

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SMITH & NEPHEW, INC. and  
ARTHROCARE CORP.,  
Petitioner,

v.

ARTHREX, INC.,  
Patent Owner.

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Case IPR2016-00487  
Patent 7,195,634 B2

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Before WILLIAM V. SAINDON, BARRY L. GROSSMAN, and  
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge*.

DECISION  
Institution of *Inter Partes* Review  
*37 C.F.R. § 42.108*

## I. INTRODUCTION

Petitioner filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 5–13 of U.S. Patent No. 7,195,634 B2 (Ex. 1103<sup>1</sup>, “the ’634 patent”). Patent Owner filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Petitioner bears the burden of establishing a reasonable likelihood of unpatentability of one or more claims. 37 C.F.R. § 42.108(c).

Upon consideration of the Petition and Patent Owner’s Preliminary Response, and based on the analysis below, we institute an *inter partes* review on claims 5–13 of the ’634 patent in accordance with the Order included with this Decision.

Our findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

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<sup>1</sup> We note that Patent Owner filed Exhibit 2105, which appears to be a duplicate of Exhibit 1103. Patent Owner also filed other exhibits that duplicate exhibits filed by Petitioner. Duplicates of exhibits already in the record should not be filed. 37 C.F.R. § 42.6 (d) (“*Previously filed paper. A document already in the record of the proceeding must not be filed again, not even as an exhibit or an appendix, without express Board authorization.*”). We, and the parties, will cite to only the first filed copy of an exhibit.

A. *Related Matters*

Patent Owner is asserting the '634 patent against Petitioners in a civil action in the U.S. District Court for the Eastern District of Texas, *Arthrex, Inc. v. Smith & Nephew, Inc.*, Civil Action No. 2:2015-cv-01047. Pet. 5; Paper 6, 1.

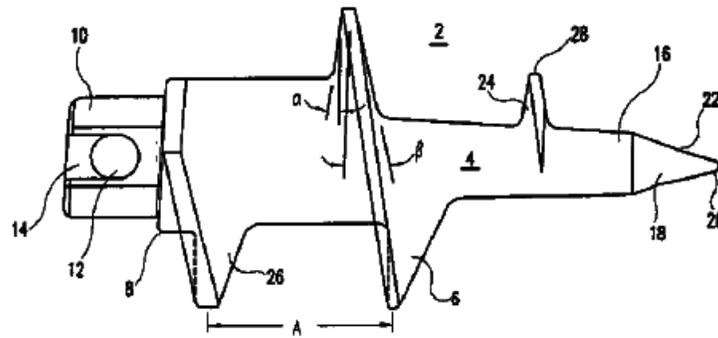
Petitioner filed another petition against the '634 patent, IPR2016-00485, challenging claims 1–4. The issues in IPR2016-00485 are substantially the same as the issues in IPR2016-00487. Petitioner summarizes the differences by stating that claims 1–4 of the '634 patent, involved in IPR2016-00485, “are similar to claims 5–13, but do not require a driver for installing the suture anchor.” Pet. 5. Our analysis of issues common to both petitions is the same in both decisions on institution.

In addition, several petitions are pending for *inter partes* reviews between the same parties that challenge patents related, directly or indirectly, to the '634 patent. These petitions include: IPR2016-00483, 00484, 00486, 00505–00508, 00817–00819, 00854, 00917, and 00918. *See* Pet. 5; Paper 6, 1.

The parties also identify a number of issued patents and pending applications that would affect, or be affected by, a decision in this proceeding. Pet. 5; Paper 6, 2.

B. *The '634 Patent*

The '634 patent relates to a suture anchor for securing suture to bone. Ex. 1103, 1:19–23. The disclosed anchor is shown generally in Figure 1, reproduced below.



The anchor preferably includes thread 6 spiraling helically around central body 4. *Id.* at 2:10–12. Proximal end 8 of the anchor body includes drive head 10 and suture eyelet 12. *Id.* at 2:20–22. Channel 14 is formed along either side of drive head 10. *Id.* at 2:57–58. Thread 6 includes a proximal face 24, distal face 26, and a “break edge” 28. *Id.* at 3:4–5. According to the Specification, thread 6 provides an increased percentage of thread surface area for each turn of the screw, thereby providing “increased pull-out strength, and a decreased tendency for back-out.” *Id.* at 2:33–37. The Specification states the increase in surface area of the thread is achieved in part by increasing the ratio of the outer diameter of the threads to the inner diameter of the threads. *Id.* at 2:37–40. The preferred ratio is between 2.25 and 2.75, with 2.5 as the most preferred ratio. *Id.* at 2:40–42. By way of example of this most preferred ratio, the Specification states “where central core 4 is approximately 2 mm. in diameter, the outer diameter of the thread is 5 mm.” *Id.* at 4:13–16. The thickness of the thread increases proximally, so that “the outer edge of the most proximal flight is thicker than the edge of each of the more distal flights.” *Id.* at 4:19–22. Adjacent sections of each flight are separated by a gap that is determined by the number of turns per inch of thread 6. *Id.* at 4:23–29.

*C. Challenged Claims*

Claim 5, reproduced below, is the sole independent claim among the challenged claims.

5. A suture anchor assembly for securing suture to soft bone, comprising:

a driver comprising a cannulated shaft having a distal end and a proximal end, and a cannulated handle disposed on the proximal end of the cannulated shaft;

a suture anchor inserted into the distal end of the driver, the suture anchor comprising:

a central body having a central axis, a distal end and a proximal end, the central body having a diameter along a major portion thereof tapering from a maximum diameter to a minimum diameter toward the distal end;

a drive head disposed on the proximal end of the central body for receiving the distal end of the driver, the drive head having an eyelet for receiving suture; and

a continuous thread disposed in a spiral around the central body, the thread having a thickness and an outer diameter, the thickness of the thread increasing proximally along a portion of the length of the thread, the outer diameter of the thread being at least twice the inner diameter of the thread along a portion of the thread; and

at least one strand of suture passed through the eyelet in the drive head of the suture anchor, through the cannulated shaft of the driver, through at least a portion of the cannulated handle of the driver, and exiting the handle.

