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Paper 24
Date: May 22, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

RSB SPINE, LLC,
Patent Owner.

IPR2020-00264
Patent 9,713,537 B2

Before PATRICK R. SCANLON, MICHAEL L. WOODS, and ERIC C. JESCHKE, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. BACKGROUND

Medacta USA, Inc., Precision Spine, Inc., and Life Spine, Inc. (collectively, "Petitioner") filed a Petition to institute an *inter partes* review 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 B2 (Ex. 1002, "the '537 patent"). Paper 2 ("Pet."). RSB Spine, LLC ("Patent Owner") filed a Patent Owner's Preliminary Response. Paper 14 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2019). Section 314(a) of Title 35 of the United States Code provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the evidence and arguments in the Petition (including its supporting testimonial evidence) as well as the evidence and arguments in the Preliminary Response, for the reasons below, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. We thus institute *inter partes* review on all challenged claims on all asserted grounds. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"); Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019) ("The Board will not institute on fewer than all claims or all challenges in a petition."), *available at*

https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf ("Consolidated Guide").

A. Related Proceedings

The parties identify five pending proceedings in the U.S. District Court for the District of Delaware involving the '234 patent: (1) *RSB Spine, LLC. v. Life Spine, Inc.*, No. 18-cv-1972 (D. Del.); (2) *RSB Spine, LLC. v. Medacta USA, Inc.*, No. 18-cv-1973 (D. Del.); (3) *RSB Spine, LLC. v. Precision Spine, Inc.*, No. 18-cv-1974 (D. Del.); (4) *RSB Spine, LLC v. Xtant Medical Holdings, Inc.*, No. 18-cv-1976 (D. Del.); and (5) *RSB Spine, LLC. v. DePuy Synthes, Inc.*, No. 19-cv-1515 (D. Del.) (collectively, the "Delaware Litigations"). Pet. 1–2; Paper 5, 2. The Delaware Litigations also involve a related patent, U.S. Patent No. 6,713,234 B2 ("the '234 patent"). Pet. 1.

On the same day as the filing of the Petition in this Proceeding (December 13, 2019), Petitioner filed an additional petition for *inter partes* review of the same challenged claims (1, 3–6, 10, 13–15, 18, 19, 21, 22, 24, 29, and 30) in IPR2020-00275. We denied institution in that proceeding.

Also that same day, Petitioner filed petitions for *inter partes* review of (1) claims 1–10, 13, 14, 16, 18–20, 22, 24, 25, 28, 29, 31 and 32 of the '234 patent in IPR2020-00274, and (2) claims 35, 37, and 39 of the '234 patent in IPR2020-00265. We granted institution in those proceedings.[1]

[1] Decisions on institution in IPR2020-00265, IPR2020-00274, and IPR2020-00275 were entered concurrently with this Decision.

Finally, the parties identify "related" U.S. Patent Application No. 15/723,522 as currently pending before the U.S. Patent and Trademark Office. Pet. 2; Paper 5, 2.

B. Real Parties in Interest

The Petition lists the following entities as real parties in interest: Medacta USA, Inc., Precision Spine, Inc., Life Spine, Inc., and Xtant Medical Holdings, Inc. Pet. 1. Patent Owner identifies itself as the sole real party in interest. Paper 5, 2.

C. The '537 Patent (Ex. 1002)

The '537 patent is titled, "Bone Plate Stabilization System and Method for its Use." Ex. 1002, code (54). The patent describes a system with a base plate configured to fit primarily between anterior portions of two adjacent vertebral bodies' (or bones') lip osteophytes for treating disorders of the spine. *See id.* at code (57), 4:6–12. The patent further describes surgical treatment of the spine accomplished by removing the intervertebral disc material from the space between two adjacent vertebral bodies, and replacing it with a surgical implant and bone graft to promote fusion of the two vertebral bodies. *See id.* at 4:7–15. To illustrate an embodiment of the described system, we reproduce Figures 1 and 2, below:

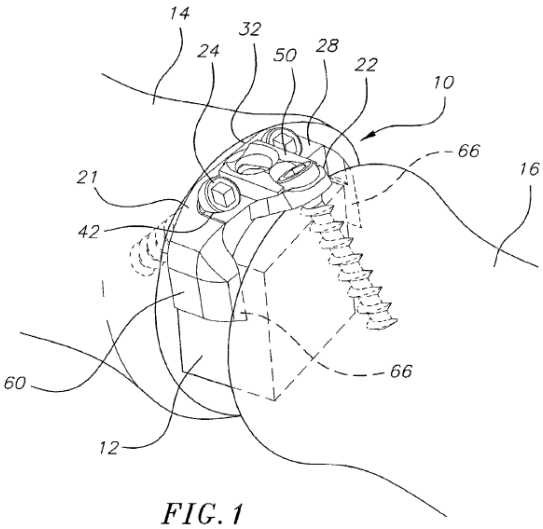
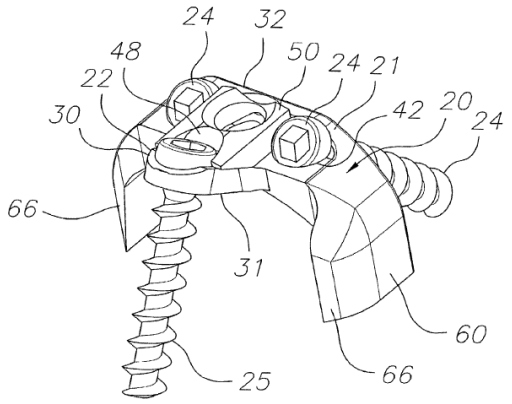


FIG. 1

FIG. 2



According to the ’537 patent, Figures 1 and 2 are perspective views of a bone stabilization plate system according to the invention, with Figure 1 (left) depicting the system assembled between adjacent vertebrae. *Id.* at 5:63–67. In particular, these figures depict bone stabilization plate system 10 comprising base plate 20 having a first end and a second end, with primary member 21 and secondary member 22 at the second end of the base plate. *Id.* at 8:33–36. In this embodiment, secondary member 22 is angled relative to primary member 21. *Id.* at 8:37–38. As shown in Figure 1, base plate 20 may be mounted to adjacent vertebral bodies (14, 16) with bone graft 12 interposed between the bodies. *See id.* at 8:46–49. Bone graft, or bone tissue, promotes fusion between the vertebral bodies. *See id.* at 13:16–18.

We also reproduce Figure 3 of the '537 patent, below:

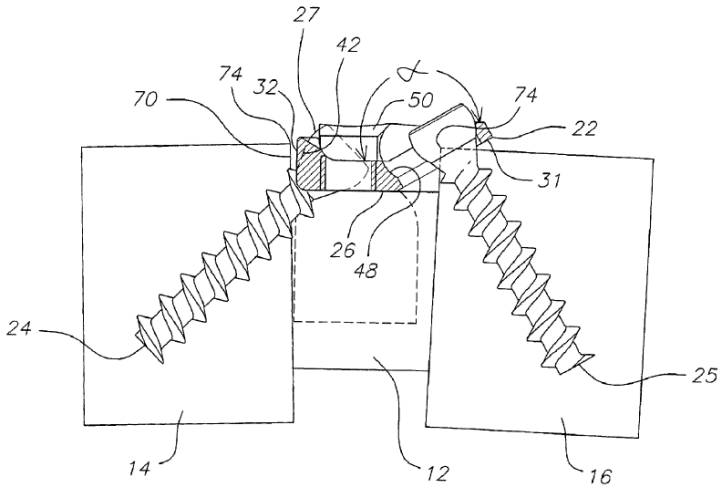


FIG. 3

Figure 3 is a cross-sectional view of the bone plate stabilization system assembled between adjacent vertebrae. *Id.* at 6:1–3. As shown in this figure, bottom surface 26 of base plate 20 (not referenced in Figure 3 above) contacts bone graft 12, and primary member 21 (not referenced in Figure 3 above) also has a top surface, denoted as 28. *See id.* at 8:48–56, Figs. 1, 2. Primary member 21 also has side wall 32 at the first end of base plate 20 that contacts first vertebral body 14. *Id.* at 8:56–58. The top surface of base plate 20 may also have apertures for receiving one or more bone screws. *See id.* at 8:58–60. In this embodiment, primary member 21 includes two first bone screw holes 42 for receiving first bone screws 24. *See id.* at 9:8–11, Fig. 2. Bone screw holes 42 are angled relative to the bottom surface of the base plate so that a first bone screw extending through the hole extends through the base plate at an angle. *Id.* at 9:11–18, Fig. 4. Secondary member 22 also includes a bone screw hole or slot 48 for receiving second bone screw 25. *Id.* at 9:26–28. Second bone screw is

received through bone screw slot 48 and into second vertebral body 16. *Id.* at 9:28–30.

D. Illustrative Claim

Petitioner challenges claims 1, 3–6, 10, 13–15, 18, 19, 21, 22, 24, 29, and 30. Pet. 1. Of these claims, claims 1, 15, and 21 are independent. Ex. 1002, 37:65–40:57. We reproduce claim 1, below, reformatted from the version provided in the '537 patent to include bracketed alphanumeric nomenclature that corresponds with Petitioner's nomenclature. *See, e.g.*, Pet. 23–41.

1. [Element 1] 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.

Ex. 1002, 37:65–38:24; Pet. 23–41.

E. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following asserted grounds (Pet. 5):

Ground	Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1	1, 10, 13, 14, 21, 22, 29	103	Fraser '106[3] (one-piece embodiment)
2	3, 15, 19	103	Fraser '106, Byrd[4]
3	1, 3, 13–15, 19, 21, 22, 29	103	Fraser '106 (two-piece embodiment)
4	4–6, 24, 30	103	Fraser '106, Michelson[5]
5	18	103	Fraser '106, Michelson, Byrd

Petitioner supports its challenge with a declaration from Mr. Michael C. Sherman (Ex. 1005).

[2] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because the application from which the '537 patent issued was filed before March 16, 2013, we apply the pre-AIA version of this statute. *See also* Pet. 4 (confirming same).

[3] US 6,432,106 B1, issued Aug. 13, 2002 (Ex. 1007).

[4] US 7,077,864 B2, issued July 18, 2006 (Ex. 1008).

[5] WO 00/66045, published Nov. 9, 2000 (Ex. 1006).

II. DISCUSSION

A. Discretion Under 35 U.S.C. § 325(d)

Patent Owner argues that we should exercise discretion under 35 U.S.C. § 325(d) to deny institution, because the examiner considered several of Petitioner's primary references during prosecution of the '537 patent. Prelim. Resp. 2–12.

After the Preliminary Response was filed, the Board designated *Advanced Bionics* as precedential, revising the framework applied under 35 U.S.C. § 325(d). *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential). In light of *Advanced Bionics*, we authorized the parties to file additional briefing to further address § 325(d). Paper 21. Petitioner filed a Reply to the Preliminary Response and Patent Owner filed a Sur-Reply. Paper 22 ("Pet. Reply"); Paper 23 ("PO Sur Reply").

Section 325(d) provides that in determining whether to institute an *inter partes* review, "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." As set forth in *Advanced Bionics*, the Board uses a two-part framework in determining whether to exercise its discretion under § 325(d), specifically:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
>
> (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, Paper 6, 8.

