

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TREACE MEDICAL CONCEPTS, INC.,
Petitioner,

v.

PARAGON 28, INC.
Patent Owner.

IPR2027-00007
Patent 11,304,693

PETITION FOR *INTER PARTES* REVIEW

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Claim 1	
[1][pre]	A method of compressing biological elements, comprising:
[1][a]	forming a first pair of apertures within a pair of biological elements, wherein the forming the first pair of apertures comprises forming the first pair of apertures within the pair of biological elements via a pair of openings in a drill guide portion of a guide;
[1][b][i]	elastically deforming a substantially horseshoe shaped bridge portion of a staple from a first state to a second state to increase a separation distance between a pair of tines of the staple from a first distance in the first state to a second distance in the second state,
[1][b][ii]	wherein the pair of openings in the drill guide portion of the guide are spaced the second distance;
[1][c]	the bridge portion connecting the pair of tines and comprising a curved portion and opposite leg portions, the curved portion having an arched inner surface and an arched outer surface, the inner surface and the leg portions bounding an open space;
[1][d]	the pair of tines extending from the bridge portion and including free ends configured to be implanted into the biological elements;
[1][e]	each tine of the tines extending along a first direction defined between the bridge portion and a free end of the free ends thereof;
[1][f]	maintaining the second state of the bridge portion;
[1][g]	implanting the pair of tines of the staple into the pair of apertures formed in the pair of biological elements to allow engagement of a plurality of engagement mechanisms of the pair of tines with the biological elements, the plurality of engagement mechanisms positioned on portions of the tines that substantially face the other tine of the pair of tines along the first direction;
[1][h]	releasing the potential energy of the elastic deformation of the second state of the bridge portion to apply a compressive force to the pair of biological elements via the tines and to engage the plurality of engagement mechanisms with the biological elements.

Claim 2	
2	The method of claim 1 wherein the applying the compressive force to the pair of biological elements via the tines comprises the compressive force closing a space between the biological elements.

Claim 3	
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3	The method of claim 1, wherein maintaining the second state of the bridge portion comprises engaging the staple with a staple engagement portion of a guide.
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Claim 4	
4	The method of claim 3, wherein releasing the energy of the elastic deformation of the second state of the bridge portion comprises disengaging the staple from the staple engagement portion of the guide.

Claim 5	
5	The method of claim 1, wherein the bridge and the pair of tines comprise substantially rectangular cross-sections.

Claim 6	
6	The method of claim 1 wherein the leg portions comprise linear portions extending opposite the open space relative to each other.

Claim 7	
7	The method of claim 1 wherein the curved portion is angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines.

Claim 8	
8	The method of claim 1, wherein the pair of tines extend from opposing ends of the bridge portion, the ends having inner surfaces opposite each other about the open space.

Claim 9	
[9][pre]	A method of compressing biological elements, comprising:
[9][a]	forming a first pair of apertures within a pair of biological elements;
[9][b][i]	elastically deforming a substantially horseshoe shaped bridge portion of a staple
[9][b][ii]	from a first state to a second state to increase a separation distance between a pair of tines of the staple from a first distance in the first state to a second distance in the second state;
[9][c]	the bridge portion connecting the pair of tines and comprising a

	curved portion and opposite leg portions, the curved portion having an arched inner surface and an arched outer surface, the inner surface and the leg portions bounding an open space;
[9][d]	the pair of tines extending from the bridge portion and including free ends configured to be implanted into the biological elements;
[9][e]	each tine of the tines extending along a first direction defined between the bridge portion and a free end of the free ends thereof;
[9][f]	the curved portion being angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines;
[9][g]	maintaining the second state of the bridge portion;
[9][h]	implanting the pair of tines of the staple into the pair of apertures formed in the pair of biological elements to allow engagement of a plurality of engagement mechanisms of the pair of tines with the biological elements, the plurality of engagement mechanisms positioned on portions of the tines that substantially face the other tine of the pair of tines along the first direction;
[9][i]	releasing the potential energy of the elastic deformation of the second state of the bridge portion to apply a compressive force to the pair of biological elements via the tines and to engage the plurality of engagement mechanisms with the biological elements.

PETITIONER’S LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,304,693 to Weiner, <i>et al.</i> (the “’693 Patent”)
1002	Declaration of Daniel C. Farber, M.D. (“Farber Declaration”)
1003	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.
1004	U.S. Patent Application Publication No. US 2014/0018809 A1, dated January 16, 2014 (“Allen”)
1005	Prosecution History of U.S. Patent Application No. 16/539,473 (Patent No. 11,304,693)
1006	<i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and MIOS Marketing, LLC d/b/a RedPoint Medical3D</i> , Amended Complaint, dated December 18, 2025
1007	U.S. Patent Application Publication No. US 2010/0125301 A1, dated May 20, 2010 (“Kinmon”)
1008	U.S. Patent Application Publication No. US 2014/0277516 A1, dated September 18, 2014 (“Miller”)
1009	European Patent Application Publication No. EP 0743045 A2, dated November 20, 1996 (“EP ’045”)
1010	U.S. Patent No. 4,838,254 to Gauthier (“Gauthier”)

I. INTRODUCTION

Treace Medical Concepts, Inc. (“Petitioner”) requests *inter partes* review of U.S. Patent No. 11,304,693 (Ex.1001, the “693 Patent”) and cancellation of claims 1–9. This Petition presents new art and arguments that were not previously considered by the Office.

A. The ’693 Patent

The ’693 patent is directed to methods of using a compressive orthopedic staple with an associated drill guide. The patent describes a known staple arrangement: a bridge portion connecting a pair of tines, with the bridge elastically deformable from a first state to a second state in which the tines are spaced farther apart and pre-loaded to apply compression after implantation.

The claims likewise recite method steps for forming apertures, elastically deforming the bridge to increase tine separation, maintaining the deformed state, implanting the tines, and releasing stored elastic energy to apply compression.

The prosecution history confirms that the purported point of novelty was narrow. During examination, the Office rejected then-pending claims as anticipated by U.S. Patent App. Pub. No. US2014/0018809A1 (Ex.1004, “Allen”), but indicated dependent claims allowable that recited the drill-guide spacing limitation recited in issued claim 1 and the downward angled curved bridge portion limitation recited in issued claims 7 and 9. Ex.1005, 6, 24–26. The Examiner found that Allen disclosed

all other features recited in the now-issued claims. *See id.* at 24–26.

Petitioner is not asserting a ground based on Allen. As explained below, Kinmon, Miller, EP '045, and Gauthier disclose all elements of the challenged claims and provide complete, more directly applicable grounds for unpatentability without reliance on Allen.

B. Evidence and Asserted Grounds

Claims 1–9 are unpatentable on the following grounds:

Ground	Reference(s)	Claims	Basis
1	Kinmon ¹ , Miller ²	1–9	§103
2	Kinmon, Miller, EP '045 ³ , Gauthier ⁴	1–9	§103

Petitioner submits the Declaration of Daniel C. Farber, M.D. Ex.1002 (“Farber Declaration”).

II. LEVEL OF ORDINARY SKILL IN THE ART

The '693 Patent claims recite methods of compressing biological elements using staples. *See* Ex.1001, 21:35–22:65. The '693 Patent states that its “disclosure generally relates to staples or retainers, and particularly relates to staples or retainers and staple or retainer delivery and drill guides.” *Id.* at 1:24–26. The '693 Patent

¹ US 2010/0125301 A1 (Ex. 1007, “Kinmon”).

² US 2014/0277516 A1 (Ex. 1008, “Miller”).

³ EP 0743045 A2 (Ex. 1009, “EP '045”).

⁴ US 4,838,254 (Ex. 1010, “Gauthier”).

explains that “staples are commonly used to close openings, incisions, or wounds.” *Id.* at 1:28–29. The disclosure discusses staples used in medical procedures, but is not limited to any particular field or portion of the anatomy. Ex.1002 ¶16.

Accordingly, a person of ordinary skill in the art (“POSA”) would have included (i) a physician with a medical degree and at least 3 years of experience performing surgery using staples to compress bone portions, (ii) an engineer with a bachelor’s degree in mechanical or biomedical engineering and at least 3 years of experience designing surgical fixation staples to compress bone portions and related installation mechanisms, or (iii) a collaborative team combining such clinical and engineering expertise. Ex.1002 ¶17. Nevertheless, the proposed definition of a POSA provided by Petitioner should not affect the outcome.

III. CLAIM CONSTRUCTION

In an *inter partes* review, a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citation omitted). Only those terms in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Realtime Data LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019). Petitioner does not believe there is a need to

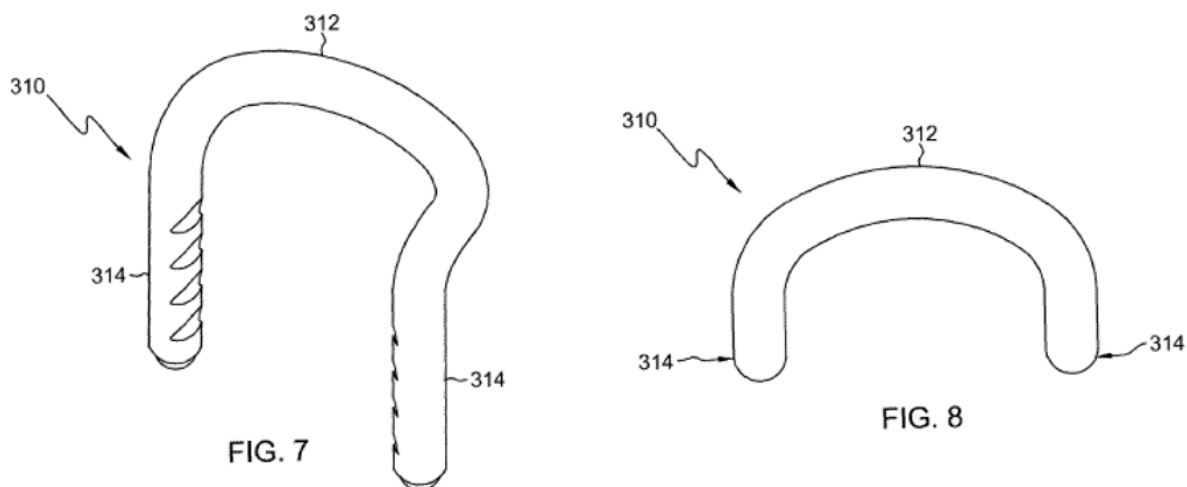
expressly construe any particular term. The discussion below provides examples of structure that meets various limitations.

A. “substantially horseshoe shaped bridge portion”

Claims 1 and 9 each recite “a substantially horseshoe shaped bridge portion of a staple.”

The '693 Patent provides examples of offset bridges having the recited “horseshoe shape.” Petitioner does not propose a single, rigid construction of this term. Rather, the plain and ordinary meaning of “substantially horseshoe shaped” at least includes the structures shown in the following examples from the '693 Patent's own specification.

Figures 7 and 8 of the '693 Patent, reproduced below, provide one example of a substantially horseshoe shape with a perspective view (FIG. 7) and a top view (FIG. 8):



Referring to Figures 7 and 8, the '693 Patent explains that “offset bridge 312 of a staple 310 according to the present discourse (sic) may form a truncated pentagon-like or horseshoe-like shape (*e.g.*, when viewed along the direction of the tines 314, as shown in the top view of FIG. 8). For example, the offset bridge 312 may form half or a portion of a pentagon or ‘C’ shape.” Ex.1001, 9:19–25.

