UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

RSB SPINE, LLC,

Patent Owner.

Case No. IPR2020-00264

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 AND 30

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PETITIONERS' EXHIBIT LIST

<u>Exhibit</u>	Description
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	December 2, 2019 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	U.S. Patent Pub. No. 2002/0147450 ("LeHuec")
Ex.1015	Dorland's Illustrated Medical Dictionary (Anderson, Douglas, ed., The Curtis Center 2003) ("Dorlands Medical Dictionary")
Ex.1016	U.S. Patent No. 5,609,635 to Michelson ("Michelson '635")
Ex.1017	December 12, 2019 Disputed Terms for Constructions
Ex.1018	RESERVED
Ex.1019	RESERVED

I. <u>INTRODUCTION</u>

Petitioners request Inter Partes Review ("IPR") of claims 1, 3-6, 10, 13-15,

18, 19, 21, 22, 24, 29 and 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, Inc. ("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.

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

- RSB Spine, LLC. v. Life Spine, Inc., No. 18-1972-RGA (DED);
- RSB Spine, LLC. v. Medacta USA, Inc., No. 18-1973-RGA (DED);
- RSB Spine, LLC. v. Precision Spine, Inc., No. 18-1974-RGA (DED);
- RSB Spine, LLC. v. RTI Surgical, Inc., No. 18-1975-RGA (DED);
- *RSB Spine, LLC. v. Xtant Medical Holdings, Inc.*, No. 18-1976-RGA (DED); and
- RSB Spine, LLC. v. DePuy Synthes, Inc., No. 19-1515-RGA (DED).

The '537 patent is a continuation-in-part application of the '234 patent.

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, and 30 of the '537 patent; and
- IPR2020-00264 challenging claims 1, 3-6, 10, 13-15, 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))

Petitioners designate Dion M. Bregman (Reg. No. 45,645) as lead counsel for this matter, and designate Jason C. White (Reg. No. 42,223) as back-up counsel for this matter.

Postal mailings and hand-deliveries for lead and back-up counsel should be

addressed to: Morgan, Lewis & Bockius LLP, 77 W Wacker Drive, Fifth Floor,

Chicago, IL, 60606 (Telephone: 312.324.1000; Fax: 312.324.1001).

Pursuant to 37 C.F.R. §42.8(b)(4), Petitioners consents to e-mail service at: Medacta-IPRs@morganlewis.com.

For compliance with 37 C.F.R. §42.10(b), a Power of Attorney is also filed concurrently herewith.

III. <u>CERTIFICATION AND FEES</u>

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.

Any additional fees for this IPR may be charged to Deposit Account No. 50,0310 (Order No. 002691-8002).

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 only, and reserve the right to challenge this date in the pending district court litigation.

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 PCT application published on November 9, 2000 as WO 2000/066045A1 ("Michelson '045"). Michelson '045 is prior art to the '234 patent under pre-AIA §102(b) because it was published before the Priority Date.

Byrd (Ex.1008): U.S. Patent No. 7,077,864 ("Byrd") to inventor John 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 '234 patent under pre-AIA **§102(e)** because it was filed before the Priority Date.

Fraser '106 (Ex.1007): U.S. Patent No. 6,432,106 ("Fraser '106") 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 issued and was filed before the Priority Date respectively.

Petitioners request that the Board find each of the Challenged Claims

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unpatentable based on the following Grounds:

Ground	Statutory Basis and Art Cited	<u>Claims</u>
1	§103 – Obviousness over Fraser '106 (fused implant embodiment)	1, 10, 13, 14, 21, 22 and 29
2	§103 – Obviousness over Fraser '106 (fused implant embodiment) in view of Byrd	3, 15 and 19
3	§103 – Obviousness over Fraser '106 (two-piece implant embodiment)	1, 3, 13-15, 19, 21, 22 and 29
4	§103 – Obvious over Fraser '106 (fused and two-piece implant embodiments) in view of Michelson '045	4-6, 24 and 30
5	§103 – Obvious over Fraser '106 (fused and two-piece implant embodiments) in view of Michelson '045 and Byrd	18

V. <u>BACKGROUND</u>

A. <u>The '537 Patent</u>

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.

In human anatomy, anterior means "toward the belly surface of the body" and posterior means "towards the back surface of the body." Ex.1015, 97, 1494. Superior means "situated above, or directed upward" and inferior means "situated below, or directed downward. Ex.1015, 929, 1793. Medial means "pertaining to the middle; closer to the median plane or the midline of a body or structure" and lateral means "denoting a position farther from the median plane or midline of the

body or of a structure." Id. at 1001, 1110. See depiction below.



Ex.1005, ¶27.

The '537 patent also refers to "vertebral bones," which are found in the human spine. Ex.1002, 37:65-40:57. The specification explains that "[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 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; *see also* Ex.1002, 2:32-59, 3:5-14.

In 1988, the Hartshill Horseshoe product was launched. Ex.1005, ¶30. The horseshoe shaped device included angled screws for securing the device between adjacent vertebral bodies and provided a large area for bone graft material. It also

provided ample support around the ring of the vertebral body. Ex.1005, ¶30.



Figure 1 Hartshill Horseshoe

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; *see infra* Section V.B.

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.



This embodiment is also depicted in Figure 3, reproduced 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 bones.

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



FIG.3

Ex.1002, Fig.3

B. <u>Prosecution History</u>

1. Prosecution of the '537 patent

U.S. Patent Application No. 15/413,945, which was issued as the '537 patent, was filed on January 24, 2017. On March 10, 2017, the Examiner issued a non-final office action rejecting the claims as anticipated by U.S. Patent No. 7,112,222 ("Fraser '222"). Below is figure 1 from Fraser '222. Ex.1004, 172.



Fraser '222, Ex.1010, Fig.1

Patent Owner initiated an interview with the Examiner on April 7, 2017 and argued that the pending claims were not anticipated by Fraser '222. The Patent Owner's subsequent interview summary stated that "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, 218 (emphasis added).

On April 27, 2017, Patent Owner initiated a second interview, during which the Examiner presented Geisler and Henderson as additional prior art references. To overcome these additional references, Patent Owner argued that these base plates, like the implant in Fraser '222, cover the top surface of the bones, while the Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 claims require the device to sit between the bones. Ex.1004, 204, 218-219. Depicted below are the Geisler and Henderson implants discussed by the Examiner and Patent Owner.





Geisler, Ex.1011, Fig.7

Henderson, Ex.1012, Fig.14

On May 11, 2017, Patent Owner initiated a third interview with the

Examiner, who 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, 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, Patent Owner argued

the claims were distinct 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,

221; 222.

In response to these amendments and arguments, the Examiner issued a

notice of allowance stating:

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, 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. On May 24, 2005, the Examiner issued a non-final

office action rejecting all of the challenged independent claims and several

dependent 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, Patent Owner argued that Benzel did not disclose the claimed base plate with "a *first <u>end</u> nearer the first bone* and a *second <u>end</u> nearer the second bone, where in the base plate has a <i>first screw hole extending through the first <u>end</u> and a <i>second screw hole extending through the second <u>end</u> . . ." Ex.1003, 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, 97-98 (emphasis added).*

Thus, according to Patent Owner, the first and second ends of the claimed

base plate do not include 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 intuition 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. Ex.1010; Ex.1011; and Ex.1012. 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 with an elongated slot that permits a bone to subside after it was implanted, which is not at issue here.

Fourth, Petitioners are not presenting the same invalidity argument about Michelson '045 and Fraser '106 that was made during examination of the '537 patent, or that was 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.

Finally, 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)

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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 years of experience designing and developing orthopedic implants and/or spinal interbody devices.

VII. CLAIM CONSTRUCTION

In the district court litigation, the parties are engaged in claim construction. On December 12, 2019, Patent Owner, Petitioners, and non-petitioners Xtant and DePuy exchanged their initial list of Proposed Claim Terms for Construction, and the constructions continue to change slightly as the parties meet-and-confer. Exs.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.

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.1005, ¶55.

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, 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, 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.³ The entire disclosure of the '234 patent is directed to a base plate 20

³ It is also not presently clear if Patent Owner's proposed construction is attempting to add the "spacer" limitation to the claims, and if so, if that means

(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).

there must be a separate spacer and a base plate (*e.g.*, a two-piece device). Petitioner's address this issue in Ground 3 below.

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

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

Patent Owner and Petitioners currently agree that a POSITA would understand the term "lip osteophyte" is "a lip located the corner of the bone" and "is structurally the strongest portion of the vertebral bone." Ex.1005, ¶55.