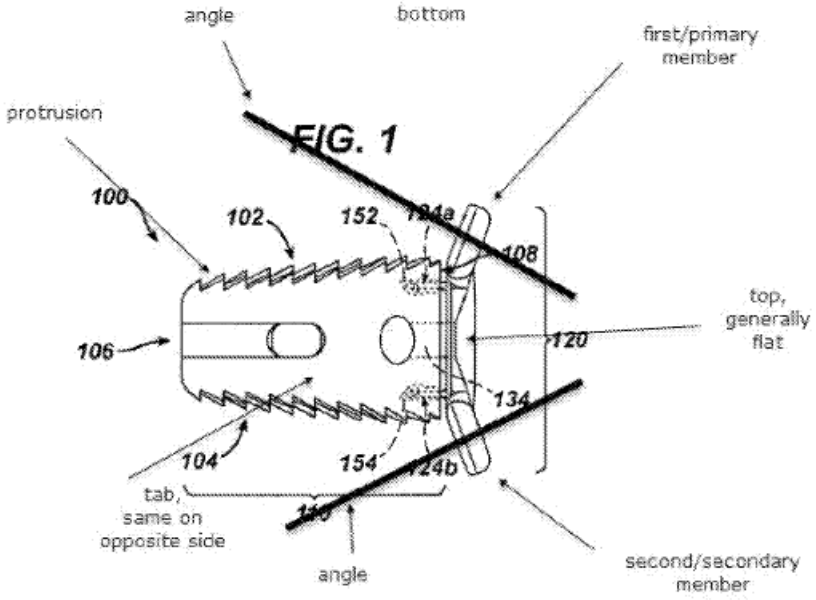
In applying the two-part framework, we consider several non-exclusive factors, including: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *Id.* at 9–11 (citing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph)). If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, then we consider factors (c), (e), and (f), which relate to whether the petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Id.* at 10.

For the reasons set forth below, under the facts presented and arguments made, we decline to exercise our discretion under 35 U.S.C. § 325(d) to deny instituting trial.

1. Prosecution History of the '537 Patent (Ex. 1004)

During prosecution of the '537 patent, the examiner rejected several of the pending claims as being anticipated by U.S. Patent No. 7,112,222 B2

to Fraser ("Fraser '222"). Ex. 1004, 170. In support of the rejection, the examiner submitted an annotated version of Fraser '222's Figure 1, which we reproduce, below:



The above depicts the examiner's annotations to Figure 1 to illustrate Fraser '222's "first/primary member," "second/secondary member," "top," "protrusions," and "tabs." The examiner further found that

> Fraser ['222] discloses a base plate with a plurality of bone screw holes, a top surface, generally flat bottom surface and first and second ends capable of retaining bone graft material between adjacent vertebral bones and capable of permitting force transmission between the bones, *configured and capable of bearing weight while holding the bones for fusion and sized to fit primarily between anterior portions of the bone bodies*; a plurality of bone screws configured for insertion through corresponding holes to anchor primarily into the lip.

Id. at 172 (emphasis added).

The applicant interviewed the examiner to discuss the rejection. *See id.* at 208 (Interview Summary). During the interview, the applicant and the

examiner discussed a proposed claim amendment to the "base plate" that would require language similar to "without covering significant portions of the top surfaces of the bone bodies." *See id.* Following the interview, the applicant amended the claim 1 as follows:

> 1. (Currently amended) A bone stabilization plate system comprising:
>
> a base plate having a top surface, first and second ends, a bottom surface, and a plurality of bone screw holes, wherein the base plate is ~~sized~~ configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes ~~and is configured~~ to bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion; and
>
> a plurality of bone screws configured to fit in the plurality of bone screw holes, respectively;
>
> wherein the vertebral bones have top surfaces and have side surfaces generally facing each other;
>
> wherein ~~one~~ a first of the bone screw holes, being ~~is~~ configured to receive ~~one~~ 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 ~~to secure the base plate to one of the vertebral bones~~;
>
> wherein ~~another~~ a second of the bone screw holes, being ~~is~~ configured to receive ~~one~~ a second of the bone screws, extends at least partially from the top surface of the base plate and opens at least partially toward ~~to secure the base plate to~~ the lip osteophyte of ~~another~~ a second of the vertebral bones; and
>
> 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.

Id. at 211.

In the corresponding remarks, the applicant stated that newly-amended "claim 1 recites that the base plate is 'configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight . . . .' As discussed above, Fraser ['222] does not have such." *See id.* at 222.

The examiner entered a Notice of Allowability. *See id.* at 231. In the "Reasons for Allowance," the examiner stated that

> [T]he claims in the instant application have not been rejected using prior art because no reference of reasonable combination thereof could be found which disclose or suggest *a bone stabilization plate with a base plate configured to fit primarily between anterior portions of adjacent bones' lip osteophytes*, wherein first and second bone screw holes extend partially from the top surface of the base plate and opens at least partially toward the side surface of the vertebral bones, as in claim 1.

Id. at 233 (emphasis added).

The patent application subsequently issued (*id.* at 250) and the issued claims include the applicant's claim amendments (*compare id.* at 211 (amended claim 1), *with* Ex. 1002, 37:65–38:24 (issued claim 1)).

The '537 patent also identifies Fraser '106 and Michelson as "References Cited" during prosecution. Ex. 1002, code (56).

2. Patent Owner's Arguments

Patent Owner contends that Fraser '106 "is materially indistinct—and, indeed, is identical in key parts—to [Fraser '222] that was the basis for rejection and was overcome during prosecution of the '537 patent." Prelim. Resp. 2; *see also* PO Sur Reply 1 ("[K]ey portions of Fraser '106 . . . are identical to key portions of Fraser '222, which was the primary basis for

rejection before the claims were amended."). Patent Owner points out that Fraser '106 and Fraser '222 "contain identical disclosure regarding the location and orientation of the bone screw holes in plate 20 that is mated with fusion cage body 10 . . . [and that] both patents contain an identical Figure 3." Prelim. Resp. 5 (emphasis omitted).

3. Petitioner's Reply

In its Reply, Petitioner contends that the examiner erred by overlooking specific teachings from Fraser '106 that are not part of Fraser '222's disclosure. *See* Pet. Reply 2. In particular, Petitioner argues that the examiner and patent applicant focused on Fraser '222's plate that attached to the anterior face of the vertebral bodies, rather than a plate that lies between the vertebral bodies. *See id.* (citing Ex. 1004, 218) ("During an examiner interview, PO argued that the prior art Fraser '222 'plate 120 is for application onto the anterior side/face of vertebral bones,' (i.e., the front side of the vertebrae), and 'the plate has apertures 122a-d that places all of the bone screws onto the anterior side/face of vertebral bones.'" (emphasis omitted)). Petitioner directs our attention to Fraser '106's Figure 8—which is not part of Fraser '222's disclosure—for disclosing "a base plate ***between*** the vertebrae, and holes that open toward the corner of the bone (lip osteophyte) and the side surface of the vertebrae." *Id.* at 4.

4. Analysis

The first prong of the *Advanced Bionics* framework is satisfied because Fraser '106 and Michelson were identified as "References Cited" during prosecution of the '537 patent. Ex. 1002, code (56). However,

Petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6, 8. In particular, we agree with Petitioner that the examiner erred materially in overlooking Figure 8 of Fraser '106.

We consider *Becton* factors (c), (e), and (f) in determining whether Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Id.* These factors are: (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (e) whether Petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *Becton*, Paper 8, 17–18.

In the Notice of Allowability, the examiner stated that the prior art did not "disclose or suggest a bone stabilization plate with a base plate configured to fit primarily between anterior portions of adjacent bones' lip osteophytes." Ex. 1004, 233. At this stage of the proceeding, however, we determine this finding to be in error, as Figure 8 of Fraser '106 appears to disclose this structure. Although the examiner rejected several claims as being anticipated by Fraser '222, importantly, Fraser '106's Figure 8 is not part of Fraser '222's disclosure.

We reproduce Fraser '106's Figure 8, below:

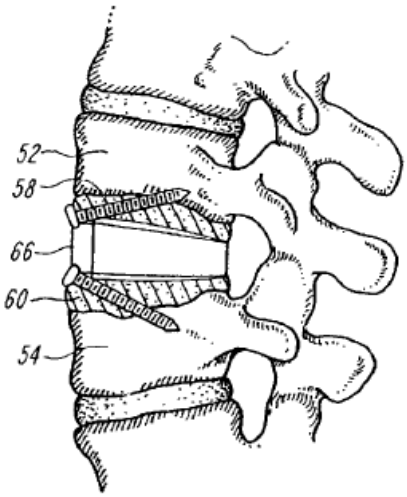


FIG. 8

Figure 8 depicts "a portion of the spine following placement of the fusion cage." Ex. 1007, 2:9–10. Petitioner submits annotated versions of this figure (Pet. 30, 32) and asserts that this figure "discloses a base plate that is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes" (*see id.* at 32).

Although the examiner rejected the claims as anticipated by Fraser '222, because the examiner did not apply Fraser '106's Figure 8 during examination, *Becton's* factor (c) weighs against exercising our discretion to deny institution under 35 U.S.C. § 325(d).

We find that Petitioner has sufficiently pointed out how the examiner erred in its evaluation of the cited art, as per *Becton* factor (e). *See, e.g.*, Pet. Reply 3 ("The Examiner's conclusion that 'no reference' 'could be found which disclose[d]' this limitation was a material error because Fraser '106 . . . explicitly discloses a base plate between the vertebrae" (citing Ex. 1007, Fig. 8) (alteration in original)). As such, Becton's factor (e) further weighs

against exercising our discretion to deny institution under 35 U.S.C. § 325(d).

Finally, and as to Becton's factor (f), the examiner found that "no reference of reasonable combination . . . 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." Ex. 1004, 233. The examiner's finding, however, was without the benefit of Mr. Sherman's declaration testimony. In referring to Figure 8 of Fraser '106—which the examiner appears to have overlooked—Mr. Sherman testifies that "Fraser '106 . . . discloses a base plate that is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes." Ex. 1004 ¶ 85. We find that the additional evidence of Mr. Sherman's testimony and Figure 8 of Fraser '106 further weighs against exercising our discretion to deny institution under 35 U.S.C. § 325(d).

After considering the framework set forth in *Advanced Bionics* and the appropriate *Becton* factors, we decline to exercise our discretion under 35 U.S.C. § 325(d) to deny institution.

B. Principles of Law

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Petitioner's challenges are based on obviousness. Pet. 3.

A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

C. SAS

The Supreme Court has held that a final written decision in an *inter partes* review must decide the patentability of all claims challenged in the corresponding petition. *SAS*, 138 S. Ct. at 1348. The USPTO has also provided guidance on implementing *SAS*. *See Guidance on the Impact of SAS on AIA Trial Proceedings* (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial ("*SAS* Guidance") ("As required by [the *SAS*] decision, the PTAB will institute as to all claims or none," and "[a]t this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition."); Consolidated Guide 5–6.

D. The Level of Ordinary Skill in the Art

The level of ordinary skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The person of ordinary skill in the art ("POSITA") is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, we may consider certain factors, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id.* (internal quotation marks and citation omitted).

Petitioner contends that a person having ordinary skill in the art "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 with at least 5 years of experience designing and developing orthopedic implants and/or spinal interbody devices." Pet. 17.

Patent Owner does not dispute Petitioner's proposed definition of the level of ordinary skill in the art, which appears consistent with the level of skill as reflected in the record at this stage of the proceeding. *See generally* Prelim. Resp. For purposes of this Decision, we adopt the definition of the level of ordinary skill in the art proposed by Petitioner.

E. Claim Construction

In *inter partes* reviews, the Board interprets claim language using the district-court-type standard, as described in *Phillips v. AWH Corp.*, 415 F.3d

1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b) Under that standard, we generally give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *See Phillips*, 415 F.3d at 1313–14. Although extrinsic evidence, when available, may also be useful when construing claim terms under this standard, extrinsic evidence should be considered in the context of the intrinsic evidence. *See id.* at 1317–19.