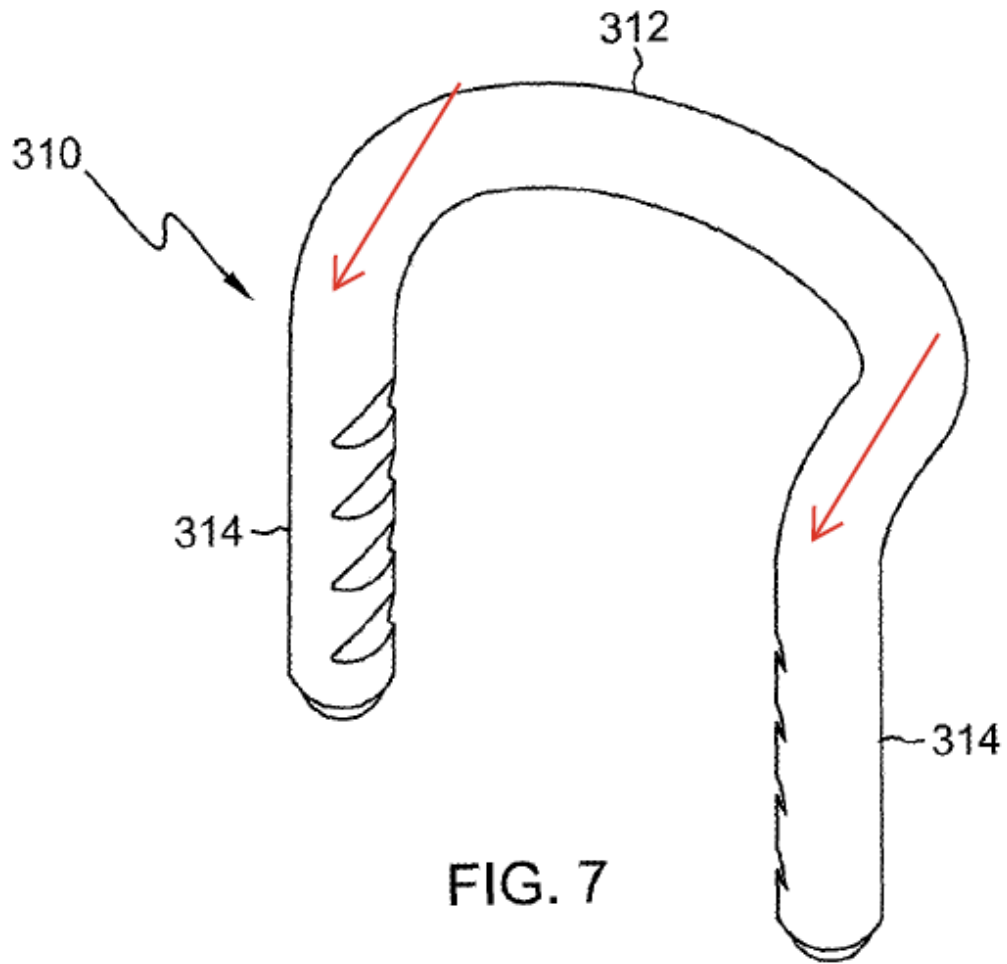
Accordingly, at least the arrangement shown and described relative to Figures 7 and 8 corresponds to a substantially horseshoe shape as recited in claims 1 and 9. Dr. Farber confirms this understanding. Ex.1002 ¶18.

That is, according to the '693 Patent, a C-shaped or similar (*e.g.*, U-shaped) structure is considered an example of “substantially horseshoe shaped.”

B. “angled downwardly toward the free end”

Claims 7 and 9 further specify that “the curved portion [of the horseshoe-shaped bridge] is angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines.”

In the arrangement shown above in Figure 7, the '693 Patent provides an example where the offset bridge 312 is angled downward toward free ends of the tines 314 as it extends toward the top or upper portions of the tines 314 opposing the free ends of the tines 314 and downward toward the free ends of the tines 314, as indicated by the arrows in annotated Figure 7 below.



Another example is shown in Figures 19 and 20, reproduced below with annotations (arrow indicating downward extent).

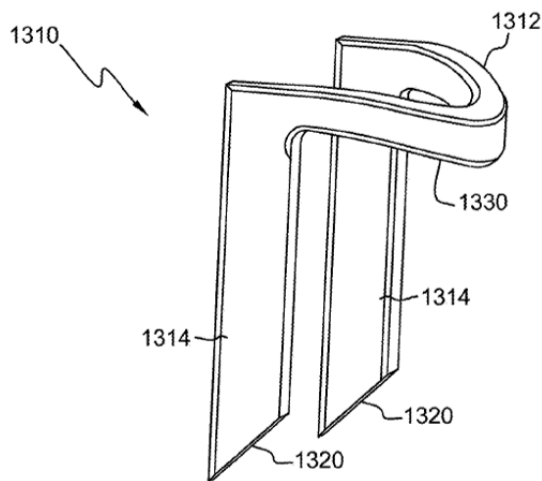


FIG. 19

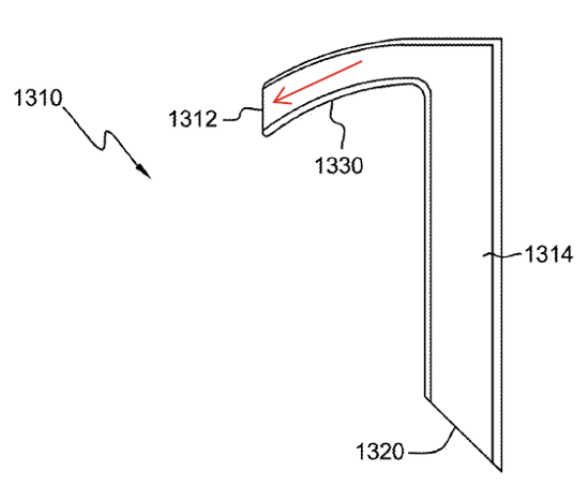


FIG. 20

“[A]s shown in FIGS. 19 and 20, the offset bridge 1312 may be curved or angled downward toward free ends 1320 of the tines 1314 as it extends between the tines and away from the top or upper portions of the tines 1314 opposing the free ends 1320 of the tines 1314.” Ex.1001, 10:52–57.

Accordingly, at least the arrangements shown and described relative to Figures 7, 8, 19, and 20 provide configurations where “the curved portion [of the horseshoe-shaped bridge] is angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines.” Dr. Farber confirms this understanding. Ex.1002 ¶19.

That is, according to the '693 Patent, a bridge extending downward toward free ends of tines and either away from (Figures 19 and 20) or toward (Figures 7 and

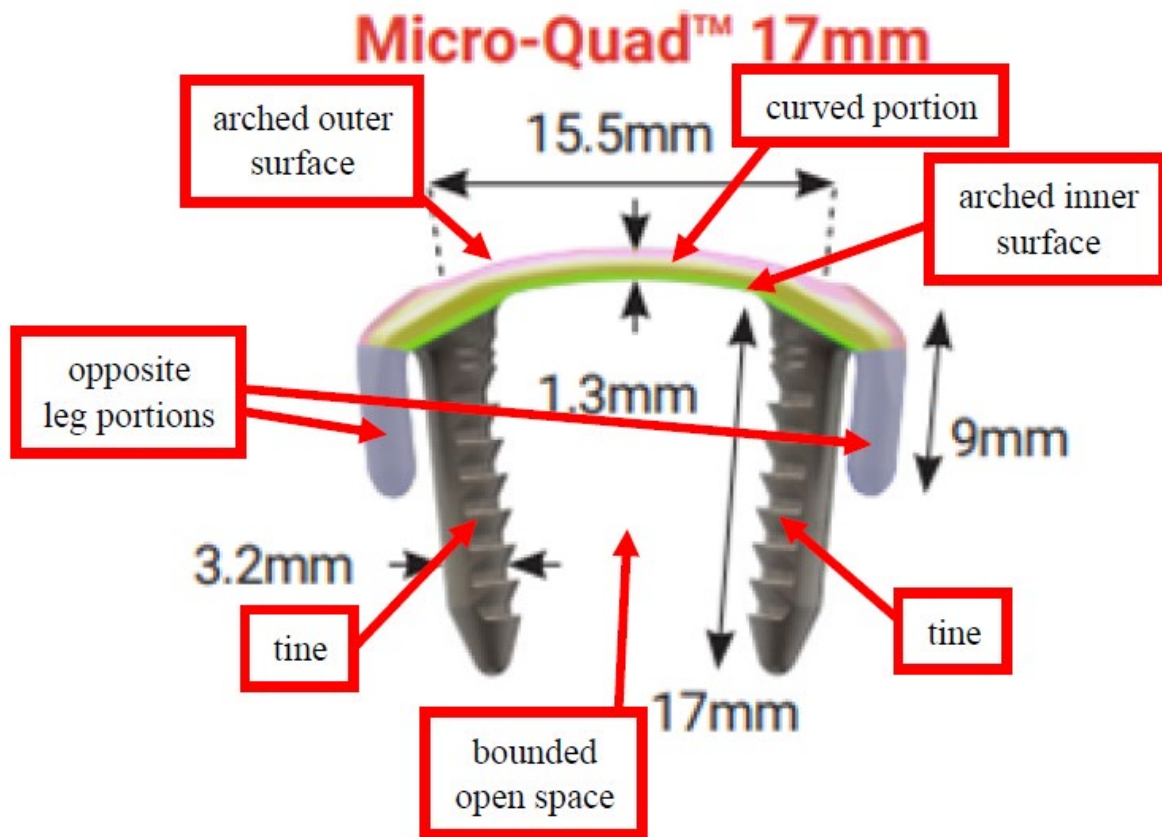
8) ends of the tines opposite the free ends is considered “angled downwardly toward the free end” of the tines.

C. “bounding an open space”

Claims 1 and 9 each recite “the inner surface [of the curved portion of the bridge portion] and the leg portions [of the bridge portion] bounding an open space.”

Neither “bounding an open space” nor “open space” appears in the ’693 Patent outside the claims. The plain language of the claim requires that some open space exists between the inner surface of the curved portion of the bridge portion and the leg portions of the bridge portion. The space is not fully enclosed.

Patent Owner is foreclosed from arguing otherwise given that its infringement contentions are consistent with this understanding of the bounded open space. *See* Ex.1006, 50. The image below is from Patent Owner’s infringement contentions in the related district court proceeding (annotations provided by Patent Owner).



As seen above, any alleged “bounded open space” is simply a space located between the purported curved portion of the bridge portion and the purported legs of the bridge portion (*i.e.*, defined by the curved portion and legs of the staple’s bridge portion).

Consistent with the plain and ordinary meaning of the claim language, and Patent Owner’s infringement contentions, “bounding an open space” corresponds to surrounding only a portion of the open space. Dr. Farber confirms this understanding. Ex.1002 ¶20.

IV. ASSERTED REFERENCES

A. Kinmon

Kinmon qualifies as prior art under at least 35 U.S.C. § 102(a)(1). Kinmon was not cited during prosecution of the '693 Patent. Kinmon relates to compression staples and their use. Kinmon explains that “[s]urgical devices used to stabilize bones during orthopedic surgical procedures, such as compression staples, are well known in the art. To correct and heal bone fractures properly, staples are often used to keep bone fragments in position by holding and compressing the bone fragments together without motion.” Ex.1007 ¶3. Kinmon characterizes drill guide use not as a novel feature but as standard practice: “a typical technique initially requires drilling holes for a staple using a drill guide.” *Id.* ¶6; Ex.1002 ¶21.

Kinmon explains that its memory-metal staple may be “memorized” in a compressed state, that an insertion tool separates/pushes the legs 3 outward before insertion, and that the staple is then inserted and allowed to return toward its compressed position. Ex.1007 ¶82. Kinmon also teaches that the guide device 12 has adjustable apertures 17 set to a desired width to guide drill 13 to drill holes for staple insertion. *Id.* ¶¶87–88. The staple is inserted into the drilled holes while its legs are pushed outward. *Id.* ¶¶92–93. Thus, the guide device hole spacing corresponds to the staple’s outwardly displaced insertion state because the outwardly held legs must align with and enter the holes drilled at the spacing. Ex.1002 ¶22.