*D. Alleged Grounds and Prior Art*

Petitioner asserts the following four grounds of unpatentability:

Reference(s)	Claims	Basis
Schmieding <sup>2</sup>	5–13	§ 102(b) <sup>3</sup>
Rosenberg '463 File <sup>4</sup> and Rosenberg '520 <sup>5</sup>	5–8, 11, 12	§ 103(a)
Rosenberg '463 File, Rosenberg '520, and Stone <sup>6</sup>	5–13	§ 103(a)
Nazre <sup>7</sup> , Lasner <sup>8</sup> , Stone, and Cerier <sup>9</sup>	5–13	§ 103(a)
Nazre, Huebner, Stone, and Cerier	5–13	§103(a)

Petitioner also relies on the declaration testimony of Alexander H. Slocum, Ph.D (Ex. 1157) and Joseph Sklar, M.D. (Ex. 1159).

II. ANALYSIS

*A. Claim Construction*

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs.*

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<sup>2</sup> U.S. Pat. Appl. No. 08/954,206, filed October, 20, 1997 (Ex. 1117).

<sup>3</sup> The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 296–07 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre-AIA versions of the statute.

<sup>4</sup> File history for U.S. Design Patent No. Des. 331,463, issued December 1, 1992 (Ex. 1116).

<sup>5</sup> U.S. Pat. No. 5,139,520, issued August 18, 1992 (Ex. 1121).

<sup>6</sup> U.S. Pat. No. 5,370,662, issued December 6, 1994 (Ex. 1122).

<sup>7</sup> U.S. Pat. No. 5,573,548, issued November 12, 1996 (Ex. 1124).

<sup>8</sup> U.S. Pat. No. 5,120,171, issued June 9, 1992 (Ex. 1120).

<sup>9</sup> U.S. Pat. No. 5,100,417, issued March 31, 1992 (Ex. 1119).

*LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). When interpreting a claim, words of the claim are generally given their ordinary and accustomed meaning, unless it appears from the specification, the file history, or other evidence asserted by the parties that the inventor used them differently. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Id.* Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Petitioner proposes several constructions of the claims. According to the Petitioner, the claim preamble does not limit the claims (Pet. 19); the ratio of outer and inner diameters of the thread are measured at a specific location (*id.* at 20–22); and the terms “cleat” and “slot” require construction.

The specific location chosen by Petitioner for the outer diameter is the diameter from crest to crest of the thread in a half revolution of the thread. The specific location chosen by Petitioner for the inner diameter is the diameter of the “adjacent root” of the thread. *Id.* at 21. Petitioner selected this specific location because it is “the shortest ‘portion’ of thread around such a central body over which one could measure both an outer diameter and an inner diameter.” *Id.* Petitioner refers to its proposed construction of

the specific location for measuring the ratio of the inner and outer thread diameters as the “Incontestable Claim Scope.” *Id.*

Recognizing that its “Incontestable Claim Scope” may be contested, Petitioner proposes an alternative, broader construction for where the inner and outer thread diameters are measured. Under Petitioner’s broader construction, “the ‘inner diameter’ need not be measured adjacent to the ‘outer diameter’ and instead can be measured several thread revolutions away.” *Id.* at 22. Petitioner states its alternative, broader construction is based on a claim interpretation “taken by Patent Owner in co-pending litigation.” *Id.*

Patent Owner takes a different view of the proper claim construction. According to Patent Owner, the claim preamble limits the claimed device to a suture anchor for securing suture to soft bone (Prelim. Resp.12–13); and the claims do not require a specific location along a portion of the thread at which the ratio of the inner and outer thread diameters is measured (*id.* at 13–17). Patent Owner states that the only “requirement” in the Specification for the location of the measured ratio is “toward the distal end.” *Id.* at 14–15 (citing Ex. 1103, 4:9–13). We note, however, that the cited passage does not state a “requirement”; it states the ratio (2.5) and location of a preferred embodiment.

Patent Owner proposes disputes Petitioner’s construction of “cleat” (Prelim. Response 18–20) and proposes its own, different construction (*id.* at 18–19). Patent Owner also disputes Petitioner’s proposed construction of “slot” and proposes a different construction, but only if one is deemed necessary. *Id.* at 20–21.

Patent Owner also proposes specific constructions for the terms “drive head” and “eyelet.” *Id.* at 17–18.

We discuss below the claim construction issues necessary for this Decision.

### *1. Preamble*

Whether to treat a preamble term as a claim limitation is “determined on the facts of each case in light of the claim as a whole and the invention described in the patent.” *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003)). Generally, “the preamble does not limit the claims.” *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). The preamble may be construed as limiting “if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). A preamble is not regarded as limiting, however, “when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.” *Catalina*, 289 F.3d at 809.

The preamble of claim 5 recites “[a] suture anchor assembly for securing suture to soft bone.” The only reference in the challenged claims to “securing” to “soft bone” is in the preamble of claim 5. We note that claim 6, dependent from claim 5, recites that “the suture is secured to the handle of the driver so as to retain the suture anchor on the distal end of the driver.” As explained in the Specification, this allows the suture anchor and driver assembly to be shipped, pre-loaded with suture, as a sterile, surgery-ready

unit. Ex. 1103, 3:15–16. This preloaded assembly does not require soft bone. Neither the body of claim 5 nor dependent claims 6–14 refer to “securing” to “soft bone.” If the preamble were removed from the challenged claims, the body of each claim still describes a structurally complete invention.

The only reference to “soft bone” or “softer” bone in the Specification is in the section labeled “Description of Related Art,” and is in the context of describing issues or unmet needs in prior devices *E.g.*, Ex. 1103, 1:49, 1:65–66, 2:2.