Petitioner proposes constructions for the following claim terms: (1) "base plate"; (2) "lip osteophyte"; and (3) "screw retainer." Pet. 17–23. In the claim construction section of its Preliminary Response, Patent Owner responds by addressing only "base plate." Prelim. Resp. 13–19; *see also id.* at 13 (stating Patent Owner "addresses other constructions proposed by Petitioner[] as necessary in the sections that follow when discussing the numerous deficiencies in the Petition").

Based on the current record and for purposes of this Decision, we only construe the terms (1) "base plate"; (2) "primarily"; and (2) "configured to . . . bear weight to hold the vertebral bones." We do not discern a need to construe explicitly any of the other claim language discussed in this section or any other claim terms because doing so would have no effect on the analysis below. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (stating that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

1. "base plate"

Petitioner proposes that the term "base plate" should be construed as "[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**." Pet. 18. This proposed construction includes a negative limitation—not in Patent Owner's proposed construction (and shown with Petitioner's emphasis above)—requiring that the "base plate" not be "used with a load-bearing fusion cage." *Id.* (emphasis omitted).

Patent Owner, on the other hand, proposes that the term "base plate" should be construed as "[a] fixation plate of a bone plate stabilization system to stabilize adjacent vertebrae for fusion and **distinct from a spacer** and bone graft material deployed across a bone graft site." Prelim. Resp. 13 (emphasis added). Patent Owner proposes a different additional limitation—not included in Petitioner's proposed construction (and shown with our emphasis above)—requiring that the "base plate" is "distinct from a spacer." *Id.*

We first address each of the additional requirements proposed as part of Petitioner's and Patent Owner's constructions (shown in emphasis above) and then address a requirement included in both proposed constructions.

a. Petitioner's Proposed Requirement–"not used with a load-bearing fusion cage"

In support of the portion of Petitioner's proposed construction requiring that the term "base plate" is "not used with a load-bearing fusion cage," Petitioner relies on an alleged prosecution history disclaimer based on

arguments made by the patent applicant during prosecution, in which, according to Petitioner, "Patent Owner took the position . . . that the claims do not cover implants that use load-bearing spacers." Pet. 18. In particular, Petitioner cites to the following argument made by the patent applicant during prosecution:

> [**F**]**usion 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.

Id. (quoting Ex. 1004, 222). Based on this particular argument that the patent applicant advanced during prosecution, Petitioner contends that the claimed "base plate" cannot be used with a separate load-bearing spacer or cage. *See id.* at 19 ("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.").

We are not persuaded by this argument, however, because Petitioner has not demonstrated that the statements relied upon amount to a "disavowal . . . 'clear and unmistakable' to one of ordinary skill in the art." *See Elbex Video. Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) (quoting *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1326 (Fed. Cir. 2003)). Based on the record at this stage of the proceeding, we understand the examiner during prosecution to have identified plate 120 in Fraser '222 (rather than, for example plate 120 *and* fusion cage 110) as the "base plate" recited in the claims of the application that later issued as the '537 patent. This view is supported by other statements in the prosecution history of the '537 patent. *See MIT v. Shire Pharms., Inc.*, 839 F.3d 1111,

1122 (Fed. Cir. 2016) (rejecting an alleged prosecution history disclaimer based on consideration of the statements "[i]n the context of the entire prosecution history").

For example, in the same filing that includes the alleged disclaimer identified by Petitioner, the applicant summarized a prior telephone interview as including a discussion of the "specifics of Fraser plate 120" in which "[i]t was noted that the plate 120 is for application onto the anterior side/face of vertebral bones" and "*not for location between the bones*." Ex. 1004, 218 (emphasis added). Then, in the Notice of Allowance that issued weeks later, the examiner included in the reasons for allowance that "no reference . . . 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*" as recited in, for example, issued claim 1 of the '537 patent. *Id.* at 233 (emphasis added) (providing reasons for allowance), 211 (providing amendments to claim 1).

Viewed in the context of these statements, in the discussion highlighted by Petitioner, the applicant did not disclaim the use of the recited "base plate" with a separate fusion cage; instead, in that discussion, the applicant merely asserts that the identified "base plate"—i.e., plate 120 in Fraser '222—does not satisfy the requirement, in each independent claim, that the "base plate" be "configured to fit primarily between" certain recited portions of the bones' lip osteophytes, either to "bear weight" or "while bearing weight." *See* Ex. 1004, 222–23. The reason for this, as explained by the applicant, is that, in Fraser '222, fusion cage 110 "is load-bearing between the two vertebral bodies" whereas plate 120 is "applied after the load-bearing fusion cage 110 is in place, to the respective anterior face of

each of the two vertebral bodies." *Id.* at 222; *see also id.* at 221 ("The fusion cage is then positioned between the vertebrae . . . . **Once the fusion cage is in position**, the plate is mated to the anterior face of the fusion cage . . . .") (quoting Ex. 1010, 8:39–49). Thus, contrary to Petitioner's assertion (Pet. 18), the applicant did not disclaim the use of the recited "base plate" with a load-bearing fusion cage.

For the forgoing reasons, we do not construe "base plate" as requiring the negative limitation that it must not be used with a load-bearing fusion cage.

b. Patent Owner's Proposed Requirement–"distinct from a spacer"

Patent Owner contends that a skilled artisan would understand that a "base plate" is "distinct from a spacer." *See* Prelim. Resp. 14. Patent Owner explains that a "person of ordinary skill would understand a spacer to refer to an interbody device . . . [for] insertion at a bone graft site." *Id.* (citing Ex. 2001, S158–59, S161–62, Figs. 1, 3 (Janssen article on lumbar interbody fusion); Ex. 2002, 5:3–5, 6:5–7, 6:22–67, 9:55–63, 11:2–5, 11:44–67, 12:1–10, 12:25–28, 12:65–13:3, Figs. 5–8 (Bagga patent for spinal implants)). Patent Owner further explains that a "spacer bears weight from the vertebral bodies in the spinal column to promote fusion." *Id.* at 15 (citing Ex. 2001, S158, S160–61; Ex. 2002, 2:1–3, 5:5–10, 10:14–51, 12:49–59).

We are not persuaded by Patent Owner's argument for at least two reasons. First, and despite Patent Owner's numerous citations to Exhibits 2001 and 2002, we find nothing in this extrinsic evidence to support Patent Owner's assertion that a skilled artisan would understand that a "base plate" *must* be distinct from a "spacer." Rather, Exhibits 2001 and 2002 merely

describe examples of base plates *that are* separate from an interbody spacer (*see, e.g.*, Ex. 2002, Figs. 7, 8). Neither of these documents defines "base plate," or otherwise establishes that one of ordinary skill in the field at issue would understand that a "base plate" must be distinct from a "spacer." Furthermore, we find nothing in the claims or the written description of the '537 patent, such as a lexicographic definition of "base plate," that supports such a requirement. We further note that Patent Owner does not submit declaration testimony to support its position that a skilled artisan would understand "base plate" to be distinct from a "spacer," rendering Patent Owner's position as to the alleged understanding of a skilled artisan as untenable attorney argument. *See Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (rejecting attorney argument as to the alleged understanding of one of skill in the art on an issue when no evidence was presented).

Second, we view Patent Owner's position that the claimed "base plate" must be distinct from a "spacer" as in conflict with the Specification's description of the "base plate" as an interbody "spacer" that bears weight. In other words, if a skilled artisan "would understand a spacer to refer to an interbody device" (Prelim. Resp. 14) that "bears weight from the vertebral bodies" (*id.* at 15), it appears that the claimed "base plate" itself is a "spacer," according to Patent Owner's own explanation. Importantly, the independent claims challenged in this proceeding each explicitly recites that the "base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight" (*see, e.g.*, Ex. 1002, 38:1–3) (or similar language) and the Specification depicts a "base

plate" as residing within the anterior disc space of adjacent vertebral bodies. To illustrate this point, we reproduce Figure 1 of the '537 patent, below:

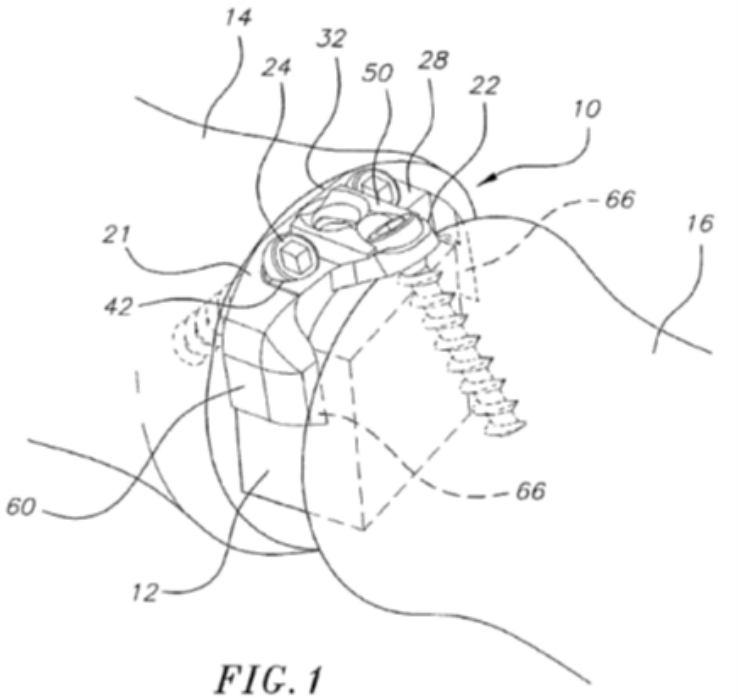


FIG. 1

The '537 patent describes Figure 1 as "a perspective view of a bone stabilization plate system according to the invention that is *assembled between adjacent vertebrae*." Ex. 1002, 5:63–65 (emphasis added).

We also reproduce Figure 3 of the '537 patent, below:

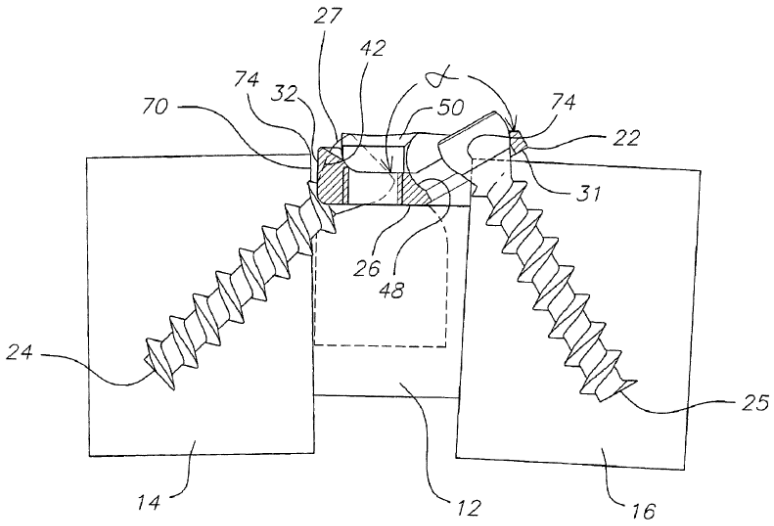


FIG. 3

Figure 3 "is a side cross-sectional view of the bone stabilization plate system of FIG. 1 *assembled between adjacent vertebrae*." *Id.* at 6:1–3 (emphasis added).

As shown in Figures 1 and 3, base plate 20 resides within the space between adjacent vertebral bodies. Furthermore, as noted above, the independent claims each requires that the "base plate" is "configured to . . . bear weight to hold the vertebral bones" or similar language. *See id.* at 38:1–4 (claim 1), 39:12–15 (claim 15, reciting "the base plate is configured to fit primarily between anterior portions of the bone bodies' lip osteophytes . . . to primarily bear weight"), 40:2–5 (claim 21, reciting that the "base plate" is "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").

