

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

Case IPR2020-01308
Patent 9,889,022

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

EXHIBIT NO.	DESCRIPTION
Ex. 2001	Globus Medical, Inc's Opening Claim Construction Brief, <i>Moskowitz Family LLC v. Globus Medical, Inc.</i> , Case No. 19-cv-672-ADA, Filed June 17, 2020.
Ex. 2002	Moskowitz Family LLC's Opening Claim Construction Brief, <i>Moskowitz Family LLC v. Globus Medical, Inc.</i> , Case No. 19-cv-672-ADA, Filed June 17, 2020.

I. INTRODUCTION

Petitioner failed to meet the requisite burden of showing a reasonable likelihood that it would prevail with respect to any of the challenged claims. The Board's rules and applicable law provide clear directions for petitioners seeking *inter partes* review on obviousness grounds. Petitioner disregards those directions and charts a different path incompatible with an instituted trial. As a result, the Petition is plagued by multiple deficiencies, which provide multiple, independent bases to deny institution. Collectively, these significant deficiencies provide overwhelming weight to deny institution.

As an initial matter, the Petition flouts the Board's rules and guidance that require a petitioner to articulate and support with evidence the constructions that the Petition is premised on, and explain where each element of the claim, so construed, is found in the prior art. Instead, the Petition recites its asserted constructions without citation to any evidentiary support, and then ignores the asserted constructions in its analysis of the prior art. Petitioner's tactic impermissibly turns the proceeding on its head.

The Petition is defective on the merits in other ways. The cited art fails to disclose a number of claim elements, deficiencies that are particularly apparent in view of the Petition's asserted claim constructions. For example, the Petition fails to demonstrate that the cited references describe a "universal," intervertebral

combination internal screw guide and fixation apparatus, an internal screw guide with an “entry opening of the internal bore formed only in a top surface of the top wall,” and a “circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall.”

The Petition’s attempts to modify Tisserand based first on “design choice” and second on Bonutti are based on speculation, rather than documentary evidence, and lack a requisite explanation as to why a POSITA would have been motivated to modify Tisserand in the proposed manner. The Petition’s failure to present documentary evidence demonstrating each element of the claim is particularly notable given that the Patent Office already considered Tisserand during original prosecution and the Petition’s use of Bonutti is cumulative to art applied in rejections by the Office.

Accordingly, the “information presented in the petition” is plainly insufficient to satisfy Petitioner’s burden under § 314(a)—especially where Petitioner cannot subsequently add theories/arguments that should have been part of the Petition. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016); *In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

For all these reasons, each discussed in more detail below, the Board should deny the Petition.

II. THE '022 PATENT¹

A. Background of the Invention

The '022 Patent's lead inventor, Dr. Nathan Moskowitz, is a prominent surgeon with decades of experience treating thousands of patients and performing thousands of spinal surgeries. The '022 Patent protects one of Dr. Moskowitz's many innovations relating to revolutionary fixation systems for minimally-invasive spinal fusion surgery.

The '022 patent is directed to surgical hardware for minimally invasive spinal fusion procedures that result in improved health outcomes for patients. Spinal fusion is a commonly performed surgical procedure to relieve pain and pressure on the spinal cord that results when a disc between two vertebrae wears out. Spinal fusion involves joining two or more vertebrae to prevent movement between the fused vertebrae.

In particular, the '022 patent relates to a “universal, intervertebral combination internal screw guide and fixation apparatus” that is inserted into a disc space between two vertebral bodies to facilitate and encourage bone and screw fusion. Ex. 1001, cl. 47. The '022 patent's recited features facilitate screw

¹ This description provides context for the arguments contained herein and is not intended to limit the scope of the '022 Patent's claims.

insertion at a shallow angle such that portions of the vertebral bone above and below the fixation apparatus need not be carved away before implantation. *Id.*, 3:31-39; Ex. 1002, 451. For example, the fixation apparatus includes an internal screw guide to facilitate screw placement at a prescribed angle. Ex. 1001, 3:31-39; 11:58-64. Additionally, the claimed configuration can facilitate biological bone fusion of not only the fixation apparatus to the bone, but also biological fusion of the screws to the fixation apparatus, preventing backing out of the screws and providing a permanent implantation of the apparatus. Ex. 1002, 451.

The '022 patent achieved the claimed features, at least in part, due to the innovative structural configuration of an “entry opening” and “exit opening” of an internal bore of the screw guide with respect to a “top wall” and “bottom wall” of the intervertebral fixation apparatus. In particular, the “entry opening” is “formed only in a top surface of the top wall,” an “exit opening” is “formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall,” and a “counterbore that is larger than and coaxial with the internal bore” “has a counterbore entry opening that is formed only in the top surface of the top wall.” Ex. 1001, cl. 47. Thus, not only do the claims require particular structures of the “top wall,” “side wall,” “entry opening” and “exit opening,” but these elements must be arranged to achieve the part-to-part relationships as recited in the claims. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*,

730 F.2d 1452, 1459 (Fed.Cir.1984) (reversible error for the factfinder to “treat[] the claims as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning”). An exemplary embodiment of these claimed features is shown and described with reference to FIGS. 1A-1E (exemplary FIG. 1B reproduced below).

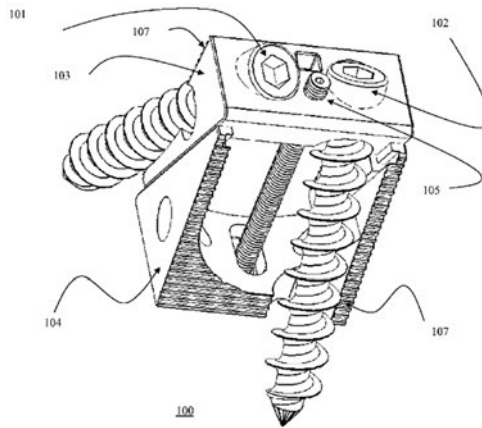


Fig. 1B

Ex. 1001, FIGS. 1B.

B. Overview of the Prosecution History

The application leading to the '022 patent was filed on Aug. 15, 2011 as a continuation of App. No. 13/084,543, filed on April 11, 2012, and a series of applications, the earliest filing date of which is Provisional App. No. 60/670,231 filed on April 12, 2005. The '022 patent was allowed on December 6, 2017 and issued on February 13, 2018.

