

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARTHREX, INC. and ACUMED LLC,  
Petitioner,

v.

JEFFREY GELFAND, M.D.,  
Patent Owner.

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IPR2023-00014  
Patent 9,149,312 B2

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

JESCHKE, *Administrative Patent Judge*.

JUDGMENT  
Final Written Decision  
Determining All Challenged Claims Unpatentable  
*35 U.S.C. § 318(a)*

## I. BACKGROUND

Arthrex, Inc. and Acumed LLC (collectively, “Petitioner”) challenge claims 1–20 of U.S. Patent No. 9,149,312 B2 (Ex. 1001, “the ’312 patent”), assigned to Patent Owner, Dr. Jeffrey Gelfand, M.D. We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons below, we conclude that Petitioner has proven the unpatentability of all of the challenged claims by a preponderance of the evidence.

### A. Procedural History

Petitioner filed a Petition to institute *inter partes* review of challenged claims 1–20. Paper 1 (“Pet.”). Patent Owner timely filed a Preliminary Response. Paper 8. Upon review of the arguments and supporting evidence, we instituted *inter partes* review of all challenged claims and on all grounds asserted in the Petition. Paper 9 (“Dec. Inst.”). After institution, Patent Owner filed a Response (Paper 23, “PO Resp.”), Petitioner filed a Reply (Paper 32, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 37, “PO Sur-reply”).

Petitioner relies on the declaration testimony of Dr. Michael McKee, M.D. (Ex. 1002 (“the McKee Declaration” or “McKee Decl.”)), the declaration testimony of Mr. Kevin Gallen (Ex. 1035 (“the Gallen Declaration” or “Gallen Decl.”)), and the declaration testimony of Mr. Mark Sommers, MS (Ex. 1044 (“the Sommers Declaration” or “Sommers Decl.”)). Patent Owner relies on the declaration testimony of Dr. Raymond Thal, M.D. (Ex. 2010 (“the Thal Declaration” or “Thal Decl.”)) and the declaration testimony of Patent Owner, Dr. Jeffrey Gelfand, M.D. (Ex. 2049 (“the Gelfand Declaration” or “Gelfand Decl.”)). An oral hearing was held

on January 9, 2024, and a copy of the transcript was entered into the record. Paper 44 (“Tr.”).

*B. 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; Paper 13 (Petitioner’s Updated Mandatory Notices) at 1. 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.

*C. 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:

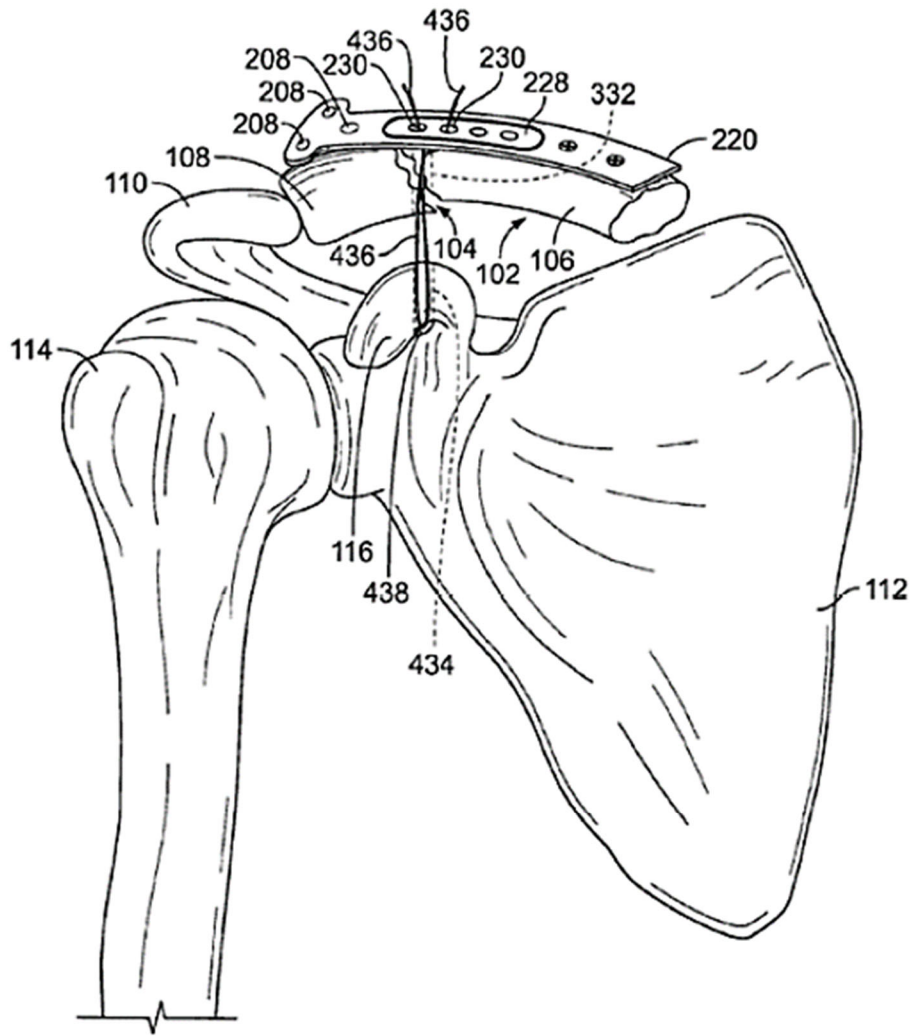


FIG. 5

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.”<sup>1</sup> *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.

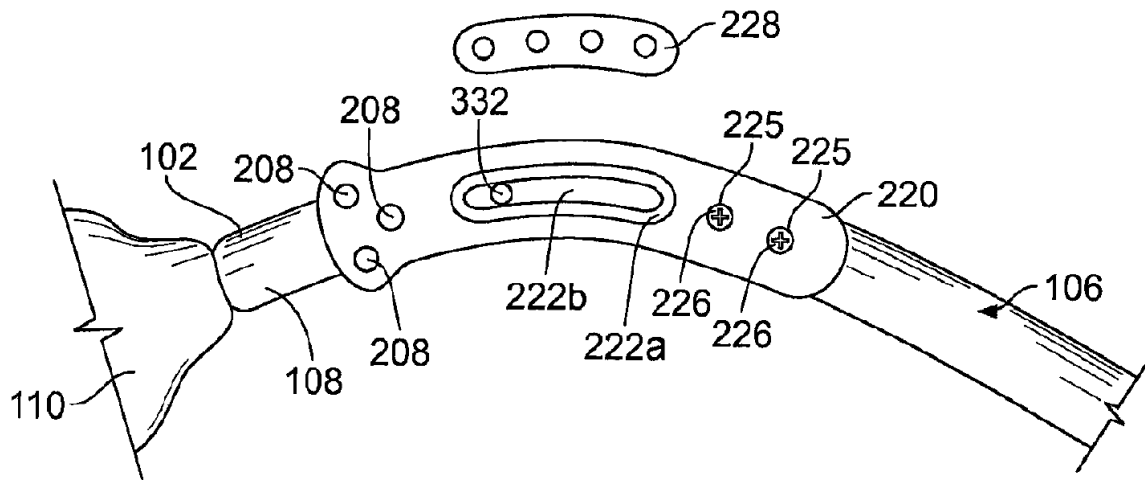
In Figure 5, “substantially rigid plate 220 is shown secured to the medial portion 106 of the clavicle 102 relative to the fracture 104,” with plate 220 “contoured to approximately follow the contours of an upper surface of a non-fractured clavicle.” Ex. 1001, 4:30–34. As shown, “[t]he distal end of 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).

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<sup>1</sup> In this Decision, we omit emphasis on reference numerals and claim numbers in quotations from the ’312 patent and the 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.

#### *D. 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.<sup>2</sup>

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<sup>2</sup> 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).

*E. Instituted Grounds of Unpatentability*

We instituted *inter partes* review of the challenged claims based on the following grounds of unpatentability asserted by Petitioner:

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

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<sup>3</sup> 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.

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

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

<sup>6</sup> 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”).

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

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



## II. DISCUSSION

### *A. 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 counters by stating that one of ordinary skill in the art “would have an M.D. or similar degree and several years of either clinical experience performing surgery on the shoulder and clavicle or designing, developing, and testing such devices.” PO Resp. 22 (citing Thal Decl. ¶ 31). Patent Owner adds that “[t]his definition is largely consistent with the definition provided by Dr. McKee in his declaration ([McKee Decl.] ¶ 31),

and the arguments below would not change if Dr. McKee’s definition were applied to this case.” *Id.* (citing Thal Decl. ¶ 34).

As noted in the Decision on Institution, Petitioner’s proposed definition appears consistent with the record, including the prior art. *See* Dec. Inst. 14 (citing *In re GPAC Inc.*, 57 F.3d at 1579). Moreover, we agree with Patent Owner that the differences in the two proposed levels of ordinary skill in the art are minor. For these reasons, and because Patent Owner acknowledges that its arguments would not change if Petitioner’s proposed level of ordinary skill were applied, in the analysis below, we continue to apply the level of ordinary skill in the art adopted in the Decision on Institution, as proposed by Petitioner. Further, the analysis would be the same under Patent Owner’s proposed level.

#### *B. 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) (2022). 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 (1) arguing that the preamble of independent claim 1 is limiting, (2) asserting error in Petitioner’s proposed construction of “washer,” and (3) contending that “substantially rigid” and “substantially parallel” do not require construction. PO Resp. 15–22.

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))); *see also* Pet. Reply 1 (stating that “the Board need not address the parties’ proposed claim constructions”).

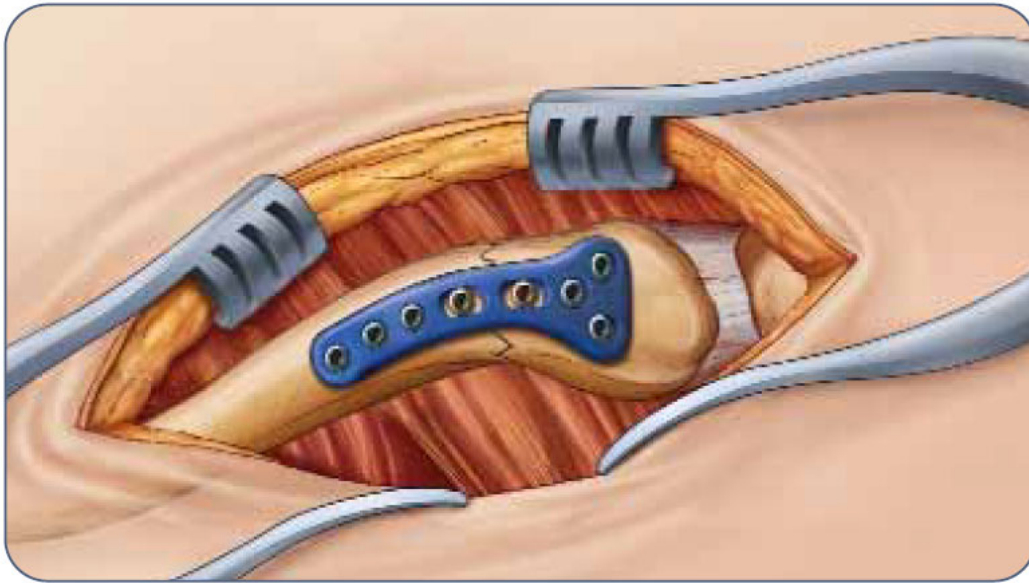
*C. Asserted Obviousness of Claims 1–20 Based on Clavicula, Hardy, and Thornes*

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; Pet. Reply 1–11. Patent Owner provides arguments specifically addressing this asserted ground. PO Resp. 49–60; PO Sur-reply 2–14. We first summarize aspects of the relied-upon prior art.