Based on the record before us, we determine that the preamble phrase “for securing suture to soft bone” states an intended use of the claimed suture anchor. Accordingly, for purposes of this Decision, based on the record before us, we determine that the preamble phrase “for securing suture to soft bone” states an intended use of the claimed suture anchor, and is limiting insofar as it requires the prior art to be structurally capable of securing suture to soft bone. *Rowe v. Dror*, 112 F.3d 473, 479–80 (Fed. Cir. 1997) (distinguishing the claimed balloon angioplasty catheter from a general balloon catheter by analyzing the structural requirements imparted by the term “angioplasty”).

*2. Outer Diameter of the Thread Being At Least Twice  
the Inner Diameter of the Thread Along a Portion of the Thread*

Claim 5 recites that “the outer diameter of the thread being<sup>10</sup> at least twice the inner diameter of the thread along a portion of the thread.”

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<sup>10</sup> The corresponding clause in independent claim 1 of the ’634 patent uses the word “is” rather than the word “being.” We view this as a distinction without a substantive difference.

Dependent claims 6–13 do not refer to the thread or its outer or inner diameters.

The challenged claims do not provide any more detail or context as to where “along a portion of the thread” the outer diameter/inner diameter ratio is measured. The parties have not directed us to any disclosure in the Specification that informs us where “along a portion of the thread” the ratio is measured. Petitioner acknowledges that “[t]he specification does not explain what constitutes a ‘portion’ of the ‘thread ... around the central body’ for identifying outer and inner diameters from which to calculate the ratio.” Pet. 20.

Petitioner relies on the testimonial evidence of Dr. Slocum to support Petitioner’s “Incontestable Claim Scope” that “the shortest ‘portion’ of thread” around over which one could measure both an outer diameter and an inner diameter “is a portion that encompasses a half revolution of thread and a corresponding root adjacent to the half revolution of thread.” *Id.* at 21 (citing Ex. 1157 ¶ 132). We note, however, that the challenged claims do not require that the claimed ratio exists at “the shortest portion” of thread over which the ratio calculation could be made.

Moreover, the claims also do not require that the outer diameter/inner diameter ratio is a constant value over the entire length of the central body. Petitioner (Pet. 20) and Dr. Slocum (Ex. 1157 ¶ 131) acknowledge that the claims require the central body to taper toward its distal end. Thus, because of the taper, if one uses Petitioner’s Incontestable Claim Scope to measure the outer diameter/inner diameter ratio of the *most proximal* thread, a different ratio is obtained than if one measured the ratio of the *most distal* thread. Moreover, Dr. Slocum testifies: “the claims do not specify any

particular taper. If the central body were more sharply tapered, the definition of ‘portion’ could have a *profound effect on the ratio* that is calculated.” *Id.* (emphasis added).

Based on the evidence before us, we are not persuaded that the claimed ratio must be satisfied along a portion of thread that encompasses a half revolution of thread and a corresponding root adjacent to the half revolution of thread, as advocated by Petitioner.

The claims state only that the claimed ratio exists at “a portion” of the thread. The ratio is not claimed to exist at the shortest portion over which one could measure both an outer diameter and an inner diameter, at all portions, or at spaced portions of the thread. Accordingly, we preliminarily construe the phrase in claim 5 “the outer diameter of the thread is at least twice the inner diameter of the thread along a portion of the thread” to require the thread at a location to have an outer diameter at least twice the inner diameter. In other words, the ratio identifies a measure of *thread depth* along some portion of the thread. Also, there is no requirement in the challenged claims that the ratio is constant along the entire thread or that the outer diameter is constant.

We determine that specific construction of other terms in the claims is not required for purposes of this Decision.

The claim constructions in this Decision are preliminary determinations. They do not preclude the parties from arguing their proposed constructions of the claims during trial. Indeed, the claim construction issues discussed in the Petition, Preliminary Response, and this Decision put the parties on notice that claim construction, in general, is an issue to be addressed at trial.

*B. Priority Date of the '634 Patent*

Petitioner asserts the challenged claims are anticipated by Schmieding (Ex. 1117), which is a patent application filed by Reinhold Schmieding and others. Mr. Schmieding is one of the named inventors in the '634 patent. According to Petitioner, the Schmieding reference is prior art as of February 22, 2000 because it was incorporated by reference into U.S. Patent No. 6,027,523 (Ex. 1018, 1:36–39), which issued that day. Pet. 13. The Schmieding patent application (Ex. 1117) asserted as a reference issued on September 12, 2000 as U.S. Patent No. 6,117,162 (Ex. 1156).

The patent application that matured into the '634 patent was filed on July 11, 2005. It stated the following priority claim to prior applications:

This application is a continuation of U.S. application Ser. No. 10/285,553, filed Nov. 1, 2002, now U.S. Pat. No. 6,916,333 [Ex. 1109], which is a continuation of U.S. application Ser. No. 09/823,988, filed Apr. 3, 2001, now U.S. Pat. No. 6,511,499 [Ex. 1108], which is a continuation of U.S. application Ser. No. 09/588,065, filed Jun. 5, 2000, now U.S. Pat. No. 6,214,031 [Ex. 1107], which is a continuation of U.S. application Ser. No. 08/954,206, filed Oct. 20, 1997, now U.S. Pat. No. 6,117,162 [Ex. 1117 – the Schmieding reference herein], which is a continuation of U.S. application Ser. No. 08/905,393, filed Aug. 4, 1997, now abandoned [Ex. 1105]. This application also claims the benefit of U.S. Provisional Application Ser. No. 60/023,011, filed Aug. 5, 1996 [Ex. 1104].