B. Miller

Miller qualifies as prior art under at least 35 U.S.C. § 102(a)(2). Miller was not cited during prosecution of the '693 Patent. Miller is directed to bone staple storage, an inserter, and a method for use therewith, and teaches a fusion implant system for a generally horseshoe-shaped bone staple together with the complete surgical method for its implantation. Miller teaches a super-elastic and shape memory bone staple having a central web member connecting two barbed legs. Ex.1008 ¶21. Miller additionally teaches an inserter to force the staple legs outward to increase the separation distance between the legs. *Id.* ¶¶21, 34. Miller teaches operational steps similar to those in the '693 Patent. *See id.* ¶¶31–37; Ex.1002 ¶23.

C. EP '045

EP '045 qualifies as prior art under at least 35 U.S.C. § 102(a)(1). EP '045 was not cited during prosecution of the '693 Patent. EP '045 is directed to staples for osteosynthesis made from shape-memory alloy material. EP '045 describes multiple device versions for bone compression, all sharing the operative principle of elastic deformation, insertion of legs into pre-prepared bone holes, and release of stored elastic energy to generate a compressive force between bone fragments.

EP '045 describes its bridge as having arched components with arc lengths exceeding 180 degrees (Ex.1009, 3:9–10) (*i.e.*, ends of the arced components converging toward one another) and further describes its bridge conforming to bone

surfaces (*id.* at 3:50–56). Ex.1002 ¶24.

D. Gauthier

Gauthier qualifies as prior art under at least 35 U.S.C. § 102(a)(1). Gauthier is cited on the face of the '693 Patent but was not applied during prosecution. Gauthier is directed to a surgical staple. Gauthier explains that its “clip 2 is of the type comprising two lateral rods 3 and 4, approximately parallel, connected together by a bridge[-]forming central part 5” and “the central part forming bridge 5 is curved and, further, it is placed so that plane 6, containing its median axis 7, forms with plane 8, containing median axes 9 of the two rods, a large angle A.” Ex.1010, 3:6–13.

Gauthier describes “making . . . drilled holes to receive [lateral rods 3, 4] in the parts of the bone in whose holding they are to participate.” Ex.1010, 3:19–21. Gauthier describes, for example, “bridge-forming part 5 of each clip 2 being brought to cortical rest in the epiphysial bone.” *Id.* at 3:64–65; *see also id.* 4:6–10 (describing the curved portion of bridge 5 resting on the big toe). Ex.1002 ¶25.

E. Analogous Art

Kinmon, Miller, EP '045, and Gauthier are analogous art to the challenged claims of the '693 Patent. Ex.1002 ¶¶21–29. The '693 Patent is directed to “Staples and Staple Delivery and Drill Guides” and describes staples and corresponding guides for applying compressive force between biological elements. The '693 Patent

describes staples having a bridge portion and tines configured for implantation into biological elements, and guides that maintain a biased staple state and/or facilitate formation of apertures spaced for staple insertion. Ex.1001, Abstract.

Kinmon is in the same field because it teaches surgical compression staples, drill guides, guide apertures, insertion tools, and methods of inserting memory-metal staples into drilled holes while the staple legs are held outward. Ex.1007 ¶¶ 3, 6, 82, 87–93; Ex.1002 ¶27. Miller is in the same field because it teaches a compression staple, an inserter, and a method for implanting a compression staple using a drill guide, inserter, locking mechanism, and releasable self-compressive staple. Ex.1008 ¶¶6, 21, 31–37; Ex.1002 ¶27. Gauthier is in the same field because it teaches a compression staple with lateral rods connected by a curved bridge-forming central part that applies elastic contact pressure to bone surfaces. Ex.1010, 3:6–21, 4:36–47; Ex.1002 ¶27. EP '045 is in the same field because it is titled “Devices for osteosynthesis” and states that its invention relates to osteosynthesis devices used in traumatology, orthopedics, and skeletal-bone applications, including fractures and surgical operations on long tubular bones. Ex.1009, 1:3–8; Ex.1002 ¶27.

The references are also reasonably pertinent to the same problem addressed by the '693 Patent: delivering/securing a staple providing compressive force between biological elements. Ex.1002 ¶28. The claims broadly recite use of staples with deformable substantially horseshoe shaped bridge portions to compress

biological elements. *See Nielsen Co. US, LLC v. Tvision Insights, Inc.*, 186 F.4th 1363 (Fed. Cir. 2026) (the question is whether the prior art is reasonably pertinent to one or more of the problems to which the challenged patent relates and is affected by claim breadth).

Kinmon addresses delivery problems by using drill guides and insertion tools to accurately place compression staples in bone while maintaining an outwardly displaced delivery state. Ex.1007 ¶¶6, 82, 87–93. Miller addresses that problem through its surgical technique including staple delivery. Ex.1008 ¶¶29–37. Gauthier addresses bridge shape and orientation selection for elastic bone fixation, cortical rest, and contact pressure. Ex.1010, 3:6–16, 4:8–12, 4:36–47. EP '045 is reasonably pertinent because it addresses form-memory osteosynthesis devices for bone-fragment fixation and compression, including devices with locking components formed as plunge legs and working parts formed from arched components. Ex.1009, 1:24–31, 1:54–58; Ex.1002 ¶28.

Thus, each reference is both in the same field of endeavor and reasonably pertinent to the problem of delivering a compression staple into bone openings while preserving stored elastic energy for post-insertion compression. Ex.1002 ¶¶21–29.

V. CHALLENGES

A. Obviousness of Claims 1–9 over Kinmon and Miller

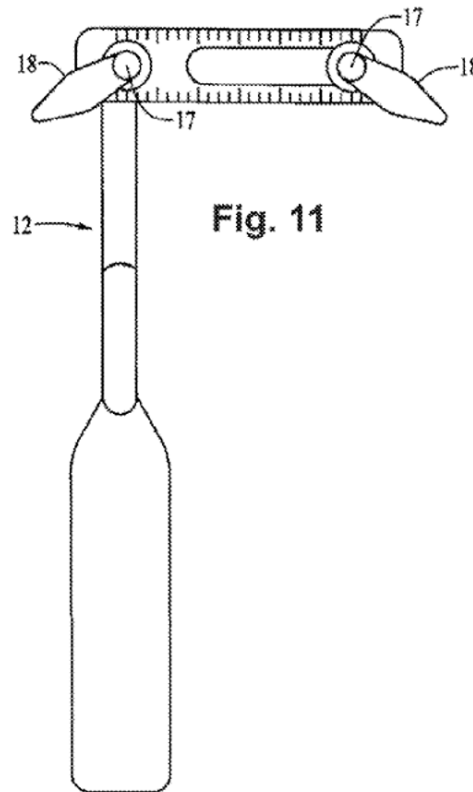
1. Claim 1

Kinmon teaches a method of compressing biological elements, as recited in the preamble of claim 1. Kinmon explains that compression staples are used during orthopedic surgical procedures to stabilize bones and to keep bone fragments in position by holding and compressing the bone fragments together without motion. Ex.1007 ¶3. Kinmon’s memory-metal staple is inserted while the legs of the staple are displaced outwardly and then the legs are allowed to bias back to a compressed position after removal of the insertion tool. *Id.* ¶82. This is a method of compressing biological elements. Ex.1002 ¶30.

a. Limitation 1[a]

Kinmon teaches “forming a first pair of apertures within a pair of biological elements, wherein the forming the first pair of apertures comprises forming the first pair of apertures within the pair of biological elements via a pair of openings in a drill guide portion of a guide.” Ex.1002 ¶31.

Kinmon states that “a typical technique initially requires drilling holes for a staple using a drill guide.” Ex.1007 ¶6. Kinmon further teaches a guide device 12 shown in Figure 11, reproduced below.



Kinmon explains that its drill guide 12 includes adjustable apertures 17 set to a desired width to guide a drill 13 to drill holes for staple insertion. *Id.* ¶¶87–88. Kinmon explains that “[a] user can place the guide device 12 in a desired position over a bone fracture and then select the desired position or width between the apertures 17.” *Id.* ¶93. The opposite sides of the fractured bone in Kinmon correspond to the recited pair of biological elements. The staple is inserted into the drilled holes to compress the pair of biological elements. *Id.* ¶¶92–93. Ex.1002 ¶32.

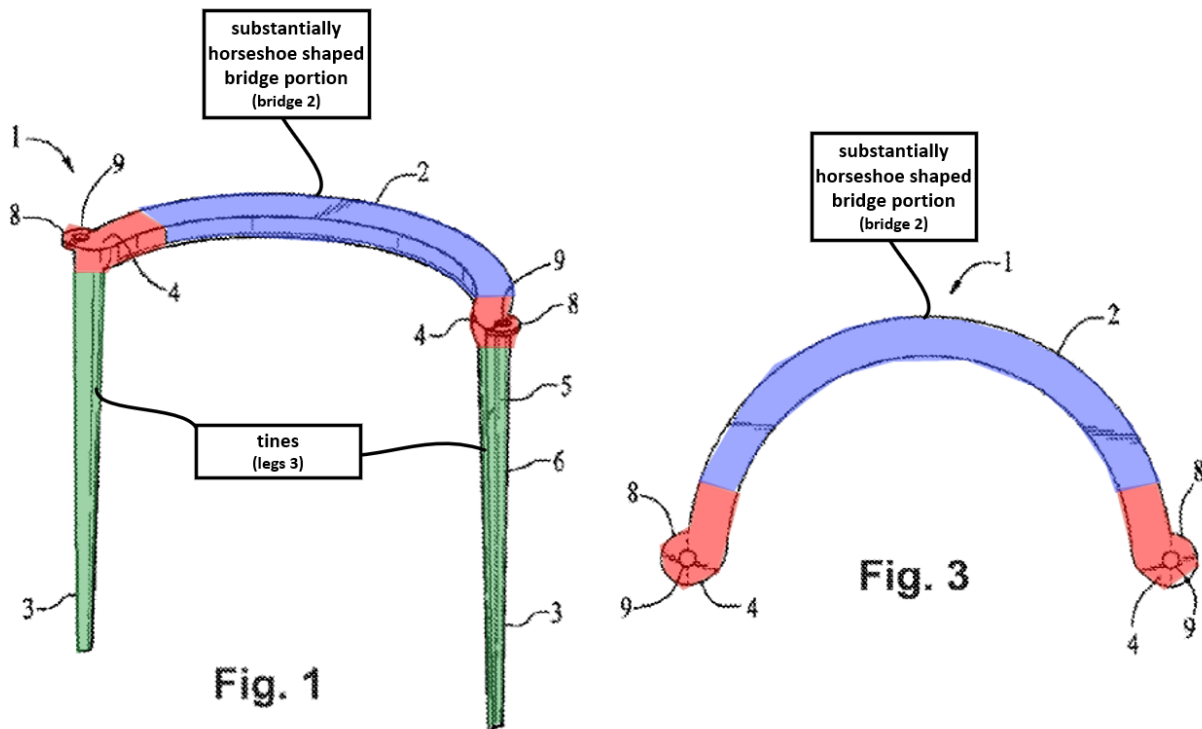
Thus, Kinmon teaches limitation 1[a]. Ex.1007 ¶¶6, 87–93.

b. Limitations 1[b][i]–[iii]

i. Limitation 1[b][i]

Kinmon teaches “elastically deforming a substantially horseshoe shaped bridge portion of a staple from a first state to a second state to increase a separation distance between a pair of tines of the staple from a first distance in the first state to a second distance in the second state.” Ex.1002 ¶33.

Annotated versions of Kinmon’s Figures 1 and 3 are reproduced below.