*1. Clavicula*

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:

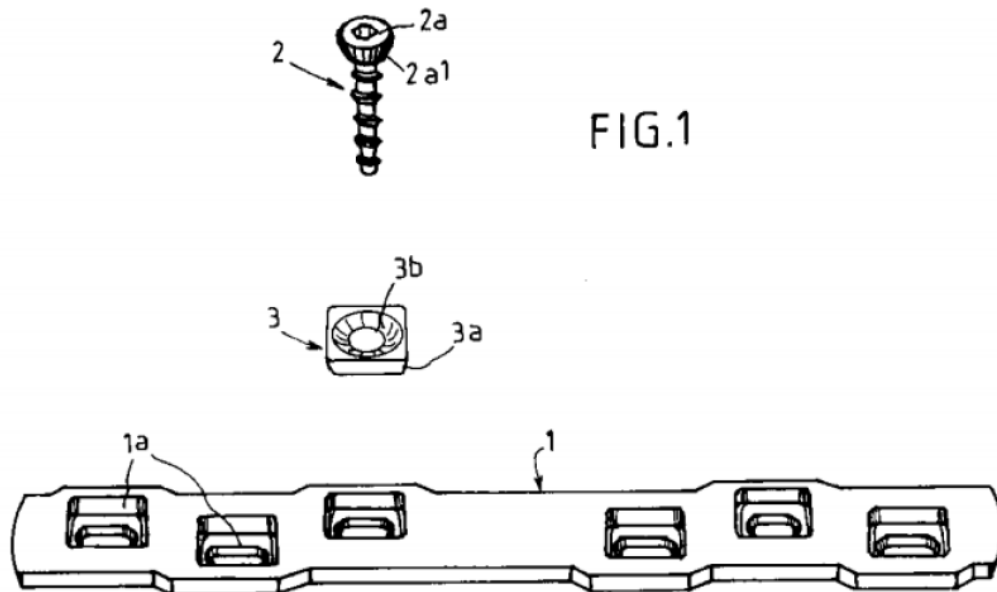


This picture depicts a pre-contoured plate fastened to a clavicle using several screws. Ex. 1009 at 3.

## 2. *Hardy*

Hardy discloses a self-compressive bone plate with washers that engage fasteners. Ex. 1006, codes (54) and (57), 2:19–3:1.<sup>9</sup>

Figure 1 of Hardy is reproduced below:



<sup>9</sup> In citations to Hardy, we (like the parties) refer to the native pagination at the top of each page of the English translation (Ex. 1006).

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:

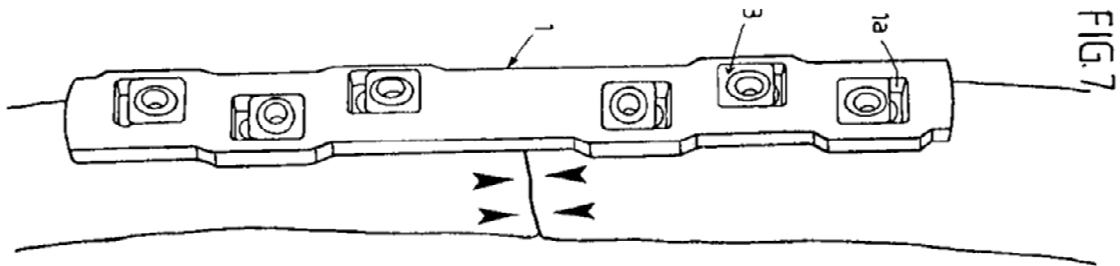


Figure 7 shows the placement of the disclosed plate and shows the reduction of the bone fracture (at the location of four black arrows). Ex. 1006, 3:13–16.

Figures 8 and 10 are reproduced below:

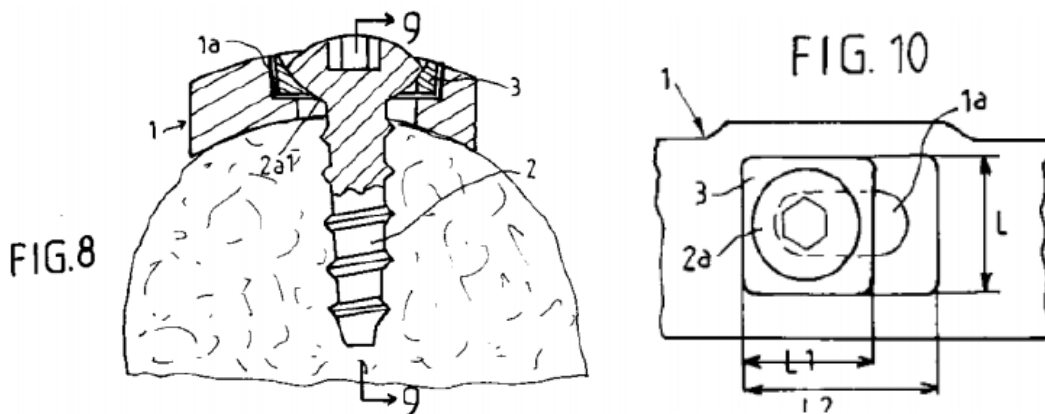
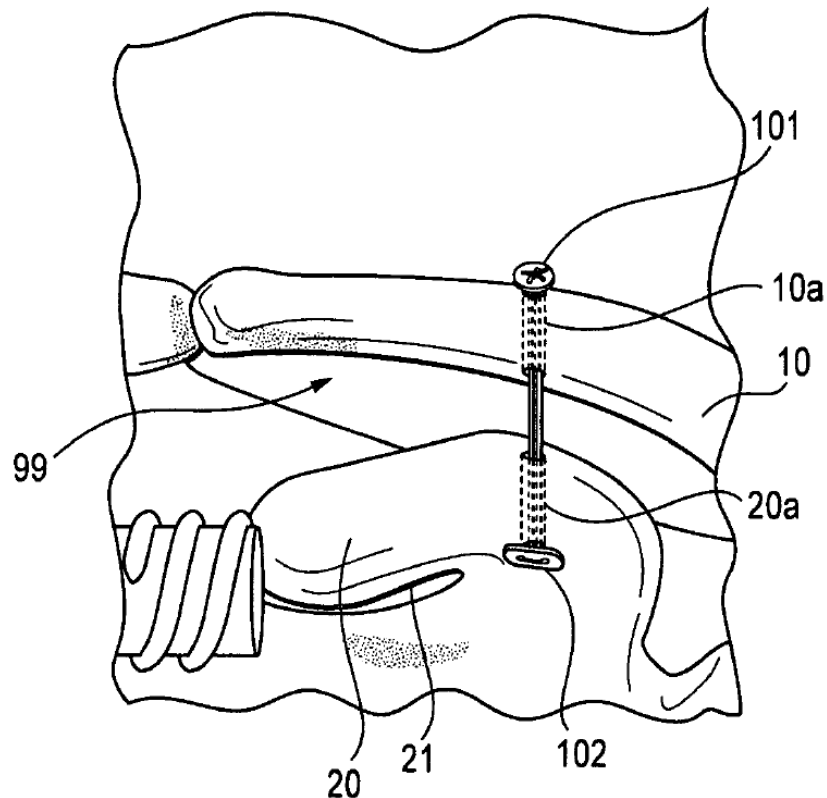


Figure 8 “is a large-scale, cross-sectional view showing the fastening of the plate,” and Figure 10 is a plan view of Figure 8. Ex. 1006, 3:17–18, 3:20. These figures show slidable washer 3 with screw 2 (and screw head 2a) inside orifice 1a in plate 1. *See id.* at 4:9–19.

### 3. *Thornes*

Thornes discloses “a joint or ligament reconstruction technique and associated fixation and reconstruction device.” Ex. 1007 ¶ 2.

Figure 7 of Thornes is reproduced below:



**FIG. 7**

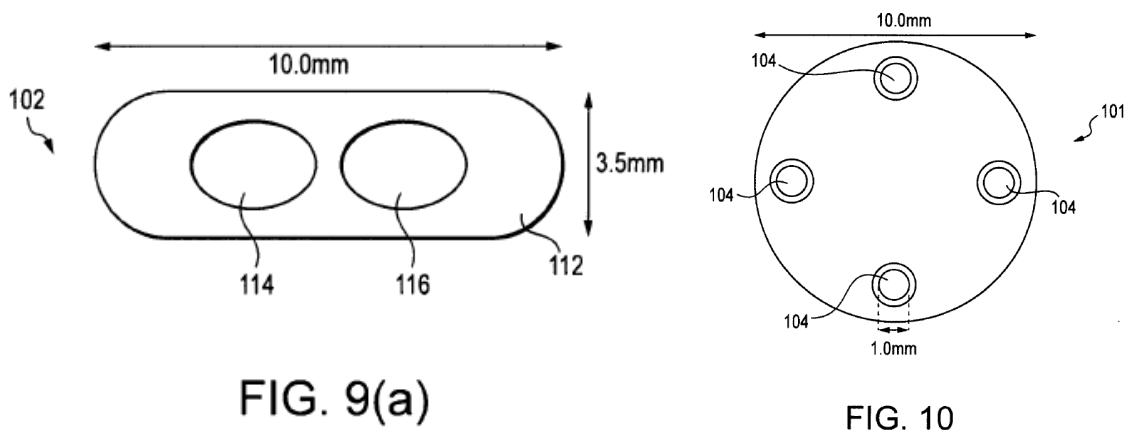
Figure 7 depicts one step in a method of joint reconstruction.<sup>10</sup> See Ex. 1007 ¶ 7. Specifically, the depicted process involves “an acromioclavicular (AC) joint 99 of the human shoulder comprising clavicle 10 and coracoid 20 and undergoing acromioclavicular (AC) joint

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<sup>10</sup> Thornes is a U.S. patent application publication, and its figures are unclear. See, e.g., Ex. 1007, Fig. 7. With that, like the parties, we use the clearer figures from U.S. Patent No. 9,005,245 B2 (Ex. 1023), which is the patent related to Thornes.

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 of Thornes are reproduced below:



Figures 9a and 10 depict 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.

#### 4. Independent Claim 1

Petitioner contends that the proposed combination of Clavicula, Hardy, and Thornes discloses each of the limitations of claim 1. 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 and argues that there would have been a reasonable expectation of success. Pet. 54–61. Patent Owner (1) challenges the articulated reasons to combine Clavicula, Hardy, and Thornes, (2) disputes whether there would have been a reasonable expectation of success in the combination, and (3) presents arguments as to objective indicia of nonobviousness. *See* PO. Resp. 49–60; PO Sur-reply 2–14, 19–22. We address in turn below the subject matter of each element in claim 1 (subsections a–f), then Petitioner’s identified reasons to combine the references and the reasonable expectation of success (subsection g), and then objective indicia (subsection h).

*a. Element 1.P*

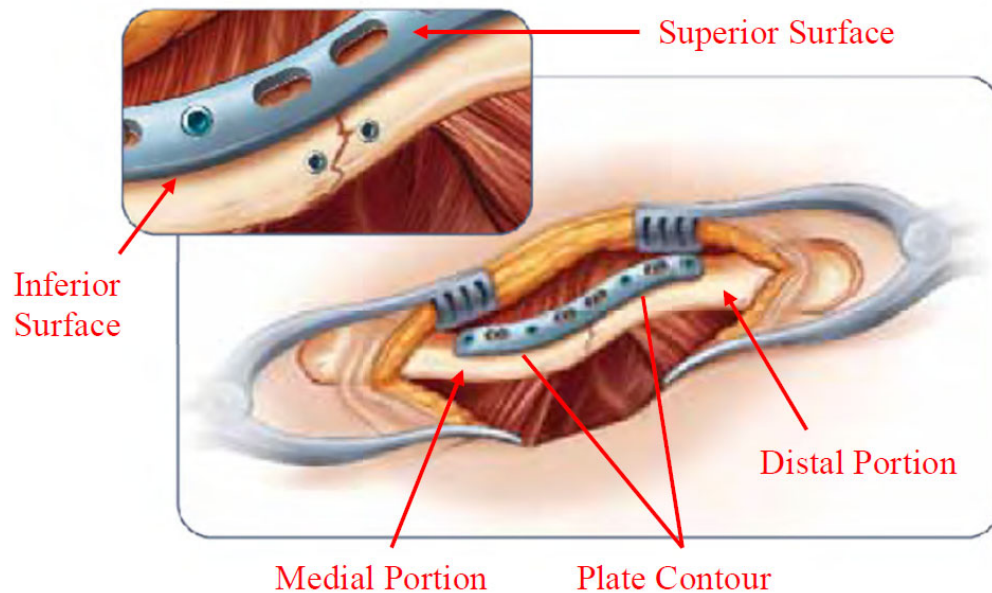
Element 1.P recites “[a] fixation system for a fractured clavicle, the fracture defining medial and distal portions of the clavicle relative to the fracture, the clavicle having a superior facing surface shape, the fixation system comprising.” Ex. 1001, 11:11–14. Petitioner states that, “[t]o the extent the preamble is limiting, Clavicula discloses” this element, before identifying certain disclosures in Clavicula. Pet. 61 (citing Ex. 1009, 2–4; McKee Decl. § IX.G.a (pages 90–91)). Patent Owner does not present arguments for this element. To the extent element 1.P is limiting, we find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Clavicula discloses this element.

