

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC. and ACUMED LLC,
Petitioner,

v.

JEFFREY GELFAND, M.D.,
Patent Owner.

IPR2023-00014
Patent 9,149,312 B2

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
ERIC C. JESCHKE, *Administrative Patent Judges*.

JESCHKE, *Administrative Patent Judge*.

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

I. BACKGROUND

Arthrex, Inc. and Acumed LLC (collectively, “Petitioner”) filed a Petition to institute *inter partes* review of claims 1–20 of U.S. Patent No. 9,149,312 B2 (Ex. 1001, “the ’312 patent”). Paper 1 (“Pet.”). Dr. Jeffrey Gelfand (“Patent Owner”) timely filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

We have authority to determine whether to institute *inter partes* review. See 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2021) (“The Board institutes the trial on behalf of the Director.”). *Inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314. Upon consideration of the evidence and arguments in the record, for the reasons below, we determine that the information presented shows a reasonable likelihood that Petitioner would prevail with respect to at least one of challenged claims 1–20. We thus institute *inter partes* review on all challenged claims on all asserted grounds. See *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); 37 C.F.R. § 42.108(a) (“When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”).

A. *Related Proceedings*

The parties identify two proceedings in the U.S. District Court for the District of Delaware involving the ’312 patent: *Jeffrey Gelfand, MD v. Acumed LLC*, No. 21-cv-1753-CFC (D. Del.), filed December 14, 2021; and *Jeffrey Gelfand, MD v. Arthrex, Inc.*, No. 21-cv-1754-CFC (D. Del.), filed

December 14, 2021 (together, “the Delaware Litigations”). Pet. xiii; Paper 6 (Patent Owner’s Mandatory Notices) at 2. The Delaware Litigations—which have been stayed—previously involved U.S. Patent No. 8,282,674 B2 (“the ’674 patent”) (Pet. xiii), but the claims related to that patent were dismissed.

Petitioner also filed a petition for *inter partes* review of claims 1–15 of the ’674 patent in IPR2023-00009. See IPR2023-00009, Paper 3. On December 1, 2022, the Board terminated that proceeding based on a joint motion filed by the parties. See IPR2023-00009, Paper 9.

B. The ’312 Patent

The ’312 patent relates to “a system and method for subcoracoid clavicle fixation to treat, for example, a fractured clavicle.” Ex. 1001, 1:13–16. According to the ’312 patent, “complications often arise with respect to distal clavicle fractures” that result in relatively high rates of nonunion of the fractured bone. *Id.* at 1:20–28.

Figure 5 is reproduced below:

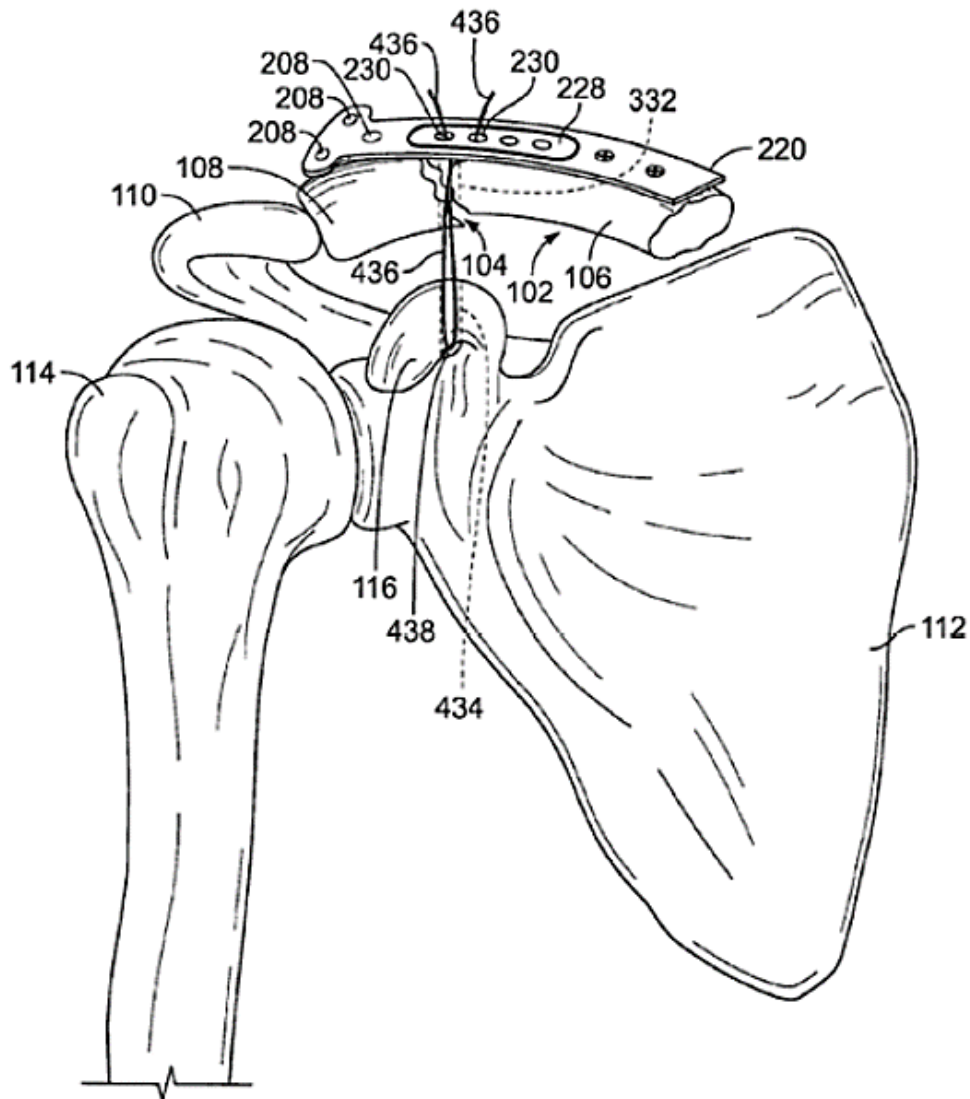


FIG. 5

Figure 5 is a view of a person's shoulder area showing a fractured clavicle and portraying one “step[] of one implementation of a treatment method for treating [the] fractured clavicle.” Ex. 1001, 3:57–61. The depicted shoulder area includes clavicle 102—which has medial portion 106 and distal portion 108 relative to fracture 104 (closer to distal portion 108)—

as well as acromion 110, scapula 112, and humerus 114. *Id.* at 4:21–26. “[C]oracoid process 116 is [the] small hook-like structure that comes off the scapula 112.”¹ *Id.* at 4:26–27. As shown, coracoid process 116 is “located at least partially beneath part of the clavicle 102.” *Id.* at 4:27–29.

In Figure 5, “substantially rigid plate 220 is shown secured to the medial portion 106 of the clavicle 102 relative to the fracture 104,” with plate 220 “contoured to approximately follow the contours of an upper surface of a non-fractured clavicle.” Ex. 1001, 4:30–34. As shown, “[t]he distal end of the illustrated plate 220 is flared to accommodate a pair of side-by-side screw holes 208. The flare and side-by-side arrangement of screw holes 208 may facilitate secure fastening of the plate 220 to the distal portion 108 of the fractured clavicle 102.” *Id.* at 4:39–43.

In the step of the process shown more particularly in Figure 5, suture 436 and “anchor 438 are affixed to the coracoid process 116 and the free ends of the suture 436 are extended above the plate 220, passing through the holes 230 in the washer 228 that are most directly above the hole 332 in the clavicle 102.” Ex. 1001, 7:11–15. Then, “the free ends of the suture 436 are tied to one another above the washer 228 and tightened a sufficient amount to reduce the clavicle and to restore approximately normal coracoclavicular distance.” *Id.* at 7:26–30 (discussing Figure 6).

¹ In this Decision, we omit emphasis on reference numerals and claim numbers in quotations from the ’312 patent and prior art references.

Figure 3 is reproduced below:

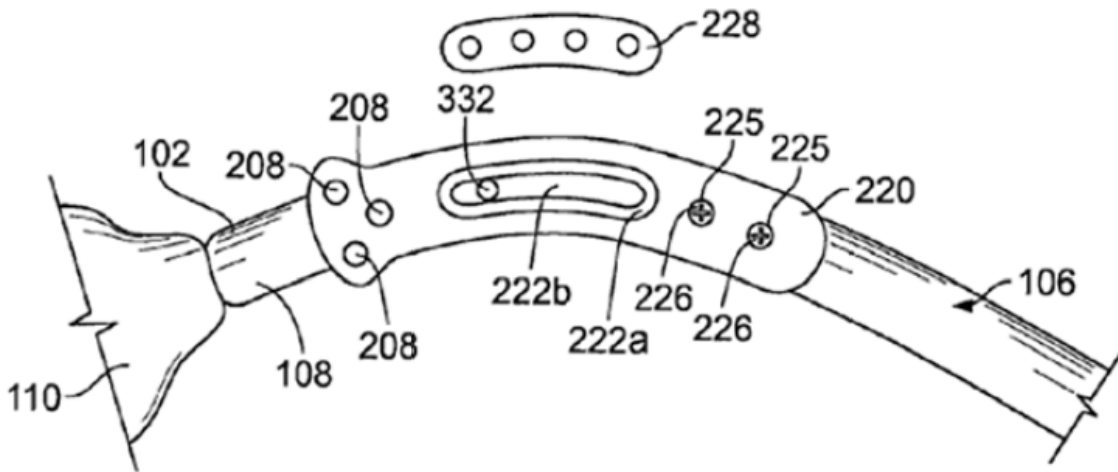


FIG. 3

Figure 3 is another view of a person's shoulder area showing a fractured clavicle and portraying one "step[]" of one implementation of a treatment method for treating a fractured clavicle." Ex. 1001, 3:57–61. As shown in Figure 3, "plate 220 has surfaces that define a first opening 222 [(unnumbered)], which is sized so that one or more sutures can pass through it, a pair of screw holes 225 at a medial end thereof and three screw holes 208 at a distal end thereof." *Id.* at 4:34–37. Washer 228 has four holes, and "is substantially oblong and dimensioned to fit substantially snugly within the upper, larger oblong section 222a of the first opening 222 in the plate 220." *Id.* at 5:7–14. Depicted hole 332 is "in the clavicle 102 at a point along the first opening 222 in the plate 220" and "is formed so that it extends substantially toward the coracoid process 116" to permit the fixation process discussed above. *Id.* at 5:26–31.