Because the evidence of record fails to support Patent Owner's position that the claimed "base plate" must be "distinct from a spacer," and

because Patent Owner's own "base plate" appears to be a "spacer," we decline to adopt Patent Owner's proposed requirement.

c. Petitioner and Patent Owner's Common Proposed Requirement–"distinct from" "bone graft material deployed across a bone graft site"

Both Petitioner and Patent Owner include as part of their proposed constructions that the claimed "base plate" is a "fixation plate" that functions to "stabilize adjacent vertebrae for fusion" and is "distinct from" "bone graft material deployed across a bone graft site." *See* Pet. 18 ("Patent Owner and Petitioner[] 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.'") (citing Ex. 1005 ¶ 55); *see also* Prelim. Resp. 14 ("The parties agree that a base plate is a 'fixation plate' that functions to 'stabilize adjacent vertebrae for fusion' and is 'distinct from . . . bone graft material [deployed] across a bone graft site.'").

In their filings in this proceeding, however, neither Petitioner nor Patent Owner provides argument or identifies evidence to support the alleged requirement that the "base plate" be "distinct from" "bone graft material deployed across a bone graft site." Although the parties agree on this aspect of their proposed constructions, for the reasons below, we do not find the asserted distinction supported by the record at this stage of the proceeding. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1556 (Fed. Cir. 1995) ("[T]he judge's task is not to decide which of the adversaries[' constructions] is correct. Instead the judge must independently

assess the claims, the specification, . . . and declare the meaning of the claims.").

Based on our review of the record, we note that *some* independent claims in the '537 patent include recitations that could be seen to support the asserted distinction between the "base plate" and "bone graft material." For example, claim 15 recites that the claimed "system" include a "base plate" "for retaining bone graft material." Ex. 1002, 39:7–9. In addition, claim 1 requires the "base plate" to "bear weight to hold the vertebral bones while sharing weight with bone graft material for fusion." *Id.* at 38:3–5. Independent claim 21, however, does not recite "bone graft material" at all. Under the doctrine of claim differentiation, these differences support that the asserted distinction is *not* part of the proper understanding of the word "base plate" itself. *See Caterpillar Tractor Co. v. Berco, S.p.A.*, 714 F.2d 1110, 1115–16 (Fed. Cir. 1983) (rejecting an argument that a structural relationship recited in two independent claims should limit another independent claim that did not recite the same relationship, stating: "Courts may not introduce into a claim limitations which are explicitly contained in other claims."). Here, claim 21 would not appear to exclude from its scope a "base plate" that was *indistinct* from "bone graft material" (which is not even recited).

Although the Specification describes embodiments in which the base plate is distinct from bone graft material (*see, e.g.*, Ex. 1002, Figs. 1, 3), it is generally improper to read limitations from specific embodiments into the claims. *See Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015) ("[E]ven if all of the embodiments discussed in the patent included a specific limitation, it would not be proper to import from

the patent's written description limitations that are not found in the claims themselves.") (internal quotations and citation omitted). Accordingly, in our preliminary construction, we do not include a requirement that the "base plate" is distinct from bone graft material.[6]

d. Patent Owner's Footnote 2

In footnote 2 of the Preliminary Response, Patent Owner cites to *the '234 patent* and states, "The parties also dispute whether the base plate is part of a 'bone plate stabilization system.' It is, *as reflected in the intrinsic record* . . . ." Prelim. Resp. 14 n.2 (citing Ex. 1001, 2:40–41, 2:60–62, 4:3–4, claim 22) (emphasis added).

By referring to the intrinsic record of the '234 patent, we understand this footnote pertains to IPR2020-00265 and IPR2020-00274 (*see supra* Part I.A), and its inclusion in this Preliminary Response is an unintentional addition.

e. "base plate" construction

At this stage of the proceeding, and for purposes of this Decision, we construe "base plate" as a "fixation plate to stabilize adjacent vertebrae for fusion."

[6] We further note that neither Petitioner nor Patent Owner relies, in the context of any argument, on the presence of this alleged requirement in the construction of "base plate."

2. "primarily"

As discussed above, neither party explicitly addresses the claim language "the base plate is configured to fit *primarily* between anterior portions of adjacent vertebral bones' lip osteophytes." Despite this fact, we find it necessary to address this term to respond to Patent Owner's arguments under Ground 1. *See Nidec*, 868 F.3d at 1017.

In the underlying Delaware Litigations, the parties agree that the term "primarily" means "mainly." Ex. 1021, 6. For purposes of this decision, we adopt the parties' interpretation and construe "primarily" to mean "mainly." If either party disagrees with our preliminary construction, we encourage that party to address this issue in future briefing, as permitted under our Rules.

3. "configured . . . to bear weight"

As discussed above, neither party explicitly addresses the claim language "the base plate is configured to . . . bear weight to hold the vertebral bones" in independent claim 1. Nevertheless, we determine a need to construe this term to address Petitioner's challenge under Ground 3. *See Nidec*, 868 F.3d at 1017.

Petitioner submits that the plate of Fraser '106's two-piece embodiment would bear weight. *See* Pet. 71; *see also infra* Part II.H. In particular, Petitioner submits the following:

> 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. 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*. As such, a POSITA would understand that Fraser '106 discloses that *the base plate shares weight with bone graft material for fusion*.

Pet. 71 (citing Ex. 1005 ¶ 279) (emphases added). In a nutshell, Petitioner submits that a skilled artisan would understand that because the bone screws "would place a compressive load on the bone graft material . . . [,] the base plate shares weight with bone graft material." *Id.*

Patent Owner argues that the Petition fails to establish that Fraser '106's plate 20 "bears weight," contending that "the relevant force that is exerted on . . . plate 20 when the implant is inserted between two vertebrae and the bone screws are tightened is one of ***tension***, not compression." Prelim. Resp. 45. According to Patent Owner, "[t]he forces exerted by the bone screws on plate 20 would have component vectors along the superior/inferior direction that are opposed to each other (*i.e.*, in tension) rather than pointed towards each other (*i.e.*, compression)." *Id.* at 45–46 (citing Ex. 1007, Fig. 3). In a nutshell, Patent Owner submits that the bone screws of Fraser '106 would place a tensile load on the base plate, and thus, the base plate would not "bear weight" as required by the claims.

The express language of claim 1 requires, "[a] base plate that 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." Ex. 1002, 38:1–5.

The Specification describes that "[t]he spinal column of vertebrates provides support to bear weight and protection of the delicate spinal court and spinal nerves. The spinal column includes a series of vertebrae stacked on top of each other." *Id.* at 3:45–48. The Specification further describes,

"Between each vertebral body is an intervertebral disk, a cartilaginous cushion to help absorb impact and dampen compressive forces on the spine" (*id.* at 3:53–55) and that, after the disk has been excavated as part of a surgical treatment, the implanted bone graft and interbody device "share in the weight bearing during settling of the vertebral bodies" (*see, e.g.*, *id.* at 22:15–17).

Giving the language of claim 1 its ordinary and customary meaning in light the Specification (*see Phillips*, 415 F.3d at 1313–14), we determine that, in order for the "base plate" to "bear weight," the anterior portions of the adjacent lip osteophytes must apply a compressive force to the base plate. This understanding is supported by the language of claim 1 itself, which, based on the location of "to bear weight" *immediately following* "configured to fit primarily between anterior portions of adjacent vertebral bones lip osteophytes," indicates a linkage between these concepts.

To be clear, the "base plate" does not "bear weight" if it only undergoes a tensile stress applied from the implanted bone screws, or simply from stresses resulting from the retention of the bone graft material in the interbody space.

4. Summary

We do not discern a need to construe explicitly any of the other claim language because doing so would have no effect on the analysis below. *See Nidec*, 868 F.3d at 1017.

Furthermore, the parties are hereby given notice that claim construction, in general, is an issue to be addressed at trial and claim constructions expressly or implicitly addressed in this Decision are

preliminary in nature. Claim construction will be determined at the close of all the evidence and after any hearing. The parties are expected to assert additional claim construction arguments in the Patent Owner's Response, Petitioner's Reply, or otherwise during trial, as permitted by our rules.

F. Ground 1: Obviousness over Fraser '106 (one-piece embodiment)

Petitioner asserts that claims 1, 10, 13, 14, 21, 22, and 29 are unpatentable under 35 U.S.C. § 103 in view of Fraser '106's "fused implant embodiment" and the knowledge of a POSITA. Pet. 23. As discussed above, Fraser '106 discloses at least two embodiments, and Petitioner relies on the "fused implant" or "one-piece implant" embodiment under this ground. *See id.*; *see also infra* n.8 (explaining Petitioner's use of "one-piece implant" and "fused implant" to refer to the same embodiment disclosed in Fraser '106).

1. Fraser '106 (Ex. 1007)

Fraser '106 describes its invention as "an implantable structure for promoting fusion of adjacent vertebral bodies." Ex. 1007, 1:14–16. Figures 1 and 2 are reproduced below:

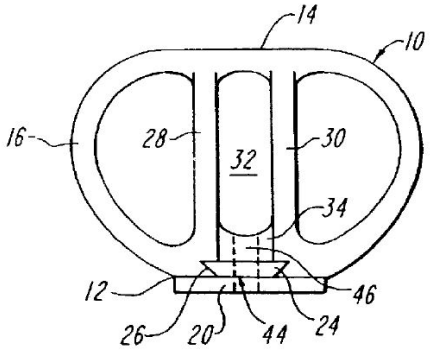


FIG. 1

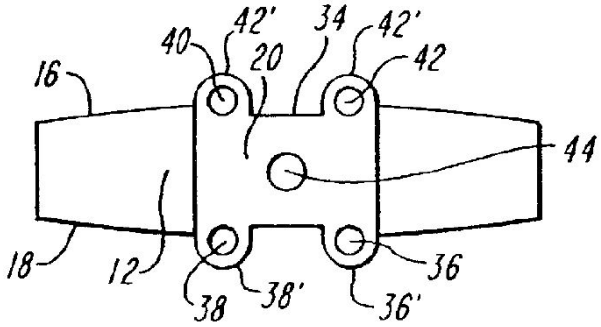


FIG. 2

Figure 1 is a "plan view of a fusion cage" and Figure 2 is a "view of the anterior face of the fusion cage" of Figure 1. *Id.* at 1:62–65. The depicted "cage" includes body 10, which, in turn, "includes an anterior face 12, a posterior face 14, a superior face 16, and an inferior face 18." *Id.* at 2:23–27. "The cage also includes a plate 20 that is matable with the body 10." *Id.* at 2:34–35. Fraser '106 discloses that "[a]lthough 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." *Id*. at 2:43–46. Figure 2 shows bone screw holes 36, 38, 40, and 42. *Id.* at 2:67–3:2. Figures 3 and 8 are reproduced below:

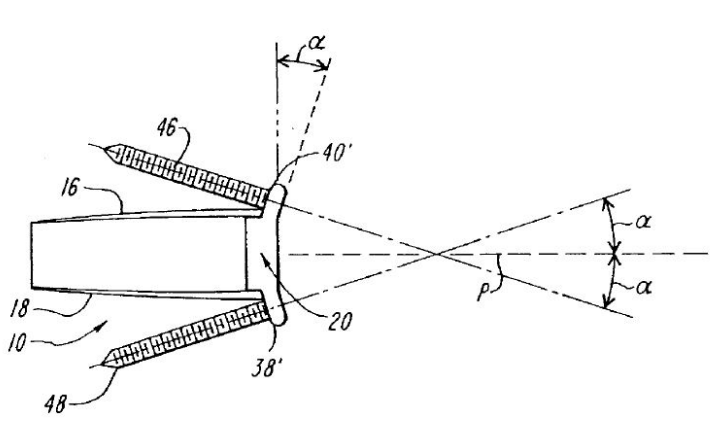


FIG. 3

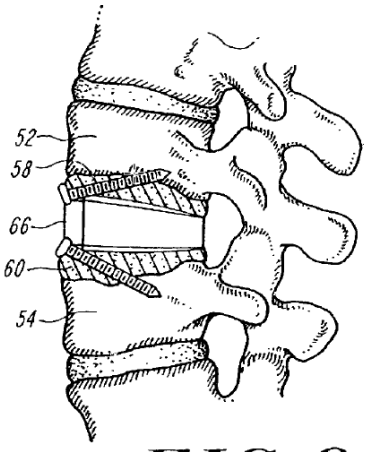


FIG. 8

Figure 3 is "a side view of the fusion cage of [Figure] 1 with bone screws" inserted and Figure 8 "depicts a portion of the spine following placement of the fusion cage" of Figure 1. *Id.* at 1:66–67, 2:9–10.[7] Fraser '106 discloses:

[7] As to Figure 8, Fraser '106 explains that "portions of the vertebral bodies are shown cut-away to illustrate the penetration of the bone screws 58 and 60 into the bodies." Ex. 1007, 4:13–15.

