

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC. and ACUMED LLC
Petitioners

v.

GELFAND, JEFFREY, DR.
Patent Owner

Case No. IPR2023-00014
Patent No. 9,149,312

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,149,312**

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<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020)	94
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PETITIONERS' EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,149,312 (“the ’312 Patent”)
1002	Declaration of Michael McKee, M.D.
1003	Curriculum Vitae of Michael McKee, M.D.
1004	U.S. Patent Publication No. 2007/0225716 (“Deffenbaugh”)
1005	French Patent Publication No. 2,726,461 (“Hardy”)
1006	Certified Translation of Exhibit 1005
1007	U.S. Patent Publication No. 2007/0179531 (“Thornes”)
1008	“Biomechanical Evaluation of Minimally Invasive Repairs for Complete Acromioclavicular Joint Dislocation” by Mathias Wellmann, et al. (“Wellmann”)
1009	“Acumed Locking Clavicle Plate System” by Acumed (“Clavícula”)
1010	Declaration of J. Elmer Regarding Ex. 1009
1011	Prosecution History of U.S. Patent Application No. 13/613,349
1012	Merriam Webster Dictionary definition of “washer”

Exhibit No.	Description
1013	MacMillan Dictionary definition of “washer”
1014	Complaint filed in <i>Jeffrey Gelfand, MD v. Acumed, LLC</i> , Case No. 21-1753
1015	Complaint filed in <i>Jeffrey Gelfand, MD v. Arthrex Inc.</i> , Case No. 21-1754
1016	Stryker SPS Small Fragment Set (2007)
1017	“Plate fixation of clavicle fractures: A comparative study between Reconstruction Plate and Dynamic Compression Plate” by Rizwan Shahid, et al. (“Shahid”)
1018	Copy of Clavícula submitted as part of non-patent literature (NPL) during prosecution of U.S. Patent No. 8,282,674
1019	U.S. Patent No. 5,954,722 (“the ’722 Patent”)
1020	“Injuries to the acromioclavicular joint” by J.A. Fraser-Moodie, et al. (“Fraser Moodie”)
1021	2007 Arthrex AC TightRope Surgical Technique
1022	Bones of Invention, available at https://www.odtmag.com/contents/view_features/2012-09-11/bones-of-invention/
1023	U.S. Patent No. 9,005,245

CLAIM LISTING

[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.

2. The fixation system of claim 1, wherein the plate defines a shoulder formed between the superior and inferior surfaces in the at least one first opening, the shoulder formed at the interface between the larger, upper portion of the first opening and the smaller, lower portion of the first opening.
3. The fixation system of claim 2, wherein the washer sits on the shoulder.
4. The fixation system of claim 2, wherein the washer fits substantially snugly in the at least one first opening above the shoulder.
5. The fixation system of claim 1, wherein a superior surface of the washer is approximately flush with the superior plate surface opposite the clavicle when positioned in the hole.
6. The fixation system of claim 1 wherein the washer has at least one hole dimensioned to receive a suture.
7. The fixation system of claim 6 further comprising an anchor for positioning at an inferior side of the coracoid process.
8. The fixation system of claim 7 wherein the anchor is configured for securing to the suture when the suture passes through a hole in the coracoid process.
9. The fixation system of claim 7 wherein the anchor is substantially oblong.

10. The fixation system of claim 9 wherein the anchor is dimensioned to pass through a hole in the clavicle and through a hole in the coracoid process, and dimensioned to resist, once positioned beneath the coracoid process, returning through the hole in the coracoid process.
11. The fixation system of claim 1 wherein the suture has a length sufficient to pass around the coracoid process.
12. The fixation system of claim 1 wherein the washer is oblong and includes a plurality of holes distributed longitudinally along the washer.
13. The fixation system of claim 1 wherein said plate further comprises at least one second opening dimensioned to receive a fastening device to secure the plate to the medial portion of the clavicle.
14. The fixation system of claim 13 further comprising at least one fastening device adapted to pass through the at least one second opening and to secure the plate to the medial portion of the clavicle.
15. The fixation system of claim 14 wherein the at least one fastening device is a locking screw.
16. The fixation system of claim 1 wherein the plate is contoured to be secured to the distal portion of the clavicle relative to the fracture.

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

[17.1] a fixation system according to claim 1;

[17.2] a second opening in said plate configured to receive a fastening device; and

[17.3] at least one fastening device adapted to pass through the second opening in the plate to secure the plate to the medial portion of the clavicle.

18. The fractured clavicle fixation kit of claim 17 further comprising a substantially oblong anchor that can be coupled to the suture.

19. The fixation system of claim 17, wherein a distal end of the plate is flared.

20. The fixation system of claim 17, wherein sides of the washer are substantially parallel to the first opening in the plate.

Pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.*, Arthrex, Inc. (“Arthrex”) and Acumed LLC (“Acumed”) request *inter partes* review (“IPR”) of claims 1-20 of U.S. Patent No. 9,149,312 (“the ’312 Patent”) (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq.* The ’312 Patent is subject to pre-AIA 35 U.S.C. §§ 102 and 103.

MANDATORY NOTICES

A. Real Party-In-Interest (37 C.F.R. § 42.8 (b)(1))

The following are real parties-in-interest pursuant to 37 C.F.R. §42.8(b)(1):

- Arthrex, Inc.
- Acumed LLC
- Colson Medical, LLC

Without conceding that the following would be determined to be real parties-in-interest under the governing legal standard, but for the purposes of identifying potential conflicts and analysis under 35 U.S.C. §315(b)¹², Petitioners identify the following additional parties that may be relevant to the determinations:

¹ See *Proppant Express Investments, LLC v. Oren Techs., LLC*, Case IPR2017-01917, Paper 86 at 14-15 (Feb. 13, 2019) (precedential).

² None of these identified parties are subject to any time bar for the filing of an *inter partes* review petition, such that a determination as to their actual status as

- Marmon Holdings, Inc.
- Berkshire Hathaway Inc.

B. Related Matters (37 C.F.R. § (b)(2))

The '312 Patent is currently involved in the following proceedings:

- *Jeffrey Gelfand, MD v. Acumed, LLC* (D. Del.) Case No. 21-CV-1753-CFC;
- *Jeffrey Gelfand, MD v. Arthrex, Inc.*, (D. Del.) Case No. 21-CV-1754-CFC.

The following IPRs challenge the other patents asserted in the above-referenced district court proceeding:

IPR2023-00009 (U.S. Patent No. 8,282,674)

C. Counsel and Service Information (37 C.F.R. § 42.8(b)(3) and (4))

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a real party-in-interest is not necessary. Nevertheless Petitioners have listed them out of an abundance of caution.

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Service information for lead and backup counsel is provided in the designation of lead and backup counsel, above. Petitioners consent to electronic service by email at the email addresses provided above.

D. Payment of Fees Under 37 C.F.R. §§ 42.15(a) & 42.103

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.103(a) and 42.15(a). If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 02-1818. Any overpayment or refund of fees may also be deposited in this Deposit Account.

I. INTRODUCTION

The '312 Patent relates to a system for treating clavicle fractures. The challenged claims all recite a system comprising 3 basic elements: (1) a bone plate contoured to follow the clavicle with an opening having a larger, upper portion and a smaller, lower portion; (2) a washer configured to fit within the opening; and (3) a suture secured to the washer that extends through the opening in the plate, through a hole in the clavicle and secured to the coracoid process. Each of these elements, individually and collectively, was well-known in the art before the filing of the '312 Patent. As shown below, U.S. Patent Publication No. 2007/0225716 ("Deffenbaugh") alone, or in combination with secondary references, and "Acumed Locking Clavicle Plate System" ("Clavicula") in combination with secondary references teach (or render obvious) these elements as recited in the challenged claims. This Petition is supported by the declaration of Dr. Michael McKee, MD, an expert in the field of the '312 Patent and the prior art. Ex. 1002.

II. GROUNDS FOR STANDING

Petitioners certify that the '312 Patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR.

III. IDENTIFICATION OF CHALLENGES AND RELIEF REQUESTED

Petitioners request (i) review of claims 1-20 on the grounds set forth below and (ii) that those claims be found unpatentable.

Ground	Claim(s)	Basis for Unpatentability
1	1-8, 13-17, 19	Obvious Over Deffenbaugh
2	1-10, 12-19	Obvious Over Deffenbaugh and Thornes
3	11	Obvious Over Deffenbaugh and Wellmann
4	11	Obvious Over Deffenbaugh, Thornes and Wellmann
5	5, 20	Obvious Over Deffenbaugh and Hardy
6	5, 20	Obvious Over Deffenbaugh, Thornes and Hardy
7	1-20	Obvious Over Clavicula, Hardy and Thornes

IV. SUMMARY OF THE '312 PATENT

A. Background of the Technology

The '312 Patent discloses a fixation system for treating clavicle fractures. Ex. 1001, 1:13-16. The '312 Patent suggests complications often arise in distal clavicle fractures (fractures that occur near the end of the bone closest to the shoulder) that result in improper healing and potential nonunion of the fracture. *Id.*, 1:10-26; Ex. 1002, ¶23. The system disclosed supposedly addresses these issues by including a substantially rigid bone plate that extends onto the distal portion of the clavicle; a washer located on the side of the plate opposite the clavicle; and a suture attached to the washer that extends through the plate, through a hole drilled in the clavicle, and

secured to the coracoid process.³ Ex. 1001, 1:33-41, 4:30-44, 5:7-23, 6:4-19, 7:11-25, Fig. 5.

However, clavicle fixation techniques using sutures passed through the clavicle and attached to the coracoid process were well-known before the priority date, as the '312 Patent acknowledges⁴ and as shown in the references described below. Ex. 1002, ¶24.

³ The coracoid process is a small hook-like bone structure on the lateral edge of the scapula located below the clavicle. Ex. 1002, ¶23.

⁴ Ex. 1001, 1:27-28; 6:52-55 (citing Ex. 1007, disclosing clavicle fixation techniques using anchors and a suture passed through holes drilled in the clavicle and coracoid process).

B. The Claimed Subject Matter

Claim 1 of the '312 Patent is directed to a clavicle fixation system that includes a contoured bone plate 220, a washer 228 configured to fit within at least one opening of the plate, and a suture 436 secured to the washer that extends through the plate, through the clavicle 102 and secured to the coracoid process 116, as shown in Figure 5. Ex. 1001, 4:30-34; 5:7-20; 6:4-8; 7:11-16; 11:11-31.

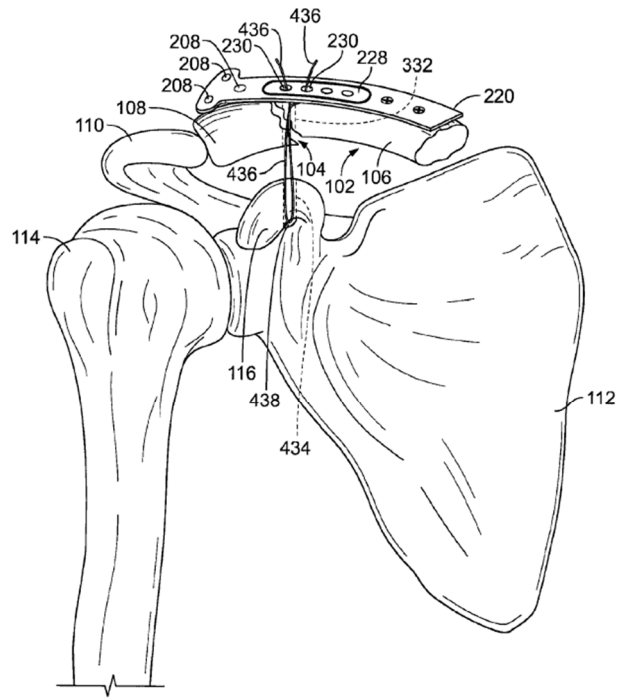


FIG. 5

Claim 1 further requires that the opening in the plate “compris[es] a larger, upper portion and a smaller, lower portion,” depicted in Figure 3 as “the upper, larger oblong section 222a of the first opening 222 and the lower, smaller oblong section 222b of the first opening 222.” *Id.*, 5:7-5:23; 11:23-24.

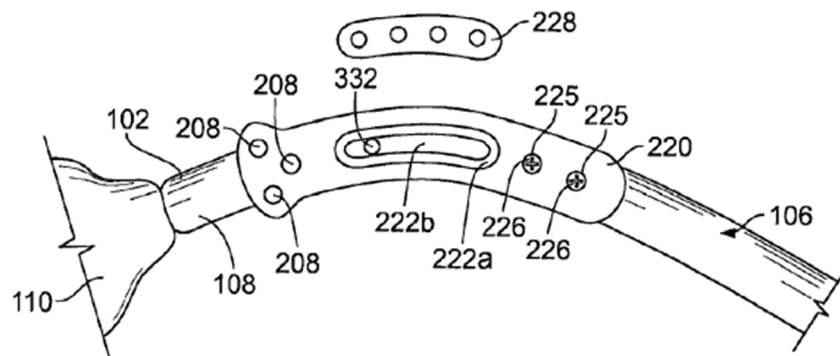


FIG. 3

Dependent claims 2-20 further describe aspects of the fixation system recited in claim 1. Some dependent claims include an anchor 438 that is passed through a hole in the coracoid process and positioned on its inferior side to secure the suture, as shown in Figure 5. Others further limit the geometry of the plate, washer or anchor, or include a fastening device for securing the plate to the medial portion of the clavicle through a second hole.

C. Prosecution History

The '312 Patent is a continuation of U.S. 8,282,674 ("the '674 Patent"). The Examiner rejected the claims based on an obviousness-type double patenting rejection over the related '674 Patent and under §103 based on U.S. 2007/0179531 ("Thornes") in view of U.S. 2002/0065517 ("Paul"). Ex. 1012, 61-69.

In response, the Applicant amended the claims to recite "the at least one first opening comprising a larger upper portion and a smaller lower portion," filed a Terminal Disclaimer to overcome the double patenting rejection, and argued that

Thornes and Paul failed to disclose a plate “contoured to follow the clavicle.” *Id.*, 50, 55-56; Ex. 1002, ¶25. A Notice of Allowance then issued.

V. PRIOR ART

A. Effective Prior Art Dates

Deffenbaugh (Ex. 1004) published on September 27, 2007.

U.S. Patent Publication No. 2007/0179531 (“Thornes,” Ex. 1007) published on August 2, 2007.

“Biomechanical Evaluation of Minimally Invasive Repairs for Complete Acromioclavicular Joint Dislocation” by Mathias Wellmann, et al. (Ex. 1008, “Wellmann”) published in 2007.

Deffenbaugh, Thornes and Wellmann constitute prior art under at least pre-AIA 35 U.S.C. § 102(a) and/or (e).

French Patent Publication No. 2,726,461 (“Hardy”, Ex. 1005) published on May 10, 1996. A certified French-to-English Translation is included as Ex. 1006.

Clavicula (Ex. 1009) was publicly available as of July, 2005. *See* Ex. 1010, ¶¶5-6.

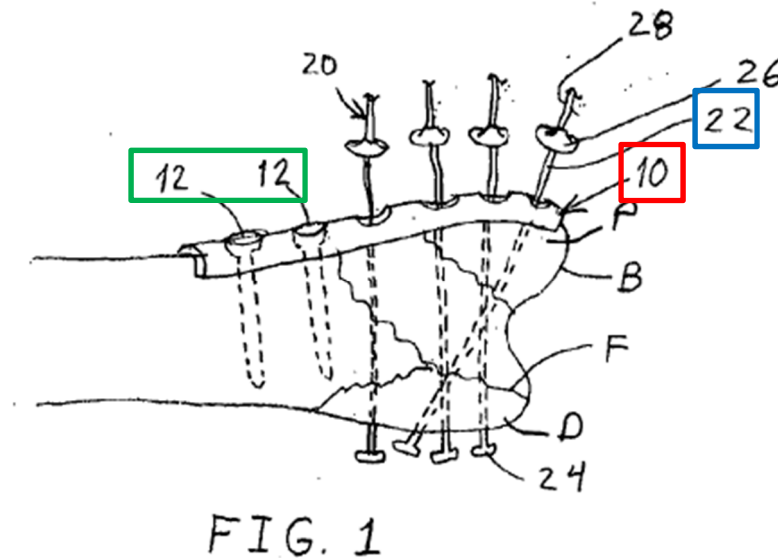
Hardy and Clavicula constitute prior art under pre-AIA 35 U.S.C. § 102(b).

B. Overview of the Prior Art

1. Deffenbaugh

Deffenbaugh discloses a bone fixation system that includes a bone plate and elongated tensioning elements. Ex. 1004, Abstract. The Deffenbaugh fixation

system reduces and fixates bone fractures by placing a bone plate 10 on the proximal surface of a bone, securing the plate with bone screws 12, passing a tensioning element through the plate and bone, and securing a proximal and distal end of the tensioning elements 22. *Id.*, ¶¶[0008], [0057]-[0059], Claim 11; Ex. 1002, ¶38.

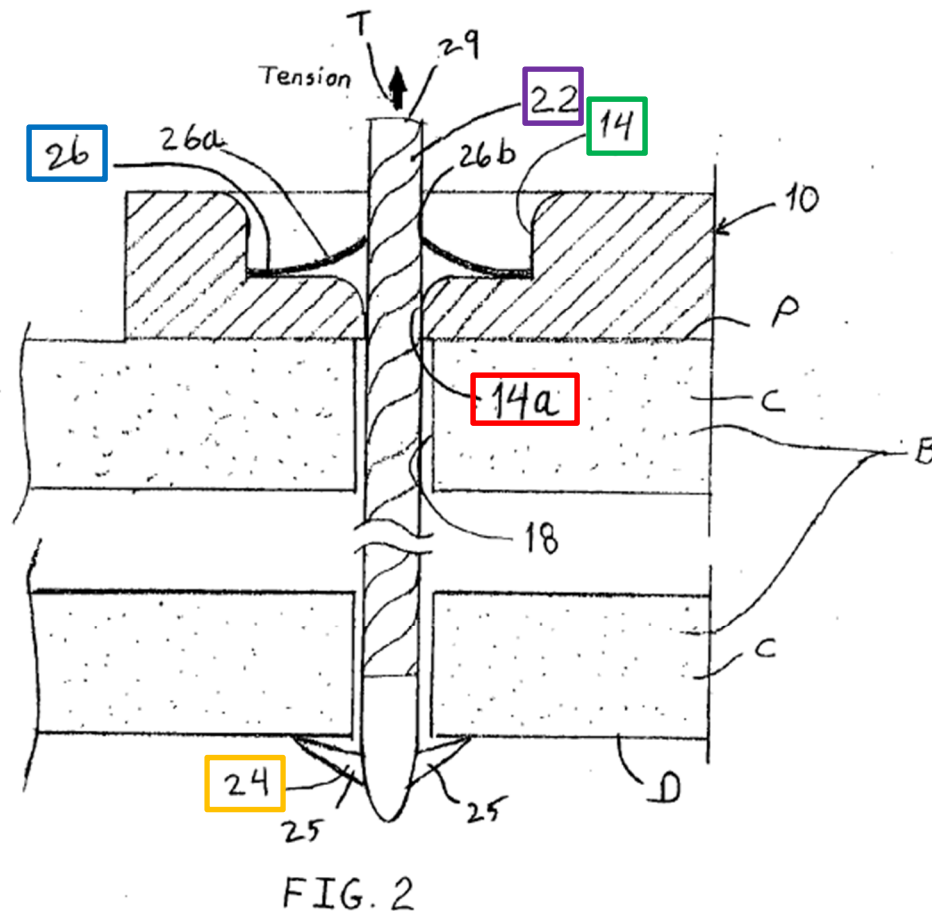


Ex. 1004, Fig. 1.

Deffenbaugh does not expressly define the dimensions, (“[t]he bone plate may be of many known configurations,” *id.*, ¶[0057]) but instead teaches the plate is “shaped to fit” a fractured bone. *Id.*, ¶¶[0008], [0075]; Figure 20; Ex. 1002, ¶39.

The plate has a plurality of openings through which fasteners, including the elongated tensioning elements and bone screws, pass. *Id.*, Abstract, Fig. 1, ¶¶[0008], [0057]. Figure 2 shows opening 14a with washer 26 positioned in recess 14 engaged at the proximal end of tensioning element 22. *Id.*, ¶¶[0057], [0058], [0060]; Ex. 1002, ¶40. Distal anchor 24 is configured to engage tensioning element 22 at its

distal end and is positioned at the side of the bone opposite the plate after passing through bone bore 18 to reduce the fracture. *Id.*, ¶¶[0058], [0060], [0066]-[0067], [0081]; Ex. 1002, ¶40.



Ex. 1004, Fig. 2.

Deffenbaugh also teaches that the tensioning element may be a braided suture. *Id.*, ¶[0059]; Ex. 1002, ¶41.

2. Thornes

Thornes discloses a “simple, reproducible, minimally invasive” means for acute acromioclavicular joint stabilization, having a washer and an anchor joined by

a suture. Ex. 1007, Abstract, ¶[0015]; Ex. 1002, ¶42. Holes are first drilled through the clavicle and coracoid process. *Id.* ¶¶[0012]-[0013]. The washer (button 101) is positioned on the surface of the clavicle and the anchor (button 102) is advanced “through the hole in the clavicle and the coracoid until it exits the coracoid base” on the underside of the coracoid. *Id.*, ¶¶[0013]-[0014], [0033]; Ex. 1002, ¶43. Tension applied to the suture reduces and stabilizes the clavicle and acromioclavicular joint. *Id.*, ¶¶[0014], [0034], Claims 19-20. Figure 7 shows the **washer** (101) on clavicle 10 and **anchor** (102) on the underside of coracoid 20 connected by **suture** 110.⁵ *Id.*, ¶¶[0017]-[0018]; Ex. 1002, ¶44.

⁵ References to figures from Thornes refer to figures from U.S. Patent No. 9,005,245 (Ex. 1023), the issued patent.

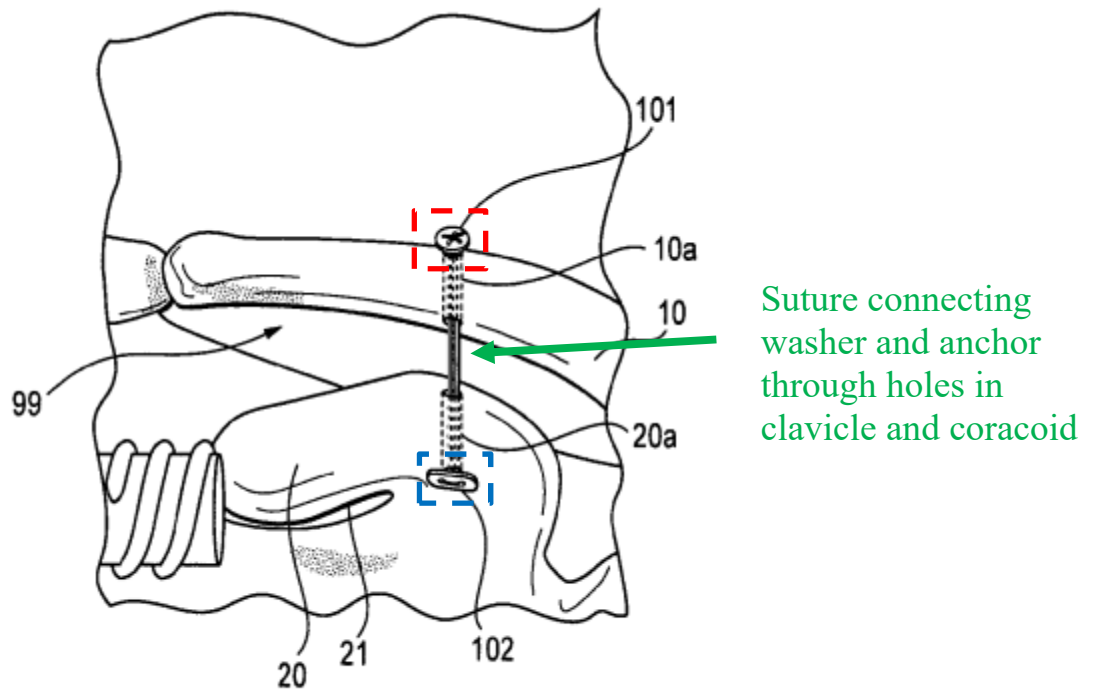


FIG. 7

Thornes teaches that the washer and anchor (buttons 101, 102) can have “various configurations and dimensions.” *Id.*, ¶[0018]. Thornes also discloses a circular washer (button 101) and an oblong anchor (button 102) having a plurality of holes for engaging the suture, as shown in Figures 9a and 10, below. *Id.*, ¶¶[0018]-[0021]; Ex. 1002, ¶45.