The parties, however, currently disagree about whether a lip osteophyte is a bony outgrowth at the anterior corner of the bone, as proposed by Petitioners. As discussed in Section V, a healthy bone does not have 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, ¶27.



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	Plain and ordinary meaning		
bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws."			

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 ¶¶55-56.

ARGUMENT

The Challenged Claims of the '537 patent are unpatentable in view of the prior art references. The grounds and the supporting reasons for the unpatentability of each Challenged Claim are discussed below.

VIII. <u>GROUND #1: FRASER '106 RENDERS CLAIMS 1, 10, 13-14, 21-22</u> AND 29 OBVIOUS

Claims 1, 10, 13-14, 21-22 and 29 of the '537 patent are rendered obvious under 35 U.S.C. §103 in view of Fraser '106 (fused implant embodiment) and the knowledge of a POSITA.

A. <u>Claim 1</u>

1. Element 1[Preamble]⁴ - A bone stabilization plate system comprising:

The preamble is not a limitation of the claim because it does not breathe life

or meaning into the claim. Aspex Eyewear, Inc. v. Marchon Eyewear, Inc., 672

⁴ The Challenged Claims are listed in a claims appendix at the end of this Petition with labeled claim elements (*e.g.*, 1[Preamble] for the preamble of claim 1, 1[a] for the first element of claim 1, *etc.*).

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Petition for IPR of U.S. Patent No. 9,713,537
Case No. IPR2020-00264
F.3d 1335, 1347 (Fed. Cir. 2012) ("as a general rule preamble language is not
treated as limiting."). Nonetheless, Fraser '106 discloses the preamble.
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In particular, Fraser '106 teaches that the "spinal fixation assembly includes a fusion cage to which a plate is mated." Ex.1007, Abstract. Fraser '106 explains that "[t]he 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." Ex.1007, 1:36-42.



'537 patent, Ex.1002, Fig.3

Fraser '106, Ex.1007, Fig.8

As such, Fraser '106 discloses this limitation.

2. Element 1[a] – Base Plate

Fraser '106 discloses this limitation and each of the following features.

a. a base plate

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

Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 deployed across a bone graft site and is not used with a load-bearing fusion cage." Fraser '106 discloses a base plate that meets this definition.

As shown below, like the '537 patent, Fraser '106 discloses a fixation plate 66 to stabilize vertebrae for fusion. Fraser '106 explains that "[t]he **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." Ex.1007, 1:36-42; Ex.1005, ¶70.





Fraser '106, Ex.1007, Fig.8

Fraser '106 also discloses that the base plate is distinct from bone graft material, which is a particulate, powder, or paste added during surgery to fill the gap between the two bones. Ex.1005, ¶71.



Fraser '106, Ex.1007, Fig.1

Fraser '106 teaches that "**[p]rior to inserting a fusion cage** between vertebral bodies, the space bounded by the body 10 and transverse elements 28 and 30 (if included) **can be filled with autograft or allograft bone, or demineralized bone matrix (DBM)** to promote fusion." Ex.1007, 4:38-43; *see* Ex.1005, ¶72.

Further, Fraser '106 discloses an implant with a base plate and an integrated load-bearing fusion cage (orange, above), *i.e.*, is not used with a separate load-bearing fusion cage or spacer. In particular, Fraser '106 states that in one embodiment "**the plate 20 can be bonded firmly to the body 10 so that the plate and body cannot move with respect to each other**." Ex.1007, 2:34-35, 43-45; Ex.1005, ¶73.

Therefore, Fraser '106 discloses the claimed base plate, *i.e.*, a fixation plate (orange) to stabilize adjacent vertebrae for fusion, which is distinct from bone graft

b. having a top surface, first and second ends, a bottom surface

Fraser '106, depicted below, discloses a base plate with a top, bottom, and two ends. The base plate has a top surface (yellow), first end (blue) and second end (purple), and a bottom surface (green).⁵ The top surface is the anterior surface. Ex.1005, ¶133. The first/second ends (blue/purple) are the portions of the base plate nearer the first bone that exclude the middle portion of the plate. *Id*. The bottom surface is opposite the top surface and it sits against the bone graft material. *Id*.



Fraser '106, Ex.1007, Figs. 1-2

⁵ A POSITA would recognize that surface 14 could also be the claimed "bottom surface." Ex.1005, ¶75.





'537 patent, Ex.1002, Fig.3

Fraser '106, Ex.1007, Fig.8

c. a plurality of bone screw holes

Fraser '106 also discloses that "**the bone screw holes 36, 38, 40 and 42 can be disposed in or defined by plate extensions or tabs 36', 38', 40' and 42',** wherein the tabs and the remainder of the plate 20 can all lie in the same plane, or one or more of the tabs can be angled with respect to the remainder of the plate or one or more of the other tabs." Ex.1007, 3:7-12; *see* Ex.1005, ¶78. These bone screw holes are depicted in figure 2 below (as shown in red).



Fraser '106, Ex.1007, Fig.2

Therefore, as described above, Fraser '106 discloses this claim limitation.

3. Element 1[b] – Base Plate Fit

Fraser '106 discloses this limitation and each of the following features.

a. wherein the base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes

Fraser '106 discloses a base plate implanted between the bones' lip osteophytes. Ex.1005, ¶81. Like the '537 patent, depicted below, Fraser '106 discloses a base plate (orange below) configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes. The '537 patent identifies lip osteophyte 74 in figure 3 and the specification describes the lip osteophyte as the corner of the vertebral body. Ex.1002, 11:27-28. In figure 8 of Fraser '106, "portions of the vertebral bodies are shown cut-away to illustrate the penetration of the bone screws 58 and 60 into the bodies" which is represented by the crosshatching. Ex.1007, 4:14-16. These screws can go through the corners of the

bones.



Fraser '106 also meets this limitation because it teaches that "[t]he cage includes **a body 10 that approximates the shape and size of the annulus portion of a disk** which normally separates two vertebral bodies." Ex.1007, 2:21-23; *see id.*, 4:48-52; Ex.1005, ¶82. Thus, Fraser '106 discloses that the shape of the implant is designed to fit in the cavity between the bones that was previously occupied by the disk.

Furthermore, during prosecution of the application that issued as the '537 patent, Patent Owner clarified that the claimed base plate must be retained between the bones (like Fraser '106 depicts), and not attached to the anterior surface of the bones (like the prior art of record). For example, as noted above in Section V.B.1,

Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 during prosecution the claims were rejected by Geisler and Henderson. Patent Owner argued to the Examiner that this rejection should be traversed because "each of these [prior art] cage devices is not configured to fit primarily between anterior portions of the bone bodies' lip osteophytes and they have top plates that cover significant portions of the top surfaces of the bones bodies." Ex.1002, 218-219 (emphasis added). Geisler and Henderson are depicted below.





Geisler, Ex.1011, Fig.7

Henderson, Ex.1012, Fig.14

In contrast, as depicted in figure 8 below, Fraser '106 fits between and attaches to the superior (portion closer to the person's' head) and inferior (portion closer to the person's feet) surfaces of the bones and is not attached to the anterior (top surface) of the bones. Fraser '106 also states that "[i]t is important to note that
screw heads 62 and 64 are flush or sub-flush with the anterior face surface 66 of

the fusion cage, thus minimizing the likelihood that major blood vessels

running along the spine will be injured."). Ex.1007, 4:16-19; Ex.1005, ¶84.



Fraser '106, Ex.1007, Fig.8

For all of these reasons, Fraser '106 discloses a base plate that is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes.

b. to bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion

Fraser '106 teaches a base plate that bears weight in conjunction with the bone graft material. Fraser '106 teaches that "**the fusion cage body** closely approximate the shape of a natural disk and **provide an excellent, stable, load-bearing surface.**" Ex.1007, 4:48-54; *see* Ex.1005, ¶86.

Fraser '106 further discloses that "the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion." Ex.1007, 4:37-42; *see* Ex.1005, ¶86. A POSITA would understand that after the Fraser '106 implant is filled with bone graft material and subsequently inserted between the surfaces of the vertebrae, the vertebrae would be in direct contact with the bone graft material. Ex.1005, ¶86. A POSITA would further understand that when the bone screws engage each of the vertebral bodies, those screws would place a compressive load on the bone graft material and promote fusion between the bones. *Id.* As such, a POSITA would understand that Fraser '106 discloses that the base plate shares weight with bone graft material for fusion. *Id.*

Finally, Fraser '106 teaches a base plate that holds the bones. Fraser '106 teaches that its "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." Ex.1007, 1:40-42; *see* Ex.1005, ¶87.