*b. Element 1.1*

Element 1.1 recites “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 [sic]

clavicle medial portion and to extend at least partially over the clavicle distal portion when secured to the clavicle.” Ex. 1001, 11:15–20.

Petitioner provides a composite of two annotated versions of a figure from page 5 of *Clavicula*:



Pet. 63 (citing Ex. 1009 at 5; McKee Decl. § IX.G.b (pages 91–92)). In general, the figure from page 5 of *Clavicula* shows a transverse incision exposing a fractured clavicle. Ex. 1009 at 4–5. In one version of the figure—a closeup provided in the upper left of the composite—Petitioner added red lines identifying an “Inferior Surface” and a “Superior Surface.” Pet. 63. In the other version of the figure—a full view provided in the bottom right of the composite—Petitioner added red lines identifying a “Medial Portion,” a “Plate Contour,” and a “Distal Portion.” *Id.*

Petitioner also highlights teachings in *Clavicula* that allegedly satisfy the requirements of element 1.1, along with supporting testimony by Dr. McKee. *See* Pet. 62 (citing Ex. 1009 at 2, 3, 5, 6; McKee Decl. ¶¶ 130–131). Patent Owner does not present arguments for this limitation.

We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Clavicula discloses this element.

*c. Element 1.2*

Element 1.2 recites “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.” Ex. 1001, 11:20–23.

Petitioner provides an annotated version of a portion of a figure from page 3 of Clavicula:



Pet. 63 (citing Ex. 1009 at 3; McKee Decl. § IX.G.c (pages 92–95)). In general, the portion of the figure from page 3 of Clavicula above shows a clavicle plate. Ex. 1009 at 3. In the annotated version above, Petitioner added dashed red boxes around four oblong openings in the plate. Pet. 63. According to Petitioner, “[t]he openings in the Clavicula device are designed to allow passage of a 3.5 mm fastener” (Pet. 64 (citing Ex. 1009 at 6)), but

one of ordinary skill in the art would have recognized that “these openings would allow passage of a suture” (*id.* (citing McKee Decl. ¶ 132)).

Petitioner adds that “Clavicula discloses a suture utilizing the coracoid process to take stress off the lateral fixation, but does not disclose a specific suture” (Pet. 64 (citing Ex. 1009 at 7)), whereas “Thornes teaches a washer and anchor joined by a suture” (*id.* (citing Ex. 1007, code (57), ¶ 11)).

Referring implicitly to the Petition’s discussion of the proposed combination in the context of this asserted ground, Petitioner contends that one of ordinary skill in the art “would have been motivated to combine the Clavicula plate with the Thornes washer-suture system, because Thornes describes a simple, reproducible means of affixing the clavicle and coracoid.” *Id.* (citing McKee Decl. ¶ 135). Petitioner adds that one of ordinary skill in the art “would have found it obvious to pass the Thornes suture through at least one of the openings in the Clavicula plate because passing the suture through the plate was a more standard technique.” Pet. 64–65 (citing McKee Decl. ¶ 133).

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that Clavicula in view of Thornes discloses the subject matter of this limitation.<sup>11</sup> We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Clavicula in view of Thornes discloses the subject matter of element 1.2.

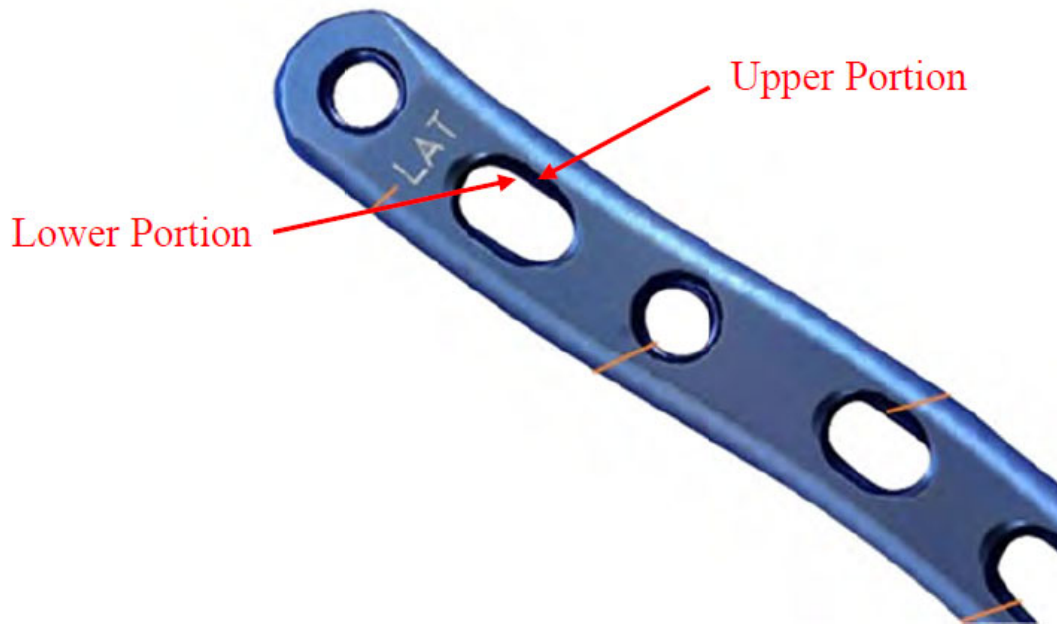
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<sup>11</sup> We address below Petitioner’s position that one of ordinary skill in the art would have modified Clavicula based on Hardy and Thornes, as proposed. *See* § II.C.4.g.

*d. Element 1.3*

Element 1.3 recites “the at least one first opening comprising a larger, upper portion and a smaller, lower portion.” Ex. 1001, 11:23–24.

Petitioner provides an annotated version of a portion of a figure from page 3 of Clavicula:



Pet. 66 (citing Ex. 1009 at 3). In general, the portion of the figure from page 3 of Clavicula shows part of a clavicle plate. Ex. 1009 at 3. In the annotated version above, Petitioner added red text and arrows to identify an “Upper Portion” and a “Lower Portion.” Pet. 66.

According to Petitioner, one of ordinary skill in the art would have understood that “the ‘plate/screw interface’ described in Clavicula is a product of the larger, upper portion and smaller, lower portion forming an interface on which the screw head is placed, which permits securement by the placement of screws.” Pet. 65 (citing McKee Decl. ¶ 136). Petitioner states that,

Whereas Clavicula describes a screw-plate interface formed by a larger, upper portion and a smaller, lower portion, Hardy further shows how this recessed hole allows the fixation device to be both flexibly positioned relative to the fracture, and also allows the profile of the fixation device to be minimized to prevent soft tissue irritation.

Pet. 66 (citing Ex. 1009 at 2; McKee Decl. ¶ 136). Dr. McKee testifies in a cited paragraph in his Declaration that one of ordinary skill in the art would have been motivated to use oblong openings like in Clavicula and Hardy “to minimize the profile of the fastener or screw above the plate which in turn helps decrease soft tissue irritation (especially in an area with thin soft tissue such as the clavicle).” McKee Decl. ¶ 136, *cited at* Pet. 65–66.

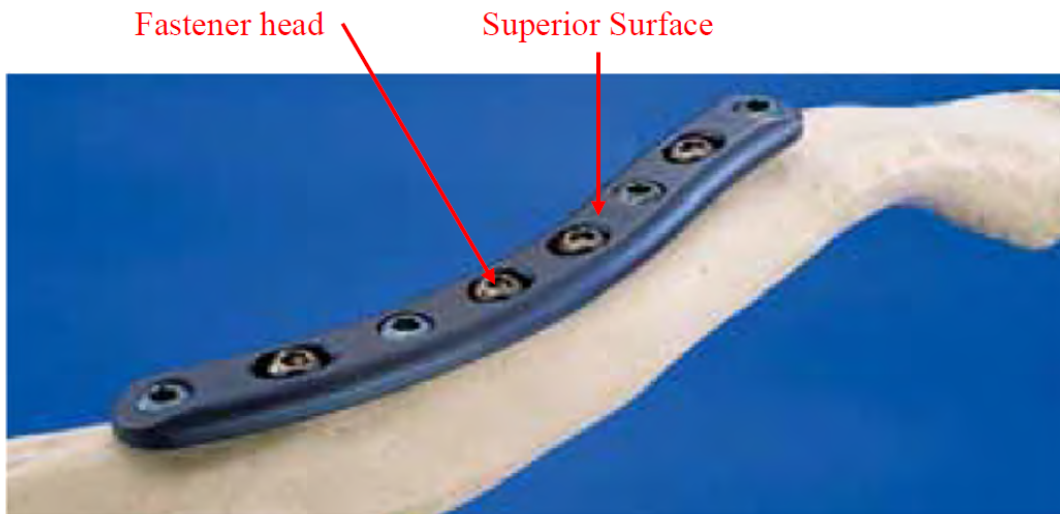
The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that Clavicula in view of Hardy discloses the subject matter of this limitation. We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Clavicula in view of Hardy discloses the subject matter of element 1.3.

*e. Element 1.4*

Element 1.4 recites “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.” Ex. 1001, 11:25–27.

Petitioner states that “Clavicula describes a plate with oblong openings extending in the direction of the length of the plate and round-headed fastener screws configured to fit within the oblong opening” (Pet. 66

(citing Ex. 1009 at 5–6; McKee Decl. § IX.G.e (pages 98–102)), with Petitioner providing this annotated figure from page 3 of Clavicula:



Pet 67 (citing Ex. 1009 at 3<sup>12</sup>). In general, the figure from page 3 of Clavicula shows a clavicle plate. Ex. 1009 at 3. In the annotated version above, Petitioner added red text and arrows to identify a “Fastener Head” and a “Superior Surface.” Pet. 67.

Petitioner then adds that “Thornes discloses a circular washer that can be positioned adjacent to the superior surface of the clavicle” (Pet. 67 (citing

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<sup>12</sup> Petitioner cites page 6 of Clavicula, but the figure is on page 3.

Ex. 1007 ¶¶ 14, 18, Figs. 9, 10)), with Petitioner providing this annotated version of Figure 7 from Thornes:

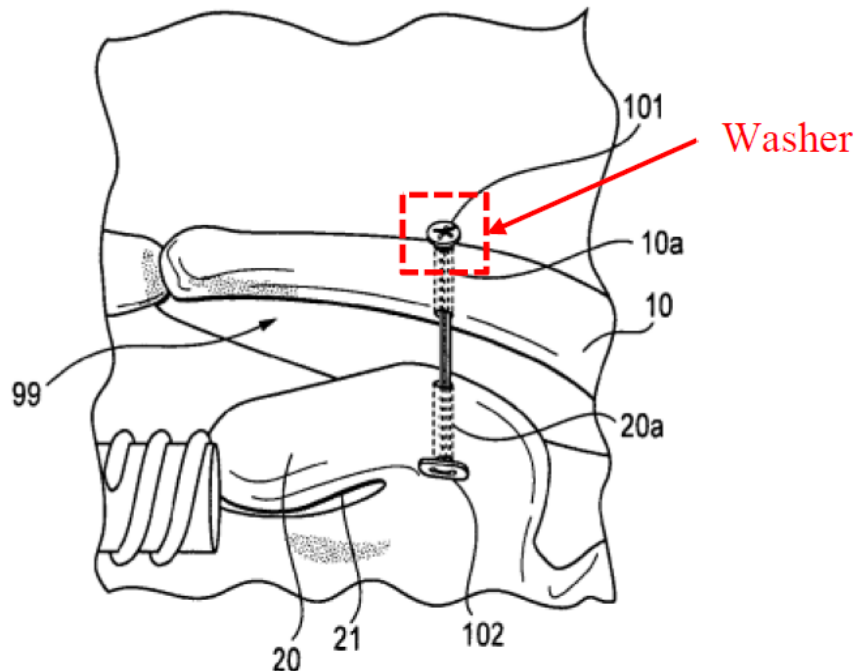


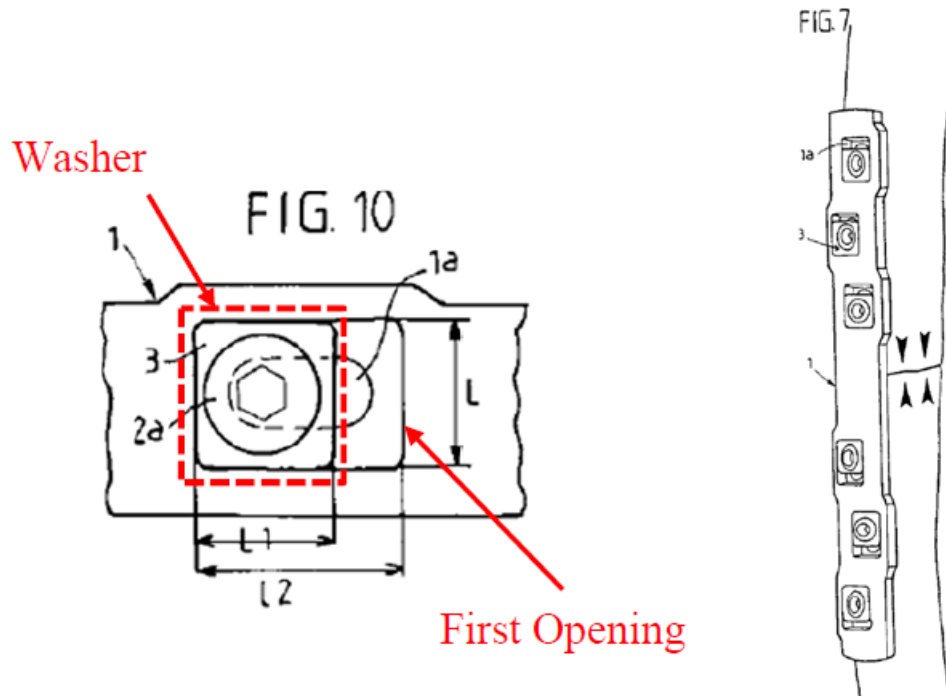
FIG. 7

Pet. 68 (citing Ex. 1007, Fig. 7). In general, Figure 7 of Thornes depicts one step in a method of joint reconstruction. *See* Ex. 1007 ¶ 7. In the annotated version above, Petitioner added a red dashed box, red text, and an arrow to identify a “Washer.” Pet. 68.