The '022 patent issued only after going through a robust examination involving **five** substantive office action response cycles. *See, generally* EX. 1002. The Patent Office applied multiple references in the rejections across the five office actions, and indicated that the Examiner considered numerous other references, including the Tisserand reference, which Petitioner recycles as the primary reference in all grounds asserted here. *See, e.g.* Ex. 1002, 145; 164-185. This Petition seeks a redo without sufficient explanation why the Board should reverse the Patent Office's original analysis and conclusion of patentability.

During prosecution, after several office actions and responses, the Examiner rejected claims based on Waugh (U.S. 2008/0249575) and Waugh in view of Messerli (U.S. 2010/0305704). Ex. 1002, 135-140 (Office Action dated February 8, 2017). The Examiner relied on Messerli as purportedly providing "evidence[] of the use of an implant wherein the entry opening of the internal screw guide is formed only in the top surface of the top wall to receive a screw." Ex. 1002, 139. In response, Applicant introduced claims (including new claim 135 corresponding to issued claim 47) reciting "the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall," and "wherein the internal screw guide further includes a counterbore that is larger than and coaxial with the internal bore and has a counterbore entry opening

that is formed only in the top surface of the top wall.” *Id.*, 125-126. A notice of allowance followed the amendments and response. Notably, while these features were central to the PTO’s determination that claim 47 was worthy of a patent, the Petition never cites to a prior art document that even mentions these structural features required by the claims.

III. CLAIM CONSTRUCTION

As an initial matter, no claim construction is necessary to deny institution. Patent Owner’s arguments for denial, including those that note Petitioner’s failure to meet its own constructions, do not hinge on the outcome of an actual controversy about claim interpretation. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed to the extent necessary to resolve the controversy.”). The deficiencies of the Petition are readily identifiable without defining the bounds of any specific claim term or phrase. *Id.*

There are at least three fatal defects, however, related to Petitioner’s asserted constructions. First, Petitioner chose not to explain or identify evidentiary support for the constructions that form the basis of the Petition. Thus, the issue of claim construction is not ripe for review on this record, and this defect independently renders the Petition fatally flawed under the Board’s rules. Second, the Petition does not identify portions of the ’022 specification that describe the corresponding

structure associated with certain means-plus-function claim limitations. Third, in its mapping of the prior art, the Petition fails to analyze how the claims so construed are disclosed by the references. Patent Owner addresses the first and second defects here, and addresses the third defect below (*Infra*, Section IV.C).

A. Petitioner Fails To Carry Its Burden To Construe the Challenged Claims

The Petition alleges multiple claim terms must be construed. Pet., 11-13. Yet, Petitioner offers its constructions without any supporting evidence. *Id.* Indeed, the Petition’s discussion of claim construction is devoid of citation to any intrinsic or extrinsic evidence. *Id.* Likewise, the Petition’s discussion of claim construction does not cite to any testimonial evidence as supporting its asserted constructions. *Id.* Instead, the Petition baldly recites specific constructions within a table without the requisite analysis or supporting evidence. *Id.*, 12. This is clearly insufficient. Petitioner has the burden to demonstrate “where the intrinsic and/or extrinsic evidence supports” its proposed construction. *Consolidated Trial Practice Guide* (“CTPG”), 44 (advising that a petitioner “must” state the construction ***and the supporting evidence***) (emphasis added); 37 C.F.R. §§ 42.104(b)(3) and 42.104(b)(4). Petitioner failed to meet its burden.

The failure to present any evidence, or explain any theory, for its constructions renders the Petition fatally defective. “Without such an explanation of Petitioner’s position and supporting evidence, [the Board] cannot conduct the

necessary factual inquiry for determining whether Petitioner has shown a reasonable likelihood in demonstrating that the prior art meets this limitation.” *United Patents Inc. v. Synchview Technologies, LLC*, IPR2019-00470, Paper 17, 5 (PTAB May 20, 2020) (citing *In re Steele*, 305 F.2d 859, 862–63 (CCPA 1962); *see also id.* (“We are unable to conclude, therefore, that there is a reasonable likelihood that Petitioner would prevail in demonstrating the unpatentability of any of the challenged claims.”)).

Worse, Petitioner withholds from the Board the theories it raised in the co-pending district court litigation when proposing its specific constructions there. Ex. 2001; *see also* Ex. 2002. Petitioner’s endgame is plain—preserve its proposed constructions in the district court by presenting the Board with a token recitation of those constructions, but withhold from the Board evidence in support of those constructions.² The Board should scrutinize such disregard of the rules, and

² Petitioner’s attempt to shirk its burden is highlighted by its mapping to the prior art, which tacitly abandons its own narrowed constructions. *See, e.g., infra*, Section IV.C. Petitioner’s strategy flouts the Board’s rules and fails to satisfy its burden to set forth both “[h]ow the challenged claim is to be construed” and “[h]ow the construed claim is unpatentable under the statutory grounds identified.” 37 C.F.R. §§ 42.104(b)(3) and 42.104(b)(4).

certainly must not adopt or sanction such tactics. 37 C.F.R. §§ 42.104(b)(3) and 42.104(b)(4); CTPG, 44.

The Petition is premised on specific constructions of multiple terms that are unsupported by any supporting explanation or evidence, and thus the Petition runs afoul of the straightforward requirements of IPR. This independently renders the Petition fatally flawed.

The Petition's claim construction is defective for an additional, independent reason. Claims 49 and 57 include means-plus-function limitations. Ex. 1001, cl. 49 ("means to facilitate integration and fusion with superior and inferior vertebral bodies."); cl. 57 ("means for receiving placement of bone filling into the open space of the intervertebral cage for the biological bone fusion."). The Petition fails to follow the straightforward rules for IPR that state Petitioner "**must** identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function" as required by 37 C.F.R. § 42.104(b)(3) (emphasis added); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1061-62 (Fed. Cir. 2016); *ICON Health & Fitness v. Nautilus, Inc.*, IPR2017-00493, Paper 9, at 21-22 (PTAB July 6, 2017); *ZTE Corp. v. Maxell, LTD.*, IPR2018-00241, Paper 9, at 8-10 (PTAB Jul. 2, 2018); *Facebook, Inc. v. Sound View Innovations, LLC*, IPR2017-01006, Paper 14, at 15-16 (PTAB Aug. 29, 2017).