Therefore, as described above, Fraser '106 discloses this claim limitation.

4. Element 1[c] - Bone Screws

As depicted below, like the '537 patent, Fraser '106 discloses "a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively."





Therefore, Fraser '106 discloses "a plurality of bone screws (58 and 60) configured to fit in the plurality of bone screw holes (36, 38, 40 and 42), respectively."

5. Element 1[d] - Vertebral Bones

As an initial matter, the limitation "wherein the vertebral bones have top surfaces and have side surfaces generally facing each other" merely describes the natural configuration of vertebral bones. The side surface is the superior or inferior surface of the bone, excluding the lip osteophyte and corner of the bone.

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Ex.1005, ¶91. The '537 patent specification explains that "[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, 1:45-48. As such, this limitation is known in the art.

In any event, Fraser '106 discloses this limitation. Fraser '106 is directed toward "medical devices, and more particularly to an implantable structure for promoting fusion of **adjacent vertebral bodies**." Ex.1007, 1:14-16; *see* Ex.1005, ¶92. With reference to figure 7, Fraser '106 discloses two adjacent vertebral bodies having top surfaces (blue) and side surfaces (red).



Fraser '106, Ex.1007, Fig.7

Therefore, Fraser '106 discloses "vertebral bones (50 and 54) have top

surfaces (blue) and have side surfaces generally facing each other (red)."

6. Element 1[e] – Side Surface

As shown below, like the '537 patent, Fraser '106 discloses "wherein a first of the bone screw holes, being configured to receive a first of the bone screws (green), 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." Fraser '106 teaches "**bone screws 46 and 48**...**disposed through the holes** in tabs 40' and 38." Ex.1007, 3:13-17; *see* Ex.1005, ¶95.







A screw hole is opens at least partially toward the side surface if it is directed towards, such that the longitudinal axis of the bone screw would intersect at least a portion of the side surface. Ex.1005, ¶96. Fraser '106 teaches that "[t]he angle formed by the tab(s) and plate, as well as by the screw(s) and medial plane, is designated as " α " and is determined by a particular situation and a patient's anatomy" and that "the angle "a" can range from 15° to 60°..."

Ex.1007, 3:24-28; *see* Ex.1005, ¶96. Fraser '106 also discloses that each of the screw angles can be adjusted independently of one another. *See* Ex.1007, 5:33-35 ("...wherein **one of the first tab and the second tab** is angled with respect to the plate at an angle between 15° and 60° .")



Fraser '106, Ex.1007, Fig.3

Fraser '106 teaches a range of angles (15°-60°) for the top and the bottom holes and also allows for different angles for those top and bottom holes. As such, the screw hole can have a shallow angle to open toward the side surface of the vertebrae or a steep angle to open toward the lip osteophyte. Fraser '106 explicitly teaches both. Furthermore, it would have been obvious to a POSITA to perform routine experimentation and optimization to choose the most suitable angle for each hole based on any particular patient or set of patients. Ex.1005, ¶97

Therefore, Fraser '106 discloses "wherein a first of the bone screw holes

[screw hole of the green screw], being configured to receive a first of the bone screws [green screw], 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 depicted above].".

7. Element 1[f] – Lip Osteophyte

As noted in the prior limitation, Fraser '106 discloses a screw hole with a wide range of screw insertion angles. This disclosure also includes "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." Ex.1007, 3:13-17; Ex.1005, ¶¶97, 100-101; *see also* Ex.1007, 3:24-28; Ex.1005, ¶96.

A screw hole opens at least partially toward the lip osteophyte if it is directed towards, such that the longitudinal axis of the bone screw would intersect at least a portion of the lip osteophyte. In Fraser '106, with respect to the midline p of the base plate, as depicted in Fig.3 below, the disclosed angle ranges from 15° to 60°. As such, the screw hole can have a shallow angle to open toward the side surface of the vertebrae or a steep angle to open toward the lip osteophyte. Fraser '106 explicitly teaches both.



Fraser '106, Ex.1007, Fig.3

Furthermore, it would have been obvious to a POSITA to perform routine experimentation and optimization to choose the most suitable angle for each hole based on any particular patient or set of patients. Ex.1005, ¶101. As shown below, like the '537 patent, Fraser '106 discloses this claim limitation.



'537 patent, Ex.1002, Fig.3

Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses "wherein a first of the bone screw holes [screw hole of the purple screw], being configured to receive a second of the bone screws [purple screw], 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 [as depicted at 60°]."

8. Element 1[g] – Bone Screw Orientation

Fraser '106 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."

As shown below, like the '537 patent, Fraser '106 discloses bone screw holes angled relative to the top surface of the base plate and facing the posterior direction.



Therefore, Fraser '106 discloses "wherein each and every one of the plurality of bone screw holes is configured to receive one of the bone screws (purple and green) angled relative to the base plate (red) and oriented generally in an anterior-posterior direction (purple and green) through at least partially the top surface of the base plate (orange)."

In summary, Fraser '106 discloses each and every limitation recited by independent claim 1.

B. <u>Claim 10 – Lateral Tabs</u>

Claim 10 depends from independent claim 1, which is rendered obvious by Fraser '106 for the reasons provided in Section VIII.A, and incorporated here.

Like the '537 patent, Fraser '106 discloses "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." The lateral tabs are projections extending from the bottom surface of the primary member fitting around the bone graft. Ex.1005, ¶¶108-112.



'537 patent, Ex.1002, Fig.3

Fraser '106, Ex.1007, Fig.8

As shown above, the tabs extend in an anterior-posterior direction, which is generally transverse to the direction of the vertebral bones. Ex.1005, ¶110.

Furthermore, as shown below, Fraser '106 discloses two lateral tabs that extend from opposite ends of the bottom surface (green) of the base plate.



Therefore, Fraser '106 discloses "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."

C. <u>Claim 13 – Flush Top Surface</u>

Claim 13 depends from independent claim 1, which is rendered obvious for the reasons provided in Section VIII.A, and incorporated here.

Fraser '106 also discloses "wherein the top surface of the base plate coincides with or generally matches an outer diameter of the anterior cortex of the vertebral bones." The anterior cortex is continuous with the outer rim of the endplate of the vertebral body. Ex.1005, ¶114. Fraser '106 discloses "that screw heads 62 and 64 are **flush or sub-flush** with the anterior face surface 66 of the fusion cage, thus **minimizing the likelihood that major blood vessels running along the spine will be injured**." Ex.1007, 4:16-19; *see* Ex.1005, ¶114. Consistent with this desire to minimize damage to major blood vessels, Fraser '106 teaches the "cage includes a **body 10 that approximates the shape and size of the annulus portion of a disk** which normally separates two vertebral bodies." Ex.1007, 2:21-23; *see* Ex.1005, ¶114. Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 As shown below, like the '537 patent, Fraser '106 discloses that the top surface of the base plate coincides with or generally matches an outer diameter of the anterior cortex of the vertebral bones.



Therefore, Fraser '106 discloses "wherein the top surface of the base plate coincides with or generally matches an outer diameter of the anterior cortex of the vertebral bones."

D. <u>Claim 14 – First and Second Ends</u>

Claim 14 depends from independent claim 1, which is rendered obvious by Fraser '106 for the reasons provided in Section VIII.A, and incorporated here.

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]." Fraser '106 also teaches "the first end comprising a first bone engaging Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 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." The first/second ends (blue/purple) are at least the tab portions of the base plate nearer the first/second bone that exclude the middle portion of the plate. Ex.1005, ¶120.





'537 patent, Ex.1002, Fig.4

Fraser '106, Ex.1007, Fig.2

In particular, Fraser '106 teaches "**the head of each screw engages the respective tab to inhibit passage of the head through the aperture in the tab**." Ex.1007, 3:13-17; *see* Ex.1005, ¶121.

Therefore, Fraser '106 discloses this claim limitation.

E. <u>Claim 21</u>

Except for portions of elements 21[c]-[d] (discussed below), independent claim 1 and dependent claim 14 recites elements that are analogous in scope to the

elements of independent claim 21. Thus, most of claim 21 is rendered obvious for

the same reasons described above with respect to claims 1 and 14, and

Claims 1 and 14	Analogous Claim 21 Limitations	Disclosure in Fraser '106
1[Preamble]	21[Preamble]	Section VIII.A.1
1[a], 14	21[a]	Sections VIII.A.2 and VIII.D
1[b]	21[b]	Section VIII.A.3

incorporated here, as shown in the table below. Ex.1005, ¶¶123-147.