> Prior 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. Over a period of about three months the vertebral bodies fuse.

Id. at 4:38–43.

Fraser '106 discloses an embodiment in which base plate 20 is bonded with body 10 (referred to as the "one-piece implant" or "fused implant" embodiment)[8] and an embodiment in which the base plate 20 can slide relative to body 10 (referred to as the "two-piece implant"). *See id.* at 2:43–50.

2. Independent Claim 1

We address the claim limitations using Petitioner's nomenclature as identified above. *See supra* Part I.D.

a. Element 1 (Preamble)

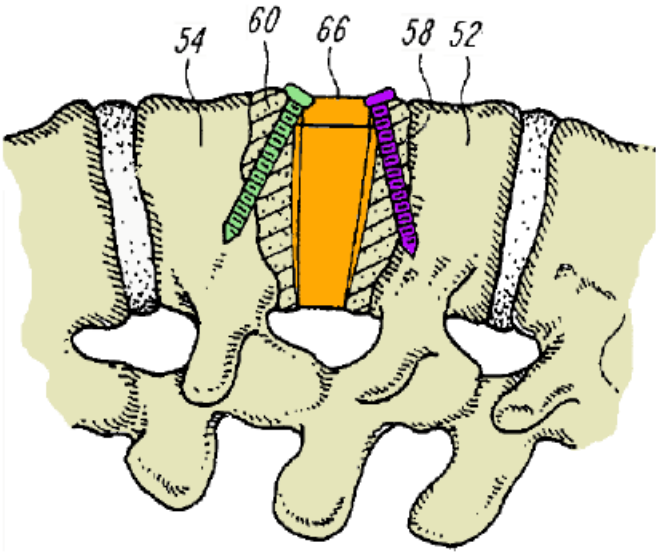
Petitioner submits that the preamble is not limiting, as it does not breathe life or meaning into the claim. Pet. 23 (citation omitted). Nevertheless, Petitioner submits that Fraser '106 discloses this recitation, quoting the abstract, which states, "[a] spinal fixation assembly [that] includes a fusion cage to which a plate is mated." *See id.* at 24.

Without determining whether the preamble is limiting, at this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 discloses this limitation.

[8] Petitioner uses the terms "one-piece implant" (*see, e.g.*, Paper 5, 5) and "fused implant" (*see, e.g.*, Pet. 5) in referring to the same embodiment disclosed in Fraser '106.

b. Element 1a – Base Plate

Petitioner submits that the "fused implant embodiment" described in Fraser '106 discloses a "base plate" as claimed. *See* Pet. 24–25. To support this assertion, Petitioner submits an annotated version of Figure 8 of Fraser '106 (*id.* at 25), which we reproduce, below:



According to Petitioner, and as shown above in annotated Figure 8, Fraser '106 discloses fixation plate 66 for fusing adjacent vertebrae. *See id.* Petitioner submits 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." *Id.* (quoting Ex. 1007, 1:36–42; citing Ex. 1005 ¶ 70).

As to the base plate "having a top surface, first and second ends, [and] a bottom surface," Petitioner submits an annotated version of Fraser '106's Figures 1 and 2 (*id.* at 27), which we reproduce below:

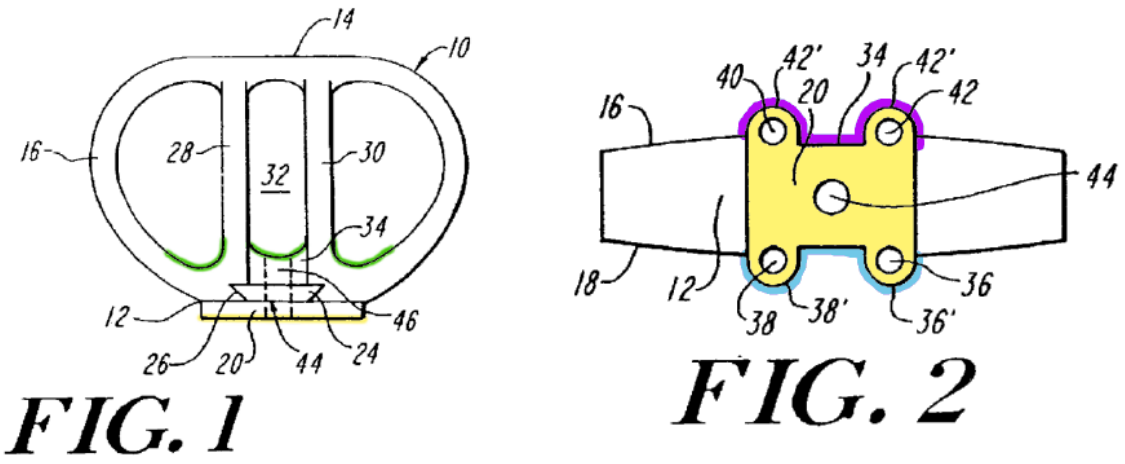


FIG. 1

FIG. 2

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

According to Petitioner, Fraser '106 discloses a base plate with a top surface (yellow), first end (blue, shown at bottom of Figure 2), second end (purple, shown at top of Figure 2), and a bottom surface (green, shown within the cavities of body 10 in Figure 1). *See* Pet. 27.

As to the claimed base plate having "a plurality of bone screw holes," Petitioner submits an annotated version of Fraser '106's Figure 2 (Pet. 29), which we reproduce, below:

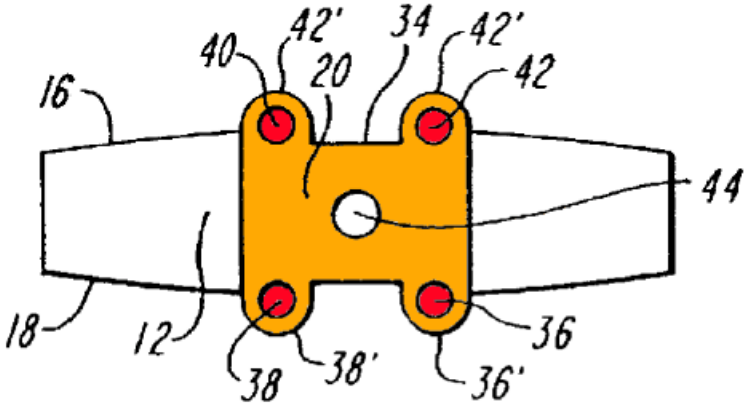


FIG. 2

Fraser '106, Ex.1007, Fig.2

Figure 2 "is a view of the anterior face of the fusion cage of" Figure 1. Ex. 1007, 1:64–65. According to Petitioner, four bone screw holes are depicted in red. Pet. 28.

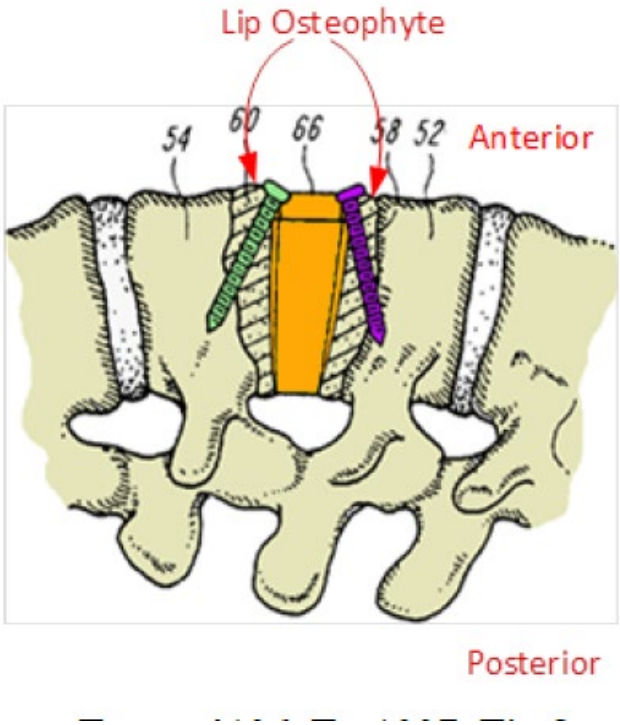
Patent Owner contends that Petitioner has failed to show how Fraser '106's "fused implant embodiment" satisfies the claimed "base plate." *See* Prelim. Resp. 21. In support of this argument, Patent Owner argues that the base plate must be "distinct from a spacer," and the "fused implant embodiment" is a plate "firmly bonded to the fusion cage body." *Id.* at 21–22 (citing Pet. 25–26). Patent Owner also argues that the "base plate" disclosed in Fraser 106's "fused implant embodiment" is used with a load-bearing fusion cage, conflicting with Petitioner's own construction of the term. *See id.* at 24–26.

Although Patent Owner is correct in that Fraser '106's "fused implant embodiment" utilizes plate 20 bonded with body 10, which for the sake of argument we will consider to also be a load-bearing fusion cage, Patent Owner's argument is not persuasive, as it is premised on a claim construction of "base plate" that we do not adopt. *See supra* Part II.E.1. As construed above, we do not interpret "base plate" as not being used "with a load-bearing fusion cage" or as being "distinct from a spacer." *Id.* Rather, we interpret "base plate" to be a "fixation plate to stabilize adjacent vertebrae for fusion." *Id.* at Part II.E.1.e.

At this stage of the proceeding, and based on our interpretation of "base plate," Petitioner has made a reasonable showing that the "fused implant embodiment" disclosed in Fraser '106 satisfies this limitation.