Petitioner states that “[t]o the extent that a washer positioned adjacent to the superior surface of the plate and configured to fit within the first opening would not have been obvious in view of Clavicula and Thornes, Hardy discloses a washer with these characteristics.” Pet. 68 (citing Ex. 1006, 3:2–5, 4:6–14, 4:20–24). Petitioner provides this composite



image with an annotated version of Figure 10 from Hardy alongside Figure 7 of Hardy:



Pet. 69 (citing Ex. 1006, Figs. 7, 10). Figure 10 of Hardy is a plan view of Figure 8, which “is a large-scale, cross-sectional view showing the fastening of the plate” (Ex. 1006, 3:17–18, 3:20), and Figure 7 shows the placement of the disclosed plate and the reduction of the bone fracture (at the location of four black arrows) (*id.* at 3:13–16). In the annotated version of Figure 10 above, Petitioner added (1) a red dashed box, red text, and an arrow to identify a “Washer” and (2) red text and a red arrow identifying a “First Opening.” Pet. 69. Petitioner contends that these Figures “depict washers 3 positioned adjacent to the superior surface of the plate 1 and configured to fit within the first opening.” Pet. 68.

According to Petitioner, one of ordinary skill in the art (1) “would have found it obvious to combine the recessed washer and plate system of

Hardy with the oblong openings in the Clavicula plate to produce a low-profile implant to minimize soft tissue irritation and improve patient outcomes” and (2) would further have recognized that “the Thornes washer-suture system could be simply substituted for the Hardy recessed washer to recognize the benefit of Thornes’ ‘simple, reproducible, minimally invasive’ means of taking stress off of the lateral fixation of the Clavicula plate, while maintaining a low profile.” Pet. 69 (citing Ex. 1007 ¶ 15; Ex. 1006, 4:9–17; McKee Decl. ¶ 138).

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that Clavicula in view of Hardy and Thornes discloses the subject matter of this limitation.<sup>13</sup> We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Clavicula in view of Hardy and Thornes discloses the subject matter of element 1.4.

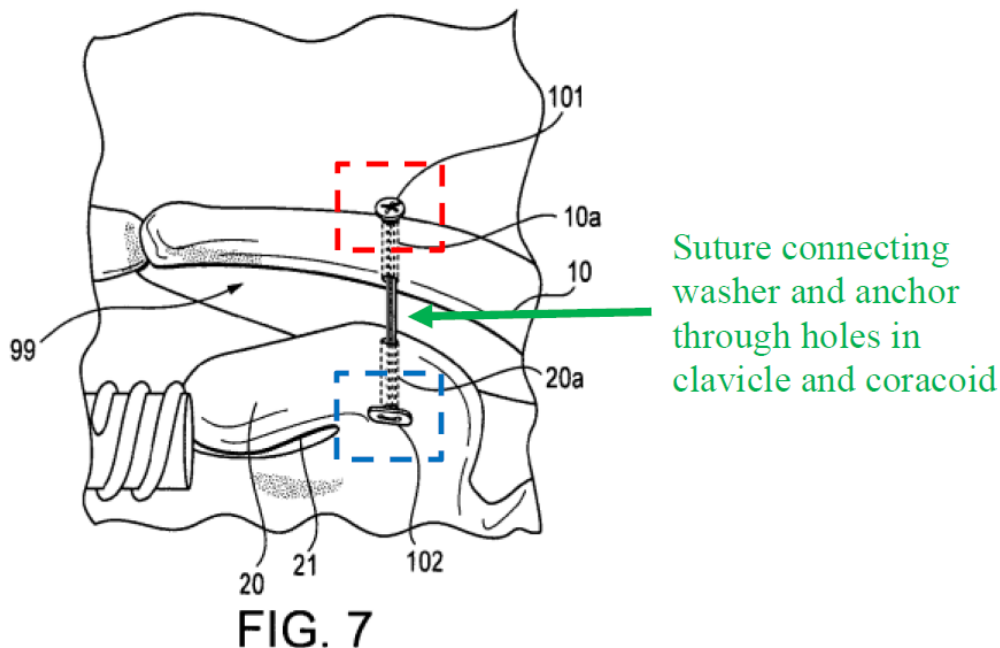
*f. Element 1.5*

Element 1.5 recites “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, 11:28–31.

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<sup>13</sup> During the oral hearing, counsel for Patent Owner alleged to have argued that element 1.4 is lacking from at least one of the asserted grounds, but did not identify the location of any related argument in the briefing, despite having an opportunity. See Tr. 31:15–32:18 (counsel for Patent Owner discussing providing during rebuttal a citation in the briefing for its alleged argument regarding element 1.4), 47:6–49:15 (counsel for Patent Owner not addressing this issue in rebuttal).

Petitioner states that “Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture.” Pet. 69 (citing Ex. 1009 at 7; McKee Decl. ¶ 139). Thornes, however, according to Petitioner, teaches “a washer and anchor joined by a suture” (Pet. 70 (citing Ex. 1007, code (57), ¶ 11)), with Figure 7 of Thornes specifically showing a “washer (101) and anchor (102) connected by suture passing through a hole in the clavicle and coracoid process” (*id.*), as shown in this annotated version of Figure 7 of Thornes:



Pet. 70 (citing Ex. 1007, Fig. 7). In general, Figure 7 of Thornes depicts one step in a method of joint reconstruction. See Ex. 1007 ¶ 7. In the annotated version above, Petitioner added a red dashed box around button 101, a blue dashed box around button 102, and a green arrow and green text identifying a “Suture connecting washer and anchor through holes in clavicle and coracoid.” Pet. 70.

According to Petitioner, one of ordinary skill in the art (1) would have recognized that “Thornes’ ‘simple, reproducible, minimally invasive technique for acute acromioclavicular joint stabilization’ would provide an optimal means of taking the stress off of the fixation because it significantly improves the mechanical strength of the construct and helps prevent the inferior displacement of the distal clavicular fracture fragment” and (2) would further have understood that “securing the clavicle to the coracoid as taught by Thornes would minimize the invasive nature of the reduction as it reduces the amount of tissue dissection necessary to secure the washer to the coracoid process.” Pet. 70–71 (citing Ex. 1007 ¶¶ 14, 15; McKee Decl. ¶¶ 139–140).

The record evidence, summarized above, supports Petitioner’s position as to this limitation. Patent Owner does not dispute that Clavicula in view of Hardy and Thornes discloses the subject matter of this limitation. We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Clavicula in view of Hardy and Thornes discloses the subject matter of element 1.5.

*g. The Proposed Combination of Clavicula, Hardy, and Thornes*

Having discussed the subject matter of each element of independent claim 1, we turn now to the Petitioner’s proposed combination of Clavicula, Hardy, and Thornes. First, we summarize the proposed combination, and then we turn to the arguments addressing that proposed combination.

*(1) Summary of the Proposed Combination*

In general, Petitioner proposes combining Clavicula’s clavicle plate with Thornes’s washer and suture, wherein Clavicula’s plate is modified—based on the teachings of Hardy—to have recessed openings, with larger,

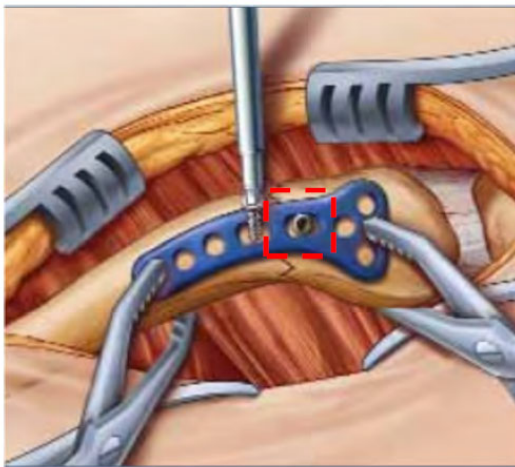
upper portions and smaller lower portions, to receive Thornes's washer. *See* Pet. 54–61 (citing McKee Decl. ¶¶ 113–128); *see also* Pet. 56 (stating that one of ordinary skill in the art “would have found it obvious to combine the contoured Clavicula plate, the Thornes washer-suture system, and the shouldered plate and washer of Hardy” (citing McKee Decl. ¶ 117)).

More specifically, Petitioner first discusses the suture, stating that Clavicula discloses that “‘sutures may be passed from medial to lateral around the coracoid process and the plate to take stress off of the lateral fixation,’ but does not disclose a specific suture.” Pet. 56 (quoting Ex. 1009 at 7). According to Petitioner, because “[o]ptimal suture technique is important,” one of ordinary skill in the art would have been “motivated to look to prior art that discloses sutures for use with the clavicle and/or coracoid process” and would have turned to Thornes, which “teaches a suture system that provides a ‘simple, reproducible, minimally invasive technique’ for stabilizing the clavicle and coracoid process.” *Id.* (quoting Ex. 1007 ¶ 15; citing McKee Decl. ¶¶ 118–119). Petitioner contends that one of ordinary skill in the art would have been “motivated to combine Clavicula with Thornes to provide a simple, reproducible means of taking stress off the lateral fixation of the plate, which prevents subsequent fracture or joint displacement.” Pet. 56–57 (citing McKee Decl. ¶ 119).

Turning to modifying the openings in Clavicula's plate based on Hardy, Petitioner states that Clavicula “discloses a plate with oblong openings having a shoulder for receiving a fastener, but does not disclose a washer” and states that “Hardy discloses a plate with oblong openings recessed to receive a washer.” Pet. 57 (citing Ex. 1009 at 3 (figures)); Ex. 1006, 2:14–3:5, 5:1–3, Figs. 1, 2, 6, 7, 10). According to Petitioner, one

of ordinary skill in the art (1) “would have been motivated to include an opening with a larger, upper portion and a smaller, lower portion to receive a washer, thus minimizing tissue irritation by reducing the profile of the implant, which reduces reoperation rates for subsequent hardware removal” and (2) “would have been motivated to make the opening oblong to permit adjustable positioning of the suture.” *Id.* (citing McKee Decl. ¶ 121).

As to the washer, Petitioner states that “Thornes teaches a washer and anchor joined by a suture for use with the clavicle and coracoid process, the washer taking any number of configurations, including circular or oblong.” Pet. 58 (citing Ex. 1007, code (57), ¶¶ 11, 15, Figs. 6–10). Petitioner adds that “Thornes discloses a round washer with a similar geometry to the round fastener heads positioned in the oblong opening of the Clavícula plate, as shown in the demonstrative figure below”:



Ex. 1009, Fig. at 6

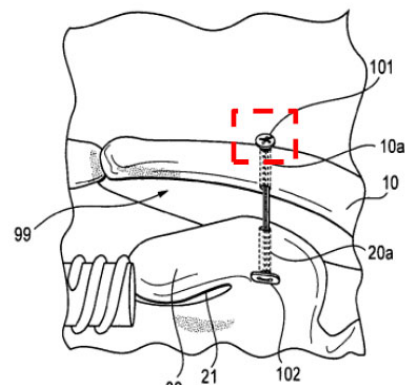


FIG. 7

Ex. 1007, Fig. 7



Pet. 58–59 (citing McKee Decl. ¶ 123). In the composite illustration above, Petitioner includes (1) an annotated version of a figure from page 6 of Clavicula (which shows an exposed human clavicle during a procedure) with a red dotted box around a screw in the clavicle, (2) an annotated version of Figure 7 of Thornes (which depicts one step in a method of joint reconstruction) with a red dotted box around washer 101, and (3) a composite drawing showing a light green racetrack shape with blue internal shading identified as “Clavicula opening” with an excerpted version of washer 101 shown in Figure 10 of Thornes (without reference numerals), identified as “Thornes washer” inside the racetrack shape. Pet. 59 (citing McKee Decl. ¶ 123).