As seen above, Kinmon teaches a memory-metal staple having a “C” shaped bridge 2 (red and blue highlighted portion). Ex.1007 ¶82. Kinmon’s C-shaped bridge 2 is a “substantially horseshoe shaped bridge portion” within the meaning of the claim. Ex.1002 ¶34. As explained above in §III.A, this is the arrangement the ’693 Patent

describes as an example of a horseshoe shape (*i.e.*, the C-shape discussed in connection with the '693 Patent's Figures 7 and 8). *Id.*

Kinmon additionally explains that “the staple's bridge 2 is curved to the side so that its axis is substantially perpendicular to the staple's legs 3” or “the staple's bridge 2 can be curved upward so that its axis is substantially parallel to the staple's legs 3.” Ex.1007 ¶81. Accordingly, Kinmon discloses a horseshoe shaped bridge portion as disclosed in the '693 Patent as discussed above (substantially perpendicular arrangement).

Kinmon further explains that “[a]lternatively, when the staple 1 is made from memory metal, the staple can be ‘memorized’ in the compressed position ***with the legs 3 and ends of ‘C’ shaped bridge 2 close together.***” Ex.1007 ¶82. That is, Kinmon teaches ends of the C-shaped bridge converging toward one another in such an alternate arrangement. Accordingly, even if the claims were construed such that the recited “substantially horseshoe shape” requires convergence at the ends of the bridge, Kinmon's paragraph 82 teaches such an arrangement. Ex.1002 ¶35.

Kinmon explains that its insertion tool separates legs 3 from under bridge 2 and pushes legs 3 outward when activated. Ex.1007 ¶82. A POSA would understand that pushing legs 3 outward elastically deforms Kinmon's memory-metal C-shaped bridge/staple structure from its memorized compressed position. *Id.* ¶¶82–83; Ex.1002 ¶36.

Kinmon's memorized compressed position is the claimed first state before its insertion tool pushes legs 3 outward. Ex.1007 ¶82. In that position, legs 3 and ends 4 of C-shaped bridge 2 are close together. *Id.*; Ex.1002 ¶37. The insertion tool then pushes legs 3 outward. Ex.1007 ¶82. That outward displacement increases the separation distance between legs 3 from the first distance in the compressed state to a second distance in the outwardly displaced delivery state. *Id.*; Ex.1002 ¶37.

Accordingly, Kinmon teaches limitation 1[b][i].

ii. Limitation 1[b][ii]

Kinmon teaches that “the pair of openings in the drill guide portion of the guide are spaced the second distance.”

Kinmon teaches guide device 12 with adjustable apertures 17 set to a desired width to guide drill 13 to drill holes for staple insertion. Ex.1007 ¶¶87–88. Kinmon further teaches that the staple is inserted into the drilled holes while legs 3 are pushed outward. *Id.* ¶¶92–93; Ex.1002 ¶38.

Because Kinmon inserts the staple while legs 3 are pushed outward, the guide apertures and resulting drilled holes are set to the spacing corresponding to the outwardly displaced second state of legs/tines 3 for insertion. Ex.1007 ¶¶82, 87–93; Ex.1002 ¶39. Because the drilled holes must be spaced to match the delivery state separation, the outwardly held legs cannot enter holes drilled at a narrower spacing. Ex.1002 ¶40. This is consistent with the explanation provided in the '693 Patent. *See*

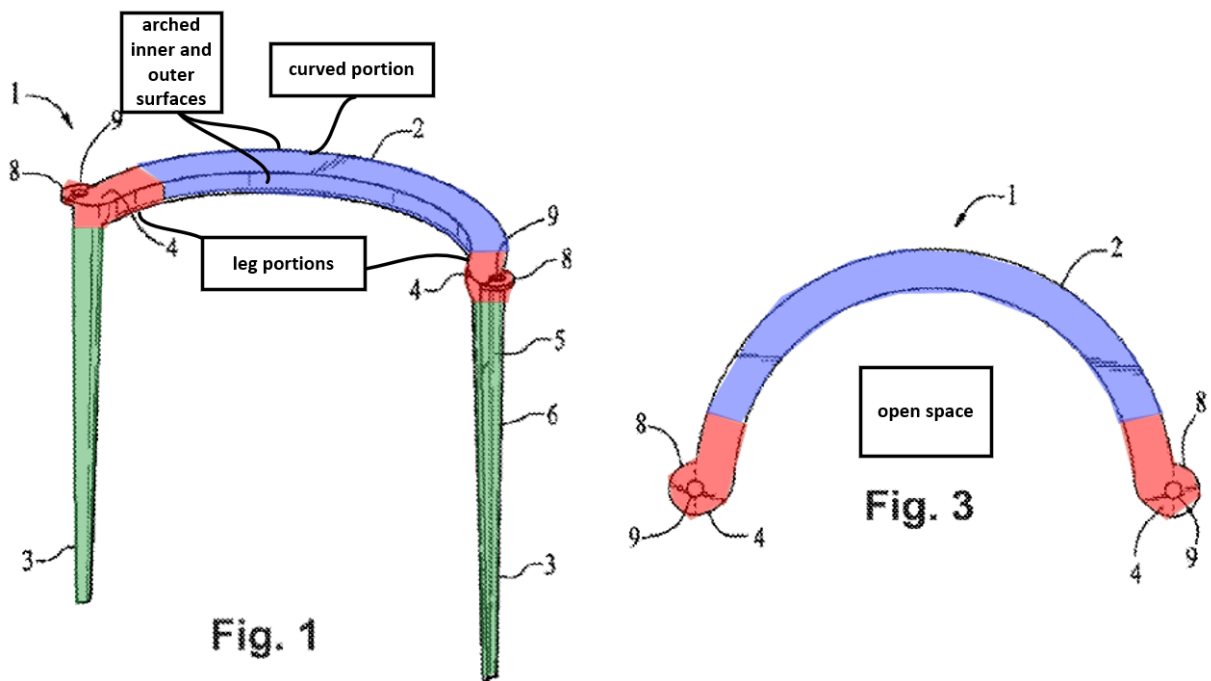
Ex.1001, 18:40–47 (describing drill guide openings spaced such that the staple must be in an extended state to be inserted in the openings formed in the biological elements).

Thus, Kinmon teaches limitation 1[b][ii].

c. Limitation 1[c]

Kinmon teaches “the bridge portion connecting the pair of tines and comprising a curved portion and opposite leg portions, the curved portion having an arched inner surface and an arched outer surface, the inner surface and the leg portions bounding an open space.”

As seen in the annotated Figures 1 and 3 from Kinmon below, Kinmon teaches the claimed bridge geometry.



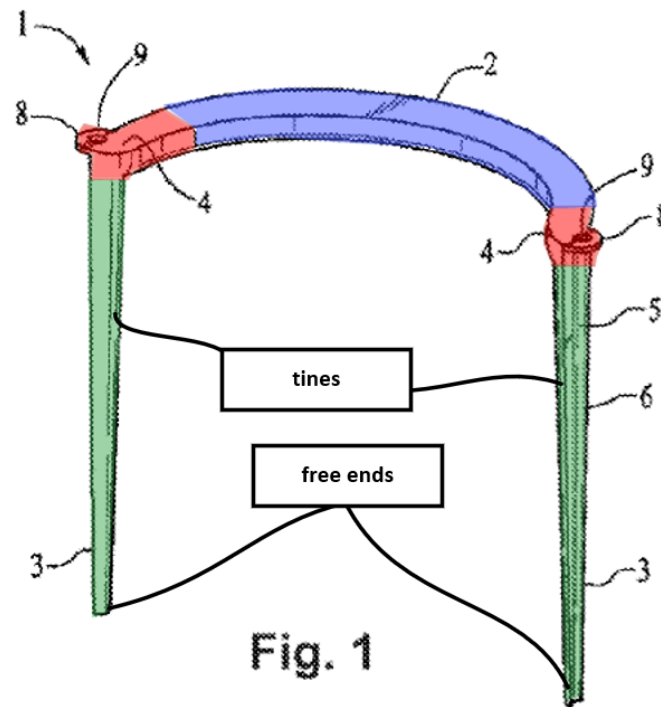
Kinmon teaches a curved bridge portion (blue highlighting) connected to legs (red highlighting). Ex.1007 ¶82. Kinmon's curved portion has an arched inner surface and an arched outer surface, and with the inner surface and leg portions bounds an open space. *Id.* A POSA would understand Kinmon's C-shaped bridge 2 as having those features because a C-shaped structure includes an arched inner surface, an arched outer surface, and an open space bounded by the curve and its ends as further defined by the leg portions. Ex.1002 ¶41.

Accordingly, Kinmon teaches limitation 1[c].

d. Limitation 1[d]

Kinmon teaches a pair of tines extending from the bridge portion and including free ends configured to be implanted into the biological elements.

Kinmon's legs 3 extend from C-shaped bridge 2. Ex.1007 ¶82. An annotated version of Kinmon's Figure 1 is reproduced below.



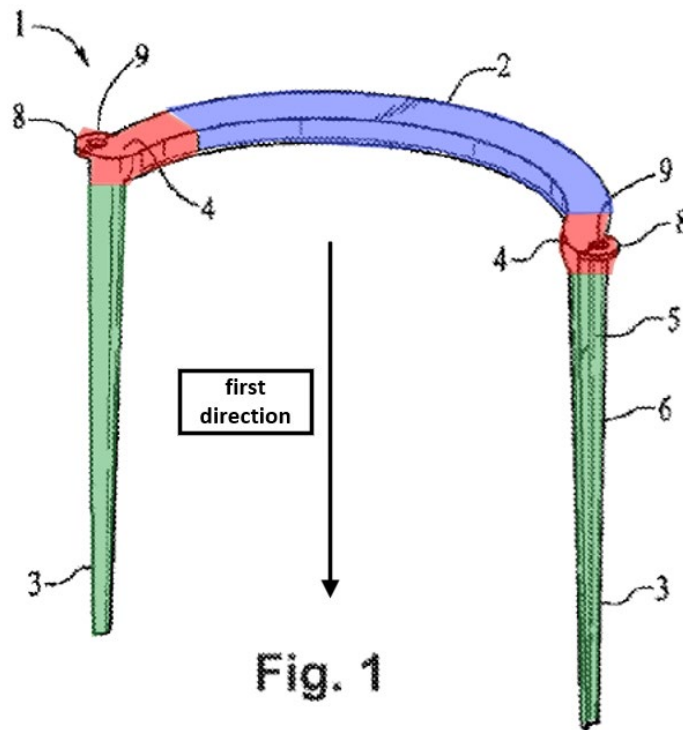
Kinmon teaches that the staple's tines are inserted into drilled holes. *Id.* ¶¶92–93. Tines 3 include free ends configured to be implanted into biological elements. Ex.1002 ¶42.

Accordingly, Kinmon teaches limitation 1[d].

e. Limitation 1[e]

Kinmon teaches “each tine of the tines extending along a first direction defined between the bridge portion and a free end of the free ends thereof.”

An annotated version of Kinmon's Figure 1 is reproduced below.



As seen above, Kinmon’s legs 3 extend from ends of C-shaped bridge 2 in a first direction toward their free ends, which are inserted into drilled holes in bone. Ex.1007 ¶¶82, 92–93. A POSA would understand each leg 3 as extending along a direction defined between bridge 2 and the free end implanted in bone. Ex.1002 ¶43.

Accordingly, Kinmon teaches limitation 1[e].

f. Limitation 1[f]

Kinmon teaches “maintaining the second state of the bridge portion.” Kinmon explains that the insertion tool separates/pushes legs 3 outward and that staple 1 is inserted before the insertion tool is removed. Ex.1007 ¶82. Removal of the insertion tool allows the staple to return toward its compressed position. *Id.*; *see also id.* ¶92

(describing insertion of staple and subsequent activation of staple's compressive force); Ex.1002 ¶44.