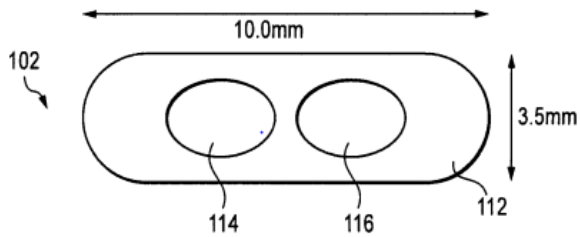


FIG. 9(a)

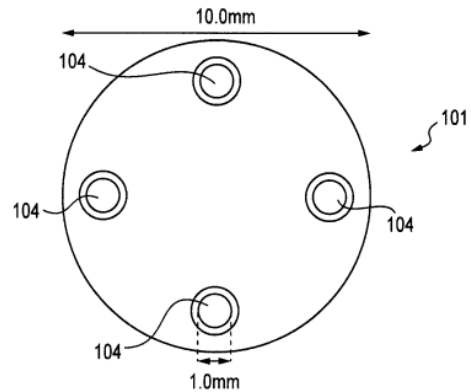
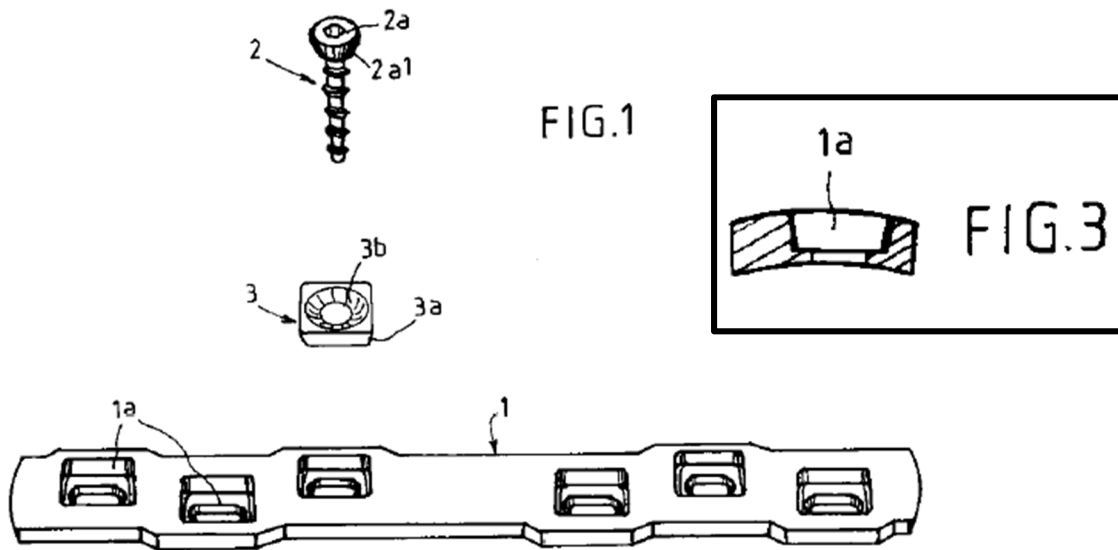


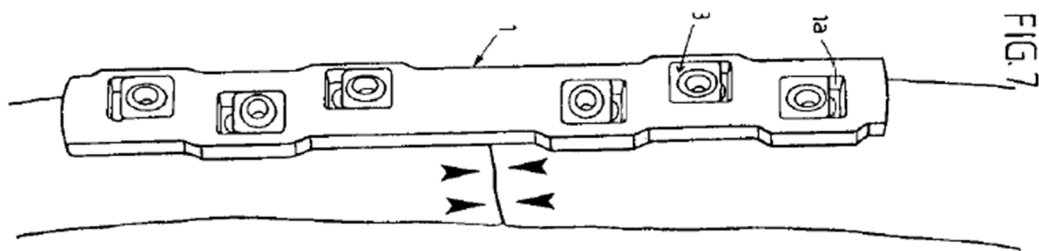
FIG. 10

3. Hardy

Hardy discloses a bone fixation device having a plate with slidable washers that engage fasteners. Ex. 1006, Title, Abstract, 2:19-3:1. The plate is designed to stabilize bone fractures and is contoured to fit the surface of the bone on either side of a fracture. *Id.*, 1:7-10, 4:1-5. Figure 3 shows a cross section shaped to match the anatomic profile of the bone surface. *Id.*, 4:1-5; Ex. 1002, ¶46.

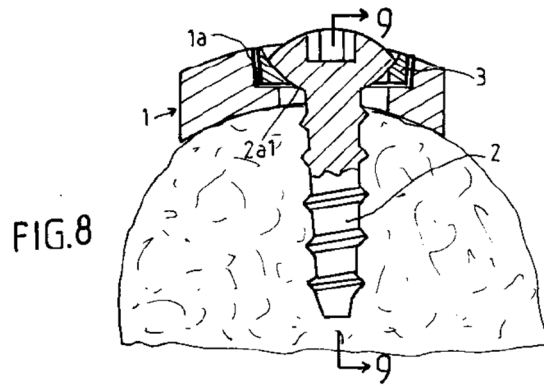
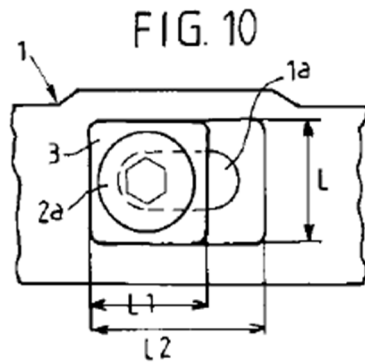


The plate has a plurality of holes dimensioned to receive screws in combination with slidable support washers.



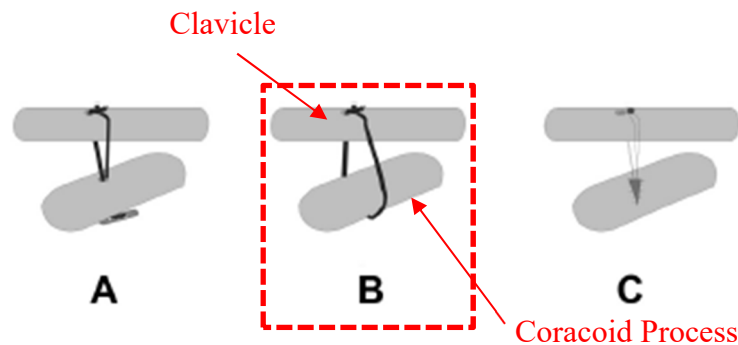
Id., Fig. 7, 4:6-8, 4:20-24, 5:5-9.

Figures 8 and 10 depict slidable washer 3, with a screw head 2a, in a plate opening (1a) where the washer sits flush in the plate with the sides parallel to the sides of the plate opening. *Id.*, 4:9-19; Ex. 1002, ¶¶47-48.



4. Wellmann

Wellmann describes various methods of securing a suture between the clavicle and coracoid process to fixate the acromioclavicular joint. Ex. 1008, Title, 955-57. Figure 1 shows the various fixation methods, including method B where a suture sling was passed under the coracoid process and through a clavicular drill hole. *Id.*, 957; Ex. 1002, ¶49.

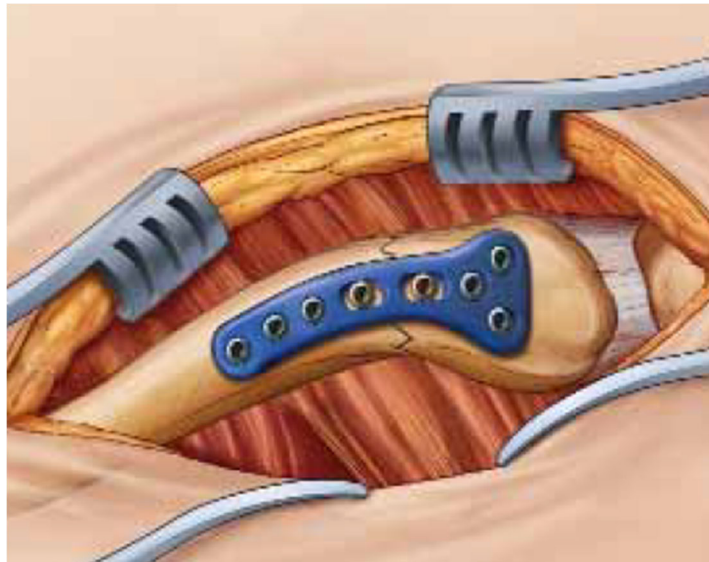


Ex. 1008, Figure 1.

The study found that methods A and B resulted in comparable load strengths and superior results when compared to a suture anchor repair (method C). *Id.*, 957-58; Ex. 1002, ¶50.

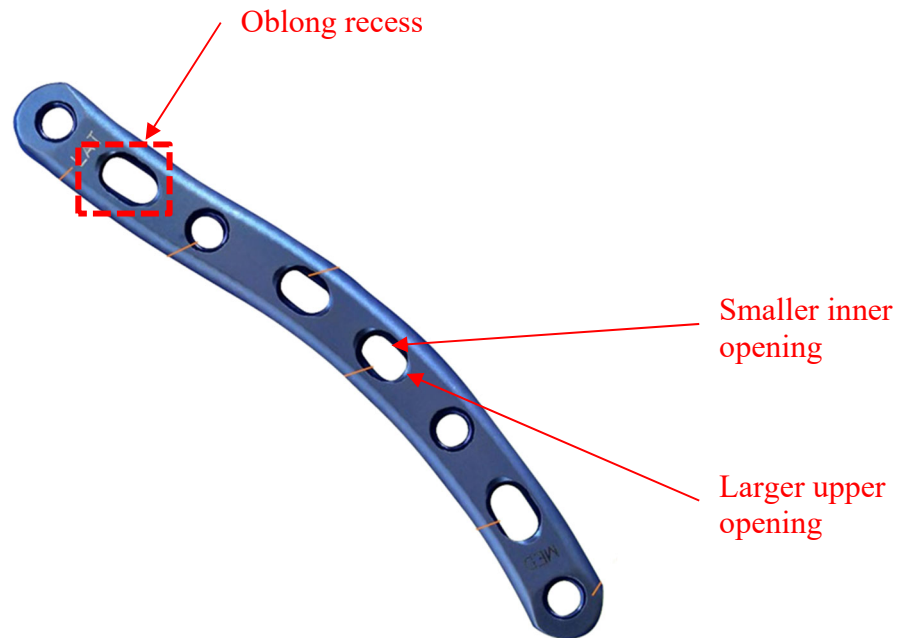
5. Clavicula

Clavicula is an instructional brochure for the Acumed Locking Clavicle Plate System, where the plates are pre-contoured to follow the clavicle, and there is a plate with a flared distal end provided for fixing distal/lateral fractures. Ex. 1009, 2-3. Clavicula explains that pre-contoured plates are superior to straight plates because they minimize irritation and can act as a template for restoring the bone. *Id.*; Ex. 1002, ¶51.



Ex. 1009, 7.

The plate includes oblong openings with a recess to accept a fastener, which can be either a locking or non-locking screw. *Id.*, 2, 6. The guide instructs the surgeon to pass sutures around the coracoid process and the plate to take stress off of the lateral fixation. *Id.*, 7; Ex. 1002, ¶52. The figures below depict the recess in the plate, and the fasteners seated in the recess.



Id., 3.

VI. CLAIM CONSTRUCTION

Under any reasonable interpretation of the claims, including the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005), all of the limitations of the challenged claims are met in the prior art as discussed below. The following constructions are offered for purposes of clarity only.

A. “washer”

The challenged claims of the '312 Patent recite a fixation system for a fractured clavicle comprising a “washer” positioned at a side of the plate opposite the clavicle. Ex. 1001, 11:25-27. A POSITA would understand a “washer” to mean a “thin ring or perforated plate.” This understanding is consistent with both relevant dictionary definitions,⁶ as well as the '312 Patent specification, which describes and shows the claimed “washer” (228) as a thin perforated plate. *Id.*, 5:7-23, 7:20-25, Figs. 2-8.

⁶ Ex. 1012, Merriam Webster Dictionary - “washer”: a flat thin ring or a perforated plate used in joints or assemblies to ensure tightness, prevent leakage, or relieve friction; Ex 1013, MacMillian Dictionary - “washer”: a small flat ring used for filling the space between two metal parts, for example between a surface and the top of a screw.

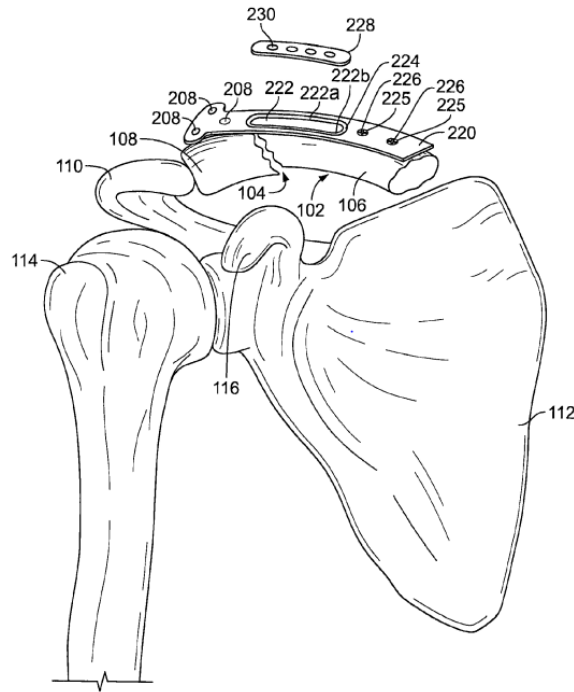


FIG. 2

B. “substantially rigid” and “substantially parallel”

The challenged claims recite a fixation system for a fractured clavicle comprising a “substantially rigid” plate which includes a washer with sides that are “substantially parallel to the first opening in the plate” in some embodiments. Ex. 1001, claims 1, 20. The intrinsic record fails to adequately define or explain what is meant by these terms. Nevertheless, in the related litigations, Gelfand has asserted that the ’312 Patent claims cover bone plates that are rigid enough to withstand deformation caused from the anatomic forces applied to the plate while the fractured bone is healing. Exs. 1014, 1015. Accordingly, Gelfand’s apparent construction of

“substantially rigid” would encompass a bone plate rigid enough to fixate a fractured bone without deformation.

Gelfand has also asserted that the ’312 Patent claims cover bone plates wherein at least a portion of the sides of the accused button are parallel to sides of the corresponding opening in the plate. *Id.* Accordingly, Gelfand’s apparent construction of “substantially parallel” would encompass a system wherein at least a portion of the sides of the washer are parallel to sides of the first opening in the plate. No further construction of these “substantially” terms is needed to resolve the issues in the Petition.

For purposes of this IPR only and without conceding alternative arguments in the counterpart litigations, Petitioners apply Gelfand’s apparent constructions in litigation. See *NEC Display Solutions of America, Inc. v. Ultravision Tech.*, IPR2019-01123, Institution Decision, Paper 7, pp. 12-14 (PTAB Dec. 2, 2019).

VII. ARGUMENTS

A. Level of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSITA”) would have (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. Ex. 1002, ¶31. Nevertheless, Petitioners submit that the claims are obvious in view of any reasonable definition of a POSITA.

B. The Petition Should Not be Denied Under §325(d)

Assessing §325(d) requires a two-part inquiry: (1) whether the same or substantially the same art or arguments were previously presented to the Patent Office; and (2) if so, whether the petitioner has demonstrated that the Patent Office erred in some material way. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, Case IPR2019-01469, Paper 6 at 8 (Feb. 13, 2020) (precedential). The Board looks to several non-exclusive factors in determining whether the first prong is met. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

With respect to the first prong of the *Advanced Bionics* inquiry—*Becton, Dickinson* factors (a), (b), and (d)—the grounds in this Petition do not present substantially the same art or arguments previously presented to the Patent Office.

First, Hardy and Wellmann were not of record during prosecution of the '312 Patent, nor are they cumulative of any art that was considered, so there are material differences between these references and the prior art evaluated during examination.

Second, while Clavicula and a reference with a similar specification as Deffenbaugh (US 2007/0225715 to Deffenbaugh) were submitted in an IDS, neither

were addressed during prosecution, nor were they included in the basis of any rejection of the claims. *See Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00379, Paper 14 at 18 (PTAB July 3, 2019); *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7-11 (PTAB Nov. 5, 2019). They were submitted as part of an extensive list of approximately 90 references and there is no indication that their relevant teachings were considered. Moreover, the copy of Clavicula submitted by the applicant was nearly unreadable. *Compare* Ex. 1018, 5 (unreadable) *with* Ex. 1009, 5 (“sutures may be passed from medial to lateral around the coracoid process and the plate to take stress off of the lateral fixation.”). The examiner could not have substantively considered the unreadable text of Clavicula. Nor did the examiner have the benefit of the knowledge of a surgeon, like Dr. McKee, to explain what the disclosures of Clavicula show expressly or inherently, or how to apply the techniques for repairing the clavicle that were described. Thus, there is not any overlap between arguments made during prosecution and the manner in which Petitioners rely on Clavicula and Deffenbaugh in the Petition.

Third, while Thornes was considered during examination, it was not considered in combination with the references proposed in the Petition. There is very little overlap, if any, between the arguments made during examination and the manner in which Petitioners rely on Thornes. Thornes was not considered in

combination with art that teaches using contoured clavicle plates⁷ with sutures that utilize the coracoid process, like Clavicula, or with art that teaches a contoured plate utilizing a suture secured to a washer configured to fit within an opening of the plate, like Deffenbaugh.

With regards to the remaining prior art considered during prosecution, none of the art relied on in this Petition is cumulative of that art, nor is there any overlap of arguments made during examination. For example, the examiner alternatively relied on Kay and Paul for §103 rejections as disclosing the claimed structural plate features. In response, the applicant argued that Kay's plate was not rigid and incapable of contouring to the clavicle, and argued that Paul did not disclose a plate "contoured to follow said clavicle superior facing surface shape." Ex. 1011, 88-90, 114. In contrast, the primary references in this Petition, Clavicula and Deffenbaugh, are contoured rigid plates which can be secured to the coracoid process utilizing sutures. Thus, the Petition should not be discretionally denied. *Oticon Medical AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15 (PTAB Oct. 16, 2019) (precedential as

⁷ When responding to the rejection over Thornes, applicant pointed to arguments made in the parent application, which led to the '674 Patent, stating the claims were amended to include the substantially rigid plate is "contoured to follow the clavicle" and those same limitations are included in the '312 Patent. Ex. 1011, 55-56.

to sections II.B and II.C) (denying §325(d) arguments because, while some prior art had been considered by the Office, the petition included new art and arguments relevant to patentability).

Even if the inquiry were to reach *Advanced Bionics* prong 2—*Becton, Dickinson* factors (c), (e), and (f)—the Petition should not be discretionally denied because the examiner erred in a manner material to the patentability of the challenged claims.

First, the primary references in all grounds were never applied during prosecution. Given the poor quality of the copy of *Clavicula*, factor (f) weighs against denial in order to fully consider this prior art in legible form. *Clavicula* and *Deffenbaugh* also explicitly disclose the purportedly distinguishing features of the claims—a plate contoured to follow the clavicle with openings comprising a larger upper portion and a smaller lower portion. By failing to consider *Clavicula* and *Deffenbaugh*, the examiner erred in a manner material to the patentability of challenged claims.

Second, while *Thornes* did form the basis for rejection, the examiner did not consider *Thornes* in combination with a reference like *Hardy*, which teaches a longitudinal opening for receiving a washer with upper and lower portions. Nor did she consider any references like *Clavicula* and *Deffenbaugh*, which teach using contoured clavicle plates with sutures.

Third, this Petition does not rely on Thornes for disclosure of the same claim elements as cited by the Examiner. Whereas the Examiner relied on the oblong Button 102 of Thornes as the “substantially rigid plate,” this Petition relies on Button 102 of Thornes for disclosing the “anchor” element of the ’312 Patent, *not* the claimed plate.

Finally, the Examiner erred in interpreting and applying Thornes because she applied Button 102 as disclosing a rigid plate for fixing the clavicle, whereas Button 102 was designed to sit on the inferior side of the coracoid process, and this “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose...” *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). This oversight likely diverted the examiner from properly considering other prior art that rendered the claims obvious, e.g. Clavicula and Deffenbaugh.

C. Grounds of Unpatentability

1. Grounds 1 & 2: Claims 1-8, 13-17, and 19 are Obvious Over Deffenbaugh; Claims 1-10, 12-18 and 19 are Obvious Over Deffenbaugh and Thornes

Deffenbaugh in combination with the knowledge of a POSITA that Deffenbaugh could be used for clavicle fractures renders claims 1-8, 13-17, and 19 obvious. To the extent the Board determines it would not have been obvious to apply Deffenbaugh to clavicle fractures, it would have been obvious to combine the

teachings of Deffenbaugh with Thornes which expressly discloses a fixation system for the acromioclavicular joint (Ex. 1007, ¶[0017]). Ex. 1002, ¶72. Thornes' system includes a washer positioned on the clavicle, an anchor positioned on the underside of the coracoid process, and a suture connecting the washer and anchor through bone holes in the clavicle and coracoid process. Ex. 1007, ¶¶[0013]-[0014], [0017]-[0018], [0033].

These references are analogous art in that they both disclose similar fixation systems that include a washer and anchor attached by a suture used for fixating bone that operate in a similar manner. Ex. 1004, ¶¶[0008], [0057]-[0059], Claim 11; Ex. 1007, ¶¶[0013]-[0014], [0033]-[0034], Claims 19-20.

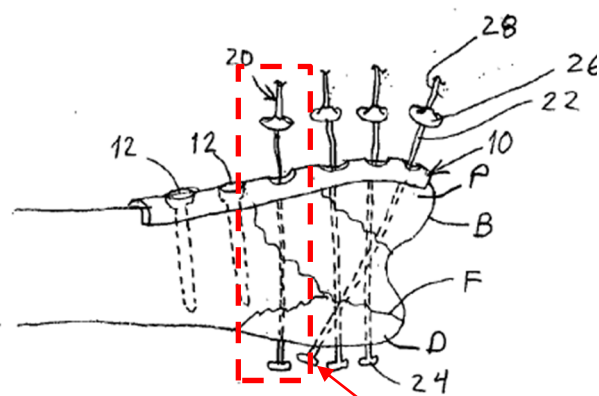


FIG. 1

Washer and anchor
connected by suture
passing through bone

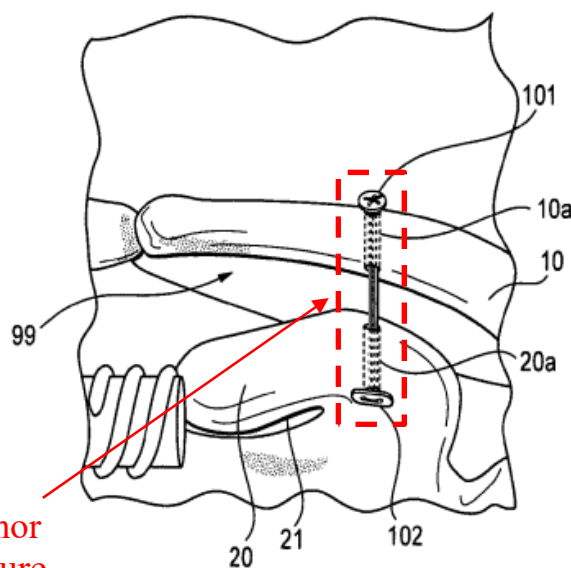


FIG. 7

Ex. 1004, Fig. 1

Ex. 1007, Fig. 7

A POSITA would have understood the Deffenbaugh plate could be used on a clavicle and would have been motivated to apply the device in a manner similar to that disclosed in Thornes to obtain and maintain proper correction of the fracture displacement, maximizing the chance of clinical success. Ex. 1002, ¶74. Dr. Gelfand himself acknowledged that his purported invention is nothing more than “the combination of two different commercially available products together to treat...distal clavicle injuries.”⁸

A POSITA would have been familiar with the practice of combining devices and methods like those disclosed in Deffenbaugh and Thornes. Ex. 1002, ¶74. A POSITA would have had a reasonable expectation of success in using the methods and devices of Deffenbaugh for clavicle fixation, using the technique of attaching the clavicle and coracoid process with a suture, as disclosed in Thornes. *Id.* ¶75. The suture, washer, and anchor of Deffenbaugh are very similar in design to those disclosed in Thornes, and any slight modifications to the Deffenbaugh system needed to make it effective for clavicle-coracoid attachment were well within the skill of a POSITA. *Id.* A POSITA would have recognized the components or shape of such components, including the washer and anchor of Thornes could have easily been used with the Deffenbaugh plate because both references teach they may be

⁸ See Ex. 1022, 4.

adapted for a variety of bone fixation applications. *Id.*; Ex. 1004, ¶¶[0002], [0036]; Ex. 1007, ¶[0017].

a. [1.p]

To the extent the preamble is limiting, it would have been obvious based on Deffenbaugh. Deffenbaugh discloses “A bone fracture fixation system.” Ex. 1004, Abstract. While the clavicle is not explicitly disclosed, a POSITA would have understood that Deffenbaugh teaches the system can be used throughout the body, including on a fractured clavicle. *Id.* ¶¶[0002] (“any bone fracture”), [0036] (“the tension elements and anchors may be provided as ‘one size fits all’”), [0056]-[0057], [0075] (“bone plate [] is shaped to fit a bone”); Ex. 1002, ¶54. Clavicle bone plates were well known at the relevant time,⁹ and it was well within the skill of a POSITA to make any minor modifications to the shape and contour of the bone plate for use on the clavicle. Ex. 1002, ¶55. Furthermore, the ’312 Patent acknowledges that modifications to the “physical shape[] and dimension” of a bone plate could be made without “departing from the spirit and scope of the invention.” Ex. 1001, 9:61-66. Accordingly, a POSITA would have found it obvious to shape the Deffenbaugh plate to fit the clavicle. Ex. 1002, ¶56.

