided a motivation for a POSITA to look to another patent describing "low residence time" reactions including "the precise residence time in the disputed claims").

A POSITA would have been motivated to look to the teachings of other references, such as Fraser '106, to find other applications for the Michelson '045 designs. Ex.1005 at ¶264. A POSITA would have combined Michelson '045 with Fraser '106 because Fraser '106 teaches using bone screws located at the upper and lower edges of the top surface of the implant in an interbody spinal implant just like the one disclosed in Michelson '045. *Id.* at ¶265.

Fraser '106 also provides a motivation to combine with Michelson '045.

Fraser '106 expressly teaches that exposed screws can cause significant harm to a patient and discloses an anti-back out mechanism. *See* Ex.1007 at 4:16-19.

Because Fraser '106 teaches use of anti-back out screws, a POSITA would have been motivated to look to the teachings of other spinal implant references that prevent screw back out, such as Michelson '045. A POSITA would have combined Fraser '106 with Michelson '045 because Michelson '045 discloses a spinal implant that utilizes a screw anti-back out system that can be used with standard bone screws to compensate for subsequent settling of the bones after implantation. Ex.1006 at 27.

A POSITA would have combined Michelson '045 with Fraser '106 because Fraser '106 teaches using an interbody spinal implant just liked the one disclosed in Michelson '045 that can be used with an anti-back out screw mechanism. Ex. ¶267 at expert.

3. The combination of Fraser '106 and Michelson '045 would have yielded an improved spinal implant

A POSITA would have also combined Fraser '106 and Michelson '045 because he or she would have recognized that Fraser '106's teachings could be applied to improve Michelson '045's spinal implant. Ex.1005 at ¶¶269-270.

In particular, a POSITA would have recognized there are significant advantages to locating the bone screw holes at the upper and lower edges of the top

surface of the baseplate. Ex.1005 at ¶271.

Therefore, a POSITA would have been motivated to apply the teachings of Fraser '106 to locate the bone screw holes at the edges of the top surface of the base plate to allow for improve screw insertion angles, such as the ones taught in Michelson '045. *Id.* at ¶273.

Therefore, Fraser '106 in view of Michelson '045 renders at least claims 1 and 14 of the '537 patent obvious.

XI. GROUND #4: MICHELSON '045 IN VIEW OF FRASER '106 AND BYRD RENDERS CLAIM 15 UNPATENTABLE AS OBVIOUS

For the reasons stated below, at least claim 15 of the '537 patent is rendered obvious under 35 U.S.C. §103 by Michelson '045 in view of Fraser '106 and Byrd.

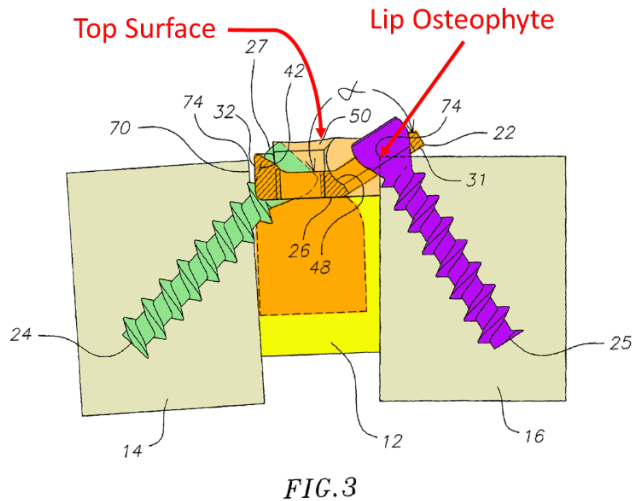
A. Claim 15

Michelson '045 in view of Byrd discloses the remainder of the claim limitations of claim 15, as set forth in Ground 3, and are incorporated here. Claim 15 recites, in part, “a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into the lip osteophytes.” To the extent this limitation is not disclosed by Michelson '045 in view of Byrd, Michelson '045 in view of Fraser '106 and Byrd discloses this claim. Ex.1005 at ¶279.

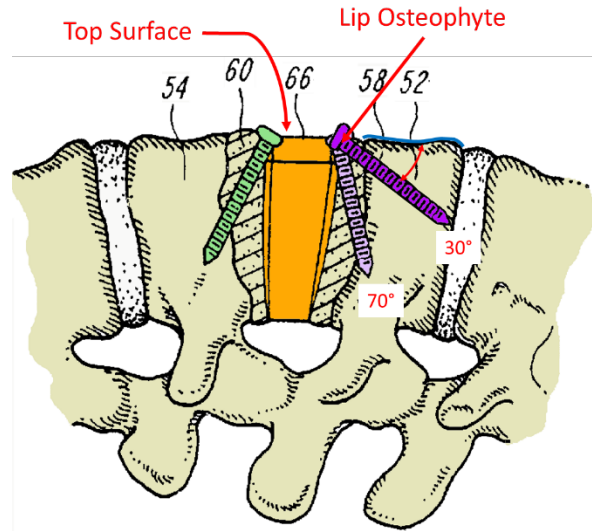
Fraser '106 discloses a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into



84



'537 patent, Ex.1002, Fig. 3



Fraser '106, Ex. 1007, Fig. 8

Therefore, Michelson '045 in view of Fraser '106 and Byrd discloses this claim limitation.

