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. IPR2023-00009
Patent No. 8,282,674

_____

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,282,674

TABLE OF CONTENTS

TABLE OF AUTHORITIES

PETITIONERS' EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 8,282,674 ("the '674 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 ("Clavicula")
1010	Declaration of J. Elmer Regarding Ex. 1009
1011	Prosecution History of U.S. Patent Application No. 12/176,032
1012	Merriam Webster Dictionary definition of "washer"
1013	MacMillan Dictionary definition of "washer"

1014	Complaint filed in *Jeffrey Gelfand, MD v. Acumed, LLC*, Case No. 21-1753
1015	Complaint filed in *Jeffrey Gelfand, MD v. Arthrex Inc.*, 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 Clavicula 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
1024	Merriam Webster Dictionary definition of "slide"
1025	U.S. Patent Publication No. 2002/0065517 ("Paul")

CLAIM LISTING

[1.P] 1. A fixation system for a fractured clavicle, the fixation system comprising:

[1.1] a substantially rigid plate contoured to follow the clavicle for securing to a medial portion of the clavicle relative to the fracture and to extend at least partially over a distal portion of the clavicle relative to the fracture when secured to the clavicle,

[1.2] the plate having one or more surfaces that define a substantially oblong first opening having a longitudinal dimension extending in a direction corresponding to the length of the plate and through which a suture can pass;

[1.3] a washer that can be positioned at a side of the plate opposite the clavicle and configured to be slidably adjusted along the longitudinal dimension of the first opening;

[1.4] a suture secured to the washer and extended through the 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 suture is configured so that upon tensioning the distance between the coracoid process and the clavicle is reduced to

thereby bring the medial portion of the clavicle and the distal portion of the clavicle in substantial alignment with one another.

3. The fixation system of claim 1 wherein the first opening in the plate defines, at a side of the plate opposite the clavicle, a recess adapted to receive the washer.

4. The fixation system of claim 3 wherein the washer fits substantially snugly in the recess.

5. The fixation system of claim 1 wherein the washer has holes dimensioned to receive the suture.

6. The fixation system of claim 1 further comprising

an anchor for positioning at an inferior side of the coracoid process and secured to the suture when the suture passes through a hole in the coracoid process.

7. The fixation system of claim 6 wherein the anchor is oblong and dimensioned to pass through the hole in the clavicle and through the hole in the coracoid process, and dimensioned to resist, once positioned beneath the coracoid process, returning through the hole in the coracoid process.

8. The fixation system of claim 1 wherein the suture is configured to pass around the coracoid process.

9. The fixation system of claim 1 wherein the washer is oblong and includes a plurality of holes distributed longitudinally along the washer.

10. The fixation system of claim 9, wherein sides of the washer are substantially parallel to the first opening in the plate.

11. 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.

12. The fixation system of claim 11, wherein a distal end of the plate is flared.

13. The fixation system of claim 1 further comprising locking screws.

[14.P]A fractured clavicle fixation kit comprising:

[14.1] a substantially rigid plate contoured to be secured to a medial portion of the clavicle relative to the fracture and to extend at least partially over a distal portion of the clavicle relative to the fracture, the plate having surfaces that define:

[14.2] a substantially oblong first opening having a longitudinal dimension extending in a direction corresponding to the length of the plate and through which a suture can pass; and

[14.3] a second opening to receive a fastening device;

[14.4] 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;

[14.5] a washer that can be positioned at a side of the plate opposite the clavicle and configured to be slidably adjusted within the longitudinal dimension of the first opening; and

[14.6] a suture extendable between the washer and the coracoid process, through the first opening in the plate and through a hole formed in the clavicle.

15. The fractured clavicle fixation kit of claim 14 further comprising a substantially oblong anchor that can be coupled to the suture.

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 1-15 of U.S. Patent No 8,282,674 ("the '674 Patent") (Ex. 1001) pursuant to 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.1 *et seq*. The '674 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)[1,2], 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 a real

- Marmon Holdings, Inc.
- Berkshire Hathaway Inc.

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

The '674 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:

- IPR2023-00014 (U.S. Patent No. 9,149,312)

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

Lead Counsel	Backup Counsel
Megan S. Woodworth Reg. No. 53,655 VENABLE LLP 600 Massachusetts Ave., NW Washington, DC 20001 mswoodworth@venable.com T: (202) 344-4507 F: (202) 344-8300	**Jason A. Engel** Reg. No. 51,654 K&L GATES LLP 70 W. Madison Street, Suite 3100 Chicago, IL 60602 Jason.Engel.PTAB@klgates.com T: (312) 807-4236 F: (312) 827-8145

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

	Katherine L. Allor Reg. No. 72,691 K&L GATES LLP 70 W. Madison Street, Suite 3100 Chicago, IL 60602 Katy.Allor@klgates.com T: (312) 807-4325 F: (312) 345-9987 **Robert E. Bugg** Reg. No. 65,949 VENABLE LLP 1270 Avenue of the Americas 24th Floor New York, NY 10020 rebugg@venable.com T: (212) 370-6241 F: (212) 307-5598 **Joseph B. Cahill** Reg. No. 80,691 VENABLE LLP 600 Massachusetts Ave., NW Washington, DC 20001 jbcahill@venable.com T: (202) 344-4201 F: (202) 344-8300

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. 22-0261. Any overpayment or refund of fees may also be deposited in this Deposit Account.

I. INTRODUCTION

The ’674 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 oblong opening; (2) a washer that is slidably adjustable 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 ’674 Patent. As shown below, U.S. Patent Publication No. 2007/0225716 (“Deffenbaugh”) 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 ’674 Patent and the prior art. Ex. 1002.

II. GROUNDS FOR STANDING

Petitioners certify that the ’674 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 1-15 on the grounds set forth below and (ii) that those claims be found unpatentable.

Ground	Claim(s)	Basis for Unpatentability
1	**1, 3, 4, 6 and 11-14**	**Obvious Over Deffenbaugh and Hardy**
2	**1-7 and 9-15**	**Obvious Over Deffenbaugh, Hardy and Thornes**
3	**8**	**Obvious Over Deffenbaugh, Hardy and Wellmann**
4	**8**	**Obvious Over Deffenbaugh, Hardy, Thornes and Wellmann**
5	**1-15**	**Obvious Over Clavicula, Thornes and Hardy**

IV. SUMMARY OF THE '674 PATENT

A. Background of the Technology

The '674 Patent discloses a fixation system for treating clavicle fractures. Ex. 1001, 1:5-8. The '674 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.*, 1:12-22; 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, 1:25-34, 4:21-35, 4:65-5:13, 7:1-14, Fig. 5.

However, clavicle fixation techniques using rigid plates and sutures passed through the clavicle and attached to the coracoid process were well-known before the filing date, as the '674 Patent acknowledges[4] and as shown in the references described below. Ex. 1002, ¶24.

B. The Claimed Subject Matter

Claim 1 of the '674 Patent is directed to a clavicle fixation system that includes a contoured bone plate 220 having a substantially oblong first opening 222, a washer 228 configured to be slidably adjusted along the longitudinal dimension of the first opening, 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 Figures 2 and 5. *Id.*, 2:16-25; 4:21-28; 4:36-38; 5:61-65; 7:1-8; 10:66-11:16.

[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, 1:20-21, 6:38-45 (citing Ex. 1007, disclosing clavicle fixation techniques using anchors and a suture passed through holes drilled in the clavicle and the coracoid process).

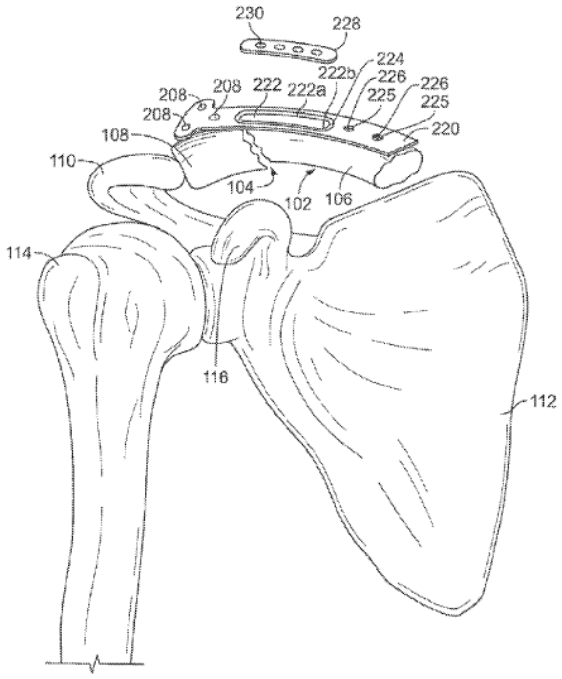


FIG. 2

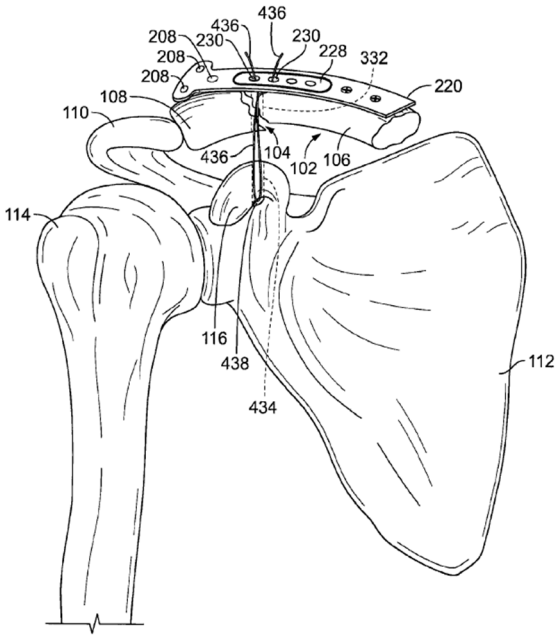


FIG. 5

Independent claim 14 is directed to a clavicle fixation kit that includes a similar bone plate, washer and suture as in claim 1, plus a fastening device for securing the plate to the medial portion of the clavicle. *Id.*, 12:14-34.

Dependent claims 2-13 and 15 further describe aspects of the fixation system recited in independent claims 1 and 14. 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, suture 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 '674 Patent issued from U.S. Patent Application No. 12/176,032 that was filed on July 8, 2008.

In an Office Action dated December 1, 2011, the Examiner rejected claims 12-28 under various grounds including 35 U.S.C. §§ 102 and 103 in view of U.S. 2007/0179531 ("Thornes") and U.S. 2002/0065517 ("Paul"). Ex. 1011, 44-48.

The Applicant amended independent claims 12 and 27 (issued claims 1 and 14) to recite a "substantially oblong first opening having a longitudinal dimension existing in a direction corresponding to the length of the plate," and "a washer … configured to be slidably adjusted along the longitudinal direction of the first opening" to distinguish Thornes. *Id.*, 26-29; Ex. 1002, ¶¶25-26. In addition, claim 12 was amended to recite "a substantially rigid plate contoured to follow the clavicle." The Applicant explained that claims 12 and 27 were "amended to recite structural features of the substantially rigid plate. The button 102 of the Thornes publication does not have such features." Ex. 1011, 31-32.

A Notice of Allowance issued after an Examiner's Amendment to claim 12 (issued claim 1) adding the limitation: "a washer that can be positioned at a side of the plate opposite the clavicle…." *Id.*, 18-19.

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 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.

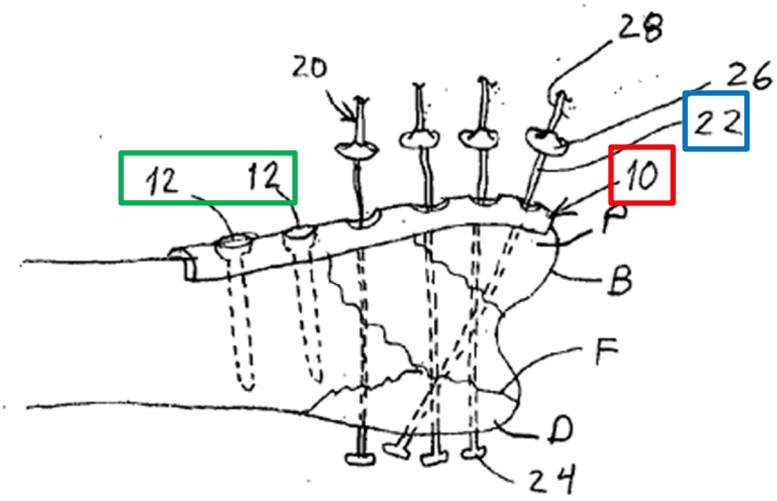
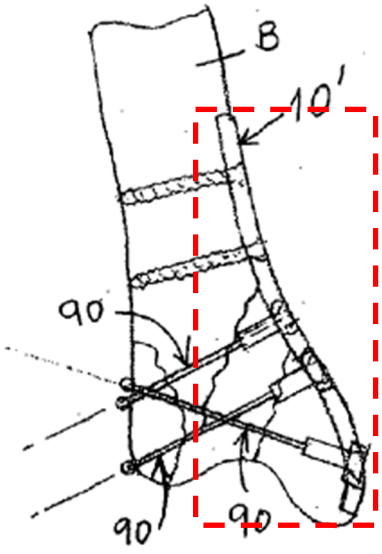


FIG. 1

Ex. 1004, Fig. 1.

Deffenbaugh does not expressly define the dimensions of the bone plate, ("[t]he bone plate may be of many known configurations," *id.*, ¶[0057]) but instead teaches the bone plate is "shaped to fit" a fractured bone. *Id.*, ¶¶[0008], [0075]. Figure 20 (shown below) shows the bone plate 10' contoured to fit the surface of bone B. Ex. 1002, ¶39.



The bone plate has a plurality of openings through which fasteners, including the elongated tensioning elements and bone screws, pass. Ex. 1004, Abstract, Figs. 1, 20, ¶¶[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. Ex. 1004, ¶¶[0058], [0060], [0066]-[0067], [0081].

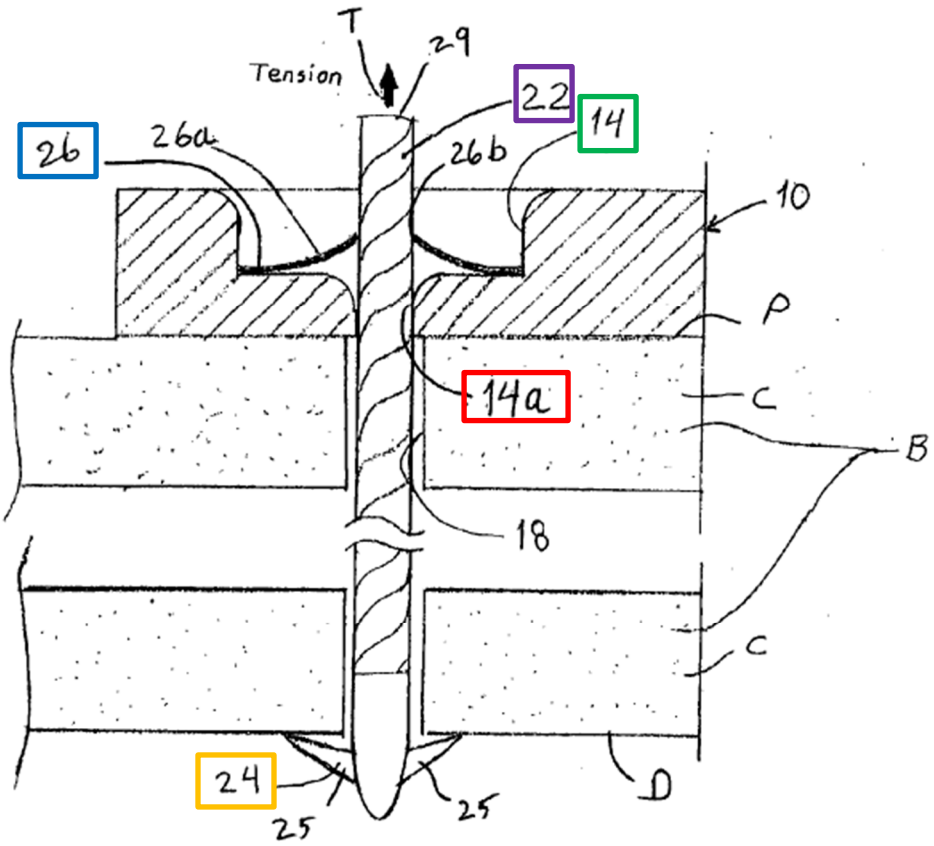


FIG. 2

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. Ex. 1007, ¶¶[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. Ex. 1007, ¶¶[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.

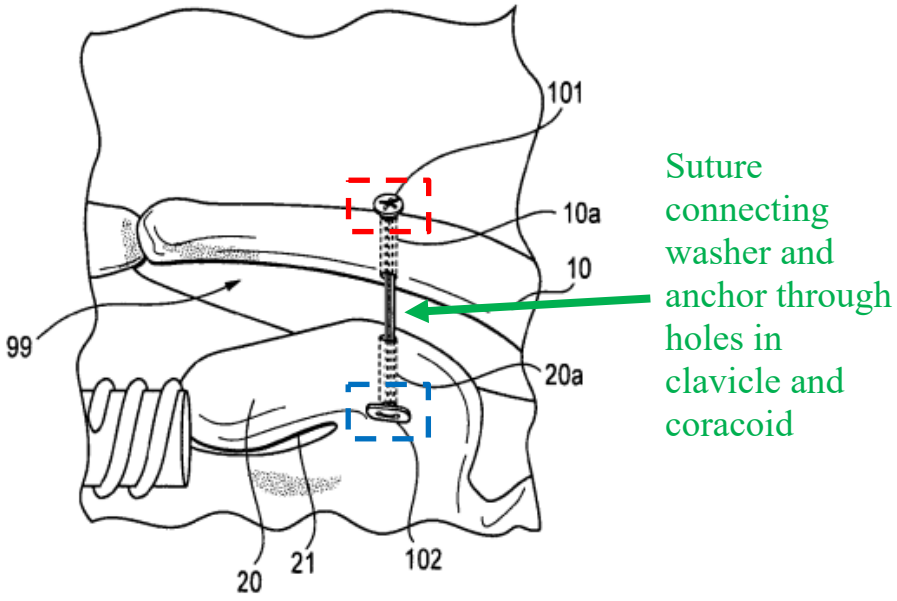


FIG. 7

Ex. 1007, Fig. 7.