1. Element 21[c] – First Bone Screw

Fraser '106 discloses this limitation and each of the following features.

a. 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

Regarding the first feature, Fraser '106 teaches this limitation, as explained

in Section VIII.A.6, and incorporated here. Ex.1005, ¶¶148-153.

b. the first bone screw configured to secure the base plate to the first bone by insertion through the first bone screw hole

Fraser '106 discloses that "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." Ex.1007, 1:40-43; see

Ex.1005, ¶¶154-156. The bone screw securing the base plate to the bone is

depicted below.



'537 patent, Ex.1002, Fig.3 Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses this claim limitation.

2. Element 21[d] – A Second Bone Screw

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. Fraser '106 discloses this limitation and each of these features.

a. 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

Fraser '106 discloses this limitation, as explained in Section VIII.A.7, and incorporated here. *See* Ex.1005, ¶¶158-162.

b. the second bone screw configured to secure the base plate to the second bone by insertion through the second bone screw hole

Fraser '106 discloses that "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." Ex.1007, 1:40-43; see

Ex.1005, \P 163-165. The bone screw securing the base plate to the bone is

depicted below.



'537 patent, Ex.1002, Fig.3 Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses this claim limitation.

In summary, Fraser '106 discloses each and every limitation recited by independent claim 21.

F. <u>Claim 22 – Top Surface Anterior Boundary</u>

Claim 22 depends from independent claim 21, which is rendered obvious by

Fraser '106 for the reasons provided in Section VIII.E, and incorporated here.

As shown below, like the '537 patent, Fraser '106 discloses that "the entire top surface of the base plate is configured to be an anterior boundary of a bone graft site [yellow]." The Fraser '106 base plate is cutaway, below, to depict how the anterior portion of the base plate is a boundary for the bone graft site.



Therefore, Fraser '106 discloses "wherein the entire top surface of the base plate (orange) is configured to be an anterior boundary of a bone graft site (yellow)."

G. <u>Claim 29 – More Than Two Bone Screw Holes</u>

Claim 29 depends from independent claim 21, which is rendered obvious by Fraser '106 for the reasons provided in Section VIII.E, and incorporated here. *a. the base plate has more than two bone screw holes*

As shown in figure 2, below, Fraser '106 discloses that the base plate has

more than two bone screw holes. See Ex.1005, ¶¶172-173.



Fraser '106, Ex.1007, Fig.2

b. 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

As explained in Section VIII.A.8, Fraser '106, depicted below, discloses this

limitation. Ex.1005, ¶¶174-178.



'537 patent, Ex.1002, Fig.3



Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 teaches "the base plate has more than two bone screw holes [red], and each and every one of the bone screw holes is configured to receive a bone screw angled relative to the base plate (green and purple screws) and oriented generally in an anterior-posterior direction through the top surface of the base plate."

IX. <u>GROUND #2: FRASER '106 IN VIEW OF BYRD RENDERS CLAIMS</u> 3, 15, AND 19 OBVIOUS

Claims 3, 15, and 19 of the '537 patent are rendered obvious under 35 U.S.C. §103 in view of Fraser '106 and Byrd.

A. <u>Claim 3 – Generally Flat Bottom Surface</u>

Claim 3 depends from independent claim 1, which is obvious in view of Fraser '106 for the reasons provided in Section VIII.A, and incorporated here.

Regarding claim 3, Fraser '106 discloses "the bottom surface of the base plate is generally flat." As shown in figure 1, Fraser '106 discloses a bottom surface⁶ (green) that contacts bone graft material (yellow).

⁶ Additionally, a POSITA would recognize that surface 14 of Fraser '106 could be the claimed "bottom surface" that "is generally flat." Ex.1005, ¶181.



Fraser '106, Ex.1007, Fig.1

Fraser '106 inherently discloses that this is a generally flat bottom surface because transverse elements 28 and 30 are optional, Ex.1007, 2:51-45, 4:39-40 ("transverse elements 28 and 30 (if included)"), and without transverse elements 28 and 30, the bottom surface would be generally flat. Ex.1005, ¶182.

Additionally, it would have been an obvious matter of design choice POSITA for to make this implant with a generally flat bottom surface, *e.g.*, by removing transverse elements 28 and 30 and making a flat surface. Ex.1005, ¶183.

If the Board determines that the bottom surface of Fraser '106 does not inherently disclose, or that it would be obvious to make, a generally flat bottom surface, it would have been obvious for a POSITA to modify the bottom surface of Fraser '106 to be generally flat in view of Byrd. Ex.1005, ¶184. Byrd discloses a base plate with a flat anterior wall (top surface) and an interior surface 24 (bottom

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Case No. IPR2020-00264 surface) with the same shape. Byrd, Ex.1008, 5:29-32 ("The cage is hollow with a center opening 22 defined by a **smooth continuous interior surface 24** that generally corresponds to the smooth continuous exterior surface of the cage 10."); *id.*, 5:55-59 ("The exterior surface 26 of the anterior wall is **substantially 'flat' or smoothly, fluidly continuous**"). Byrd's generally flat bottom surface (green) is depicted below.

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Byrd, Ex.1008, Figs.1-2

Like the '537 patent, Byrd discloses that this surface contacts bone graft material. *Compare* Ex.1008, 5:40-42 ("The center opening is for the inclusion of a suitable bone graft material used to promote fusion.") *with* Ex.1002, 8:49-52 ("[t]he base plate 20 has a bottom surface 26 that contacts the bone graft 12.").

Therefore, it would have been an obvious matter of design choice for a POSITA to modify the bottom surface of Fraser '106 to be generally flat in view of Byrd by not including optional transverse elements 28 and 30 from the Fraser '106 implant and then making the resulting bottom surface generally flat, which is See Section IX.D, below, for full discussion of the motivation to combine Fraser '106 with Byrd.

Therefore, Fraser '106 in view of Byrd discloses "the bottom surface of the base plate is generally flat".

B. <u>Claim 15</u>

1. Element 15[Preamble] – Bone Stabilization Plate System

The preamble recites elements that are identical to the elements of the claim 1 preamble. The preamble is not a limitation of the claim, as it does not breathe life or meaning into the claim. *Aspex Eyewear*, 672 F.3d at 1347. Nonetheless, as shown above in Section VIII.A.1, incorporated here, Fraser '106 discloses a "bone stabilization plate system." *See* Ex.1005, ¶189-191.

2. Element 15[a] – Base Plate

a. a base plate

This element is the identical element recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.2 (Ground 1), and incorporated here. *See* Ex.1005, ¶¶192-198.

b. a plurality of bone screw holes

This element is the identical element recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.2 (Ground 1), and incorporated here. See Ex.1005, ¶¶199-200.

c. a top surface, a generally flat bottom surface and first and second ends

The elements "a top surface, a...bottom surface and first and second ends" are the identical elements recited in claim 1, and are disclosed by Fraser '106 for the reasons provided in Section VIII.A.2 (Ground 1), and incorporated here. The element "a generally flat bottom surface" is the identical element recited in claim 3, and is disclosed by Fraser '106 in view of Byrd for the reasons provided in Section IX.A (Ground 3), and incorporated here. *See* Ex.1005, ¶201-210.

3. Element 15[b] – Retaining Bone Graft

a. retaining bone graft material between adjacent vertebral bone

Fraser '106 discloses that "the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion." Ex.1007, 4:37-42; *id*. Ex.1007, 1:40-42; *see* Ex.1005, ¶¶212-213. Figure 1, below, depicts bone graft material (yellow) being retained within body 10.



Fraser '106, Ex.1007, Fig.1

Additionally, as depicted below, like the '537 patent, Fraser '106 discloses retaining bone graft material (yellow) between adjacent vertebral bone bodies. Fraser '106 is depicted with a cutaway to show the how the base plate retains the bone graft material between the bones.





'537 patent, Ex.1002, Fig.3 (cutaway)

Therefore, Fraser '106 discloses "retaining bone graft material between

adjacent vertebral bone bodies having top surfaces and having side surfaces

generally facing each other."

b. vertebral bone bodies having top surfaces and having side surfaces generally facing each other

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.5 (Ground 1), and incorporated here. *See* Ex.1005, ¶215-217.