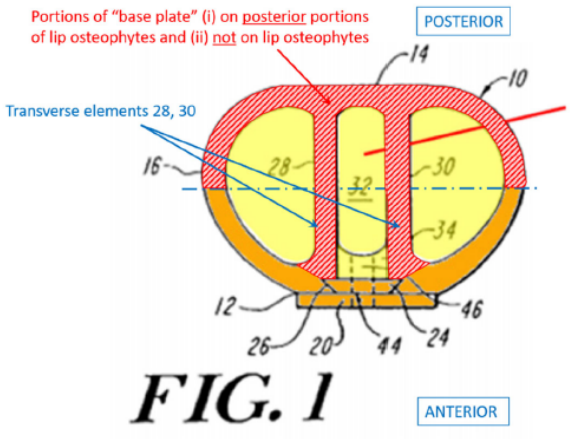
c. Element 1b – Base Plate Fit

In addressing "wherein the base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes," Petitioner submits an annotated version of Fraser 106's Figure 8 (Pet. 30), which we reproduce below:

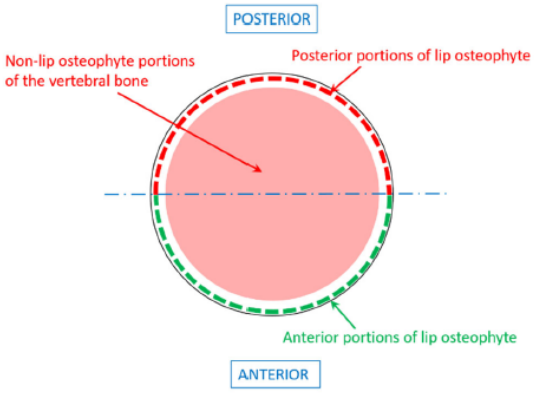


Petitioner submits that this annotated figure shows that the "cage includes a body that approximates the shape and size of the annulus portion of a disk which normally separates two vertebral bodies." *See id.* (quoting Ex. 1007, 2:21–23). Mr. Sherman testifies that "Fraser '106 explicitly teaches it is important for the implant to sit flush with, or recessed below, the anterior surface of the vertebrae." Ex. 1005 ¶ 84 (citing Ex. 1007, 4:16–19). Fraser '106 discloses, "It 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.

Patent Owner contends that "the fused implant embodiment . . . is not 'configured to fit primarily between the anterior portions of adjacent vertebral bones' lip osteophytes" (Prelim. Resp. 31) because it is instead "configured to fit (i) between all portions (both anterior and posterior portions) of the adjacent vertebral bones' lip osteophytes, as well as (ii) between non-lip osteophyte portions of the adjacent vertebral bones—i.e., 'transverse elements 28 and 30' of body 10" (*id.* at 30–31). To illustrate this point, Patent Owner submits an annotated version of Figure 1 of Fraser '106 and a second figure depicting a "[s]implified plan view of anterior and posterior portions of lip osteophytes" (*id.* at 31), both of which we reproduce below.



***See* Pet. at 26 (additional annotations added to Fraser '106, Fig. 1)**



Simplified plan view of anterior and posterior portions of lip osteophytes

Figure 1 (left) depicts a plan view of Fraser '106's fusion cage (Ex. 1007, 1:61–62) and the figure on the right depicts a "simplified plan view of anterior and posterior portions of lip osteophytes" (Prelim. Resp. 31). According to Patent Owner, and as shown above, the "base plate" of Fraser '106's "fused implant embodiment" fits between *posterior portions* of the adjacent lip osteophytes *and* at transverse elements 28, 30. *See id.* at 30–31.

Patent Owner's argument has some merit, as it appears that the "base plate" of Fraser '106's "fused implant embodiment" occupies space between the adjacent vertebral bodies beyond just the anterior portion between the adjacent lip osteophytes. The term "primarily," however, does not mean "exclusively," such that the base plate must not fit within space other than the space between anterior portions of adjacent vertebral bones' lip osteophytes. Rather, we construe "primarily" to mean "mainly" (*supra* Part II.E.2), and Petitioner submits the uncontroverted testimony of Mr. Sherman, who testifies, "in my opinion, Fraser '106 discloses a base plate that is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes." Ex. 1005 ¶ 85.

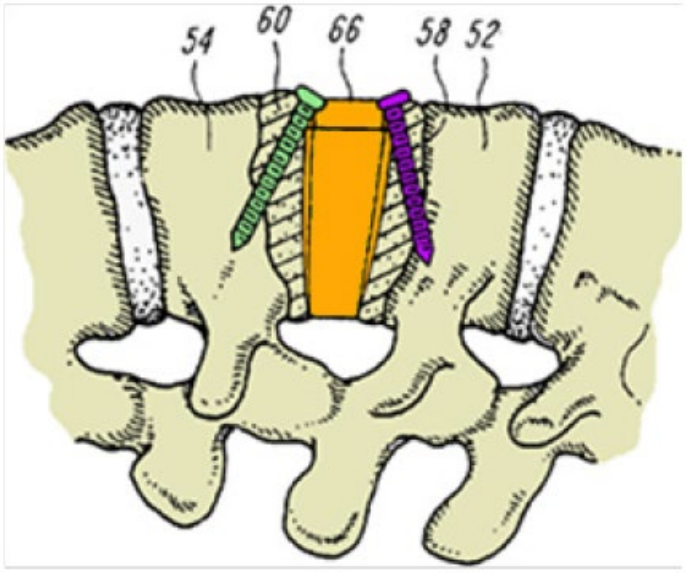
Mr. Sherman cites to Fraser '106's disclosure that "[i]t is important to note that screw heads 62 and 64 are flush or sub-flush with the anterior surface 66 of the fusion cage, thus minimizing the likelihood that major blood vessels running along the spine will be injured." *Id.* ¶ 84 (quoting Ex. 1007, 4:16–19) (emphasis omitted). Indeed, as shown in Fraser '106's Figure 8, it appears that Fraser '106's "base plate" sits between the anterior portions of the vertebral bones' lip osteophytes, and Mr. Sherman's uncontroverted testimony that Fraser '106 discloses this limitation is reasonably supported.

At this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 discloses this limitation.

d. Element 1c – Bone Screws

Claim 1 recites, "a plurality of bone screws configured to fit in the plurality of bone screw holes." Ex. 1002, 38:6–7. Petitioner asserts that

Fraser '106 discloses this limitation, submitting an annotated version of Figure 8 (Pet. 34), which we reproduce, below:

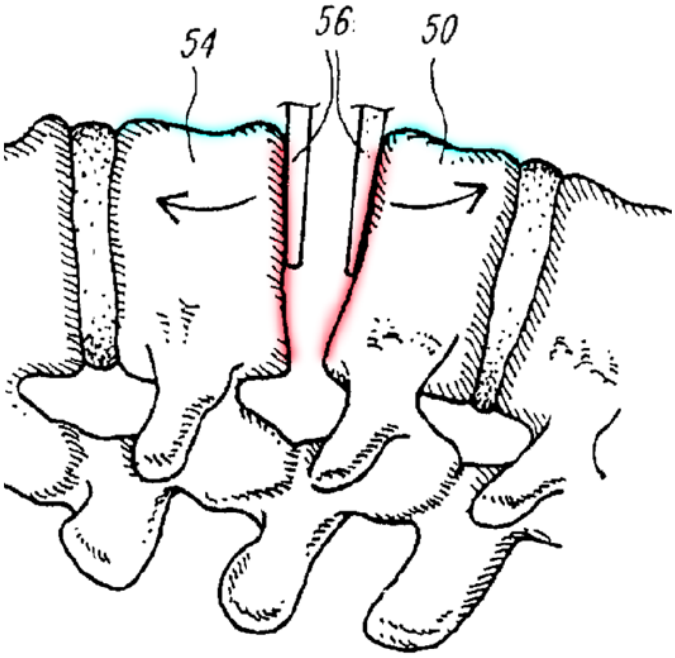


According to Petitioner, and as shown in the above figures, Fraser '106 discloses bone screws 58 (purple), 60 (green) disposed in bone screw holes of Fraser '106's plate. *See id.*

At this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 discloses this limitation.

e. Element 1d – Vertebral Bones

Claim 1 recites, "wherein the vertebral bones have top surfaces and have side surfaces generally facing each other." Ex. 1002, 38:8–9. Petitioner submits that Fraser '106 discloses this limitation, submitting an annotated version of Figure 7 (Pet. 35), which we reproduce, below:



Fraser '106, Ex.1007, Fig.7

As shown above, and according to Petitioner, Fraser '106 discloses adjacent vertebral bodies 54, 50, each having a top surface (shown in blue) and a side surface (shown in red). *Id.*

At this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 discloses this limitation.

f. Element 1e – First Bone Screw Hole - Side Surface

Claim 1 requires "a first of the bone screw holes . . . 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." Ex. 1002, 38:10–14. Petitioner submits that Fraser '106 discloses this limitation. Pet. 36. Petitioner provides an annotated version of Fraser '106's Figure 3 (Pet. 37) and Figure 8 (*id.* at 36), which we reproduce below:

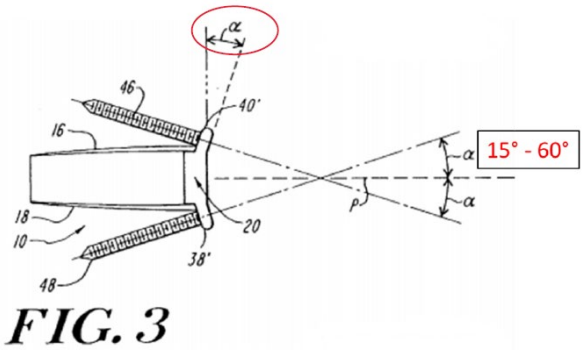
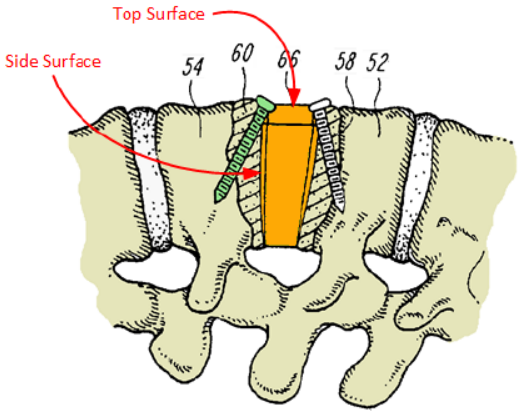


FIG. 3



As shown above in annotated Figures 3 (left) and 8 (right), Fraser '106 discloses first bone screw 46 (green in Figure 8) disposed through a hole within plate 20 and toward the side surface of first vertebral bone 54. *See id.* (citing Ex. 1007, 3:13–17; Ex. 1005 ¶ 95). Petitioner further submits that Fraser '106 teaches that the angle of insertion (α) may range from 15° to 60°. *Id.* at 36–37 (citing Ex. 1007, 3:24–28; Ex. 1005 ¶ 96). Petitioner relies on this range of screw angles in addressing the next limitation, "lip osteophyte." *See id.* at 38.

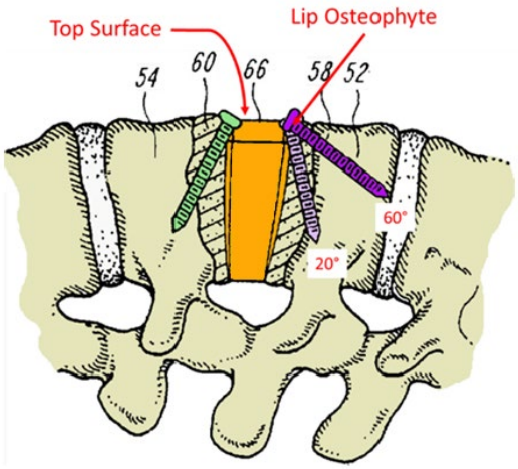
At this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 discloses this limitation.

g. Element 1f – Second Bone Screw Hole - Lip Osteophyte

Claim 1 recites "a second of the bone screw holes . . . 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. 1002, 38:15–19.

Petitioner submits that Fraser '106's teaching of screw angles between 15° to 60° include screw holes that would "open toward the side surface of the vertebrae *or a steep angle to open toward the lip osteophyte.*" Pet. 38

(emphasis added). Petitioner submits that "Fraser '106 discloses this claim limitation." *Id.* at 39. Petitioner also submits an annotated version of Figure 8 (*id.*), which we reproduce, below:



According to Petitioner, and as shown above, annotated Figure 8 depicts a bone screw (in purple) that extends at "a steep angle to open toward the lip osteophyte." *See id.* Petitioner also submits that it would have been obvious for a skilled artisan "to perform routine experimentation and optimization to choose the most suitable angle for each hole based on any particular patient or set of patients." *Id.* (citing Ex. 1005 ¶ 101).