C. The Challenged Claims

Petitioner challenges claims 1–20, of which only claim 1 is independent. Independent claim 1 is reproduced below, reformatted from

the version in the '312 patent and with bracketed alphanumerical designations added to identify each clause:

1. [1.P] A fixation system for a fractured clavicle, the fracture defining medial and distal portions of the clavicle relative to the fracture, the clavicle having a superior facing surface shape, the fixation system comprising:

[1.1] a substantially rigid plate having superior and inferior surfaces, the plate being contoured to follow said clavicle superior facing surface shape, the plate being configured to be secured to a the clavicle medial portion and to extend at least partially over the clavicle distal portion when secured to the clavicle, [1.2] the plate having at least one first opening between the superior and inferior surfaces, the at least one first opening through which a suture can pass, [1.3] the at least one first opening comprising a larger, upper portion and a smaller, lower portion;

[1.4] a washer configured to be positioned adjacent the plate superior surface opposite the clavicle and configured to fit within the at least one first opening; and

[1.5] a suture secured to the washer and extending through the at least one first opening in the plate, configured to be passed through a hole in the clavicle and secured to the coracoid process.

Ex. 1001, 11:11–31.²

² We adopt and apply below Petitioner's designations for the elements of the challenged claims. See Pet. viii–xi (showing alphanumerical designations for the language in the challenged claims).

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–20 on the following grounds:

Claim(s) Challenged	35 U.S.C. §³	Reference(s)/Basis
1–8, 13–17, 19	103(a)	Deffenbaugh ⁴
1–10, 12–19	103(a)	Deffenbaugh, Thornes ⁵
11	103(a)	Deffenbaugh, Wellmann ⁶
11	103(a)	Deffenbaugh, Thornes, Wellmann
5, 20	103(a)	Deffenbaugh, Hardy ⁷
5, 20	103(a)	Deffenbaugh, Thornes, Hardy
1–20	103(a)	Clavicula, ⁸ Hardy, Thornes

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because there is no dispute that the challenged claims of the ’312 patent have an effective filing date before March 16, 2013, we apply the pre-AIA version of this statute.

⁴ US 2007/0225716 A1, published September 27, 2007 (Ex. 1004, “Deffenbaugh”).

⁵ US 2007/0179531 A1, published August 2, 2007 (Ex. 1007, “Thornes”).

⁶ Mathias Wellmann, M.D., et al., *Biomechanical Evaluation of Minimally Invasive Repairs for Complete Acromioclavicular Joint Dislocation*, 35 Am. J. of Sports Med. 955 (2007) (Ex. 1008, “Wellmann”).

⁷ FR 2 726 461 (and translation), published October 5, 1996 (Ex. 1005 (French version) and Ex. 1006 (English translation), “Hardy”).

⁸ Acumed, *Locking Clavicle Plate System* (July 2005) (Ex. 1009, “Clavicula”).

Petitioner supports its challenges with a declaration from Dr. Michael McKee, M.D. Ex. 1002 (“the McKee Declaration” or “McKee Decl.”).

II. DISCUSSION

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

Patent Owner argues that we should exercise discretion to deny institution under 35 U.S.C. § 325(d). *See* Prelim. Resp. 25–31. Petitioner opposes. *See* Pet. 19–23.

1. *Legal Framework*

Section 325(d) provides that, in determining whether to institute *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d): (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). In applying this framework, we consider several non-exclusive factors, including:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art

was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph). If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 10.

2. *Summary of the Prosecution History*

The '312 patent issued from U.S. Application No. 13/613,349, filed on September 13, 2012. *See* Ex. 1001, codes (21), (22). In an Information Disclosure Statement, the applicant listed—and the Examiner initialed as considered—Clavicula and Thornes as well as a published application that Petitioner acknowledges has a “similar specification” to Deffenbaugh. *See* Ex. 1011 (prosecution history) at 209 (listing Thornes as Cite No. AQ and US 2007/0225715 A1 to Deffenbaugh as Cite No. AS), 210 (identifying Clavicula as Cite No. CG)⁹; Pet. 19. Neither the applicant nor the Examiner identified Wellman or Hardy during prosecution.

⁹ Patent Owner provides and cites to certain individual documents in the prosecution history of the '312 patent (such as Exhibits 2002–2004 and 2007) despite Petitioner providing *the entire* prosecution history as Exhibit

In the first of two rejections, the Examiner rejected then-pending claims 43–62 as obvious over U.S. Patent Publication No. 2006/0173459 A1 to Kay, in view of U.S. Patent No. 3,604,414 to Borges, and further in view of U.S. Patent Publication No. 2009/0182335 A1 to Struhl. *See* Ex. 1011 at 95–102 (Office Action dated August 14, 2014). The Examiner also rejected claims 43–62 as obvious over Thornes in view of U.S. Patent Publication No. 2002/0065517 A1 to Paul. *See id.* at 151–60 (Office Action dated March 26, 2015).

In an Amendment following the rejection based on Thornes and Paul, the applicant amended pending claim 43 (which issued as claim 1) to recite “the at least one first opening comprising a larger, upper portion and a smaller, lower portion.” Ex. 1011 at 171 (adding the underlined text to pending claim 43 in a Reply and Amendment dated April 22, 2015). In that filing, the applicant argued that Thornes and Paul failed to disclose or suggest all the features of amended pending claim 43. *See id.* at 176–77. Following that, the Examiner allowed the claims, which issued as claims 1–20. *See id.* at 181–86.

3. Analysis

We first consider “whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.” *Advanced Bionics*, Paper 6 at 8. Patent Owner argues that the Petition presents the same or substantially the same art previously presented to the Office. *See* Prelim. Resp. 26; *see also id.* at 26–31 (entire argument on the first part of

1011. For future filings, the parties should not refile documents or portions of documents already present in the record. *See* 37 C.F.R. § 42.6(d).

the framework). As argued by Patent Owner and acknowledged by Petitioner, Clavicula, Thornes, and a published application “with a similar specification” to Deffenbaugh were identified during prosecution. *See* Ex. 1011 at 209, 210; Pet. 19.

Petitioner argues that, although Clavicula and a publication similar to Deffenbaugh were identified, “there is no indication that their relevant teachings were considered” because “[t]hey were submitted as part of an extensive list of approximately 90 references.” Pet. 20 (citing *Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00379, Paper 14 at 18 (PTAB July 3, 2019); *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7–11 (PTAB Nov. 5, 2019)). The precedential decision in *Advanced Bionics*—decided *after* the two nonprecedential Board decisions cited by Petitioner—undermines Petitioner’s argument by stating that “[p]reviously presented art includes . . . art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS).” *Advanced Bionics*, Paper 6 at 7–8. Petitioner acknowledges that Thornes “was considered during examination.” Pet. 20. Thus, we agree with Patent Owner that three of the five references—Clavicula, Thornes, and Deffenbaugh—are the same or substantially the same art as previously presented.

We turn now to the two other references relied on—Wellman and Hardy—which Petitioner applies in five of the seven grounds. Pet. 48–94. Patent Owner does not mention Wellman or Hardy at all in the discussion of § 325(d). Prelim. Resp. 25–31. Thus, we do not understand Patent Owner to argue that Hardy or Wellman is the same or substantially the same as art previously presented, and also do not understand Patent Owner to argue that Hardy or Wellman is cumulative of art previously presented. *See* Pet. 19

(arguing that “Hardy and Wellmann were not of record during prosecution of the ’312 Patent, nor are they cumulative of any art that was considered”).

Further, we note that the five grounds in which Petitioner relies on either Hardy or Wellman address all twenty claims at issue in the Petition. *See* Pet. 2. When considering the Petition as a whole, because the specific combination of references asserted in these five grounds were not considered during prosecution and because those five grounds cover all challenged claims, we find that the same or substantially the same art or argument was not presented to the Office such that the first part of the framework in *Advanced Bionics* is not satisfied.

4. Conclusion

For the reasons above, we find that the same or substantially the same art was not presented to the Office. Accordingly, we do not exercise discretion to deny institution under § 325(d).

B. The Level of Ordinary Skill in the Art

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

Petitioner contends, with accompanying declaration testimony, that a person having ordinary skill in the art at the time of the alleged invention would have had “(1) at least an MD or equivalent degree; and (2) at least two years’ experience (i) designing, developing, or testing implantable medical devices, such as bone fixation devices, or (ii) performing surgeries with implantable medical devices, such as bone fixation devices.” Pet. 18–19 (citing McKee Decl. ¶ 31).

Patent Owner “disagree[s]” with Petitioner’s proposed definition and states that it “reserve[s] the right to offer a correct definition.” Prelim. Resp. 9. According to Patent Owner, “given the deficiencies in the [P]etition, institution should be denied under any definition of” one of ordinary skill in the art. *Id.* at 9–10.

Patent Owner does not present its own definition of the level of ordinary skill in the art or explain any alleged error in Petitioner’s proposed definition. Petitioner’s proposed definition appears consistent with the record at this stage of the proceeding, including the prior art. *See In re GPAC Inc.*, 57 F.3d at 1579. Furthermore, Patent Owner does not argue at this stage of the proceeding that Petitioner’s proposal for the level of ordinary skill leads to an improper understanding of how a skilled artisan would understand either the ’312 patent or the prior art. For purposes of this Decision, we adopt the definition of the level of ordinary skill in the art proposed by Petitioner.