4. Element 15[c] – Without Covering Top Surfaces

a. the base plate is configured to fit primarily between anterior portions of the bone bodies' lip osteophytes

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.3 (Ground 1), and incorporated here. *See* Ex.1005, ¶219-223.

b. without covering significant portions of the top surfaces of the bone bodies

Fraser '106 discloses "a base plate that does not cover[] significant portions of the top surfaces of the bone bodies." Specifically, Fraser '106 discloses that the implant does not extend beyond the anterior surface of the bones because "screw heads 62 and 64 are **flush or sub-flush** with the anterior face surface 66 of the fusion cage, thus **minimizing the likelihood that major blood vessels running along the spine will be injured**." Ex.1007, 4:16-19; *see* Ex.1005, ¶224. Fraser '106 also discloses that the "cage includes a body 10 that approximates the shape

and size of the annulus portion of a disk which normally separates two vertebral bodies." Ex.1007, 2:21-23; *see* Ex.1005, \P 224. As a result, Fraser '106 discloses an implant located between the bones, shaped like a bone disk, and not significantly protruding beyond the anterior surface of the bones.

Further, as depicted below, this implant does not have any feature that cover significant portions of the top surfaces of the bones. Ex.1005, ¶¶225-226.



'537 patent, Ex.1002, Fig.3

Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 discloses "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."

5. Element 15[d] – Primarily Bear Weight

a. a base plate that primarily bears weight in conjunction with the bone graft material

The elements "to…bear weight, and to permit force transmission between the bone bodies through the bone graft material" are analogous in scope to Fraser '106 further discloses that the base plate primarily bears weight in conjunction with the bone graft material, *i.e.*, mainly bears the weight. Ex.1005, ¶227. Fraser '106 states the fusion cage body provides an excellent, stable, load-bearing surface and that the plate ensures that the body will not become dislodged from the spine. Ex.1007, 4:48-54; *see* Ex.1005, ¶227-232.

Fraser '106 also discloses that "[t]itanium or carbon fiber composites are suitable materials for the plate 20." Ex.1007, 2:34-36; *see* Ex.1005, ¶¶314-321. A POSITA would understand that because the plate 20 is made of titanium or carbon fiber composites, like the base plate 20 described in the '537 patent, and because the plate holds the bones in a stable relationship during fusion, Ex.1007, 1:40-42; *see* Ex.1005, ¶¶314-321, the plate 20 primarily bears weight with respect to the non-structural demineralized bone matrix. *See* Ex.1002, 8:40-41; Ex.1005, ¶¶227-232; 314-321.

A POSITA would further understand that because the bone graft described in Fraser '106 is less stiff (*e.g.*, lower modulus of elasticity) than the plate 20, the bone graft would necessarily bear less weight than the plate. Ex.1005, ¶¶227-232; 314-321. Thus, after implantation, when the vertebrae compress on the implant, the majority of the weight will be loaded onto the combined plate 20 and body 10 due

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to their higher modulus of elasticity, and that some weight will still be carried by the bone graft material. Therefore, a POSITA would understand that the Fraser '106's base plate (plate 20 and body 10) primarily bear weight in conjunction with the bone graft material. Ex.1005, ¶227-232.

A POSITA would also understand the plate 20 primarily bears weight as the patient moves (*e.g.*, bending forward). Ex.1005, ¶¶314-321. Because the plate 20 is fixed to the bones, yet allowed to move with respect to the body 10, when a patient bends forward the anterior portions of the vertebrae will compress and place the majority of the load onto the plate 20. Ex.1005, ¶¶314-321. This motion may also cause the vertebrae and plate 20 (which are fixed to one another) to shift with respect to the body 10. *Id*. A POSITA would understand isolating the body 10 from such shifting is desirable so fusion through the body 10 is not disturbed. *Id*. Therefore, a POSITA would understand that the Fraser '106's plate 20 primarily bears weight.

b. holding the bone bodies for fusion

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.3 (Ground 1), and incorporated here. Ex.1005, ¶¶233-234.

Therefore, Fraser '106 discloses a base plate "to primarily bear weight, and to permit force transmission between the bone bodies through the bone graft

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material while holding the bone bodies for fusion."

6. Element 15[e] – Lip Osteophytes

a. a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.4 (Ground 1), and incorporated here. *See* Ex.1005, ¶235-237.

b. the bone screws configured to anchor primarily into the lip osteophytes

The claim recites elements that are analogous in scope to the elements of claim 1, and disclosed by Fraser '106 for the reasons provided in Sections VIII.A.7 and VIII.A.8 (Ground 1), and incorporated here. This limitation in Ground 1 is directed to bone screw holes that open toward the lip osteophytes, while this limitation is directed to bone screws that anchor primarily into the lip osteophytes. Bone screws follow the bore hole of a bone screw hole. Thus, if a bone screw hole is open toward a lip osteophytes, then the associated bone screw is also configured to anchor primarily into the lip osteophytes. Ex.1005, ¶238-242.

7. Element 15[f] – Side Surface

a. bone screws extending from the top surface of the base plate to the side surface of the bone

The claim recites elements that are analogous in scope to the elements of claim 1, and disclosed by Fraser '106 for the reasons provided in Sections VIII.A.6

and VIII.A.8 (Ground 1), and incorporated here. This limitation in Ground 1 is directed to bone screw holes that extend from the top surface of the base plate and opens toward the side surface of the bone, while this limitation is directed to bone screws that extending from the top surface of the base plate to the side surface of the bone. Bone screws follow the bore hole of a bone screw hole. Thus, if a bone screw hole extends from the top surface of the base plate to the side surface of the bone, then the associated bone screw will also extend from the top surface of the base plate to the surface of the base plate to the side surface plate pl

b. the bone screws securing the base plate

Fraser '106 discloses that "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**." Ex.1007, 1:40-43; *see* Ex.1005, ¶¶243-250. Screws retaining the base plate are depicted below.



'537 patent, Ex.1002, Fig.3

Fraser '106, Ex.1007, Fig.8

Therefore, Fraser '106 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, such that the base plate is secured."

In summary, Fraser '106 in view of Byrd renders claim 15 obvious.

C. <u>Claim 19 – Bone Screw Orientation</u>

Claim 19 depends from independent claim 15, which is rendered obvious by Fraser '106 in view of Byrd for the reasons provided in Section IX.B, and incorporated here.

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in VIII.A.8 (Ground 1), and incorporated here. *See* Ex.1005, ¶251-254.

D. <u>Reasons and Motivations to Combine Fraser</u> <u>'106 in view of Byrd</u>

A POSITA would have been motivated to modify the Fraser '106 base plate in view of Byrd so that the bottom surface that contacts the bone graft is generally flat for the following reasons. Ex.1005, ¶255.

First, a POSITA would have appreciated that Fraser '106 and Byrd are analogous to the claimed subject matter in the '537 patent because they are all within the same field of endeavor and address the same problem. *See Bigio*, 381 F.3d at 1325, 72 USPQ2d at 1212.

The '537 patent defines its "Technical Field" as "implant devices for the

fixation and support of bone bodies." Ex.1002, 1:32-33. The problem addressed in the '537 patent is a way to treat degenerative conditions by "immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space." Ex.1002, 2:3-6. Consistent with this, the claims are directed to a "bone stabilization plate system."

Just like the '537 patent, Fraser '106 and Byrd are also directed to a spinal implant for fixation and support of vertebrae to promote fusion. Fraser '106, Ex.1007, 1:14-16 ("The present invention relates to . . . an implantable structure for promoting fusion of adjacent vertebral bodies"); Byrd, Ex.1008, 2:26-28 ("an object of the invention to provide for relative stability of the adjacent vertebrae to facilitate spinal fusion."), *see also* Abstract.

Furthermore, the '537 patent states that its implant is designed to retain bone graft material. Ex.1002, 5:13-19. Fraser '106 and Byrd also disclose implants that retain bone graft material. Fraser '106, Ex.1007, 9 ("the space bounded by the body 10...can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion"); Byrd, Ex.1008, 5:29-42 ("[the] center opening is for the inclusion of a suitable bone graft material used to promote fusion."). Therefore, Fraser '106 and Byrd are analogous art and would have been considered by a POSITA attempting to solve the problem of a damaged spine. Ex.1005, ¶¶255-259.

Second, a POSITA would have been motivated to combine Fraser '106 and Byrd. In particular, a POSITA would have appreciated that an implant with an open interior portion without Fraser's central ribs (i.e., first and second transverse elements 28 and 30) would be simpler and less expensive to manufacture, while also promoting additional bone growth. Ex.1005, ¶260. Therefore, removing transverse elements 28 and 30 disclosed by Fraser '106 so as to create an open interior with a generally flat bottom surface taught by Byrd would be a simple removal of one extraneous element to obtain an improved device. *Id*.