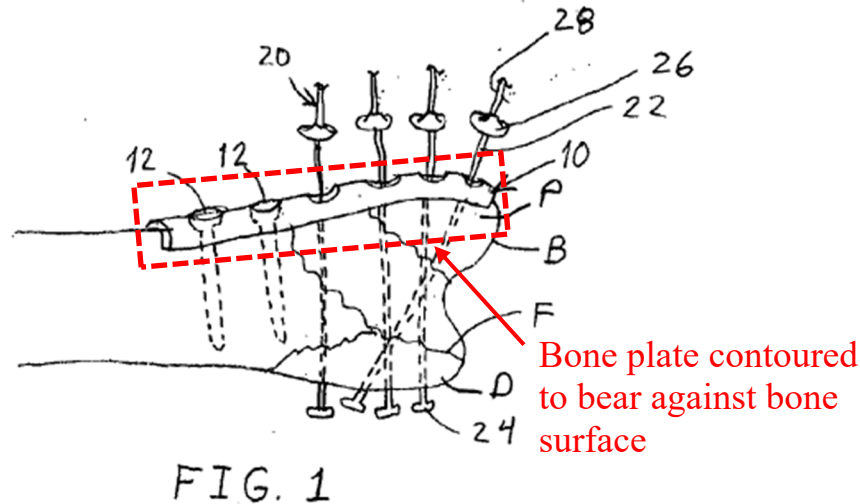
⁹ See generally Exs. 1009, 1016, 1017.

Alternatively, to the extent Deffenbaugh does suggest a fixation system for use on the clavicle, a POSITA would have looked to Thornes that expressly teaches a joint fixation system for a clavicle. Ex. 1007, ¶¶[0012], [0017] (“[The] acromioclavicular (AC) joint [] of the human shoulder comprising clavicle 10 and coracoid 20 and undergoing acromioclavicular (AC) joint reconstruction according to an embodiment of the present invention.”); Ex. 1002, IX.B.a. Based on these teachings, a POSITA would be motivated to use the Deffenbaugh system for clavicle fixation.

b. [1.1]

Deffenbaugh describes a plate contoured to follow a bone surface that is installed over the fracture site. As described in Section VI.B, above, based on Gelfand’s apparent understanding of this term, a POSITA would understand the Deffenbaugh plate is “substantially rigid” as it is rigid enough to fixate a fractured bone without bending or deformation after the tensioning elements are secured, and to retain its shape while the bone healed. Ex. 1004, Abstract, ¶¶[0008], [0057]; Ex. 1002, ¶58. Furthermore, U.S. Patent No. 5,954,722 (“’722 Patent”), incorporated by reference in Deffenbaugh, expressly describes a “rigid” bone plate. Ex. 1019, 3:65-67. (“Locking plate 12 includes a rigid body portion 20”); Fig. 2; Ex. 1002, ¶59.

Deffenbaugh teaches a variety of plate shapes that are contoured to follow the superior facing surfaces of bones within the body. Ex. 1004, Abstract (“configured to bear against a proximal surface of the bone”), ¶¶[0057] (“[t]he bone plate may be of many known configurations”), [0075] (“bone plate [] is shaped to fit a bone”).

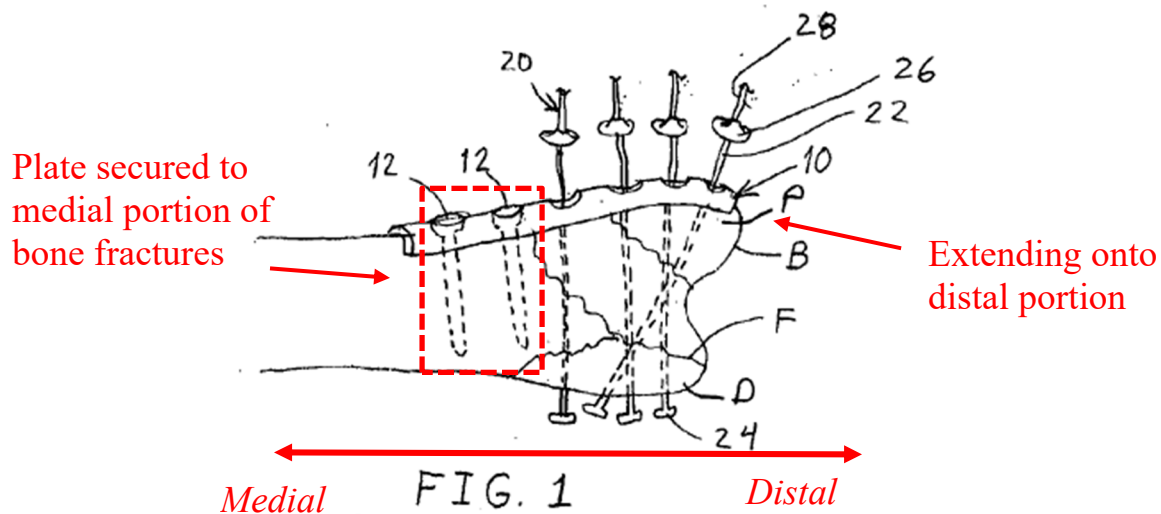


Ex. 1004, Fig. 1.

A POSITA would have understood the Deffenbaugh plate and technique could be used throughout the body, including on a fractured clavicle. Ex. 1002, ¶54.

A POSITA would also have understood the Deffenbaugh plate, applied to a distal clavicle fracture, would necessarily extend from a portion medial to the fracture—over the fracture—and onto a distal portion of the clavicle in order to

successfully reduce the fracture.¹⁰ Ex. 1002, ¶57. To effectively reduce the fracture, the plate may be secured to the medial portion of the clavicle. *Id.*, ¶¶[0057], [0065], Fig. 1. Figure 1, below, shows multiple fractures with fasteners securing the plate to the medial portion of the bone fracture, with the plate extending beyond the fractures onto the distal portion of the bone.



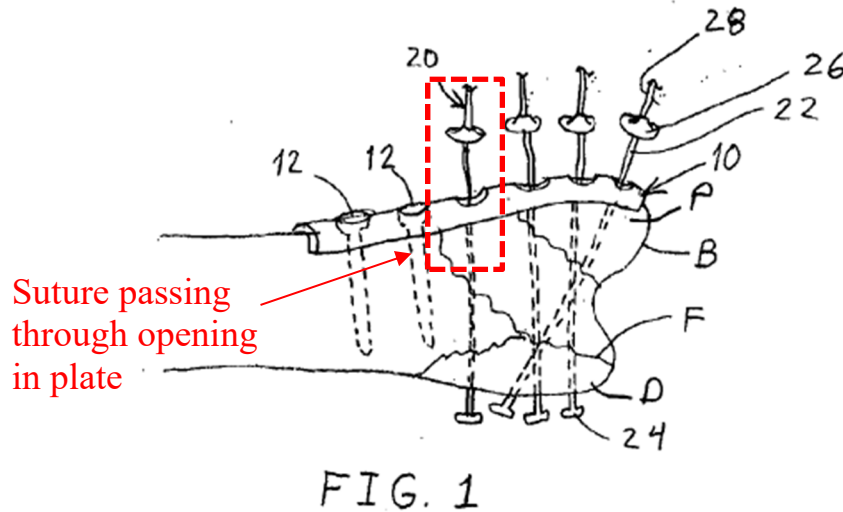
Ex. 1004, Fig. 1.

c. [1.2]

Deffenbaugh describes a plate with a number of openings through which tensioning elements (sutures) can pass. As shown in Figure 1, the plate has a plurality of tensioning elements “each sized to pass through an opening in the bone

¹⁰ The distal portion is the portion furthest away from the center of the body while the medial portion is closer to the center of the body. Ex. 1001, 4:12-15, Fig. 1.

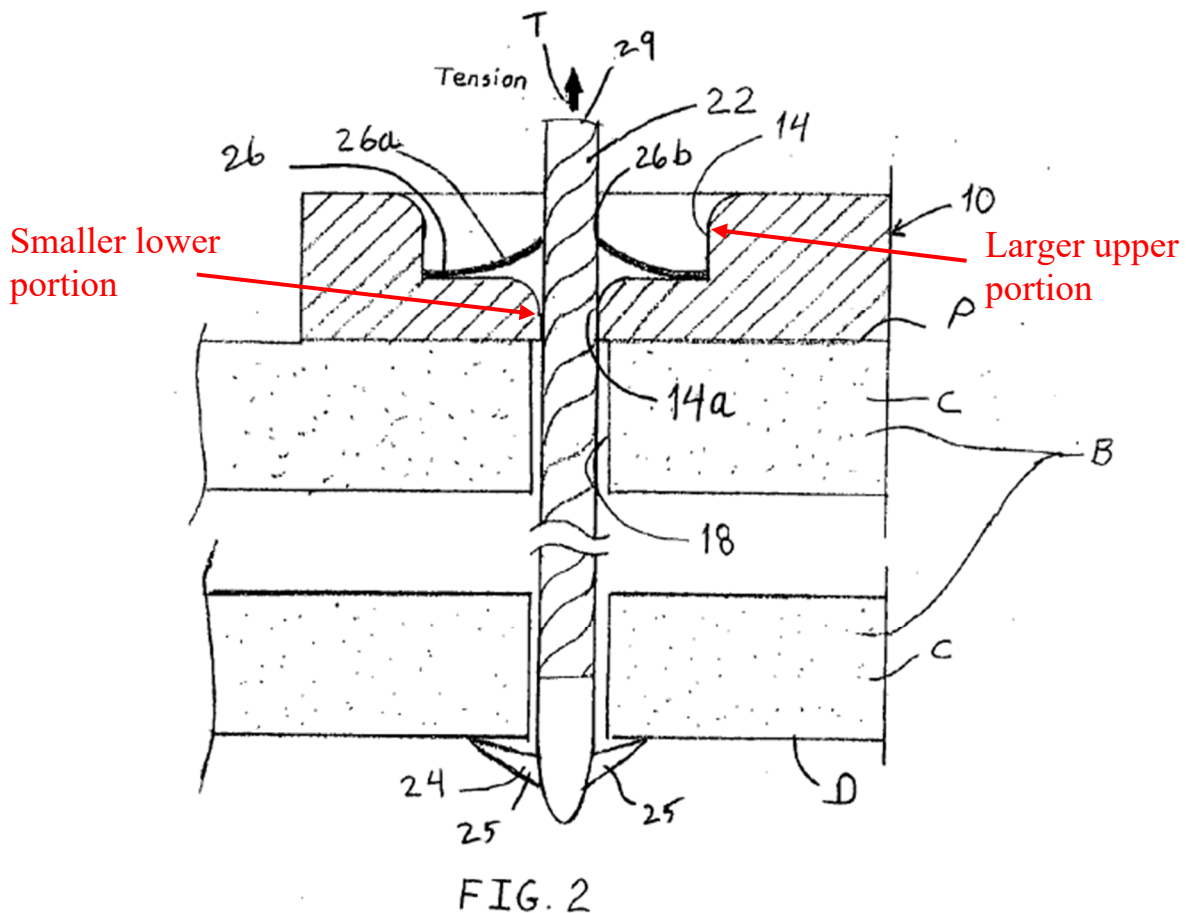
plate.” Ex. 1004, Abstract, [0008]; Ex. 1002, IX.A.c. The tensioning elements “may be a...braided suture.” Ex. 1004, ¶[0059].



Id., Fig. 1.

d. [1.3]

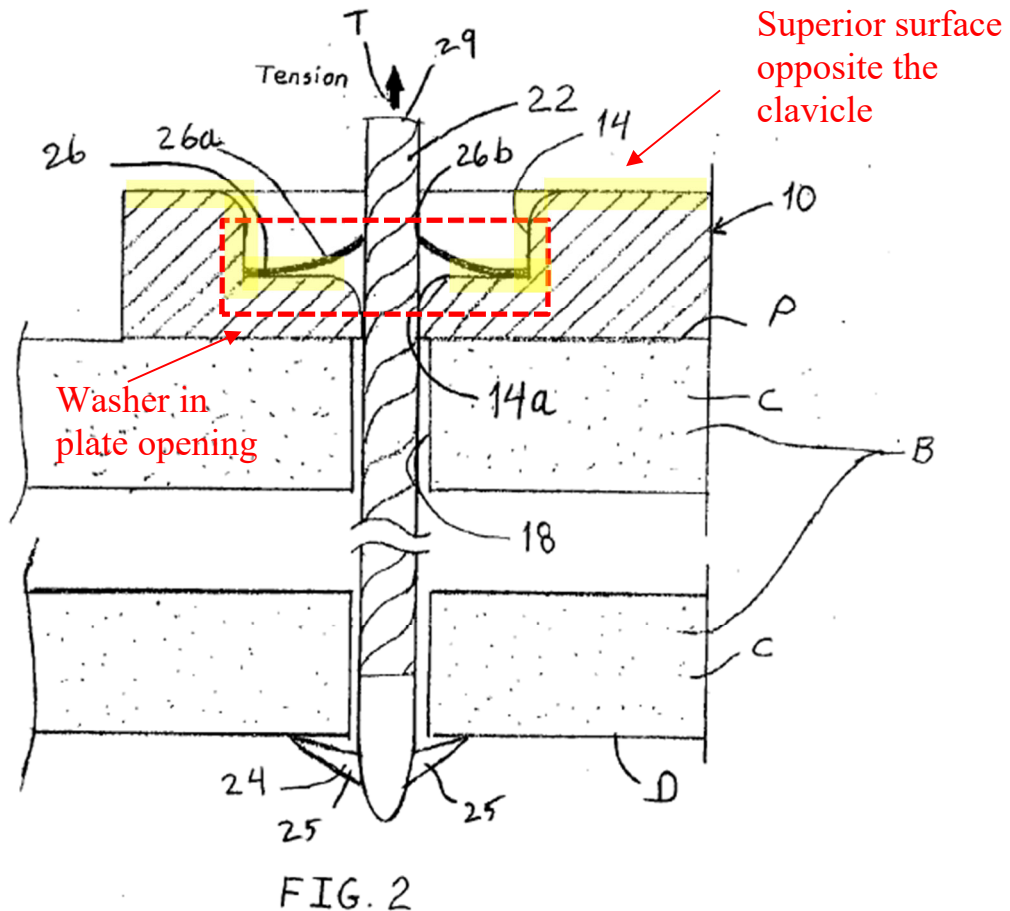
Deffenbaugh illustrates and describes plate openings that include a larger, upper portion, and a smaller, lower portion, as shown in Figure 2. *Id.* ¶¶[0058], [0060] (“the proximal anchor or washer 26 is positioned within the recess 14 in the plate”), [0085]; Ex. 1002, IX.A.d.



Ex. 1004, Fig. 2.

e. [1.4]

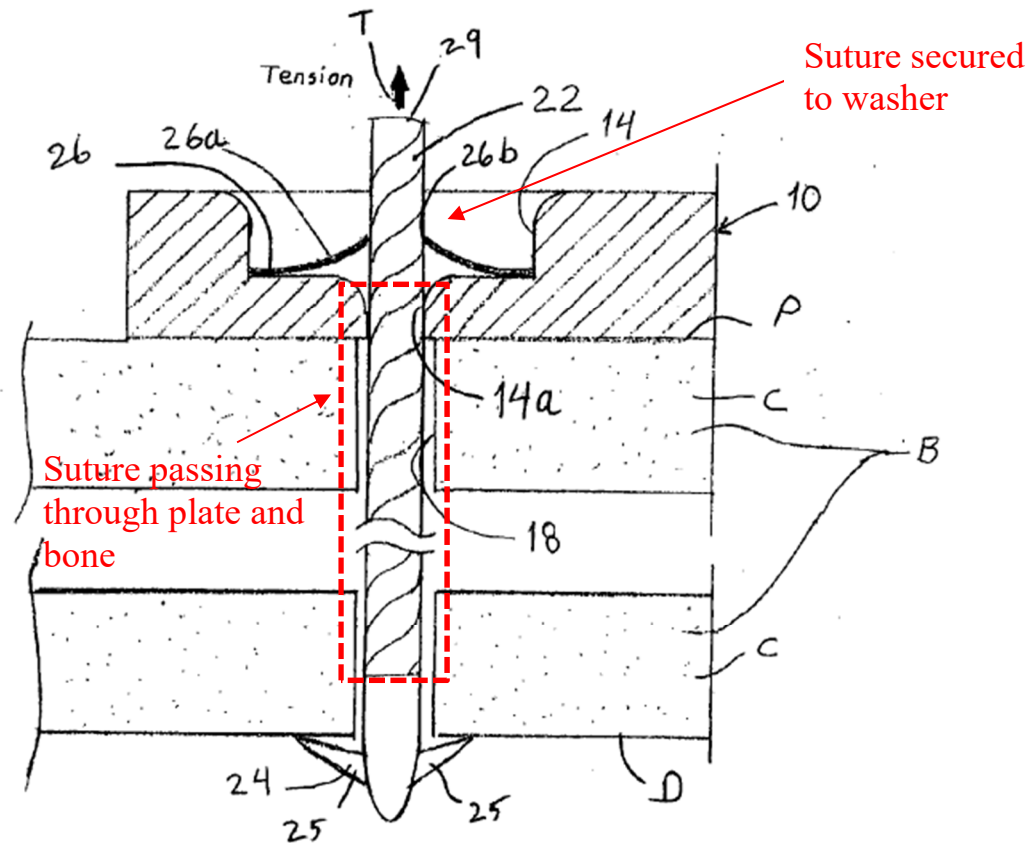
Deffenbaugh describes a washer positioned adjacent the plate superior surface opposite the bone. As discussed in Section VI.A, a POSITA would understand a washer to be a thin ring or perforated plate. Figure 2 shows a “Tinnerman washer” positioned in the opening of the plate opposite the bone. Ex. 1004, ¶[0060]; Ex. 1002, IX.A.e. The washer is adjacent to the plate superior surface opposite the clavicle (highlighted in Figure 2 below). *Id.*; Ex. 1002, ¶60.



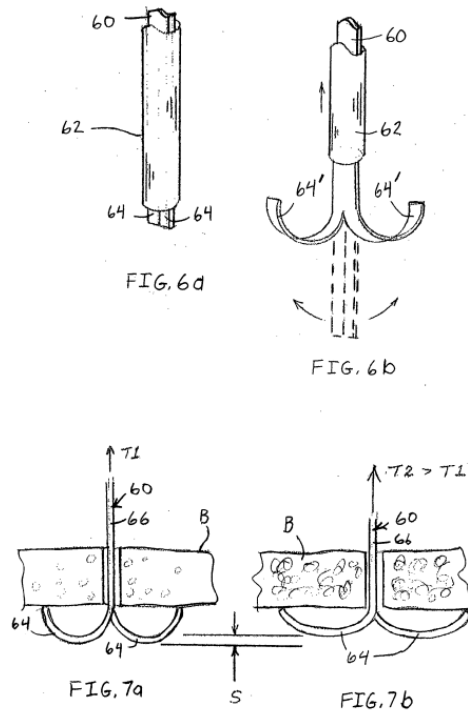
As explained for limitation [1.p], a POSITA would have found it obvious to apply the Deffenbaugh plate to a fractured clavicle. Ex. 1002, ¶54.

f. [1.5]

Deffenbaugh describes a suture secured to a washer where the suture extends through an opening in a plate and bone. Washer (26) “engages the proximal end” of suture (22). Ex. 1004, ¶¶[0058]-[0059]. The washer and suture are secured so that tension is maintained in the suture during fixation. *Id.* The suture passes through the plate and bone and engages with the distal anchor on the opposite side of the bone, as shown in Figure 2. *Id.*, ¶¶[0060], [0072]; Ex. 1002, IX.A.f.



Deffenbaugh also teaches using an introducer sheath 62 that helps facilitate passage of the tension element and distal anchor. Ex. 1004, ¶¶[0066], [0068].

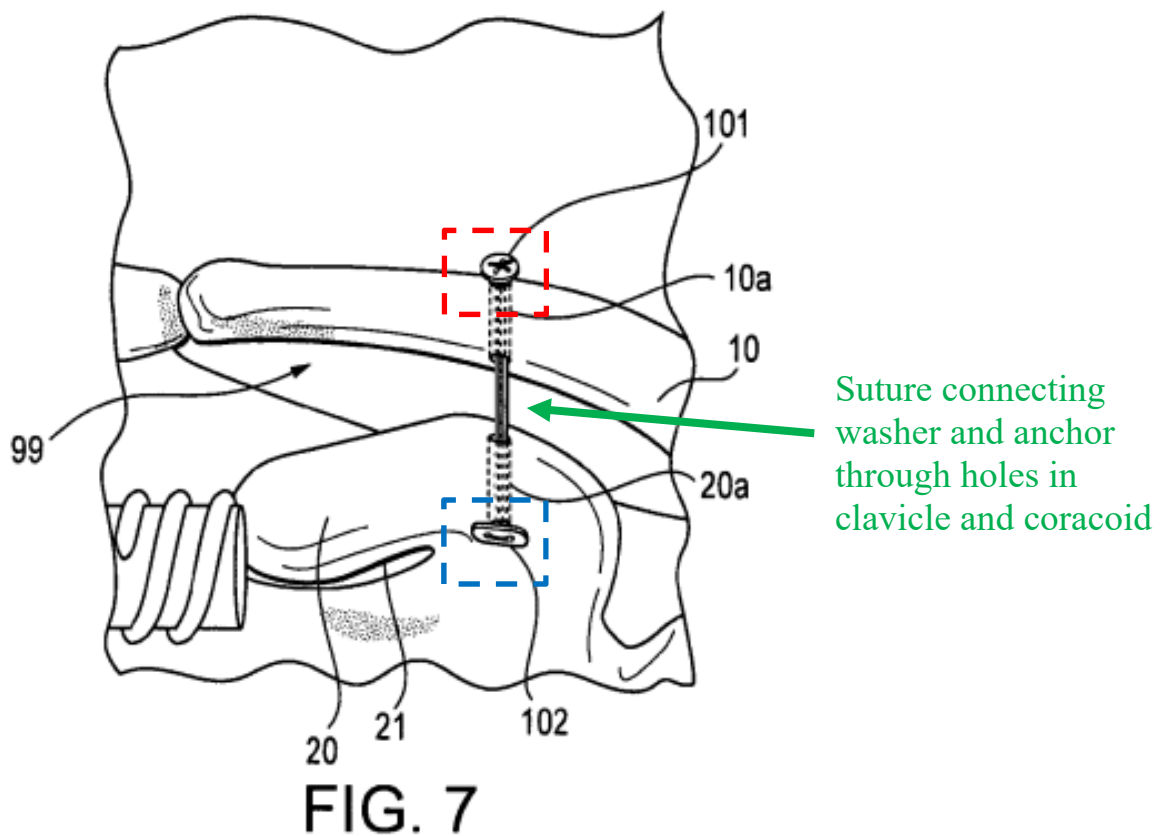


Ex. 1004, Figs. 6a-7b.