Here, the Petition does not discuss these elements in the claim construction section at pages 11-13. Likewise, the Petition does not address the corresponding structure in its analysis of claims 49 (Pet., 49) and 57 (Pet., 46). The Petition simply fails to identify any portion of the specification as the corresponding structure of these means-plus-function limitations. In doing so, Petitioner violates § 42.104(b)(3), which requires the Petition to “identify the specific portions of the specification” disclosing the corresponding structure. This is yet another defect that renders it impossible, based on the arguments and evidence set forth in this Petition, for Petitioner to satisfy its burden of proving unpatentability of claims 49 and 57. This is yet one more flaw among many that collectively compel denial of institution.

IV. PETITIONER CANNOT PREVAIL AS TO ANY CHALLENGED CLAIM

A. The Tisserand Translation (Ex. 1029) Is Not Properly Authenticated and Cannot Be Relied Upon

The Petition relies on Tisserand, a French language patent document, as its primary reference in every Ground of the Petition. Petitioner submits Exhibit 1029 as an English translation of Tisserand. Exhibit 1029, however, is not properly authenticated. The purported certification that accompanies the translation does not meet the requirements of an affidavit or declaration. 37 C.F.R. §§ 1.68; 42.2. Additionally, the purported certification is not signed by the linguist with personal

knowledge of the accuracy of the translation. Accordingly, the translation is insufficient, and cannot be relied upon in an IPR proceeding.

A declaration relied upon in an IPR proceeding must comply with 37 C.F.R. § 1.68, which states:

Any document to be filed in the Patent and Trademark Office and which is required by any law, rule, or other regulation to be under oath may be subscribed to by a written declaration. Such declaration may be used in lieu of the oath otherwise required, **if, and only if, the declarant is on the same document, warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true.**

37 C.F.R. §1.68 (emphasis added). These warnings are, of course, imposed as safeguards to ensure credibility of the witness and maintain the integrity of the proceeding. *See Fedex v. Katz*, CBM2015-00053, Paper 9 at 7-8 (PTAB June 29, 2015) (giving no weight to declaration because the declaration does not meet the required form of evidence because the declarant was not warned that willful false statements are punishable by fine or imprisonment, or sworn under penalty of perjury.).

Here, the signer never indicated he was aware “that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001)” or that “all statements made of the declarant’s own knowledge are true and that all statements made on information and belief are believed to be true.” Ex. 1029, 1. The document is not an “affidavit” or “declaration” under 37 C.F.R. § 42.2, and is therefore entitled to no weight. *Fedex*, Paper 9 at 7-8; *see also Bumble Bee Foods v. Kowalski*, IPR2014-00224, Paper 18 at 14-15 (PTAB June 5, 2014); *IBM Corporation v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 38 at 10-12 (PTAB September 27, 2016).

The translation is defective for a second reason—the signer does not present facts demonstrating personal knowledge of the substance of the translation. “When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an affidavit attesting to the accuracy of the translation must be filed with the document.” 37 C.F.R. § 42.63(b). The affidavit required must be from a person with personal knowledge who can attest to the accuracy of the translation. FED. R. EVID. § 602 (“A witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter.”).

Petitioner has not provided any such affidavit or declaration in connection with the Tisserand reference. The purported certification is not signed by the linguist that prepared the translation, and does not offer any facts that demonstrate the signor has personal knowledge of the substance of the translation. Ex. 1029, 1. Indeed, there is no indication the signer is proficient in the French language at all. *Id.* These deficiencies are substantive, not trivial. *Compare* Ex. 1029 *with* Ex. 1002, 176-184. The Petition fails to provide any explanation of the language selected in its purported translation, and relied upon in its prior art mapping.

Exhibit 1029 cannot be considered in the form presented by the Petition. Tisserand is relied upon as the primary reference in all Grounds, and thus this deficiency infects the entire Petition.

B. The Patent Office Already Considered and Addressed Tisserand and the Content of Bonutti During Original Prosecution of the '022 Patent

The Board should decline institution because the Patent Office already considered the primary Tisserand reference relied on by the Petition in determining patentability of the '022 patent claims, and the Petition fails to present meaningful issues that the Patent Office failed to address during original prosecution. As explained below, the Examiner considered both Tisserand and the teachings of Bonutti during prosecution and the Petition seeks to improperly rehash the issues previously considered.

Tisserand is the primary reference for all Grounds in the Petition, and the Petition relies on Tisserand for nearly every element of the challenged independent claim (independent claim 47). Yet, tellingly, the Petition never addresses the fact that the Examiner previously considered Tisserand—including a complete English translation—during original prosecution. *See, e.g.* Ex. 1002, 145 (“considered”); 164-185 (Tisserand and English translation of Tisserand). Tisserand was one of only 11 other references cited in the IDS submitted December 7, 2016, and thus this is not a case where Tisserand was buried among many dozens of disparate references in an Information Disclosure Statement (IDS) where it might have been overlooked. The Petition, however, inexplicably represents that “Tisserand was not considered by the Examiner during the prosecution of the application leading to the ’022 patent.” Pet., 15. Petitioner’s assertion is simply false.

The Petition’s failure to address that the Examiner previously considered Tisserand and allowed the ’022 patent in view of it is not remedied by the Petition’s combination of Tisserand with Bonutti. The Examiner also knew of devices structurally similar to Bonutti, and even applied them in rejections of the claims of the application that led to the ’022 patent. For example, the Petition relies on Bonutti as purportedly showing a “counterbore formed only in the top surface.” Pet., 27. But this feature is like the Examiner’s use of the Messerli reference in a substantive rejection of claims. For example, the Examiner

indicated that “Messerli provides the evidence[] of the use of an implant wherein the entry opening of the internal screw guide is formed only in the top surface of the top wall to receive a screw,” and applied Messerli in combination with a primary reference that allegedly did not disclose this structure. Ex. 1002, 139.

The Petition never explains any difference between the Petition’s reliance on Bonutti and the features purportedly disclosed by Messerli and cited in a rejection during original prosecution.

Worse, while the Petition relies on the art and issues already considered during original prosecution, the Petition fails to address that none of the references it relies upon describe the required structural configuration of “the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.” Ex. 1001, cl. 47. In other words, the Petition never cites to a prior art document that discloses this claim element—an element central to the allowance of claim 47 over Tisserand, Messerli, and the other cited art.

Supra, Section IV.D-E.