C. Claim Construction

In *inter partes* reviews, the Board interprets claim language using the same claim construction standard that would be used in a civil action under 35 U.S.C. § 282(b), as described in *Phillips v. AWH Corp.*, 415 F.3d 1303

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

Petitioner discusses constructions for certain claim terms: (1) “washer”; (2) “substantially rigid”; and (3) “substantially parallel.” Pet. 15–18. Patent Owner responds by addressing the term “washer.” Prelim. Resp. 8–9.

At this stage of the proceeding and based on the current record, we need not construe explicitly any of the claim language discussed in this section or any other claim terms because doing so would not change the outcome of the analysis below. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (stating that “we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).¹⁰

¹⁰ Claim construction, in general, is an issue that may be addressed further at trial. Claim construction will be determined at the close of all the evidence and after any hearing. The parties are expected to assert all of their claim construction arguments and evidence in the remaining briefing during trial, as permitted by our rules.

D. Alleged Word Limit Violation by Petitioner

Patent Owner asserts that we should deny the Petition because Petitioner allegedly exceeded the 14,000-word limit for *inter partes* review petitions. *See* Prelim. Resp. 31–35. Specifically, Patent Owner alleges that Petitioner (1) failed to include in the word count the 65-word paragraph at the top of page xii of the Petition, (2) “removed the spaces that typically appear after words such as ‘¶’ and ‘¶¶’ . . . at least 223 times,” (3) failed to include in the word count text within the drawings and figures in the Petition, and (4) improperly incorporated by reference large portions of the McKee Declaration. *See id.*

According to Patent Owner, denial is the appropriate remedy because “the word limit is mandatory,” “the Board has repeatedly warned the Patent Bar that it is improper to use formatting tricks to try to circumvent word limits,” and the alleged improper incorporation by reference of the McKee Declaration was a “deliberate attempt to circumvent the word limits.” Prelim. Resp. 33–35. For the reasons below, we do not deny the Petition but provide Patent Owner additional words in any response to the Petition filed.

As an initial matter, Petitioner did not request a preliminary reply to respond to this argument by Patent Owner. Thus, we do not have a contrary position on whether Petitioner failed to include in the word count the 65-word paragraph at the top of page xii of the Petition (issue 1 above) or failed to include in the word count text within the drawings and figures in the Petition (issue 3 above). The Board will not perform an independent assessment in this situation. We adopt Patent Owner’s position on these issues.

As to removing spaces between, for example, the paragraph symbol and the paragraph number in citations in the Petition (issue 2 above), we again agree with Patent Owner. The Consolidated Trial Practice Guide provides that “[e]xcessive words in figures, drawings, or images, *deleting spacing between words*, or using excessive acronyms or abbreviations for word phrases, in order to circumvent the rules on word count, may lead to a party’s brief not being considered,” and also states that, “[i]f an opposing party raises a word count limit violation or abuse, the Board will consider such a violation or abuse on a case-by-case basis.” Consolidated Trial Practice Guide 40 (Nov. 2019), <https://www.uspto.gov/TrialPracticeGuideConsolidated> (“TPG”) (emphasis added). Petitioner does not include spaces between the paragraph symbols and numbers in citations, as would be the norm. *See, e.g.*, Pet. 7; *see also* Editors of the Columbia Law Review et al., *The Bluebook: A Uniform System of Citation* 90 (21st ed. 2020) (“When the symbols are used, insert a space between ‘§’ and ‘¶’ and the numeral.”).

As the fourth issue, Patent Owner contends that “Petitioner[] rel[ies] on the 25,729 word declaration of Dr. McKee, entire pages and paragraphs of which are improperly incorporated by reference into the Petition.” Prelim. Resp. 32. Patent Owner then provides examples of citations to sections of the McKee Declaration, along with the length, in pages and words, of each section. *See id.* at 32–33.

As stated in the Consolidated Trial Practice Guide, “parties that incorporate expert testimony by reference in their petitions, motions, or replies without providing explanation of such testimony risk having the testimony not considered by the Board.” TPG 35–36 (citing *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014))

(informative)); *see also* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.” (emphasis added)). The mere fact that the Petition cites lengthy sections of the McKee Declaration does not necessarily indicate improper incorporation by reference. Instead, the proper approach in a situation like this is for Patent Owner to address the issue, as appropriate, in any response filed, and for the Board, when considering the arguments and evidence as a whole, to not consider any “arguments”—rather than supporting evidence or testimony—found *only* in the declaration testimony and not adequately explained in the Petition. *See IBG LLC v. Trading Techs. Int’l, Inc.*, CBM2016-00054, Paper 38 at 4 (PTAB April 7, 2017).

We turn now to the remedy. Issues 1–3 above total (by Patent Owner’s uncontroverted estimate) approximately 664 words, leading to an overage of approximately 657 words. Although the relevant regulation provides that “Petitions to institute a trial must comply with the stated word counts” (37 C.F.R. § 42.24(a)(2), *quoted at* Prelim. Resp. 33), that regulation is not “mandatory” in the sense that any potential violation *requires* denial of the petition (Prelim. Resp. 33–34). *See* 37 C.F.R. § 42.5(b) (“The Board may waive or suspend a requirement of parts 1, 41, and 42 and may place conditions on the waiver or suspension.”). Moreover, Patent Owner has not identified *any* proceeding in which the Board denied a petition for exceeding the word count. *See* Prelim. Resp. 34–35. In addition, Patent Owner has not adequately explained how the 657-word net overage amounts to undue prejudice. *See* TPG 40 (“If a party feels that it would suffer undue prejudice from an opposing party’s alleged word count limit violation or abuse, that party should raise the issue with the Board promptly after discovering the

issue.”). For these reasons, we do not view denying the Petition on this basis as appropriate; instead, we permit Patent Owner an additional 700 words (for a total of 14,700 words) for any response filed (but not for any sur-reply filed). *See* 37 C.F.R. § 42.24(b)(2) (setting 14,000 words as the limit for a patent owner response to a petition for *inter partes* review). We also notify Petitioner that all future filings *must* use proper citation format with, for example, a space between “¶” and the paragraph number. Future violations may result in the Board not considering the filing. *See* TPG 40.

E. Asserted Obviousness of Claims 1–8, 13–17, and 19 Based on Deffenbaugh & Asserted Obviousness of Claims 1–10 and 12–19 Based on Deffenbaugh and Thornes

Petitioner asserts that claims 1–8, 13–17, and 19 of the ’312 patent would have been obvious under 35 U.S.C. § 103(a) based on Deffenbaugh. Pet. 2, 23–48. Petitioner also asserts, in the alternative, that claims 1–10 and 12–19 of the ’312 patent would have been obvious under 35 U.S.C. § 103(a) based on Deffenbaugh and Thornes. *Id.* Patent Owner provides arguments addressing these asserted grounds along with arguments addressing all six grounds involving Deffenbaugh. Prelim. Resp. 11–16. Prior to addressing those arguments, we first summarize aspects of the relied-upon prior art.

1. Deffenbaugh

Deffenbaugh discloses “a system for internal fixation of a bone, and especially for the fixation of fractures of the bone.” Ex. 1004 ¶ 1.

Figure 1 of Deffenbaugh is reproduced below:

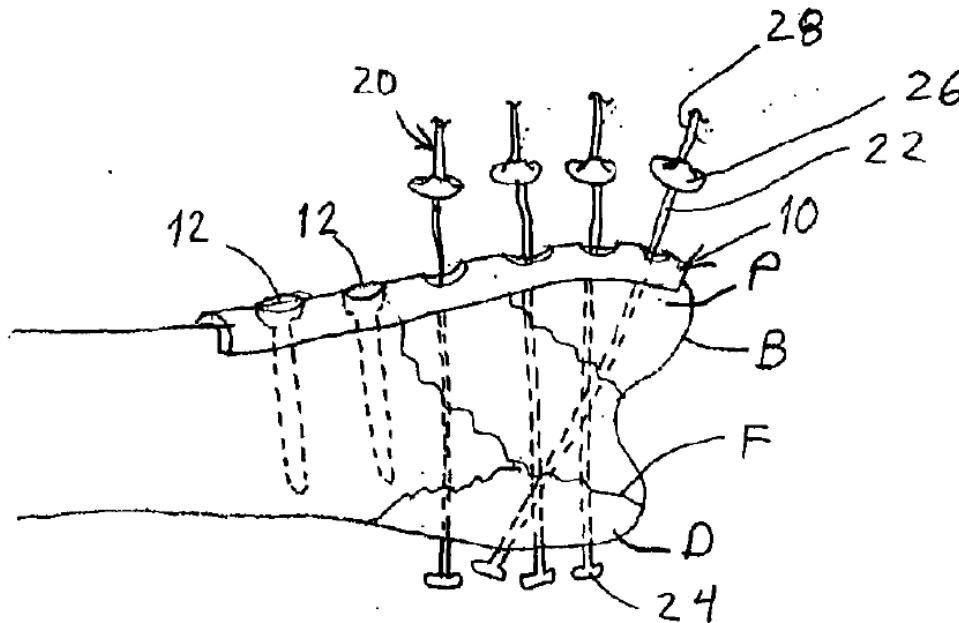


FIG. 1

Figure 1 depicts “a side perspective of a fracture fixation system.”

Ex. 1004 ¶ 38. Deffenbaugh discloses that “bone screws 12 may be used to anchor one end of the bone plate 10 away from the fractures F.” *Id.* ¶ 57.