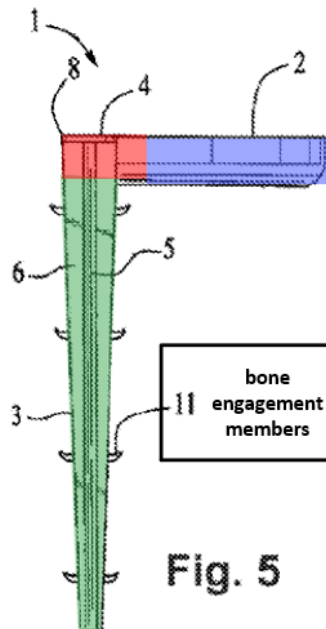
A POSA would understand that Kinmon teaches the insertion tool maintaining the outwardly displaced state (*i.e.*, the second state) during insertion because if the insertion tool did not maintain that state, the legs of the staple would not return toward their compressed position after removal of the insertion tool. Ex.1002 ¶45.

Accordingly, Kinmon teaches limitation 1[f].

g. Limitation 1[g]

Kinmon teaches “implanting the pair of tines of the staple into the pair of apertures formed in the pair of biological elements” and “the plurality of engagement mechanisms positioned on portions of the tines.”

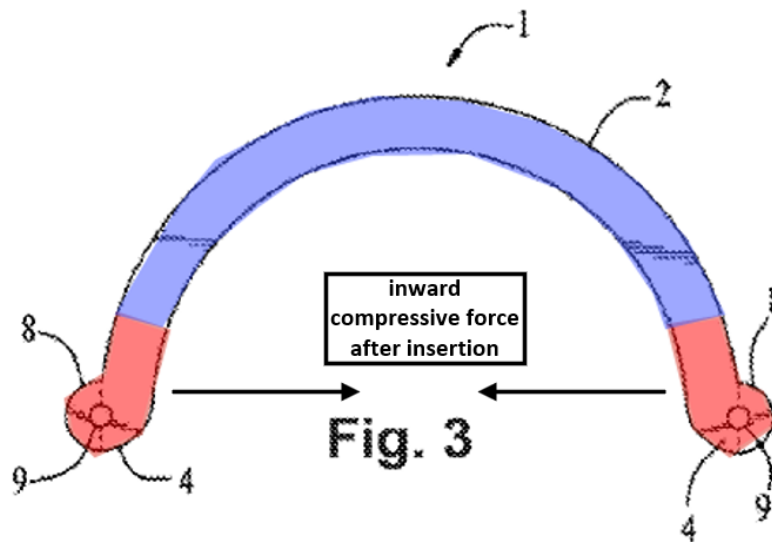
Kinmon teaches that the staple is inserted into drilled holes while legs 3 are pushed outward. Ex.1007 ¶¶92–93. Kinmon also teaches bone engagement members, as seen in Figure 5, reproduced below.



Kinmon teaches “spikes, barbs, or other similar type of projections 11 along the legs 3 of the staple 1” to stabilize staple placement in bone. *Id.* ¶85. Kinmon does not expressly show that its bone engagement members are positioned on portions of its legs 3 (tines) “that substantially face the other tine of the pair of tines along the first direction” since the above projections 11 of FIG. 5 appear to point outward in a perpendicular direction, but Kinmon nonetheless generally explains that the purpose of its projections 11 is to “help stabilize the staple’s placement in a bone.” *Id.*; Ex.1002 ¶46.

Kinmon explains, however, in the memory-metal embodiment, that legs 3 are pushed outward by the insertion tool and then return toward one another after removal of the insertion tool. Ex.1007 ¶82. An annotated version of Kinmon’s

Figure 3 is reproduced below illustrating the inward compressive force applied after insertion.



The inner surfaces of tines 3 are not visible in the side view shown in Kinmon's Figure 5 and the disclosed projections 11 are not shown at all in Figure 3 above. To the extent that Kinmon's projections 11 are not explicitly disclosed "substantially fac[ing] the other tine of the pair of tines along the first direction," a POSA would understand that Kinmon's disclosed spikes, barbs, or projections would benefit from being positioned at least on portions of legs 3 that substantially face the other tine. Ex.1002 ¶47. The compressive force is applied as legs 3 return inward toward one another, and the bone-engaging projections would further stabilize the staple in that inward compression direction. Ex.1007 ¶¶82, 85; Ex.1002 ¶47. The compressive force would provide the engagement between the projections 11 and the surrounding

bone. Ex.1002 ¶47.

Such orientation of bone engaging projections on staples was well known in the art. Ex.1002 ¶48. Miller, for example, teaches a compression staple having a central web member connecting two barbed legs. Ex.1008 ¶21. Miller's barbs help hold the staple in position in bone after implantation. *Id.* Miller's Figures 8 and 9 depict barbs on opposing staple legs positioned along the inward-facing portions of the legs, facing toward the other leg/tine. *Id.*, Figs. 8–9.

An annotated version of Miller's Figure 9 illustrating barb orientation is reproduced below.

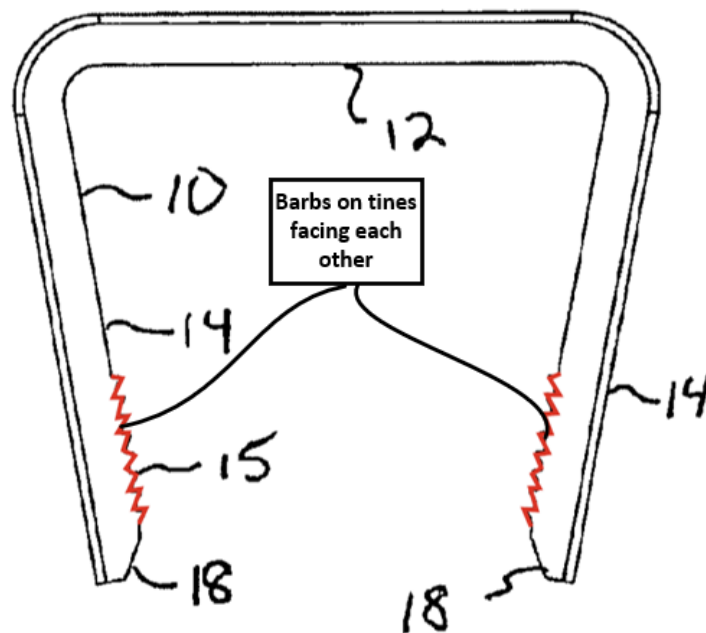


FIG. 9

As seen above, the barbs on opposite tines in Miller (annotated in red) face one

another. A POSA would understand those inward-facing barbs as engagement mechanisms positioned on portions of the tines that substantially face the other tine. Ex.1002 ¶48. Like Kinmon, Miller describes its staple as providing an inward compressive force. *See, e.g.*, Ex.1008 ¶¶21, 34.

A POSA would have found it obvious to implement Kinmon's spikes, barbs, or projections on the inward-facing portions of legs/tines 3, as taught by Miller. Ex.1002 ¶49. Kinmon and Miller both address compression staples that are inserted into bone and apply compressive force after release. Ex.1007 ¶¶3, 82, 85; Ex.1008 ¶¶6, 21. In Kinmon's memory-metal embodiment, legs 3 return inward toward one another after removal of the insertion tool. Ex.1007 ¶82. Placing the retention projections on the inward-facing portions of Kinmon's legs/tines 3 would predictably engage bone in the direction of compression, resist withdrawal, and maintain fixation while the staple compresses the biological elements. Ex.1007 ¶¶82, 85; Ex.1008 ¶21; Ex.1002 ¶49.

Inward-facing barbs were the conventional orientation for compression-staple legs in the art: the compressive force travels inward as the legs return toward one another, so engagement mechanisms that face inward resist withdrawal in the same direction as the applied compression. Ex.1002 ¶50. The function of the barbs is identical in Kinmon and Miller (stabilizing the implanted staple in bone and resisting withdrawal after the compressive force is applied). Ex.1007 ¶85; Ex.1008 ¶21

(confirming that Miller's barb orientation directly addresses Kinmon's disclosed retention problem); Ex.1002 ¶50.

Thus, Kinmon in view of Miller renders limitation 1[g] obvious.

h. Limitation 1[h]

Kinmon teaches “releasing the potential energy of the elastic deformation of the second state of the bridge portion to apply a compressive force to the pair of biological elements via the tines and to engage the plurality of engagement mechanisms with the biological elements,” but does not specifically teach the recited orientation of the engagement members, as discussed above.

Kinmon's memory-metal staple is memorized in the compressed state with legs 3 and the ends 4 of C-shaped bridge 2 close together. Ex.1007 ¶82. The insertion tool pushes the ends 4 and legs 3 outward, and the staple is inserted before removal of the insertion tool. *Id.* Removal of the insertion tool allows staple 1 to return to its compressed position. *Id.* That return releases stored elastic/shape-memory energy from the outwardly displaced second state and applies compression through legs 3. *Id.* ¶¶82–83; *see also id.* ¶73 (“compression is more evenly distributed throughout the staple”); Ex.1002 ¶52.

As discussed with respect to limitation 1[g], it would have been obvious to have Kinmon's spikes, barbs, or projections 11 along legs 3 facing one another and engage bone and stabilize staple placement. Ex.1007 ¶85; Ex.1002 ¶53.

Accordingly, Kinmon in view of Miller renders limitation 1[h] obvious.

2. Claim 2

Claim 2 depends from claim 1 and adds that “applying the compressive force to the pair of biological elements via the tines comprises the compressive force closing a space between the biological elements.”

Kinmon teaches this limitation. Kinmon explains that compression staples hold and compress bone fragments together without motion. Ex.1007 ¶3. Kinmon’s memory-metal staple returns to its compressed position after insertion tool removal, thereby applying compression through legs/tines 3. *Id.* ¶82; Ex.1002 ¶54. That compressive force closes or reduces the space between the biological elements. Ex.1002 ¶54.

Accordingly, claim 2 would have been obvious based on the combined teachings of Kinmon and Miller.

3. Claim 3

Claim 3 depends from claim 1 and recites that “maintaining the second state of the bridge portion comprises engaging the staple with a staple engagement portion of a guide.”

Kinmon teaches this limitation. Kinmon teaches that the insertion tool separates legs 3 from under bridge 2 and pushes legs 3 outward when activated, and that staple 1 is inserted before removing the insertion tool. Ex.1007 ¶82. Because

removal of the insertion tool allows the staple to return toward its compressed position, the insertion tool engages the staple and maintains the outwardly displaced second state during insertion. *Id.*; Ex.1002 ¶55. The insertion tool portion that engages the staple to push and maintain legs 3 outward is the claimed staple engagement portion of the guide.

Accordingly, claim 3 would have been obvious based on the combined teachings of Kinmon and Miller.

4. Claim 4

Claim 4 depends from claim 3 and recites that “releasing the energy of the elastic deformation of the second state of the bridge portion comprises disengaging the staple from the staple engagement portion of the guide.”

Kinmon teaches this limitation. Kinmon teaches that staple 1 is inserted before removing the insertion tool and that removal of the insertion tool allows staple 1 to return to its compressed position. Ex.1007 ¶82. Removing the insertion tool disengages the staple from the staple engagement portion and releases the stored energy of the outwardly displaced second state. *Id.*; Ex.1002 ¶56.

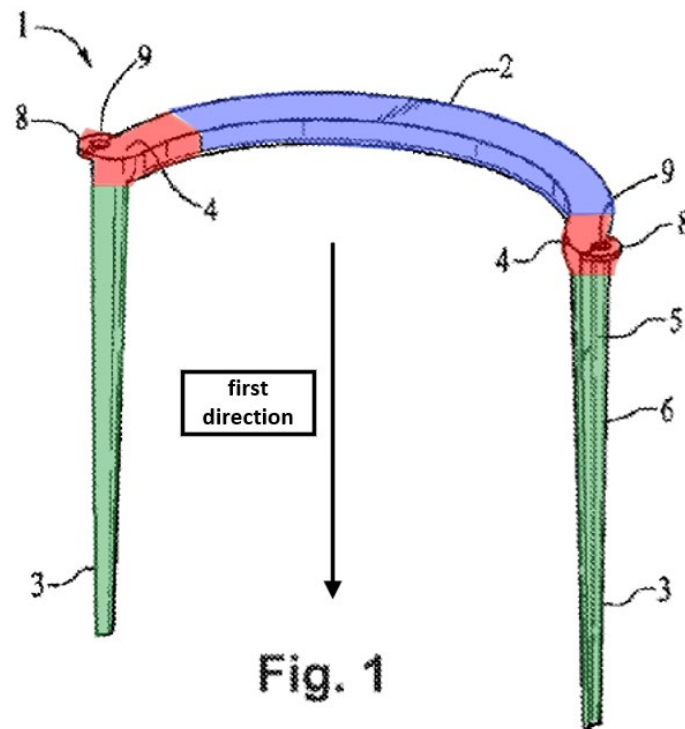
Accordingly, claim 4 would have been obvious based on the combined teachings of Kinmon and Miller.