The modification Fraser '106 in view of Byrd would also be simple for a POSITA to undertake, and would lead to a reasonable expectation of success, as the only modification required to Fraser '106 would be to remove the two transverse elements 28 and 30 of the implant. Ex.1005, ¶261.

As such, it would have been obvious for a POSITA to modify Fraser '106 to have the flat bottom surface taught by Byrd, thereby rending claims 3, 15 and 19 unpatentable as obvious.

X. <u>GROUND #3 FRASER '106 IN VIEW OF THE KNOWLEDGE OF A</u> <u>POSITA RENDERS CLAIMS 1-3, 8-16, 19-23, 25-27 AND 29</u> <u>OBVIOUS</u>

Patent Owner's preliminary construction in district court states that the base plate is distinct from both bone graft material and a spacer. The parties agree that the base plate is separate from the bone graft, however, it is unclear from Patent Owner's proposed construction whether the claims also require a separate spacer. Therefore, for the sake of completeness in this petition, and to the extent that the Patent Owner argues and the Board agrees that the claims require both a base plate and a separate spacer (*i.e.*, a two-piece implant), this ground explains how Fraser '106 discloses a two-piece implant. As such, claims 1-3, 13-15, 19, 21, 22 and 29 of the '537 patent are rendered obvious under 35 U.S.C. §103 in view of Fraser '106 (two-piece implant) and the knowledge of a POSITA.

A. <u>Base Plate</u>

Fraser '106 discloses a two-piece embodiment where the plate 20 and body 10 are not bonded. In particular, Fraser '106 teaches "[a]though the plate 20 can be bonded firmly to the body 10 so that the plate and body cannot move with respect to each other, **they can also be mated to allow movement with respect to each other**." Ex.1007, 2:43-46. In particular, Fraser '106 teaches "**the plate 20 includes a tenon 24 that is disposed within a mortise 26 defined by the body 10**, wherein the tenon can slide in a superior/inferior direction within the mortise." Ex.1007, 2:46-50. The base plate in this embodiment of Fraser '106 is below.



Fraser '106, Ex.1007, Fig.1

B. <u>Claim 1</u>

Claim limitations not discussed below are incorporated here from Ground 1.

1. Element 1[a] – Base Plate

Fraser '106 discloses this limitation and each of the following features.

a. a base plate

In the event the Board determines that the term "base plate" requires a plate that is distinct from a load-bearing fusion cage, Fraser '106 discloses a two-piece embodiment where the plate 20 and body 10 are not bonded (*i.e.*, they are distinct) as discussed in Section X.A above, and incorporated here. *See* Ex.1005, ¶266-267.
b. having a top surface, first and second ends, a bottom surface

Fraser discloses a base plate with a top, bottom, and two ends, as depicted in the figures below. Specifically, the base plate has a top surface (yellow), first end (blue) and second end (purple), and a bottom surface (green). *See* Ex.1005, ¶268-269. The first/second ends (blue/purple) are the portions of the base plate nearer the first/second bone that exclude the middle portion of the plate. Ex.1005, ¶268.



Fraser '106, Ex.1007, Figs.1-2

c. a plurality of bone screw holes

Fraser '106 also discloses that "**the bone screw holes 36, 38, 40 and 42 can be disposed in or defined by plate extensions or tabs 36', 38', 40' and 42'**..." Ex.1007, 3:7-12; *see* Ex.1005, ¶270. These bone screw holes are depicted in figure 2 below (red).



Fraser '106, Ex.1007, Fig.2

Therefore, Fraser '106 in view of the knowledge of a POSITA renders this

claim limitation obvious.

2. Element 1[b] – Base Plate Fit

Fraser '106 discloses this limitation and each of the following features.

a. wherein the base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes

Fraser '106 discloses a base plate (orange) configured to fit primarily

between anterior portions of adjacent vertebral bones' lip osteophytes.





'537 patent, Ex.1002, Fig.3 Fraser '106, Ex.1007, Fig.8

Furthermore, Fraser '106 also meets this limitation because the specification teaches that "screw heads 62 and 64 are **flush or sub-flush with the anterior face surface 66** of the fusion cage, thus minimizing the likelihood that major blood vessels running along the spine will be injured." Ex.1007, 4:15-18; *see* Ex.1005, ¶¶273-277. Thus, Fraser '106 discloses that the plate and its screws are designed to sit flush with anterior surface 66, which is within the cavity between the bones that was previously occupied by the disk.

For these reasons, as well as the reasons discussed in Section VIII.A.3 (Ground 1), incorporated here, Fraser '106 discloses a base plate that is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes. b. a base plate that bears weight in conjunction with the bone graft material

Fraser '106 discloses that "**[t]he 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**." Ex.1007, 1:40-42; *see* Ex.1005, ¶278. A POSITA would understand that in order to hold the adjacent vertebral bodies in a stable relationship to promote fusion, the plate would bear weight.

Fraser '106 further discloses that "the space bounded by the body 10 and transverse elements 28 and 30 (if included) can be filled with autograft or allograft bone, or demineralized bone matrix (DBM) to promote fusion." Ex.1007, 4:37-42; *see* Ex.1005, ¶279. A POSITA would understand that after the Fraser '106 implant is filled with bone graft material and subsequently inserted between the surfaces of the vertebrae such that the vertebrae would be in direct contact with the bone graft material. Ex.1005, ¶279. A POSITA would further understand that when the bone screws engage each of the vertebral bodies, those screws would place a compressive load on the bone graft material and promote fusion between the bones. *Id.* As such, a POSITA would understand that Fraser '106 discloses that the base plate shares weight with bone graft material for fusion. *Id.*

Finally, Fraser '106 teaches a base plate that holds the bones. Fraser '106 teaches that its "plate is configured to receive, retain and orient bone screws,

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thereby holding the fusion cage and adjacent vertebral bodies in a stable relationship to promote fusion." Ex.1007, 1:40-42; *see* Ex.1005, ¶280.

Therefore, Fraser '106 in view of the knowledge of a POSITA renders the claim limitation "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" obvious.

C. <u>Claim 3 – Generally Flat Bottom Surface</u>

Claim 3 depends from independent claim 1, which is rendered obvious by Fraser '106 for the reasons provided in Section X.B, and incorporated here.

Fraser '106 discloses "the bottom surface [green] of the base plate is generally flat." *See* Ex.1005, ¶¶282-285.



Fraser '106, Ex.1007, Fig.1

Therefore, Fraser '106 in view of the knowledge of a POSITA renders this claim obvious.

D. <u>Claim 13 – Flush Top Surface</u>

For the reasons discussed with respect to claim 13 in Section VIII.C (Ground 1), incorporated here, Fraser '106 in view of the knowledge of a POSITA renders this claim obvious. *See* Ex.1005, ¶¶286-291.

E. <u>Claim 14 – First and Second Ends</u>

For the reasons discussed with respect to claim 14 in Section VIII.D, (Ground 1), incorporated here, Fraser '106 in view of the knowledge of a POSITA renders this claim obvious. *See* Ex.1005, ¶¶292-295.

F. <u>Claim 15</u>

Fraser '106 discloses the remainder of the claim limitations of claim 15 as set forth in Ground 2 above. Claim limitations not discussed are incorporated by reference from Ground 2.

1. Element 15[a] – Base Plate

Fraser '106 discloses this limitation and each of the following features.

a. a base plate

In the event the Board determines that the term "base plate" requires a plate that is distinct from a load-bearing fusion cage, Fraser '106 discloses a two-piece embodiment where the plate 20 and body 10 are not bonded as discussed in Section X.A above, incorporated here. *See* Ex.1005, ¶¶297-298.

b. a plurality of bone screw holes

This element is similarly recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section X.B.1 (Ground 3), and incorporated here. *See* Ex.1005, ¶¶299-300.

c. a top surface, a generally flat bottom surface and first and second ends

This element is similarly recited in claims 1 and 3, and is disclosed by Fraser '106 for the reasons provided in Sections X.B.1 and X.C (Ground 3), and incorporated here.

Therefore, Fraser '106 in view of the knowledge of a POSITA discloses "retaining bone graft material between adjacent vertebral bone bodies having top surfaces and having side surfaces generally facing each other." *See* Ex.1005, ¶¶301-304.

2. Element 15[c] – Without Covering Top Surfaces

Fraser '106 discloses this limitation and each of the following features.

a. a base plate configured to fit primarily between anterior portions of the bone bodies' lip osteophytes

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section VIII.A.3 (Ground 1), and incorporated here.