Thornes teaches that the washer and anchor (buttons 101, 102) can have "various configurations and dimensions." *Id.*, ¶[0018]. Thornes also discloses a

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

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.

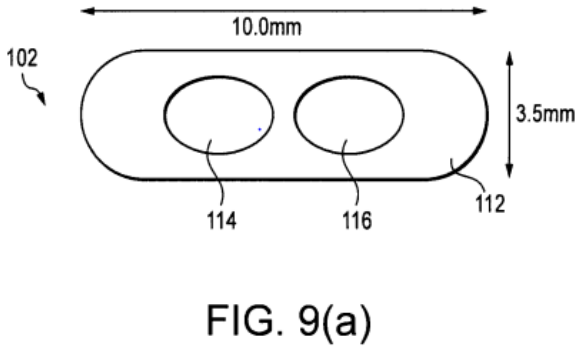


FIG. 9(a)

Ex. 1007, Fig. 9a.

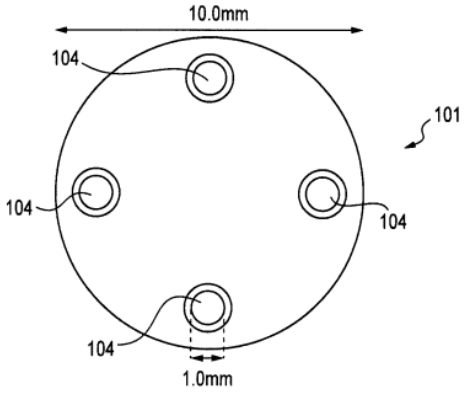


FIG. 10

Id., Fig. 10.

3. Hardy

Hardy discloses a bone fixation device having a plate with slidable washers that engage fasteners and that may slide within orifices along the length of the plate. 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.

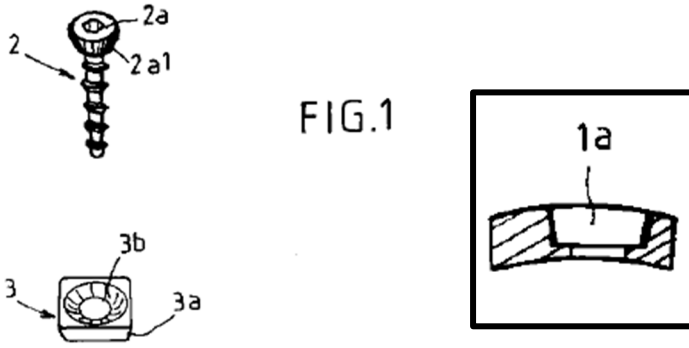


FIG.1

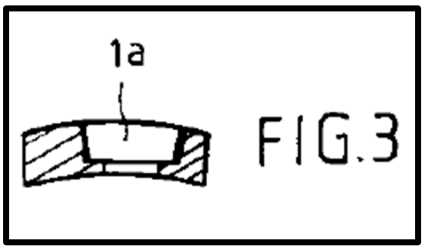
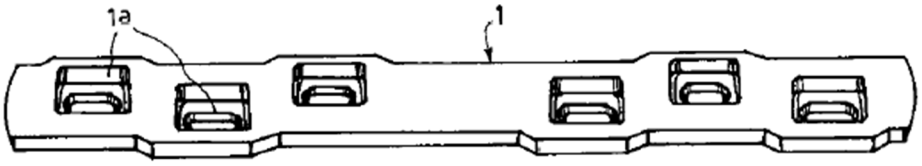


FIG.3



The plate has a plurality of holes dimensioned to receive screws in combination with slidable support washers. Ex. 1006, 4:6-8; 4:20-24; 5:5-9; Fig. 7. The slidable washers help to ensure a successful osteosynthesis of the bone fracture by creating a stable fixation, while also allowing the weight of the body to pass through the fracture site, which promotes proper healing. *Id.*, 2:14-3:1; 5:1-3; Ex. 1002, ¶47.

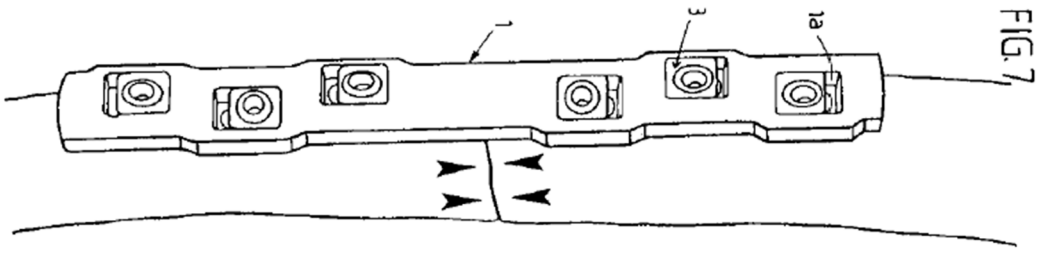
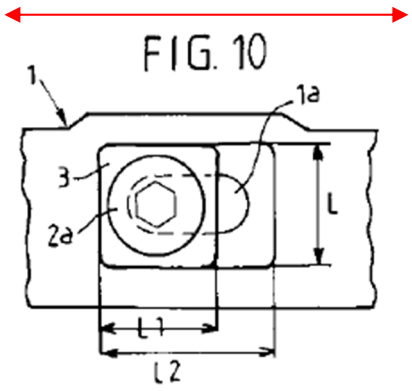


FIG.7

Ex. 1006, Fig. 7.

In order to allow the washers to slide, the openings in the plate are oblong in shape. Ex. 1007, 3:2-5; 4:9-14. Figure 10 below depicts slidable washer 3, with a screw head 2a, in a plate opening (1a). Ex. 1002, ¶48.

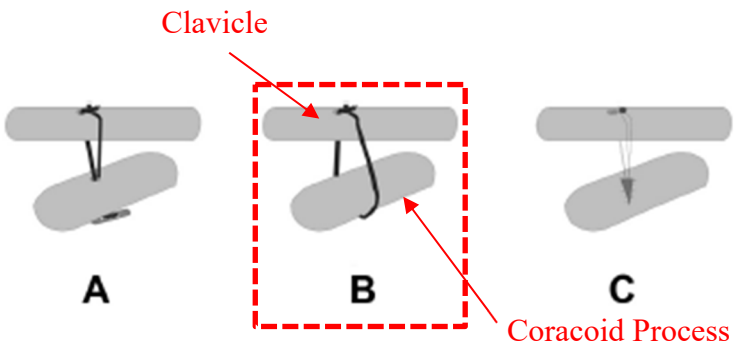
Slidable within opening of the plate



Ex. 1006, Fig. 10.

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.

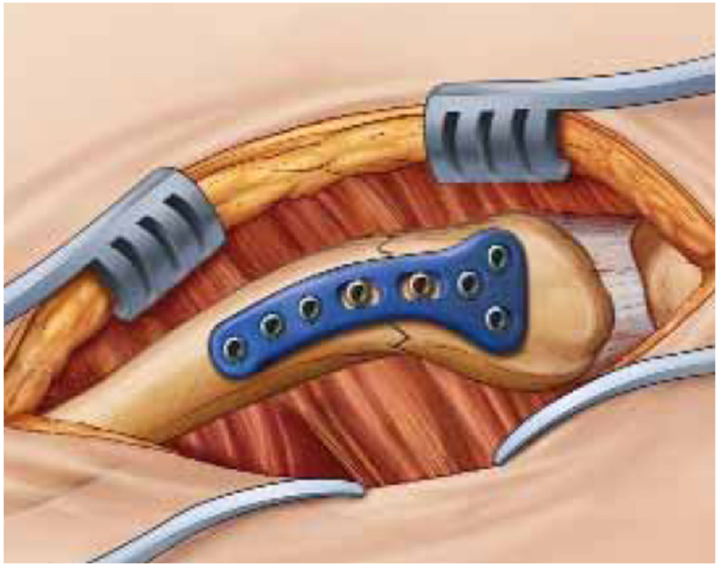


Ex. 1008, Figure 1.

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.

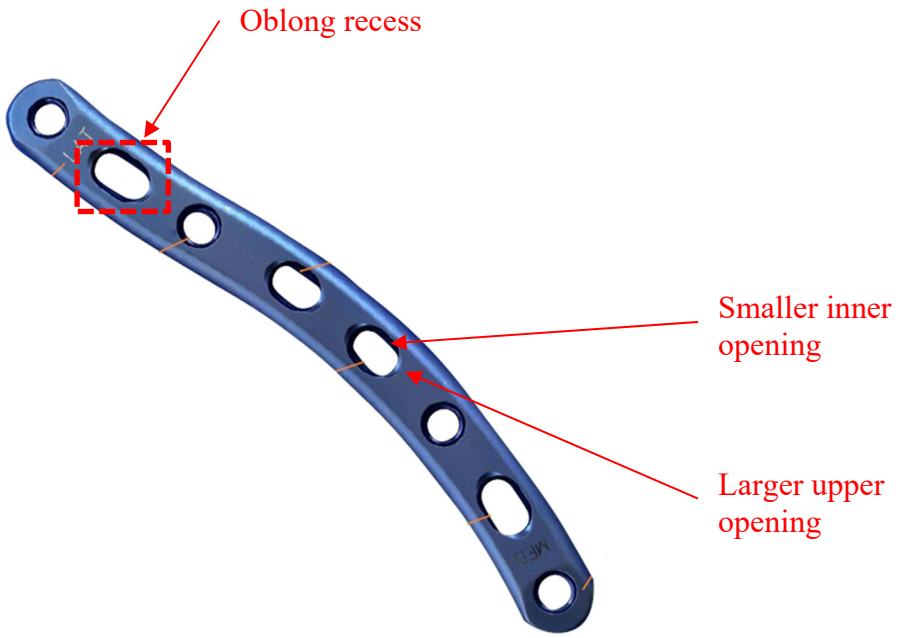
5. Clavicula

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 contoured plates minimize irritation and can act as a template for restoring the bone. *Id.*, 2-3; 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. The figures below depict the recess in the plate, and the fasteners seated in the recess.



Id., 3; Ex. 1002, ¶52.

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 '674 Patent recite a fixation system for a fractured clavicle comprising a "washer" positioned at a side of the plate opposite the clavicle. Ex. 1001, 11:10-11. 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 '674 Patent specification, which describes and shows the claimed "washer" (228) as a thin perforated plate. Ex 1001, 4:65-5:13, 7:9-14; 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.

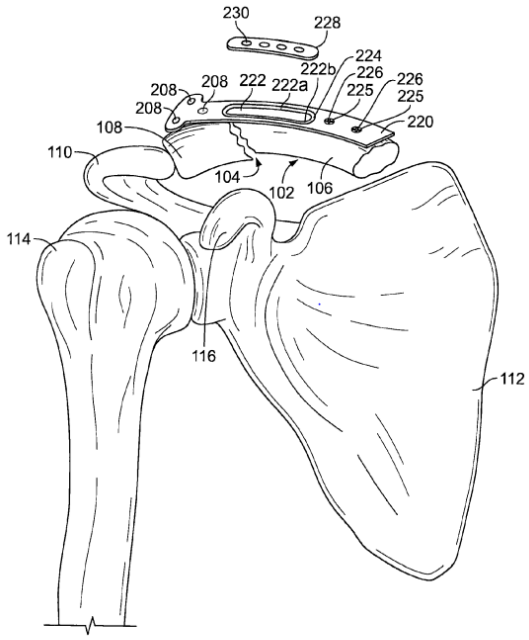
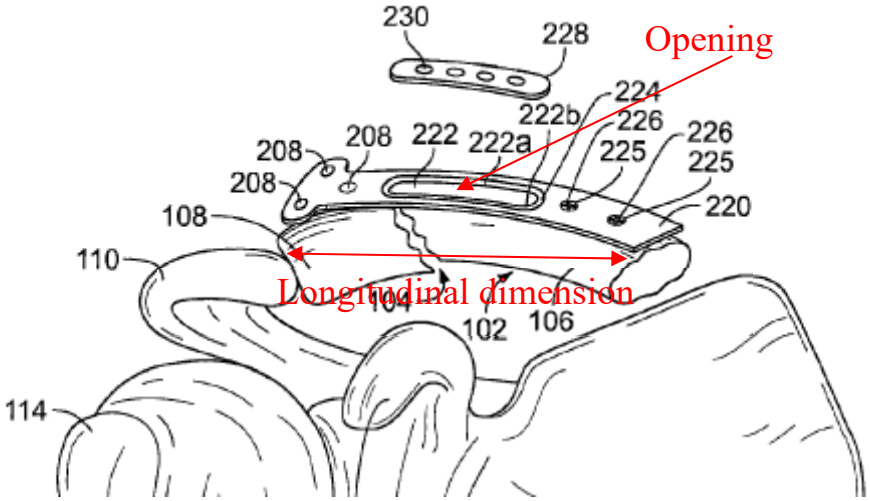


FIG. 2

Ex. 1001, Fig. 2.

B. "slidably adjusted along/within the longitudinal dimension of the first opening"

The '674 Patent claims require that the washer is "configured to be slidably adjusted ***along/within*** the longitudinal dimension of the first opening" in the plate. Ex. 1001, 11:11-12; 12:29-30 (emphasis added). A POSITA would understand this limitation to mean that the washer is capable of being moved smoothly inside the elongated opening of the plate in the longitudinal direction.



Ex. 1001, Fig. 2.

The term "slide" means "to move smoothly along a surface." Ex. 1024. The '674 Patent does not further explain what this limitation means, but simply discloses:

> The first opening in the plate typically is oblong and extends in a longitudinal direction along the plate. … In certain embodiments, the first opening in the plate defines a recess at a side of the plate opposite the clavicle. The recess is adapted to receive the washer. … In some implementations, the washer can slide in a longitudinal direction within the recess.

Ex. 1001, 2:16-25.

C. "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, 10. The intrinsic record fails to adequately define or explain what

these terms mean. Nevertheless, in the related litigations, Gelfand has asserted that the '674 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 '674 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 this Petition. 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, ¶¶28-32. 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 '674 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); *see also 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. Specifically, Thornes was considered by the examiner as an anticipatory reference with regards to the claimed plate and washer (Ex. 1011, 45-46), and was not considered in combination with art that teaches using contoured clavicle plates 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 considered Thornes in combination with Paul for certain dependent claims, where Paul is a plate used to treat spinal cord injuries that utilizes a washer that can fit snugly in the recess. *See* Ex. 1025, Abstract. 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 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. The references also explicitly disclose the purportedly distinguishing features of the claims—a substantially rigid plate contoured to follow the clavicle having oblong openings and slidable washers. By failing to consider these references, 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 slidable washer. 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 '674 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. Ground 1: Claims 1, 3, 4, 6 and 11-14 are Obvious Over Deffenbaugh and Hardy

The combination of Deffenbaugh and Hardy renders claims 1, 3, 4, 6, and 11-14 obvious. Ex. 1002, ¶53.

Deffenbaugh teaches a bone fixation system with a plate and elongated tensioning elements that pass through openings in the plate and bone. While Deffenbaugh does not expressly disclose clavicle fixation, it does not limit the fixation system to any specific bone fracture or region of the body. *See, e.g.*, Ex. 1004, ¶¶[0002] ("any bone fracture"). A POSITA would have understood that the

disclosed system could be used on different bones throughout the body, including on clavicle fractures. Ex. 1002, ¶54.

Deffenbaugh does not expressly teach a plate with an oblong opening or a slidable washer. Hardy expressly teaches a plate for fracture fixation with an oblong plate opening and slidable washer. Ex. 1006, 3:2-5; 4:6-14; 4:20-24; 5:5-9; Ex. 1002, ¶55.

A POSITA would have found it obvious to combine the Deffenbaugh fixation system with the oblong openings of the Hardy bone plate. Ex. 1002, ¶56. Bone plates having oblong holes were well-known in the industry at the relative time,[7] and a POSITA would have been motivated to include an oblong plate opening to allow for more flexible fastener positioning, and to accommodate washers that can slide relative to the plate. Ex. 1006, 4:6-8; 4:20-24; 5:5-9; Ex. 1002, ¶56. As Hardy explains, the use of slidable washers helps to ensure a successful osteosynthesis of the bone fracture by creating a stable fixation, while also allowing the fracture to heal under the natural anatomic stress of a healthy bone, promoting consolidation. Ex. 1006, 2:14-3:1; 5:1-3; Ex. 1002, ¶56.

A POSITA would have had a reasonable expectation of success in using the methods and device of Deffenbaugh to reduce distal clavicle fractures, including

[7] *See, e.g.*, Exs. 1006, 1009.

fixation of the suture to the coracoid process. Ex. 1002, ¶57. The suture and distal anchor of Deffenbaugh could be used on the clavicle and coracoid without modification, and adjusting the contour of the plate to fit the clavicle would be well within the ability of a POSITA. *Id.*, ¶58. A POSITA also would have had a reasonable expectation of success in using the methods and device of Deffenbaugh with oblong plate openings and the slidable washers disclosed in Hardy. *Id.*, ¶59. This combination would have yielded predictable results. *Id.* The minor modifications needed to alter the plate disclosed in Deffenbaugh to include oblong openings that would allow for slidable washers were well within the skill of a POSITA. *Id.* Oblong bone plate openings were well-known in the art, and by simply increasing the length of recess 14, the washer of Deffenbaugh would be able to slide relative to the plate along its longitudinal direction. *Id.*

Deffenbaugh and Hardy are analogous art, because they are in the same field as the '674 Patent (Ex. 1001, Abstract, Title) (Ex. 1004, Abstract, Title) (Ex. 1006, Abstract, Title), and all relate to treating bone fractures using bone plates and other devices. Ex. 1002, ¶60.

(a) [1.p] A fixation system for a fractured clavicle, the fixation system comprising:

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 that the system can be used throughout the body, including on a fractured clavicle. Ex. 1004, ¶¶[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"), [0075]; Ex. 1002, ¶62. Clavicle bone plates were well-known at the relevant time,[8] and it was well within the skill of a POSITA to make any minor modifications to the shape and contour of the bone plate disclosed in Deffenbaugh for use on the clavicle. Ex. 1002, ¶63. Furthermore, the '674 Patent acknowledges that modifications to the "physical shape[] and dimension" of a plate could be made without "departing from the spirit and scope of the invention." Ex. 1001, 9:51-54. Accordingly, a POSITA would have found it obvious to shape the Deffenbaugh plate to fit the clavicle. Ex. 1002, ¶64.