As discussed previously, a POSITA would have known the plate could be applied to the clavicle, and would have found it obvious to extend the suture through holes in both the clavicle and coracoid process. Ex. 1002, ¶61. A POSITA would have understood that, when applying the Deffenbaugh fixation device to a fractured clavicle, the suture should be extended through holes in both the clavicle and coracoid process in order to properly fix the fractured bone and stabilize the acromioclavicular joint. *Id.* This method of securing the clavicle to the coracoid process was well-known in the art at the relevant time.¹¹ *Id.*

¹¹ For example, see Exs. 1007, 1020, 1021.

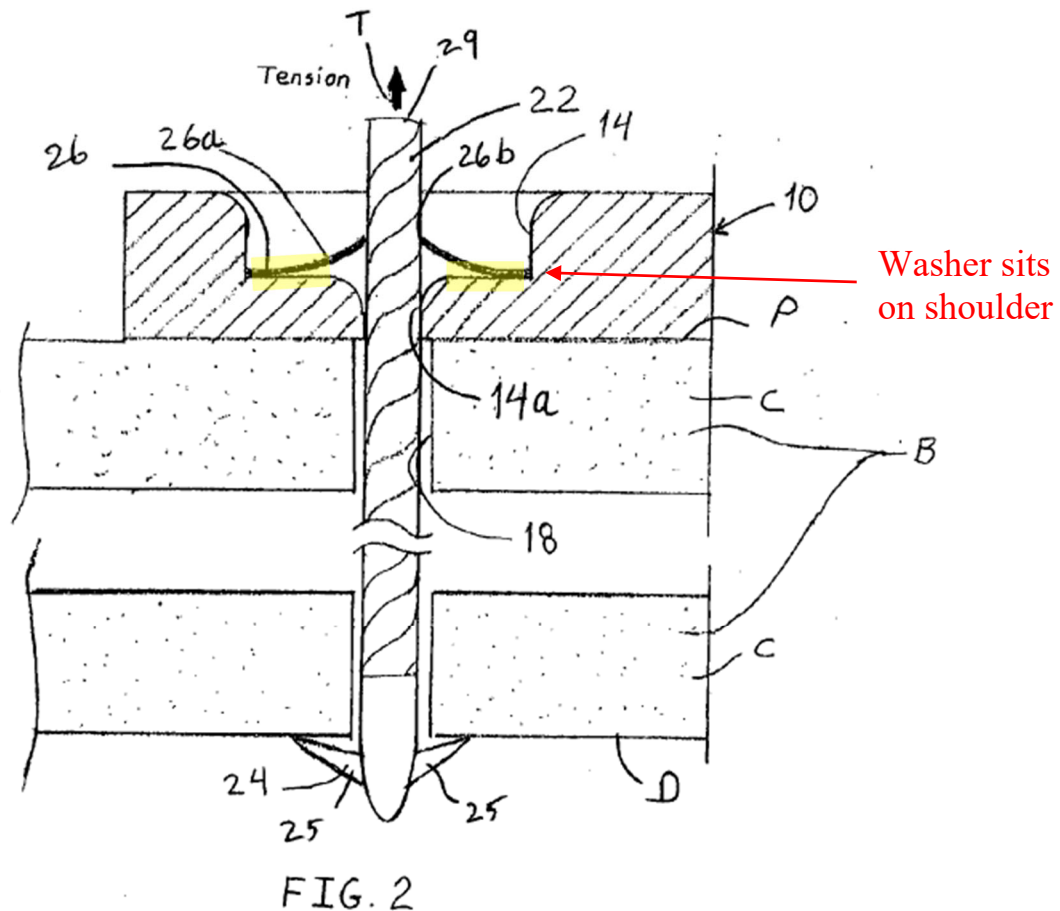
Alternatively, to the extent Deffenbaugh does not suggest passing a suture through a hole in the clavicle and securing it to the coracoid process, Thornes does expressly. Thornes teaches a washer and anchor joined by a suture. Ex. 1007, Abstract, ¶[0011]; Ex. 1002, IX.B.f. The washer (button 101) is positioned on the surface of the clavicle and the anchor (button 102) is advanced “through the hole in the clavicle and the coracoid until it exits the coracoid base” on the underside of the coracoid. *Id.*, ¶¶[0013]-[0014], [0033]. Figure 7 shows the washer (101) and anchor (102) connected by suture passing through a hole in the clavicle and coracoid process.



g. Claims 2 & 3

Deffenbaugh teaches a shoulder at the interface between the larger, upper portion and the smaller, lower portion of the plate opening on which the washer sits.

Ex. 1004, ¶¶[0058], [0060], [0085]; Ex. 1002, IX.A.g.

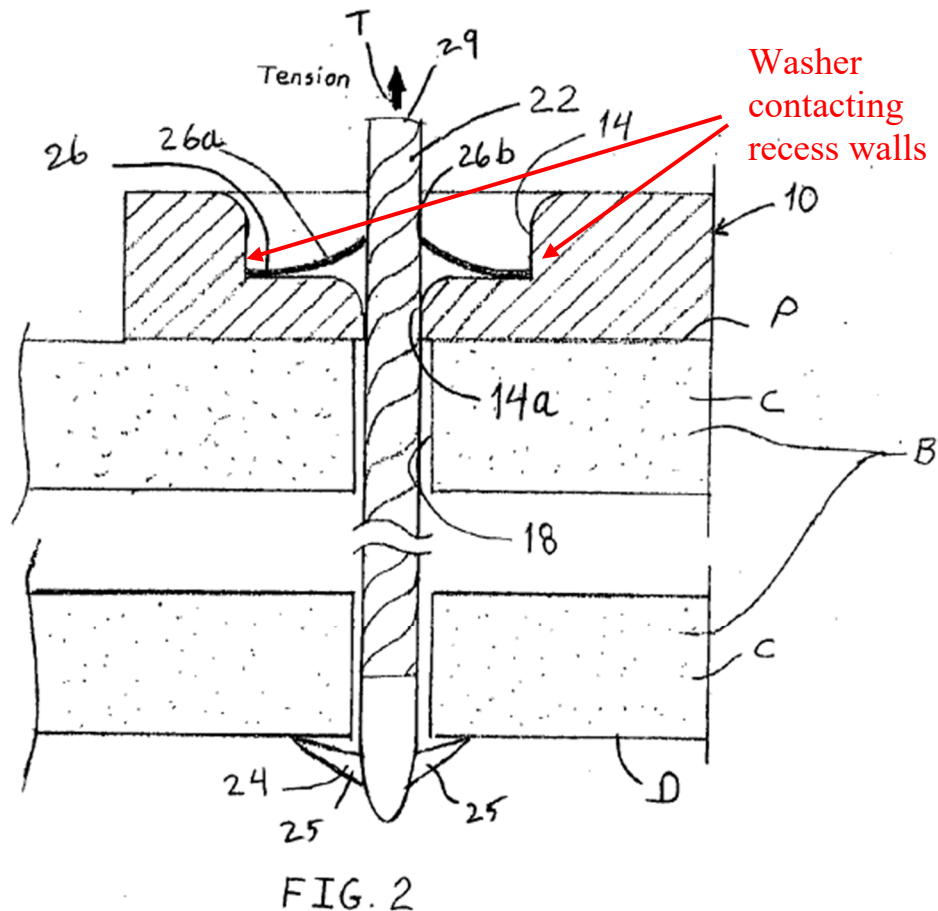


Ex. 1004, Fig. 2.

h. Claim 4

Deffenbaugh describes a washer that fits in the recess such that the sides of the washer and the walls of the recess are in contact with each other. As shown in Figure 2 below, the washer sits in the recess of the plate such that the “walls of the

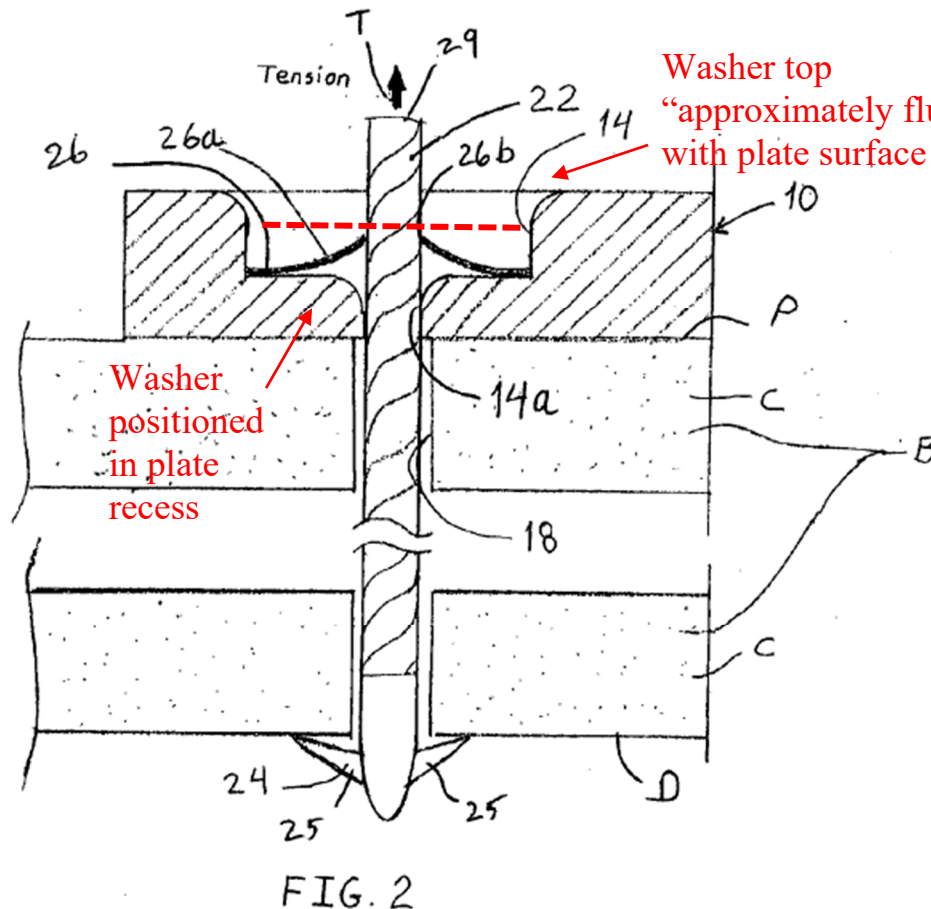
recess 14 keep the washer 26 from flattening so the washer will act to maintain the tension” in the suture. *Id.*, ¶¶[0009], [0060]; Ex. 1002, IX.A.h.



i. Claim 5

Deffenbaugh discloses a washer that sits approximately flush with the superior surface of the plate. Specifically, Deffenbaugh teaches a washer “sized to be received within the recess” so that it does not “project outside the exposed surface of the bone plate, to minimize trauma to surrounding tissue.” Ex. 1004, ¶¶[0009], [0085]; Ex. 1002, IX.A.i. A POSITA would understand the exact width of the washer with respect to the depth of the recess is merely a design choice. Ex. 1002,

¶62. As long as the washer does not protrude above the surface of the plate, trauma to the surrounding tissue would be reduced. *Id.* Thus, a POSITA would understand Deffenbaugh to teach or suggest washer 26 as being “approximately flush” with the plate’s surface. *Id.*

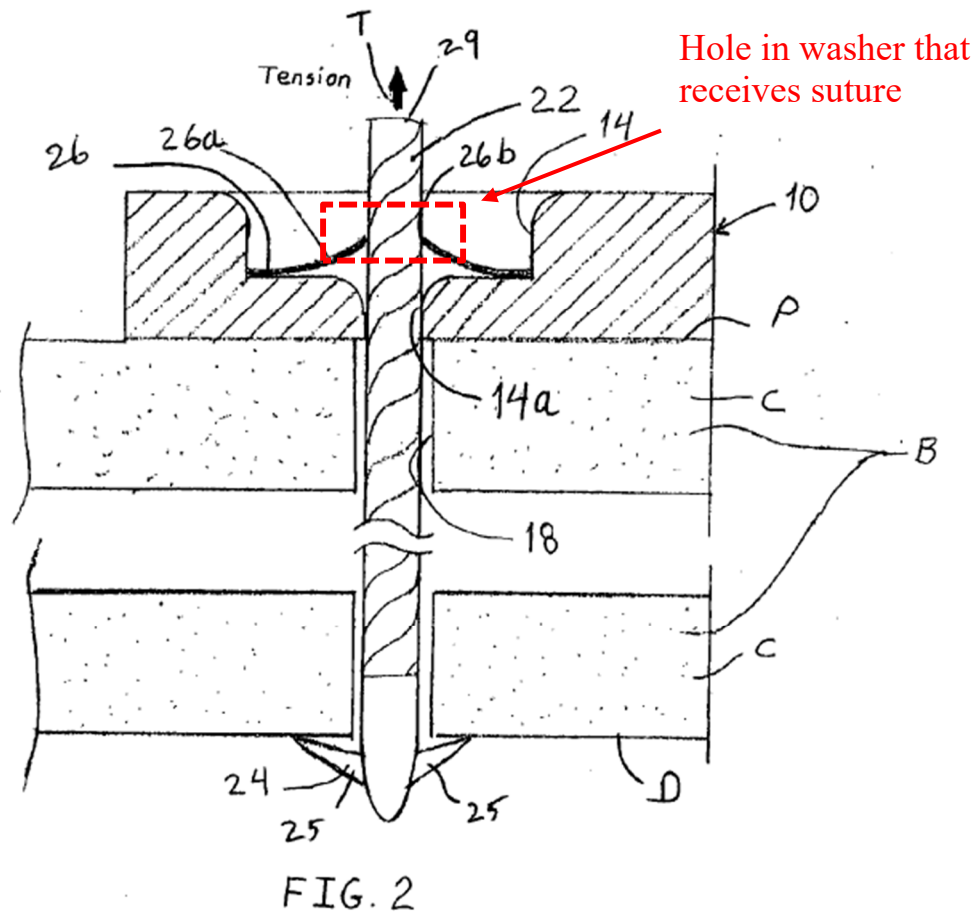


Ex. 1004, Fig. 2.

As discussed previously, a POSITA would have known the plate could be applied to the clavicle. Ex. 1002, ¶54.

j. Claim 6

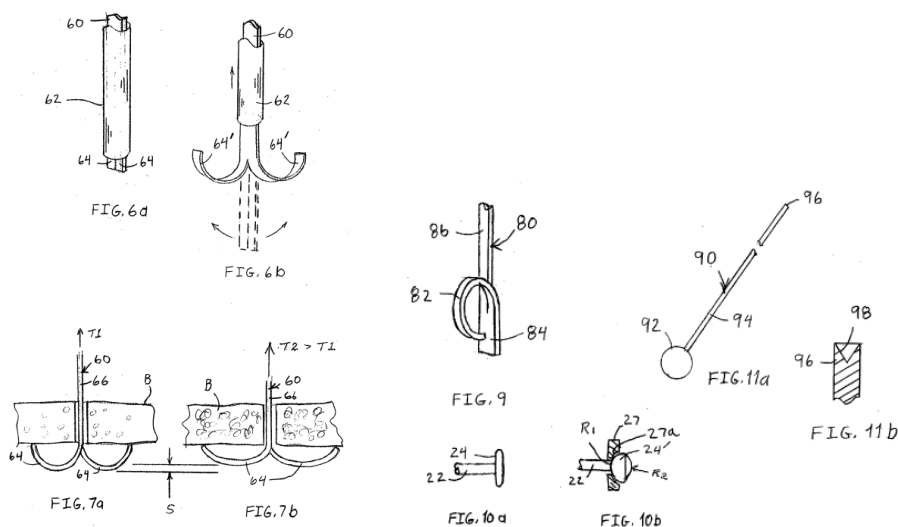
Deffenbaugh teaches the use of a Tinnerman washer which has a hole dimensioned to receive a suture as shown in Figure 2. Ex. 1004 ¶[0060], Figs. 1-2; Ex. 1002, ¶IX.A.j.



k. Claims 7 & 8

The Deffenbaugh fixation system includes a distal anchor 24 that engages with “the distal surface [] of the bone” after passing through a hole in the bone. Ex. 1004, ¶¶[0066]-[0067]. Deffenbaugh also teaches the use of distal anchors of varying shapes and design, and embodiments that include a sheath that helps

facilitate passage of the tension element and distal anchor. *Id.*, ¶¶[0066]-[0072]; Ex. 1002, IX.A.k.



Ex. 1004, Figs. 6a-11b.

As discussed with respect to limitation [1.5] above, a POSITA would have found it obvious to position the Deffenbaugh anchor on the underside (inferior side) of the coracoid when applying the plate to a clavicle fracture. Ex. 1002, ¶63. The application of the Deffenbaugh fixation device to a distal clavicle fracture would simply require using enough suture to ensure the tensioning elements of Deffenbaugh can span to the inferior side of the coracoid process. *Id.*, ¶64. Deffenbaugh specifically provides for excess suture material so the disclosed fixation device can be adapted to various applications. Ex. 1004, ¶[0033] (“[a]nother benefit is that the tension elements and anchors may be provided as ‘one size fits all’. In other words, once the tension elements are tensioned and anchored, excess material is removed.”); Figure 1 below.

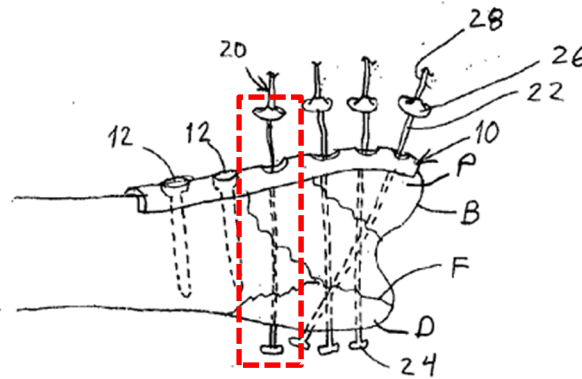


FIG. 1

Alternatively, to the extent Deffenbaugh does not teach or suggest an anchor placed on the inferior side of the coracoid process attached to a suture passed through a hole in the coracoid process, Thornes expressly describes this limitation.

Thornes teaches:

advanc[ing] the oblong button 102 through the bone tunnels 10a, 20a in the clavicle 10 and the coracoid 20 under direct visualization, until it exits the coracoid base 21. Independently pull on each of the white traction sutures 102a of the oblong button 102, to flip the button 102 onto the underside of the coracoid base 21.

Ex. 1007, ¶[0033]. As shown in Figure 7, Thornes teaches an anchor on the inferior side of the coracoid process secured to a suture that passes through a hole in the coracoid process. Ex. 1002, IX.B.1.

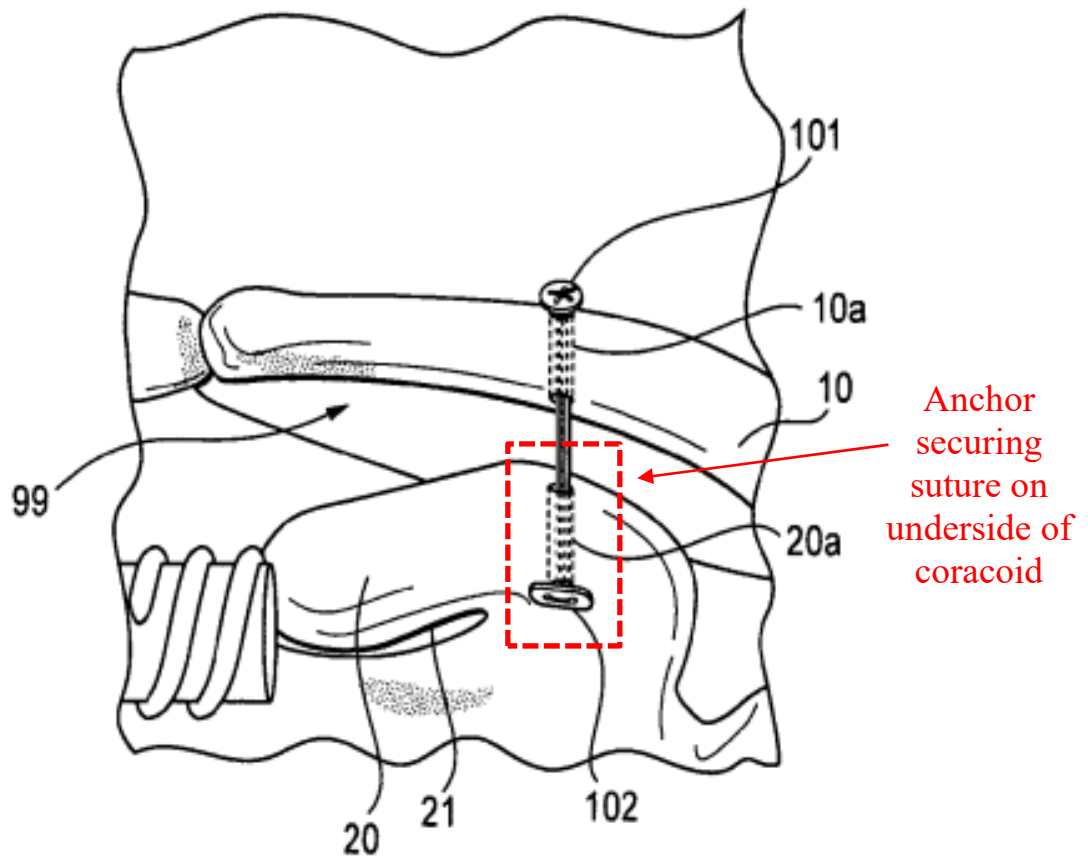


FIG. 7

l. Claims 9 & 10 (Ground 2 only)

Deffenbaugh expressly teaches passing a distal anchor through a bone hole and placing it such that its dimension and positioning prevent the anchor from returning through the bone hole. Specifically, after a bone hole has been created, “tension element 22 is passed through the plate opening and bone bore until the distal anchor 24 has exited at the distal surface D of the bone.” Ex. 1004, ¶[0066]. Deffenbaugh further describes an anchor dimensioned to resist returning through the bone hole. *Id.*, ¶¶[0058] (“the distal anchor [is]...adapted to anchor against the cortical bone [] at the distal surface.”), [0073] (“the distal anchors are... incapable

of passing through the plate opening [] or the bone opening.”). Deffenbaugh also teaches the distal anchor that may “come in a variety of forms” which include “a disc” and “a rounded element.” *Id.* ¶¶[0058], [0072]; Ex. 1002, IX.B.m.

While Deffenbaugh does not expressly teach an oblong anchor, Thornes does. Specifically, Thornes teaches an oblong anchor (button 102) that is advanced through “bone tunnels [] in the clavicle 10 and the coracoid” and then flipping the anchor to sit against the underside of the coracoid to resist returning through the bone tunnel. Ex. 1007, ¶¶[0018] , [0032], [0033], Fig. 9a.