In the event the Board determines that the term "base plate" requires a plate that is distinct from a load-bearing fusion cage, Fraser '106 also discloses a twoalternative embodiment, Fraser '106 also discloses this claim limitation. *See* Ex.1005, ¶306-310. As shown below, the Fraser '106 two-piece embodiment discloses the base plate (orange) being sized to have an inter-fit between the first and second adjacent bone bodies:



Fraser '106, Ex.1006, Fig.8

b. without covering significant portions of the top surfaces of the bone bodies

For the reasons discussed with respect to claim 15 in Section IX.B.4

(Ground 2), incorporated here, Fraser '106 discloses this limitation.

Therefore, Fraser '106 in view of the knowledge of a POSITA discloses "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." *See* Ex.1005, ¶¶311-313.

3. Element 15[d] – Primarily Bear Weight

Fraser '106 discloses this limitation and each of the following features.

a. a base plate that primarily bears weight in conjunction with the bone graft material

This element is similar to the bears weight element addressed in Sections VIII.A.3.b, X.B.2.b (Grounds 1 and 3), and this same element was addressed above in Section IX.B.5.a (Ground 2). Both sections are incorporated here. Ex.1005, ¶272-281.

Therefore, Fraser '106 in view of the knowledge of a POSITA renders this claim limitation obvious. Ex.1005, ¶¶314-321.

b. a base plate that holds the bones

This element is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in Section X.B.2 (Ground 3), and incorporated here.

Therefore, Fraser '106 in view of the knowledge of a POSITA renders this claim limitation obvious. *See* Ex.1005, ¶¶322-323.

G. <u>Claim 19 – Bone Screw Orientation</u>

The element "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" is analogous in scope to elements recited in claim 1, and is disclosed by Fraser '106 for the reasons provided in

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Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 VIII.A.8 (Ground 1), and incorporated here. *See* Ex.1005, ¶¶324-327.

H. <u>Claim 21</u>

Except for portions of elements 21[c]-[d] (discussed below), independent claim 1 and dependent claim 14 recites elements that are analogous in scope to the elements of independent claim 21. Thus, most of claim 21 is rendered obvious for the same reasons described above with respect to claims 1 and 14, and incorporated here, as shown in the table below. *See* Ex.1005, ¶328-348.

Claims 1 and 14	Analogous Claim 21 Element	Discussion of Fraser '106
1[Preamble]	21[Preamble]	Section VIII.A.1
1[a], 14	21[a]	Sections X.B.1 and X.E
1[b]	21[b]	Section VIII.A.3

Fraser '106 discloses the remainder of Elements 21[c]-[d] for the reasons set forth in Sections VIII.E.1 and VIII.E.2 above, incorporated here. *See* Ex.1005, ¶¶349-367.

I. <u>Claim 22 – Top Surface Anterior Boundary</u>

For the reasons discussed with respect to claim 22 in Section VIII.F (Ground 1), incorporated here, Fraser '106 in view of the knowledge of a POSITA renders this claim limitation obvious. *See* Ex.1005, ¶¶368-371.

J. <u>Claim 29 – More Than Two Bone Screw Holes</u>

Claim 29 depends from independent claim 21, which is rendered obvious by

Fraser '106 for the reasons provided in Section X.H, and incorporated here.

As shown in figure 2, below, Fraser '106 discloses "the base plate has more than two bone screw holes."



Fraser '106, Ex.1007, Fig.2

Fraser '106 also 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" for the reasons discussed in Section VIII.A.8 (Ground 1), incorporated here. *See* Ex.1005, ¶372-379.

Therefore, Fraser '106 in view of the knowledge of a POSITA renders obvious the limitation "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."

XI. <u>GROUND #4: FRASER '106 IN VIEW OF MICHELSON '045</u> <u>RENDERS CLAIMS 4-6, 24, AND 30 UNPATENTABLE AS</u> <u>OBVIOUS</u>

Claims 4-6, 24, and 30 of the '537 patent are rendered obvious under 35

U.S.C. §103 by Fraser '106 in view of Michelson '045.

A. <u>Claims 4, 5, and 6 – Screw Retainer and Plate or Screw</u>

Claims 5 and 6 depend from claim 4, which depend from independent claim 1. Claim 1 is rendered obvious by Fraser '106 for the reasons provided in Sections VIII.A and X.B, and incorporated here. Fraser '106 in view of Michelson '045 discloses claims 4-6. Ex.1005, ¶381.

> a. Claim 4: wherein the system further comprises a screw retainer configured to prevent at least one of the plurality of bone screws from backing out

As discussed in Section VII, incorporated here, the term "screw retainer" has a claimed function of "preventing at least one of the bone screws from backing out," and the corresponding structure for performing the function is "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" and equivalents thereto.

Michelson '045 discloses "Lock 461 differs from lock 462 in that extending from head portion 463 is a threaded shaft 468 for threading into a threaded hole between opposed holes 430 within common hole 428 of implant 400." Ex.1007, 19; *see* Ex.1005, ¶383. Therefore, Fraser '106 in view of Michelson '045 Petition for IPR of U.S. Patent No. 9,713,537 Case No. IPR2020-00264 teaches "a screw retainer [lock 461 comprising head portion 463 and threaded shaft 468] configured to prevent at least one of the plurality of bone screws [screws 442'] from backing out."

b. Claim 5: wherein the screw retainer is a plate or a screw
Michelson '045 discloses that "head 463 of lock 461 tightens against heads
452' of screws 442'." *Id.*



Michelson '045, Ex.1007, Figs.28-29

Therefore, Fraser '106 in view of Michelson '045 teaches "the screw

retainer is a plate or a screw [head 463]." See Ex.1005, ¶¶386-388.

c. Claim 6: 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 "Lock 461 differs from lock 462 in that extending

from head portion 463 is a threaded shaft 468 for threading into a threaded

hole between opposed holes 430 within common hole 428 of implant 400."

Ex.1007, 19; *see* Ex.1005, ¶¶389-392. The base plate is recessed to permit access to holes 430, and the lock 461 sits in this recessed region.



Michelson '045, Ex.1007, Figs.28-29

Therefore, Fraser '106 in view of Michelson '045 discloses "the top surface of the base plate is configured to have a recessed region [common holes 428] and the screw retainer [lock 461] is configured to sit in the recessed region of the base plate."

B. <u>Claim 24 – More Than Two Bone Screw Holes</u>

Claim 24 depends from independent claim 21, which is rendered obvious by Fraser '106 for the reasons provided in Sections VIII.E and X.H, and incorporated here.

Michelson '045 discloses a "base plate has more than two bone screw holes."



Michelson '045, Ex.1006, Fig.23

Michelson '045 further discloses "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." The first/second ends (blue/purple) are the portions of the base plate nearer the first/second bone that exclude the middle portion of the plate. Ex.1005, ¶395.



Michelson '045, Ex.1006, Fig.23

Michelson '045, Ex.1006, Fig.27

Therefore, Fraser '106 in view of Michelson '045 teaches "the base plate has more than two bone screw holes [screw holes 430], 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]." *See* Ex.1005, ¶¶393-396.

C. <u>Claim 30 – Screw Retainer</u>

Claim 30 depends from independent claim 21, which is rendered obvious by Fraser '106 for the reasons provided in Sections VIII.E and X.H, and incorporated here.

The claim element "a screw retainer configured to prevent at least one of the first and second bone screws from backing out" is analogous in scope to elements recited in claim 4, and is disclosed by Fraser '106 in view of Michelson '045 for

the reasons provided in Section XI.A (Ground 4), and incorporated here. *See* Ex.1005, ¶¶397-401.

Therefore, Fraser '106 in view of Michelson '045 renders at least claims 4-6, 24 and 30 of the '537 patent obvious.

D. <u>Reasons and Motivations to Combine Fraser '106 in view of</u> <u>Michelson '045</u>

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, ¶¶402-407.

First, Fraser '106 and Michelson '045 are both analogous art to the alleged invention claimed in the '537 patent because they are in the same field of endeavor. *In re Bigio*, 381 F.3d at 1325. The '537 patent defines its "Technical Field" as "implant devices for the fixation and support of bone bodies" Ex.1002, 1:32-33. Fraser '106 and Michelson '045 are also directed to spinal implant devices for fixation and support of vertebrae. *See* Fraser '106, Ex.1007, Abstract ("A spinal fixation assembly"), 1:36-38; Michelson '045, Ex.1006, Abstract ("an interbody spinal fusing implant (100)"). Fraser '106 and Michelson '045 also disclose ways to prevent bone screws from backing-out. *Compare* Ex.1002, 2:46-49 *with* Ex.1006, 9; Ex.1005, ¶403.