Ex. 1103, 1:3–14. Petitioner refers to this list of as the “Alleged Priority Documents.”<sup>11</sup> Pet. 24. According to Petitioner, the Alleged Priority Documents “only disclose a thread diameter ratio of ‘between 2.25 and 2.75’ and never mention, as required by all of the '634 patent claims, an ‘outer

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<sup>11</sup> We will refer to them as the “priority applications,” unless quoting or citing to Petitioner’s assertions.

diameter of the thread . . . *at least twice* the inner diameter of the thread along a portion of the thread.” *Id.* at 25. Petitioner asserts that to support the “at least twice” requirement, the Alleged Priority Documents would have to support both the lower limit (“twice”) and the open-ended reach (“at least”). *Id.* at 25. Thus, it is Petitioner’s position that the ’634 patent is entitled only to its actual filing date of July 11, 2005. *Id.* at 24.

Patent Owner asserts it “*was* in possession of ‘at least twice,’ as indicated by the drawings filed with the provisional and non-provisional applications and because of what one skilled in the art would have understood based on Patent Owner’s disclosure.” Prelim. Resp. 22. Patent Owner also argues that “one skilled in the art would understand that the open-ended range brought about by the ‘at least’ language has a practical upper limit.” *Id.* Patent Owner concludes that “one skilled in the art could readily derive the claimed lower bound of the range . . . and one would understand ‘at least twice’ has an inherent upper limit.” *Id.* at 32. Patent Owner concludes “the Schmieding reference is not prior art and cannot anticipate the claims of the ’634 Patent.” *Id.* Patent Owner does not address the merits of whether Schmieding, if an applicable reference, anticipates the challenged claims.

Claims in the ’634 patent are entitled to the earlier filing date of the ’011 provisional application (Ex. 1004) to which it claims priority only if the provisional application, and each intervening non-provisional application, provided adequate written description under 35 U.S.C. § 112, ¶ 1. *New Railhead Mfg. v. Vermeer Mfg.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002); *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1572 (Fed.Cir.1997). The “prior application itself must describe an invention . . . in sufficient detail that one

skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.” *Lockwood*, 107 F.3d at 1572 (Fed.Cir.1997); *see also SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1377 (Fed. Cir. 2013) (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)) (A claim is entitled to the filing date of an earlier application if “the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.”). Precisely how close the original description must come to comply with the description requirement of 35 U.S.C. § 112 must be determined on a case-by-case basis. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985).

Support for a priority claim also must be met by each intervening application. *Lockwood*, 107 F.3d at 1572 (“[E]ach application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112.”) (emphasis added).

*1. Upper Bound: open-ended*

As to the open-ended aspect of “at least twice,” Patent Owner argues: “there is an inherent upper limit to ‘at least twice.’ One would never make a suture anchor having a 100,000-to-1 relationship between the outer diameter and inner diameter, because the anchor has to fit in a bone of the human body.” Prelim. Resp. 27. We note the claims are not limited to “the human body.”

The priority analysis uses the written description analysis, *Lockwood*, 107 F.3d at 1571, but the priority analysis is different from an assertion of

unpatentability for failing to provide sufficient written description.<sup>12</sup> In turn, the written description analysis is different from the enablement analysis. *Ariad*, 598 F.3d at 1344; *cf.* Prelim. Resp. 27 (“Petitioners are raising an enablement issue”). Accordingly, Patent Owner’s arguments that a person of ordinary skill in the art would have recognized an inherent upper limit to the ratio does not tend to prove that the inventor considered the invention to be one with an open-ended interval. As our reviewing court has stated:

The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

*Lockwood*, 107 F.3d at 1572 (citations omitted).

Patent Owner does not offer sufficient evidence or arguments that tend to show that a person of ordinary skill in the art reviewing the specifications of the priority applications would clearly conclude that the inventor of the ’634 patent envisioned an open-ended range of ratios. Although the exact terms need not be used, “the specification must contain an *equivalent description* of the claimed subject matter.” *Id.* at 1572 (emphasis added).

The specifications of the priority application do not contain such an equivalent description. Each discusses the invention as having a preferred ratio of between 2.25 and 2.75, with a most preferred ratio of 2.5. The range

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<sup>12</sup> Priority tests written description support between patents/applications, whereas § 112 tests written description support for a claim in a given patent. Failure of priority means that an earlier date cannot be used for a given claim. Failure of § 112 means a claim is unpatentable or invalid.

provided is narrow compared to the range claimed and, importantly, the range provided is *inward*-looking, i.e., it suggests looking for the best results *between* the end points. Patent Owner cites to the disclosure of the '634 patent of various ratios for support of the asserted "inherent disclosure" (Prelim. Resp. 27–28 (citing Ex. 1103, 2:33–42 and 4:42–55)). We do not find this persuasive.

Reviewing Patent Owner's arguments and the facts asserted by Patent Owner on the record before us, we are not persuaded that the priority applications provide an equivalent description of an inherent, albeit not precisely known, upper limit.

Accordingly, we find on this record insufficient evidence to support Patent Owner's priority claim to an open-ended range of ratios.

2. *Lower Bound: "twice" (or, 2.0)*

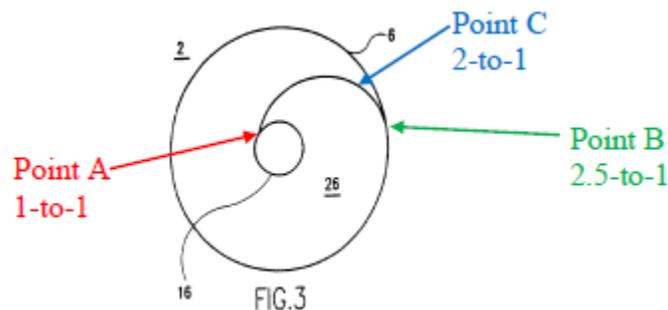
As to the lower bound, Patent Owner asserts "one skilled in the art would readily appreciate that a 2-to-1 ratio is disclosed in Patent Owner's provisional *and* non-provisional drawings." Prelim. Resp. 26.