5. Claim 5

Claim 5 depends from claim 1 and recites that “the bridge and the pair of tines

comprise substantially rectangular cross-sections.”

Kinmon explains that “[t]he legs 3 of the staple 1 can be formed in any shape, including, but not limited to, a flat shape or a circular shape.” Ex.1007 ¶73. The “flat shape” is shown in Kinmon’s Figure 1, in which the bridge 2 has a substantially rectangular cross-sectional shape and every cross-section (*i.e.*, any cross-section perpendicular to the “first direction” depicted below) of the legs 3 is also substantially rectangular, as shown below:

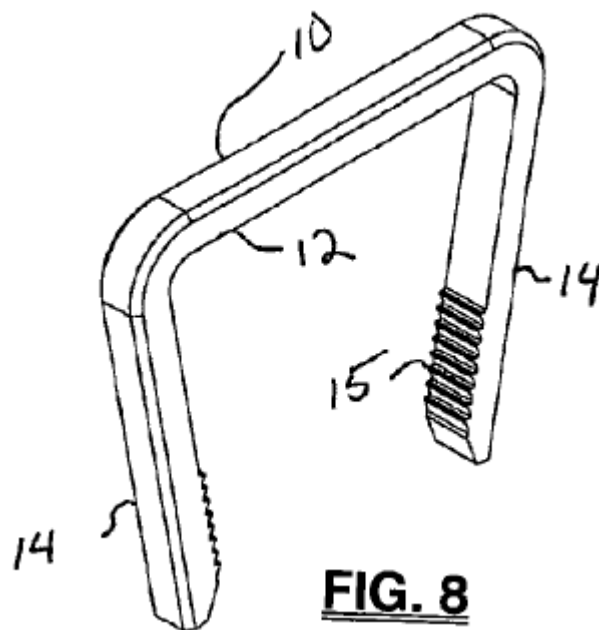


Although Figure 1 depicts a perspective view rather than a cross-sectional cut, the flat, straight-edged rendering of legs 3 (as opposed to a rounded or curved profile) is consistent with, and indicates, the substantially rectangular cross-sectional

shape reflected in each such cross-section.

Accordingly, Kinmon teaches the recited “substantially rectangular cross-sections.” Ex.1002 ¶57.

Miller also teaches the recited “substantially rectangular cross-sections.” Miller’s Figures 8 and 9 show the staple with flat-sided web and leg structures. Figure 8 is reproduced below.



Miller describes the staple dimensions in terms of web length, leg length, and thickness. Ex.1008 ¶21; Figs. 8–9. A POSA would have understood Miller’s depicted flat-sided staple as having a substantially rectangular cross-section for the web and legs. Ex.1002 ¶58. A POSA would have found it obvious to use Miller’s flat-sided/substantially rectangular cross-sectional geometry in Kinmon’s memory-

metal compression staple based at least on Kinmon's own teaching of such geometry. Ex.1002 ¶59. Kinmon and Miller both concern compression staples inserted into bone and released to apply compression. Ex.1007 ¶¶3, 82; Ex.1008 ¶¶6, 21. Cross-sectional shape was a predictable structural parameter affecting manufacturing, stiffness, insertion tool engagement, and bone engagement. Ex.1002 ¶59. Kinmon expressly identifies flat and circular leg shapes as known alternatives, and Miller confirms that flat-sided staple structures were known for compression staples. Ex.1007 ¶73; Ex.1008 ¶21, Figs. 8–9.

The '693 Patent itself treats circular and rectangular cross-sections as alternative embodiments of the same staple concept, rather than changing the operative method of forming apertures, deforming the bridge, implanting the tines, and releasing stored elastic energy. *See, e.g.*, Ex.1001, 2:14–18 (“at least one of the bridge portion and the pair of tines may have a circular or rectangular cross-section”); *see also id.* at 9:12–16 (“the tines 214 may be substantially circular or elliptical in cross-section, and the bridge 212 may be substantially rectangular, square or other cross-sectional shape with substantially linear or planar sides”). Thus, the patent does not describe a rectangular cross-section as changing the claimed method of deforming, maintaining, implanting, and releasing the staple, but instead as an alternative staple geometry. Ex.1002 ¶60.

A POSA would have understood that the substantially rectangular cross-

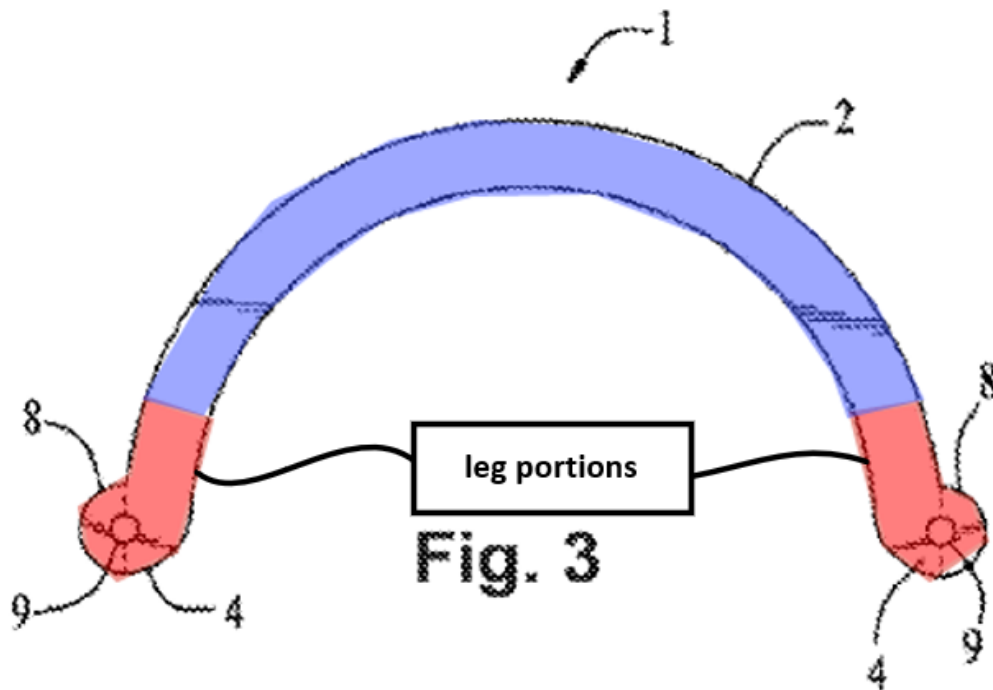
section is a known structural variant of staple bridge/tine geometry that can provide predictable performance compared to a circular cross-section, including directional stiffness, lower profile in one dimension, improved orientation control, and flat bearing surfaces for load transfer. Ex.1002 ¶61.

Accordingly, claim 5 would have been obvious based on the combined teachings of Kinmon and Miller.

6. Claim 6

Claim 6 depends from claim 1 and recites that “the leg portions comprise linear portions extending opposite the open space relative to each other.”

Kinmon teaches this limitation. Kinmon teaches a C-shaped bridge 2 with legs 3 and ends 4 of the C-shaped bridge close together in the compressed position. Ex.1007 ¶82. A POSA would understand the ends 4 of Kinmon’s C-shaped bridge as opposite leg portions extending on opposite sides of the open space defined by the C-shaped bridge. *Id.*; Ex.1002 ¶62. An annotated version of Kinmon’s Figure 3 is reproduced below.



As seen above, Kinmon's leg portions (red highlighting) extend linearly on opposite sides of the open space. That is, the entirety of each of the ends 4 extends linearly from bridge 2, on an opposite side of the open space defined by bridge 2 and ends 4. Ex.1002 ¶62.

To the extent that it can be argued that the leg portions defined at least in part by ends 4 do not extend linearly because they terminate in a circular portion, making the leg portions of Kinmon's bridge linear would have been a predictable way to implement the same bridge geometry. Ex.1002 ¶62. Kinmon already teaches that its bridge may be a curved or slight "C" shape and that compression is enhanced when the ends of the "C" are brought together.

It would have been obvious to configure the ends 4 of Kinmon's C-shaped bridge as purely linear end portions because linear terminal portions were a known and predictable example of the finite geometric variants of offset, horseshoe-like compression staple bridges. *See, e.g.*, Ex.1010, Figs. 1, 2; Ex.1002 ¶63. Purely linear end portions do not change the claimed method. Ex.1002 ¶63. The method still requires forming apertures, deforming the bridge to increase tine spacing, maintaining the deformed state, implanting the tines, and releasing stored elastic energy to apply compression. The claimed linearity of the bridge ends merely defines the geometry of the staple structure on which those known method steps are performed.

A POSA would have understood that straightening the terminal portions of a C-shaped bridge adjacent the tines would preserve the same operative function (*i.e.*, elastic deformation of the bridge to increase tine spacing, followed by release to apply compression) while providing a straightforward transition between the curved bridge portion and the tines. Ex.1002 ¶64.

Purely linear end portions would have predictably facilitated alignment of the bridge with the tines and provided defined terminal regions for transmitting the bridge's spring force into the tines. Ex.1002 ¶65. That is the same function described in both Kinmon and the '693 Patent. Kinmon's C-shaped bridge urges the legs toward one another to create compression after outward displacement of the legs,

while the '693 Patent's offset bridge elastically deforms to vary tine spacing and then releases stored energy to compress biological elements. Ex.1007 ¶¶81–84; Ex.1001, 6:50–65, 7:1–8; Ex.1002 ¶65. Further use of linear ends of a staple bridge would have been obvious to provide offset as needed for placement based on specific bone geometry. *See, e.g.*, Ex.1010, Figs. 3, 5, 7; Ex.1002 ¶65.

Accordingly, claim 6 would have been obvious based on the combined teachings of Kinmon and Miller.

7. Claim 7

Claim 7 depends from claim 1 and recites that “the curved portion is angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines.”

Kinmon teaches this limitation. Kinmon explains that “the staple's bridge 2 is curved to the side so that its axis is substantially perpendicular to the staple's legs 3” or “the staple's bridge 2 can be curved upward so that its axis is substantially parallel to the staple's legs 3.” Ex.1007 ¶81. Kinmon thus treats bridge-to-tine orientation as a design variable, disclosing a range of configurations. A POSA would have appreciated that Kinmon indicates that the disposition of bridge 2 need not be perfectly parallel or perpendicular, meaning it is also contemplated by Kinmon that its bridge 2 extends at an angle between 90 and 180 degrees relative to tines 3 (*i.e.*, somewhere between parallel and perpendicular). Ex.1002 ¶67. At a minimum, a

POSA also would have found orienting Kinmon's bridge at an angle that is not perpendicular to its legs obvious. Ex.1002 ¶68.

The '693 Patent's own disclosure confirms that the claimed "curved portion angled downwardly toward the free end" is satisfied by a curved bridge surface that opens or faces downward toward the biological elements and tine free ends. In Figures 7 and 8 discussed above, the '693 Patent depicts a downward-opening curved bridge.