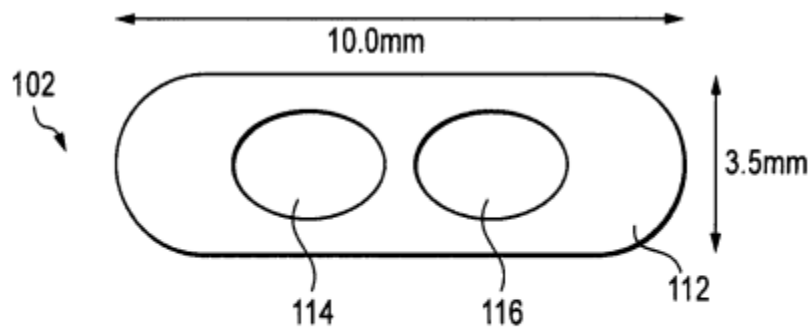


FIG. 9(a)

A POSITA would understand that this oblong button advantageously allows the anchor to pass easily through the plate and bone hole, while still providing an adequate method for securing the suture at the distal end of the hole. Ex. 1002, ¶87.

a. Claim 12 (Ground 2 only)

Thornes teaches an oblong washer with a plurality of holes distributed longitudinally. Thornes teaches buttons 101, 102 may be a variety of shapes including “circular, oblong, rectangular or parallelepipedal.” Ex. 1007, ¶[0018]. Figure 9a below shows an oblong shaped washer. *Id.*, ¶¶[0018]-[0019]; Ex. 1002, IX.B.n.

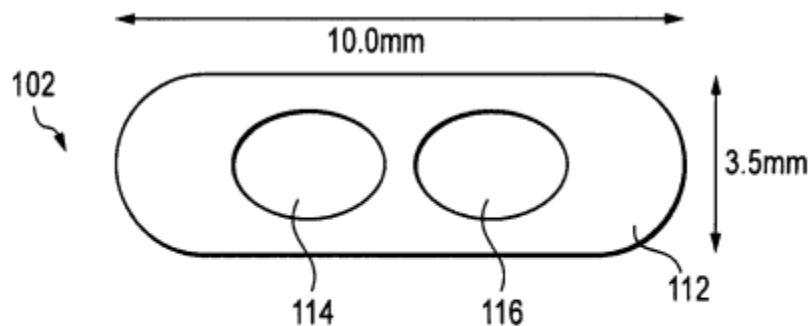
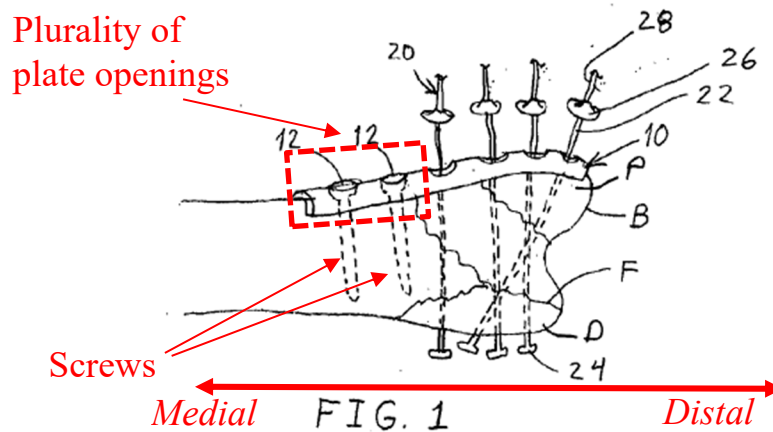


FIG. 9(a)

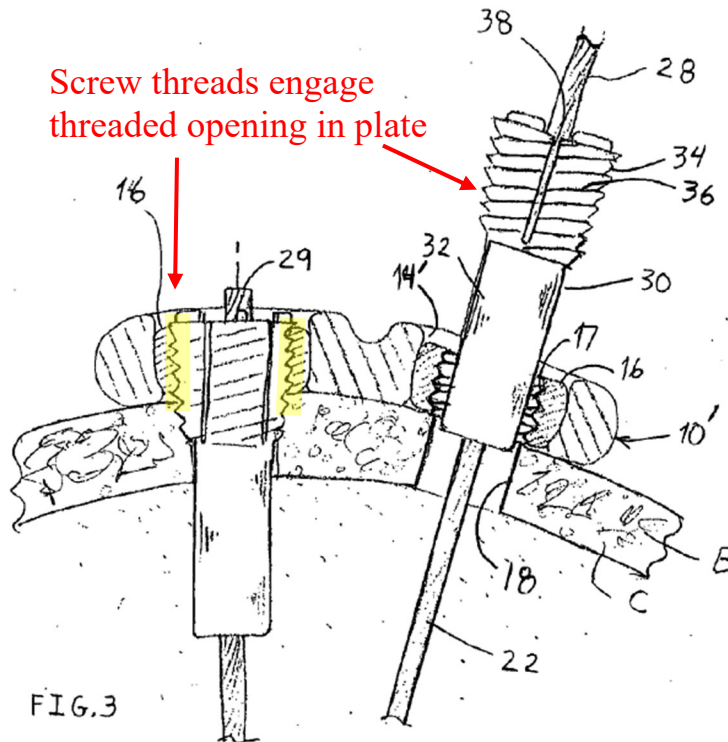
b. Claims 13 & 14

Deffenbaugh discloses a second opening in the plate that can receive a fastening device. Ex. 1004, ¶¶[0008], [0057] (“bone screws [] may be used to anchor one end of the bone plate”), [0065], [0075]. The Deffenbaugh plate has a plurality of openings with screws entering the medial portion of the bone. *Id.*, Fig. 1; Ex. 1002, IX.A.1.



c. Claim 15

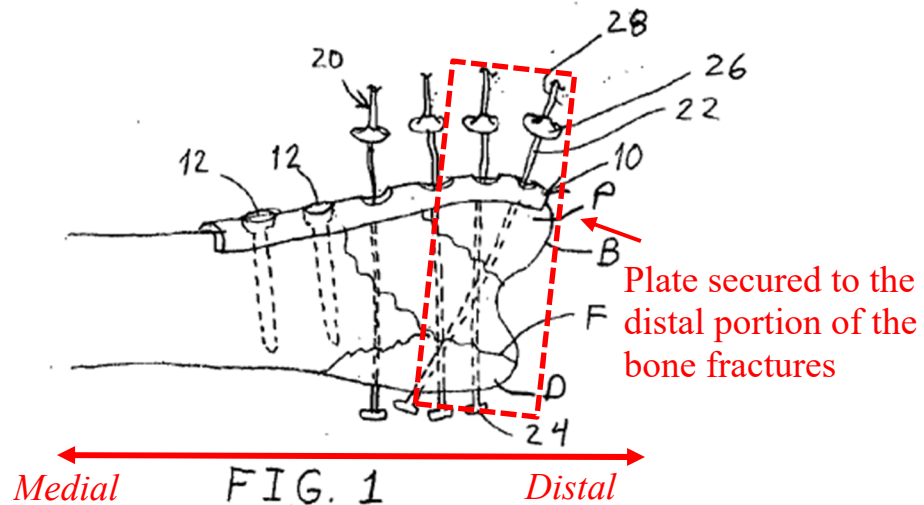
Deffenbaugh expressly teaches a fixation system with a locking bone screw that engages the bone plate. Ex. 1004, ¶¶[0010], [0061]-[0062]. The '312 Patent defines a locking screw as “a screw that has threads that engage ... corresponding threads in the [] hole in the plate.” Ex. 1001, 7:50-53. The Deffenbaugh locking screw threads engage with a “locking bushing” in the hole in the plate. Ex. 1004, ¶¶[0010] (“[t]he head of the anchor and the locking bushing define a tapered threaded interface so that the bushing expands into the spherical wall as the head is threaded into the bushing.”), [0061]-[0062]. Figure 3 of Deffenbaugh below shows the locking bone screw and bushing. Ex. 1002, IX.A.m.



While the locking bushing and screw are described as an “alternative proximal anchor” (Ex.1004, ¶[0061]), a POSITA would understand they could be used in addition to the fixation technique shown in Deffenbaugh, and described above in place of screws in the medial openings where suture is not used. Ex. 1002, ¶66.

d. Claim 16

As discussed with respect to limitation [1.p] and [1.1], a POSITA would have found it obvious to contour the Deffenbaugh plate to fit the distal portion of the clavicle. Ex. 1002, ¶67. As shown in Figure 1, the Deffenbaugh plate is contoured to securely fit the distal end of the bone. Ex. 1004, ¶¶[0057], [0058], [0075]; Ex. 1002, IX.A.n.



e. [17.p]

See [1.p].

f. [17.1], [17.2], [17.3]

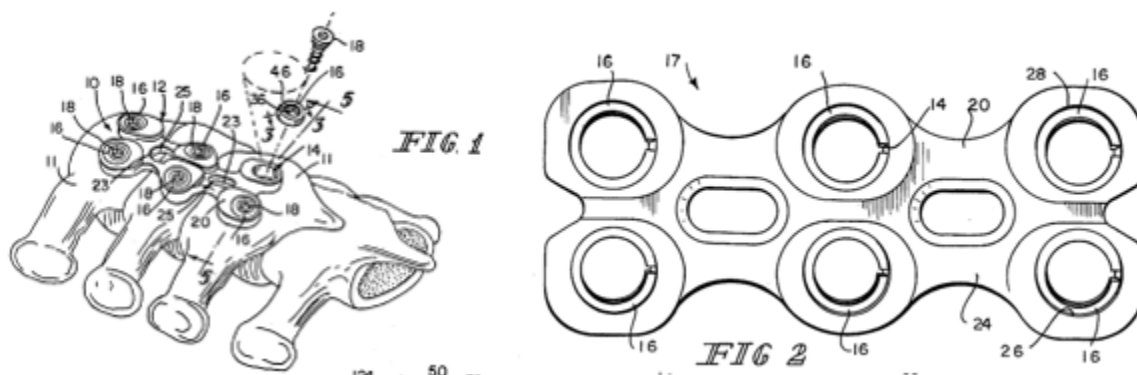
See claims 13 and 14.

g. Claim 18

See claim 9.

h. Claim 19

The '722 Patent, incorporated by reference in Deffenbaugh, teaches a plate having flared ends. "As shown in FIGS. 1 and 2, three sets of two plate holes 14 are positioned to lie in a side-by-side relationship through body portion 20." Ex. 1019, 3:65-4:23; Ex. 1002, IX.A.q.



Ex. 1019, Figs. 1-2.

As Deffenbaugh and the '722 Patent make clear, and as a POSITA would appreciate, the bone plate can be of any manner of shape and size, as appropriate for the particular indication. Ex. 1002, ¶70. Bone plates with flared ends were well-known at the relevant time and would be useful in anatomic situations where the bone region upon which the plate will sit is flared or where the end needs to accommodate multiple or offset fastening devices to ensure the strength and quality of fixation. *Id.* A POSITA looking to fix a distal clavicle fracture would understand that this is an indication where a plate having a flared end is advantageous, as evidenced by the commercially available Acumed plate discussed in Clavícula. *Id.*

2. Grounds 3 & 4: Claim 11 is Obvious Over Deffenbaugh, Thornes and/or Wellmann

The combination of Deffenbaugh and Wellmann renders claim 11 obvious. Ex. 1002, ¶95. For the reasons described in Ground 1, Deffenbaugh suggests fixation of a fractured clavicle using a plate, washer, and suture secured to the

coracoid process. While Deffenbaugh fails to teach passing the suture around the coracoid process, Wellmann discloses the same. Ex. 1008, 957; Ex. 1002, ¶96.

A POSITA would have found it obvious to use the Deffenbaugh system with a suture that is passed around the coracoid process, as taught by Wellmann since both Wellmann and Deffenbaugh disclose a fixation system utilizing a suture to hold opposing bone elements under tension. Ex. 1004, ¶¶[0008], [0013], [0057]-[0059], Fig. 1; Ex. 1008, 956-57, Fig. 1; Ex. 1002, ¶97. A POSITA would have been motivated to combine the Deffenbaugh plate with the Wellmann fixation system to achieve suitable fixation results and would have understood the deforming forces in an acromioclavicular joint dislocation and distal clavicle fracture are nearly identical. Ex. 1002, ¶98. Thus, an integral part of reduction and fixation of either of these injuries could include the Deffenbaugh plate and suture with Wellmann's suggestion to wrap the suture around the coracoid process to assist in reducing the acromioclavicular joint or distal clavicle fracture. *Id.*

A POSITA would have had a reasonable expectation of success in combining the methods taught in Deffenbaugh and Wellmann and would have understood that a knotted suture loop could be easily combined with the Deffenbaugh plate such that a suture could be passed through a hole in the plate and the clavicle, around the coracoid process, and either 1) brought back up around the coracoid process and tied to the suture in a manner shown in Wellmann, 2) placed through the original hole

secured with a washer with little or no modification to the fixation system disclosed in Deffenbaugh, or 3) placed through a second hole in the clavicle and bone plate and then tied over the plate itself (i.e. between the entry and exit holes of the suture). Ex. 1002, ¶99.

These references are analogous art because they are in the same field as the '312 Patent (Ex. 1001, Abstract, Title); (Ex. 1004, Abstract, Title); (Ex. 1008, Title, 955-57), and both relate to treating damaged body tissue. Ex. 1002, ¶100.

Alternatively, it would have been obvious to combine the teachings of Deffenbaugh and Thornes with Wellmann to render claim 11 obvious. Ex. 1002, ¶102.

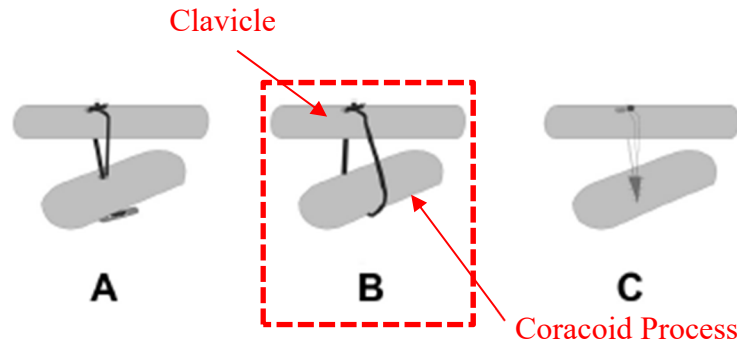
a. Claim 11

Wellmann discloses passing a suture around the coracoid process:

[A] sling was fashioned using a 1.3-mm-diameter braided PDS suture and passed under the coracoid process. ... One end of the loop was passed through a 3.5-mm clavicular drill hole placed in the position described above for the flip button procedure. The other tail of the sling was passed around the anterior border of the clavicle. The loop was tied using a surgeon's knot followed by 3 square knots, as performed in the flip button procedure.

Ex. 1008, 957. Figure 1 below shows passing a suture around the coracoid process.

Ex. 1002, IX.C.a. A POSITA would be motivated to wrap the suture in the Deffenbaugh system around the coracoid process in this manner to improve reduction of the acromioclavicular joint or distal clavicle fracture. Ex. 1002, ¶98.



3. Grounds 5 & 6: Claims 5 and 20 are Obvious Over Deffenbaugh, Hardy and/or Thornes

The combination of Deffenbaugh and Hardy renders claims 5 and 20 obvious. Ex. 1002, ¶103. While Deffenbaugh does not expressly teach a plate wherein sides of the washer are substantially parallel to the first opening in the plate, Hardy does. Ex. 1006, 3:2-5, 4:6-16, 4:20-24, 5:5-9; Ex. 1002, ¶104.

A POSITA would have found it obvious to combine the Deffenbaugh fixation system with washers having sides parallel to the sides of the plate opening, as taught by Hardy. Ex. 1002, ¶105. A POSITA would have been motivated to use a washer with sides that are substantially parallel to the plate opening to ensure a secure fit between the washer and the plate. *Id.*

To the extent the Board determines Deffenbaugh fails to disclose a washer having a surface approximately flush with the superior surface of the plate, Hardy discloses this as well. A POSITA would be motivated to use a washer that is approximately flush with the plate so as to reduce potential tissue damage and irritation and promote proper healing. Ex. 1002, ¶106.

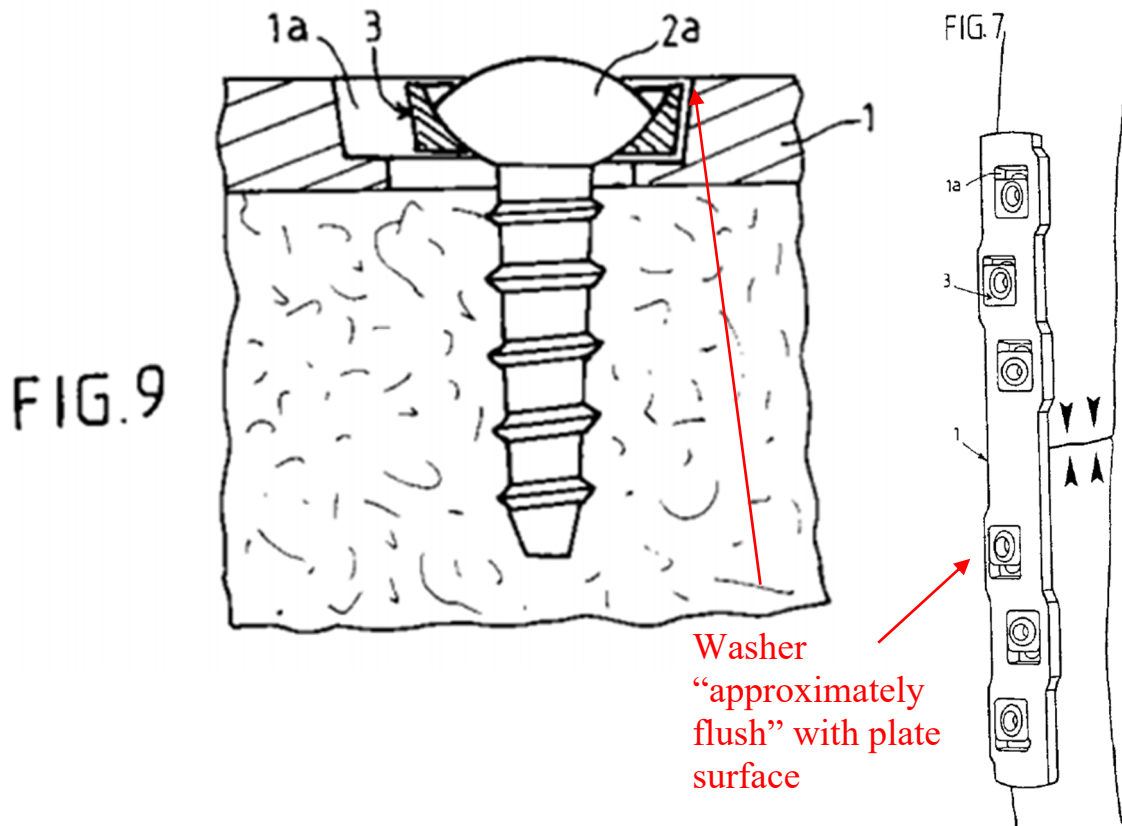
Including these design choices was well within the skill and knowledge of a POSITA, as these features were well known in the prior art at the time, and incorporating them would have required little to no modification. *Id.*, ¶107.

These references are analogous art because they are in the same field as the '312 Patent (Ex. 1001, Abstract, Title) (Ex. 1004, Abstract, Title) (Ex. 1006, Abstract, Title), and relate to treating bone fractures using bone plates and other devices. Ex. 1002, ¶108.

Alternatively, it would have been obvious to combine the teachings of Deffenbaugh and Thornes with Hardy to render claims 5 and 20 obvious. Ex. 1002, ¶110.

a. Claim 5

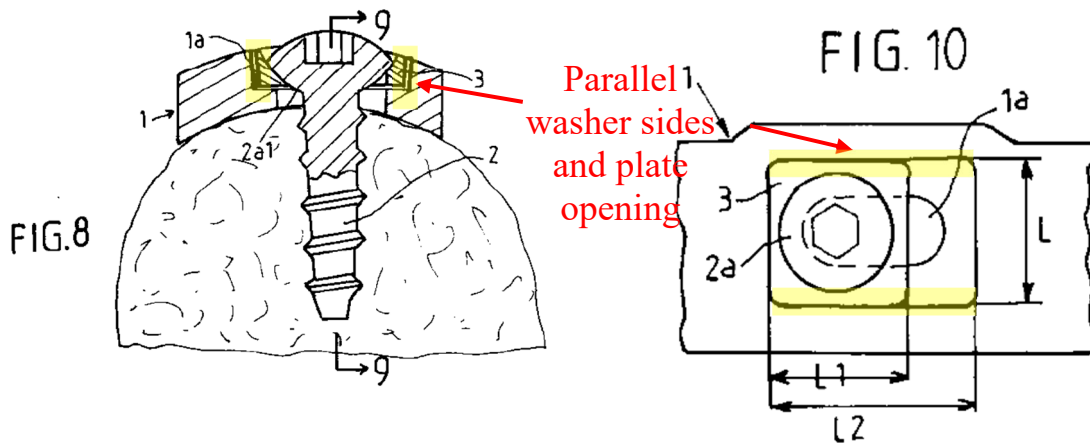
Hardy teaches a washer that is approximately flush with the surface of a bone plate. Ex. 1006, 4:9-16, Claim 4 (“the washers (3) are generally quadrangular in shape, the edges (3a) being chamfered in a complementary manner around (1a1) the orifices”), Figs. 6-9; Ex. 1002, IX.E.a.



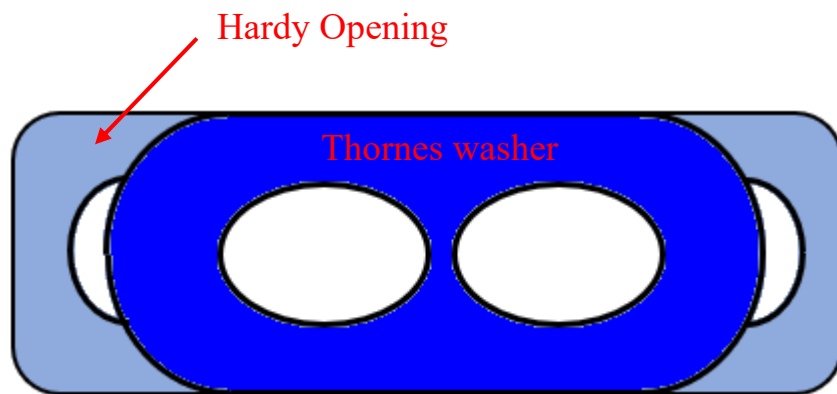
Ex. 1005, Figs. 7, 9.

b. Claim 20

Hardy teaches a washer with sides that are parallel to the opening of a plate. The Hardy washers are rectangular and sit within rectangular openings such that the width of the washer and the opening are approximately equal and the sides of the washer and opening are parallel. Ex. 1006, 4:9-17; Ex. 1002, IX.E.b. Figures 8 and 10 of Hardy show parallel sides of a washer and plate opening.



Furthermore, oblong plate openings and oblong washers were known, and it would have been a sensible choice from a limited set of washer designs to use an oblong washer, like that disclosed in Thornes, in an oblong hole, like that in Hardy, which would result in the sides of the washer being substantially parallel to the plate opening, as shown below. Ex. 1002, IX.E.b.



4. **Ground 7: Claims 1-20 are Obvious Over Clavicula, Hardy and Thornes**

The combination of Clavicula, Hardy and Thornes renders claims 1-20 obvious. Ex. 1002, ¶113.

Clavicula teaches a bone fixation system for a fractured clavicle that includes a plate contoured to follow the clavicle with oblong openings to receive a fastener, including a locking screw. Ex. 1009, 3, 5. The oblong openings comprise a larger, upper portion and a smaller, lower portion, forming a shoulder that interfaces with the fastener head. *Id.*, 3. Clavicula discloses the bone plate can have a flared distal end for fixing distal fractures. *Id.* Clavicula further discloses that suture may be passed around the plate and coracoid process to take stress off of the lateral fixation, but does not disclose a specific suture. *Id.*, 7; Ex. 1002, ¶114.

Thornes includes a washer positioned on the clavicle, an anchor positioned on the underside of the coracoid process, and a suture connecting the washer and anchor through holes in the clavicle and coracoid process. Ex. 1007, ¶¶[0013]-[0014], [0017]-[0018], [0033]. Thornes further teaches its washer-suture system “provides a simple, reproducible, minimally invasive technique for acute acromioclavicular joint stabilization.” *Id.*, ¶[0015]. A POSITA would recognize the Thornes washer could fit in any standard opening in a plate, such as in Clavicula, without modification to the plate or washer. Ex. 1002, ¶115.