(b) [1.1] a substantially rigid plate contoured to follow the clavicle for securing to a medial portion of the clavicle relative to the fracture and to extend at least partially over a distal portion of the clavicle relative to the fracture when secured to the clavicle,

Deffenbaugh describes a plate contoured to follow a bone surface that is installed over the fracture site. Ex. 1004, Fig. 2; Ex. 1002, ¶65. As described in Section VI, above, based on Gelfand's apparent understanding of this term, a

[8] *See generally* Exs. 1009, 1016, 1017.

POSITA would understand that 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, ¶66. 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, ¶67.

Deffenbaugh teaches a variety of plate shapes that are contoured to follow the surface 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").

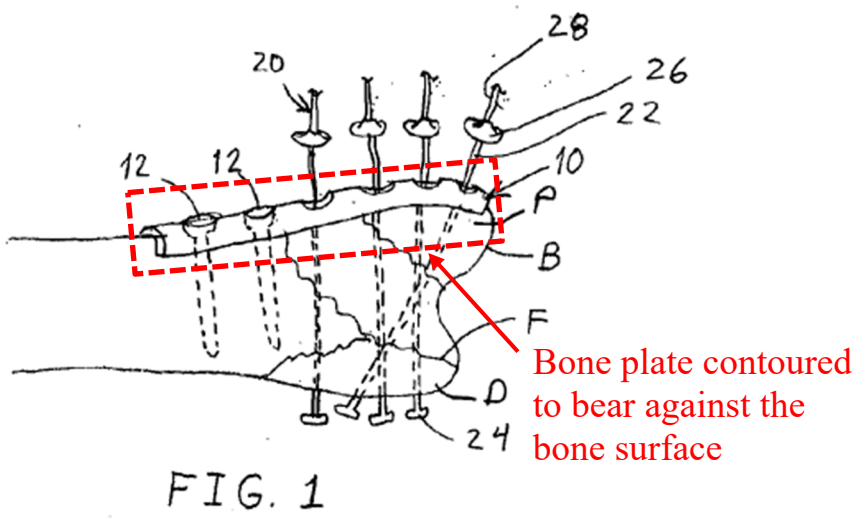


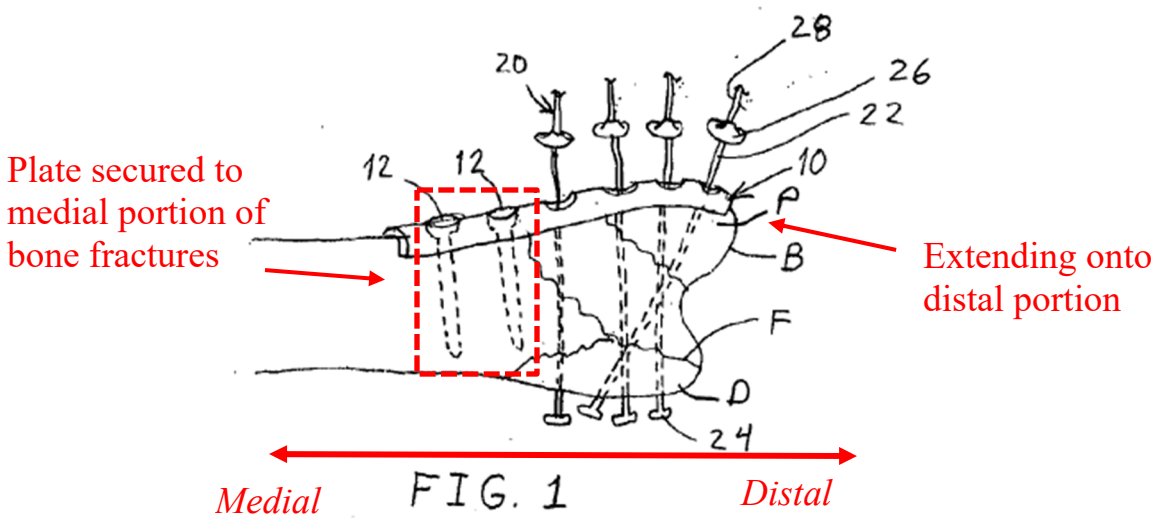
FIG. 1

Ex. 1004, Fig. 1.

As also discussed above, a POSITA would have understood that the Deffenbaugh plate and technique could be used throughout the body, including on a fractured clavicle. Ex. 1002, ¶62.

A POSITA would also have understood that 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.[9] *Id.*, ¶65. To effectively reduce the fracture, the plate may be secured to the medial portion of the clavicle. Ex. 1004, ¶¶[0057], [0065]. 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.

[9] The distal portion of the clavicle 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.



Ex. 1004, Fig. 1; Ex. 1002, IX.A.b.

(c) [1.2] the plate having one or more surfaces that define a substantially oblong first opening having a longitudinal dimension extending in a direction corresponding to the length of the plate and through which a suture can pass;

Deffenbaugh describes a plate with a number of openings though which tensioning elements (e.g., 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 plate." Ex. 1004, Abstract, ¶[0008]; Ex. 1002, IX.A.c. The tensioning elements "may be a…braided suture." Ex. 1004, ¶[0059].

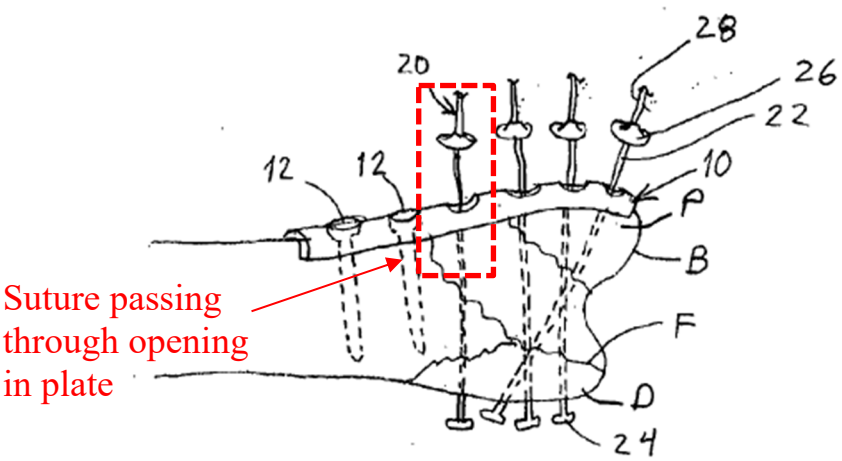
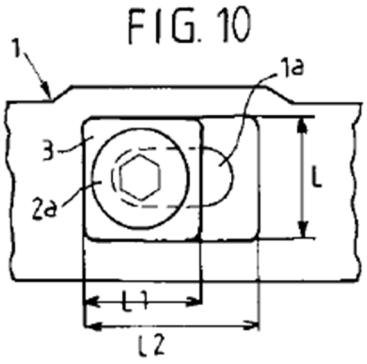
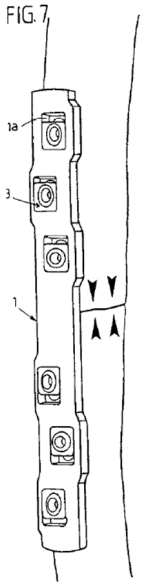


FIG. 1

Id., Fig. 1.

While Deffenbaugh does not expressly disclose an oblong plate opening, Hardy does. The Hardy plate has a plurality of oblong holes having a longitudinal dimension extending in a direction corresponding to the length of the plate dimensioned to receive screws in combination with slidable support washers. Ex. 1006, 3:2-5; 4:6-14; 4:20-24; 5:5-9. Figures 7 and 10, depict slidable washers 3, with a screw head 2a, in oblong plate openings.





Id., Figs. 7, 10.

A POSITA would have found it obvious to include an oblong opening, as in Hardy. Ex. 1002, ¶68. Bone plates having oblong holes were well-known in the industry at the relative time, and a POSITA would have been motivated to include an oblong plate opening to allow for more flexible fastener positioning, as well as the ability to accommodate washers that can slide relative to the plate. *Id.*

(d) [1.3] a washer that can be positioned at a side of the plate opposite the clavicle and configured to be slidably adjusted along the longitudinal dimension of the first opening;

Deffenbaugh describes a washer positioned at a side of the plate 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.d. As explained for limitation [1.p], a POSITA would have found it obvious to apply the Deffenbaugh plate to a fractured clavicle. Ex. 1002, ¶62.

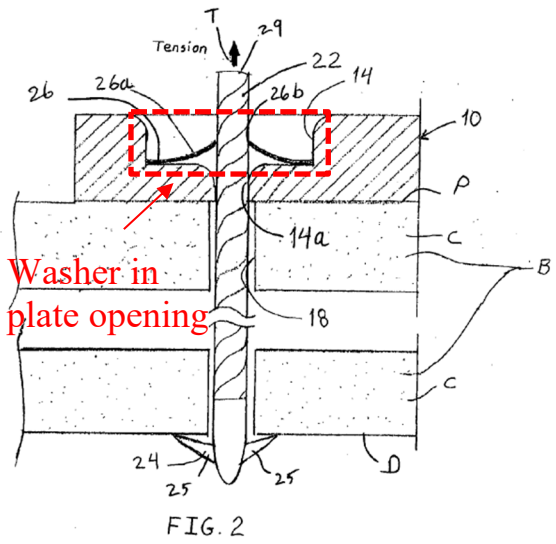
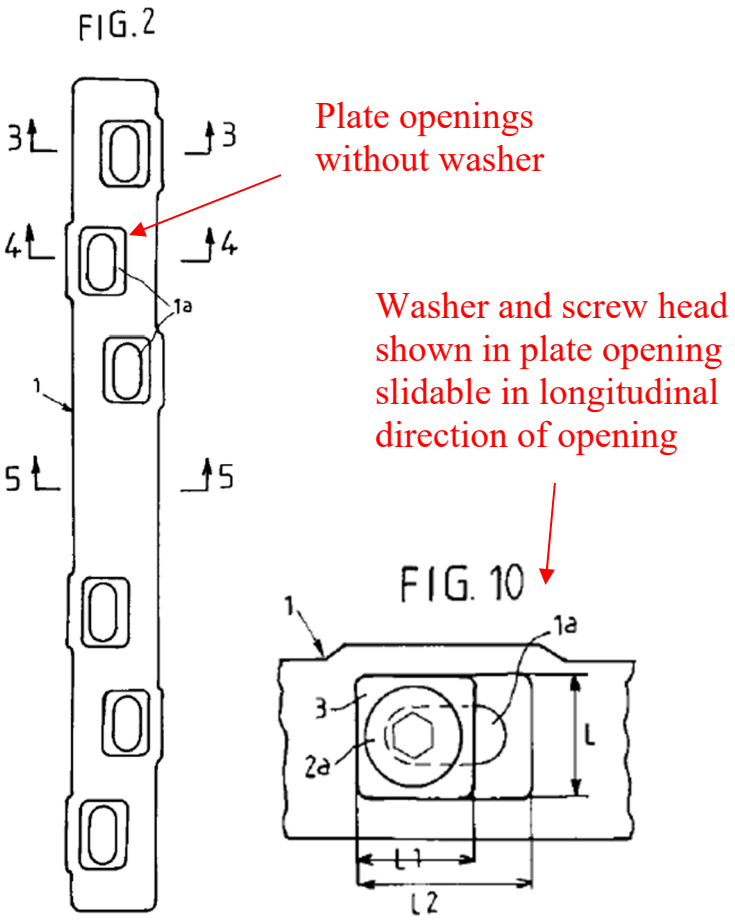


FIG. 2

Hardy expressly describes washers that can slide along the longitudinal dimension of the opening. Ex. 1006, 4:10-12 ("***washers*** (3)… are shaped to be displaced by ***sliding*** in said orifices.") (emphasis added). Figures 2 and 10 depict washers 3 sliding in the plate openings 1a.



Ex. 1006, Figs. 2, 10.

A POSITA would have been motivated to include an oblong plate opening and slidable washers in the Deffenbaugh plate. Ex. 1002, ¶69. As Hardy explains, the use of slidable washers helps to ensure a successful osteosynthesis of the bone fracture by creating a stable fixation, while also allowing the fracture to heal under the natural anatomic stress of a healthy bone, promoting consolidation. *Id.*, IX.A.d. The slidable washers also enable more flexible and precise positioning of fasteners when applying the fixation device. *Id.*, ¶69.

(e) [1.4] a suture secured to the washer and extended through the first opening in the plate, configured to be passed through a hole in the clavicle and secured to the coracoid process.

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. Ex. 1004, ¶¶[0060], [0072]; Ex. 1002, IX.A.e.

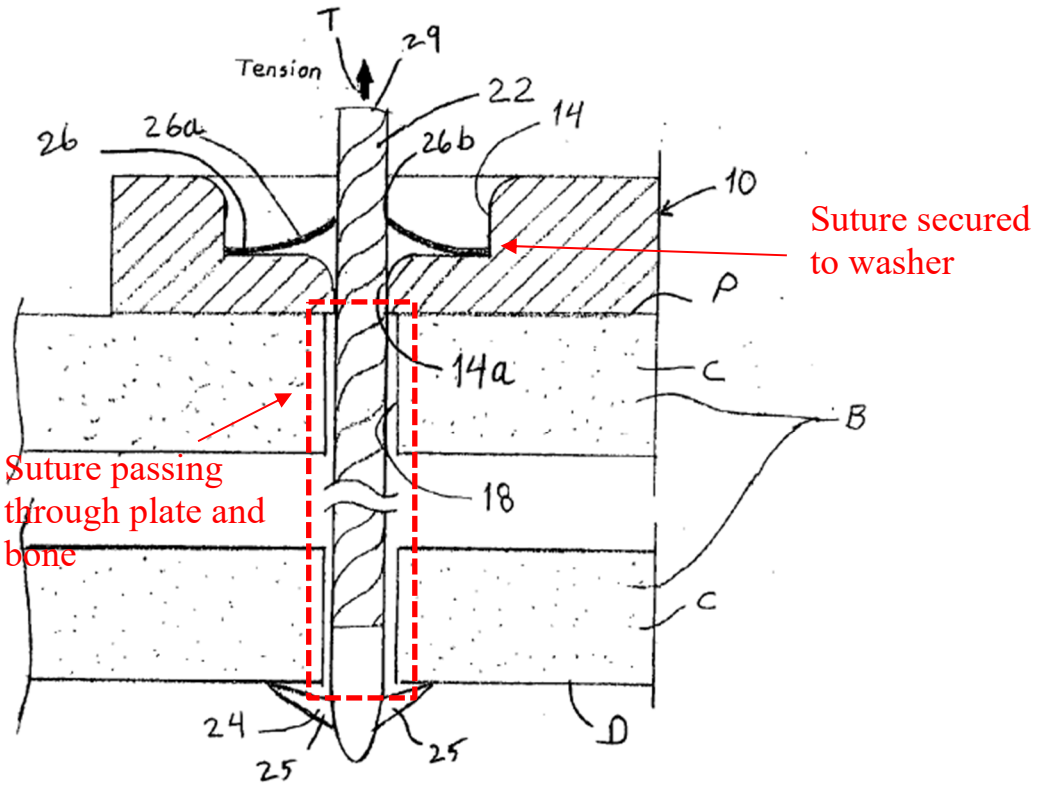
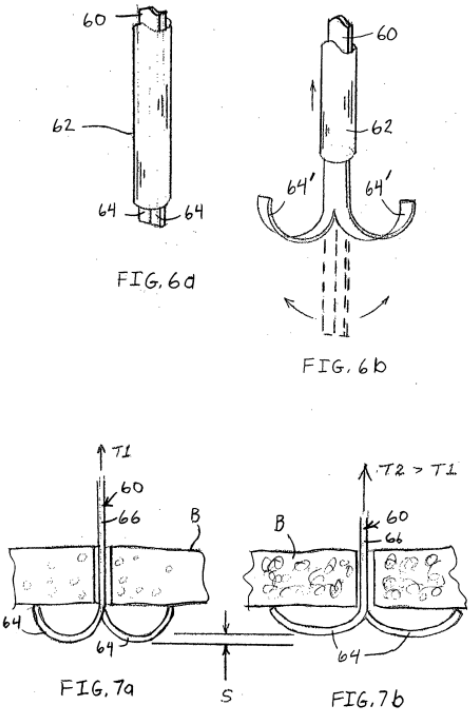


FIG. 2

Ex. 1004, Fig. 2.

Deffenbaugh also teaches using an introducer sheath 62 that helps facilitate passage of the tension element and distal anchor. Ex. 1004, ¶¶[0066], [0068]; Ex. 1002, IX.A.e.



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

As discussed previously, a POSITA would have known the plate could be applied to the clavicle, and a POSITA would have found it obvious to extend the suture through holes in both the clavicle and the coracoid process. Ex. 1002, ¶70. A POSITA would understand that, when applying the Deffenbaugh fixation device to a fractured clavicle, the suture should be extended through holes in both the clavicle and the coracoid process 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.[10] *Id.*

(f) [3] The fixation system of claim 1 wherein the first opening in the plate defines, at a side of the plate opposite the clavicle, a recess adapted to receive the washer.

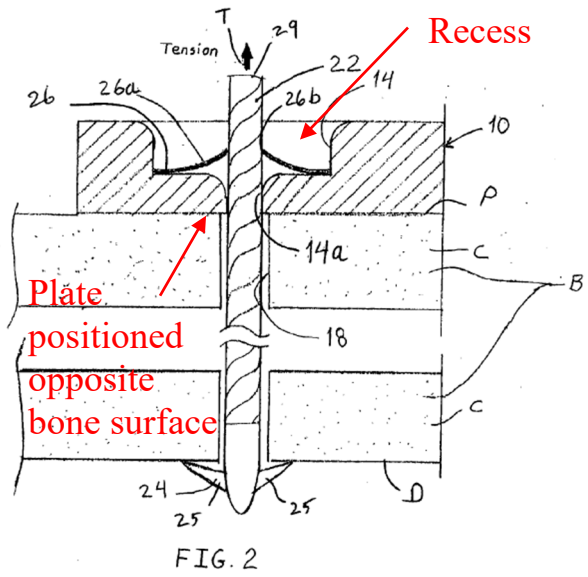


FIG. 2

Deffenbaugh describes a plate with an opening opposite the superior surface of a bone and a recess adapted to receive a washer. Deffenbaugh teaches a "washer 26 is positioned within the recess 14 in the plate" and engages suture that is "configured to extend through recess 14 and opening 14a in the bone plate." Ex. 1004, ¶¶[0009], [0058], [0060]. The recess (14) is positioned on the superior surface of the bone. *Id.* ¶¶ [0057], [0058], Figs. 1-2; Ex. 1002, IX.A.f.