The Petition’s analysis of dependent claims in subsequent Grounds likewise attempts to rehash art already considered by the Examiner. Ground 2 adds the Matheiu reference, and Ground 4 adds the Waugh reference. Notably, Waugh was substantively applied in a rejection of the ’022 Patent. The Petition asserts that

“Waugh was never applied in a rejection to the Challenged Claims,” but this overly formalistic theory does not accurately reflect the prosecution history. Pet., 19 (emphasis in original). In the February 8, 2017 Office Action, *all* pending claims were rejected based on Waugh, alone or in combination with Messerli. Ex. 1002, 135-141. In response, applicant amended the pending independent claims, and added a new claim 135—corresponding to independent claim 47 challenged here. Applicant’s remarks in the response to the rejections highlighted that the amended features distinguished the new claim over Waugh, and the Examiner issued a Notice of Allowance in view of same. Ex. 1002, 114 (Patentee remarks indicating “New claims 135-144 also distinguish over Waugh.”); *id.*, 86-90 (Notice of Allowance). In other words, the record confirms that the Examiner substantively applied the Waugh reference in a rejection of the then-pending claims, and ultimately determined that independent claim 47 was patentable over Waugh and the other references. Petitioner’s faulty theory is yet another example of its attempt to ignore the analysis and conclusions of the USPTO reflected in the prosecution history of the ’022 patent.

Ultimately, the Petition presents art and arguments that have already been addressed by the USPTO—Tisserand was identified and considered by the Examiner, and portions of Bonutti relied upon by the Petition are substantially identical to the Examiner’s application of the Messerli reference. Likewise, the

Examiner considered the Mathieu reference (Ground 2), and applied the Waugh reference (Ground 4) substantively against the claims in an office action.

Petitioner improperly seeks a do-over without providing sufficient reasons for doing so. While the Petition ignores the art and issues addressed during original prosecution, the Board should not do the same.

C. Petitioner’s Prior Art Analysis Does Not Reach Claim Constructions Asserted in the Petition, a Critical Failing Under the Board’s Rules (All Grounds)

The Petition fails to explain how the prior art meets the Petition’s asserted construction for a “universal, intervertebral combination internal screw guide and fixation apparatus.” Pet., 12. As a result, the Petition fails to sufficiently explain “[h]ow the challenged claim is to be construed” and “[h]ow *the construed claim* is unpatentable.” 37 C.F.R. §§ 42.104(b)(3)-(b)(4) (emphasis added). This omission renders the Petition fatally defective and provides an independent reason the Board should deny institution. *See Eiko Global, LLC v. Blackbird Tech LLC*, IPR2017-00980, Paper 16, 35-36 (PTAB, Sept. 1, 2017) (denying institution and noting that the Petition “does not apply [the construction it endorses and supports] in arguing how the asserted prior art renders claim 12 unpatentable, thereby *failing to comply with § 42.104(b)(4) for this construction*” (emphasis added)); *see also id.* (“we deny institution . . . *based on the Petition’s failure to comply with 37 C.F.R.*

42.104(b)(3)-(b)(4) for the claim term ‘housing.’” (emphasis added)); *United Patents*, IPR2019-00470, Paper 17, 5; *Steele*, 305 F.2d at 862–63.

The Petition proposes a specific construction of the “universal, intervertebral combination internal screw guide and fixation apparatus”:

“an intervertebral bone fusion spacer designed to be inserted between two adjacent vertebrae in **any region** of the spine, i.e., cervical, thoracic, or lumbar, using **any approach**, e.g., posterior, anterior, or lateral.”

Pet., 12 (emphasis added). Yet, the Petition’s analysis of element [1] does not explicitly address its construction of this element, and does not allege any theory that the cited art discloses this element as construed.³ Petitioner simply ignores its proposed construction of this element, never explaining “[h]ow **the construed claim** is unpatentable.” 37 C.F.R. §§ 42.104(b)(3)-(b)(4) (emphasis added).

³ This flaw is fatal irrespective of whether Patent Owner disputes Petitioner’s construction. The Board need not reach the conclusion that Petitioner’s construction is fully accurate because the Petition never performed the requisite comparison of the prior art to Petitioner’s specific construction. The question here is whether Petitioner met its burden to demonstrate that the prior art falls within the scope of Petitioner’s proposed construction. 37 C.F.R. § 42.104(b)(4) (“the **construed claim**”). The Petition failed to do so.

For example, the heading for element [1] at pages 21-22 of the Petition repeats the claim language, but the following paragraphs never address how Tisserand or Bonutti purportedly disclose the “universal” element. Indeed, these pages of the Petition never mention the term “universal,” or the terms “any region,” or “any approach,”—language central to Petitioner’s asserted construction. Moreover, the Petition does not even explicitly allege that Tisserand’s device is “designed to be inserted between two adjacent vertebrae in any region of the spine, i.e., cervical, thoracic, or lumbar, using any approach, e.g., posterior, anterior, or lateral.” *Id.* Nor could Petitioner do so, because Tisserand likewise never mentions such features. *See generally*, Ex. 1029.

Petitioner’s arguments to the district court in the co-pending litigation confirm Petitioner’s asserted construction is improperly narrow. Petitioner emphasized the purported “whole-spine applicability” of the claimed apparatus, and asserted that “universal” reflects “whole-spine and approach-agnostic features.” *See, e.g.*, Ex., 2001, 8. Petitioner’s position is unequivocal—it asserts a construction that requires a spacer designed to be inserted between two adjacent vertebrae in “**any**” of the “cervical, thoracic, or lumbar” region using “any” of a “posterior, anterior, or lateral,” approach, as opposed to merely a **single one** of those regions or a **single one** of those approaches. Fatal to its Petition, Petitioner chose not to address its construction in the analysis of the cited art. Pet., 21-23.