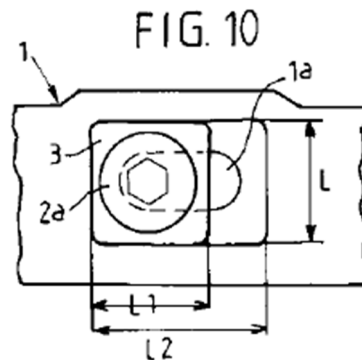
Hardy expressly teaches a plate for fracture fixation with an oblong opening forming a shoulder to receive a washer. Ex. 1009, 3:2-5; 4:6-14; 4:20-24; 5:5-9; Ex. 1002, ¶116.

A POSITA would have found it obvious to combine the contoured Clavicula plate, the Thornes washer-suture system, and the shouldered plate and washer of Hardy. Ex. 1002, ¶117. 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. Ex. 1009, 7. Passing a suture around the clavicle and coracoid process requires more dissection, causing greater tissue damage and longer recovery times. Ex. 1002, ¶117.

Optimal suture technique is important because the primary force on the distal fragment is inferior displacement and the suture would specifically resist displacement. *Id.*, ¶118. Sub-optimal suturing can cause complications by not applying the proper tension, or placing the suture in the wrong position. *Id.* Thus, a POSITA would be motivated to look to prior art that discloses sutures for use with the clavicle and/or coracoid process. *Id.* Thornes teaches a suture system that provides a “simple, reproducible, minimally invasive technique” for stabilizing the clavicle and coracoid process. Ex. 1007, ¶[0015]; Ex. 1002, ¶119. Such techniques minimize soft tissue complications, maximize the strength of the fixation, and thus optimize patient outcomes. *Id.* It was known that fixation with screws alone had a relatively high failure rate, and that augmentation with a suture and/or washer system significantly improved biomechanical strength. *Id.* A POSITA would be 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. *Id.*

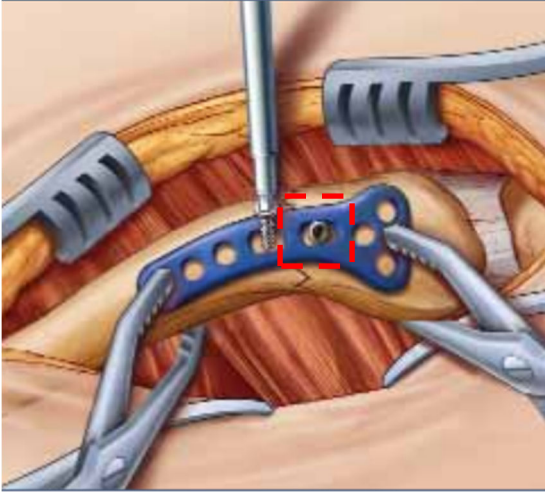
Clavícula further discloses a plate with oblong openings having a shoulder for receiving a fastener, but does not disclose a washer. Ex. 1009, Figs. at 3. Bone plates that received fasteners recessed into the oblong opening of the plate, which provide improved fastener positioning allowing for precise placement, were well known at the relevant time. Ex. 1002, ¶120. For instance, Hardy discloses a plate with oblong openings recessed to receive a washer. Ex. 1006, 2:14-3:5, 5:1-3, Figs. 1-2, 6-7, 10.



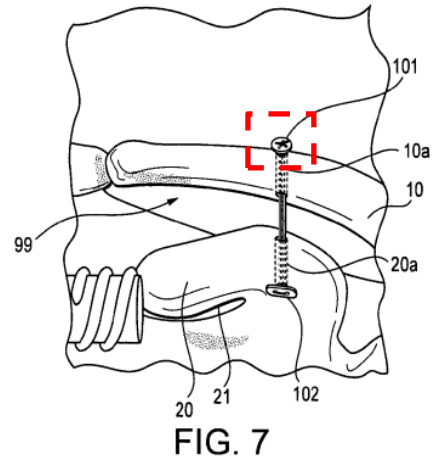
A POSITA would have been motivated to include an opening with a larger, upper portion and a smaller, lower portion to receive a washer, thus minimizing tissue irritation by reducing the profile of the implant, which reduces reoperation rates for subsequent hardware removal. Ex. 1002, ¶121. A POSITA would have been motivated to make the opening oblong to permit adjustable positioning of the suture. *Id.*

As Clavicula teaches, in most distal clavicle fractures, it is beneficial to fix a suture between the plate and the coracoid to take stress off the lateral fixation. Ex. 1002, ¶122. The stability of the fracture is significantly increased by such a suture, allowing for more reliable healing and better clinical outcome. *Id.* A POSITA 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. *Id.*

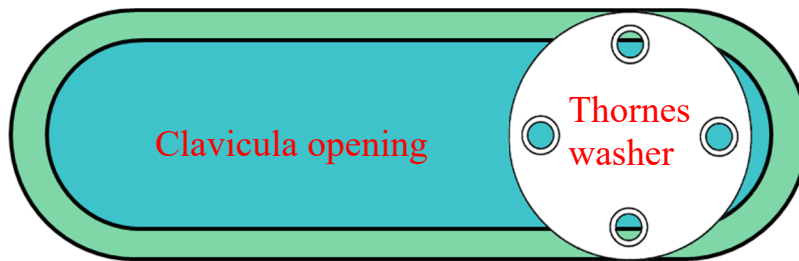
A POSITA would have expected this combination of fixation devices to yield predictable results. Ex. 1002, ¶123. A POSITA would have had a reasonable expectation of success in combining the plate features of Clavicula and Hardy with the Thornes washer-suture system for fixing the clavicle and coracoid process. *Id.* 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. Ex. 1007, Abstract, ¶¶[0011], [0015], Figs. 6-10. Notably, Thornes discloses a round washer with a similar geometry to the round fastener heads positioned in the oblong opening of the Clavicula plate, as shown in the demonstrative figure below. Ex. 1002, ¶123.



Ex. 1009, Fig. at 6



Ex. 1007, Fig. 7



Ex. 1002, ¶123. Any slight modifications to the Clavicle plate needed to utilize the Thornes washer were routine and well within the skill of a POSITA. *Id.*, ¶124. A POSITA would recognize that by incorporating an oblong hole (as Hardy teaches), the plate could be secured to the clavicle (as taught by Clavicle) 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). *Id.* A POSITA would recognize this configuration would significantly improve biomechanical strength to the fixation and minimize the risk of loss of reduction. *Id.*

Thornes expressly teaches that its fixation system could be adapted for a variety of bone/tissue fixation applications and a POSITA would have understood the Thornes fixation technique could have been applied to the Clavicula plate for distal clavicle fracture fixation. Ex. 1007, ¶[0017] (“[T]he invention...contemplates reconstruction and/or fixation systems for any structures (bone, cartilage, soft tissue, etc.) that need to be stabilized, fixated and/or reconstructed.”); Ex. 1002, ¶125.

Both the Clavicula plate and the Thornes washer-suture system perform the same function individually as they do in combination—they fixate the bone and stabilize the acromioclavicular joint, respectively. *Id.*, ¶126. The combination merely substitutes the non-specific suture disclosed in Clavicula for the Thornes washer-suture system with predictable results. *Id.* Furthermore, the Clavicula plate was ready for improvement because it fails to disclose the optimal suture technique for reducing stress on the fixation. *Id.* A POSITA would recognize the application of Thornes’ 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. *Id.*

The use of bone plates with oblong, recessed openings was well-known in the art at the relevant time. *Id.*, ¶127. A POSITA would have a reasonable expectation of success in combining the Hardy washer with the Clavicula plate because Clavicula discloses an oblong opening that a POSITA would recognize as capable

of receiving a washer to provide additional stability. *Id.* A POSITA would further have a reasonable expectation of success in substituting the Hardy washer for the Thornes suture-affixed washer—which was more standard at the relevant time—because the combination merely involves the substitution of one washer for another. *Id.* 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. *Id.*

Clavicula, Thornes, and Hardy are analogous art as all three relate to treating damaged body tissue. Ex. 1002, ¶128.

a. Independent Claim 1

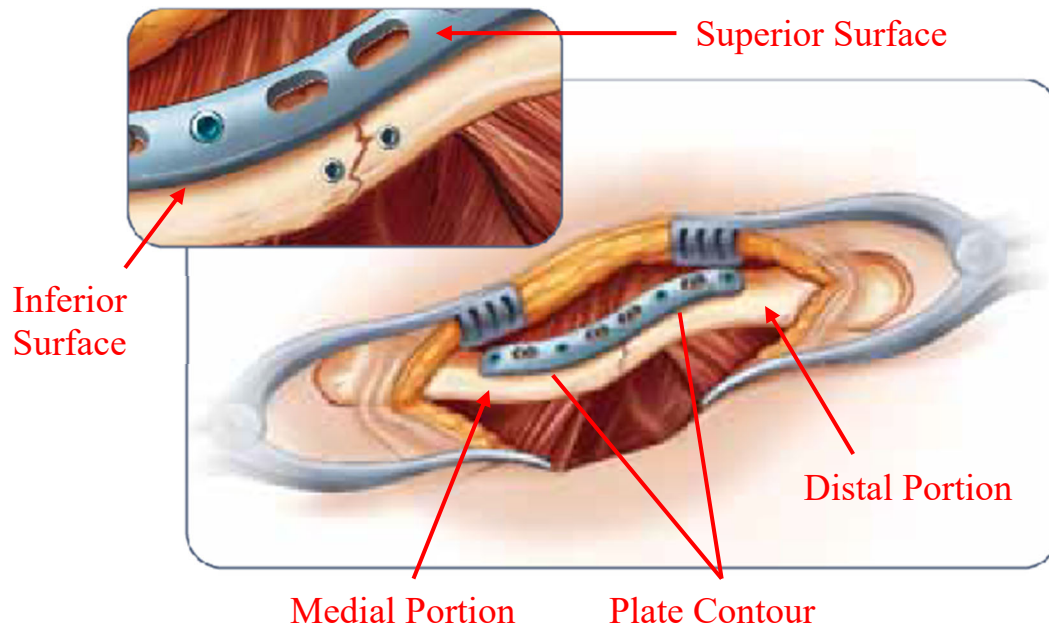
(i) [1.p]

To the extent the preamble is limiting, Clavicula discloses a fixation system for a fractured clavicle, the fracture defining a medial and distal portion of the clavicle relative to the fracture, and the clavicle having a superior facing surface shape. Ex. 1009, 2 (“Acumed has designed a comprehensive solution for repairing fractures located from the middle third to the distal third of the clavicle.”), 3 (“Plating the superior aspect of the clavicle has been found to be biomechanically the most stable.”), 4 (“The two middle slots may be placed over the fracture, ideally leaving two to three locking and/or non-locking holes both proximal and distal to the fracture fragments.”). Ex. 1002, IX.G.a.

(ii) [1.1]

Clavicula describes a plate contoured to follow the clavicle that is secured over the fracture site. As described in Section VI, above, Gelfand's apparent understanding of the term "substantially rigid" would encompass a plate rigid enough to fixate a fractured bone without deformation. A POSITA would understand the Clavicula plate is rigid enough to fixate a fractured bone without bending or deformation after the tensioning elements are secured, and to retain its shape while the bone healed. Ex. 1009, 2 ("[T]his titanium plate offers increased strength..."); Ex. 1002, ¶131.

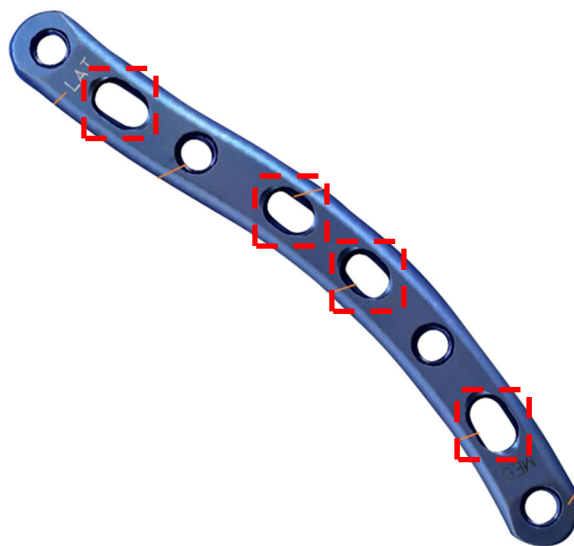
Clavicula teaches the plate is contoured to follow the superior surface shape of the clavicle. For example, Acumed offers "[m]ultiple plate options are available to fit a wide variety of clavicle curvatures." Ex. 1009, 3. The plate is also configured to extend at least partially over the distal portion of the fracture when secured to the medial portion. See Ex. 1009, 5 ("[P]lace the 3.5mm locking screws...into the threaded holes so that there are at least three screws (if possible) on each side of the fracture."), 6; Ex. 1002, ¶130. The figure below shows the contoured plate secured to the clavicle.



Ex. 1009, 5; Ex. 1002, IX.G.b.

(iii) [1.2]

Clavicula describes a plate with at least one opening through which a suture can pass. For example, Clavicula discloses four oblong openings as shown in the figure below. Ex. 1002, IX.G.c.



Ex. 1009, 3.

The openings in the Clavicula device are designed to allow passage of a 3.5 mm fastener. *Id.*, 6 (“3.5 mm screws [] are recommended...place the screws into the slots”). A POSITA would recognize these openings would allow passage of a suture. Ex. 1002, ¶132.

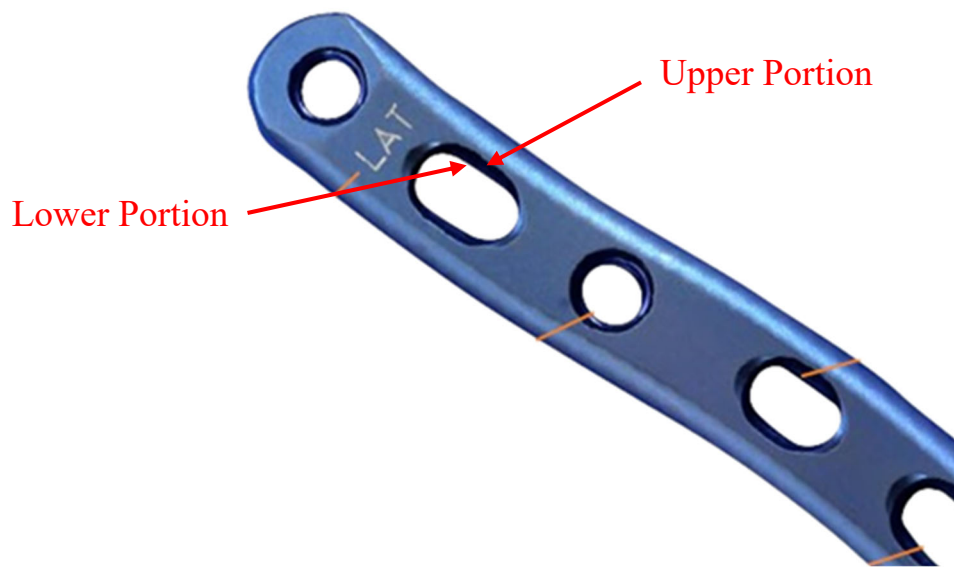
Clavicula discloses a suture utilizing the coracoid process to take stress off the lateral fixation, but does not disclose a specific suture. Ex. 1009, 7. Thornes teaches a washer and anchor joined by a suture. Ex. 1007, Abstract, ¶[0011]. The washer (button 101) is positioned on the surface of the clavicle and the anchor (button 102) is advanced “through the hole in the clavicle and the coracoid until it exits the coracoid base” on the underside of the coracoid. *Id.*, ¶¶[0013]-[0014], [0033]. As discussed above, a POSITA 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. Ex. 1002, ¶135.

A POSITA would recognize that placing the washer and suture beneath the plate would be suboptimal because it would prevent the plate from contacting the bone along the entire length of the plate, decreasing mechanical strength and increasing plate prominence, and causing soft-tissue irritation due to the relatively thin tissue coverage in the area. Ex. 1002, ¶134. A POSITA 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. *Id.*, ¶133.

(iv) [1.3]

Clavicula describes recesses in the bone plate that include a larger, upper portion, and a smaller, lower portion, such that the plate would be secured to the clavicle by placement of screws. Ex. 1009, 6 (“[P]lace the screws into the slots with the assembled driver. Once the two screws are installed, the bone clamps [] holding the plate to the clavicle may be removed.”); Ex. 1002, IX.G.d. A POSITA would understand 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. Ex. 1009, 2; Ex. 1002, ¶136. The figure below demonstrates the upper and lower portions of the opening.

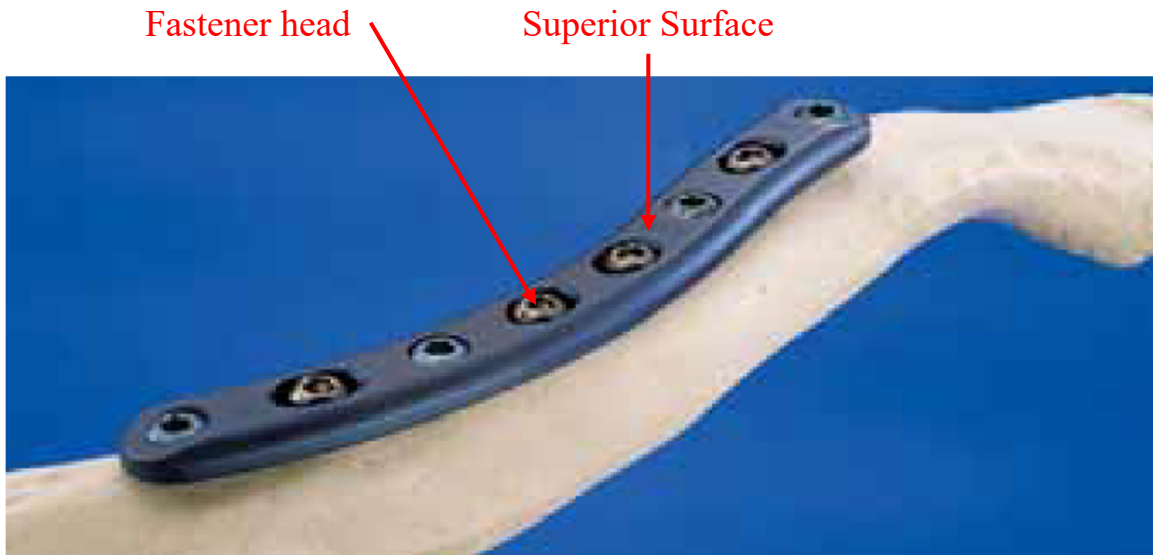


Ex. 1009, 3.

Hardy expressly describes a plate with a plurality of openings which include a recess configured to receive screws and support washers. Ex. 1006, 3:2-5, 4:6-14. 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. Ex. 1009, 2; Ex. 1002, ¶ 136.

(v) [1.4]

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. Ex. 1009, 5-6; Ex. 1002, IX.G.e.



Ex. 1009, 6.

Thornes discloses a circular washer that can be positioned adjacent to the superior surface of the clavicle. Ex. 1007, ¶¶[0014] (“[T]he acromioclavicular (AC) joint reconstruction technique of the present invention comprises the steps of:...(vii) pulling on suture tails of the round button, to advance the round button down to the surface of the clavicle; and (viii) tying the sutures to stabilize the acromioclavicular joint.”), [0018] (“The [washers] may be circular, oblong, rectangular or parallelepipedal, among many other configurations”), Figs. 9-10.

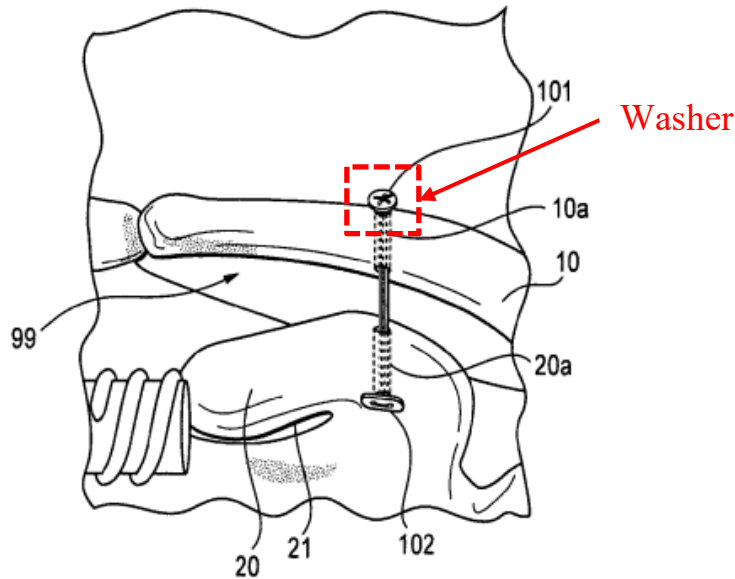
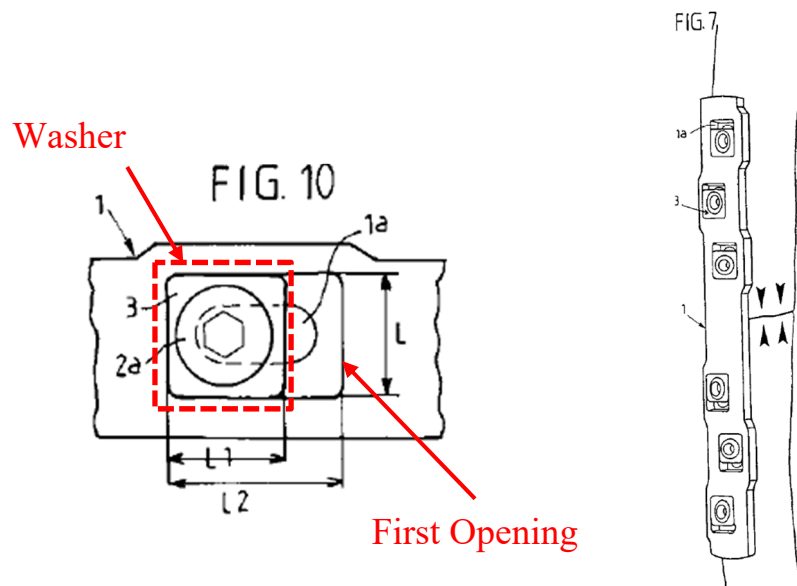


FIG. 7

Ex. 1007, Fig. 7.

As discussed for limitation [1.2] above, a POSITA would have found it obvious to apply the Thornes washer-suture system to the Clavicle plate. Ex. 1002, ¶137.

To 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 Clavicle and Thornes, Hardy discloses a washer with these characteristics. Ex. 1006, 4:20-24 (“The edges (3a) of the washers are chamfered in a complementary manner to edges (1) and (2) of the orifices.”); 3:2-5; 4:6-14. Figures 7 and 10, below, depict washers 3 positioned adjacent to the superior surface of the plate 1 and configured to fit within the first opening.



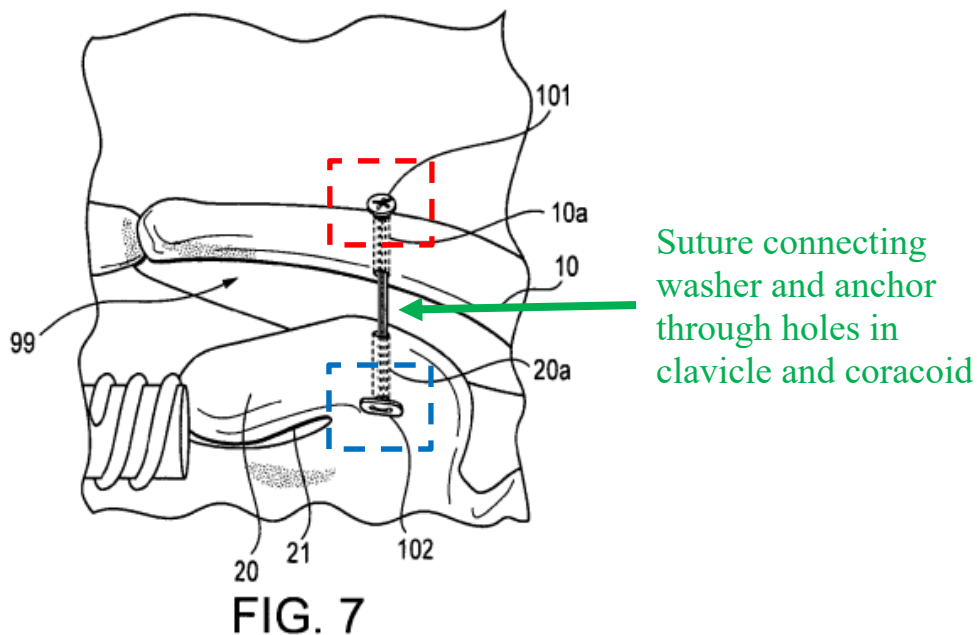
Ex. 1006, Figs. 7, 10.