(g) [4] The fixation system of claim 3 wherein the washer fits substantially snugly in the recess.

Deffenbaugh describes a washer that fits in a recess such that the sides of the washer and the walls of the recess are in contact with each other. As shown in Figure

[10] For example, see Exs. 1007, 1020, 1021.

2, the washer sits in the recess of the plate such that the "walls of the recess 14 keep the washer 26 from flattening so that the washer will act to maintain the tension" in the suture. Ex. 1004, ¶¶[0009], [0060]; Ex. 1002, IX.A.g.

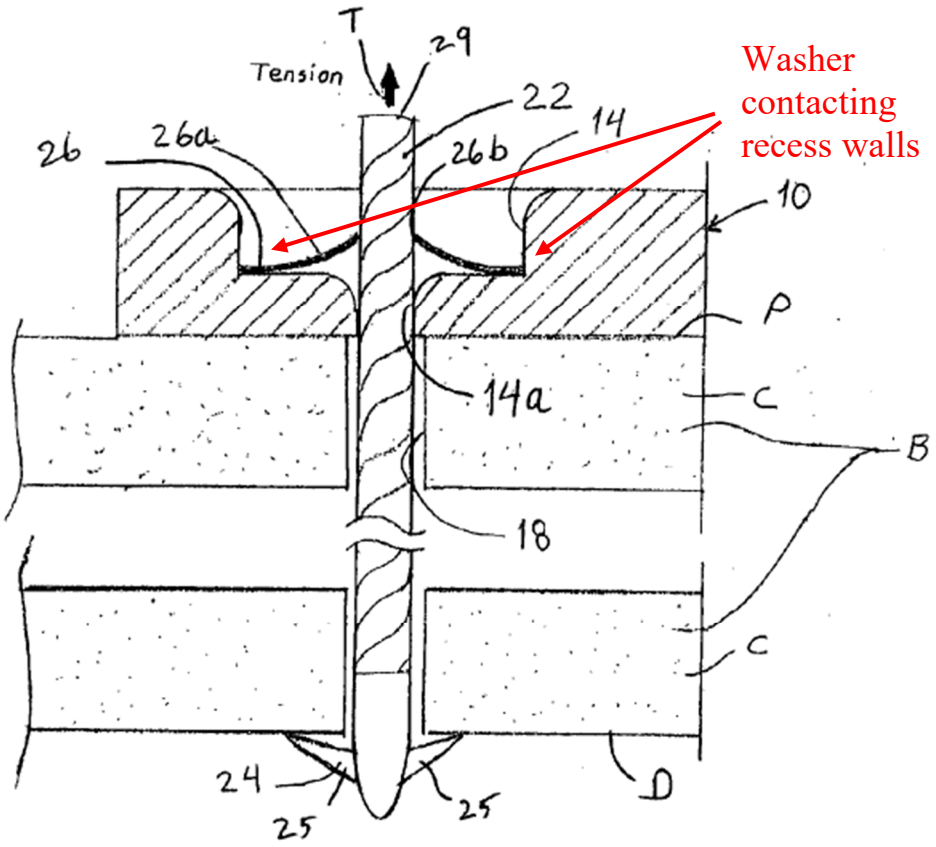
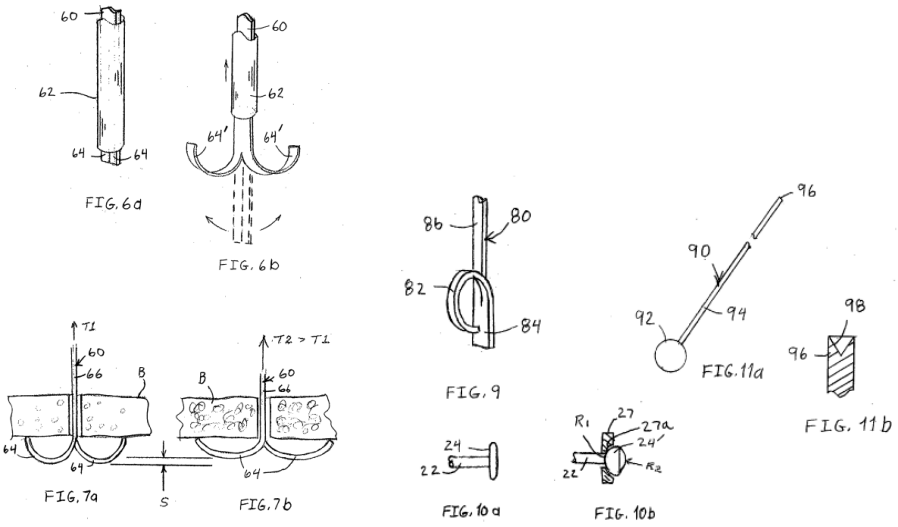


FIG. 2

(h) [6] The fixation system of claim 1 further comprising an anchor for positioning at an inferior side of the coracoid process and secured to the suture when the suture passes through a hole in the coracoid process.

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 includes a sheath that helps facilitate passage of the tension element and distal anchor. *Id.*, [0011]-[0013], [0066]-[0072]; Ex. 1002, IX.A.h.



Ex. 1004, Figs. 6a-7b, 9-11b.

As discussed with respect to limitation [1.4], 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. 1004, ¶¶[0058]-[0059], [0066], [0068], [0072], Figs. 2, 6a-7b; Ex. 1002, IX.A.e, ¶¶70-71. The application of the Deffenbaugh fixation device to a distal clavicle fracture would simply require using enough suture to ensure the tensioning elements can span to the inferior side of the coracoid process. *Id.*, ¶72. 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.").

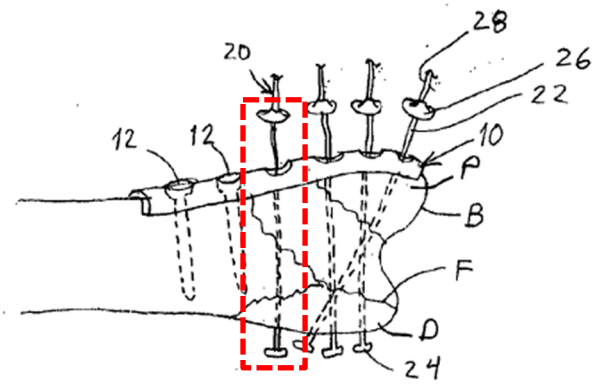


FIG. 1

Id., Fig. 1.

(i) [11] 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.

As discussed with respect to limitations [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, ¶73. As shown in Figure 1 below, the Deffenbaugh plate is contoured to securely fit the distal end of the bone. Ex. 1004, ¶¶[0057]-[0058]; Ex. 1002, IX.A.i.

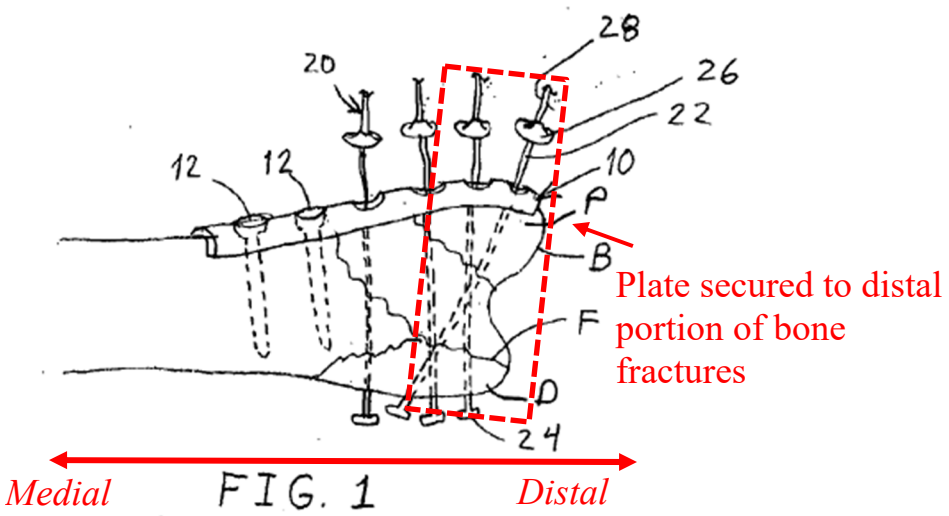


FIG. 1

(j) [12] The fixation system of claim 11, wherein a distal end of the plate is flared.

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.j.

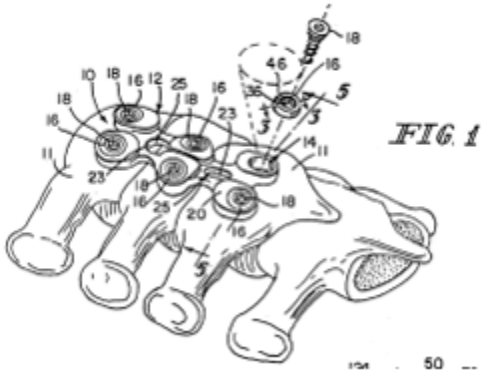


FIG 1

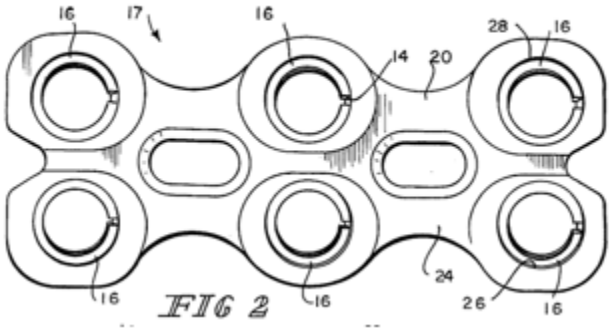


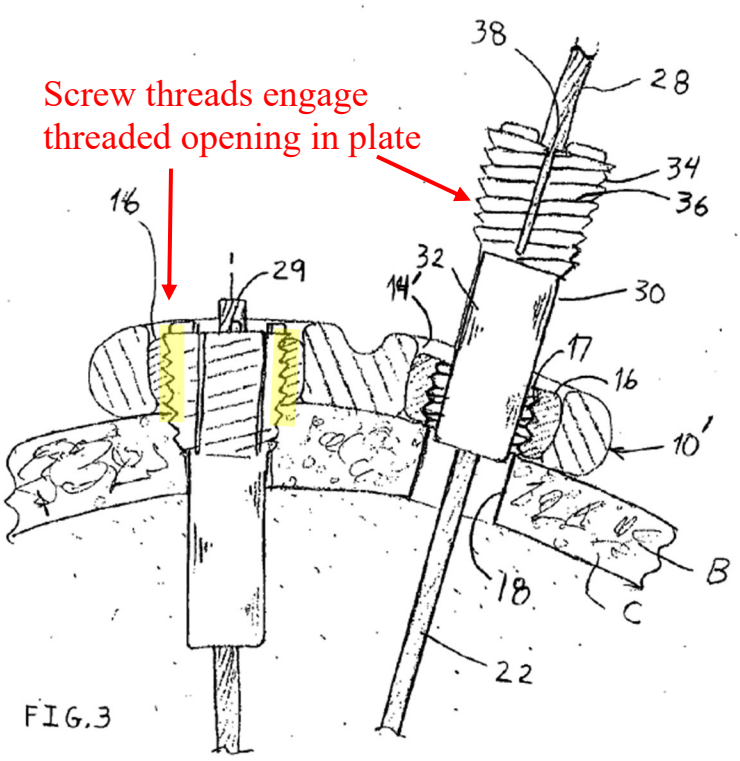
FIG 2

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, ¶74. 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 Clavicula. *Id.*

(k) [13] The fixation system of claim 1 further comprising locking screws.

Deffenbaugh expressly teaches a fixation system with a locking bone screw that engages the bone plate. Ex. 1004, ¶¶[0010], [0061]-[0062]. The '674 Patent defines a locking screw as "a screw that has threads that engage … corresponding threads in the [] hole in the plate." Ex. 1001, 7:39-42. 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.k.



While the locking busing and screw are described as an "alternative proximal anchor" (Ex. 1004, ¶[0061]), a POSITA would understand that they could be used in addition to the fixation technique shown in Figures 1 and 2 of Deffenbaugh, and described above in place of screws in the medial openings where suture is not used. Ex. 1002, ¶75.

(l) [14.p] A fractured clavicle fixation kit comprising:

See [1.p]. Ex. 1004, Abstract, ¶¶[0002], [0036], [0056]-[0057], [0075]; Ex. 1002, ¶¶62-64, 76.

(m) [14.1] a substantially rigid plate contoured to be secured to a medial portion of the clavicle relative to the fracture and to extend at least partially over a distal portion of the clavicle relative to the fracture, the plate having surfaces that define:

See [1.1]. Ex. 1004, Abstract, ¶¶[0008], [0057]; Ex. 1019, 3:65-67, Fig. 2; Ex. 1002, IX.A.b, ¶¶62, 65-67, 77.

(n) [14.2] a substantially oblong first opening having a longitudinal dimension extending in a direction corresponding to the length of the plate and through which a suture can pass; and

See [1.2]. Ex. 1004, Abstract, ¶¶[0008], [0059]; Ex. 1006, 3:2-5; 4:6-14; 4:20-23; 5:5-8, Figs. 7, 10; Ex. 1002, IX.A.c, ¶¶68, 78.

(o) [14.3] a second opening to receive a fastening device; and [14.4] 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

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]. As shown below, the Deffenbaugh plate has a plurality of openings with screws entering the medial portion of the bone. *Id.*, Ex. 1002, IX.A.o.

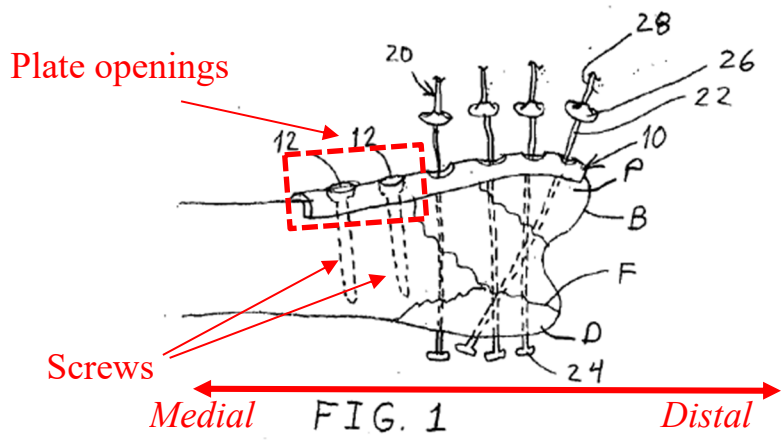


FIG. 1

As discussed above, a POSITA would have found it obvious to apply the Deffenbaugh plate to a fractured clavicle. Ex. 1002, ¶79.

(p) [14.5] a washer that can be positioned at a side of the plate opposite the clavicle and configured to be slidably adjusted within the longitudinal dimension of the first opening; and

See [1.3]. Ex. 1004, ¶[0060]; Ex. 1006, 4:10-12, Figs. 2, 10; Ex. 1002, IX.A.d, ¶¶62, 69, 80.

(q) [14.6] a suture extendable between the washer and the coracoid process, through the first opening in the plate and through a hole formed in the clavicle.

See [1.4]. Ex. 1004, ¶¶[0058]-[0059], [0066], [0068], [0072], Figs. 2, 6a-7b; Ex. 1002, IX.A.e, ¶¶70, 81.

2. Ground 2: Claims 1-7, 9-15 are Obvious Over Deffenbaugh, Hardy and Thornes

The combination of Deffenbaugh, Hardy and Thornes renders claims 1-7, and 9-15 obvious. Ex. 1002, ¶82.

To the extent the Board determines it would not have been obvious to apply the Deffenbaugh system to clavicle fractures based on Deffenbaugh alone, 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, ¶83. The Thornes fixation 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].

A POSITA would have used the Deffenbaugh fixation system on the clavicle and coracoid process in a similar manner as disclosed in Thornes. Ex. 1002, ¶84. Both Thornes and Deffenbaugh disclose similar fixation systems that include a washer and anchor attached by a suture for fixating bone in a similar manner. Ex. 1004, ¶¶[0008], [0057]-[0059], Claim 11; Ex. 1007, ¶¶[0013]-[0014], [0033]-[0034], Claims 19-20; Ex. 1002, ¶84.

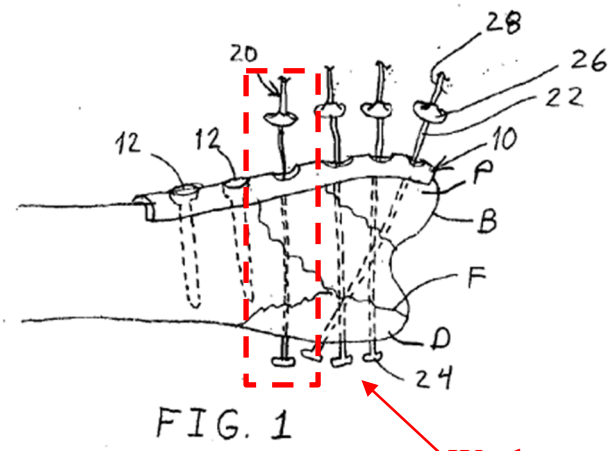


FIG. 1

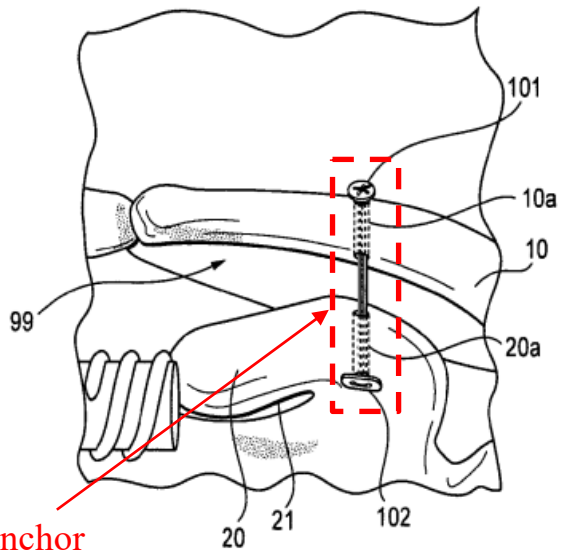


FIG. 7

Washer and anchor connected by suture passing through bone

Ex. 1004, Fig. 1 Ex. 1007, Fig. 7

A POSITA would have understood that the Deffenbaugh plate could be used on a clavicle and would have been motivated to combine the plate with the technique disclosed in Thornes to obtain and maintain proper correction of the fracture displacement, maximizing the chance of clinical success. Ex. 1007, ¶¶[0013]-[0014], [0017]; Ex. 1002, ¶85. 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."[11]

A POSITA would have expected this combination of fixation devices would have yielded predictable results, and would have had a reasonable expectation of

[11] *See* Ex. 1022, 4.

success in using the methods and devices of Deffenbaugh and Hardy for clavicle fixation, with the technique of attaching the clavicle and coracoid process with a suture, as disclosed in Thornes. Ex. 1002, ¶86. The suture, washer and anchor of Deffenbaugh are very similar in design to those disclosed in Thornes, and any slight modifications to the system needed to make it effective for clavicle-coracoid attachment were well within the skill of a POSITA. *Id.* Furthermore, a POSITA would have recognized that 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 that they may be adapted for a variety of bone fixation applications. *Id.*; Ex. 1004, ¶¶[0002], [0036]; Ex. 1007, ¶[0017].