Kinmon teaches that same downward-opening curved bridge orientation in the embodiment where its C-shaped bridge 2 is substantially vertically oriented relative to legs/tines 3, and in that configuration the curved portion of bridge 2 opens downward toward the bone and toward the free ends of legs/tines 3 relative to the longitudinal dimension of the tines, similar to the Figure 7, 8 embodiment in the '693 Patent. Ex.1007 ¶81. A POSA would therefore understand Kinmon's substantially vertically oriented C-shaped bridge as teaching, or at least suggesting, "the curved portion angled downwardly toward the free end relative to a longitudinal dimension of a tine." Ex.1002 ¶¶70–71.

Even if Kinmon did not expressly disclose this orientation, it would have been obvious to a POSA to orient the curved bridge portion downward toward the tine free ends in order to seat the bridge against the bone surface and bear against bone to transmit the compressive force applied by the staple. Ex.1002 ¶72. Seating the

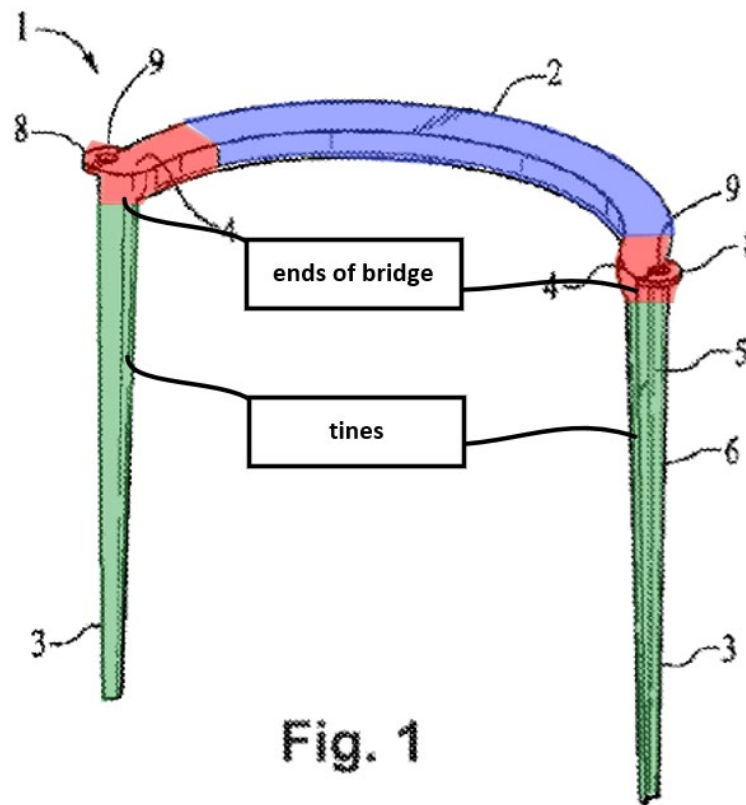
bridge against bone was a recognized functional requirement in the compression-staple art, as confirmed by Gauthier's explicit teaching of "cortical rest" and EP '045's teaching that the bridge should be shaped "according to the curved metaphysis surface." Ex.1010, 3:64–65; Ex.1009, 3:50–56; Ex.1002 ¶73. A downward bridge orientation is the natural consequence of that requirement. Ex.1002 ¶73.

Accordingly, claim 7 would have been obvious based on the combined teachings of Kinmon and Miller.

8. Claim 8

Claim 8 depends from claim 1 and recites that "the pair of tines extend from opposing ends of the bridge portion, the ends having inner surfaces opposite each other about the open space."

Kinmon teaches this limitation. As seen in the annotated Figure 1 from Kinmon below, Kinmon teaches tines 3 extending from opposing ends 4 of the C-shaped bridge 2.



A POSA would understand Kinmon's C-shaped bridge and legs as defining bridge ends having inner surfaces opposite one another about the open space of the C-shaped bridge. Ex.1002 ¶74.

Accordingly, claim 8 would have been obvious based on the combined teachings of Kinmon and Miller.

9. Claim 9

Kinmon and Miller render claim 9 obvious for the same reasons stated for claims 1 and 7. Claim 9 recites a method of compressing biological elements and includes limitations corresponding to limitations of claim 1, except that claim 9 does

not require the drill guide openings to be spaced the second distance and additionally requires the downward angled bridge orientation recited in claim 7.

a. Limitation 9[a]

Kinmon teaches forming a first pair of apertures within a pair of biological elements for the reasons stated for limitation 1[a]. Ex.1002 ¶76.

b. Limitation 9[b][i]–[ii]

Kinmon teaches elastically deforming a substantially horseshoe-shaped bridge portion from a first state to a second state for the reasons stated for limitations 1[b][i] and 1[b][ii]. Ex.1002 ¶77.

c. Limitation 9[c]

Kinmon teaches the claimed bridge portion for the reasons stated for limitation 1[c]. Ex.1002 ¶78.

d. Limitation 9[d]

Kinmon teaches tines extending from the bridge portion and including free ends configured to be implanted into biological elements for the reasons stated for limitation 1[d]. Ex.1002 ¶79.

e. Limitation 9[e]

Kinmon teaches each tine extending along a first direction defined between the bridge portion and a free end for the reasons stated for limitation 1[e]. Ex.1002 ¶80.

f. Limitation 9[f]

Kinmon teaches the curved portion angled downwardly toward the free end relative to a longitudinal dimension of a tine for the reasons stated for claim 7. Ex.1002 ¶81.

g. Limitation 9[g]

Kinmon teaches maintaining the second state for the reasons stated for limitation 1[f]. Ex.1002 ¶82.

h. Limitation 9[h]

Kinmon and Miller render obvious implanting the tines and engaging engagement mechanisms for the reasons stated for limitation 1[g]. Ex.1002 ¶83.

i. Limitation 9[i]

Kinmon and Miller render obvious releasing stored energy to apply compression and engage the engagement mechanisms for the reasons stated for limitation 1[h]. Ex.1002 ¶84.

Accordingly, claim 9 would have been obvious based on the combined teachings of Kinmon and Miller.

10. Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in applying Miller's inward-facing barb orientation and flat-sided/substantially rectangular staple geometry to Kinmon's memory-metal compression staple. The proposed

combination does not require replacing Kinmon's staple or changing Kinmon's delivery method. Kinmon already teaches the operative open–hold–insert–release sequence. Kinmon's staple 1 is memorized in a compressed position, an insertion tool pushes legs 3 outward, the staple is inserted before the insertion tool is removed, and removal of the insertion tool allows the staple to return toward its compressed position. Ex.1007 ¶82. Kinmon also teaches guide apertures being set to a desired width and inserting the legs into drilled holes while the legs are pushed outward. *Id.* ¶¶87–93; Ex.1002 ¶86.

Miller's inward-facing barb orientation would have worked predictably in Kinmon because Kinmon already teaches spikes, barbs, or projections along legs 3 to stabilize staple placement in bone, and Miller teaches barbs on compression-staple legs that hold the staple in bone after implantation. Ex.1007 ¶85; Ex.1008 ¶21; Figs. 8–9. Because Kinmon's legs return inward toward one another after release, a POSA would have expected inward-facing barbs to engage bone in the direction of compression, resist withdrawal, and maintain fixation while compression is applied. Ex.1007 ¶82; Ex.1002 ¶87.

A POSA also would have expected Miller's flat-sided/substantially rectangular staple-stock geometry to work in Kinmon. Ex.1002 ¶88. Kinmon teaches that staple legs may be formed in different shapes, including flat or circular shapes, confirming that cross-sectional shape was a known design variable. Ex.1007 ¶73.

Miller's Figures 8 and 9 depict flat-sided web and leg structures, and Miller describes the staple using web length, leg length, and thickness. Ex.1008 ¶21; Figs. 8–9. A POSA would have understood such flat-sided staple stock as a predictable substantially rectangular cross-section implementation for Kinmon's bridge and tines. Ex.1002 ¶88.

Nothing in the proposed combination would change Kinmon's principle of operation. Kinmon's staple would still be opened by an insertion tool, held outward during insertion, inserted into prepared holes, and released so the memory-metal staple returns toward its compressed position. Ex.1007 ¶¶82, 87–93. Miller's inward-facing barbs and flat-sided cross-section merely provide predictable structural implementations for Kinmon's disclosed bone-engaging projections and known selectable leg shapes. Ex.1007 ¶¶73, 85; Ex.1008 ¶21. Accordingly, a POSA would have reasonably expected the Kinmon/Miller combination to successfully deliver, retain, and compress the biological elements as claimed. Ex.1002 ¶89.

11. Summary

For at least these reasons, claims 1–9 would have been obvious over Kinmon in view of Miller.

B. Obviousness of Claims 1–9 over Kinmon, Miller, EP '045, and Gauthier

The claims recite a known surgical technique using a known surgical staple. A POSA would have found the claimed method obvious based on the combined

teachings of Kinmon, Miller, EP '045, and Gauthier. Ex.1002 ¶¶90.

As discussed above, Kinmon and Miller alone disclose the claimed method of compressing biological elements using a compression staple, including the recited forming, elastic deformation, maintaining, implanting, and releasing steps. EP '045 and Gauthier are discussed throughout this ground as further, independent support for staple-geometry features, such as the shape, orientation, and cross-section of the bridge and tines, even though Kinmon and Miller alone are sufficient to render the claims obvious. The use of known staple geometries in a known method of compressing biological elements would have been obvious based on the combined teachings discussed below. Ex.1002 ¶¶91.

The references provide complementary teachings that would have led a POSA to the claimed method. Ex.1002 ¶¶92. Kinmon and Miller teach the guide/insertor delivery sequence for opening, maintaining, implanting, and releasing a compression staple. EP '045 confirms that arched bridge deformation increases leg spacing and that recovery of the arched bridge develops compression. Gauthier confirms that an angled curved bridge can be placed for cortical rest and can use elastic bridge recovery to apply contact pressure. Together, those teachings would have led a POSA to use known bridge-shape and bridge-orientation refinements in Kinmon's compression-staple method with a reasonable expectation of success. Ex.1002 ¶¶92.

1. Claim 1

Kinmon, Miller, EP '045, and Gauthier each teach a method of compressing biological elements, as recited in the preamble of claim 1 (limitation 1[p]). *See, e.g.*, §V.A.1 (discussing Kinmon's teachings); Ex.1008 ¶6; Ex.1009, 2:55–3:4, 4:47–56; Ex.1010, 4:36–47; Ex.1002 ¶93.

a. Limitation 1[a]

Limitation 1[a] recites “forming a first pair of apertures within a pair of biological elements, wherein the forming the first pair of apertures comprises forming the first pair of apertures within the pair of biological elements via a pair of openings in a drill guide portion of a guide.”

Kinmon teaches limitation 1[a] as discussed above in §V.A.1.a.

Miller also teaches limitation 1[a]. Miller describes a surgical technique to fuse bone segments and teaches “using the provided drill guide” to “drill pilot holes for the staple legs.” Ex.1008 ¶32. Miller therefore confirms that use of a drill guide to form staple-receiving pilot holes was a known implementation of the same technique disclosed by Kinmon. Ex.1002 ¶94.

Gauthier further confirms that forming holes to receive staple rods/tines was known. Gauthier teaches making drilled holes to receive rods/tines 3 and 4 in the bone parts to be held. Ex.1010, 3:19–21.

Thus, Kinmon teaches limitation 1[a], and Miller and Gauthier confirm that

forming staple-receiving apertures through a guide-based drilling technique was a known and predictable compression-staple practice. Ex.1002 ¶95.