As to the overall configuration of the proposed combination, Petitioner states that one of ordinary skill in the art would have recognized:

that by incorporating an oblong hole (as Hardy teaches), the plate could be secured to the clavicle (as taught by Clavicula) leaving the oblong hole open and allowing the treating physician to locate the optimal location for the washer-suture placement, drill through the plate at the location, and install the washer-suture system (as taught by Thornes).

Pet. 59 (citing McKee Decl. ¶ 124). This configuration, asserts Petitioner, “would significantly improve biomechanical strength to the fixation and minimize the risk of loss of reduction.” *Id.* (citing McKee Decl. ¶ 124).

According to Petitioner, one of ordinary skill in the art would have recognized “the application of Thornes’[s] technique to Clavicula would predictably improve the strength of the overall fixation because it was a known technique to secure the clavicle to the coracoid process with suture to stabilize the acromioclavicular joint.” Pet. 60 (citing McKee Decl. ¶ 126).

Petitioner states that 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). Petitioner adds that one of ordinary skill in the art “would have had a reasonable expectation of success in combining the plate features of Clavicula and Hardy with the Thornes washer-suture system for fixing the clavicle and coracoid process.” Pet. 58 (citing McKee Decl. ¶ 123); *see also* Pet. 61 (“Any slight modification necessary to permit combination of the Thornes washer and the Clavicula plate would have been well within the skill of a POSITA.” (citing McKee Decl. ¶ 123)), 60–61 (further discussing reasonable expectation of success and analogous art (citing McKee Decl. ¶¶ 125–128)).

*(2) Arguments Addressing the Proposed Combination*

Patent Owner presents several arguments regarding the proposed combination of Clavicula, Hardy, and Thornes, which we address below. *See* PO Resp. 49–55; PO Sur-reply 2–4, 6–11, 12–14.

First, Patent Owner highlights this sentence from the McKee Declaration addressing why Clavicula and Thornes are combinable: “Thornes does not disclose the washer interacting with a plate, however it is my opinion that a POSITA would *immediately have recognized* that the washer could fit in any standard opening or slot in a plate *without modification*.” PO Resp. 50 (quoting McKee Decl. ¶ 115).<sup>14</sup> Patent

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<sup>14</sup> Patent Owner misquotes the McKee Declaration slightly, but not in a way that changes the meaning. We provide the correct quotation here.



Owner’s declarant, Dr. Thal, responds, “[i]f it was so obvious then why did the prior art not disclose placement of a washer in any standard opening or slot?” Thal Decl. ¶ 92, *quoted at* PO Resp. 50. With this argument, neither Patent Owner nor Dr. Thal addresses the actual basis of the ground at issue here: *obviousness* based on *the combination* of Clavicula, Hardy, and Thornes. As discussed above (*see* § II.C.4.e), Petitioner does not rely on *a single* prior art reference as to element 1.4 (reciting “a washer configured to . . .”), but rather relies on either (1) the combination of Clavicula and Thornes, or (2) the combination of Clavicula, Hardy, and Thornes. *See* Pet. 66–69; *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) (“A finding of obviousness, however, cannot be overcome ‘by attacking references individually where the rejection is based upon the teachings of a combination of references.’” (quoting *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986))).

Second, Patent Owner argues that a 2007 article titled “Acromioclavicular Joint Reduction, Repair and Reconstruction Using Metallic Buttons—Early Results and Complications” by Yeow Wai Lim et. al (Ex. 2014, “the Lim article”)<sup>15</sup> would have demonstrated to one of ordinary skill in the art that the proposed combination of Clavicula, Hardy, and Thornes would not have had a reasonable expectation of success. *See* PO Resp. 50–55; PO Sur-reply 2–4, 6–11, 12–14. Petitioner contests this argument, asserting that the Lim article in fact supports obviousness. *See*

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<sup>15</sup> In citations to the Lim article (Ex. 2014), we (like the parties) refer to the native pagination at the bottom of the last nine pages (i.e., page numbers 213–221).

Pet. Reply 1–4, 5–8, 9–11. For the reasons below, the record does not support Patent Owner’s position.

As background, the Lim article reports on the use of a “new technique to reduce and maintain reduction of the coracoclavicular interval using a low-profile double-metallic button technique (Tightrope; Arthrex Inc., Naples, Fla)” (Ex. 2014 at 213), using the suture device disclosed in Thornes. *See* PO Resp. 52 (arguing that the Tightrope suture is disclosed in Thornes); Tr. 9:25–10:1 (Petitioner acknowledging that the Lim article involves the Tightrope suture). In the Response, Patent Owner summarizes the patient pool and procedures from the Lim article:

The device the authors used was a No. 5 Fibrewire sutured “that is tensioned and secured at both ends by metallic buttons against the cortices of the clavicle and the coracoid.” [Thal Decl. ¶ 62 (citing Ex. 2014 at 213)]. The authors used the device in eight patients—one Grade 5 ACJ dislocation, one Grade 4 ACJ dislocation, one Grade 3 ACJ dislocation, and four lateral clavicle fractures. Of the four fractures, two patients underwent open reduction and internal fixation (ORIF) using a plate in addition to Tightrope fixation. In the other two fracture cases, the lateral end of the clavicle was excised. *Id.*, (citing Ex. 2014, 218).

PO Resp. 33. The Lim article reports a “50% fixation failure rate”—i.e., four of the eight total patients—which includes two fixation failures by the two patients who received clavicle plating. *See* Ex. 2014 at 219 (“Overall, there was a 50% fixation failure rate when Tightrope fixation was used in primary procedures. . . . Both patients who underwent clavicle plating in addition to the Tightrope fixation had failure of fixation.”).

The parties agree that the Lim article, at least for two of the eight patients, involves a clavicle plate (as disclosed in Clavicula) and the Tightrope suture device (as disclosed in Thornes) to perform clavicle

fracture fixation. *See* PO Resp. 52 (stating that “the closest anyone came to that precise combination was Lim, which failed despite the fact that it used an actual clavicle plate (like Clavícula) and the actual Tightrope system described in Thornes”) (citing Thal Decl. ¶ 96; Ex. 2014 at 214); Pet. Reply 5 (acknowledging that “Lim describes a combination of an Acumed clavicle plate with Arthrex’s TightRope® for distal clavicle fracture fixation”).

Petitioner argues that the Lim article would not have dissuaded one of ordinary skill in the art from the proposed combination because the Lim article had only a small patient pool. Pet. Reply 6. As noted above, the Lim article involved eight patients total, and only two of the eight had a clavicle plate as part of their procedures. *See* Ex. 2014. We are persuaded by Petitioner that one of ordinary skill in the art would not have drawn a strong conclusion from the “failures” in a study like the Lim article with such a small patient pool. *See* Pet. Reply 6. This conclusion is supported by the deposition testimony of Dr. Thal, highlighted by Petitioner, in which he is hesitant to draw any “firm conclusions” from studies with less than ten patients. *See* Ex. 1033, 96:6–97:20, *cited at* Pet. Reply 6; *see also* Ex. 1033, 130:7–9 (discussing how the Lim article was not “conclusive evidence that it wasn’t successful”), 132:3–14 (discussing how, with “two patients” “[i]t’s hard to draw, to make a conclusion”), 97:21–98:14 (discussing how a study with failure for four patients would not lead to a conclusion that the technique used was “a failure itself”). In the Sur-reply, Patent Owner does not seek to reframe Dr. Thal’s testimony in any way, but rather argues that if the Lim article should not be relied upon due to its small patient pool, Petitioner should not be able to rely on Exhibits 1025 through 1028, which allegedly involve similarly small patient pools. *See* PO Sur-reply 7.

Although no motion to exclude is pending, we note that we do not rely on Exhibits 1025 through 1028 in this Decision. Based on the small patient pool in the Lim article, we are persuaded that one of ordinary skill in the art would not have viewed the Lim article as dissuading one of ordinary skill in the art from the proposed combination.

Next, Petitioner argues that the Lim article would not have dissuaded one of ordinary skill in the art from the proposed combination because the proposed combination adds *an additional feature*, based on Hardy, which represents an improvement over the process of the Lim article: a recessed washer at the top of the suture. *See* Pet. Reply 5 (“Each ground of the Petition differs from the device in Lim in that they include a recessed washer at the top of the suture construct that is set into the plate, wherein Lim teaches use of ‘the superior metallic button . . . positioned and secured over a hole’ on top of the plate.”) (quoting Ex. 2014 at 217)). According to Petitioner, using a recessed washer would reduce irritation and the chance of complications. *See id.* at 5–6 (citing McKee Decl. ¶ 106; Ex. 1033, 71:22–72:14; Ex. 1034, 28:18–29:3).

Patent Owner does not address this issue in the Sur-reply, except to argue that a recessed washer (as recited in limitation 1.4<sup>16</sup>) is “critical” to the “success” of his invention as it “was key to ‘reduce potential tissue damage and irritation and promote proper healing.’” *See* PO Sur-reply 3–4 (quoting McKee Decl. ¶ 106). Patent Owner highlights that the Lim article describes the TightRope as “relatively low profile” (PO Sur-reply 7 (quoting Ex. 2014

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<sup>16</sup> Like the parties, we use the term “recessed washer” as shorthand for the claim phrase “a washer configured to fit within the at least one first opening” of the clavicle plate. *See* PO Sur-reply 3; Pet. Reply 5.

at 213)), but Patent Owner does not argue that a recessed washer is present in the Lim article device or is not present in the proposed combination.

We are persuaded by the testimony of Dr. McKee (McKee Decl. ¶ 106)—quoted and relied upon by the Patent Owner for this issue (PO Sur-reply 3–4)—that a recessed washer such as that taught in Hardy, and present in the proposed combination, would provide the benefits stated and would thus represent an improvement over the procedures in the Lim article. *See* McKee Decl. ¶¶ 106, 122 (providing similar reasoning for this proposed ground), *cited at* Pet. 58. Accordingly, we agree with Petitioner that the added feature of the recessed washers in the proposed combination—not present in the Lim article device—weakens Patent Owner’s argument that the Lim article would have dissuaded one of ordinary skill in the art from the proposed combination.

Further, Petitioner points out that, although the Lim article did have a “50% fixation failure rate” (Ex. 2014 at 219), the authors stated that the “concept of this fixation technique is good” and that there are “many attractive potential advantages of using the Tightrope system.” Ex. 2014 at 220, *quoted at* Pet. Reply 6–7. Indeed, the final takeaway from the Lim article is that “further biomechanical analysis of this fixation device is required to evaluate and address the potential cause” of its failures. Ex. 2014 at 220. We are persuaded by Petitioner’s view that the Lim article—which purports to be the first article reporting on the use of “Tightrope fixation in [AC joint] dislocations” (*id.*)—included certain failures but would, in totality, be viewed as indicating the potential for future development rather than a sign that the disclosed technique should be jettisoned in its entirety. *See* Pet Reply 6–8. Directly supporting this

conclusion, Dr. Thal testifies that the Lim article “tells us that there is room for further innovation to get a more predictable result in treatment of this challenging problem.” Ex. 1033, 135:22–136:4, *quoted at* Pet. Reply 7, 10–11. For these reasons, the record does not support Patent Owner’s argument that the Lim article would have dissuaded one of ordinary skill in the art from the proposed combination because there would not have been a reasonable expectation of success.