Deffenbaugh, Thornes, and Hardy are analogous art, because they are in the same field as the '674 Patent (Ex. 1001, Abstract, Title) (Ex. 1004, Abstract, Title) (Ex. 1007, Abstract, Title, ¶[0011]) (Ex. 1006, Abstract, Title), and all three relate to treating a displaced fracture or joint injury. 1002, ¶87.

(a) Claim 1

(i) *[1.p]*

To the extent the preamble is limiting, it is disclosed by Deffenbaugh in view of Thornes. To the extent Deffenbaugh does not 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.

(ii) *[1.1]-[1.3]*

See Ground 1, [1.1]-[1.3]. Ex. 1004, Abstract, ¶¶[0008], [0057], [0059]-[0060]; Ex. 1006, 3:2-5, 4:6-14, 4:20-23, 5:5-8, Figs. 2, 7, 10; Ex. 1019, 3:65-67, Fig. 2; Ex. 1002, IX.A.b-d, ¶¶62, 65-69, 77-78, 80, 89-91.

(iii) *[1.4]*

To the extent Deffenbaugh does not disclose passing a suture through a hole in the clavicle and secured 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.e. 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. Ex. 1007, ¶¶[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.

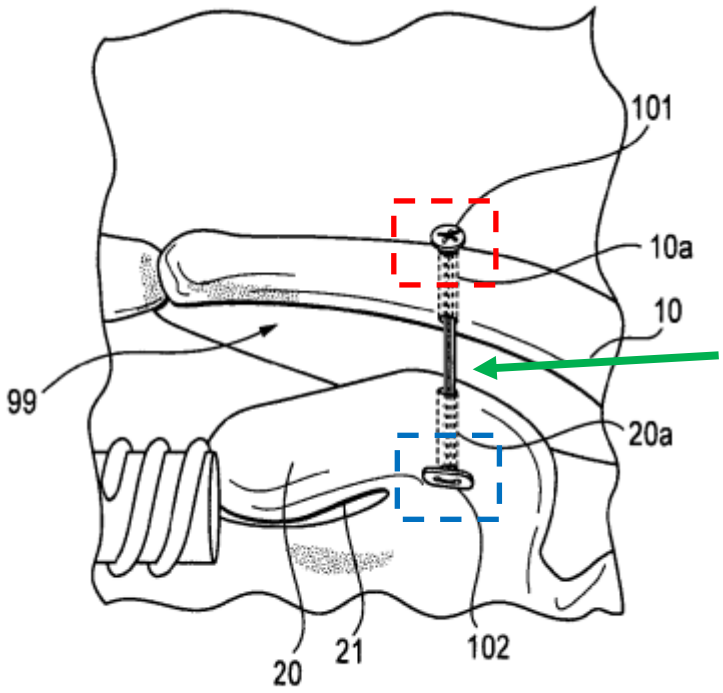


FIG. 7

(b) Claim [2]

Deffenbaugh teaches tensioning suture to fixate fractured bone. While Deffenbaugh does not disclose tensioning the fixation system to reduce the distance between the coracoid process and the clavicle, Thornes expressly teaches pulling on the suture extending from the washer (button 101) and tying "the suture over top of the fixation system 100…[to] complete[] the reduction and stabilization." Ex. 1007, ¶¶[0033]-[0034]; Ex. 1002, IX.B.f.

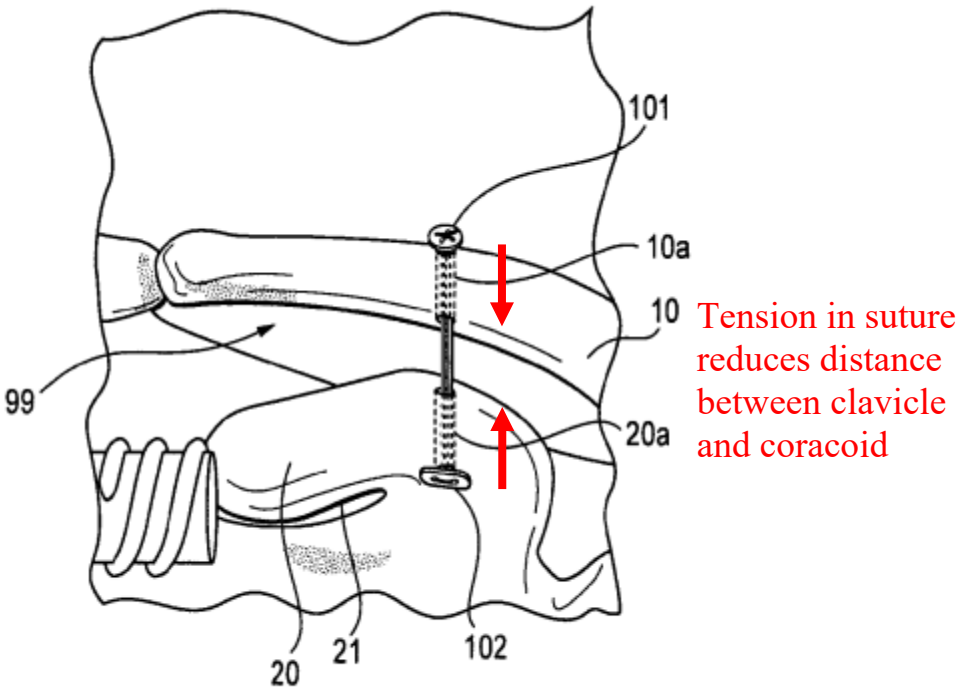


FIG. 7

Ex. 1007, Fig. 7.

(c) Claim [3]

See Ground 1, claim 3. Ex. 1004, ¶¶[0009], [0012], [0057]-[0058], [0060], Figs. 1-2; Ex. 1002, IX.A.f, ¶92.

(d) Claim [4]

See Ground 1, claim 4. Ex. 1004, ¶¶[0009], [0060], Fig. 2; Ex. 1002, IX.A.g, ¶93.

(e) Claim [5]

Deffenbaugh teaches the use of a Tinnerman washer, but fails to disclose a washer with more than one hole. Ex. 1002, IX.B.i. Thornes, however, teaches the use of a washer (101) with multiple holes dimensioned to receive a suture. Ex. 1007,

¶[0021] (washer (101) having "at least two flexible coupling-locating apertures."); ¶[0022].

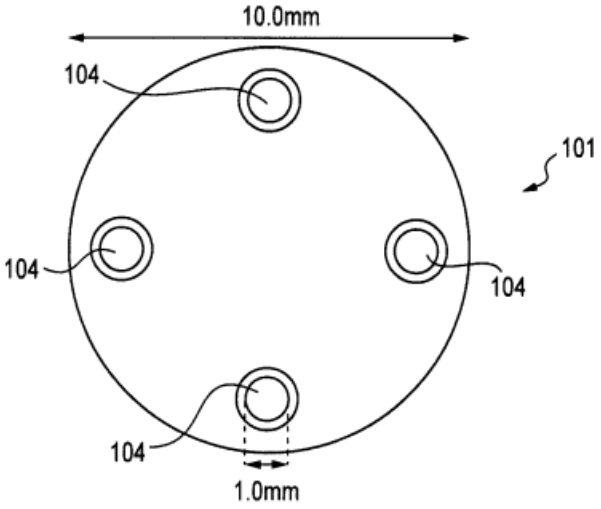


FIG. 10

Id., Fig. 10 (showing four apertures 104 for receiving a suture). A POSITA would have found it obvious to use a washer with more than one hole because this would make the process of securing the suture to the washer via a knot easier, and would allow for more flexible positioning. Ex. 1002, ¶94.

(f) Claim [6]

To the extent Deffenbaugh does not disclose 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.j.

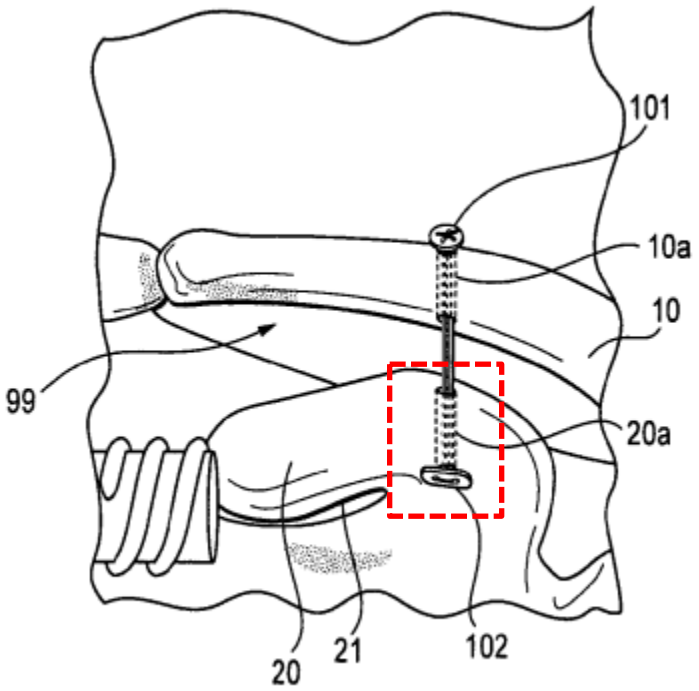


FIG. 7

(g) Claim [7]

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 that 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.k.

While Deffenbaugh does not expressly teach an oblong anchor, Thornes does. Specifically, Thornes teaches an oblong anchor (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.

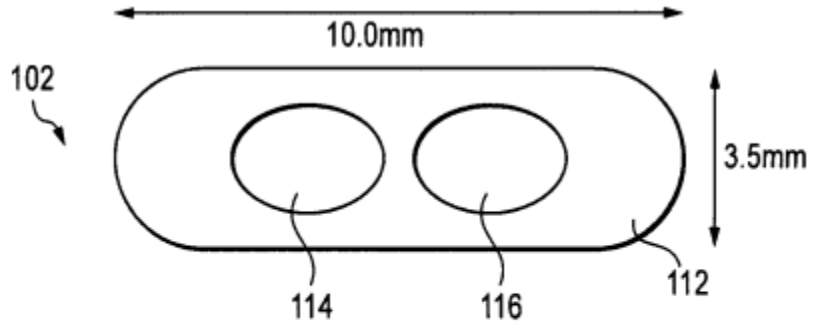


FIG. 9(a)

A POSITA would understand 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, ¶95.

(h) Claim [9]

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 exemplary embodiment of an oblong shaped washer. *Id.*, ¶¶[0018]-[0019]; Ex. 1002, IX.B.l.

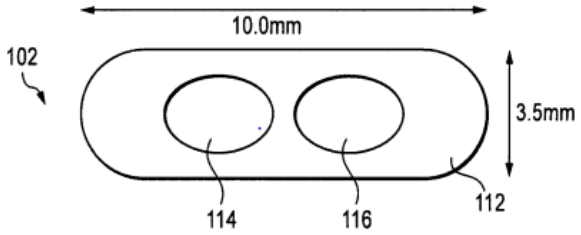
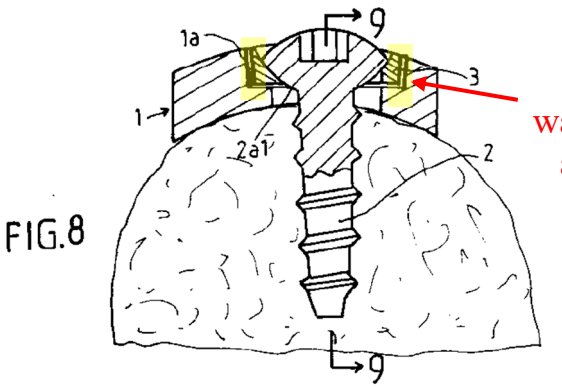
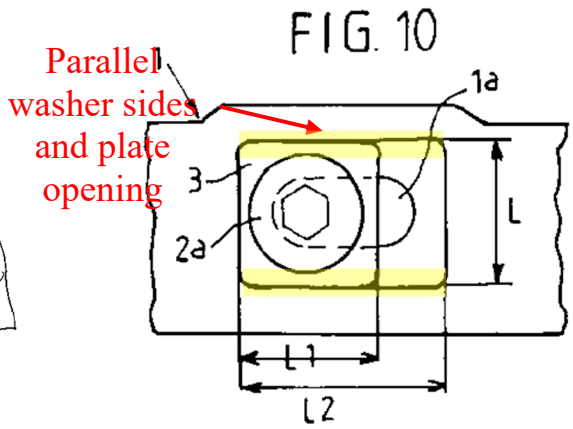


FIG. 9(a)

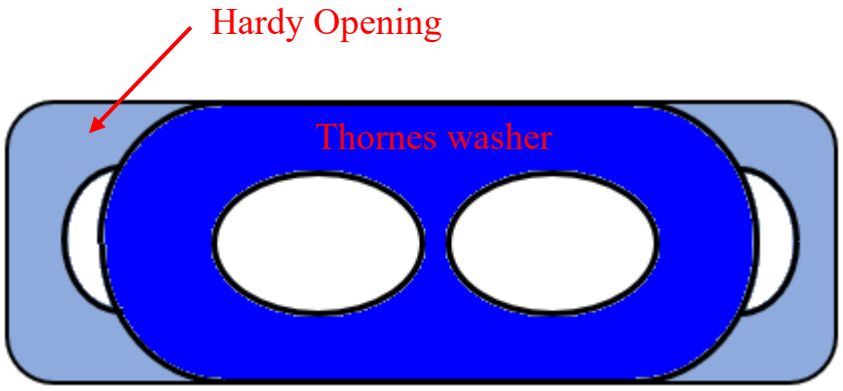
(i) Claim [10]

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, 4:9-16; Ex. 1002, IX.B.m. 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 in Hardy, which would result in the sides of the washer being substantially parallel to the plate opening, as shown below. Ex. 1002, IX.B.m.



A POSITA would have found it obvious to include washers having sides parallel to the sides of the plate opening, as taught by Hardy. Ex. 1002, ¶96. 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.*

(j) Claims 11-13

See Ground 1, claims 11-13. Ex. 1004, ¶[0058], Fig. 1; Ex. 1002, IX.A.i, ¶¶73, 97-99.

(k) Claim 14

(i) *[14.p]*

See [1.p] in this Ground. Ex. 1007 ¶¶[0012], [0017]; Ex. 1002, IX.B.a, ¶100.

(ii) *[14.1]-[14.5]*

See Ground 1, [14.1]-[14.5]. Ex. 1004, Abstract, ¶¶[0008], [0057], [0059]-[0060], [0065], [0075]; Ex. 1006, 3:2-5, 4:4-14, 4:20-23, 5:5-8, Figs. 7, 10; Ex. 1019, 3:65-67, Fig. 2; Ex. 1002, IX.A.b-d, IX.A.o, ¶¶62, 65-70, 77-81, 101-104.

(iii) *[14.6]*

See [1.4] in this Ground. Ex. 1007 Abstract, ¶[0011], [0013]-[0014], [0033], Fig. 7; Ex. 1002, IX.B.e, ¶105.

(l) Claim [15]

See claim 7 in this Ground. Ex. 1004, ¶¶[0058], [0066], [0072]; Ex. 1007, ¶¶[0018], [0032], [0033], Fig. 9a; Ex. 1002, IX.B.k, ¶¶95, 106.

3. Ground 3: Claim 8 is Obvious Over Deffenbaugh, Hardy and Wellmann

The combination of Deffenbaugh, Hardy, and Wellmann renders claim 8 obvious. Ex. 1002, ¶107.

For the reasons described above in Ground 1, Deffenbaugh and Hardy suggest fixation of a fractured clavicle using a plate, washer and suture secured to the coracoid process. While Deffenbaugh and Hardy fail to teach passing the suture around the coracoid process, Wellmann discloses the same. Ex. 1008, 957; Ex. 1002, ¶108.

A POSITA would have found it obvious to use the Deffenbaugh fixation system with a suture passed around the coracoid process, as taught by Wellmann. Ex. 1002, ¶109. Both Wellmann and Deffenbaugh disclose a fixation system utilizing a suture to fixate opposing bone elements. Ex. 1004, ¶¶[0008], [0057]-[0059], Fig. 1; Ex. 1008, 956-57, Fig. 1. 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 that the deforming forces in an acromioclavicular joint dislocation and distal clavicle fracture are nearly identical. Ex. 1002, ¶110. 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 acromial clavicular 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, ¶111.

Deffenbaugh, Wellmann, and Hardy are analogous art, because they are in the same field as the '674 Patent (Ex. 1001, Abstract, Title) (Ex. 1004, Abstract, Title) (Ex. 1008, Title, 955-57) (Ex. 1006, Abstract, Title), and all three relate to treating damaged body tissue. Ex. 1002, ¶112.