Patent Owner asserts that the '011 provisional application (Ex. 1004) includes engineering drawings that have dimensions. Prelim. Resp. 20. Patent Owner points to Figure 6, which shows a minor diameter of 0.068 inches and a major diameter of .138 inches. *Id.* Patent Owner states that this represents a ratio "of *exactly twice*, factoring the tolerances provided in Figure 6 (+0.003 inches). *Id.* Thus, Patent Owner concludes that the '011 provisional application provides support. *Id.*

The application that issued as the '634 patent could not claim priority directly to the '011 provisional because it was filed more than a year after the provisional application. 35 U.S.C. § 119(e)(1) (a non-provisional

application is “as though filed on the date of the provisional application . . . if the [non-provisional] application . . . is filed not later than 12 months after the date on which the provisional application was filed”). As such, Patent Owner’s argument that the ’011 provisional includes written description that supports the lower bound is not sufficient to show that the claims are entitled to priority to the provisional unless the intervening non-provisional applications also support that limitation.

Patent Owner argues that the non-provisional applications provide support based on an implication of measurements taken of its drawings in the non-provisional priority applications and their corresponding issued patents. Prelim. Resp. 21–23. Patent Owner offers an annotated version of Figure 3 from the non-provisional priority applications and resulting patents to explain its position:



Patent Owner’s annotated Figure 3 depicts a distal end view of the suture anchor (Ex. 1103, 3:41), with various points labeled as having various outer-to-inner thread diameter ratios. “Point A” has a “1-to-1” ratio, “Point B” a “2.5-to-1” ratio, and “Point C” there between has a “2.0-to-1” ratio. Prelim. Resp. 22–23. Patent Owner’s argument is essentially that the threads begin at the same size as the inner body, and thus start at 1-to-1, and

that if they get up to 2.5-to-1, then at some point they must have passed 2.0-to-1. *Id.*

There are several reasons why Patent Owner's arguments are not persuasive. Patent Owner merely shows that the 2-to-1 value is obvious in view of Patent Owner's alleged range of values extending from 1-to-1 to 2.5-to-1. Patent Owner points to nothing in the drawing or the specification that would show the inventors envisioned "at least twice," specifically with 2 as a starting point. Instead, the specification provides a range of 2.25–2.75. Ex. 1103, 2:40–41. Patent Owner has not explained sufficiently how the specifications of the provisional applications demonstrate a person of ordinary skill in the art "can clearly conclude that the inventor invented [an anchor with a ratio as low as 2] as of the filing date sought." *Lockwood*, 107 F.3d at 1572.

Patent Owner also argues that "[t]he Examiner's priority determination should be given special weight." Prelim. Resp. 24. This argument overstates the record. We are not apprised of any statements the examiner made regarding priority. Silence is not a determination.

### *3. Conclusion Regarding Priority*

Based on the arguments and evidence of the parties, we determine on this record that there is insufficient evidence to support Patent Owner's priority claims. Accordingly, for purposes of this Decision, Schmieding is available as a reference against the '634 patent. We reiterate that this determination is a preliminary determination. The priority issues discussed in the Petition, Preliminary Response, and this Decision put the parties on notice that Patent Owner's priority claim, and whether Schmieding is a

reference against the challenged claims, is an issue that may be addressed at trial.

*C. Anticipation by Schmieding (Ex. 1117)*

Petitioner alleges that claims 5–13 are anticipated by Schmieding. Pet. 27–31. Petitioner asserts that Schmieding “is almost identical to the ’634 patent specification.” *Id.* at 27. According to Petitioner, “there are only two minor differences”—Schmieding does not include certain sentences in the ’634 patent discussing proximally increasing thread thickness, and describes the drive head as including “slots” for the suture rather than “channels.” *Id.* However, Petitioner argues that these features are disclosed in the figures of Schmieding, as Patent Owner argued when amending the Specification of the ’634 patent. *Id.*

Other than asserting that Schmieding is not available as a reference because of Patent Owner’s priority claim, discussed above, Patent Owner does not address the merits of whether Schmieding anticipates the challenged claims.

Reviewing Petitioner’s assertions and supporting claim charts, we are persuaded that Petitioner has shown a reasonable likelihood of demonstrating claims 5–13 are anticipated by Schmieding.

*D. Obviousness of Claims 5–8, 11, and 12  
Based on Rosenberg ’463 File and Rosenberg ’520*

Petitioner asserts that claims 5–8, 11, and 12 would have been obvious based on Rosenberg ’463 File and Rosenberg ’520. Pet. 31–40. Rosenberg ’463 File is the file history (Ex. 1116) for U.S. Patent No. D331,463, which issued on December 1, 1992 (Ex. 1115).

Patent Owner asserts that the design drawings are not dimensioned and not to scale, and thus cannot teach the claimed ratio of “at least twice.” Prelim. Resp. 33.

We acknowledge that drawings may be relied upon for all they teach. *In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972). The key in *Mraz*, however, was that the drawings depicted a relationship “*well within* the range recited in appellant’s claims.” *Id.* (emphasis added). There is a difference, therefore, between measuring the precise proportions in a drawing versus taking stock of the clear proportions depicted. *See Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000) (“it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue”).

Petitioner’s use of Rosenberg ’463 File’s drawing in this case relies on Figure 4 (Pet. 33, 39 (claim chart)) for the precise proportions of the asserted “at least twice” ratio of Rosenberg ’463 File’s inner and outer diameters.

Figure 4 from Rosenberg ’463 File is shown below.



Fig- 4

Petitioner has not directed us to any persuasive evidence in support of its position that Figure 4 shows the “at least twice” ratio recited in the challenged claims. We note that Dr. Slocum, for example, opines that “[t]he proportions are readily evident and confirmed through measurements.”