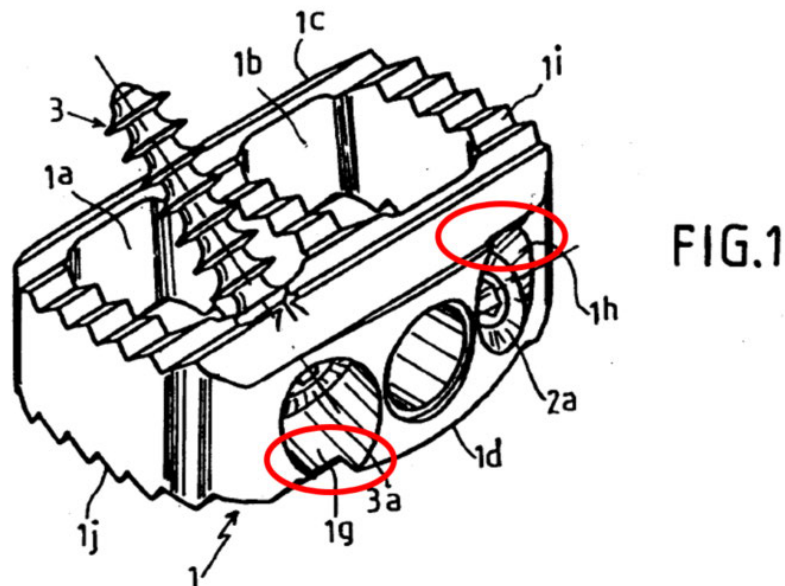
The Petition's conclusory analysis that never addresses Petitioner's asserted construction, and Tisserand's lack of disclosure of this feature, should not be held against Patent Owner. Petitioner had the burden to establish obviousness under the construed claim scope expressly proposed in the Petition. 37 C.F.R. § 42.104(b)(4) ("the construed claim"). The Petition failed to do so, and is thus not worthy of institution. This is especially the case where the Board's precedent and due process considerations forbid Petitioner from "rely[ing] on an unpatentability theory that could have been included in a properly-drafted petition, but was not." *Magnum Oil*, 829 F.3d at 1378-81; *Henny Penny*, 938 F.3d at 1330-1331; *Intelligent Bio-Systems*, 821 F.3d at 1369.

D. The Petition Fails To Show That Tisserand Discloses the Claimed "Entry Opening of the Internal Bore Formed Only in a Top Surface of the Top Wall" (All Grounds)

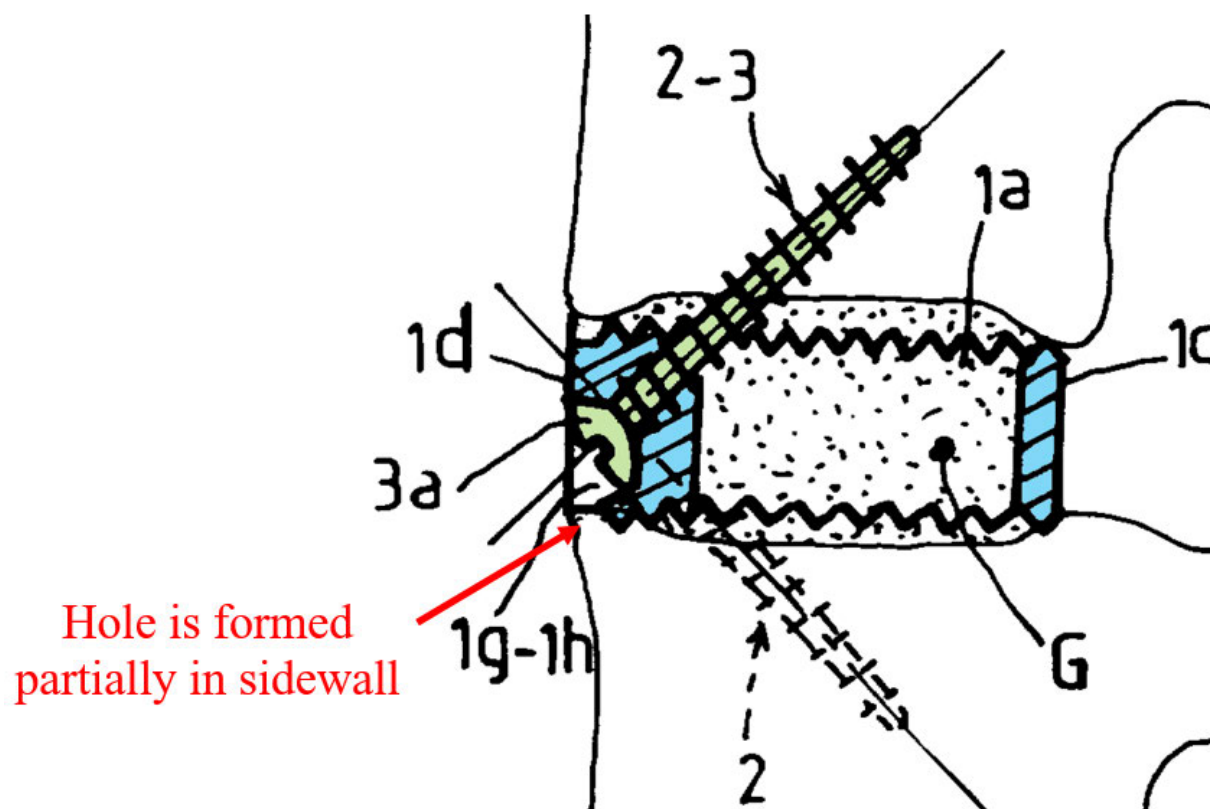
Petitioner has failed to meet its burden of showing that the cited references teach an "entry opening of the internal bore formed only in a top surface of the top wall," as recited by independent claim 47. The Petition proposes multiple theories for this element, asserting that Tisserand discloses this element, that it would have been a matter of "design choice," or that it would have been obvious based on further combination with Bonutti. Pet., 24-25. Each of these theories is deficient. Patent Owner turns first to errors in the Petition's theories based on Tisserand

alone, and addresses further errors in its proposal based on “design choice”/Bonutti in Section IV.E, *infra*.

The Petition first relies on Tisserand’s “holes 1g, 1h” as purportedly disclosing the claimed “entry opening of the internal bore formed only in a top surface of the top wall,” but such reliance is misplaced. Pet., 24. The Petition then assumes, without any explanation or evidence, that Tisserand’s purported entry openings “are formed only in a top surface of the top wall.” *Id.* To the contrary, Tisserand illustrates the opposite—openings of “holes 1g, 1h” are **not** formed “only in a top surface of the top wall.” *See, e.g.* Ex. 1028, FIGS. 1 and 3. Unlike the structural configuration recited by claim 47, Figures 1 and 3 of Tisserand show openings of “holes 1g, 1h” that are formed through **both** the purported top surface and other (e.g., side) surfaces.



Ex. 1028, FIG. 1 (annotated). Tisserand's cross-sectional view shown in FIG. 3 further confirms the presence of Tisserand's hole on multiple surfaces. No wall is present at the bottom in the view shown in FIG. 3, indicating the hole is formed in the top and side surfaces.



Ex. 1028, FIG. 3 (annotated). There is no dispute that holes (1g) and (1h) are formed on—nearly entirely—Tisserand's anterior (“top”) surface. Ex. 1029, FIGS. 1, 3; 2:35-3:9. But Tisserand never mentions or depicts the claimed structure in which entry openings are formed “*only* in a top surface of the top wall,” as the challenged claims require.