Patent Owner argues that Petitioner "fails to show that Fraser '106 teaches a base plate having bone screw holes that satisfy the 'side surface bone screw hole orientation' limitations." Prelim. Resp. 51. Patent Owner contends that Petitioner provides "nothing but attorney argument or *ipse dixit* declaration testimony to support [its] contention that the green [first] bone screw is oriented towards the side surface of a bone while the purple [second] bone screw is oriented towards the lip osteophyte." *Id.* at 54.

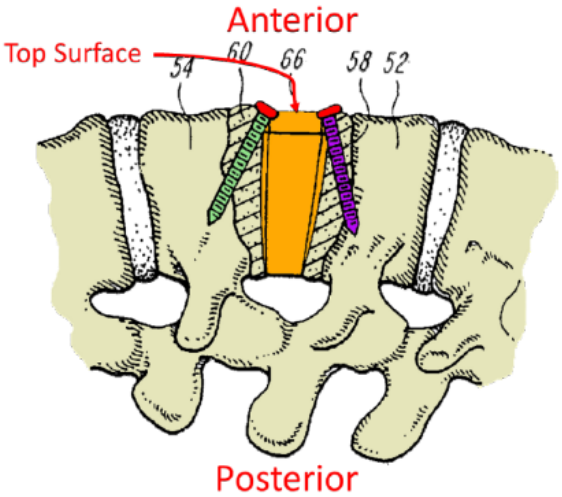
Patent Owner's argument is not persuasive.

Mr. Sherman testifies that a skilled artisan would have recognized that "each of the screw angles can be adjusted independently of one another" (Ex. 1005 ¶ 96) and we are persuaded by Mr. Sherman's testimony that a first screw with a shallow screw angle of 15° would be oriented towards the side surface of the first vertebral body while a second screw with a steep angle of 60° would open toward the lip osteophyte of the second vertebral body (*see id.* ¶ 97; *see also* Pet. 39 (annotating Figure 8 of Fraser '106)).

At this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 satisfies this limitation.

h. Element 1g – Bone Screw Orientation

Petitioner submits that 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." Pet. 40. Petitioner provides an annotated version of Fraser '106's Figure 8 (*id.*), which we reproduce, below:



According to Petitioner, and as shown above, Fraser '106 discloses bone screw holes that are angled relative to the top surface of the base plate and face the posterior direction. *Id.*

At this stage of the proceeding, Petitioner has made a reasonable showing that Fraser '106 discloses this limitation.

i. Summary of Independent Claim 1

We have reviewed Petitioner's contentions and Patent Owner's arguments with respect to the limitations of claim 1 and, for the reasons discussed above, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to the contention that claim 1 would have been obvious based Fraser '106.

3. Claims 10, 13, 14, 21, 22, and 29

Patent Owner does not offer any additional arguments specifically addressing the remaining limitations of claims 10, 13, 14, 21, 22, and 29. *See generally* Prelim. Resp. We have reviewed Petitioner's contentions with respect to the remaining limitations of these claims and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that Fraser '106 satisfies the subject matter of these limitations. *See* Pet. 41–51.

4. Summary of Ground 1

For the reasons above, we determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to the contention that claims 1, 10, 13, 14, 21, 22, and 29 would have been obvious based on Fraser '106.

G. Ground 2: Obvious over Fraser '106 and Byrd

Petitioner submits that claims 3, 15, and 19 are unpatentable under 35 U.S.C. § 103 in view of Fraser '106 and Byrd. Pet. 51.

1. Byrd (Ex. 1008)

Byrd discloses a "vertebral cage . . . for use in preserving the space between adjacent vertebral during the process of spinal fusion." Ex. 1008, code (57). We reproduce Figures 1 and 2 of Byrd, below:

FIG.-1

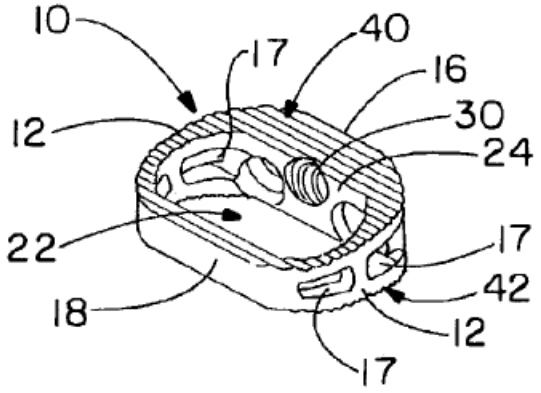
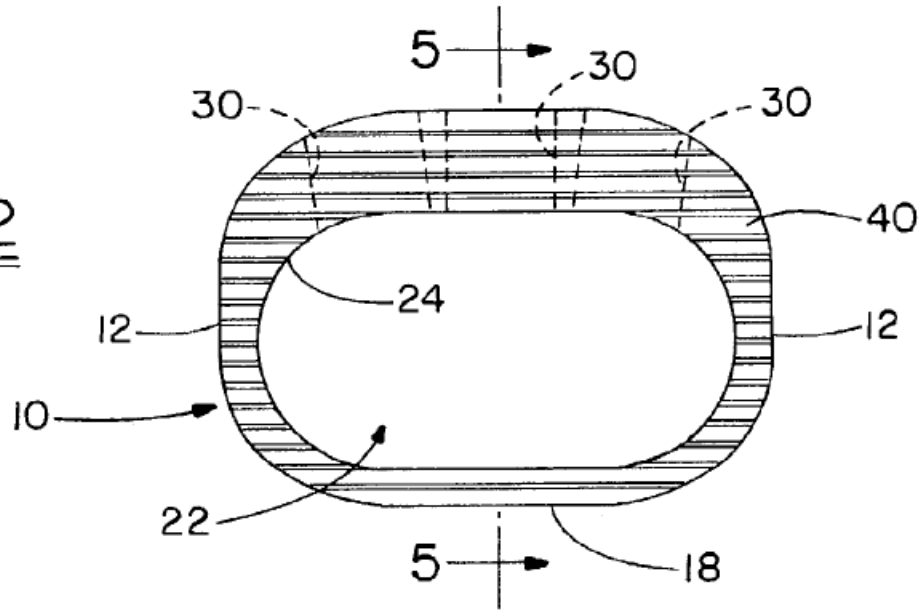


FIG.-2



According to Byrd, Figure 1 depicts a top perspective view of Byrd's vertebral gage and Figure 2 depicts a top view of the cage. *Id.* at 4:62–64.

2. Analysis

These claims further recite, "wherein the bottom surface of the base plate is generally flat" (or similar language). *See, e.g.*, Ex. 1002, 38:28–39 (dependent claim 3). To satisfy these limitations, Petitioner submits that Byrd discloses a base plate with a generally flat surface and reasons that a

skilled artisan would have modified Fraser '106's base plate to include a generally flat bottom surface as a matter of design choice and that the modified device "would be simpler and less expensive to manufacture, while also promoting additional bone growth." *See* Pet. 53 (submitting annotated Figures 1, 2 from Byrd); *see also id.* at 65 (citing Ex. 1005 ¶ 260).

Patent Owner does not offer any additional arguments specifically addressing the remaining limitations of claims 3, 15, and 19. *See generally* Prelim. Resp. We have reviewed Petitioner's contentions with respect to the remaining limitations of these claims and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that Fraser '106 in view of Byrd satisfies the subject matter of these limitations. *See* Pet. 51–65.

H. Ground 3: Obvious over Fraser '106 in view of the Knowledge of a POSITA (two-piece embodiment)

Petitioner challenges claims 1–3, 8–16, 19–23, 25–27, and 29 as being unpatentable under 35 U.S.C. § 103 in view of Fraser '106 and the knowledge of a POSITA. Pet. 65. Fraser '106 discloses at least two embodiments, and Petitioner relies on the "two-piece embodiment" under this ground. *See id.* at 66; *see also supra* Part II.F.1 (describing the slidable two-piece embodiment).

In presenting this challenge, Petitioner explains, "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." Pet. 66.

In addressing the claimed "base plate," Petitioner submits annotated versions of Figures 1 and 2 of Fraser '106 (*id.* at 68), which we reproduce, below:

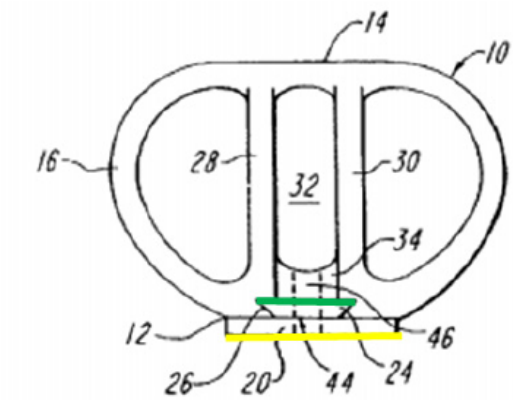


FIG. 1

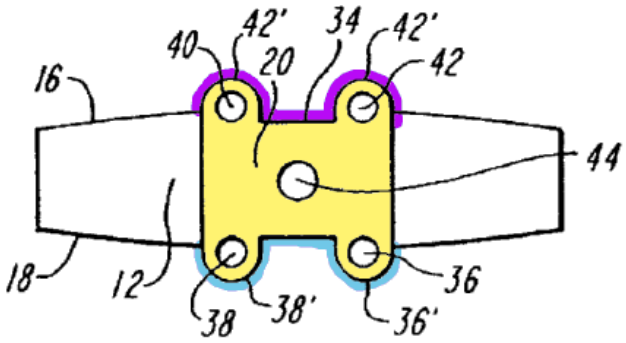
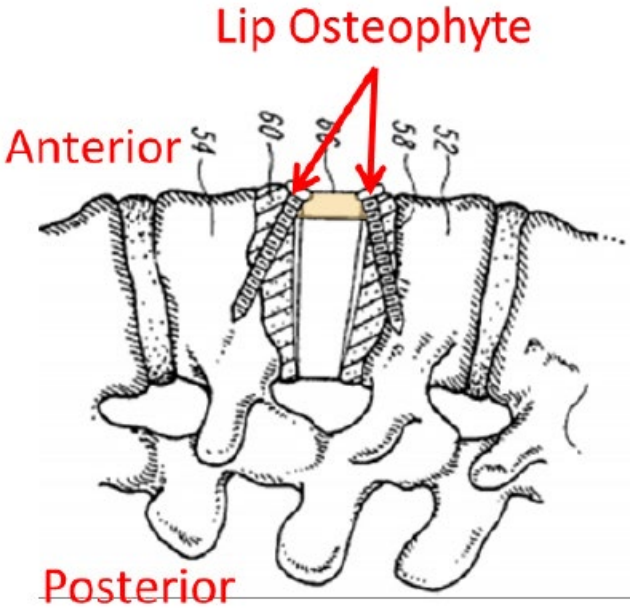


FIG. 2

According to Petitioner, Fraser '106 depicts base plate 20 and body 10 that are distinct, and not bonded. *Id.* at 67. In this two-piece embodiment, base plate 20 has a top surface (yellow), a first end (blue), a second end (purple), and a bottom surface (green). *Id.* at 68.

To address the claimed "base plate is configured to fit primarily between anterior portions of adjacent vertebral bones' lip osteophytes to bear weight and hold the vertebral bones while sharing weight with bone graft material," Petitioner submits an annotated version of Figure 8 of Fraser '106 (*id.* at 70), which we reproduce, below:



According to Petitioner, 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." *Id.*

Petitioner further submits that

> 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. As such, a POSITA would understand that Fraser '106 discloses that the base plate shares weight with bone graft material for fusion.
>
> 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**."
>
> 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.