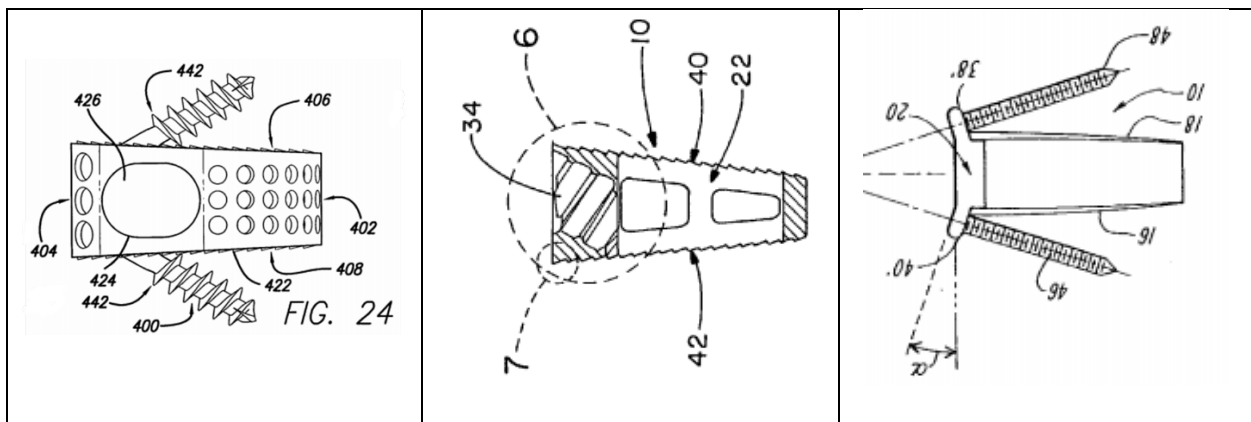
B. Reasons and Motivations to Combine Michelson '045 in view of Fraser '106 and Byrd

As discussed above in Section IX.E, Michelson '045 and Byrd are analogous to the '537 patent. A POSITA would have been motivated to implement Byrd's teaching of a flat bottom surface into the implant disclosed by Michelson '045. Ex.1005 at ¶¶284-85.

As discussed above in Section X.C, Michelson '045 and Fraser '106 are analogous to the '537 patent. Michelson '045 provides an express motivation for the combination with Fraser '106 because Michelson '045 teaches its improved spinal implant designs may be used in other spinal implant devices. *See* Ex.1006 at 5. A POSITA would have been motivated to look to the teachings of other

references, such as Fraser '106, to find other applications for the Michelson '045 designs. Ex.1005 at ¶290. A POSITA would have been motivated to incorporate the use of bone screws located at the upper and lower edges of the top surface of the implant. Ex.1005 at ¶290. Modifying Michelson '045's bone screw hole location would be a simple substitution of one known element for another to obtain an improved and/or predictable result (*e.g.*, screws that can achieve a greater screw insertion angle into the bone). Ex.1005 at ¶290.

A POSITA would have been motivated to combine the teachings of Fraser '106, Byrd, and Michelson '045 because he or she would have appreciated that all three references are analogous are to the '537 patent and all are spinal implant devices for fixation and support of vertebrae. Byrd's flat bottom surface and Michelson '045's anti-back out screw plate were both well-known elements that could be easily implemented into the Fraser '106 implant for the reasons already addressed above.



<p>Michelson '045, Ex. 1006, Figs. 21 and 24</p>	<p>Byrd, Ex. 1007, Figs. 2 and 5</p>	<p>Fraser '106, Ex. 1007, Figs. 1 and 3</p>

As seen in side-by-side figures above, a POSITA would further be motivated to combine Byrd's and Michelson '045's teachings with the disclosures of Fraser '106 because each spinal implant design is similar. Ex.1005 at ¶288. Each discloses a spinal implant for insertion between two vertebrae. *Id.* These spinal implants all include openings for bone graft material to promote fusion between the vertebra through the implant itself. *Id.* Furthermore, each of spinal implants include bone screws designed for unicortical purchase and incorporate screw anti-back out mechanisms. *Id.* Finally, each spinal implant is designed to sit completely between the perimeter of the intervertebral disc space, without any portion sitting anteriorly of the vertebral bones. *Id.*

Therefore, a POSITA would be motivated to combine the teachings of Fraser '106, Byrd, and Michelson '045.

XII. CONCLUSION

Trial should be instituted and the Challenged Claims should be cancelled as unpatentable.

Dated: December 13, 2019

Respectfully Submitted,

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CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 13,932 words, as counted by Microsoft Word, and is therefore in compliance with the 14,000-word limit established by 37 C.F.R.

42.24(a)(1)(i). Accordingly, pursuant to 37 C.F.R. 42.24(d), lead counsel for the Petitioners hereby certify that this Petition complies with the type-volume limits established for a petition requesting IPR.

Dated: December 13, 2019

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. 42.6(4) and 42.105, lead counsel for Petitioners hereby certifies that on December 13, 2019, copies of this Petition and all supporting exhibits were sent via Federal Express to the correspondence address of record for the '537 patent:

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A courtesy copy of this Petition and supporting exhibits was also served via email on Patent Owner's counsel of record in the district court litigation:

Dated: December 13, 2019

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