Depicted fixation system 20 “includes a plurality of tension elements 22 that are adapted to work with the plate 10 to reduce the fractures F in the bone B,” with each tension element 22 being “an elongated flexible element that is capable of being pulled into tension and then anchored at its opposite ends.” *Id.* ¶¶ 58–59. Deffenbaugh discloses how tension elements 22 are used in the fixation process:

The distal end of the tension elements 22 is provided with a distal anchor 24 which may come in a variety of forms that are adapted to anchor against the cortical bone C at the distal surface D of the bone when tension is applied to the tension element 22. A proximal anchor 26 engages the proximal end of the tension element to the bone plate at the proximal surface P of the bone and is configured to hold tension in the tension element 22.

. . . When the fixation system 20 is initially installed, the tension element 22 includes an excess portion 28 that projects beyond the bone B and plate 10. Once the proximal anchor 26 is fixed, the excess portion 28 can be severed, leaving a cut end 29 that is preferably as close to the proximal surface P of the bone B as possible.

Ex. 1004 ¶¶ 58–59.

Figure 2 is reproduced below:

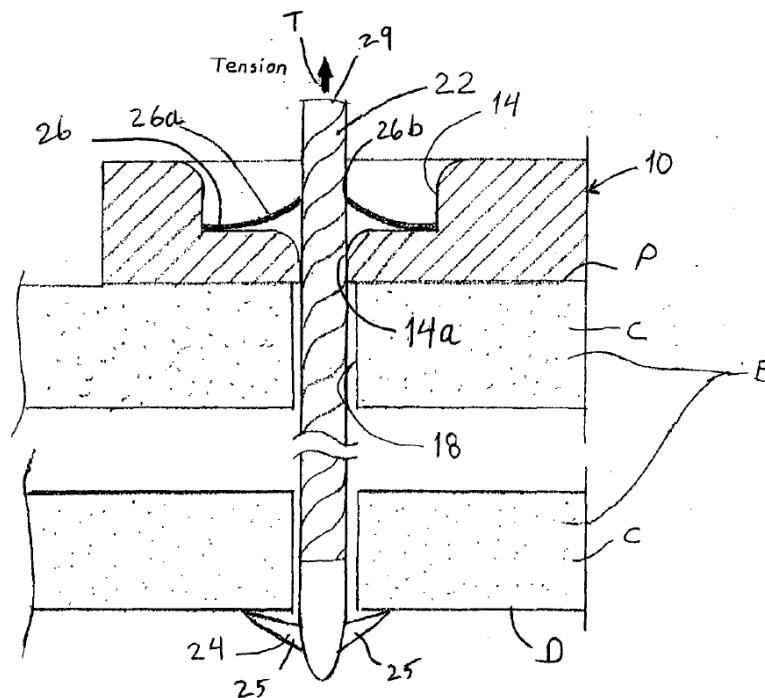


Figure 2 is “an enlarged cross-sectional view of the fracture fixation system” in Figure 1. Ex. 1004 ¶ 39. Depicted tension elements 22 “are configured to extend through the recess 14 and opening 14a in the bone plate 10 and through a bore 18 formed in the bone.” *Id.* ¶ 58. Tension elements 22 are “sized to span from a proximal surface P to an opposite distal surface D of the bone B.” *Id.* Deffenbaugh discloses that proximal anchor 26 is a “gripping washer,” which “includes a conical central portion 26a having a

central opening 26b” that “has an effective diameter slightly less than the effective diameter of the tension element 22.” *Id.* ¶ 60.

2. *Thornes*

For one of the asserted grounds addressed in this section, Petitioner relies on Thornes, in addition to Deffenbaugh (summarized above (*see* § II.E.1)). Thornes discloses “a joint or ligament reconstruction technique and associated fixation and reconstruction device.” Ex. 1007 ¶ 2.

Figure 1 of Thornes is reproduced below:

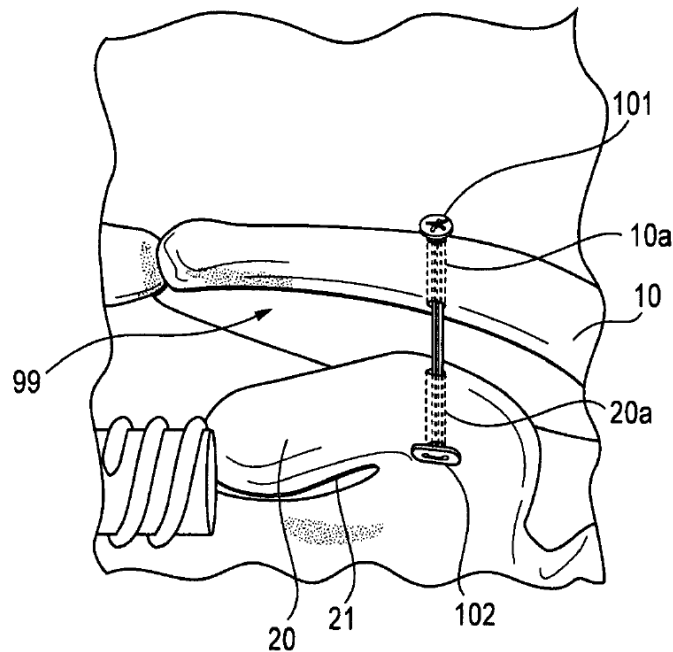
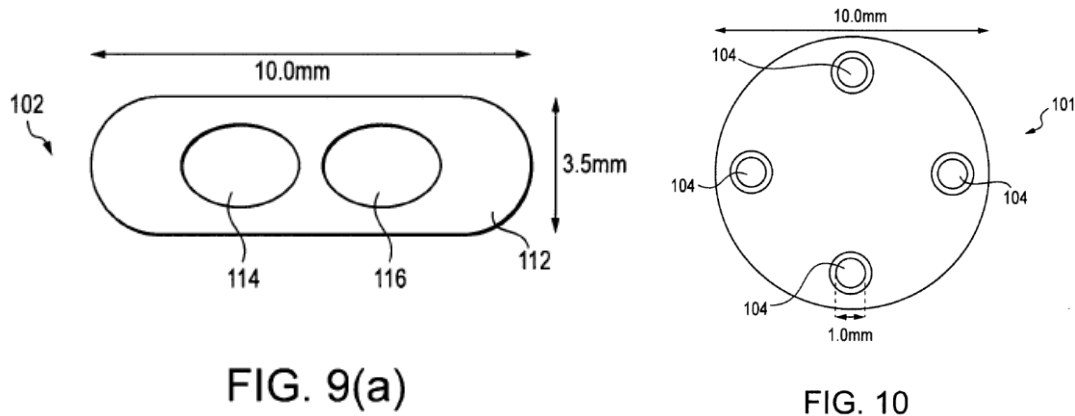


Figure 7 depicts one step in a method of joint reconstruction. *See* Ex. 1007 ¶ 7. Specifically, the depicted process involves “an acromioclavicular (AC) joint 99 of the human shoulder comprising clavicle 10 and coracoid 20 and undergoing acromioclavicular (AC) joint reconstruction.” *Id.* ¶ 17. As of the depicted step, holes 10a and 20a have been drilled in clavicle 10 and coracoid 20, respectively, button 101 has been positioned on the top surface of clavicle 10, and button 102 has been

advanced through holes 10a and 20a “until it exits the coracoid base 21.” *Id.* ¶¶ 33; *see id.* ¶¶ 13–14. The structures have, via unnumbered suture 110, been placed in tension to reduce and stabilize joint 99. *Id.* ¶¶ 14, 34.

Figures 9a and 10 are reproduced below:



Figures 9a and 10 depicts exemplary embodiments for button 102 (Fig. 9a) and button 101 (Figure 10) shown, for example, in Figure 7 above. *See Ex. 1007* ¶¶ 9, 10, 18–21. As shown in Figure 9a, button 102 has body 112 with first and second apertures 114, 116. *Id.* ¶ 19. Thornes discloses that button 101 has “at least two flexible coupling-locating apertures 104” and shows in the Figure 10 embodiment “four apertures 104 circumferentially arranged about the outer edge of the button.” *Id.* ¶ 21.

3. Independent Claim 1

For independent claim 1, Petitioner contends that Deffenbaugh discloses or renders obvious each limitation and, in the alternative, that the proposed combination of Deffenbaugh and Thornes renders obvious each limitation. Pet. 23–35. To support its arguments, Petitioner identifies certain passages in the cited references and explains the significance of each passage with respect to the corresponding claim limitation. *Id.* Petitioner also articulates reasons to combine the relied-upon aspects of Deffenbaugh

and Thornes. Pet. 23–26. Patent Owner presents several arguments addressing some or all of the six asserted grounds involving Deffenbaugh, and one argument (as to objective indicia) addressing all seven asserted grounds. See Prelim. Resp. 11–16, 22–25. We address all those arguments by Patent Owner in this section.

We have reviewed Petitioner’s contentions with respect to claim 1, and for the reasons below, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail in demonstrating that claim 1 would have been obvious based on at least the combination of Deffenbaugh and Thornes. We address in turn below each of Patent Owner’s arguments.

a. Use of Deffenbaugh in Distal Clavicle Fractures

In the discussion of the preamble of claim 1 for the asserted ground involving only Deffenbaugh, Petitioner states that “Deffenbaugh discloses ‘[a] bone fracture fixation system’” and that, although “the clavicle is not explicitly disclosed, one of ordinary skill in the art] would have understood that Deffenbaugh teaches the system can be used throughout the body, including on a fractured clavicle.”¹¹ Pet. 26 (quoting Ex. 1004, code (57)) (citing Ex. 1004 ¶¶ 2, 36, 56–57, 75; McKee Decl. ¶ 54).