Critically, Petitioner's own declarant undermines Petitioner's assumption.

The Petition cites to paragraph 54 of the Ochoa Declaration, but paragraph 54 conspicuously omits "only" when describing the location of the openings in Tisserand's device. Instead, the Ochoa Declaration merely notes that Tisserand's "entry openings are formed in a top surface of the top wall"—not the claimed structure, which requires the entry opening formed "**only** in a top surface of the top wall." Ex. 1003, ¶ 54. In other words, this is not a case in which the Board should give deference to Petitioner's declarant at the institution stage—Dr. Ochoa never testifies that Tisserand discloses this structural feature at all. *Id.* Dr. Ochoa's omission is telling, and thus, the Board should give his testimony no weight.

Simply put, the Petition lacks any evidence that Tisserand discloses the claimed structure of an "entry opening of the internal bore formed only in a top surface of the top wall," as required by independent claim 47.

E. The Petition Fails To Show a POSITA Would Have Modified Tisserand, Alone or in View of Bonutti, To Have the Claimed "Entry Opening of the Internal Bore Formed Only In a Top Surface of the Top Wall"

In an attempt to remedy Tisserand's failure to disclose the claimed "entry opening of the internal bore formed only in a top surface of the top wall," Petitioner embarks on an improper hindsight analysis in which various "design factors" are purportedly modified, or Tisserand is combined with Bonutti, to follow the roadmap of the claimed solution. Pet., 24-25. Critically, however, the Petition

never provides the required analysis of the *Graham* factors showing why a POSITA would have modified Tisserand's device to include the affirmatively recited structures. 37 C.F.R. § 42.104(b)(4) ("must specify where each element of the claim is found"); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007), 550 U.S. at 406-07 (the *Graham* factors are "the controlling inquiry" and "rejections on obviousness cannot be sustained by mere conclusory statements."). Each of the Petition's theories fail.

1. Petitioner's alternative theory that "choice of a counterbore" and "exact location and size of the entry opening would vary depending on design factors" fails to meet its burden

The Petition proposes an alternative theory (which appears to be based on Tisserand alone or in combination with Bonutti) that the "choice of a counterbore" and "the exact location and size of the entry opening would vary depending on known design factors such as the size of the screw head, the selected screw angle, lordotic angle, and the wall thickness and height of the intervertebral cage." Pet., 25. The Petition's theory, however, relies on speculation, not documentary evidence, to bridge the gap between Tisserand's original design and the expressly claimed structure of the "entry opening of the internal bore formed only in a top surface of the top wall." *Id.* The Petition's conclusory analysis is insufficient to satisfy Petitioner's burden for institution under § 314(a).

For example, the Petition lists multiple design factors that purportedly affect “the exact location and size of the entry opening.” Pet., 25. But a mere recitation of potential design factors does not demonstrate an entry opening having the structure required by claim 47. The Petition never provides any parameters, angles, or particular combination of these purported design factors that would have resulted in the claimed entry opening formed “only in a top surface of the top wall.” Pet., 24-26. Without such an explanation, Petitioner has provided nothing more than mere speculation that the location and size of the entry opening might be affected by these purported design factors in a way that could potentially lead to the recited structure of claim 47. This impermissibly flips the burden, forcing the Board and Patent Owner to speculate as to the actual structure of the proposed combination, and whether a functioning device having the claimed features would even result. *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) (a showing of obviousness must rest on a factual basis, and it may not resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis). This is insufficient to satisfy Petitioner’s burden.

Moreover, aside from never explaining how the recited “design factors” would have been modified in Tisserand’s device, the Petition additionally fails to explain any reason *why* a POSITA would have modified Tisserand in such a manner. In other words, even if the size of the screw head, the selected screw

angle, lordotic angle, and the wall thickness and height could be modified to provide a configuration in which the purported entry opening were formed “only in a top surface of the top wall,” the Petition fails to articulate a motivation to deviate from Tisserand’s original structure in which the entry opening is not formed “only in a top surface of the top wall.”

A recitation that the claimed structure is a matter of “design choice” is not a substitute for articulating a reason why a POSITA would have been motivated to make the proposed modifications. As the Board has explained, “[m]erely stating that each modification of [the primary reference] would have been ‘a matter of routine design choice’ is not sufficient to explain why it would have been obvious to make those modifications.” *Exacq Technologies, Inc. v. JDS Technologies, Inc.*, IPR2016-00567, Paper 7, 20 (denying institution); *Fanduel, Inc. v. Interactive Games LLC*, IPR2017-01491, Paper 38, 41-42 (“a statement that a proposed modification ‘is a design choice and is obvious . . . alone is not enough to explain’ a finding of obviousness, and instead ‘[t]he Board must offer a reason for why a person of ordinary skill in the art would have made the specific design choice’ at issue.”); *see also In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002) (“legal error and arbitrary agency action.”).

Instead, Petitioner “must provide a specific reason why an ordinarily skilled artisan would have made the particular design choice.” *Id.*; *In re Warner*, 379 F.2d

1011, 1017 (CCPA 1967) (“may not resort to speculation, unfounded assumptions or hindsight reconstruction”). Here, Petitioner’s conclusory reliance on “design choice” omits any articulated reason (supported by rational underpinnings) why a POSITA would have modified Tisserand to arrive at the claimed structure. The Board must avoid Petitioner’s invitation for legal error.

Petitioner’s reliance on “design choice” fails for yet an additional reason. The Petition appears to offer multiple discrete changes in unison, proposing possible modifications of “the size of the screw head, the selected screw angle, lordotic angle, and the wall thickness and height of the intervertebral cage.” In other words, the Petition alleges several modifications that collectively arrive at the claimed structure. The Petition fails to provide sufficient evidence that a POSITA would have manipulated these parameters *in unison* in such a way as to result in the claimed structural configuration.

The Petition’s citation to paragraph 58 of the Ochoa Declaration fails to remedy the deficiencies of the Petition’s “design choice” theory. Paragraph 58 of the Ochoa Declaration follows the same terse analysis of the Petition, void of any additional facts or data that the selection of particular “design factors” would have led to the claimed structure. Here again, no analysis or examples are provided of how those parameters would have been modified to arrive at the claimed structure.

And, like the Petition, paragraph 58 never provides any reason *why* a POSITA would have been motivated to modify Tisserand's device in the manner proposed.