Third, after summarizing a portion of Petitioner’s reasons to combine Clavicula, Hardy, and Thornes, Patent Owner argues that “[t]his combination is obvious only in hindsight and only after it was disclosed by Dr. Gelfand, who described for the first time in one place” certain alleged requirements of the claimed invention. PO Resp. 51–52 (citing Thal Decl. ¶ 95). For the reasons discussed above, however, the record does not support Patent Owner’s argument that the Lim article shows there would not have been a reasonable expectation of success in the proposed combination. Moreover, we determine that the record, including the testimony of Dr. McKee, supports the motivation to combine Clavicula, Hardy, and Thornes as proposed by Petitioner and that there would have been a reasonable expectation of success in that combination. *See* Pet. 54–61 (citing McKee Decl. ¶¶ 113–128). Thus, we do not agree with Patent Owner’s generalized assertion of “hindsight.” PO Resp. 51; *see In re Cree, Inc.*, 818 F.3d 694, 702 n.3 (Fed. Cir. 2016) (viewing an “impermissible hindsight” argument as “essentially a repackaging of the argument that there was insufficient evidence of a motivation to combine the references”). Further, as discussed in the context of the first argument above, that Dr. Gelfand may have “described for the first time in one place” the claimed invention does not

necessarily undermine a ground based on obviousness. *See Bradium Techs.*, 923 F.3d at 1050.

For the reasons above, we determine, in light of the complete record, that Petitioner has shown by a preponderance of the evidence that one of ordinary skill in the art at the time of the invention would have had reason to combine Clavicula, Hardy, and Thornes, as proposed, and that there would have been a reasonable expectation of success in the combination.

*h. Objective Indicia of Nonobviousness*

We next turn to Patent Owner’s objective evidence of nonobviousness and Petitioner’s rebuttal evidence. Objective evidence of nonobviousness, when present, must be considered as part of an obviousness inquiry.

*Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that one or more of the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984).

“In order to accord substantial weight to secondary considerations in an obviousness analysis, ‘the evidence of secondary considerations must have a “nexus” to the claims, *i.e.*, there must be “a legally and factually sufficient connection” between the evidence and the patented invention.’”

*Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019)). Applying *Fox Factory*, the Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence of

nonobviousness. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 33 (PTAB Jan. 24, 2020) (precedential). We first consider whether a patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* If not, that does not end the inquiry; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* (quoting *Fox Factory*, 944 F.3d at 1373–75).

The parties address Patent Owner’s arguments that the record allegedly demonstrates long-felt but unsolved need, copying, licensing, and industry praise, and address Petitioner’s argument that the record allegedly shows simultaneous invention. PO Resp. 55–60; Pet. Reply 19–25; PO Sur-reply 19–22. We address each of these, in turn, below.

“The patentee bears the burden of showing that a nexus exists.” *Fox Factory*, 944 F.3d at 1373 (quoting *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). Like Patent Owner, we will address nexus in the context of each of the asserted objective indicia of nonobviousness below. *See, e.g.*, PO Resp. 55–60 (discussing nexus in each of the three sections of briefing addressing objective indicia).

*(1) Long-felt but Unsolved Need*

Evidence of a long-felt but unsolved need tends to show nonobviousness “because it is reasonable to infer the need would not have persisted had the solution been obvious.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016) (en banc). Establishing long-felt but unsolved need requires evidence that a recognized problem existed in the art



for a long period of time without solution (*Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988)) and requires that the claimed invention satisfies the long-felt need (*Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988)). Moreover, the alleged long-felt need must not have been satisfied by another before the claimed invention. *See Newell*, 864 F.2d at 768 (“[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved . . .”).

Patent Owner argues that the record shows that the location of distal clavicle fractures prevented the use of traditional surgical plates for repair. *See* PO Resp. 56 (citing Ex. 2055 at 1052<sup>17</sup>; Gelfand Decl. ¶ 7). In addition, Patent Owner argues that the “operative standards at the time of the invention” had complications, and thus “there was a long felt need to develop treatment of a distal fracture of a clavicle with reduced issues of complications.” *Id.* (citing Thal Decl. ¶¶ 45, 101; Gelfand Decl. ¶¶ 6–8); *see also* PO Sur-reply 19 (providing additional evidence of a long-felt unsolved need existing). Petitioner does not dispute that, at the time of the invention at issue here, the art recognized a need to solve the problem of distal clavicle fractures. *See* Pet. Reply 19–25.

Patent Owner also asserts that the invention claimed in the ’312 patent satisfied this alleged long-felt need, or, as stated by Patent Owner, “there is a nexus between the invention of the ’312 patent and that it was the solution to this problem.” PO Resp. 56–57 (citing Ex. 1011, 125; Thal Decl. ¶ 102; Gelfand Decl. ¶¶ 10, 16, 17). Petitioner argues that the record does not support Patent Owner’s position that the claimed invention solves the

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<sup>17</sup> In citations to the Klein article (Ex. 2055), we (like the parties) refer to the native pagination at the top of each page.

alleged long-felt need. *See* Pet. Reply 19 (arguing that “Patent Owner has no support for its suggestion that its invention addresses a long felt need in the industry”). To provide context and clarity for the discussion on this issue, we state as an initial matter that Patent Owner relies *only* on products produced by other entities (including the two Petitioner entities, Acumed and Arthrex) that allegedly practice the invention claimed in the ’312 patent; Patent Owner does not argue that *any* of his products satisfied the alleged long-felt need. *See* Sur-reply 20 (Patent Owner discussing his company, Suspension Orthopedic Solutions, and its efforts to bring a product to market). With that clarification, for the reasons below, we agree with Petitioner that the record *does not* show that the claimed invention satisfied the alleged long-felt need.

As to whether the invention claimed in the ’312 patent satisfied the alleged long-felt need, Patent Owner provides two statements, with Patent Owner first stating, “since the widespread propagation of [the] invention, studies have shown that the suture system provided a repair rate of over 90% while keeping complication rates well below 6.25%.” PO Resp. 56 (citing Ex. 1011, 125; Thal Decl. ¶ 102; Gelfand Decl. ¶ 10). The cited evidence does not support this first statement. Exhibit 1011 is the prosecution history of the U.S. Patent Application No. 13/613,349, which issued as the ’312 patent. Cited page 125 in that Exhibit is internal page 8 of a Reply and Amendment filed by Patent Owner on November 14, 2014. *See* Ex. 1011, 125. In the relevant discussion, applicant (Patent Owner) argued that “[i]n his Declaration Dr. Gelfand testifies that the presently claimed invention satisfies a long-felt need in the art for a system that permits surgical repair of distal clavicle fractures without the complications associated with prior art

plates.” *Id.* As we stated in the Decision on Institution, however, “the alleged declaration by the applicant addressing long-felt but unresolved need . . . [is] *not in the record* in this proceeding (and do[es] not appear to be present even in the file history of the ’312 patent (Ex. 1011)).” Dec. Inst. 34. This issue was not addressed during trial as the declaration at issue is still not in the record. Moreover, the sole independent claim was amended again *after* the Amendment on November 14, 2014, thereby changing the claimed invention at issue in the analysis. *See* Ex. 1011, 171 (showing amendments to the sole independent claim in a Reply and Amendment dated April 22, 2015).

The second citation allegedly supporting Patent Owner’s first statement—paragraph 102 of the Thal Declaration (reproduced below)—also does not support Patent Owner:

Dr. Gelfand’s invention has since seen widespread acceptance in the field, with union rates of over 90% with correspondingly minimal complication rates (< 6.25%). Ex. 2055, 1053. I am also familiar with and have used in my practice both with Acumed’s Acu-Sinch Repair System and Arthrex’s Clavicle Plate and Screw System with TightRope, both of which are shown below. I understand these to be embodiments of Dr. Gelfand’s invention described and claimed in the ’312 patent.

Thal Decl. ¶ 102. The first sentence of paragraph 102 relies on the Klein article (Ex. 2055), which we address below. In the final two sentences, Dr. Thal asserts that the Acumed and Arthrex products satisfy the alleged long-felt need (and thus Dr. Thal has “used [them] in [his] practice”) and that those products practice the invention claimed in the ’312 patent, but Dr. Thal *fails to provide any analysis* of that latter issue. *Id.* On the complete record, Dr. Thal does not adequately explain the basis for his alleged

“understand[ing]” that the Acumed and Arthrex products practice the claimed invention. *See* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”). Instead, that statement is an unsupported conclusory assertion.

The final citation for this first statement—paragraph 10 of the Gelfand Declaration—also does not support Patent Owner. There, Dr. Gelfand testifies regarding the Klein article (like the first sentence in paragraph 102 of the Thal Declaration), stating that “[t]he failure rate of my patented system is much lower than that of the traditional plates with union rates reported at 93.8% when coracoid suture augmentation is added to superior clavicle locking plates.” Gelfand Decl. ¶ 10 (citing Ex. 2055 at 1049–1055).

As noted by Petitioner, however, both Dr. Thal and Dr. Gelfand admitted in their depositions that the activity documented in the Klein article occurred *before* Patent Owner’s date of invention. Pet. Reply 19 (Ex. 1033, 158:18–162:12, 164:5–165:21; Ex. 1034, 53:9–60:4); *see* Ex. 1034, 59:21–60:4 (Dr. Gelfand acknowledging that the procedures in the Klein article were performed between 1998 and 2008, before he filed any of his patent applications). In the Sur-reply, Patent Owner does not dispute the argument by Petitioner regarding the Klein article from the Reply. *See generally* PO Sur-reply; *see also* Tr. 40:15–20 (Patent Owner’s counsel: “We have a little bit of egg on our face regarding this Klein article. I will be upfront about that. We weren’t aware that when Dr. Gelfand submitted Klein to the Patent Office in 2014, in response to an office action claiming commercial success, that he wasn’t talking about his own device, he was talking about these

constructs in general, some of which may have the flaws that I’m talking about here.”).

Thus, to the extent the Klein article shows products that allegedly practiced the invention claimed in the (later-issued) ’312 patent, those products satisfied the alleged long-felt need *before* the claimed invention, which undermines Patent Owner’s showing as to this indicia. *See Newell*, 864 F.2d at 768 (“[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved . . . .”); Pet. Reply 19 (“The alleged success rate is associated with *prior art* techniques, not Dr. Gelfand’s.”).

We turn now to the second of Patent Owner’s two statements addressing whether the invention claimed in the ’312 patent satisfied the alleged long-felt need, in which Patent Owner states that “the design has since been copied by others seeking to repair distal fractures.” PO Resp. 56 (citing Gelfand Decl. ¶¶ 16–17; Thal Decl. ¶ 102). The cited evidence does not support Patent Owner’s second statement. For the same reasons discussed above, in paragraph 102 of his Declaration, Dr. Thal does not adequately explain the basis for his alleged “understand[ing]” that the Acumed and Arthrex products practice the claimed invention. Thal Decl. ¶ 102. Similarly, in paragraphs 16 and 17 of his Declaration, Dr. Gelfand provides images of Acumed’s and Arthrex’s products that he “believe[s] copies [his] invention and reads on the claims of the ’312 patent,” but he *does not explain the basis* for that alleged belief (to the extent relevant to this analysis, given that he is the Patent Owner as well). Gelfand Decl. ¶¶ 16–17.

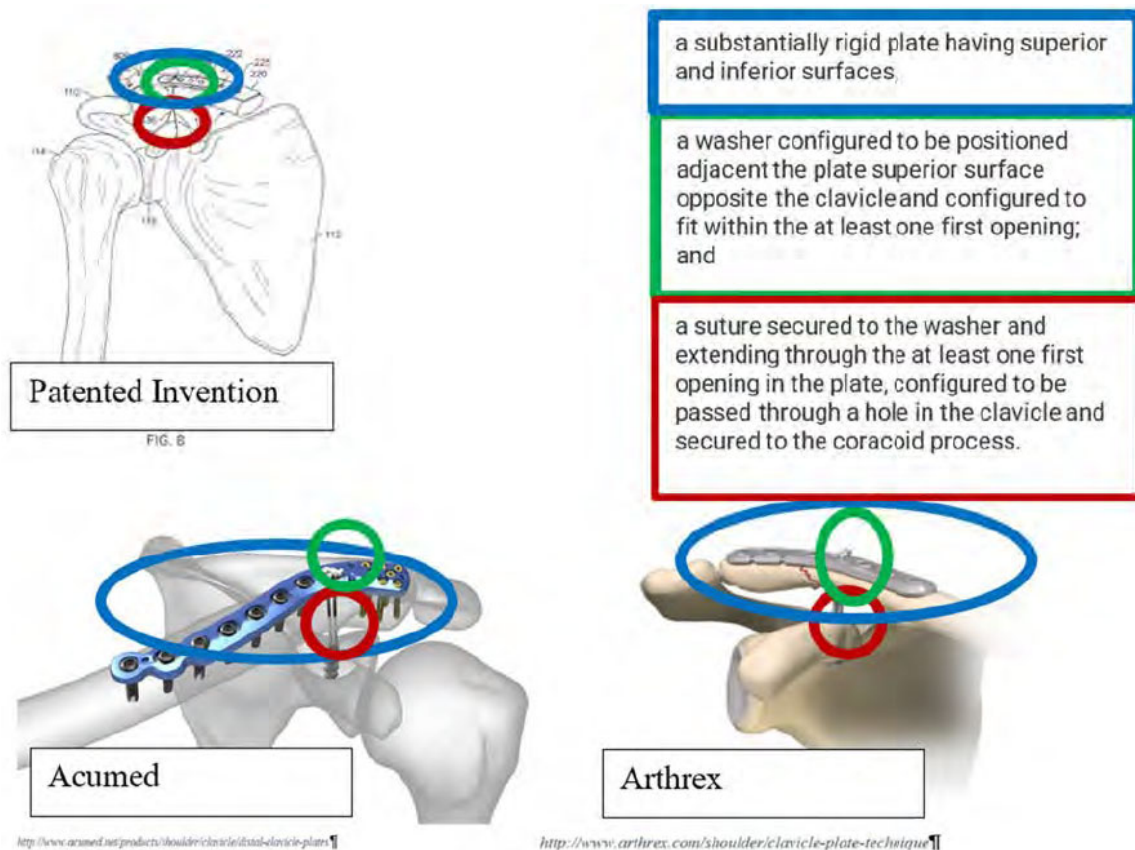
On the complete record here, Patent Owner has not adequately shown that the claimed invention satisfies the alleged long-felt need. Thus, we assign this objective indicium little to no weight.