Patent Owner argues that Petitioner’s “only support for this incredibly broad conclusion is by cherry picking through Deffenbaugh—including ‘any bone fracture,’ ‘one size fits all,’ and ‘shaped to fit a bone,’ as well as the

¹¹ These positions taken by Petitioner also apply to the grounds involving (1) Deffenbaugh and Wellman for claim 11 (which depends from claim 1) and (2) Deffenbaugh and Hardy for claims 5 and 20 (which depend from claim 1).

ultimate conclusion by Dr. McKee offered without citation in paragraph 54 of his declaration.” Prelim. Resp. 11–12. Patent Owner adds:

Are we really to belief [(sic – believe)] from Petitioner[] and Dr. McKee that Deffenbaugh is applicable to every one of those bones, regardless of location, size, shape, or orientation? Moreover, the clavicle is unique in that it is the only long bone in the human body with a horizontal orientation—a fact entirely ignored by Petitioner[].

Prelim. Resp. 12.

We do not agree with these arguments. As an initial matter, Patent Owner assumes that the preamble in claim 1 is limiting without addressing the issue. Further, as to the applicability of Deffenbaugh’s device to the clavicle, Petitioner states, with supporting testimony from Dr. McKee (and other record evidence), that “[c]lavicle bone plates were well known at the relevant time, and it was well within the skill of [one of ordinary skill in the art] to make any minor modifications to the shape and contour of the bone plate for use on the clavicle.” Pet. 26 (citing Exs. 1009, 1016, 1017; McKee Decl. ¶ 55).

Patent Owner rhetorically questions the sufficiency of Petitioner’s evidence but does not explain why it is inadequate or offer contrary evidence from a declarant or otherwise. See Prelim. Resp. 12. For example, Patent Owner’s counsel states—without any supporting evidence or testimony—that “the clavicle is unique in that it is the only long bone in the human body with a horizontal orientation.” *Id.*; see also *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (rejecting attorney argument as to the alleged understanding of one of skill in the art on an issue when no evidence was presented). At this stage of the proceeding, we view as sufficient Petitioner’s discussion and evidence on this issue, including Dr.

McKee’s statement that “[t]he underlying princip[le] of Deffenbaugh’s system would be applicable to any bone and [one of ordinary skill in the art] would have understood that, clinically, a precontoured plate of this nature would be a useful adjunct to fracture fixation in many body areas, including the clavicle.” McKee Decl. ¶ 54, *cited at* Pet. 26.

Patent Owner also argues that “even if it were well within the skill of [one of ordinary skill in the art] to make modifications to the shape and contour of a bone plate [in Deffenbaugh], that does not mean that there was a reason for doing so apparent from the art or from the marketplace.”

Prelim. Resp. 12. Patent Owner adds that “Petitioner[] provide[s] no evidence of this to establish a teaching, suggestion, motivation, or other reason to make the modification, so a *prima facie* case is not made out.” *Id.*

Based on the current record, we do not agree with this argument. We understand Petitioner’s ground based on Deffenbaugh alone as to claim 1 (and the two grounds flowing from that) to include the assertion that one of ordinary skill in the art would have implicitly understood Deffenbaugh to include use of its plate on a clavicle fracture (as required by the preamble to claim 1). *See* Pet. 26 (“While the clavicle is not explicitly disclosed, [one of ordinary skill in the art] would have understood that Deffenbaugh teaches the system can be used throughout the body, including on a fractured clavicle.” (citing McKee Decl. ¶ 54)); *see also In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976) (“[T]he question under 35 U.S.C. § 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made.”); *In re Preda*, 401 F.2d 825, 826–27 (CCPA 1968) (“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of

the reference, but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.”). With this understanding, we question whether Petitioner needed to present a separate reason to modify Deffenbaugh’s plate in the context of the ground based on Deffenbaugh alone to address the preamble (assuming it to be limiting).

Patent Owner also questions “[w]here is the teaching in Deffenbaugh to involve anchoring in a second ancillary bone.” Prelim. Resp. 14. We understand this to refer to the claim language, in element 1.5, that the “suture” is “configured to be passed through a hole in the clavicle and secured to the coracoid process.” Ex. 1001, 11:28–31 (the “‘secured to’ limitation”). As to the “secured to” limitation in the context of the ground based on Deffenbaugh alone (and the grounds (1) challenging claim 11 based on Deffenbaugh and Wellman and (2) challenging claims 5 and 20 based on Deffenbaugh and Hardy), Petitioner takes the position that one of ordinary skill in the art would have “found it obvious to extend the suture through holes in both the clavicle and coracoid process” in part because “[t]his method of securing the clavicle to the coracoid process was well-known in the art at the relevant time.” Pet. 34 (citing McKee Decl. ¶ 61; Exs. 1007, 1020, 1021). At this stage of the proceeding, we question the propriety of Petitioner’s apparent reliance on Exhibit 1007 (Thornes), Exhibit 1020 (a journal article titled “Injuries to the acromioclavicular joint”), Exhibit 1021 (an Arthrex document titled “AC Joint TightRope Fixation”) to address the “secured to” limitation in the context of the ground ostensibly based on Deffenbaugh *alone* (and the two grounds flowing from that). The parties should consider developing this issue at trial.

b. Reasons to Combine Deffenbaugh and Thornes

Petitioner states that, “[t]o the extent the Board determines it would not have been obvious to apply Deffenbaugh to clavicle fractures, it would have been obvious to combine the teachings of Deffenbaugh with Thornes[,] which expressly discloses a fixation system for the acromioclavicular joint.” Pet. 23–24 (citing Ex. 1007 ¶ 17; McKee Decl. ¶ 72). Petitioner then discusses why Deffenbaugh and Thornes are analogous art to the claimed invention, and states that one of ordinary skill in the art “would have understood the Deffenbaugh plate could be used on a clavicle and would have been motivated to apply the device in a manner similar to that disclosed in Thornes to obtain and maintain proper correction of the fracture displacement, maximizing the chance of clinical success.” Pet. 24–25 (citing McKee Decl. ¶ 74). Petitioner also discusses why one of ordinary skill in the art would have allegedly had a reasonable expectation of success in the proposed combination. See Pet. 25–26 (citing McKee Decl. ¶¶ 74–75; Ex. 1004 ¶¶ 2, 36; Ex. 1007 ¶ 17).¹²

Patent Owner first argues that Petitioner presents “no evidence” to support that one of ordinary skill in the art would have combined Deffenbaugh and Thornes “to obtain and maintain proper correction of the fracture displacement, maximizing the chance of clinical success,” as argued by Petitioner. Prelim. Resp. 16 (citing Pet. 25). According to Patent Owner,

¹² These positions taken by Petitioner also apply to the grounds involving (1) Deffenbaugh, Thornes, and Wellman for claim 11 (which depends from claim 1) and (2) Deffenbaugh, Thornes, and Hardy for claims 5 and 20 (which depend from claim 1).

the only “alleged support for that proposition is merely an identical paragraph in the McKee declaration.” *Id.* (citing McKee Decl. ¶ 74).

At this stage of the proceeding, we determine that Petitioner has adequately set forth reasons to combine Deffenbaugh and Thornes. Although the McKee Declaration contains a statement essentially aligning with the motivation to combine provided in the Petition, Dr. McKee provides *additional* discussion supporting that motivation to combine. *Cf. Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 14–17 (PTAB Aug. 24, 2022) (precedential) (determining that “conclusory and unsupported” declarant testimony was entitled to little weight as it merely repeated *verbatim* the petition’s assertions, without “cit[ing] any additional supporting evidence or provid[ing] any technical reasoning”). For example, Dr. McKee addresses how (1) “[t]echniques used to treat AC joint dislocation, including fixation of the clavicle to the coracoid process with a suture, are the same or similar to those used during the treatment of distal clavicle fractures” and (2) “[a]pplying suture fixation through or around a clavicular plate is a long standing, and standard technique, to augment plate fixation and minimize the typical displacement at the fracture site (in which the coracoid and scapula move inferiorly and the clavicle moves superiorly).” McKee Decl. ¶ 74, *cited at* Pet. 25.

Patent Owner also argues that “Petitioner[] offer[s] Thornes (Ex. 1007) but fail[s] to explain what would teach, suggest, or motivate [one of ordinary skill in the art] to make th[e] alleged combination.” Prelim. Resp. 13. According to Patent Owner, “Petitioner[] consistently rel[ies] on the conclusory statements of Dr. McKee that [one of ordinary skill in the art ‘]at the relevant time would have also been aware of a number of clinical

studies published, both biomechanical and clinical, that would clearly support the use of the Deffenbaugh fixation device in this setting” but that neither Petitioner nor Dr. McKee actually identifies the relied-upon studies. *Id.* (quoting McKee Decl. ¶ 61).

We do not agree with this argument. As an initial matter, Petitioner *does* at least present reasoning as to why one of ordinary skill in the art would have combined Deffenbaugh, as discussed above: “to obtain and maintain proper correction of the fracture displacement, maximizing the chance of clinical success.” Pet. 25. Moreover, the discussion of the “studies” in paragraph 61 of the McKee Declaration appears to be relied on by Petitioner only in the context of the ground based on Deffenbaugh alone, rather than in the context of the asserted ground based on Deffenbaugh combined with Thornes (and the two grounds flowing from that). See Pet. 34–35 (presenting a discussion relying on paragraph 61 of the McKee Declaration and then transitioning, using “Alternatively,” to a discussion of the proposed combination of Deffenbaugh and Thornes). Patent Owner may wish to develop that issue at trial, as appropriate.

c. Other Arguments Addressing Grounds Involving Deffenbaugh in Combination with Other References

Patent Owner also presents arguments generally addressing all five asserted grounds involving Deffenbaugh in combination with other references (i.e., Thornes, Wellman, and Hardy). First, Patent Owner argues that “Petitioner[’s] arguments boil down to the identification of elements scattered throughout the prior art tied together with a string of conclusory assertions that [one of ordinary skill in the art] would know to combine the references based on some unsupported statement.” Prelim. Resp. 13. Patent Owner adds that, “[a]bsent citations to any specific reference suggesting a

particular combination, there is little basis for this Board to find that the proposed combinations render the claims obvious.” *Id.* at 13–14.