Pet. 71–72 (citing Ex. 1007, 4:37–42; Ex. 1005 ¶¶ 279, 280).

As discussed above, Petitioner submits that a skilled artisan would understand that because the bone screws "would place a compressive load on the bone graft material . . . [,] the base plate shares weight with bone graft material." *Id.*; *supra* Part II.E.3.

Patent Owner contends that "Fraser '106 expressly provides that it is the fusion cage body 10—not plate 20—that is configured to bear weight when inserted between vertebral bones." Prelim. Resp. 35. Patent Owner further argues,

> Petitioner[] present[s] no argument or evidence showing that when a spinal implant consisting of fusion plate 10 with locking plate 20 is inserted and used between two vertebral bones, these bones will settle or subside to such a degree that part of the bones may rest on these superior and inferior faces or any other part of plate 20.

Id. at 38 n.5.

Patent Owner's argument is persuasive.

As discussed above, giving the language of claim 1 its ordinary and customary meaning in light the Specification, we determine that, in order for the "base plate" to "bear weight," the anterior portions of the adjacent lip osteophytes must apply a compressive force to the base plate.

Because Petitioner submits that base plate 20 (of the two-piece implant of Fraser '106) bears weight because the "screws would place a compressive load on the bone graft material" (Pet. 71; *see also* Ex. 1005 ¶¶ 278, 279 (testifying to the same)), at this stage of the proceeding, we are not persuaded that the base plate of Fraser 106's two-piece implant "bears weight" as required by the claims.

Nevertheless, and pursuant to *SAS* and the *SAS* Guidance, we institute review of claims 1–3, 8–16, 19–23, 25–27, and 29 under Ground 3. *See also PGS*, 891 at 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"); Consolidated Guide 64 ("The Board will not institute on fewer than all claims or all challenges in a petition.").

I. Ground 4: Obvious over Fraser '106 in view of Michelson

Petitioner submits that claims 4–6, 24, and 30 are unpatentable under 35 U.S.C. § 103 in view of Fraser '106 and Michelson. Pet. 79.

1. Michelson (Ex. 1006)

According to Michelson, certain spinal instabilities can be treated by fusion, which is "the joining together permanently of the unstable vertebrae via a bridge of bone so as to eliminate all motion along [a] portion of the spine." Ex. 1006, 2.[9] Michelson discloses various "interbody spinal fusion implants" that are "placed at least in part within a disc space and in contact with each of the vertebral bodies adjacent that disc space for spacing apart and aligning those vertebral bodies and for allowing for the growth of bone in continuity from vertebral body to adjacent vertebral body." *Id.* Michelson provides this summary of the process:

> In order to perform anterior interbody spinal fusion, a significant amount of disc material is removed from the interspace to be fused. After removing the disc material, the

[9] Both Petitioner and Patent Owner cite to the internal pagination in Michelson rather than the page numbers added by Petitioner (e.g., "Petitioners 1006-1" on the first page). For consistency, we do the same.

> disc space is filled with an implant, which generally includes bone or bone in combination with a reinforcing structure, such as an artificial (other than bone) interbody spinal fusion implant.

Id. at 3. Figures 24 and 25 of Michelson are reproduced below:

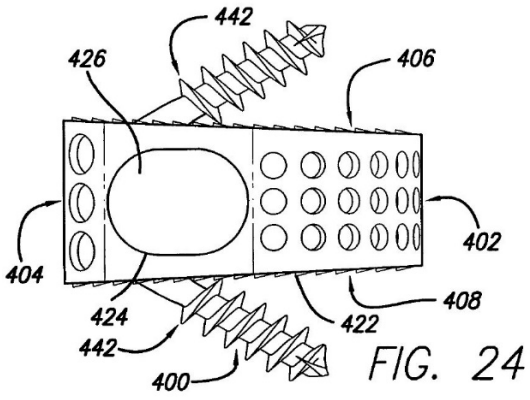


FIG. 24

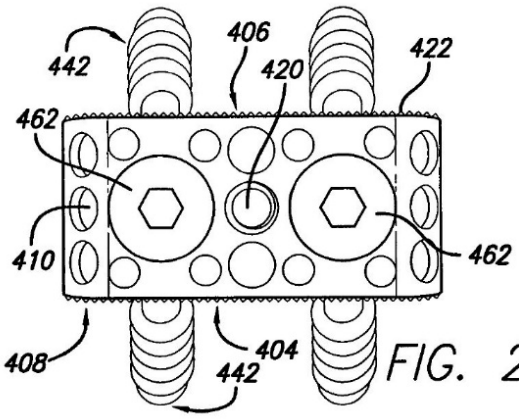


FIG. 25

Figure 24 is "a side elevation view of the fourth embodiment implant with opposed bone engaging screws." *Id.* at 7. Figure 25 is "a trailing end view of the implant of Figure 24 with screws and screw locks in place." Ex. 1006, 7. Michelson describes implant 400 as including convex leading end 402 and opposite trailing end 404, both of which are "highly perforate to allow for vascular access to hollow interior 426 of implant 400, and to allow for the growth of bone therethrough." *Id.* at 16. Implant 400 also includes opposed upper and lower vertebral body engaging surfaces 406 and 408, respectively, and bone screws 442. *Id.* at 16–17. Figure 25 also depicts "threaded lock members 462, preventing screws 442 from backing out." *Id.* at 17. Figures 23 and 21 are reproduced below:

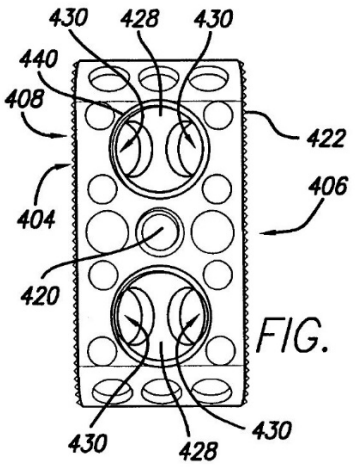


FIG. 23

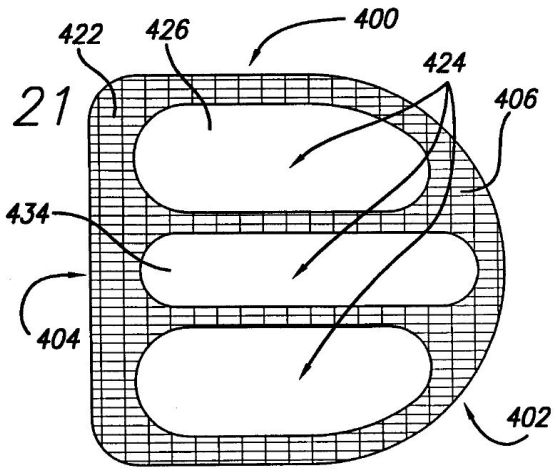


FIG. 21

Figure 23 is a "trailing end view" and Figure 21 is a "top plan view" of the same embodiment shown above. *Id.* at 6. Figure 23 shows two common holes 440 (which receive threaded lock members 462 shown in Figure 25) as well as four holes 430, each of which is "adapted to receive a bone screw 442" that is directed "into [a] vertebral body itself at an angle preferably between 25° and 75°." *Id.* at 17. As shown in Figure 21, Michelson discloses that "[i]mplant upper and lower surfaces 406 and 408 have large windows or slots 424 therethrough, each in communication with the central hollow chamber 426 of the implant and each forming a direct path to its counterpart on the opposite surface through implant 400." *Id*. at 16–17. Michelson also discloses that "[t]o the extent that such implants are hollow and have openings through the surfaces, those openings and those hollows can preferably be filled with fusion promoting substances, including substances that are osteogenic, osteo-inductive, or osteo-conductive, whether naturally occurring, or artificially produced." *Id.* at 9.

2. Analysis

The challenged claims further recite, "wherein the system further comprises a screw retainer configured to prevent at least one of the plurality of bone screws from backing out." *See, e.g.*, Ex. 1002, 38:30–32 (dependent claim 4). To satisfy the claimed "screw retainer," Petitioner relies on Michelson's disclosure of threaded lock members 461 for preventing screws 442 from backing out. Pet. 79–80 (citing Ex. 1006, 19; Ex. 1005 ¶ 383). Petitioner reasons that a skilled artisan would have modified Fraser '106 to include Michelson's locking members to prevent the bone screws of Fraser '106 from backing out. *Id.*; *see also id.* at 85–86 (providing additional reasoning).

Patent Owner contends that Petitioner and Mr. Sherman "fail to explain, however, how a [POSITA] would have implemented these modifications from Michelson . . . to Fraser '106's plate and what this modified implant would look like." Prelim. Resp. 58. Patent Owner further argues that Petitioner has "failed to present any plausible reason, supported by evidence, for why a [POSITA] would combine Michelson . . . with Fraser '106." *Id.* at 60.

Patent Owner's arguments are not persuasive.

At this stage of the proceeding, Petitioner submits sufficient explanation and reasoning to persuade us that a skilled artisan would have modified Fraser '106 to include a screw retention mechanism, as taught by Michelson. We find uncontroverted Mr. Sherman's testimony that

> A POSITA would have recognized that the anti-back out plates are easy to use and implement in a variety of implant designs. Further, Fraser '106 does not disclose any structure that would preclude or interfere with an anti-back out plate. 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.

Ex. 1005 ¶ 406 (citing Ex. 1007, 4:16–19).

We have reviewed Petitioner's contentions with respect to the these limitations and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that Fraser '106 in view of Michelson satisfies the subject matter of claims 4–6, 24, and 30. *See* Pet. 79–86.

J. Ground 5: Obvious over Fraser '106, Michelson, Byrd

Petitioner submits that claim 18 is unpatentable under 35 U.S.C. § 103 in view of Fraser '106, Michelson, and Byrd. Pet. 86.

As explained above in connection with Grounds 2 and 4, Petitioner relies on Byrd's teaching of a flat bottom surface (*id.* at 87) and Michelson's teaching of anti-back out screw plates (*id.* at 88). As discussed above, Petitioner proposes to modify Fraser '106's base plate to include Michelson's anti-back out plate and Byrd's flat bottom surface for the same reasons discussed above. *See id.* at 87–89.

Patent Owner does not offer any additional arguments specifically addressing the remaining limitations of claim 18. *See generally* Prelim. Resp. We have reviewed Petitioner's contentions with respect to the remaining limitations of claim 18 and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that Fraser '106 in view of Michelson and Byrd satisfies the subject matter of this claim. *See* Pet. 86–89.

III. CONCLUSION

For the reasons above, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to at least one of challenged claims 1, 3–6, 10, 13–15, 18, 19, 21, 22, 24, 29, and 30 of the '537 patent.

At this stage of the proceeding, no final determination has yet been made with regard to the patentability of any of the challenged claims or any underlying factual or legal issues, including the construction of claim terms. The final determination will be based on the record as developed during the *inter partes* review.[10]

IV. ORDER

For the reasons above, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1, 3–6, 10, 13–15, 18, 19, 21, 22, 24, 29, and 30 of the '537 patent on all asserted grounds and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review shall commence on the entry date of this Decision, with notice hereby given of the institution of a trial.

[10] As highlighted in the accompanying Scheduling Order, "Patent Owner is cautioned that any arguments not raised in the response may be deemed waived." Paper 25, 8; *see also In re NuVasive, Inc.*, 842 F.3d 1376, 1379–82 (Fed. Cir. 2016) (holding that a patent owner waived an argument addressed in a preliminary response by not raising the same argument in the patent owner response).

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