Ex. 1157, ¶¶ 661, 662; *see also id.* ¶¶ 141–43. Dr. Slocum does not provide sufficient detail, however, regarding the process of making the actual measurements and the results obtained. Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a). Moreover, it is not our role to comb through the record looking for evidence that may support a party’s case, and then speculate about the substance of the evidence found. “A brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record.” *DeSilva v. DiLeonardi*, 181 F.3d 865, 867 (7th Cir. 1999). *See also Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1353 (Fed. Cir. 2001) (“It is not the trial judge’s burden to search through lengthy technologic documents for possible evidence.”).

Rosenberg is a design patent, and thus there is no specification to provide written description as to the precision of the drawing. *See also In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977) (“Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.”) (citation omitted).

Based on the arguments in the Petition and the evidence on which Petitioner relies in support of those arguments, we are not persuaded that the ratio of the Rosenberg ’463 File’s diameters is in the claimed range. As such, we agree with Patent Owner that Petitioner has failed to show sufficiently the claimed “at least twice” relationship required by the claims, and the Rosenberg ’463 File grounds fail for this reason.

Petitioner relies on Rosenberg '520 for the “Driver Tool Features”<sup>13</sup> in the challenged claims. Pet. 36. Rosenberg '520 does not compensate for the deficiencies in the Rosenberg '463 File discussed above. Accordingly, we are not persuaded that Petitioner is reasonably likely to prevail on the asserted ground that the challenged claims would have been obvious based on Rosenberg '463 File and Rosenberg '520.

*E. Obviousness of Claims 5–13 based on  
Rosenberg '463 File, Stone, and Rosenberg '520*

Petitioner relies on Stone for the drive head and eyelet configuration as well as the additional Suture Anchor Features (*see* Pet. 9) in claims 9 and 10, and the additional Driver Tool Feature in claim 13. *Id.* at 40. Stone does not compensate for the deficiencies in the Rosenberg '463 File discussed above. Accordingly, we are not persuaded that Petitioner is reasonably likely to prevail on the asserted ground that the challenged claims would have been obvious based on Rosenberg '463 File, Stone, and Rosenberg '520.

*F. Obviousness of Claims 5–13 in View of  
Nazre, Lasner, Stone, and Cerier*

Petitioner asserts that claims 5–13 would have been obvious based on Nazre, Lasner, Stone, and Cerier. Pet. 45–59. Figure 4 of Nazre is reproduced below:

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<sup>13</sup> Petitioner defines the phrase “Driver Tool Features” as claim limitations that “concern[] aspects of the driver for inserting the suture anchor into bone.” Pet. 9.

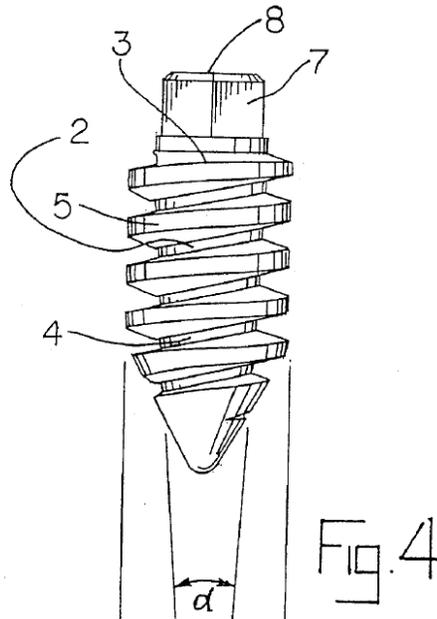


Figure 4 of Nazre depicts a suture anchor with a shaft that tapers from the distal to proximal end while the major diameter of the screw thread remains constant over most of its length. Ex. 1124, Abstract. Screw thread 5 extends from shaft 2 and spirals around the longitudinal axis from proximal end 3 to distal end 4. Preferably, screw thread 5 is continuous and uninterrupted between the proximal end 3 and distal end 4. *Id.* at 3:17–18. Driven portion 7 is formed near proximal end 3 and extends outwardly away from the proximal end 3 and terminates at free end 8. *Id.* at 3:18–21. Driven portion 7 is adapted for positive engagement with a driver to facilitate transmission of torsional loads from the driver to the driven portion 7. *Id.* at 3:21–23. Preferably the driven portion 7 is hexagonal. *Id.* at 3:25. The shaft and thread have a cross-sectional area depicted in FIG. 6. Cross-hole 6 extends through shaft 2 and screw thread 5, preferably near the proximal end 3. *Id.* at 3:29–31; Fig. 1.

The benefits of this structure are explained in the Specification:

Maintaining a constant major diameter S [for screw thread 5] while tapering the shaft 2 distally, increases the purchase or

depth of engagement of the screw thread 5 into the bone 60 toward the distal end 4 of the suture anchor 1. By combining a screw thread 5 having a constant major diameter and a tapering minor diameter with a cross-hole 6 located near the largest cross-sectional area of the suture anchor 1, strength and bone engagement are optimized. ·

*Id.* at 3:58–65.

As explained in Nazre, the strength of the suture anchor and the attachment of the suture anchor to the bone are “optimized” in the disclosed preferred embodiment. *Id.* at 2:35–37.