This argument does not identify a deficiency in Petitioner’s positions as to the grounds involving Deffenbaugh in combination with other references. Although “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does,” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), “[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents,” *id.* at 419. Thus, we do not agree that Petitioner needed to provide “citations to any specific reference suggesting a particular combination,” as argued. Prelim. Resp. 13–14.

Further, Petitioner does not assert that one of ordinary skill in the art would have combined Deffenbaugh with the other prior art references merely because all those references are analogous to the claimed invention. See Prelim. Resp. 14 (citing *Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2018-00827, Paper 9 at 10–11 (PTAB Oct. 16, 2018) (informative)). Instead, Petitioner presents analogousness as *one aspect* of three lengthy discussions as to combining Deffenbaugh with the other prior art references. See Pet. 24 (discussing analogousness in the context of a broader discussion of combining Deffenbaugh and Thornes (Pet. 23–26)), 50 (discussing analogousness in the context of a broader discussion of combining Deffenbaugh with either Wellman or Thornes/Wellman (Pet. 48–50)), 52 (discussing analogousness in the context of a broader discussion of combining Deffenbaugh with either Hardy or Thornes/Hardy (Pet. 51–52)).

Second, Patent Owner argues that “there is nothing in the Petition to suggest that the references could be predictably combined.” Prelim.

Resp. 15. According to Patent Owner, the McKee Declaration “merely suggests that [one of ordinary skill in the art] would know to combine certain references.” *Id.*

We do not agree with this argument. In each of the discussions of the reasons to combine the prior art references with Deffenbaugh, Petitioner has expressly addressed—with supporting testimony from Dr. McKee—why there would have been a “reasonable expectation of success” in the proposed combinations. Pet. 25–26 (discussing why one of ordinary skill in the art “would have had a reasonable expectation of success in using the methods and devices of Deffenbaugh for clavicle fixation, using the technique of attaching the clavicle and coracoid process with a suture, as disclosed in Thornes” (citing McKee Decl. ¶ 75 (preceded with the heading “Reasonable Expectation of Success”)))); Pet. 49–50 (discussing why one of ordinary skill in the art “would have had a reasonable expectation of success in combining the methods taught in Deffenbaugh and Wellmann” (citing McKee Decl. ¶ 99 (preceded with the heading “Reasonable Expectation of Success”)))); Pet. 51–52 (discussing how incorporating the relied-upon features of Hardy into the system of Deffenbaugh or Deffenbaugh/Thornes “would have required little to no modification” (citing McKee Decl. ¶ 107 (preceded with the heading “Reasonable Expectation of Success”)))).

d. Objective Indicia of Nonobviousness

In a discussion addressing all seven asserted grounds, Patent Owner argues that we should deny institution because Petitioner failed to address objective indicia of nonobviousness, which, according to Patent Owner, “are

of record in this proceeding and were considered by the Examiner in allowing the '312 patent.” Prelim. Resp. 22–23; *see id.* at 22–25 (entire similar argument). Specifically, Patent Owner asserts that the record includes evidence of long-felt need and commercial success that Petitioner failed to address in the Petition. *See id.* at 24–25.

We disagree with this argument. In the two nonprecedential decisions cited by Patent Owner for the proposition that denial is appropriate here (*see* Prelim. Resp. 22–23), the Board faulted petitioners for not addressing in the petition objective indicia evidence discussed by the examiners during prosecution as part of the reason for allowing the claims at issue. *See Merial Ltd. v. Virbac*, IPR2014-01279, Paper 13 at 26 (PTAB Jan. 22, 2015) (“In submitting the Petition, [Petitioner] had an opportunity to address the Examiner’s rationale in support of allowance of claims in the application maturing into the ’799 patent. [Petitioner] elected not to address the Examiner’s allowance rationale.”), 27 (“[Petitioner] was aware of the unexpected results showing which the Examiner found persuasive in showing nonobviousness in view of substantially the same prior art combination [Petitioner] now relies upon.”); *Praxair Distr. Inc. v. INO Therapeutics, Inc.*, IPR2015-00522, Paper 12 at 16–17 (PTAB July 29, 2015) (discussing how petitioner did not address certain “evidence of nonobviousness” in the petition and stating how “Petitioner and its declarant should have addressed these arguments in the Petitions to show a reasonable likelihood of success on the merits,” given that “the Examiner found these arguments persuasive and allowed the claims”).

That, however, is not the situation here; Patent Owner has not shown that the Examiner relied on the alleged evidence of long-felt but unresolved

need or of commercial success in allowing the claims of the '312 patent. As noted by Patent Owner, during prosecution leading to the '312 patent, the applicant stated that an alleged declaration by the applicant shows that “the invention satisfies a long-felt need in the art, and [that the invention] has been copied by the two largest manufacturers of clavicle plates”—i.e., Petitioners. Ex. 1011 at 125; *see also* Prelim. Resp. 24–25 (citing Prelim. Resp. 7).

We do not agree, however, with the assertion that Petitioner improperly failed to address this alleged evidence. First, the alleged declaration by the applicant addressing long-felt but unresolved need and copying are *not in the record* in this proceeding (and do not appear to be present even in the file history of the '312 patent (Ex. 1011)). Second, Patent Owner has not established, and the record does not support based on independent review, that the declaration or alleged objective indicia of nonobviousness was considered by the Examiner at all, let alone *in allowing* the challenged claims.

Further, the mere fact that Patent Owner asserts infringement of the challenged claims by Petitioner in the Delaware Litigations does not require Petitioner to present, in the Petition, a case rebutting commercial success. *See* Prelim. Resp. 24–25 (citing Exs. 2005 (infringement contentions to Petitioner Arthrex) & 2006 (infringement contentions to Petitioner Acumed); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (“Not every competing product that arguably falls within the scope of a patent is evidence of copying; otherwise, ‘every infringement suit would automatically confirm the nonobviousness of the patent.’”

(quoting *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)).

The issue of objective indicia of nonobviousness is highly fact-specific. At this stage, the record is incomplete; for example, Petitioner has not had the opportunity to respond to the arguments and evidence raised by Patent Owner for the first time in the Preliminary Response, including the alleged licensing by Medartis AG (*see* Prelim. Resp. 25 (citing Ex. 2008)). We will consider the full record as to objective indicia developed during trial as part of the analysis in the final written decision. *See* TPG 41 (Nov. 2019) (“In determining whether the subject matter of a claim would have been obvious over the prior art, the Board will review any objective evidence of nonobviousness proffered by the patent owner where appropriate.”).

e. Conclusion as to Claim 1

Patent Owner does not offer any arguments specifically addressing any other issues with these two asserted grounds as to claim 1. We have reviewed Petitioner’s contentions with respect to the remaining aspects addressing claim 1 and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that at least the combination of Deffenbaugh and Thornes satisfies each limitation and that one of ordinary skill in the art would have had reason to combine the references as proposed. For the reasons above, we determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail in demonstrating that claim 1 would have been obvious based on Deffenbaugh and Thornes.

We need not and do not address whether the ground based on Deffenbaugh alone satisfies the reasonable likelihood standard. We include

that asserted ground, however, in the instituted *inter partes* review. *See SAS*, 138 S. Ct. at 1354, 1359–60; 37 C.F.R. § 42.108(a) (“When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”).

4. *Claims 2–10 and 12–19*

Claims 2–10 and 12–19 (addressed collectively in these two grounds) depend from claim 1. Patent Owner does not present any arguments specifically addressing claims 2–10 and 12–19 not already discussed as to claim 1 above. *See* Prelim. Resp. 11–16, 22–25. We include claims 2–10 and 12–19 in the context of these asserted grounds in the instituted *inter partes* review. *See SAS*, 138 S. Ct. at 1354, 1359–60; 37 C.F.R. § 42.108(a).

F. Asserted Obviousness of Claim 11 Based on Deffenbaugh and Wellman & Asserted Obviousness of Claim 11 Based on Deffenbaugh, Thornes, and Wellman

Petitioner asserts that claim 11 of the ’312 patent would have been obvious under 35 U.S.C. § 103(a) based on Deffenbaugh and Wellman. Pet. 2, 48–51. Petitioner also asserts, in the alternative, that claim 11 of the ’312 patent would have been obvious under 35 U.S.C. § 103(a) based on Deffenbaugh, Thornes, and Wellman. *Id.* Patent Owner provides arguments addressing these asserted grounds, many of which we addressed above. Prelim. Resp. 11–21. We address below one argument specifically addressing these two asserted grounds. But first, we summarize aspects of the relied-upon prior art.

1. *Wellman*

In these two asserted grounds, Petitioner relies on Wellman, in addition to Deffenbaugh (summarized above (*see* § II.E.1)) and, in one

ground, also on Thornes (summarized above (*see* § II.E.2)). Wellman discloses methods to secure a suture between the clavicle and coracoid process to stabilize the acromioclavicular joint. Ex. 1008 at 955–57.¹³

Figure 1 of Wellman is reproduced below:

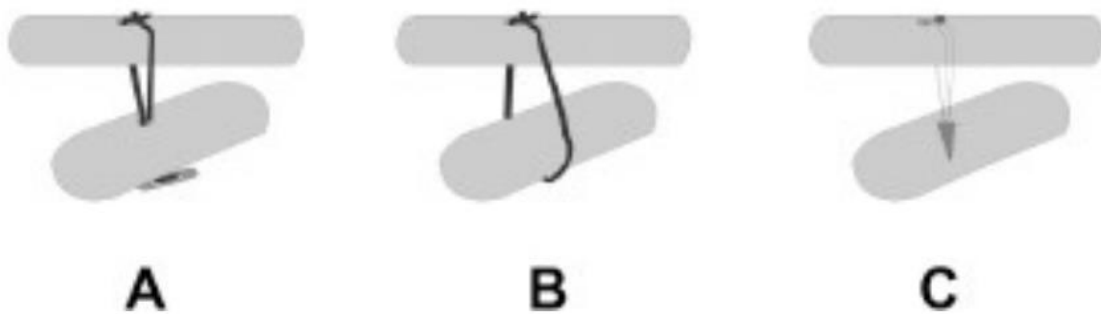


Figure 1 depicts three different methods to secure a suture between the clavicle (upper structure) and coracoid process (lower structure). Ex. 1008 at 956–57.