The Federal Circuit has recently held that such an "*ipse dixit* declaration" from a petitioner cannot provide substantial evidence support of an obviousness decision, and thus reversed the Board's finding of obviousness. *TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1362-63 (Fed. Cir. 2019) (refusing to give weight to petitioner's "*ipse dixit* declaration" where the original declaration failed to explain why a POSITA "would have combined elements from specific references in the way the claimed invention does" (emphasis in original)). Paragraph 58 of the Ochoa Declaration does nothing to remedy the Petition's failure to satisfy its burden.

Furthermore, the Petition's failure is not remedied by its theory that "Moskowitz does not disclose any reason for the specific configuration." Pet., 25. First, Petitioner's theory overlooks the benefits of the claimed configuration in the '022 patent and its prosecution history. The features recited by claim 47 facilitate beneficial angles for screw insertion compatible with the small space available for fastening of the device. *Id.*, 3:31-39 (describing "built-in prescribed angles of the integral screw guides which allow the posterior transvertebral penetration into the vertebral bodies" and "small anatomically restricted work zone" which "is very narrowly prescribed by obtuse angulations between screw and intervertebral bone

surfaces, and by nerve root, facet joint and pedicle.”); *see also* Ex. 1002, 451 (“avoiding interference with screws of other adjacent implantation devices and enabling multiple level fusion,” and providing “biological bone fusion of not only the cage to the bone, but also biological fusion of the screws to cage, thereby preventing backing out of the screws and providing a permanent implantation of the apparatus.”). The claimed structure in which the entry opening is only in a top surface facilitates insertion and advancement of the screw, at a particular angle, while providing desirable geometry that facilitates insertion of the device and reduces potential interference and rubbing, etc.

Second, Petitioner’s theory is based on an erroneous premise, contrary to the authority cited above, that if the ’022 patent “does not disclose any reason for the specific configuration” then Petitioner is no longer burdened to articulate a reason why a POSITA would have been motivated to make the proposed modifications. Petitioner cites no basis for this theory. Federal Circuit precedent requires the Petition to articulate a motivation for its proposed modification to Tisserand’s original device. *See, e.g., Exacq Technologies*, IPR2016-00567, Paper 7, 20; *Fanduel*, IPR2017-01491, Paper 38, 41-42; *Lee*, 277 F.3d 1338, 1343-44. The Petition ignored this precedent.

Ultimately, Petitioner had the burden of establishing a reason why a POSITA, starting from Tisserand’s device and without hindsight, would have been

motivated to make the sequence of modifications required by the Petition's theory. The Petition's speculative reliance on "design choice" failed to do so.

2. The Petition fails to show that a POSITA would have been motivated to modify Tisserand in view of Bonutti

The Petition relies upon a further hindsight rationale that a POSITA would have been motivated to modify Tisserand's device based on Bonutti in order "to recess the heads of the fasteners in the implant." Pet., 26-27; *see also id.* ("to prevent the heads from projecting from the anterior of the implant."). Petitioner's theory, however, ignores that Tisserand's solution undermines the Petition's alleged motivation for combination. Tisserand is clear that its device was already optimized to provide this feature—"The heads (2a) and (3a) of the screws (2) and (3) are ***embedded in the recess*** so as to be supported in the base thereof, and do not extend beyond the front face (1d)." Ex. 1029, 5:11-12 (emphasis added). A POSITA would not have had a reason to recess the heads of the fasteners in the implant because Tisserand's screw heads are already recessed such that they do not project from the anterior of the implant. *Id.* Where the reference already discloses the purported reason for modifying the reference, this gives rise to an especially strong "inference of nonobviousness." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009) ("***An inference of nonobviousness is especially strong*** where the prior art's teachings undermine the

very reason being proffered as to why a person of ordinary skill would have combined the known elements.” (emphasis added)); *see also Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018).

The Petition ignores the fact that Tisserand’s original solution already resolved this purported problem that was the Petition’s **sole** alleged motivation for modifying Tisserand’s device based on Bonutti. *Sony Corp. v. Fujifilm Corp.*, IPR2018-01751, Paper 14, 11 (PTAB April 12, 2019) (denying institution where the primary reference “already address[ed] the problem” purportedly motivating the combination and “it is not evident why [the primary reference] would have benefited from modifications based on [the secondary reference].”); *Microsoft Corp. v. Koninklijke Philips N.V.*, IPR2018-00026, Paper 7, 15 (PTAB April 27, 2018) (no explanation why POSITA would have been motivated to modify the primary reference when the primary reference “already provides for” the benefit that is Petitioner’s alleged motivation to combine).

Critically, even if a POSITA would have been motivated to modify Tisserand’s device with Bonutti’s purported counterbore “to recess the heads of the fasteners in the implant” (which the Petition fails to demonstrate), this does not address the claimed structure of an entry opening formed “**only**” in the top surface. Indeed, the Petition never explains any reason for such modification to Tisserand, or why including a counterbore would have resulted in relocating the entry opening

to be formed “only” in the top surface. Tisserand does not have this feature, and the Petition simply fails to provide any reason a POSITA would have been motivated to modify Tisserand to have this feature.

The Petition’s theory thus, at best, reduces to assertion that the proposed combination **could** have been made, without the requisite reasoning as to why a POSITA **would** have been motivated to modify Tisserand’s original solution in the manner proposed. *One World Technologies, Inc.*, IPR2016-01772, Paper 9, at 30 (denying institution where “Petitioner’s argument and [declarant’s] testimony conflate combinability of the references with a motivation to combine the references.”). This is insufficient, especially where Tisserand’s original design already achieved a solution in which its screws were “embedded in the recess,” without the need for modifying the location of its entry openings. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only **could** have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention.” (emphasis in original)); *PersonalWeb Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993 (Fed. Cir. 2017) (explaining that it is insufficient to allege “that a skilled artisan, once presented with the two references, would have understood that they could be combined.”).

Notably, the Petition's hindsight theory fails for yet another reason. The Petition ignores Tisserand's straightforward preference that its screws "are oriented at an angle of very substantially 45°," and the "two recesses (1g) and (1h) are angularly offset by approximately 90°." Ex. 1029, 5. At a minimum, the Petitioner was obligated to address Tisserand's "statements regarding preferences" (above) because such statements "are relevant to a finding regarding whether a skilled artisan would have been motivated to combine that reference with another reference." *Polaris*, 882 F.3d at 1069 (vacating a finding of obviousness). The Petition never explains what its proposed combination would look like with respect to its modified "screw angle" and other purported "design choices," or what "screw angle" would be used in the resulting device. Instead, the Petition's hindsight analysis characterizes "screw angle" and other features as mere "design choice" while ignoring Tisserand's stated preferences for such aspects of its design the problems that its design already solved. This is insufficient to meet Petitioner's burden.