Petitioner asserts that Nazre describes all Screw Features<sup>14</sup> of claim 5 other than (1) the thickness of the outer edge of the thread increasing proximally along a portion of the length of the thread and (2) the outer diameter of the thread being “at least twice the inner diameter of the thread along a portion of the thread.” Pet 45. Petitioner asserts that a person of ordinary skill “would have had reason to integrate” the two missing Screw Features into Nazre’s design, because “both were known to increase a screw’s holding power.” *Id.*

According to Petitioner, “a POSA implementing Nazre would have had reason (1) to incorporate proximally increasing thread thickness and (2) select a thread depth such that the outer diameter was ‘at least twice the inner diameter of the thread along a portion of the thread’ under the Incontestable Claim Scope.” Pet. 47–48 (citing Ex. 1157 ¶¶ 114–15, 154; Ex. 1159 ¶¶ 146–149). Dr. Slocum opines that “a person of ordinary skill in

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<sup>14</sup> Petitioner defines the “Screw Features” to be “attributes of the screw,” which Petitioner distinguishes from the “Suture Anchor Features,” which Petitioner defines as “structures (e.g., a drive head and an eyelet) incorporated into the screw to make it useful for anchoring suture.” Pet. 9.

the art would have understood that there is a direct relationship between (1) the ratio of the outer thread diameter to the inner thread diameter and (2) the holding power of the screw,” relying on various background prior art references. Ex. 1157 ¶¶ 149–153. After discussing various background prior art references, Dr. Sklar opines that “[g]iven this known relationship of the benefits associated with increasing the ratio of the outer thread diameter to the inner thread diameter, a person of ordinary skill would have evaluated a number of particular ratios in the course of routine optimization of the screw-based suture anchors disclosed in . . . Nazre.” Ex. 1159 ¶ 122.

#### *1. Increasing Thickness*

Lasner discloses that the thread “gradually increases in thickness from the tip to the head of the screw.” Ex. 1120, Abstract. Lasner discloses that proximally increasing thread thickness is desirable in cancellous bone, which is compressed between the threads so as to “increase the pull-out resistance of the screw.” *Id.* at 5:9–21.

Patent Owner discloses that “[o]ne would not look to Lasner as a relevant teaching to Nazre.” We disagree.

Dr. Slocum, for example, testifies that the proposed combination would have been obvious for the reasons stated in his analysis. Ex. 1157 ¶¶ 827–831. Patent Owner has not directed us to persuasive evidence establishing that the bone screw in Lasner is so fundamentally different from the suture anchor in Nazre that a person of ordinary skill in the relevant technology would not look to each reference for relevant disclosures. The Supreme Court made clear that we apply “an expansive and flexible approach” to the question of obviousness. *KSR Int’l. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). Moreover, when a work is available in one

field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. *Id.* at 417.

## 2. “At Least Twice” Ratio

As to the particular “at least twice” ratio, Petitioner asserts that “[t]he ratio of outer thread diameter to inner thread diameter was a recognized ‘thread parameter,’ with higher ratios known to correlate with higher pullout strength.” Pet. 49 (citing Ex. 1132, 173; Ex. 1146, 465; Ex. 1157 ¶¶ 148–54). Petitioner concludes that a person of ordinary skill implementing Nazre’s suture anchor would have selected an outer thread diameter at least twice the inner diameter along a portion of the thread “in the routine course of ‘optimization.’” *Id.* at 49 (citing Ex. 1157 ¶¶ 155, 158-62; Ex. 1159 ¶¶ 122–125). Indeed, according to Petitioner, “ratios of 2.0 or greater were known in the prior art and known as ‘cancellous threads.’” *Id.* (citing Ex. 1134, 34–35; Ex. 1152, 3:18–21<sup>15</sup>; Ex. 1157 ¶¶ 80, 150–53; Ex. 1159 ¶¶ 119–121).

Patent Owner asserts “[i]n order to modify Nazre to include the ‘at least twice’ relationship, the Petitioners would either have to change the outer thread dimension (S) such that it is no longer constant.” Prelim. Resp. 53. Patent Owner has not directed us to persuasive evidence to support its argument. Moreover, there is no requirement in the challenged claims that the “at least twice” limitation extend the entire length of the thread, nor is there a requirement that the outer thread dimension be constant

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<sup>15</sup> E.g., “[t]he major diameter of the thread 20 is preferably 0.256 inches (6.5 mm), and the minor diameter of the thread is preferably 0.118 inches” (resulting in a ratio of 2.17).



compared to certain prior art.” *Id.* at 53 (citing Ex. 1113, 4:66-5:9, 8:9-14). Moreover, according to Petitioner, a person of ordinary skill would make the proposed modifications “to reduce manufacturing costs, permit increased thread depth, and to develop a product that would be accepted by physicians familiar with threading suture through eyelets formed directly in the drive head.” *Id.* (citing Ex. 1159 ¶¶ 186-189; Ex. 1157 ¶¶ 50, 200-01).

Patent Owner asserts Nazre teaches away from the claimed “drive head having an eyelet for suture.” Prelim. Resp. 52 (“Nazre strongly teaches away”). We disagree.

“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Whether or not a reference teaches away from a claimed invention is a question of fact. *In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012). The disclosure of a specific alternative design for a specific reason does not teach away from other designs. *Id.* at 1334. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is *unlikely to be productive* of the result sought by the applicant. *Gurley*, 27 F.3d 553 (emphasis added).

As discussed above, Nazre discloses that the specific reason for the preferred location of the eyelet is to obtain greater strength due to the larger cross-sectional area of shaft 2 and screw thread 5. On the record before us, if greater strength is not a variable to be maximized, there is no suggestion that other arrangements are unlikely to be productive.

Accordingly, we are persuaded on the record before us that Petitioner has met its burden of establishing a reasonable likelihood that the proposed modification would have been obvious.

Patent Owner also argues that it has “established criticality for the claimed thread arrangement” (Prelim. Resp. 55) but offers little more than its own attorney argument in support.

Patent Owner points to a PTAB decision reversing an examiner that rejected a claim having an “at least twice” feature. *Id.* at 56 (citing Ex. 2124). That is a different proceeding with different facts, and Patent Owner does not explain how that proceeding is relevant to this one.

Patent Owner also notes that the references were cited and considered by the Examiner during prosecution of the ’634 Patent. Prelim. Resp. 50. This fact is noted, but is not dispositive of whether it is reasonably likely Petitioner will prevail in its challenge to patentability.