A POSITA 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. Ex. 1002, ¶138. A POSITA would further recognize 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. Ex. 1007, ¶[0015]; Ex. 1006, 4:9-17, Fig. 7; Ex. 1002, ¶138.

(vi) [1.5]

Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Ex. 1009, 7; Ex. 1002, ¶139. To the extent Clavicula does not disclose passing a suture through a hole in the clavicle

and coracoid process, Thornes discloses the same. Ex. 1002, IX.G.f. Thornes teaches a washer and anchor joined by a suture. Ex. 1007, Abstract, ¶[0011]. The washer (button 101) is positioned on the surface of the clavicle and the anchor (button 102) is advanced “through the hole in the clavicle and the coracoid until it exits the coracoid base” on the underside of the coracoid. *Id.*, ¶¶[0013]-[0014], [0033]. Figure 7 shows the **washer** (101) and **anchor** (102) connected by **suture** passing through a hole in the clavicle and coracoid process.



Ex. 1007, Fig. 7.

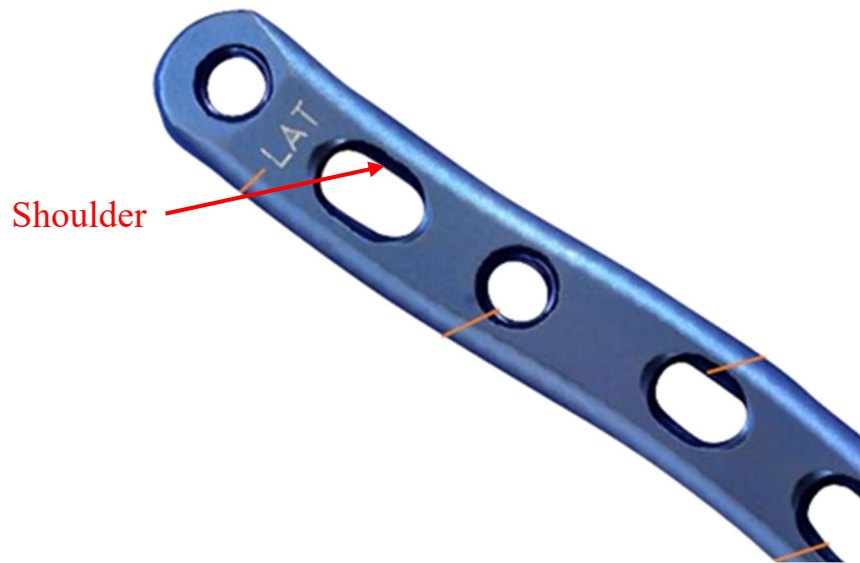
As discussed for limitation [1.2] above, a POSITA would have found it obvious to apply the Thornes washer-suture system to the Clavicle plate. Ex. 1002, ¶135. A POSITA would have further recognized the importance of optimal suture technique, which Clavicle does not describe. Ex. 1002, ¶140. A POSITA would

recognize 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. Ex. 1007, ¶¶[0015], [0014]; Ex. 1002, ¶140. Simple, reproducible techniques improve patient access because they would allow a greater number of surgeons to use the technique. Ex. 1002, ¶140. A POSITA would further understand 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. *Id.*, ¶139. A POSITA would have a reasonable expectation of success because the Clavicula openings receive fastener heads with the same geometry as the Thornes washer. *Id.*, ¶141.

b. Claim 2

As discussed above in limitations [1.2] and [1.3] in this Ground, Clavicula teaches a plate with an opening between the superior and inferior surfaces having a larger, upper portion and a smaller, lower portion. Clavicula teaches a shoulder at the interface between the larger, upper portion and the smaller, lower portion of the plate opening such that the plate would be secured to the clavicle by placement of the screws. Ex. 1009, 6 ("[P]lace the screws into the slots with the assembled driver.

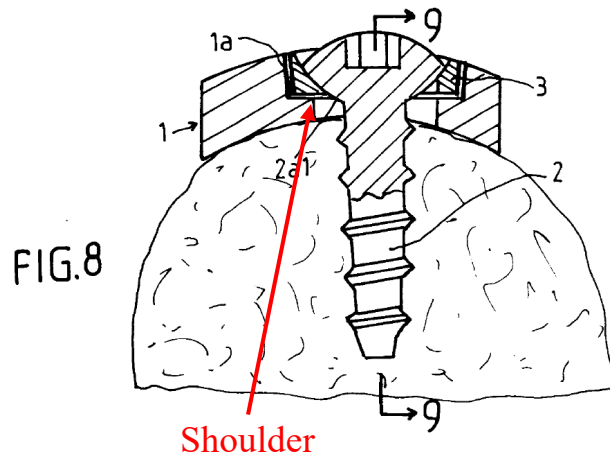
Once the two screws are installed, the bone clamps [] holding the plate to the clavicle may be removed.”); Ex. 1002, IX.G.g.



Ex. 1009, 3.

Clavicula further describes the “plate/screw interface,” confirming an upper portion to admit the screw head and a smaller lower portion defining a shoulder to interface with the screw head. Ex. 1009, 2.

To the extent that Clavicula does not disclose a plate with a shoulder, Hardy discloses the same. Ex. 1006, 2:14-3:1, 5:1-3, Figs. 1-4, 6-11.



Ex. 1006, 8. A POSITA would have understood that only minor, routine modifications would be required to adapt the recessed openings in Clavicula to include the shoulder disclosed by Hardy and to substitute the Thornes washer-suture system for the Hardy recessed washer to provide a low-profile, simple means of taking stress off of the lateral fixation of the Clavicula plate and to permit flexible positioning of the suture relative to the fracture. Ex. 1007, ¶¶[0014]-[0015]; Ex. 1009, 7; Ex. 1002, ¶¶142-43.

c. Claim 3

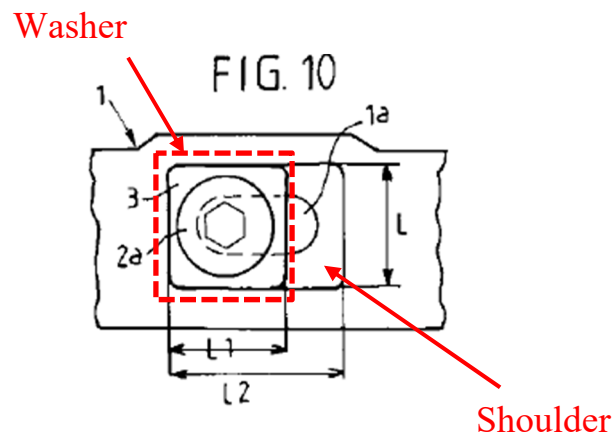
As discussed above in limitations [1.2], [1.3], and [2] in this Ground, Clavicula describes an opening with a larger, upper portion and a smaller, lower portion that defines a shoulder on which the screw head rests. Ex. 1009, 3; Ex. 1002, IX.G.h. As described in limitations [1.2] and [1.4] in this Ground, Thornes discloses a washer that can be positioned adjacent to the superior surface of the clavicle. Ex. 1007, ¶¶[0014], [0018], Figs. 9-10. A POSITA would have found it obvious to apply

the Thornes washer-suture system to the Clavicula plate. Ex. 1002, ¶135. In particular, a POSITA would have recognized that a washer would be equally capable of sitting on the shoulder as the screw head disclosed in Clavicula, especially given the similar shape of a washer and a screw head:



Ex. 1002, ¶144.

While neither Clavicula nor Thornes explicitly disclose a washer that sits on a shoulder in an opening in a plate, a POSITA would have found this modification obvious. Ex. 1002, ¶144. To the extent that a washer sitting on a shoulder in a plate would not have been obvious in view of Clavicula and Thornes, Hardy expressly discloses a plate with a plurality of openings comprising a shoulder on which a washer sits. Ex. 1006, 2:14-3:5; 4:6-14; 4:20-24; 5:5-9.



Ex. 1006, Fig. 10.

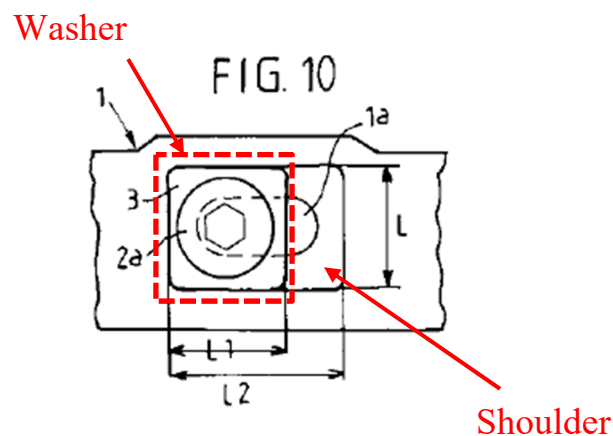
A POSITA would have found it obvious to combine the washer of Hardy with the oblong openings in the Clavicula plate to provide a low-profile washer-plate interface. Ex. 1002, ¶143. A POSITA would further recognize the Thornes washer-suture system could be simply substituted for the Hardy washer to recognize the benefits of Thornes’ “simple, reproducible, minimally invasive” means of taking stress off of the lateral fixation of the Clavicula plate, while maintaining a low-profile. Ex. 1007, ¶¶[0014]-[0015]; Ex. 1009, 7; Ex. 1002, ¶140.

d. Claim 4

As described in claim [3] in this Ground, a POSITA would have found it obvious to include a washer, such as a washer from the Thornes washer-suture system, sitting on the shoulder of the opening of the Clavicula plate. *See supra* Section VIII.C.4.c, Ex. 1002, ¶¶135, 138, 140-144; Ex. 1006, 2:14-3:5, 4:6-14, 4:20-24, 5:5-9, Fig. 10; Ex. 1007, ¶¶[0014], [0018], Figs. 9-10; Ex. 1009, 6, 7. A POSITA would have understood that in order to “take stress off of the lateral fixation” as Clavicula contemplates, and to prevent bone irritation by altering the amount of tension on the suture, the installation of a suture would need to remain stable once installed. Ex. 1009, 7; Ex. 1002, ¶146. To accomplish this, a POSITA would have found it obvious to size the washer so that it fit substantially snugly above the

shoulder in the first opening of the plate in order to prohibit movement of the washer once installed and prevent the risk of further injury to the patient. Ex. 1002, ¶145.

To the extent that a washer fitting substantially snugly in an opening on a plate above the shoulder of the opening would not have been obvious in view of Clavicula and Thornes, Hardy expressly discloses a plate wherein the washer fits substantially snugly in the opening above the shoulder. Ex. 1006, 4:6-14 (“The washers have a width (L) very substantially equal to that of the orifices”); 3:2-5; 4:20-24; Ex. 1002, IX.G.j.



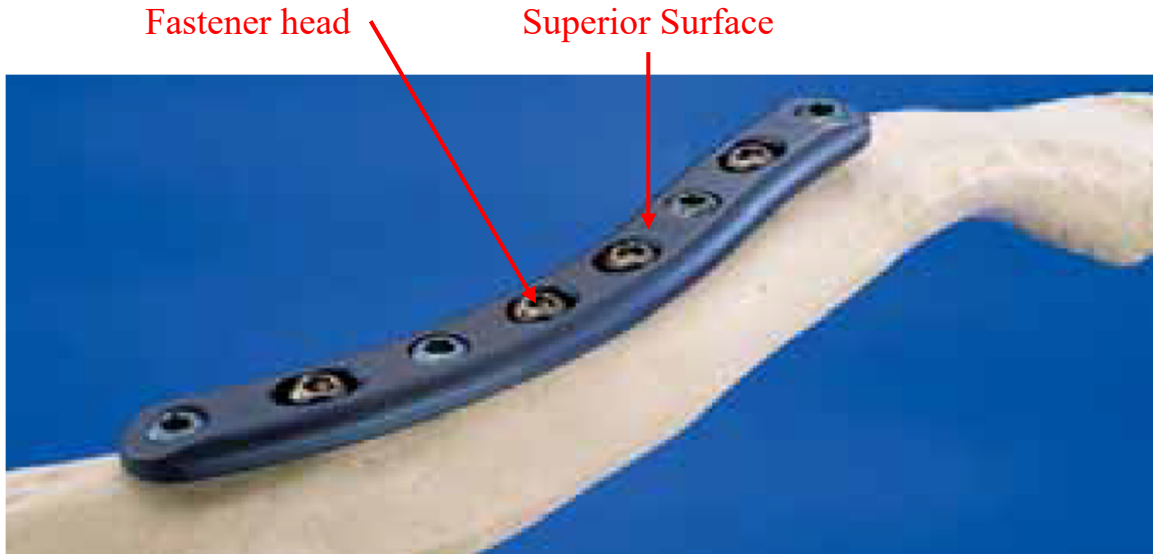
Ex. 1006, Fig. 10.

A POSITA would have found it obvious to combine the washer of Hardy with the oblong openings in Clavicula for the reasons discussed above.

e. Claim 5

Clavicula describes a plate wherein the superior surface of a fastener is approximately flush with the superior surface of the plate when positioned in the

hole. Ex. 1002, IX.G.j. For example, Clavicula includes screws attaching the plate to the clavicle that are approximately flush with the superior surface of the plate when positioned in the holes in order to “minimize[] soft-tissue irritation for the patient.” Ex. 1009, 2 (describing the screw-plate interface as “low profile”).

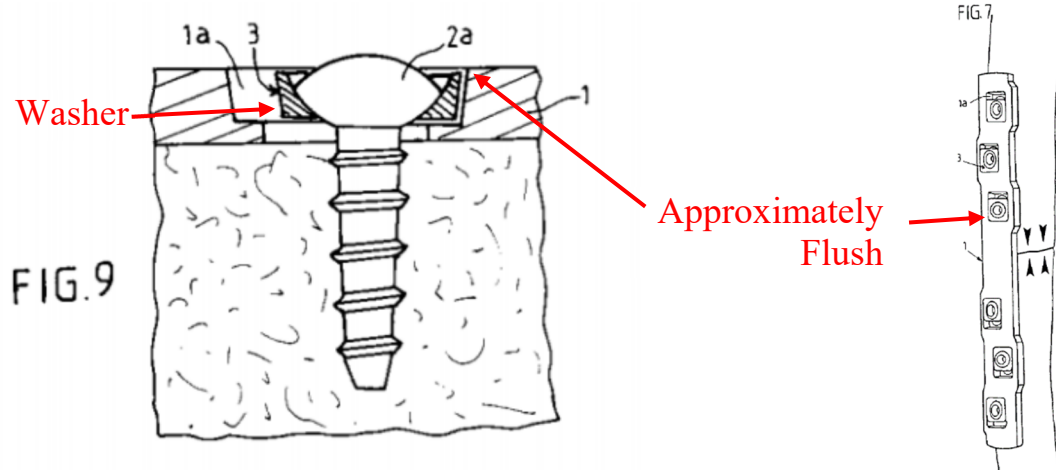


Ex. 1009, 3.

Thornes teaches a washer and anchor joined by a suture. Ex. 1007, Abstract, ¶[0011]. As discussed for limitations [1.2] and [3] above, a POSITA would have found it obvious to apply the Thornes washer-suture system to the Clavicula plate. Ex. 1002, ¶¶132-135, 138, 140-144, IX.G.c, h, Ex. 1006, 2:14-3:5, 4:6-14, 4:20-24, 5:5-9, Fig. 10, Ex. 1007, Abstract, ¶¶[0011], [0013]-[0014], [0018], [0033], Figs. 9-10, Ex. 1009, 3, 6, 7. A POSITA would have sought to incorporate the “low-profile” design of Clavicula in order to “minimize[] soft-tissue irritation for the patient” in combining Thornes and Clavicula. Ex. 1009, 2; Ex. 1002, ¶147. The Clavicula-

Thornes system would therefore include a washer that is approximately flush with the superior surface of the plate.

To the extent that a washer that is approximately flush with the superior surface of the plate would not have been obvious in view of Clavicula and Thornes, Hardy expressly discloses a plate wherein the washer is approximately flush with the superior surface of the plate. Ex. 1006, 4:20-24; 3:2-5; 4:3-14; 5:5-9; Ex. 1002, ¶148.

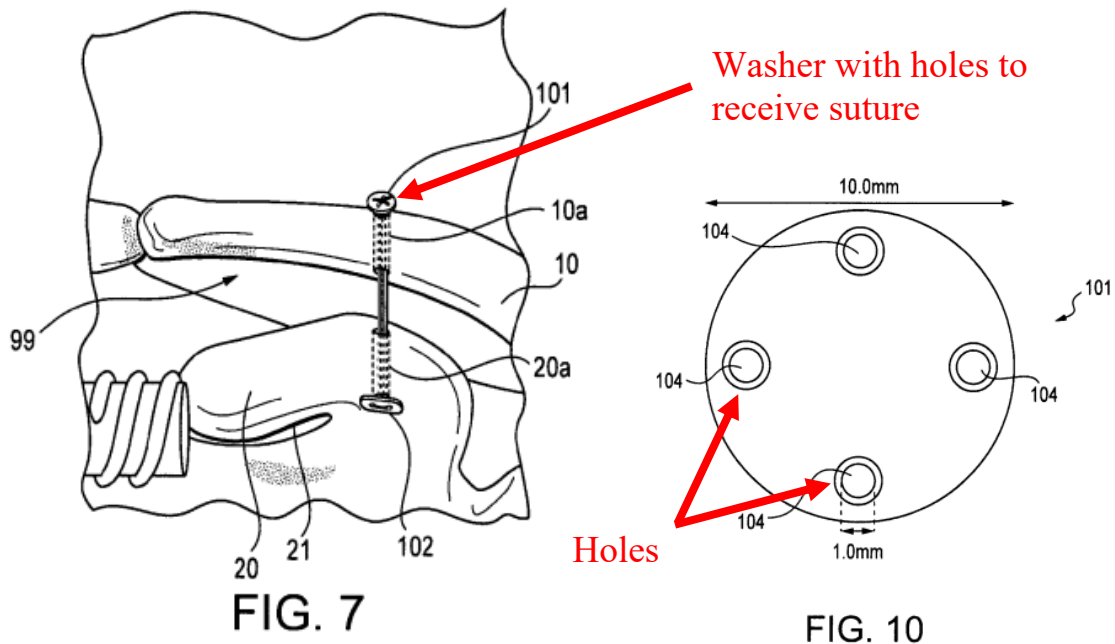


Ex. 1006, Figs. 7, 9.

As discussed for limitation [1.4] above, a POSITA would have found it obvious to apply the Hardy washer to the Thornes washer-suture system and the Clavicula plate. Ex. 1002, ¶¶137-138, IX.G.e, Ex. 1006, 4:20-24, 3:2-5, 4:6-14, Figs. 7, 10, Ex. 1007, ¶¶[0014]-[0015], [0018], Figs. 9-10, Ex. 1009, 5-6.

f. Claim 6

As discussed above in Section [1.5] of this Ground, Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Ex. 1009, 7. A POSITA would have been motivated to look to Thornes' washer-suture system to incorporate a suture that interacts with the coracoid process and plate. Ex. 1002, ¶149. The washer (button 101) of Thornes is positioned on the surface of the clavicle and has holes dimensioned to receive a "flexible strand or continuous loop 110" which "may be formed of suture." Ex. 1007, ¶¶[0013], [0014], [0021]-[0022], [0033]. A POSITA would have further been motivated to join the suture to the washer by means of a hole in the washer to permit fine adjustment to the tension on the suture while tying the suture tails. Ex. 1002, ¶150. Figure 10 shows the washer 101 with holes 104 dimensioned to receive a suture while Figure 7 shows the washer with suture passing through the holes.



Ex. 1007, Figs. 7, 10.

As discussed for limitation [1.2] above, a POSITA would have found it obvious to apply the Thornes washer-suture system to the Clavicle plate. Ex. 1002, ¶¶132-135, IX.G.c, Ex. 1007, ¶¶[0011], [0013]-[0014], [0033], Ex. 1009, 3, 7.

g. Claim 7

As discussed above in Section [1.5] of this Ground, Clavicle explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Ex. 1009, 7. A POSITA would have been motivated to look to Thornes' washer-suture system to incorporate a suture that interacts with the coracoid process. Ex. 1002, ¶152. Thornes teaches:

advanc[ing] the oblong button 102 through the bone tunnels 10a, 20a in the clavicle 10 and the coracoid 20 under direct visualization, until it exits the coracoid base 21. Independently pull on each of the white

traction sutures 102a of the oblong button 102, to flip the button 102 onto the underside of the coracoid base 21.

Ex. 1007, ¶¶[0033], [0013], [0014]. A POSITA would have found it obvious that anchoring the fractured clavicle to the coracoid process would reduce stress by distributing the load and anchoring the clavicle in place. Ex. 1002, ¶151. Figure 7 shows anchor (102) which passes through a hole in the coracoid process and anchors the fixation system at an inferior side of the coracoid process. Ex. 1007, ¶¶[0013], [0014], [0033].

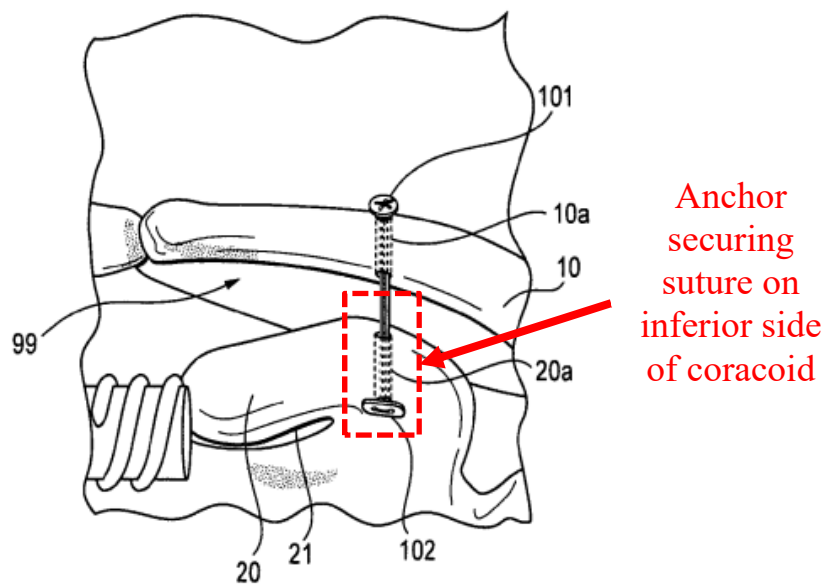


FIG. 7

Ex. 1007, Fig. 7.

A POSITA would recognize that positioning an anchor on the underside of the bone, even in conjunction with a plate,¹² was a common technique in the surgical field, and its application to the clavicle-coracoid process interface was known. Ex. 1002, IX.G.m, ¶151. A POSITA reading Clavicula would recognize the benefit of reducing stress on the fixation using suture anchored to the coracoid process and, as discussed for limitation [1.2] above, would have found it obvious to apply the Thornes washer-suture system to the Clavicula plate. Ex. 1002, ¶¶132-35, 152, IX.G.c, Ex. 1007, ¶¶[0011], [0013]-[0014], [0033], Ex. 1009, 3, 7.

h. Claim 8

As discussed above in Sections [1.5] and [7] of this Ground, Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Thornes expressly teaches advancing the anchor—oblong button 102—through a hole in the coracoid process—bone tunnel 20a—such that the suture passes through the hole when the anchor is secured. Ex. 1007, ¶¶[0013], [0014], [0033]. Figure 7 demonstrates this arrangement:

¹² See, e.g., Ex. 1021, Arthrex AC Joint Tightrope Surgical Technique, 2.