*(2) Copying*

“‘Copying may indeed be another form of flattering praise for inventive features,’ and thus evidence of copying tends to show nonobviousness.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1336 (Fed. Cir. 2016) (quoting *Crocs, Inc., v. Int’l Trade Comm’n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010)). “[A]lthough copying is not alone dispositive of nonobviousness, we have usually considered a determination of copying to be ‘strong evidence of nonobviousness.’” *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1213 (Fed. Cir. 2023) (quoting *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985), *cert. granted, judgment vacated on other grounds*, 475 U.S. 809 (1986)). “Evidence of copying may include internal documents, direct evidence such as photos of patented features or disassembly of products, or access and similarity to a patented product.” *Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019).

Patent Owner asserts that both Petitioner entities—Acumed and Arthrex—copied Patent Owner’s invention. *See* PO Resp. 13–15, 57–59; PO Sur-reply 20. Specifically, Patent Owner alleges to have presented the invention to both Acumed and Arthrex during different meetings in about 2008 (the “2008 Meetings”), and argues that both companies “passed on the invention” but began selling alleged “cop[ies]” of the invention after those

meetings. *See* PO Resp. 13–15.<sup>18</sup> Patent Owner asserts that these meetings (along with related slides and other information) provided *access* to the claimed invention, and Patent Owner argues that *similarity* is evident from the following “comparison of the three products [to] clearly show that Petitioners’ products are exact copies of all of the claimed features of the ‘312 patent”:



PO Resp. 57–58. In the composite illustration here, Patent Owner includes (1) an annotated version of Figure 8 of the '312 patent (identified as

<sup>18</sup> Patent Owner also presents facts as to licensing by Medartis in the factual background of the alleged copying, but Patent Owner does not argue that Medartis copied the claimed invention. *Compare* PO Resp. 57–59 (arguing copying by Petitioner, not Medartis), *with id.* at 13–15 (discussing meetings with Acumed and Arthrex, as well as licensing by Medartis). We address licensing as a separate objective indicium below. *See* § II.C.4.h(3).

“Patented Invention”) with a red oval around certain structures, a green oval around certain structures, and a blue oval around certain structures, (2) an annotated version of an apparent Acumed clavicle plate device on a bone structure (identified as “Acumed”) with a red circle around certain structures, a green circle around certain structures, and a blue oval around certain structures, (3) an annotated version of an apparent Arthrex clavicle plate device on a bone structure (identified as “Arthrex”) with a red circle around certain structures, a green oval around certain structures, and a blue oval around certain structures, and (4) a text box with (4.a) a portion of element 1.1 from claim 1 of the ’312 patent in a blue box, (4.b) element 1.4 from claim 1 in a green box, and (4.c) element 1.5 from claim 1 in a red box. *Id.* at 58. According to Patent Owner, “[t]he explicit copying of all claimed features of the ’312 patent establishes a clear nexus between the novel aspects of the claimed evidence, when coupled with the fact that these features only emerged after meetings with Dr. Gelfand.” *Id.* (citing Gelfand Decl. ¶¶ 11–13.

Petitioner argues that both Acumed and Arthrex developed the allegedly copied products independently of any information from the 2008 Meetings, and also argues that Patent Owner has not adequately shown that the allegedly copied products actually practice the limitations of claim 1 of the ’312 patent. *See* Pet. Reply 19–22.

We assign this objective indicium little to no weight for the two reasons argued by Petitioner. First, Patent Owner has failed to meet its burden to show that the allegedly copied products actually fall within the scope of claim 1 of the ’312 patent—a necessary aspect to show copying. *See Liqwd, Inc.*, 941 F.3d at 1139 (vacating and remanding to the Board to



address alleged copying when “[t]he evidence presented by [the patent owner] shows more than merely a ‘competing product that arguably falls within the scope of a patent’” (quoting *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1245–46 (Fed. Cir. 2010)); *id.* at 1138 (“[T]he proponent of objective evidence offered to show nonobviousness, such as copying, must show that a nexus exists between the evidence and the claimed features of the invention.”). As noted by Petitioner (Pet. Reply 22), Patent Owner’s briefing relies *only* on the testimony of Dr. Gelfand on this issue. *See* PO Resp. 13–15 (citing Gelfand Decl. ¶¶ 15–17), 57–59 (citing Gelfand Decl. ¶¶ 11–13). In the relevant paragraphs of his Declaration, Dr. Gelfand states that he “believe[s]” that each of the allegedly copied products “reads on the claims of the ’312 patent,” but Dr. Gelfand does not provide an objective basis for that belief. Gelfand Decl. ¶¶ 15–17.

Moreover, the composite illustration from the Patent Owner Response reproduced above (*see* PO Resp. 58) does not adequately show that the allegedly copied products actually fall within the scope of claim 1 of the ’312 patent. As an initial matter, that composite illustration only addresses *certain portions* of claim 1, and does not address elements 1.2 and 1.3 or aspects of element 1.1. *See id.* The text following the composite illustration provides attorney argument that “[t]he explicit copying of all claimed features of the ’312 patent establishes a clear nexus between the novel aspects of the claimed evidence,” but that assertion relies only on paragraphs 11–13 of Dr. Gelfand’s Declaration, which address only the 2008 Meetings with Acumed and Arthrex (rather than evidence of explicit copying).

Notably, nowhere in the discussion of alleged copying does Patent Owner cite to the Thal Declaration. *See* PO Resp. 13–15, 57–59; PO

Sur-reply 20. Regardless, even if we were to consider that Declaration, Dr. Thal does not provide supporting analysis on this issue, stating only that he “understand[s]” the allegedly copied products “to be embodiments of Dr. Gelfand’s invention described and claimed in the ’312 patent.” Thal Decl. ¶ 102. Dr. Thal does not, however, provide any objective basis for that understanding. *See* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

As the second reason we assign this objective indicium little to no weight, we agree with Petitioner that the record shows significant design efforts by both Acumed and Arthrex on clavicle plate products beginning *prior to* the 2008 Meetings and does not show that either company deviated from those development paths to, for example, incorporate (i.e., copy) a particular feature presented by Dr. Gelfand in the 2008 Meetings. *Cf. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1328–29 (Fed. Cir. 2009) (holding that a patent challenger’s initial attempts at one design together with the “prompt adoption of the claimed feature soon after the patent issued, are relevant indicia of nonobviousness”), *cited at* PO Resp. 58–59. As to Arthrex, the record—including the Gallen Declaration and its discussion of work by Dr. Evan Lederman—shows the independent development of its allegedly copied product began in at least 2007 based on its existing AR-8943 plates for ankles. *See* Pet. Reply 19–21 (citing Gallen Decl. ¶¶ 2–5, 7–10). And as to Acumed, the record—including the Sommers Declaration—shows the independent development of its allegedly copied product began around 2008 using a distal clavicle plate available prior to 2008. *See* Pet. Reply 21–22 (citing Sommers Decl. ¶¶ 1–28).

Even assuming that Patent Owner *had* demonstrated similarity between the allegedly copied products by the two Petitioner entities and the claimed invention (which he has not, as discussed above), Patent Owner has not adequately shown that the 2008 Meetings preceded any actual copying efforts by either of the two Petitioner entities. *See Liqwd, Inc.*, 941 F.3d at 1137–38 (discussion prior Federal Circuit decisions addressing alleged copying, and stating that, “[i]n each case, the question of legal relevancy was determined by whether there was *actual evidence of copying efforts* as opposed to mere allegations regarding similarities between the accused product and a patent” (emphasis added)).

For the reasons discussed above, on the complete record, we assign the evidence of alleged copying little to no weight.

*(3) Licensing*<sup>19</sup>

“The significance of licensing a patent as a secondary consideration in enhancing the nonobviousness of an invention is that an independent party with an interest in being free of the patent has chosen to respect it and pay a royalty under it rather than litigate and invalidate it.” *Teva Pharms. Int’l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 1363 (Fed. Cir. 2021). “[T]he relevant inquiry is whether there is a nexus between the patent and the licensing activity itself, such that the factfinder can infer that the licensing ‘arose out of recognition and acceptance of the subject matter claimed’ in

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<sup>19</sup> In the section in the Patent Owner Response addressing licensing, Patent Owner uses the heading “Licensing/industry praise.” PO Resp. 59. The discussion, however, addresses only the licensing activity, not any praise in the industry. In line with that understanding, in the Sur-reply, Patent Owner uses the heading “The Medartis License.” *See* PO Sur-reply 20–21. Accordingly, we do not address industry praise.

the patent.” *S. Alabama Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015) (quoting *GPAC Inc.*, 57 F.3d at 1580 (Fed.Cir.1995)).

Patent Owner states that, in 2020, a Swiss surgical device firm known as Medartis AG, contacted Patent Owner through counsel to license both the ’674 patent and the ’312 patent. *See* PO Resp. 15, 59–60 (citing Gelfand Decl. ¶¶ 18–29 (discussing the events leading to the Medartis License (Ex. 2061))). Following negotiations, Medartis and Patent Owner entered into the Medartis License in the public record, which provides Patent Owner a license issue fee and a running royalty for each licensed product made (Ex. 2061 at 2). *See id.* at 15, 59–60. According to Patent Owner, the Medartis License is “strong evidence” of nonobviousness because it was not to avoid litigation, based on prior business relationships, or for other economic reasons, but rather, “is a recognition of the unique features of the claimed device.” *Id.* at 60 (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1294 (Fed. Cir. 2012)).

Petitioner does not appear to dispute any of the facts leading to the Medartis License; instead, Petitioner argues that the Medartis License is not “relevant” for purposes of the obviousness analysis because of an alleged lack of nexus between the Medartis License and the invention claimed in the ’312 patent. *See* Pet. Reply 23–24. Specifically, Petitioner argues that (1) the Medartis License “simply states that ‘[Medartis] sells product(s) that are covered by [Patent Owner’s] Patent Rights,’ without distinguishing between the invention claimed in the ’312 Patent or the ’674 patent” and (2) Patent Owner “does nothing to establish that the Medartis License is attributable to the ’312 Patent.” Pet. Reply 23 (quoting Ex. 2061 § 9.12 (page 7)).

In addition, Petitioner argues that nexus is undermined here because Medartis’s Clavicle System 2.8—the only product Patent Owner asserts is made under the Medartis License (*see* Gelfand Decl. ¶ 27)—can be used in a noninfringing manner, i.e., with a cortical screw, rather than a “suture” as recited in element 1.5 of claim 1 of the ’312 patent. *See* Pet. Reply 23–24 (citing Ex. 2062 at 22 (discussing the use of a cortical screw in Medartis’s Clavicle System 2.8); Ex. 1034, 107:22–112:22).