Ultimately, the Petition's proposed modification of Tisserand relies upon multiple layers of errors, none of which the Board should adopt.

3. Even if Tisserand's purported entry opening was modified in the proposed manner, the Petition failed to demonstrate that the claimed result would have each feature required by independent claim 47

Even if a POSITA would have been motivated to modify Tisserand so that the purported entry opening was formed “only in a top surface of the top wall” (which the Petition failed to demonstrate), the Petition fails to show that the resulting device would simultaneously include the exit opening formed “at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.” Notably, the Petition never provides any explanation of how these purported parameters would have been changed such that *both* the entry opening and exit opening have the structure required by claim 47.

For example, the Petition generically proposes a POSITA could have modified the size of the screw head, selected screw angle, lordotic angle, and wall thickness and height to arrive at an entry opening formed “only in a top surface of the top wall.” But the Petition never addresses how these purported changes would have affected the location of the exit opening. As one example, the Petition proposes a “size” of the screw could have been modified based on Bonutti, but does not explain what affect such a change would have on the exit opening. Indeed, Bonutti visibly lacks the claimed construction that includes an exit opening formed “at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.” *See, e.g.,* Ex. 1030, FIGS. 5-10. Bonutti describes

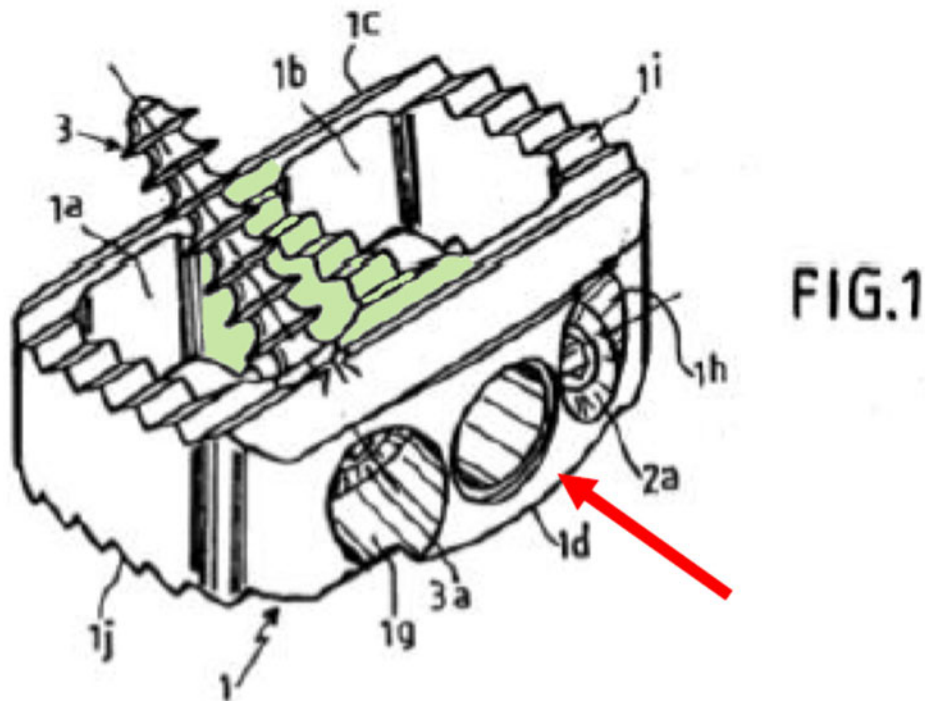
a different geometry in which the exit openings are entirely in a single surface, not “partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.” *Id.*

The Petition ignores the claimed structural relationship found nowhere in the cited references. By doing so, the Petition never explains what the resultant device would look like, or that an operative device would have resulted having both an entry opening formed “only in a top surface of the top wall” and the exit opening formed “at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.” The Petition’s proposed modifications of Tisserand based on “design choice”/Bonutti are fatally flawed for this additional reason.

4. The Petition fails to show that the proposed Tisserand-Bonutti combination discloses the claimed “circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall”

Independent claim 47 recites an additional structural element of a “circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall.” The Petition relies exclusively on FIG. 1 of Tisserand as purportedly disclosing this feature. Pet., 28. The Petition’s terse, two-sentence analysis fails to fully address this claimed feature. For example, the Petition’s conclusory analysis never explains its theory that the purported hole extends “through the top wall.” Indeed, as can be seen from annotated Tisserand FIG.1

reproduced below, the limited view of the central hole shown in FIG. 1 does not show the hole extending “through the top wall” as claimed. Moreover, the Petition fails to address the structure of Tisserand’s central wall (green) and the effect, if any, it has on the extension of the hole through the top wall. *Id.* The Petition does not cite to any other figure of Tisserand as disclosing the claimed structure.



Pet., 28 (annotated green).

Here again, the Ochoa Declaration adds nothing. The Petition cites to paragraph 60 of the Ochoa declaration, but paragraph 60 repeats the same assumption of the Petition, without any explanation or evidence addressing the “circular hole” or the recited structure of the circular hole “extending through the top wall.” In fact, paragraph 60 of the Ochoa Declaration does not even identify

which “hole” it is referring to. An expert’s bare conclusion does not provide evidentiary support, and is insufficient to demonstrate the affirmatively recited structure of a “circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall.”

Ultimately, the Petition’s deficient analysis of the “circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall” is yet another defect that renders it impossible, based on the arguments and evidence set forth in the Petition, for Petitioner to satisfy its burden of proving unpatentability of the challenged claims.

V. CONCLUSION

For all the foregoing reasons, the Petition is deficient and beyond repair. Going forward with an IPR would serve only to expend further resources highlighting what is already clear: Petitioner cannot satisfy its burden of proving unpatentability based on the arguments and evidence set forth in this Petition. Patent Owner, therefore, respectfully requests that the Board decline to institute IPR of the ’022 Patent.

Respectfully submitted,

Date: October 28, 2020

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner Preliminary Response to Petition totals 8,325, which is less than the 14,000 allowed under 37 CFR § 42.24(b)(1).

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned certifies that on October 28, 2020, a complete and entire copy of this Patent Owner's Preliminary Response and its exhibits were provided via email, to the Petitioner by serving the correspondence addresses of record as follows:

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