2. *Dependent Claim 11*

Dependent claim 11 recites: “[t]he fixation system of claim 1 wherein the suture has a length sufficient to pass around the coracoid process.” Ex. 1001, 12:11–12. Petitioner contends that the proposed combination of Deffenbaugh and Wellman renders obvious each limitation, and, in the alternative, that the proposed combination of Deffenbaugh, Thornes, and Wellman renders obvious each limitation. Pet. 48–51. Specifically, Petitioner relies on Wellman as to drawing B in Figure 1 to address the additional limitation in claim 11. *See id.*

Patent Owner argues that Petitioner has not adequately shown that Wellman is a “printed publication[]” under 35 U.S.C. § 311(b). *See Prelim.*

¹³ In citations to Wellman, we (like the parties) refer to the native pagination (which starts at page 955).

Resp. 17–21. Specifically, according to Patent Owner, “[i]n summary fashion, Petitioner[] conclude[s] that Wellman is prior art under at least pre-AIA 35 U.S.C. § 102(a) and/or (e),” but the “only evidence appears to be that Wellman ‘published in 2007.’” *Id.* at 18 (quoting Pet. 7) (citing Pet. 6; Ex. 1008 at 955 (“© 2007 American Orthopaedic Society for Sports Medicine”)). Patent Owner then cites nonprecedential Board decisions for the proposition that a copyright notice *alone* is insufficient evidence of printed publication status. *See id.* at 18–19. Patent Owner also contends that Petitioner has (1) “fail[ed] to establish that Wellman was *catalogued* or *indexed* in a way that might establish public accessibility” (citing *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009)) and (2) failed to show that one of ordinary skill in the art “would have looked [to] Wellman or even known it existed, let alone how to access it.” *Id.* at 19–20. For the reasons below, these arguments do not show a deficiency in these two asserted grounds based on the current record.

A petitioner in an *inter partes* review may challenge the claims of a patent “*only* on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b) (emphasis added). “[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that [a] reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication.” *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential).¹⁴ In *Hulu*, the Precedential Opinion Panel (“POP”)

¹⁴ Patent Owner did not discuss the precedential decision in *Hulu* in the analysis of this issue. *See* Prelim. Resp. 17–21.

rejected the petitioner’s argument that a reference necessarily meets “the standard for institution where the reference bears conventional markers of publication, such as a copyright date, edition identifiers, publication by a commercial publisher, and the assignment of an ISBN number.” *Hulu*, Paper 29 at 17. The POP stated: “We do not hold that any particular indicia per se is sufficient at the institution stage. Rather, the indicia on the face of a reference, such as printed dates and stamps, are considered as part of the totality of the evidence.” *Id.* at 17–18 (citing *Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1377 (Fed. Cir. 2018)).

Because the Petition shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims based on at least one of the asserted grounds (*see supra* § II.E.3), we need not address whether Petitioner has adequately explained the printed publication status of Wellman at this stage of the proceeding. We note, however, that Wellman contains more than *merely* a copyright date indicating its public accessibility. For example, Wellman indicates that it was published in Volume 35, Number 6 of the American Journal of Sports Medicine, and it also contains a Digital Object Identifier (“DOI”). *See* Ex. 1008 at 955 (bottom right corner). We include these asserted grounds in the instituted *inter partes* review. *See SAS*, 138 S. Ct. at 1354, 1359–60; 37 C.F.R. § 42.108(a).

G. Asserted Obviousness of Claims 5 and 20 Based on Deffenbaugh and Hardy & Asserted Obviousness of Claims 5 and 20 Based on Deffenbaugh, Thornes, and Hardy

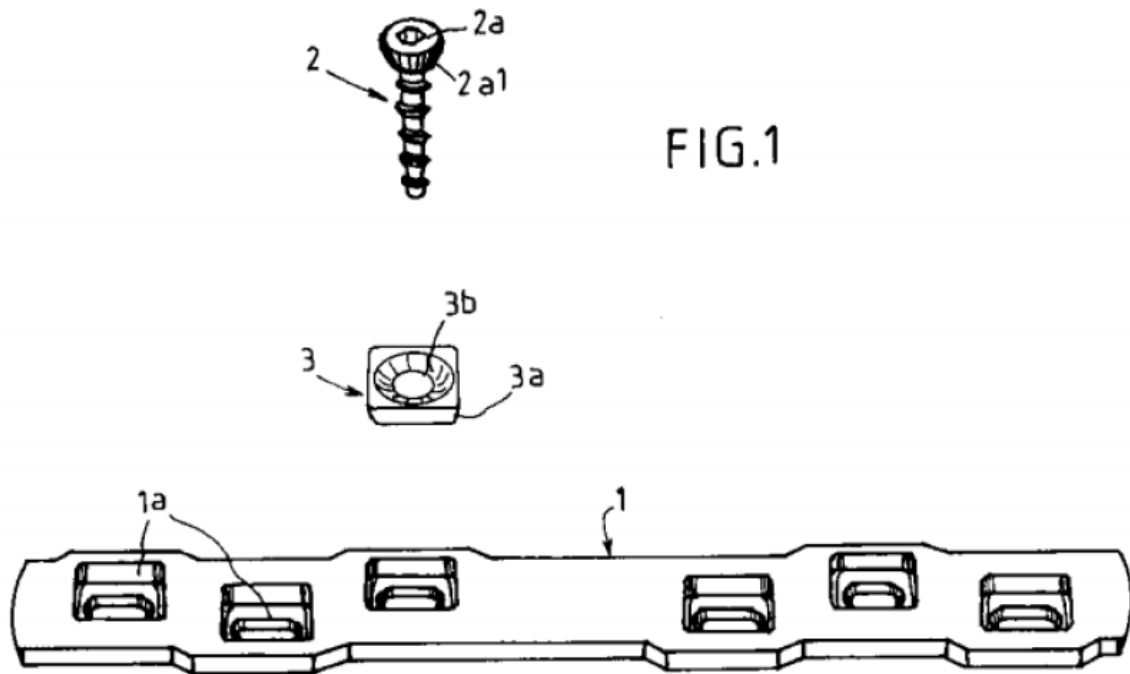
Petitioner asserts that claims 5 and 20 of the ’312 patent would have been obvious under 35 U.S.C. § 103(a) based on Deffenbaugh and Hardy. Pet. 2, 51–54. Petitioner also asserts, in the alternative, that claims 5 and 20

of the '312 patent would have been obvious under 35 U.S.C. § 103(a) based on Deffenbaugh, Thornes, and Hardy. *Id.* For these asserted grounds, Patent Owner relies on many of the same arguments addressed above (*see* § II.E.3). Prelim. Resp. 11–16. Patent Owner does not present any arguments specifically addressing these two asserted grounds. For completeness, however, we summarize aspects of the relied-upon prior art.

1. *Hardy*

In this asserted ground, Petitioner relies on Hardy, in addition to Deffenbaugh (summarized above (*see* § II.E.1)) and (in one ground) Thornes (summarized above (*see* § II.E.2)). Hardy discloses a self-compressive bone plate with washers that engage fasteners. Ex. 1006, codes (54) and (57), 2:19–3:1.¹⁵

Figure 1 of Hardy is reproduced below:



¹⁵ In citations to Hardy, we (like the parties) refer to the native pagination.

Figure 1 depicts the main parts of the disclosed invention. Ex. 1006, 3:8–9. Specifically, Figure 1 shows plate 1, orifices 1a, washers 3, and screws 2. *See id.* at 4:1–19. Hardy discloses that “washers (3) are of different dimensions from those of the orifices (1a) and are shaped to be displaced by sliding in said orifices.” *Id.* at 4:10–12.

Figure 7 is reproduced below:

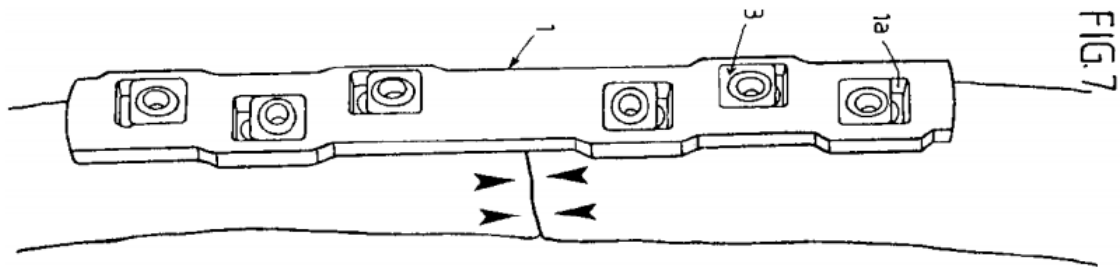


Figure 7 shows the placement of the disclosed plate and shows the reduction of the bone fracture (at the location of four black arrows). Ex. 1006, 3:13–16.