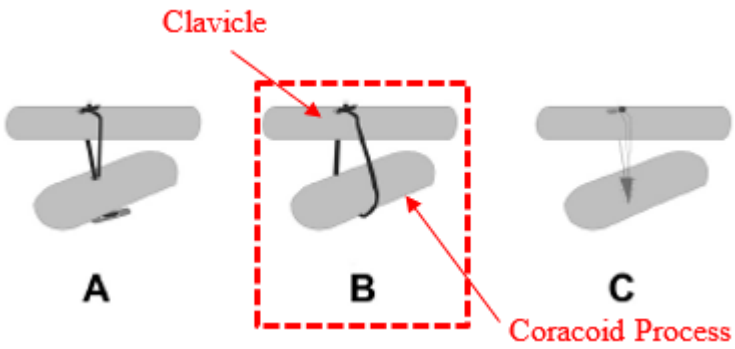
(m) [8] The fixation system of claim 1 wherein the suture is configured to pass around the coracoid process.

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, ¶¶109-110.



4. Ground 4: Claim 8 is Obvious Over Deffenbaugh, Hardy, Thornes and Wellmann

Claim 8 is also obvious over Deffenbaugh in Combination with Hardy, Thornes, and Wellmann. This ground is simply a combination of the analyses in Grounds 2 and 3. The bases for the combinations and manner of combining the references are articulated in those grounds. Ex. 1002, ¶114.

5. Ground 5: Claims 1-15 are Obvious Over Clavicula, Hardy and Thornes

The combination of Clavicula, Hardy and Thornes renders claims 1-15 obvious. Ex. 1002, ¶115.

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 bone plate of Clavicula can have a flared distal end for fixing distal fractures. *Id.*, 3. Clavicula 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, ¶116.

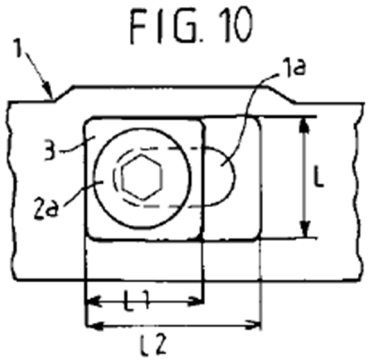
Thornes includes a washer positioned on the clavicle, an anchor positioned on the underside of the coracoid process, and a suture connecting the washer and anchor through bone holes in the clavicle and coracoid process. Ex. 1009, ¶¶[0013]-[0014], [0017]-[0018], [0033]. Thornes further teaches its washer-suture 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, ¶117.

Hardy expressly teaches a plate for fracture fixation with an oblong opening and slidable washer. Ex. 1009, 3:2-5; 4:6-14; 4:20-24; 5:5-9; Ex. 1002, ¶118.

A POSITA would have found it obvious to combine the contoured Clavicula plate with the Thornes washer-suture system and the slidable features of the Hardy washer. Ex. 1002, ¶119. 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; Ex. 1002, ¶119. Thus, a POSITA would be motivated to look to prior art that discloses sutures for use with the clavicle and/or coracoid process. Ex. 1002, ¶119. 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, ¶120. A POSITA would be motivated to combine Clavicula with Thornes to provide a simple, reproducible means of taking stress off of the lateral fixation of the plate that prevents subsequent fracture or joint displacement. Ex. 1002, ¶120.

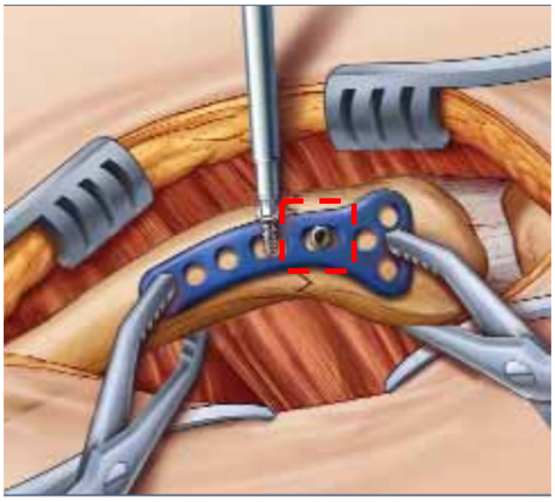
Clavicula further discloses a plate with oblong openings for adjustable positioning of a fastener, but does not disclose a washer. Ex. 1009, Figs. at 3. Bone plates utilizing washers slidably adjustable in the oblong opening of the plate were known at the relevant time, and a POSITA would have been motivated to include a slidable washer to allow for more flexible fastener positioning. Ex. 1002, ¶121. For instance, Hardy discloses a plate with oblong openings permitting slidable adjustment of a washer, and explains that the use of slidable washers helps to ensure a successful osteosynthesis of the bone fracture by creating a stable fixation. Ex. 1006, 2:14-3:1, 5:1-3, Figs. 1-2, 6-7, 10; Ex. 1002, ¶123.



Ex. 1006, Fig. 10. A POSITA would have been motivated to make the opening oblong to permit adjustable positioning off the suture. Ex. 1002, ¶121.

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. A POSITA would have been motivated to combine the contoured Clavicula plate with the Thornes washer-suture system and the slidable washer of Hardy to provide an optimal fixation with a simple, reproducible, and adjustable means of taking stress off the clavicle fixation. *Id.*, ¶124.

A POSITA would have expected this combination of fixation devices would have yielded predictable results, and 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. Ex. 1002, ¶125. 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. 1009, Fig. at 6

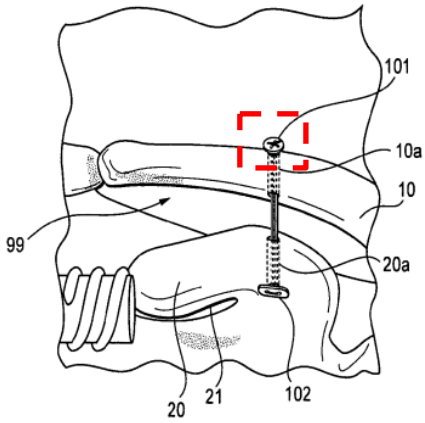
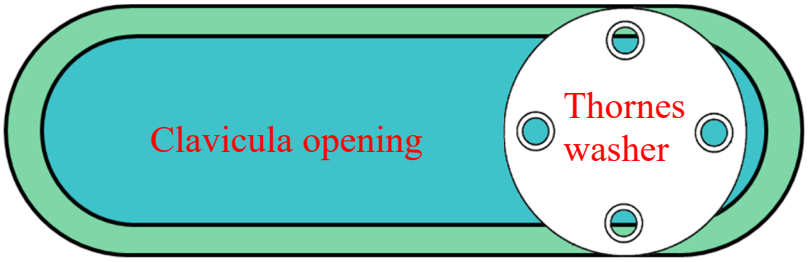


FIG. 7

Ex. 1007, Fig. 7



Ex. 1002, ¶125. Any slight modifications to the Clavicula plate needed to make the opening capable of receiving the Thornes washer were well within the skill of a POSITA. *Id.*, ¶126. A POSITA would recognize that by incorporating an oblong hole (as Hardy teaches), the plate could be secured to the clavicle (as taught by Clavicula) leaving the oblong hole open and allowing the treating physician to locate the optimal location for the washer-suture placement, drill through the plate at the location, and install the washer-suture system (as taught by Thornes). *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 adopted for a variety of bone/tissue fixation applications and a POSITA would have understood the Thornes fixation technique could have been easily been used with 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, ¶127.

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. Ex. 1002, ¶128. 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 that the application of the Thornes technique to Clavicula would predictably improve the strength of the overall fixation because it was a known technique to apply a washer-suture system to stabilize the acromioclavicular joint. *Id.*

A POSITA would have recognized that the Thornes washer would have been slidably adjustable within the oblong opening of the Clavicula plate with little to no modification. *Id.*, ¶129.

A POSITA would also have looked to plates explicitly disclosing slidable washers, such as the Hardy plate, and would have had a reasonable expectation of success in combining the slidable washer feature with the Clavicula plate because it has oblong openings capable of receiving a circular member. *Id.*, ¶130. A POSITA would further have a reasonable expectation of success in substituting the slidable washer of Hardy for the Thornes suture-affixed washer because the combination merely involves the substitution of one washer for another. *Id.* In general, the suture fix washer technique of Thornes was at the relevant time a more standard method of fixation. *Id.* Any slight modification necessary to permit slidable adjustment of the Thornes washer in the Clavicula plate would have been well within the skill of a POSITA. *Id.*

Clavicula, Thornes, and Hardy are analogous art, because they are in the same field as the '674 Patent (Ex. 1001, Abstract, Title) (Ex. 1009, Abstract, Title) (Ex. 1007, Abstract, Title, ¶[0011]) (Ex. 1006, Abstract, Title), and all relate to treating damaged body tissue. Ex. 1002, ¶131.

(a) Claim 1

(i) *[1.p]*

To the extent the preamble is limiting, it is disclosed by Clavicula. Ex. 1009, 2 ("Acumed has designed a comprehensive solution for repairing fractures located from the middle third to the distal third of the clavicle."), 2 ("Locking Clavicle Plates

are included in a comprehensive system of implants and instrumentation specifically designed to treat clavicle injuries"). Ex. 1002, IX.E.a.

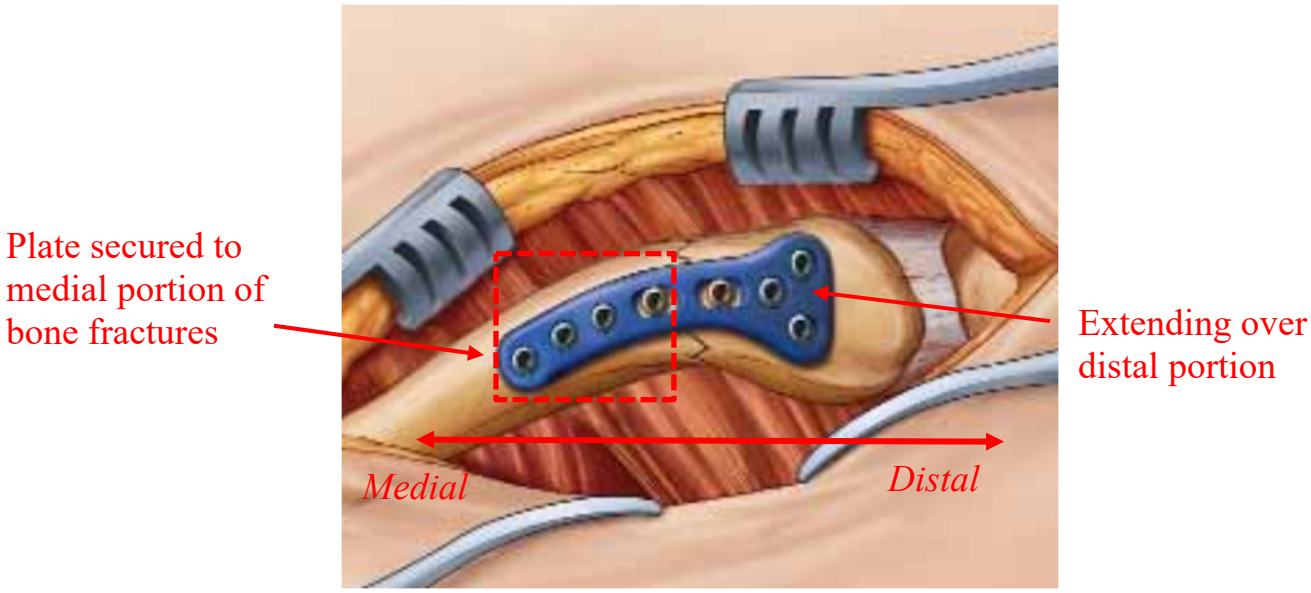
(ii) *[1.1]*

Clavicula discloses a substantially rigid bone plate contoured to follow the clavicle. Ex. 1009, 2 ("Pre-contoured to match the natural S-shape of the clavicle, this titanium plate offers increased strength, with a rounded profile and a low-profile screw-plate interface."), 3 ("Multiple plate options are available to fit a wide variety of clavicle curvatures."); Ex. 1002, IX.E.b. A POSITA would understand that the titanium plate of Clavicula is "substantially rigid" because titanium is a material rigid enough to fixate a fractured bone without deformation. *Id.*, ¶134.

Ex. 1009, Fig. 2.

Clavicula further discloses securing the plate to a medial portion of the clavicle relative to the fracture such that the plate extends at least partially over a

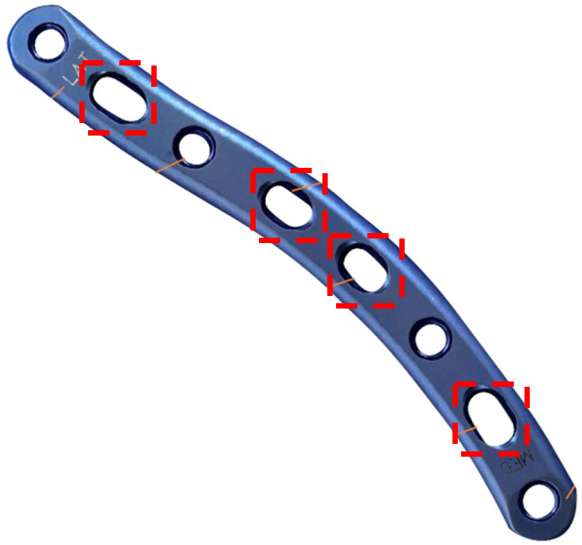
distal portion of the clavicle relative to the fracture. Ex. 1009, 5 ("place the 3.5 mm locking screws [] into the threaded holes so that there are at least three screws (if possible) on each side of the fracture."). A POSITA would understand that "each side of the fracture" references the distal and medial portion of the clavicle relative to the fracture. Ex. 1002, ¶133.



Ex. 1009, Fig. at 6.

(iii) *[1.2]*

Clavicula discloses a plate having one or more surfaces that define a substantially oblong first opening having a longitudinal dimension extending in a direction corresponding to the length of the plate and through which a suture can pass. For example, Clavicula discloses four oblong openings as shown in the figure below. Ex. 1002, IX.E.c.



Ex. 1009, 3.

The openings in the Clavicula device are designed to allow passage of a 3.5 mm fastener. Ex. 1009, 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, ¶¶135-136.

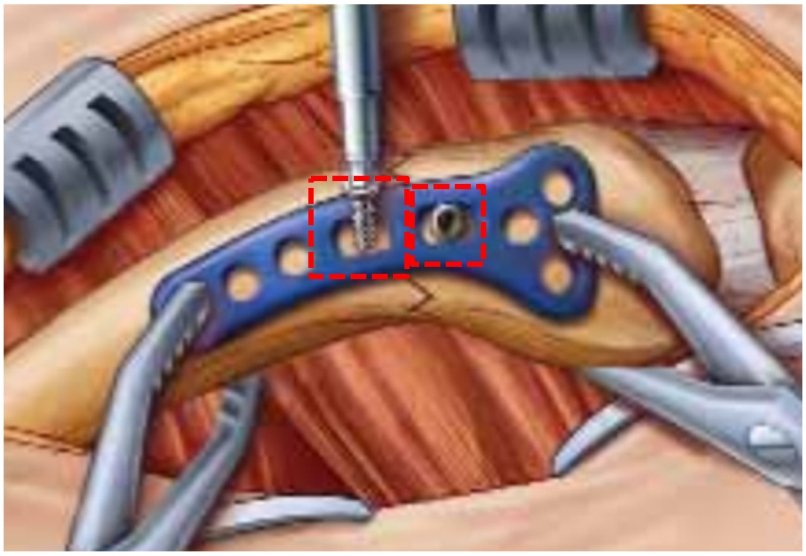
Thornes teaches a washer and anchor joined by a suture. Ex. 1007, Abstract, ¶[0011]. The washer (button 101) is positioned on the surface of the clavicle and the anchor (button 102) is advanced "through the hole in the clavicle and the coracoid until it exits the coracoid base" on the underside of the coracoid. *Id.*, ¶¶[0013]-[0014], [0033]. 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. A POSITA would have found it obvious to pass the Thornes suture through the oblong opening in the Clavicula plate to provide a simple, reproducible means

to take stress off of the lateral fixation and avoid inducing stress on the bone-plate interface or decreasing mechanical strength of the reduction, while allowing flexible positioning of the suture. Ex. 1002, ¶¶137-138.

(iv) *[1.3]*

Clavicula describes a plate with oblong openings extending in the direction of the length of the plate and fastener screws, having round heads, whose position can be adjusted along the direction of the opening. Ex. 1009, 5-6. The figure below demonstrates how the screw can be positioned in any location along the opening.

Fastener position can be adjusted along oblong opening



Round fastener head

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. As discussed in Section VI.A, above, a POSITA would understand a washer to be a thin ring or perforated plate.

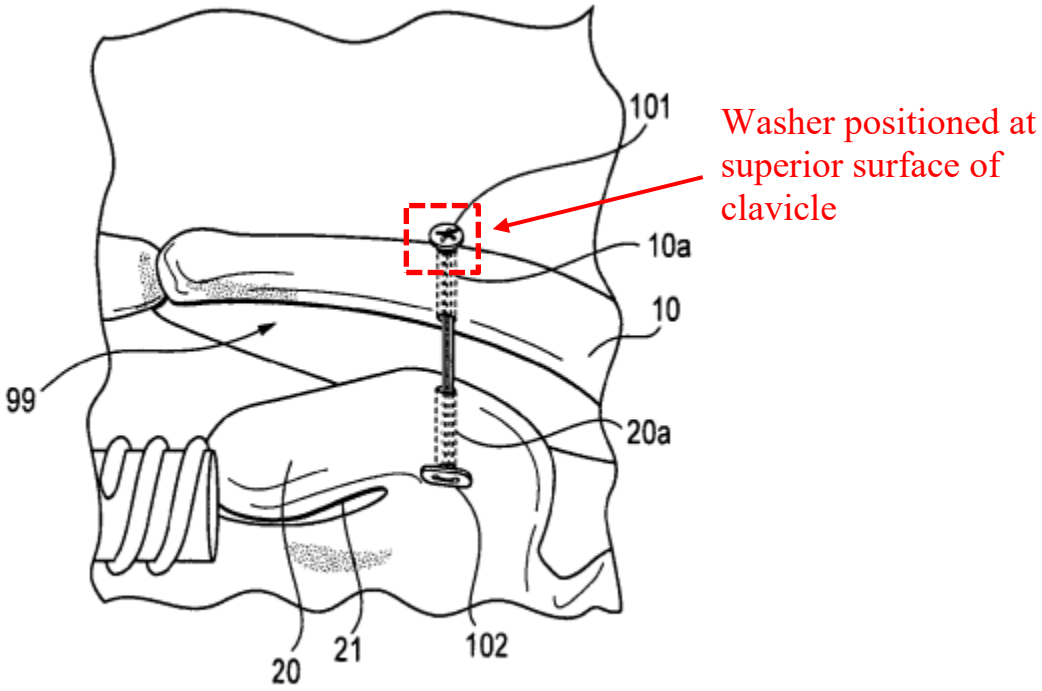
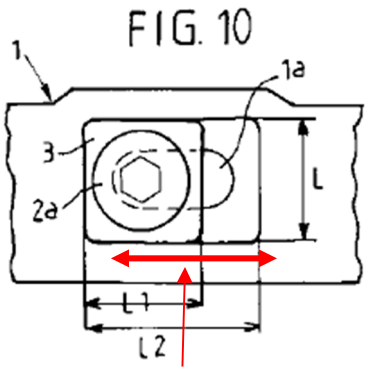


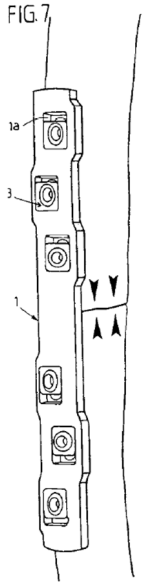
FIG. 7

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. 1009, 3, 6, 7; Ex. 1007, Abstract, ¶¶[0011], [0013]-[0014], [0033]; Ex. 1002, IX.E.c, ¶¶135-138.