Fraser '106 and Michelson '045 are also pertinent to the problem allegedly addressed by the claimed invention. *In re Bigio*, 381 F.3d at 1325. According to

the '537 patent, the problem is providing an implant that supports adjacent vertebrae for fusion without damaging the spinal cord or adjacent tissue. *See* Ex.1002, 2:25-29, 2:52-63. Fraser '106 and Michelson '045 address this problem. Ex.1005, ¶404. Fraser '106 discloses an implant that sits "flush or sub-flush...thus minimizing the likelihood that major blood vessels running along the spine will be injured." Ex.1007, 2:21-23, 4:16-19. Michelson '045 discloses that nothing should sit on the anterior surface of the vertebrae because that could cause ruptured blood vessels or death. Ex.1006, 4 and 16.

Second, a POSITA would have combined Fraser '106 and Michelson '045 because the combination merely involves the simple substitution of one known element (*i.e.*, the Fraser '106 locking screw) for another (*i.e.*, the Michelson '045 toggle screw with locking plate). Fraser '106 teaches that exposed screws can cause significant harm to a patient. *See also* Ex.1004, 4:16-19; Ex.1005, ¶405. A POSITA would have recognized that the Michelson '045 toggle screw with locking plate was a known anti-back out device that could be substituted for the locking screws disclosed in Fraser '106. *Id*.

Third, Michelson '045 discloses using a screw anti-back out system with standard bone screws to compensate for settling of the bones after implantation. A POSITA would have recognized that using toggle screws to permit the bones to settle was advantageous, so long as there was an anti-back out mechanism.

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Ex.1005, ¶406. A POSITA would have recognized that anti-back out plates are easy to use and implement. *Id.* Further, Fraser '106 does not disclose any structure that would preclude using an anti-back out plate. *Id.* The result of this simple modification to Fraser '106 would have yielded predictable and successful result—namely, a spinal implant with an anti-back out plate that can securely hold bone screws in place but still enable the bone to settle subsequent to implantation. *Id.*

XII. <u>GROUND #5: FRASER '106 IN VIEW OF MICHELSON '045 AND</u> <u>BYRD RENDERS CLAIM 18 UNPATENTABLE AS OBVIOUS</u>

Claim 18 of the '537 patent is rendered obvious under 35 U.S.C. §103 by Fraser '106 in view of Michelson '045 and Byrd.

A. <u>Claim 18 – Recessed Screw Retainer</u>

Claim 18 depends from independent claim 15, which is rendered obvious by Fraser '106, or Fraser '106 in view of Byrd for the reasons provided in Sections X.F and IX.B, respectively, and incorporated here.

Claim 18 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." This element is nearly identical to this element in claim 6, *see* Section XI.A.b. (Ground 4), and is incorporated here.

Claim 18 further recites "screw retainer . . . configured to prevent one or more of the bone screws from backing out." Michelson '045 discloses a "trailing

end 404 of implant 400 is adapted...to receive into common holes 440 threaded

lock members 462, preventing screws 442 from backing out." Ex.1006, 18; see

Ex.1005, ¶¶409-413. As shown in figures 26 and 27, below, Michelson '045 discloses a base plate with a recessed region, which includes a lock 462 that covers part of the first and second bone screws to prevent them from backing out.



Michelson '045, Ex.1006, Fig.27

Therefore, Fraser '106 in view of Michelson '045 and Byrd renders this claim obvious.

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

As discussed above in Section IX.D, Fraser '106 and Byrd are analogous to the '537 patent. A POSITA would have been motivated to implement Byrd's teaching of an open interior, flat bottom surface into the implant disclosed by Fraser '106. Ex.1005, ¶¶414-418. As discussed above in Section XI.D, Fraser '106 and Michelson '045 are analogous to the '537 patent. A POSITA would have been motivated to incorporate the anti-back out screw plate of Michelson '045 that can be used with standard bone screws to compensate for subsequent settling of the bones after implantation. Ex.1005, ¶¶255-262. Replacing Fraser '106's locking screws with the Michelson '045 anti-back out screw plate would be a simple substitution of one known element for another to obtain an improved and/or predictable result (*e.g.*, screws that can compensate for settling but not back out). Ex.1005, ¶¶402-407.

A POSITA would have also been motivated to combine the teachings of Fraser '106, Byrd, and Michelson '045 because he or she would have appreciated that all three 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.



A POSITA would further be motivated to combine these reference because their designs are similar. Ex.1005, ¶¶416-417. Each discloses an interbody device with screw holes on the anterior surface, openings for bone graft material, screws designed for unicortical purchase, and an anti-back out mechanism. *Id*.

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

XIII. CONCLUSION

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

Dated: December 13, 2019

Respectfully Submitted,

/ Dion M Bregman / Dion M. Bregman, Reg. No. 45,645

No.	Claim Elements
1[Preamble]	A bone stabilization plate system comprising:
1[a]	a base plate having a top surface, first and second ends, a bottom surface, and a plurality of bone screw holes,
1[b]	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
1[c]	a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively;
1[d]	wherein the vertebral bones have top surfaces and have side surfaces generally facing each other;
1[e]	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;
1[f]	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
1[g]	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.
3[Preamble]	The system as set forth in claim 1,
3[a]	wherein the bottom surface of the base plate is generally flat.
4[Preamble]	The system as set forth in claim 1,

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No.	Claim Elements
4[a]	wherein the system further comprises a screw retainer configured to prevent at least one of the plurality of bone screws from backing out.
5[Preamble]	The system as set forth in claim 4,
5[a]	wherein the screw retainer is a plate or a screw.
6[Preamble]	The system as set forth in claim 4,
6[a]	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.
10[Preamble]	The system as set forth in claim 1,
10[a]	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.
13[Preamble]	The system as set forth in claim 1,
13[a]	wherein the top surface of the base plate coincides with or generally matches an outer diameter of the anterior cortex of the vertebral bones.
14[Preamble]	The system as set forth in claim 1,
14[a]	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.
15[Preamble]	A bone stabilization plate system comprising:
15[a]	a base plate having a plurality of bone screw holes, a top surface, a generally flat bottom surface and first and second ends

No.	Claim Elements
15[b]	for retaining bone graft material between adjacent vertebral bone bodies having top surfaces and having side surfaces generally facing each other,
15[c]	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,
15[d]	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
15[e]	a plurality of bone screws configured for insertion through the plurality of corresponding bone screw holes to anchor primarily into the lip osteophytes,
15[f]	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.
18[Preamble]	The system as set forth in claim 15,
18[a]	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.
19[Preamble]	The system as set forth in claim 15,
19[a]	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.
21[Preamble]	A bone stabilization plate system for anchoring between side surfaces of first and second adjacent vertebral bones, comprising:
21[a]	a base plate having a top surface, a first end nearer the first bone comprising a first bone screw hole extending at least partially

No.	Claim Elements
	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
21[b]	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
21[c]	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
21[d]	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.
22[Preamble]	The system as set forth in claim 21,
22[a]	wherein the entire top surface of the base plate is configured to be an anterior boundary of a bone graft site.
24[Preamble]	The system as set forth in claim 21,
24[a]	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.
29[Preamble]	The system as set forth in claim 21,
29[a]	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

No.	Claim Elements
	oriented generally in an anterior-posterior direction through the top surface of the base plate.
30[Preamble]	The system as set forth in claim 21,
30[a]	wherein the system further comprises a screw retainer configured to prevent at least one of the first and second bone screws from backing out.

This Petition includes 13,985 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

Respectfully Submitted,

/ Dion M. Bregman / Dion M. Bregman, Reg. No. 45,645

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. 42.6(4) and 42.105, lead counsel for Petitioners

hereby certify that on December 13, 2019, copies of this Petition, Power of

Attorney, Petitioners' Ranking and Explanation for Two Petitions Challenging

U.S. Patent No. 9,713,537, and all supporting exhibits were sent via Federal

Express to the correspondence address of record for the '537 patent:

Ronald M. Kachmarik COOPER LEGAL GROUP LLC 6505 Rockside Road, Suite 330 Independence, OH 44131

A courtesy copy of this Petition, Power of Attorney and supporting exhibits

was also served via email on Patent Owner's counsel of record in the district court litigation:

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