Figures 8 and 10 are reproduced below:

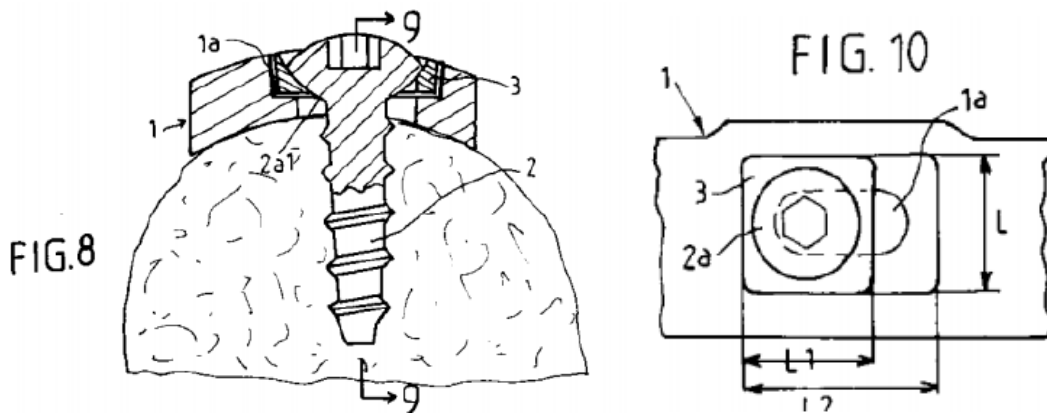


Figure 8 “is a large-scale, cross-sectional view showing the fastening of the plate,” and Figure 10 is a plan view of Figure 8. Ex. 1006, 3:17–18, 3:20. These figures show slidable washer 3 with screw 2 (and screw head 2a) inside orifice 1a in plate 1. *See id.* at 4:9–19.

2. *Analysis*

Claims 5 and 20 depend from claim 1, and recite certain features of the “washer.” *See* Ex. 1001, 11:42–45, 12:46–48. Petitioner relies on Hardy or Thornes and Hardy as to those features. *See* Pet. 51–54. Patent Owner does not present any arguments specifically addressing these asserted grounds aside from the arguments addressed above (*see* § II.E.3). *See* Prelim. Resp. 11–16. Because the Petition shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims based on at least one of the asserted grounds (*see supra* § II.E.3), we include these asserted grounds in the instituted *inter partes* review.

H. Asserted Obviousness of Claims 1–20 Based on Clavicula, Hardy, and Thornes

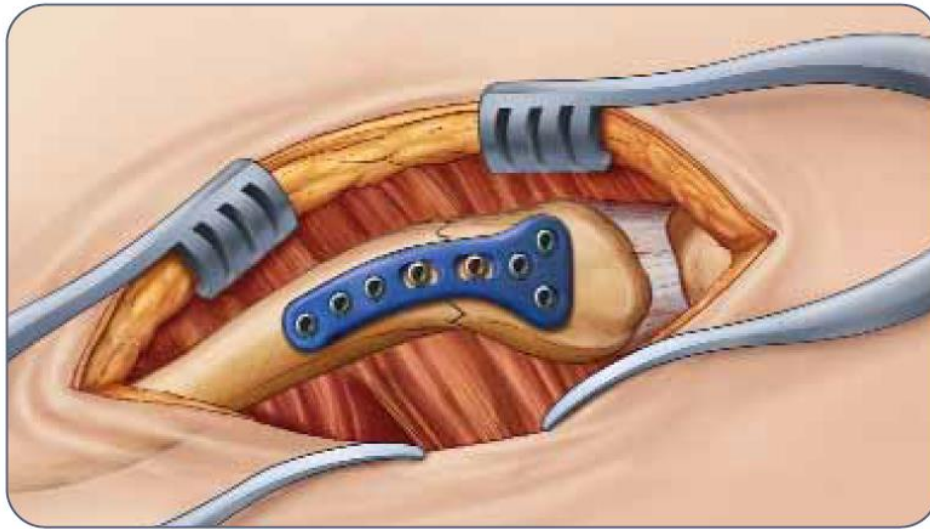
Petitioner asserts that claims 1–20 of the ’312 patent would have been obvious under 35 U.S.C. § 103(a) based on Clavicula, Hardy, and Thornes. Pet. 2, 54–94. Patent Owner provides arguments specifically addressing this asserted ground. Prelim. Resp. 22. We first summarize aspects of the relied-upon prior art.

1. *Clavicula*

In this asserted ground, Petitioner relies on Clavicula, in addition to Hardy (summarized above (*see* § II.G.1)) and Thornes (summarized above

(see § II.E.2)). Clavicula discloses Acumed's "Locking Clavicle Plate System." Ex. 1009 at 1.

A drawing from page 7 of Clavicula is reproduced below:



The reproduced drawing depicts an exposed human clavicle at or near the end of the disclosed procedure, showing the final plate and screw position. Ex. 1009 at 7. Clavicula discloses that the plates are pre-contoured rather than straight because that design reduces operating room time, "minimizes soft-tissue irritation for the patient," and can "act as [a] guide or template for restoring the patient's original anatomy." *Id.* at 2, 3. In addition, Clavicula discloses that, "[i]f the surgeon feels the bone quality of the lateral fragment is poor, sutures may be passed from medial to lateral around the coracoid process and the plate to take stress off of the lateral fixation." *Id.* at 7.

A picture from page 3 of Clavicula is reproduced below:



This picture depicts a pre-contoured plate fastened to a clavicle using several screws. Ex. 1009 at 3.

2. *Independent Claim 1*

For independent claim 1, Petitioner contends that the proposed combination of Clavicula, Hardy, and Thornes discloses each limitation. Pet. 54–71. To support its arguments, Petitioner identifies certain passages in the cited references and explains the significance of each passage with respect to the corresponding claim limitation. *Id.* Petitioner also articulates reasons to combine the relied-upon aspects of Clavicula, Hardy, and Thornes. Pet. 54–61. Patent Owner challenges the articulated reasons to combine Clavicula, Hardy, and Thornes, and whether there would have been a reasonable expectation of success. See Prelim. Resp. 22. We have reviewed Petitioner’s contentions with respect to claim 1, and for the reasons below, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail in demonstrating that claim 1 would have been obvious based on Clavicula, Hardy, and Thornes. Pet. 54–71.

For completeness, we reproduce here the entirety of Patent Owner's argument for this asserted ground (aside from its argument under § 325(d)):

While Clavicula, unlike Deffenbaugh, is specific to the collarbone, [this asserted ground] fares no better under scrutiny than the six Deffenbaugh grounds. Once again, Petitioners do not offer the necessary teaching, suggestion, or motivation to combine Clavicula with Hardy and Thornes, nor would there any reasonable expectation of success to [one of ordinary skill in the art]. Instead, Petitioners offer only the lengthy but entirely conclusory declaration of Dr. McKee, virtually devoid of citations to any prior art that would justify either the combination of the three secondary references or give [one of ordinary skill in the art] a reasonable expectation of success. For the same reasons articulated [in pages 11–16 of the Preliminary Response, this asserted ground] should not be instituted.

Prelim. Resp. 22.

With this argument, Patent Owner concludes that Petitioner has not met its burden, but Patent Owner does not identify any *specific* alleged failings as to the reasons to combine or reasonable expectation of success provided in approximately seven pages of discussion in the Petition and approximately sixteen paragraphs of discussion in the McKee Declaration. See Pet. 54–61 (citing McKee Decl. ¶¶ 113–128). We will not develop specific arguments based on Patent Owner's general assertion of failure by Petitioner. See *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (“Judges are not like pigs, hunting for truffles buried in briefs.” (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991))). Here, we determine that the Petition adequately addresses the reasons to combine Clavicula, Hardy, and Thornes at this stage of the proceeding, including the statement of how one of ordinary skill in the art “would have been motivated to combine the Clavicula plate, with the

Thornes washer-suture system, and the Hardy recessed washer to minimize tissue irritation, permit adjustability, and provide optimal fixation with a simple, reproducible means of eliminating stress on the clavicle fixation.” Pet. 58 (citing McKee Decl. ¶ 122).

Further, we determine that the Petition has adequately shown a reasonable expectation of success in the proposed combination at this stage of the proceeding, including the statements as to how (1) the alleged similarities in structure and function between relevant aspects of Clavicular and Thornes would have created a reasonable expectation of success as to that combination (Pet. 58–60 (citing McKee Decl. ¶¶ 123–126)) and (2) how one of ordinary skill in the art “would have [had] a reasonable expectation of success in combining the Hardy washer with the Clavicula plate because Clavicula discloses an oblong opening that [one of ordinary skill in the art] would [have] recognize[d] as capable of receiving a washer to provide additional stability” (Pet. 60–61 (citing McKee Decl. ¶ 127)).

Patent Owner does not offer any arguments specifically addressing any other aspects of this asserted ground as to claim 1. *See* Prelim. Resp. 22. We have reviewed Petitioner’s contentions with respect to claim 1, and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that the combination of Clavicula, Hardy, and Thornes satisfies each limitation and that one of ordinary skill in the art would have had reason to combine Clavicula, Hardy, and Thornes as proposed. *See* Pet. 54–71. For these reasons, we determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail in demonstrating that claim 1 would have been obvious based on Clavicula, Hardy, and Thornes.

3. *Claims 2–20*

Claims 2–20 depend from claim 1. Patent Owner does not present any arguments specifically addressing claims 2–20 in the context of this asserted ground. *See* Prelim. Resp. 22. We include claims 2–20 in the context of this asserted ground in the instituted *inter partes* review. *See* SAS, 138 S. Ct. at 1354, 1359–60; 37 C.F.R. § 42.108(a).

III. CONCLUSION

For the reasons above, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to at least one of challenged claims 1–20 of the ’312 patent. At this stage of the proceeding, no final determination has yet been made with regard to the patentability of any of the challenged claims or any underlying factual or legal issues, including the construction of claim terms. The final determination will be based on the record as developed during the *inter partes* review.

IV. ORDER

Accordingly, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review is hereby instituted as to claims 1–20 of the ’312 patent on all asserted grounds;

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

FURTHER ORDERED that Patent Owner is permitted 700 additional words for any response filed in this proceeding.

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Patent 9,149,312 B2

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