While Clavicula does not explicitly disclose a washer slidable along an oblong opening in a plate, slidable washers were well-known in the art, and a POSITA would have configured the Thornes washer to be slidably adjustable in the Clavicula plate with only routine modification. Ex. 1002, ¶139. To the extent that a slidable washer would not have been obvious, Hardy discloses a plate with a plurality of oblong openings configured to receive screws in combination with slidable support washers. Ex. 1006, 3:2-5; 4:6-14; 4:20-24; 5:5-9. Figures 7 and 10, below, depict slidable washers 3, with a screw head 2a, in oblong plate openings.





Ex. 1006, Figs. 7, 10.

A POSITA would have found it obvious to combine the slidable washer of Hardy with the oblong openings in the Clavicula plate to permit more flexible positioning of the suture relative to the fracture. Ex. 1002, ¶140. A POSITA would further recognize that the Thornes washer-suture system could be substituted for the

Hardy slidable washer to allow flexible, accurate, and precise positioning of Thornes' "simple, reproducible, minimally invasive" means of taking stress off of the lateral fixation of the Clavicula plate. Ex. 1007, ¶¶[0014]-[0015]; Ex. 1009, 7; Ex. 1002, ¶141.

(v) *[1.4]*

Clavicula explicitly discloses a suture that interacts with the coracoid process and plate, but does not disclose a specific suture. Ex. 1009, 7. To the extent Clavicula does not disclose passing a suture through a hole in the clavicle and the coracoid process, Thornes discloses the same. Thornes teaches a washer and anchor joined by a suture. Ex. 1007, Abstract, ¶[0011]; Ex. 1002, IX.E.e. 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.

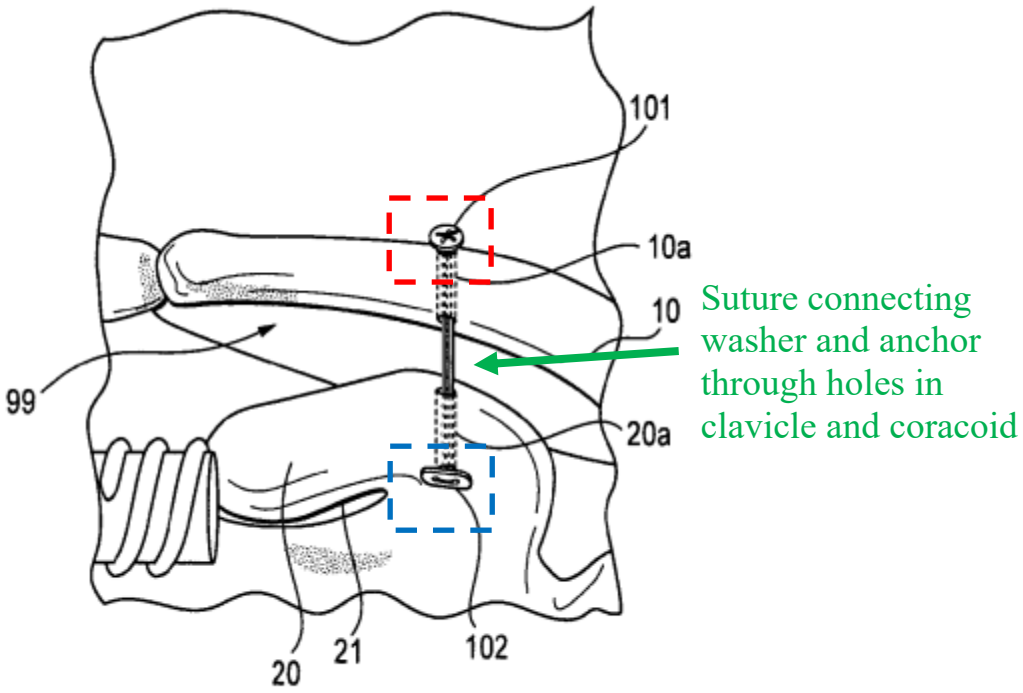


FIG. 7

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, ¶¶137-138. A POSITA would have further recognized the importance of optimal suture technique, which Clavicula does not describe. Ex. 1002, ¶142. 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, ¶142. 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. Ex. 1002, ¶143.

(b) Claim [2]

Clavicula explicitly discloses a suture that interacts with the coracoid process and plate to take stress off of the lateral fixation, but does not disclose a specific suture. Ex. 1009, 7. A POSITA would recognize that stress on the fracture site would be predominately an inferior displacement of the distal clavicle fracture or an AC joint or both. Ex. 1002, ¶144. A POSITA would recognize that this would have the effect of pulling the distal fragment away from the plate and screw construct. *Id.* A POSITA would further understand that, in order to take stress off of the lateral fixation, the suture described in Clavicula would require tensioning, which would reduce the distance between the coracoid and clavicle, bringing the medial and distal portions of the clavicle into substantial alignment. *Id.*

While Clavicula does not expressly disclose that tensioning the fixation system reduces the distance between the coracoid process and the clavicle, Thornes expressly teaches pulling on the suture extending from the washer (button 101) and tying "the suture over top of the fixation system 100…[to] complete[] the reduction and stabilization." Ex. 1007, ¶¶[0033]-[0034]. The tensioning of suture reduces the acromioclavicular joint which a POSITA would have understood reduces the

distance between the coracoid process and the clavicle, as shown in Figure 7 below. Ex. 1002, ¶144.

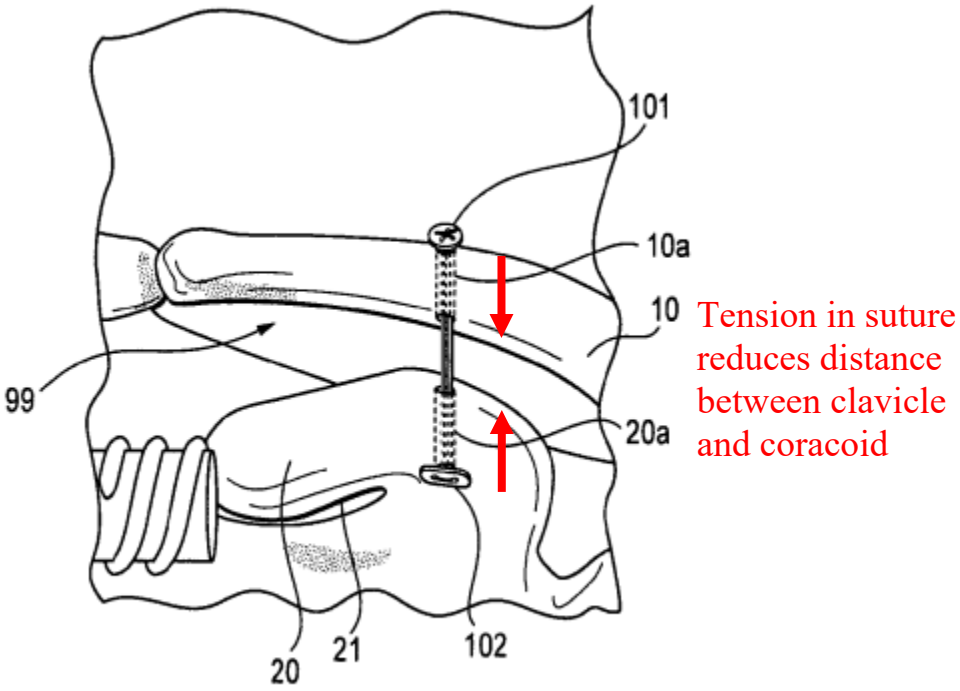


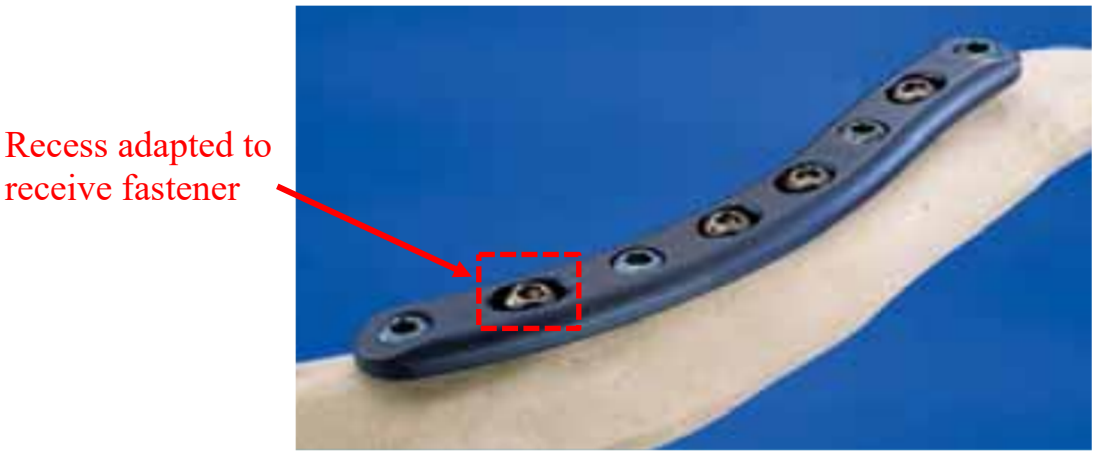
FIG. 7

A POSITA would understand that both Clavicula and Thornes disclose sutures that interact with the clavicle and coracoid process, and would require only minor, routine modification to combine, rendering this obvious. Ex. 1002, ¶145.

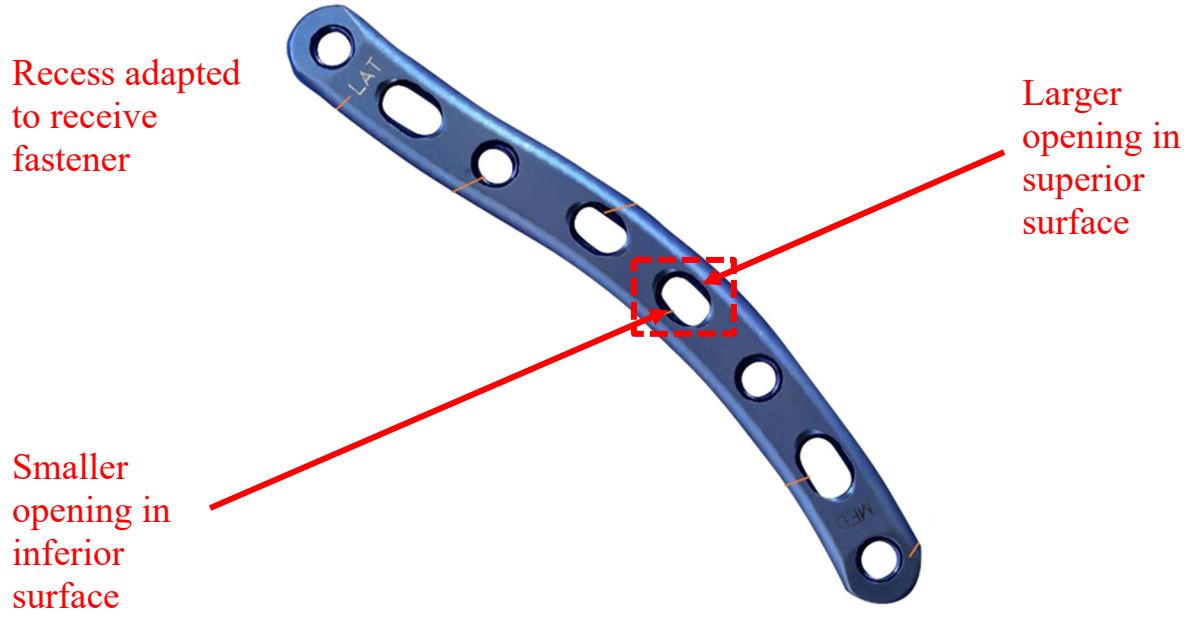
As discussed for limitation [1.2] above, a POSITA would have found it obvious to apply the Thornes washer-suture system to the Clavicula plate. Ex. 1009, 3, 6, 7; Ex. 1007, Abstract, ¶¶[0011], [0013]-[0014], [0033]; Ex. 1002, IX.E.c, ¶¶135-138.

(c) Claim [3]

Clavicula describes a plate with an opening opposite the superior surface of the clavicle adapted to receive a circular fastener head. Clavicula explains the plate provides "a low-profile screw-plate interface" that "minimizes soft-tissue irritation to the patient." Ex. 1009, 2. A POSITA reading Clavicula would have understood the recess in the plate would be capable of receiving washer with little to no modification, and would be motivated to use a recess to minimize irritation, rendering this limitation obvious. Ex. 1002, ¶146. As shown in the figures below, the plate forms a recess between the larger, upper opening and the smaller, lower opening. Ex. 1002, IX.E.g.



Ex. 1009, 3.



Ex. 1009, 3.

While Clavicula does not expressly disclose a recess adapted to receive a washer, Hardy discloses the same. Ex. 1006, 4:20-22 ("it therefore appears that the plate (1) is screwed onto the bone through the washers (3), with the ability to slide in the orifices (1a)."), 2:14-18, 3:3-5, 4:6-14. Thornes discloses a washer-suture system for use with the coracoid process that is generally the same geometry as the Hardy washer and the Clavicula fastener heads. Ex. 1007, ¶[0018]; Ex. 1002, ¶146. A POSITA would have understood that only minor, routine modification would be required to adapt the Thornes washer-suture system for use with recesses in the Clavicula plate in the manner demonstrated by Hardy. Ex. 1002, ¶147.

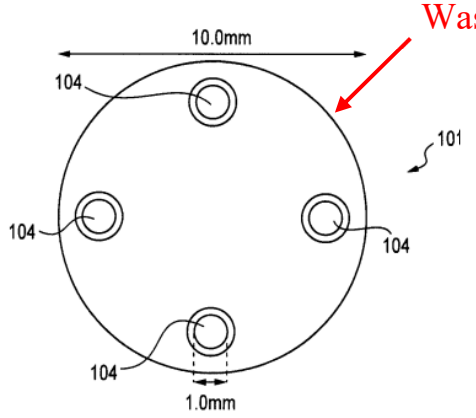


FIG. 10

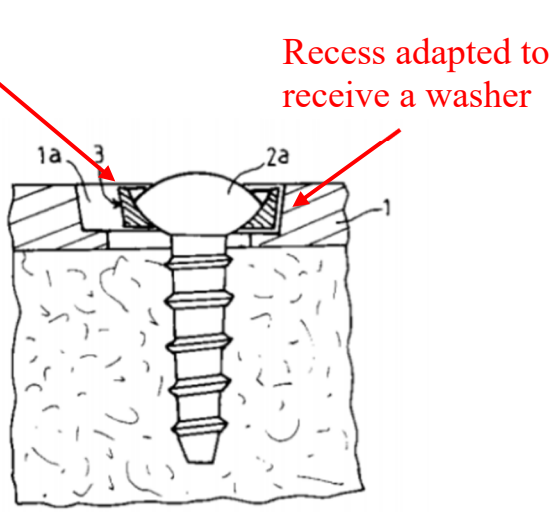
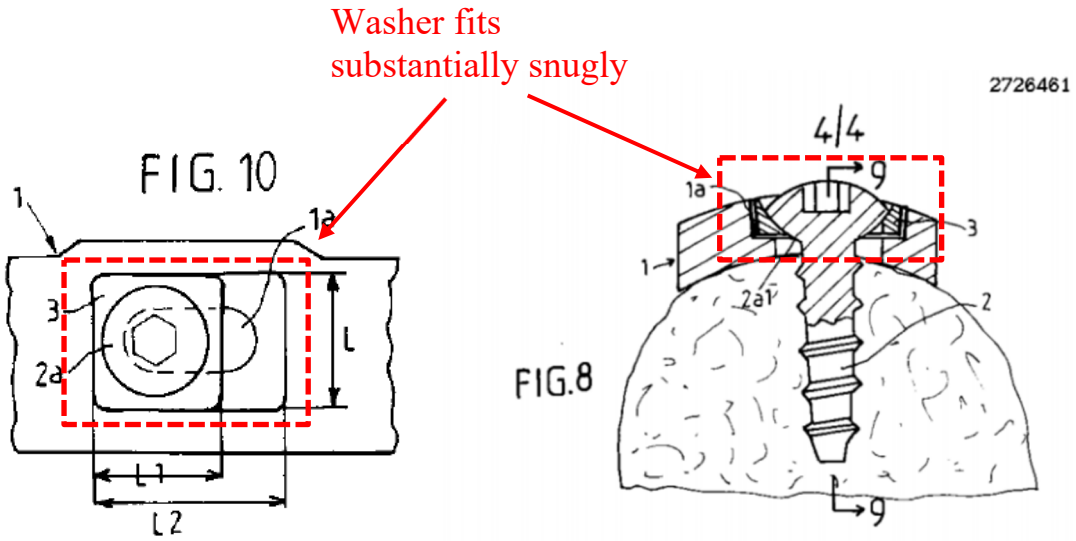


FIG.9

Ex. 1007, Fig. 10; Ex. 1006, Fig. 9.