#### *4. Driver Tool Features*

Petitioner asserts Cerier (Ex. 1119) and Nazre discloses all Driver Tool Features recited in claims 5-12. Pet. 52. Petitioner relies on Nazre for the disclosure of a hexagonally shaped distal end of the driver and a hexagonal socket at the driver’s distal end disposed over the drive head. Petitioner relies on Cerier for the disclosure of cannulated driver 80, including handle 82 and shaft 84. *Id.* at 52 (citing Ex. 1119, 5:25–27, Fig. 9; Sklar ¶ 247). Cerier’s cannulated design allows suture 18 to be “passed down the length of the driver and affixed on a fixation post 86” near “the end 88 of the handle 82.” *Id.* at 5:27-29.

Petitioner asserts that the rationale for the proposed combination is that Cerier's cannulated driver met the "need" for a cannulated driver assembly, suggested in Nazre.

Patent Owner asserts that Cerier's fixation post 86 on the end of the driver handle is a "cleat for holding the suture on an outer surface of the handle" under the broadest reasonable interpretation of that phrase. Pet. 52 (citing Ex. 1159 ¶ 258). Petitioner also states that this is consistent with the Examiner's determination during prosecution. *Id.* (citing Ex. 1112 at 71).

Patent Owner asserts Cerier does not disclose the cleat and slot recited in claims 7 and 8, respectively. Prelim. Resp. 57. According to Patent Owner, a "post" is not a "cleat." Patent Owner offers no evidence to support this argued distinction.

Thus, we are persuaded for purposes of this Decision that that Nazre and Cerier disclose the Driver Tool Features recited in the challenged claims.

Accordingly, we are persuaded that Petitioner is reasonably likely to prevail on the asserted ground that the challenged claims would have been obvious based on Nazre, Lasner, Stone, and Cerier

*G. Obviousness of Claims 5–13 in View of Nazre, Huebner, Stone, and Cerier*

Petitioner's final basis for unpatentability is the same as discussed above in Section F, with Huebner substituted for Lasner. Pet. 59–60.

Huebner is directed to an "orthopedic fixation screw" (Ex. 1123, Abstract). The screw has a thread having an outer edge that increases in thickness toward the proximal end of the screw, such that every turn "cuts a wider groove into a wall than the proceeding turn," thus ensuring that each

turn of the thread is held firmly in the bone mass, reducing the possibility of the screw coming loose” (*id.* at 3:61–67).

Figure 4 from Huebner is reproduced below.

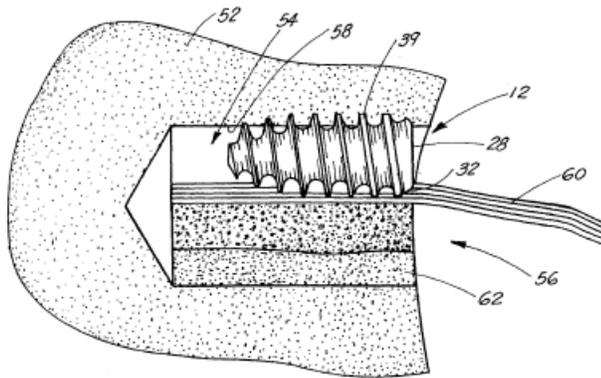


Figure 4 is the side section view of a fixation screw fully inserted into a bore between an interior wall of a bone mass and a ligament graft.

Petitioner asserts that, based on Huebner, a person of ordinary skill would have had reason to increase the thickness of Nazre’s thread toward the proximal end, thus increasing Nazre’s pull-out strength. Pet. 59 (citing Ex. 1157 ¶¶ 116–22; Ex. 1159 ¶¶ 150-151).

Patent Owner asserts we should deny this asserted ground of unpatentability because “substituting Lasner for Huebner leaves the Petitioners without any teachings relative to the ‘at least twice’ feature.” Prelim. Resp. 58. It is our understanding, however, that Petitioner is relying on Nazre and background prior art for the “at least twice” claim limitation, as argued in Ground 4. Pet. 49.

For purposes of this Decision, based on the evidence before us, we determine that Petitioner has established a reasonable likelihood of success on its Ground 5. “The ‘reasonable likelihood’ standard is a somewhat flexible standard that allows the Board room to exercise judgment.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765 (Aug. 14,

2012). However, this is a preliminary determination. It does not preclude the parties from arguing their positions at trial as to whether a preponderance of the evidence supports Petitioner's position. Indeed, the Ground 5 issues discussed in the Petition, Preliminary Response, and this Decision put the parties on notice that whether Petitioner's evidence supports its position with respect to the "at least twice" limitation in the challenged claims is an issue to be addressed at trial.

Accordingly, we are persuaded to institute trial on this asserted ground.

#### *H. Objective Evidence*

Patent Owner asserts "there is strong evidence of commercial success and copying in this case." Prelim. Resp. 60. Based on the current record, we disagree. Patent Owner has not directed us to *any* evidence to support its argument. "Argument in the brief does not take the place of evidence in the record." *In re Schulze*, 346 F.2d 600, 602 (CCPA 1965).

#### *I. Conclusion*

For the reasons set forth above, based on the arguments and evidence asserted by the parties, we are persuaded for purposes of this Decision that Petitioner has shown a reasonable likelihood of prevailing on its ground 1 (anticipation by Schmieding of claims 5–13) and its ground 4 (obviousness in view of Nazre, Lasner, Stone, and Cerier of claims 5–13).

### III. ORDER

In view of the foregoing, it is hereby:

ORDERED that *inter partes* review of the '634 patent is instituted on the following grounds set forth in the Petition:

Whether claims 5–13 are anticipated by Schmieding;

Whether claims 5–13 would have been obvious in view of  
Nazre, Lasner, Stone, and Cerier;

Whether claims 5–13 would have been obvious in view of  
Nazre, Huebner, Stone, and Cerier; 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  
Order, and notice is hereby given of the institution of a trial.

IPR2016-00487  
Patent 7,195,634 B2

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