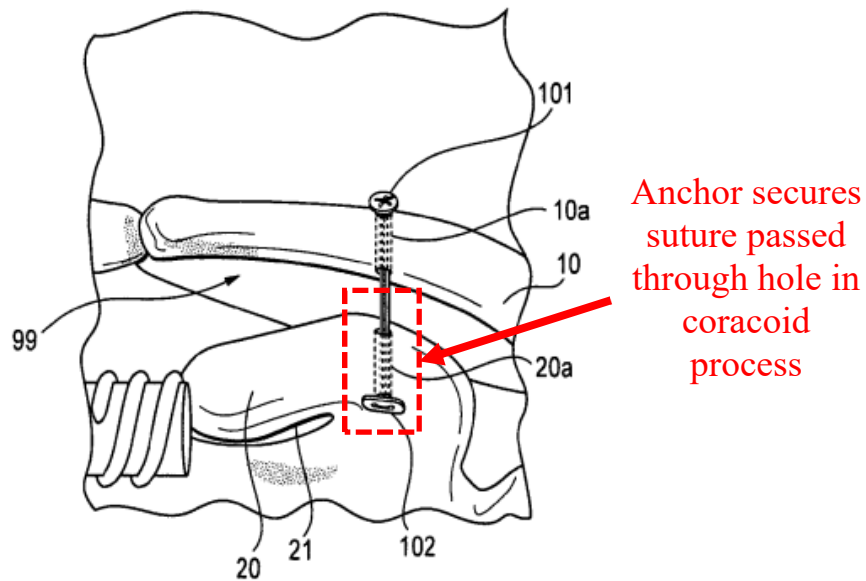


FIG. 7

Ex. 1007, Fig. 7.

As discussed for limitation [1.2] above, a POSITA would have found it obvious to apply the Thornes washer-suture system to the Clavicula plate. Ex. 1002, ¶¶132-35, IX.G.c, Ex. 1007, ¶¶[0011], [0013]-[0014], [0033], Ex. 1009, 3, 7.

i. Claim 9

Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Ex. 1009, 7. A POSITA would have been motivated to look to Thornes' washer-suture system to incorporate a suture that interacts with the coracoid process and plate and takes stress off of the lateral fixation. Ex. 1002, ¶¶155-56.

Thornes teaches an oblong washer with a plurality of holes distributed longitudinally. Ex. 1007, ¶¶[0018]-[0019]. Using an oblong shaped washer having

a plurality of longitudinally distributed holes would have been an obvious design choice and Thornes teaches that either of the two buttons 101, 102 may be a variety of shapes including “circular, oblong, rectangular or parallelepipedal.” Ex. 1007, ¶[0018]. Figure 9a below shows an exemplary embodiment of an oblong shaped washer. *Id.*, ¶¶[0018]-[0019].

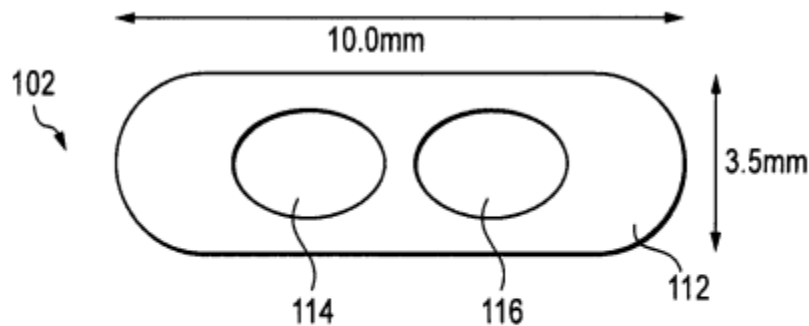


FIG. 9(a)

Ex. 1007, Fig. 9a. A POSITA would have recognized that this oblong washer is advantageous because it allows the anchor to more easily pass through the holes in the plate and bone, yet still provide adequate securing force on the underside of the coracoid. Ex. 1002, ¶154.

j. Claim 10

Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Ex. 1009, 7. A POSITA would have been motivated to look to Thornes’ washer-suture system to incorporate a

suture that interacts with the coracoid process and plate and takes stress off of the lateral fixation, as discussed above.

Ex. 1007, ¶¶[0033], [0013], [0014]. A POSITA would have recognized that by “flip[ing] the button onto the underside of the coracoid base,” it would resist returning through the hole or bone tunnel in the coracoid process. Ex. 1002, ¶153.

k. Claim 11

Clavicula expressly teaches that “sutures may be passed from medial to lateral *around the coracoid process* and the plate to take stress off of the lateral fixation.” Ex. 1009, 7 (emphasis added). A POSITA would have recognized that passing the sutures through the plate and around the coracoid process is one of a limited number of solutions for affixing the clavicle plate to coracoid process via suture. Ex. 1002, ¶158. A POSITA would have a reasonable expectation of success in combining Clavicula’s wraparound suture with Thornes’ technique of passing a suture through a hole in the bone. *Id.*, ¶157.

l. Claim 12

Thornes teaches an oblong washer with a plurality of holes distributed longitudinally. Using an oblong shaped washer having a plurality of longitudinally distributed holes would have been an obvious design choice and Thornes teaches that either of the two buttons 101, 102 may be a variety of shapes including “circular,

oblong, rectangular or parallelepipedal.” Ex. 1007, ¶¶[0018]-[0019]; Ex. 1002, IX.G.p.

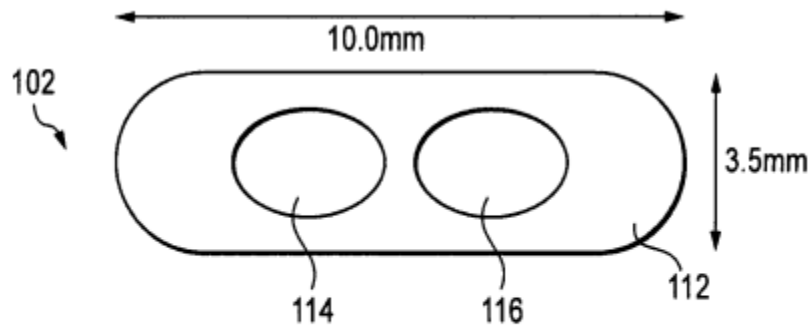
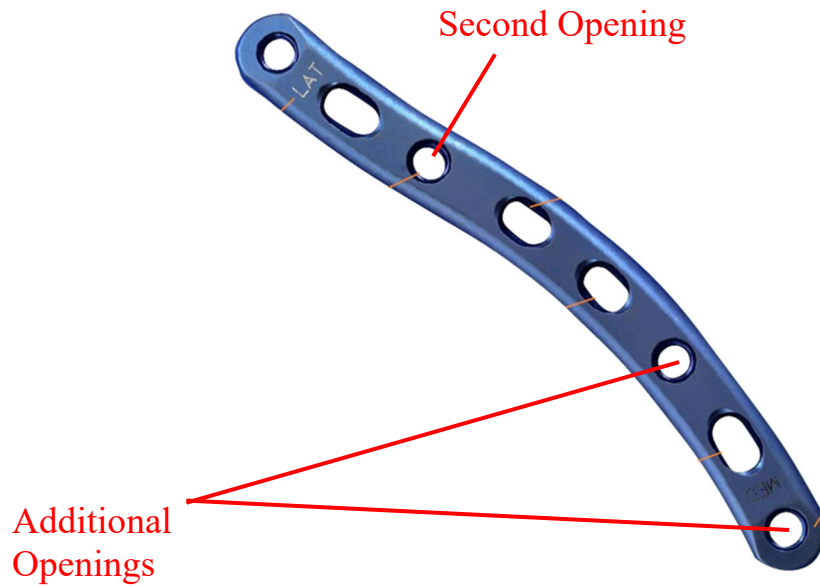


FIG. 9(a)

Ex. 1007, Fig. 9a. A POSITA would have found it obvious to combine Thornes’ technique using an oblong washer with the Clavicula plate. Ex. 1002, ¶159.

m. Claim 13

Clavicula describes openings in the bone plate configured to receive a fastening device. Ex. 1009, 6 (“[P]lace the 3.5mm locking screws [] into the threaded holes so that there are at least three screws on each side of the fracture.”), 5; Ex. 1002, IX.G.q. A POSITA would understand the Clavicula “plate/screw interface” is the portion of the second opening which is configured to receive a fastening device (screw). Ex. 1009, 2; Ex. 1002, ¶160. The figure below demonstrates the second opening.



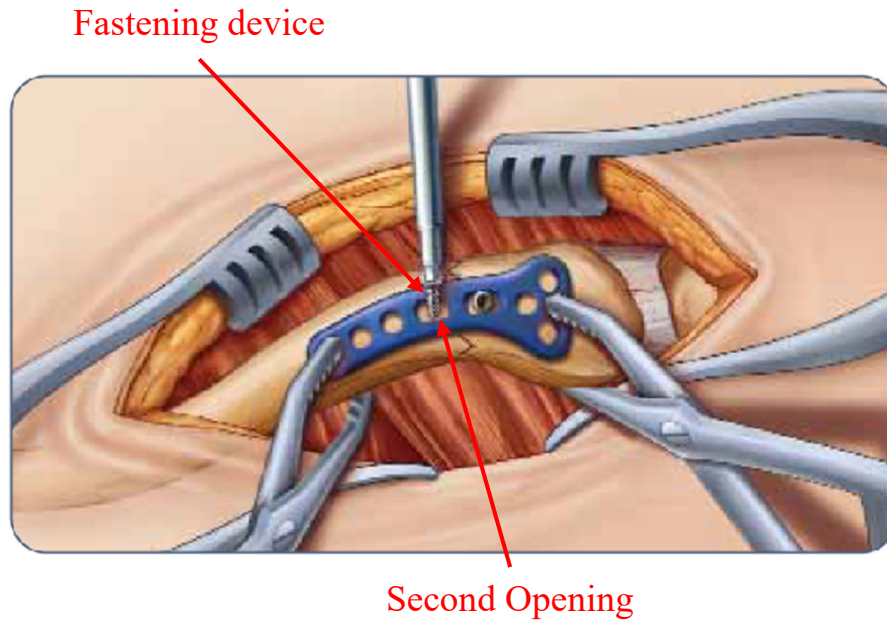
Ex. 1009, 3.

n. Claim 14

Clavicula describes at least one fastening device adapted to pass through the second opening in the plate to secure the plate to the medial portion of the clavicle.

Ex. 1009, 6 (“[P]lace the 3.5mm locking screws [] into the threaded holes so that there are at least three screws on each side of the fracture.”), 5; Ex. 1002, IX.G.q.

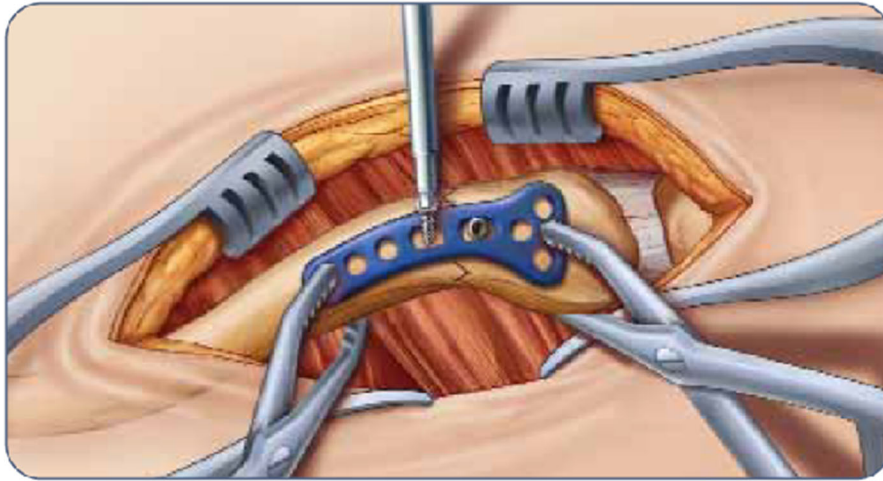
The figure below demonstrates a fastening device passing through the opening of the plate.



Ex. 1009, 6.

o. Claim 15

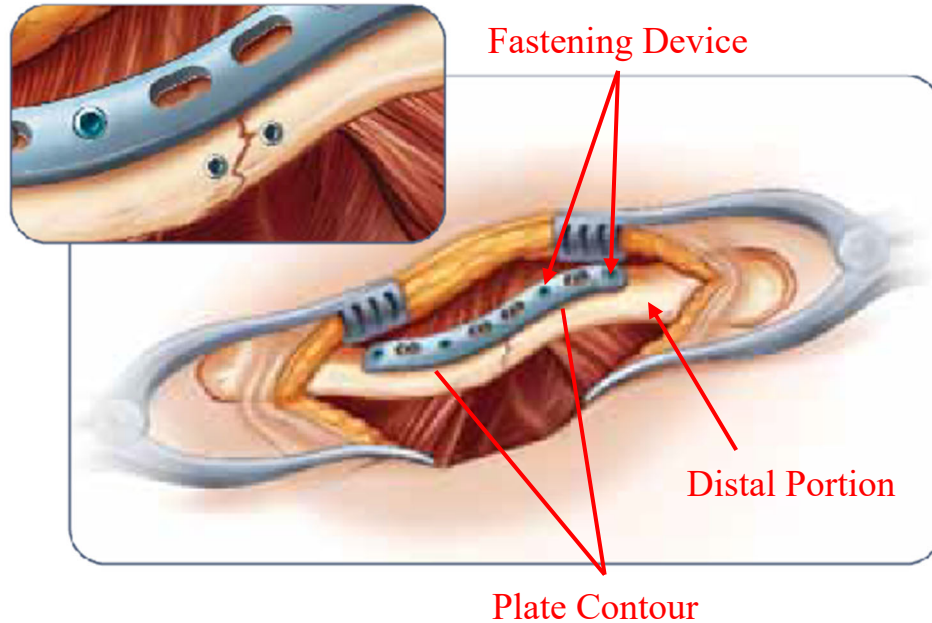
Clavicula expressly teaches the use of locking screws as fixation devices in the bone plate fixation system. Ex. 1009, 6 (“[P]lace the 3.5mm locking screws [] into the threaded holes so that there are at least three screws on each side of the fracture.”), 5; Ex. 1002, IX.G.r. A POSITA would have recognized that locking screws were among the fixation devices available to affix a plate to a bone, and would have known that locking screws provide better fixation than non-locking screws. Ex. 1002, ¶161.



Ex. 1009, 7.

p. Claim 16

Clavicula describes a plate contoured to be secured to the distal portion of the clavicle relative to the fracture. Ex. 1009, 3 (“wide variety of clavicle curvatures.”); Ex. 1002, ¶162. The plate is also configured to be secured to the distal portion of the clavicle relative to the fracture. Ex. 1009, 5 (“[P]lace the 3.5mm locking screws... on each side of the fracture.”), 6. Step 7 also shows the contour of the plate and the securing of the plate on the distal portion of the clavicle bone.



Id. 5, 7; Ex. 1002, IX.G.s. Contoured plates were also common in the industry at the relevant time, and a POSITA would have recognized they were advantageous over straight plates because they remove the stress of torque or other forces necessary to shape the plate in the operating room. Ex. 1002, ¶163.

q. Independent Claim 17

(i) 17.p

See limitation [1.p] in this Ground. Ex. 1002, ¶164, IX.G.a, Ex. 1009, 2, 4. Clavicle is sold in a kit. *See* Ex. 1009, 2 (“The Locking Clavicle Plates are included in a comprehensive system of implants and instrumentation specifically designed to treat clavicle injuries.”).



Ex. 1009, 8.

(ii) 17.1

See claim 1 in this Ground. Ex. 1002, ¶¶130-141, 165, IX.G.a-e; Ex. 1006, 3:2-5, 4:6-14, Figs. 7, 10; Ex. 1007, Abstract, ¶¶[0011], [0013]-[0014], [0018], [0033], Figs. 9-10, Ex. 1009, 2-7.

(iii) 17.2

See claim 13 in this Ground. Ex. 1002, ¶¶160, 165, IX.G.p; Ex. 1009, 2-3, 6.

(iv) 17.3

See claim 14 in this Ground. Ex. 1002, ¶165, IX.G.p; Ex. 1009, 5-6.

r. Claim 18

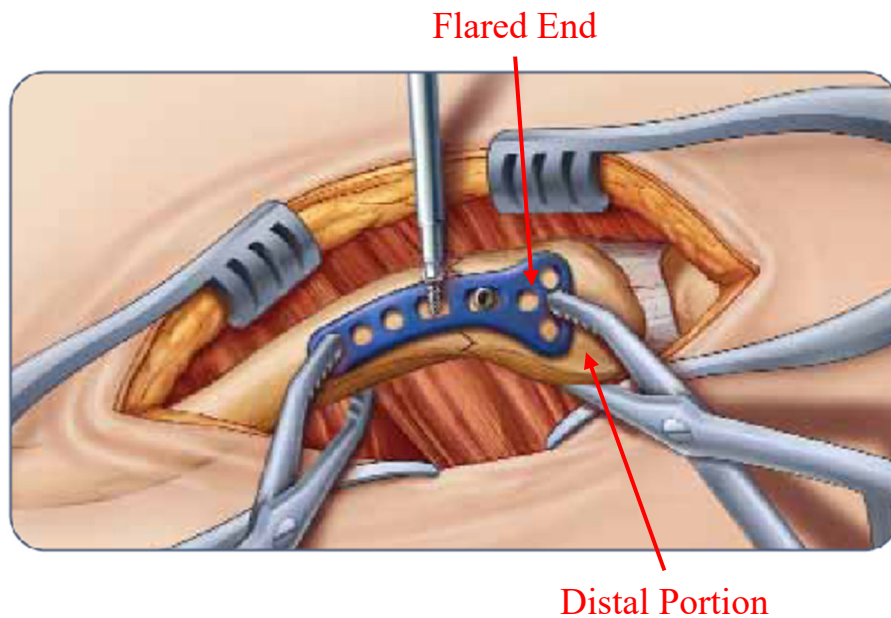
See claims 8 and 9 in this Ground. Ex. 1002, ¶¶132-35, 153-55 IX.G.m-n; Ex. 1007, ¶¶[0011], [0013]-[0014], [0018]-[0019], [0033], Fig. 7, 9(a); Ex. 1009, 3, 7.

s. Claim 19

Clavicula expressly teaches a fixation plate wherein the distal end is flared.

Ex. 1009, 3 (“Multiple Plate Options are available to fit a wide variety of clavicle curvatures.... [F]or distal/lateral fractures two specialized ‘J’ plates are available.”);

Ex. 1002, IX.G.w.



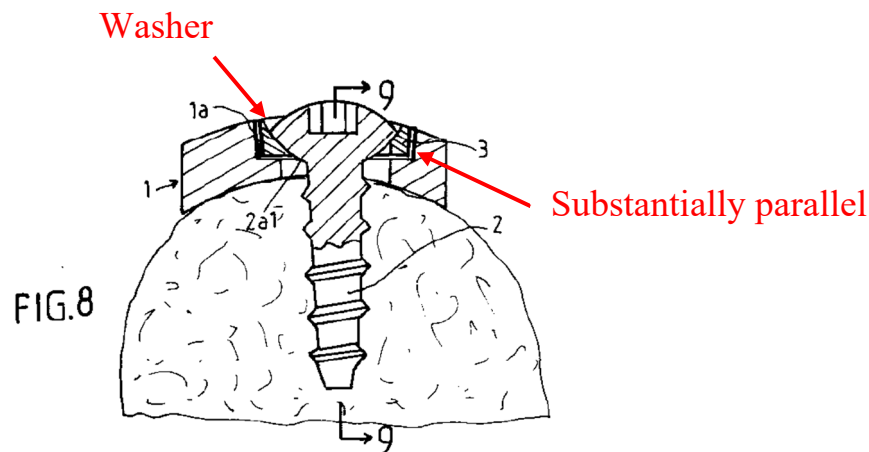
Ex. 1009, 7.

t. Claim 20

For the reasons described above in claim [3] in this Ground, a POSITA would have found it obvious to include a washer, such as a washer from the Thornes system, configured to sit on the shoulder of the opening of the Clavicula plate. *See supra* Section VII.C.4.c; Ex. 1002, ¶¶135, 138, 140-144; Ex. 1006, 2:14-3:5, 4:6-14, 4:20-24, 5:5-9, Fig. 10; Ex. 1007, ¶¶[0014], [0018], Figs. 9-10; Ex. 1009, 6, 7. A POSITA

would have understood that in order to “take stress off of the lateral fixation” as Clavicula contemplates, the installation of a suture would need to remain stable once installed. Ex. 1009, 7; Ex. 1002, ¶167. One way to ensure the washer does not shift after fixation is to include a washer with sides that are substantially parallel to the sides of the opening in the plate. *Id.*

To the extent that a washer with sides substantially parallel to the opening in the plate would not have been obvious in view of Clavicula and Thornes, Hardy expressly discloses such a plate. Ex. 1006, 4:20-24 (“The edges (3a) of the washers are chamfered in a complementary manner to edges (1) and (2) of the orifices.”), 3:2-5; 4:6-14.



Ex. 1006, Fig. 8.

As discussed for limitation [1.4] above, a POSITA would have found it obvious to apply the Hardy sliding washer to the Thornes washer-suture system and

the Clavicula plate. Ex. 1002, ¶¶137-138, IX.G.e; Ex. 1006, 4:20-24, 3:2-5, 4:6-14, Figs. 7, 10; Ex. 1007, ¶¶[0014]-[0015], [0018], Figs. 9-10; Ex. 1009, 5-6.

VIII. THE BOARD SHOULD INSTITUTE UNDER 35 U.S.C. § 314

The *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (June 21, 2022) (“Interim Procedure”), *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020) provides no basis for a discretionary denial in this case. This Petition “presents a compelling unpatentability standard,” which, alone, “demonstrates that the PTAB should not discretionarily deny institution under *Fintiv*.” Interim Procedure at 4-5.

Second, Petitioners stipulate that, if IPR is instituted, they will not pursue the same invalidity grounds in the parallel District Court proceedings. The Board recognizes that such a stipulation “avoids inconsistent outcomes between the PTAB and the district court and allows the PTAB to review grounds that the parallel district court litigation will not resolve.” See *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A); see also *Acuity Brands Lighting, Inc. v. Ultravision Technologies, LLC*, IPR2020-01638, Paper 8 at 12-13 (PTAB May 6, 2021) (determining Fintiv factor 4 weighs against exercising discretion in view of similar stipulation).

Third, trial in the parallel District Court proceedings will commence no earlier than February 29, 2024, which is at most two months before the due date of a Final

Written Decision of this Petition. In a similar context, and with a gap of “upward of six months” between the expected Final Written Decision and start of trial, the Board has instituted IPR. *See Equipmentsshare.com Inc. v. Ahern Rentals, Inc.*, IPR2021-00834, Paper 19 at 13 (PTAB Nov. 6, 2021); *Resi Media LLC v. Boxcast Inc.*, IPR2022-00067, Paper 16 at 10 (PTAB Apr. 26, 2022) (instituting IPR notwithstanding understanding that trial was scheduled to begin “approximately eight months before [the Board’s] deadline to reach a final decision.”).

Fourth, the Board’s Decision on Institution likely will be due in or around April 2023, which is well before the completion of fact and expert discovery (June 16, 2023 and October 20, 2023, respectively) and the deadline for dispositive motions (November 17, 2023). Notably, fact discovery opened on April 28, 2022, and to date, Patent Owner has failed to serve any written discovery in the parallel District Court proceedings or take any depositions. Additionally, Petitioners are filing a motion to stay the parallel District Court proceedings soon after the Petition given the upcoming deadlines for claim construction (opening brief is due October 28, 2022).

Thus, at least *Fintiv* Factors 2-5 weigh in favor of Institution.

II. CONCLUSION

For the reasons stated above, Petitioners submit that claims 1-20 of the ’312 Patent are unpatentable.

Respectfully submitted by

K&L GATES LLP,

By: /Jason A. Engel/
Jason A. Engel
Reg. No. 51,654

Certification of Service Under 37 C.F.R. §42.6(e)(4)

A copy of this Petition for *Inter Partes* Review and supporting materials has been served at the following correspondence address of record for the subject patent via Federal Express Priority Overnight® on this 5th day of October, 2022:

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Alexandria, VA 22314

With an electronic courtesy copy to litigation counsel:

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Certification of Word Count Under 37 C.F.R. §42.24(d)

The undersigned hereby certifies that the foregoing Petition for *Inter Partes* Review contains 13,993 words, not including a table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits or appendix of claim listing as specified by 37 C.F.R. §42.24, according to the word count feature of the word-processing software used to prepare the Petition.

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