(d) Claim [4]

Clavicula discloses a clavicle plate with a screw head that fits snugly in a recess, but does not disclose a washer. Ex. 1002, IX.E.h. Hardy discloses a washer that fits substantially snugly in the recess of a plate. Ex. 1006, 4:9-13 ("The orifices are generally rectangular in shape…the washers have a width (L) very substantially equal to that of the orifices"). A POSITA would have understood that a washer with a width substantially equal to that of the recess would fit snugly in that recess. Ex. 1002, ¶148. It would be routine to modify the dimensions of the Thornes washer to fit snugly in the recess of the Clavicula plate in the manner disclosed by Hardy, rendering this claim obvious. *Id.*



Ex. 1006, Figs. 8, 10. The snug fit between the washer and the recess would reduce lateral shifting of the suture and prevent irritating the bone and altering the tension in the suture. Ex. 1002, ¶149. A POSITA would recognize the importance of this snug fit as maximizing patient outcomes and minimizing risk of future intervention. *Id.*

(e) Claim [5]

Clavicula teaches the use of a round fastener head, but does not disclose a washer. Thornes, however, teaches the use of a washer with multiple holes dimensioned to receive a suture. Specifically, Thornes describes a washer (101) having "at least two flexible coupling-locating apertures." Ex. 1007, ¶[0021]. The apertures of the washer are dimensioned to receive a suture. *Id.*, ¶[0022] ("continuous loop 110 extends between at least one of the apertures of the first button 101 and at least one of the apertures of the second button 102…continuous loop 110

may be formed of suture."). As shown in Figure 10, the Thornes washer (101) includes four apertures at the outer edge dimensioned to receive a suture. *Id.*; Ex. 1002, IX.E.i.

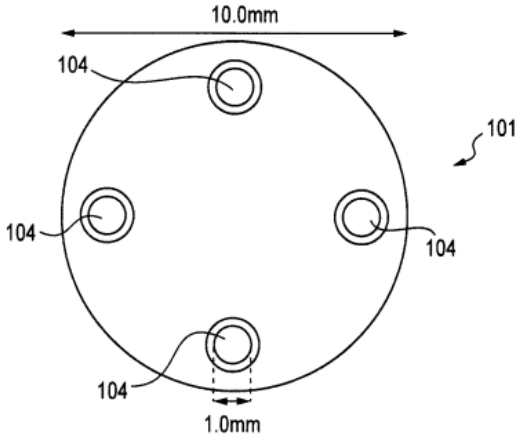


FIG. 10

Ex. 1007, Fig. 10. A POSITA would have found it obvious to use a washer with more than one hole because this would make the process of securing the suture to the washer via a knot easier, and would allow for more flexible positioning. Ex. 1002, ¶150.

(f) Claim [6]

Clavicula teaches stabilizing the fixation using suture with the coracoid process, but does not disclose a specific suture. Ex. 1009, 7. To the extent Clavicula does not disclose 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], Fig. 7; Ex. 1002, IX.E.j.

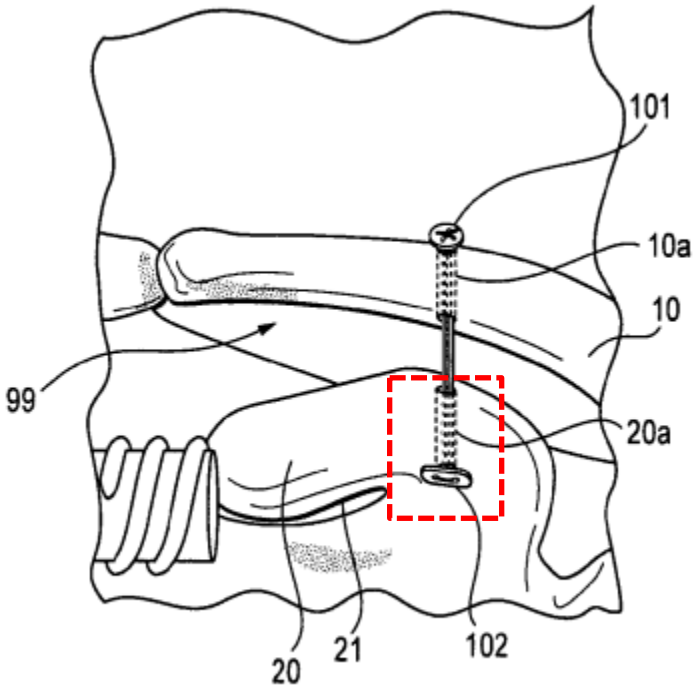


FIG. 7

A POSITA reading Clavicula would recognize the benefit of reducing stress on the fixation utilizing suture and the coracoid process, and would be motivated to combine Clavicula with Thornes, which provides a "simple" and "minimally invasive" means of stabilizing the clavicle utilizing an anchor. Ex. 1007, ¶[0015]; Ex. 1002, ¶151.

(g) Claim [7]

While Clavicula does not expressly teach an oblong anchor dimensioned to pass through a clavicle and coracoid, Thornes teaches advancing the oblong anchor (102) 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, ¶¶[0032]-[0033], Fig 7. A POSITA would have understood that an oblong shape would allow the anchor to more easily pass through the plate and bone holes, while still allowing for adequate securements on the distal end of the hole. Ex. 1002, IX.E.k.

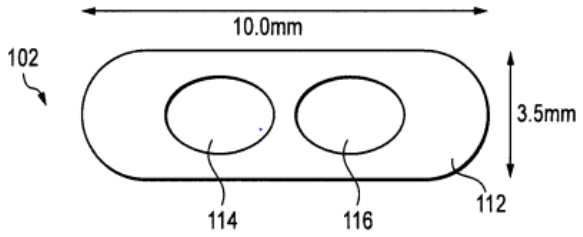


FIG. 9(a)

Ex. 1007, Fig. 9a.

(h) Claim [8]

Clavicula expressly discloses a clavicle plate and suture configured to pass around the coracoid process. Ex. 1009, 7 ("Sutures may be passed from medial to lateral around the coracoid process and the plate to take stress off of the lateral fixation.").

To the extent that Clavicula does not disclose a suture passing through the plate and around the coracoid process, this limitation is obvious in view of Thornes. Ex. 1002, IX.E.l; *see* limitation [1.4] in this ground. A POSITA would recognize that the Clavicula wraparound suture could be combined with the suture passing through a hole in the clavicle, thus resulting in a suture that passes through the clavicle and around the coracoid process. Ex. 1002, ¶152. A POSITA would have a reasonable expectation of success because the features are performing essentially the same function in combination as they do separately, the same way, and with predictable results. *Id.* A POSITA would have further recognized the advantages of this arrangement, such as minimizing the risk of slippage and preventing soft-tissue disruption as compared to passing the suture around the bone/plate. *Id.*, ¶153.

(i) Claim [9]

Thornes teaches an oblong washer with a plurality of holes distributed longitudinally. 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]; Ex. 1002, IX.E.m.

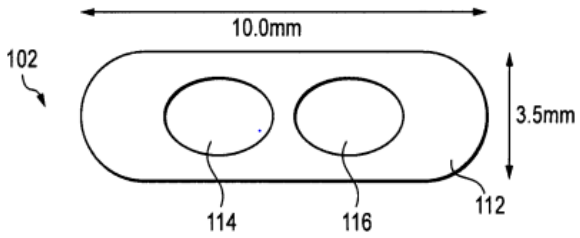


FIG. 9(a)

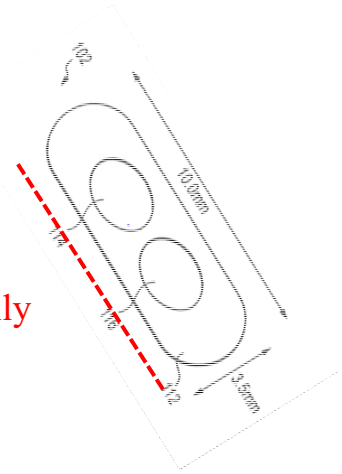
Ex. 1007, Fig. 9a.

(j) Claim [10]

If the Thornes oblong washer was used with the Clavicula plate, the sides of the washer would be substantially parallel to the first opening in the plate, as shown in the figures below. Ex. 1002, IX.E.n.

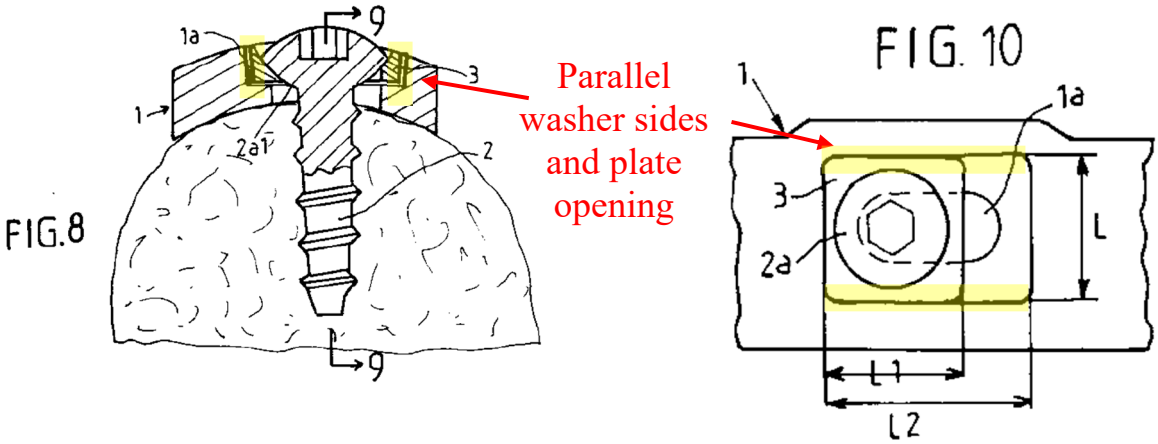
Ex. 1009, 3.

Substantially parallel



Ex. 1007, Fig. 9a.

Additionally, 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, 4:9-22; Ex. 1002, IX.E.n.

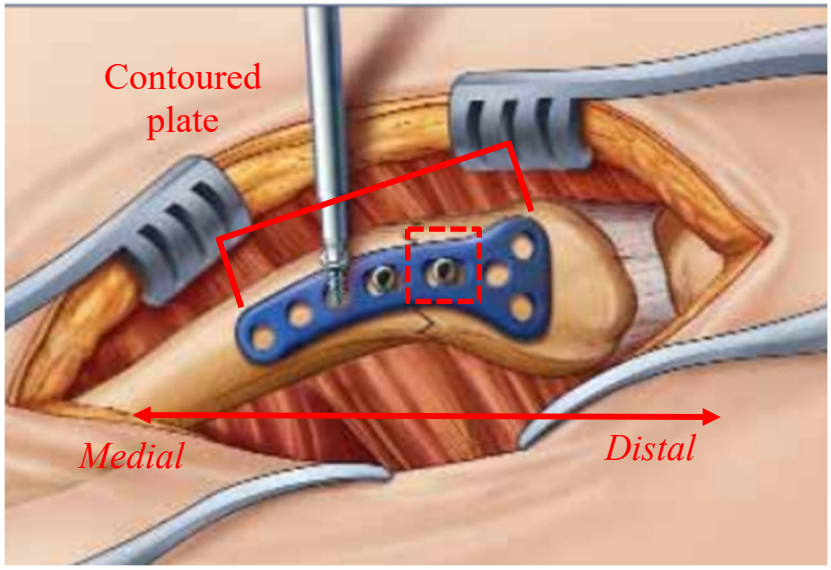


Ex. 1006, Figs. 8, 10. A POSITA would have recognized the benefits of using a washer with sides parallel to the opening in the plate—such as reduced motion of the suture which would result in less secure stabilization of the acromioclavicular joint—and would therefore have found it obvious to implement. Ex. 1002, ¶154.

(k) Claim [11]

Clavicula discloses a "precontoured plate" for fixing a fractured clavicle which matches "the anatomy of the patient" and fits the "clavicle curvature." Ex. 1009, 3; Ex. 1002, IX.E.o. Clavicula instructs the surgeon to place fastener screws on "each side of the fracture." Ex. 1009, 6. A POSITA would have understood that the plate was contoured to be secured to the distal portion of the clavicle. Ex. 1002,

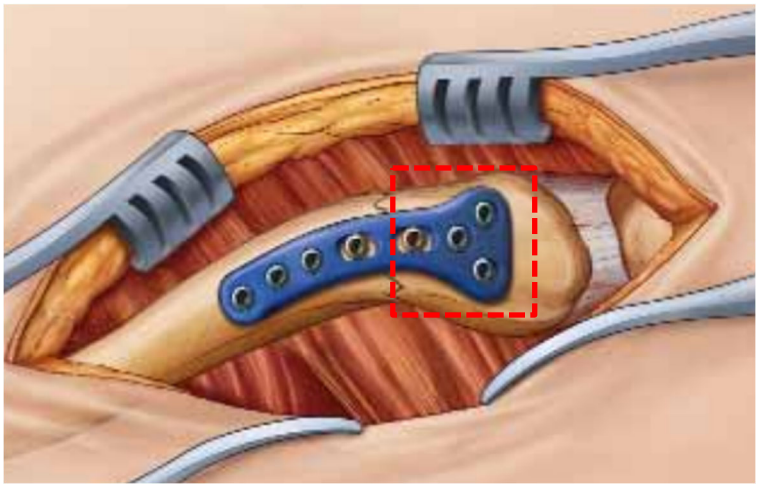
IX.E.o. The figure (below) shows the contoured plate secured to the distal portion of the clavicle.



Ex. 1009, 6.

(l) Claim [12]

The Clavicula kit offers "two specialized 'J' plates" for use in fixing distal/lateral fractures, rendering this claim obvious. Ex. 1009, 3. The figure (below) shows the flared distal end of the "J" plate. Ex. 1002, IX.E.p.



Ex. 1009, 7.

(m) Claim [13]

Clavicula expressly instructs the surgeon to "place the 3.5mm locking screws [] into the threaded holes" on either side of the fracture, rendering this claim obvious. Ex. 1009, 5-6; Ex. 1002, IX.E.q.

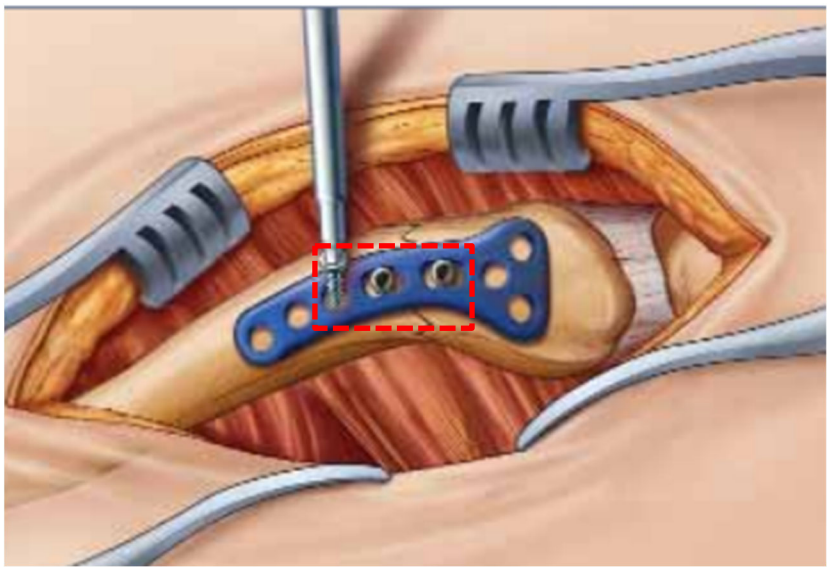
(n) Claim 14

(i) *[14.p]-[14.2]*

See [1.p]-[1.2] in this Ground. Ex. 1009, 2-3, 5-6, 7; Ex. 1007, Abstract, ¶[0011], [0013]-[0014], [0033]; Ex. 1002, IX.E.a-c, ¶¶133-138, 155-157.

(ii) *[14.3], [14.4]*

Clavicula discloses a plate having multiple openings through which fastening devices are used to secure the plate to the medial portion of the clavicle.



Ex. 1009, 6; Ex. 1002, IX.E.u.

(iii) *[14.5]-[14.6]*

See [1.3]-[1.4] in this Ground. Ex. 1009, 5-6, 7; Ex. 1007, Abstract, ¶¶[0011], [0013]-[0015], [0018], [0033], Figs. 7, 9-10; Ex. 1006, 3:2-5; 4:6-14; 4:20-23; 5:5-8, Figs. 7, 10; Ex. 1002, IX.E.c-e, ¶¶135-143, 158-159.

(o) Claim 15

See claim 7 in this Ground. Ex. 1007, ¶¶[0032]-[0033], Figs. 7, 9a; Ex. 1002, IX.E.k, ¶160.

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 Equipmentshare.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.

IX. CONCLUSION

For the reasons stated above, Petitioners submit that claims 1-15 of the '674 Patent are unpatentable.

Respectfully submitted by

/Megan S. Woodworth/
Reg. No. 53,655
VENABLE LLP
600 Massachusetts Ave., NW
Washington, DC 20001
T 202-344-4507
F 202-344-8300

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing petition for *inter partes* review, together with all exhibits and other documents filed therewith, was served by Federal Express on October 5, 2022, on the Patent Owner's counsel of record at the U.S. Patent and Trademark Office having the following address:

CERMAK, NAKAJIMA & MCGOWAN LLP
2000 Duke Street, Suite 300
Alexandria, VA 22314

With an electronic courtesy copy to litigation counsel:

STAMOULIS & WEINBLATT LLC
Stamatios Stamoulis
stamoulis@swdelaw.com
Richard C. Weinblatt
weinblatt@swdelaw.com

DAIGNAULT IYER LLP
Ronald M. Daignault
rdaignault@daignaultiyer.com
Chandran B. Iyer
cbiyer@daignaultiyer.com
Richard Juang
rjuang@daignaultiyer.com
Tedd Van Buskirk
tvanbuskirk@daignaultiyer.com

Date: October 5, 2022

/Megan S. Woodworth/
Reg. No. 53,655
VENABLE LLP
600 Massachusetts Ave., NW
Washington, DC 20001
T 202-344-4507
F 202-344-8300

CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing petition for *inter partes* review contains 13,960 words according to the word processing program used to prepare it.

Date: October 5, 2022

/Megan S. Woodworth/
Reg. No. 53,655
VENABLE LLP
600 Massachusetts Ave., NW
Washington, DC 20001
T 202-344-4507
F 202-344-8300