For the reasons below, we determine that Patent Owner has not adequately shown a nexus between the ’312 patent and the Medartis License such that we could infer that the License “arose out of recognition and acceptance of the subject matter claimed” *in the ’312 patent specifically*. *GPAC Inc.*, 57 F.3d at 1580, *cited at S. Alabama Med. Sci. Found.*, 808 F.3d at 827. Here, the undisputed fact that Medartis *independently* reached out to Patent Owner to begin the negotiations that resulted in the Medartis License—i.e., without any apparent threat of litigation, without a prior business relationship, or for other economic reasons (*see Antor Media Corp.*, 689 F.3d at 1294)—shows *at least some level* of “recognition and acceptance” of the *collective* subject matter claimed in the ’674 patent *and* in the ’312 patent. *GPAC Inc.*, 57 F.3d at 1580; *see* Gelfand Decl. ¶ 18 (discussing how Medartis’s attorney sent an initial email to Patent Owner “saying that he represented a client who was potentially interested in licensing my ’312 and ’674 patents”), *cited at* PO Resp. 59.

That said, only the ’312 patent is at issue in this proceeding, and, as argued by Petitioner, the specific nexus *between that patent* and the Medartis License is undermined by the fact that the License does not identify the

portion of the value of the licensing fee or running royalty specifically attributable to *each* of the '312 patent and the '674 patent, respectively. *See* Pet. Reply 23 (presenting this argument); Ex. 2061 § 1.1 (defining the “LICENSOR’S Patent Rights” as including both the '674 patent and the '312 patent), § 9.12 (stating that Medartis “sells product(s) that are covered by LICENSOR’S Patent Rights”); *see also Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 838 (Fed. Cir. 2015) (concluding that the Board’s finding that the evidence of licensing should not be afforded much weight was reasonable where the license agreement covered several patents and “[i]t is . . . difficult to determine the extent to which the licensing agreement was a result of the novel features in the [challenged patent], as opposed to the other patents involved”).

In the Sur-reply, Patent Owner asserts that *both* the licensed '674 patent *and* the '312 patent are “directed to the claimed invention” relevant to the nexus inquiry. PO Sur-reply 20–21. The relevant inquiry, however, must focus on the invention claimed *in the '312 patent* at issue in this proceeding, not the *combined* claimed inventions of the *two* licensed patents. *See Merck & Cie*, 808 F.3d at 838.

Although evidence that Medartis manufactured a product that embodies the invention claimed in the '312 patent *may* be probative of a nexus between the claimed invention and the licensing activity, Patent Owner here need not establish an independent nexus between Medartis’s product(s) and the claimed invention for the licensing activity to be relevant. *S. Alabama Med.*, 808 F.3d at 827–28. To the extent Patent Owner sought to establish nexus in this manner, however, we determine for completeness that such a showing was not adequately made here. First, Patent Owner does not

perform an element-by-element analysis showing that any Medartis product practices the invention claimed in the '312 patent. *See* PO Resp. 59–60; PO Sur-reply 20–21. Instead, Patent Owner relies on the statement in the Medartis License that Medartis “sells product(s) that are covered by [Patent Owner’s] Patent Rights.” Ex. 2061 § 9.12, *cited at* Gelfand Decl. ¶ 26, *cited at* PO Resp. 59–60. No analysis, however, supports this statement.

Next, Patent Owner appears to argue that Medartis’s Clavicle System 2.8 *does not* practice the invention claimed in the '674 patent, thereby assumedly leading to the inference that the Medartis License was entered into *solely* due to the '312 patent. *See* PO Sur-reply 20–21. Specifically, Patent Owner argues that “the figure shown at page 24 of Petitioners’ Reply shows that the Medartis product does not use the elongated sliding hole of the '6[7]4 patent but rather the washer claimed in the '312 patent.” *Id.* at 21. We find this attorney argument, first presented in the Sur-reply, inadequately developed. As an initial matter, Patent Owner does not identify the claim language at issue in the '674 patent’s independent claim(s) corresponding to the “elongated sliding hole” allegedly not present in the Medartis product shown on page 24 of the Reply. *Id.* We will not develop specific arguments based on such a generalized statement. *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))).

Moreover, Patent Owner does not address Petitioner’s argument that that same embodiment lacks the “suture” recited in element 1.5 and thus does not in fact practice the claimed invention of the '312 patent. *See* Pet. Reply 24.

For the reasons discussed above, on the complete record, Patent Owner has not adequately shown a nexus between the invention claimed in the '312 patent and the licensing activity. Thus, we assign this objective indicium minimal weight.

*(4) Simultaneous Invention*

“[T]he possibility of near simultaneous invention by two or more equally talented inventors working independently, . . . may or may not be an indication of obviousness when considered in light of all the circumstances.” *Ecolochem, Inc. v. S. Calif. Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000) (quoting *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984) (emphasis added)).

Petitioner asserts that simultaneous invention further suggests obviousness in that, here, “many surgeons independently decided to fix distal clavicle injuries with the combination of a bone plate and a suture construct attached to the coracoid at around the same time.” Pet. Reply 24 (referencing Pet. Reply 4–9). According to Petitioner, “[t]his evidence of ‘independently made, simultaneous inventions, made within a comparatively short space of time, are persuasive evidence that the claimed apparatus was the product only of ordinary mechanical or engineering skill . . . .’” *Id.* (quoting *Geo M. Martin Co. v. All. Mach. Sys. Int’l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010)). Patent Owner responds that Petitioner’s argument here is premised on “an oversimplification of the facts.” PO Sur-reply 21.

Given the overall weight of the evidence of obviousness and nonobviousness, we determine it is unnecessary to address this argument by Petitioner. Thus, we make no findings as to whether this objective indicium supports Petitioner’s position as to obviousness.



*i. Conclusion as to Independent Claim 1*

“Once all relevant facts are found, the ultimate legal determination [as to obviousness or nonobviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1361 (Fed. Cir. 2017). In particular, for the reasons discussed above (§ II.C.4.a–g), the unrebutted evidence presented by Petitioner establishes that the combination of Clavicula, Hardy, and Thornes teaches or suggests the subject matter of claim 1. Moreover, as discussed above, Petitioner establishes that one of ordinary skill in the art would have been motivated to modify Clavicular with Hardy and Thornes, as proposed, and would have had a reasonable expectation of success in achieving the combination proposed.

In our balancing of the evidence weighing in favor of and against obviousness, we consider the summation of the weight we attribute to each of the objective indicia identified by Patent Owner. *See Volvo*, 81 F.4th at 1215 (discussing the summation of the weight attributed to objective indicia evidence). For the reasons explained above (§ II.C.4.h), Patent Owner’s evidence of objective indicia of nonobviousness garners minimal weight. To reiterate some of our reasoning here, (1) we assign the evidence of long-felt but unsolved need little to no weight because Patent Owner has not adequately shown that the claimed invention satisfies the alleged long-felt need, (2) we assign the evidence of alleged copying little to no weight because Patent Owner has not shown that the allegedly copied products fall within the scope of claim 1 of the ’312 patent and has not adequately shown that the 2008 Meetings preceded any actual copying efforts by either of the

two Petitioner entities, (3) we assign the evidence of licensing minimal weight because, although the record shows at least some level of interest with Medartis initiating contact with Dr. Gelfand to license the '312 patent, the specific nexus *between that patent* and the Medartis License is undermined by the fact that the License does not identify the portion of the value of the licensing fee or running royalty specifically attributable to *each* of the '312 patent and the '674 patent, and (4) we make no findings as to Petitioner's argument regarding simultaneous invention.

On balance, considering the complete record before us, Petitioner's evidence of obviousness is substantial and far outweighs Patent Owner's minimal evidence of nonobviousness. Therefore, we determine that Petitioner has established, by a preponderance of the evidence, that claim 1 would have been obvious to one of ordinary skill in the art as of the time of the invention based on the combination of Clavicula, Hardy, and Thornes.

#### 5. *Claims 2–20*

Claims 2–20 of the '312 patent all depend—either directly or indirectly—from sole independent claim 1. *See* Ex. 1001, 11:32–12:49. To address these claims, Petitioner identifies portions of Clavicula, Hardy, and Thornes that describe or suggest the additional limitations in these claims. Pet. 71–94 (citing McKee Decl. ¶¶ 142–167). The record evidence supports Petitioner's position as to the limitations in these claims. *Id.* Patent Owner does not present arguments addressing these claims. *See, e.g.*, PO Resp. 55 (“The nonobviousness of claim 1 against the three references in this ground applies equally to the remaining claims 2–20 of the '312 patent. In other words, if claim 1 is patentable, then further claims adding additional details are similarly nonobvious in view of Clavicula, Thornes, and Hardy.” (citing

Thal Decl. ¶ 98)); *see also* Pet. Reply 9 (stating that “Patent Owner does not address any elements from claims 2–20 of the ’312 Patent as it relates to the combination of Clavicula + Hardy + Thornes”).

The unrebutted evidence presented by Petitioner establishes that the combination of Clavicula, Hardy, and Thornes teaches or suggests the subject matter of claims 2–20. Moreover, Petitioner establishes that one of ordinary skill in the art would have been motivated to modify Clavicular with Hardy and Thornes, as proposed, and would have had a reasonable expectation of success in achieving the combination proposed.

On balance, considering the complete record before us, Petitioner’s evidence of obviousness as to claims 2–20 is substantial and far outweighs Patent Owner’s minimal evidence of nonobviousness. Therefore, we determine that Petitioner has established, by a preponderance of the evidence, that claims 2–20 would have been obvious to one of ordinary skill in the art as of the time of the invention based on the combination of Clavicula, Hardy, and Thornes.

*D. Asserted Grounds of Obviousness Involving Deffenbaugh*

Petitioner contends that the challenged claims are rendered obvious—in the alternative to the combination of Clavicula, Hardy, and Thornes—by (1) Deffenbaugh (claims 1–8, 13–17, and 19), (2) Deffenbaugh and Thornes (claims 1–10 and 12–19), (3) Deffenbaugh and Wellman (claim 11), (4) Deffenbaugh, Thornes, and Wellman (claim 11), (5) Deffenbaugh and Hardy (claims 5 and 20), and (6) Deffenbaugh, Thornes, and Hardy (claims 5 and 20). *See* Pet. 23–54; Pet. Reply 1–9, 12–25.

Because the ground based on Clavicula, Hardy, and Thornes is dispositive as to all of the challenged claims (*see* § II.C), we need not reach

the additional asserted grounds. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (nonprecedential) (stating that the “Board need not address issues that are not necessary to the resolution of the proceeding,” such as “alternative arguments with respect to claims [the Board] found unpatentable on other grounds”); *SK Hynix Inc. v. Netlist, Inc.*, IPR2017-00692, Paper 25 at 40 (PTAB July 5, 2018) (determining all challenged claims to be unpatentable and not addressing additional grounds).

*E. Patent Owner’s Motion to Exclude*

Patent Owner filed a Motion to Exclude certain exhibits and portions of exhibits relied on by Petitioner. *See* Paper 38. Petitioner filed an Opposition to the Motion to Exclude. *See* Paper 39. Prior to the oral hearing, Patent Owner contacted the Board, stating that all parties to this proceeding agreed that the panel need not consider the Motion and Opposition. *See* Ex. 3002 (email from parties regarding Patent Owner’s Motion to Exclude); *see also* Tr. 4:6–9 (counsel for Patent Owner confirming at the oral hearing that the Motion to Exclude has been withdrawn via Exhibit 3002). Accordingly, we *dismiss* the Motion to Exclude as withdrawn by Patent Owner.

### III. CONCLUSION

Upon consideration of the briefing and the evidence of record, we determine that Petitioner has proven, by a preponderance of the evidence, the unpatentability of all of the challenged claims.<sup>20</sup>

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<sup>20</sup> Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (April 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

In summary:

<b>Claim(s)</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/ Basis</b>	<b>Claims Shown Unpatentable</b>	<b>Claims Not Shown Unpatentable</b>
1–8, 13– 17, 19	103(a)	Deffenbaugh <sup>21</sup>		
1–10, 12– 19	103(a)	Deffenbaugh, Thornes <sup>21</sup>		
11	103(a)	Deffenbaugh, Wellmann <sup>21</sup>		
11	103(a)	Deffenbaugh, Thornes, Wellmann <sup>21</sup>		
5, 20	103(a)	Deffenbaugh, Hardy <sup>21</sup>		
5, 20	103(a)	Deffenbaugh, Thornes, Hardy <sup>21</sup>		
1–20	103(a)	Clavícula, Hardy, Thornes	1–20	
<b>Overall Outcome</b>			1–20	

#### IV. ORDER

For the reasons above, it is:

ORDERED that Petitioner has proven by a preponderance of the evidence that claims 1–20 are unpatentable;

FURTHER ORDERED that Patent Owner’s Motion to Exclude is *dismissed* as withdrawn; and

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<sup>21</sup> As explained above, we do not reach any of the grounds involving Deffenbaugh. *See* § II.D.

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FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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