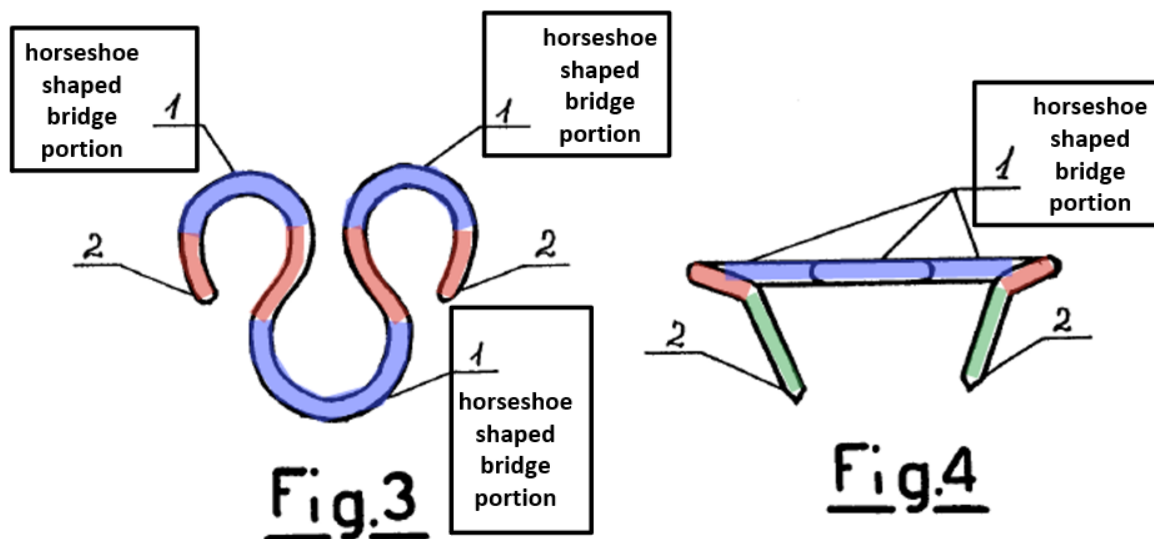
b. Limitations 1[b][i]–[ii]

i. Limitation 1[b][i]

Limitation 1[b][i] recites “elastically deforming a substantially horseshoe shaped bridge portion of a staple from a first state to a second state to increase a separation distance between a pair of tines of the staple from a first distance in the first state to a second distance in the second state.”

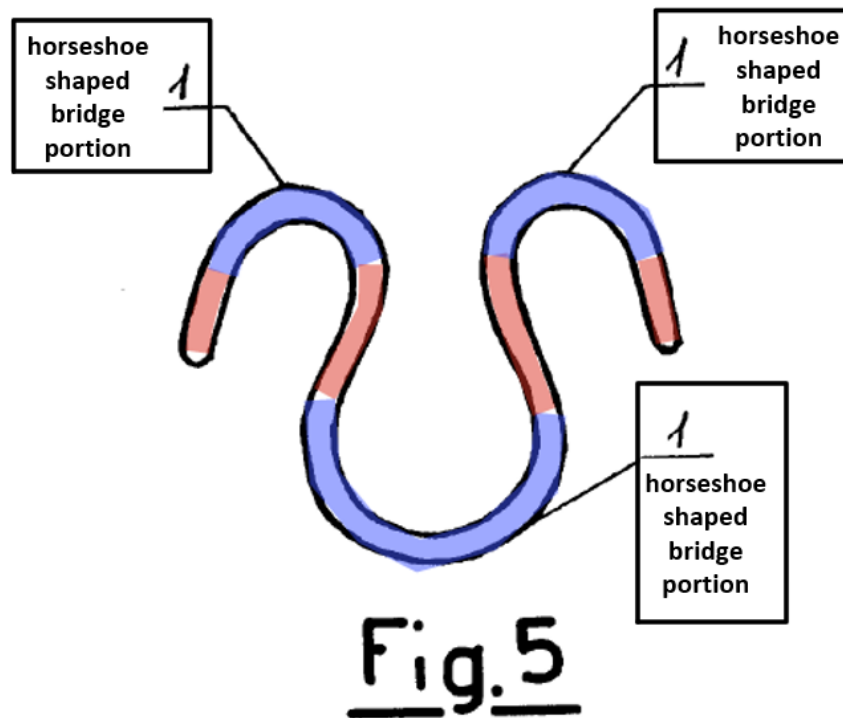
Kinmon teaches limitation 1[b][i] as discussed above in §V.A.1.b.i.

EP '045 additionally teaches this limitation. Annotated Figures 3 and 4 of EP '045 are reproduced below.



EP '045 teaches horseshoe shaped bridge portions 1 with an arc length exceeding

180 degrees as shown above. *See, e.g.*, Ex.1009, 3:9–10. Figure 5, reproduced below, shows the staple in the deformed state for insertion into biological elements. *Id.* at 3:7–8.



EP '045 explains that “[b]efore installation . . . [t]he working part is deformed so that the distance between plunge legs [2] increases at the expense of decrease of the working part [1] curvature.” *Id.* at 4:47–50. That is the same deformation relationship recited in limitation 1[b][i]: deformation of an arched or horseshoe-shaped bridge/working part increases the separation distance between the implantable legs/tines. Ex.1002 ¶96.

Gauthier also teaches a staple having a horseshoe-shaped bridge portion, as

splayed delivery state using an inserter and maintaining that state with a sliding lock. Ex.1008 ¶¶25, 34–35. Thus, the references collectively teach elastically deforming a substantially horseshoe-shaped bridge portion to increase the separation distance between a pair of tines.

ii. Limitation 1[b][ii]

Limitation 1[b][ii] recites that the pair of openings in the drill guide portion of the guide are spaced the second distance.

Kinmon teaches limitation 1[b][ii] as discussed above in §V.A.1.b.ii.

Miller confirms the same guide-based implementation as taught by Kinmon. Miller’s Step 2 uses a sizer to mark placement of the staple legs, and Step 3 uses the provided drill guide to drill pilot holes at those marked locations. Ex.1008 ¶¶31–32. Step 6 uses the inserter to “maintain the splayed position of the staple legs” while positioning “the staple legs in the pilot holes.” Ex.1008 ¶35. The pilot holes therefore are spaced at the distance between the legs in the splayed second state so that the legs can enter the holes during implantation. A POSA would have understood that the drill guide openings used to form those holes would likewise be spaced at that second distance. Ex.1002 ¶99.

Gauthier also teaches drilled holes for receiving rods/tines 3 and 4. Ex.1010, 3:19–21. When applied to Kinmon’s guide-based delivery method, the holes would be formed at the spacing necessary to receive the tines in their opened delivery state.

Ex.1002 ¶100.

Thus, Kinmon teaches limitation 1[b][ii], and Miller and Gauthier confirm that staple-receiving apertures are formed to correspond to the delivery spacing of the implantable legs/tines. Ex.1002 ¶101.

c. Limitation 1[c]

Limitation 1[c] recites “the bridge portion connecting the pair of tines and comprising a curved portion and opposite leg portions, the curved portion having an arched inner surface and an arched outer surface, the inner surface and the leg portions bounding an open space.”

Kinmon teaches limitation 1[c] as discussed above in §V.A.1.c.

EP '045 also teaches limitation 1[c]. Annotated versions of EP '045's Figures 3 and 4 are provided below illustrating the features of limitation 1[c].

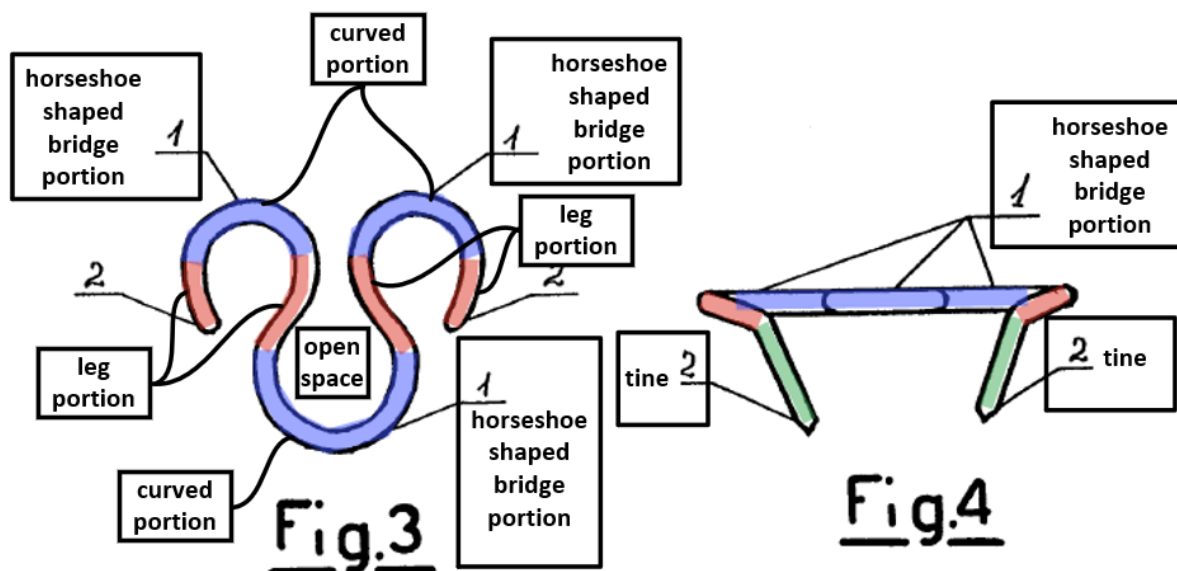
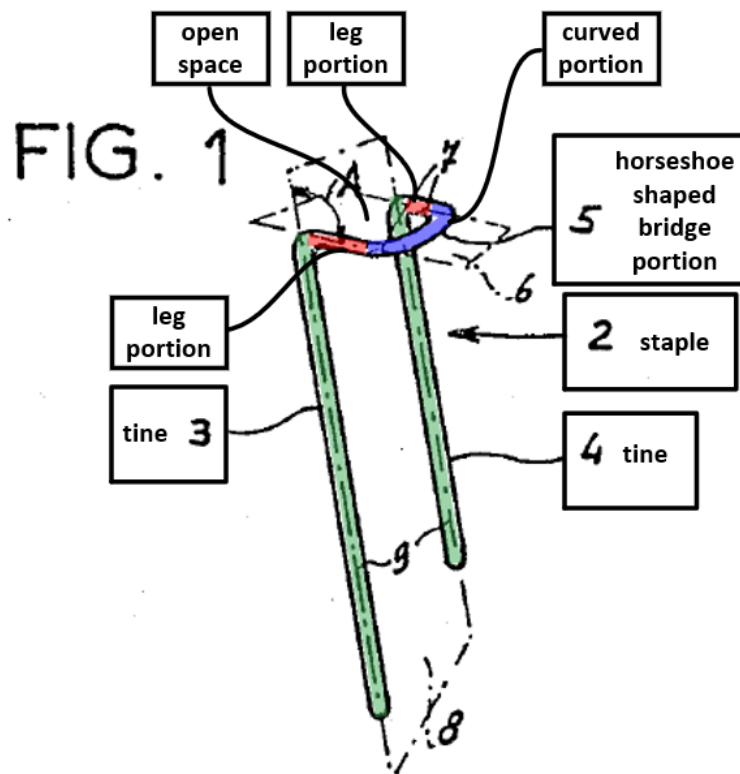


Figure 3 is a top view of EP '045's staple in a compressed (working) state and Figure 4 is a side view of the staple in a compressed state. Ex.1009, 3:5–6. As seen above, ends of the bridge portions (red highlighting) connect to the tines (green highlighting). The bridge portion includes curved portions (blue highlighting) and opposite leg portions (red highlighting). The curved portions (blue highlighting) have arched inner and outer surfaces, and the inner surface and leg portions bound an open space. EP '045 specifically states that “the middle part of the device is made arch-shaped.” *Id.* at 1:50–51; Ex.1002 ¶103.

Gauthier also teaches limitation 1[c]. An annotated version of Gauthier’s Figure 1 is reproduced below.



Gauthier explains that clip 2 includes “two lateral rods 3 and 4, approximately parallel, connected together by a bridge[-]forming central part 5,” and that “the central part forming bridge 5 is curved.” Ex.1010, 3:6–10. Gauthier’s curved bridge portion 5 includes a concave arched inner surface, a convex arched outer surface, and opposite portions extending toward rods/tines 3 and 4. Those surfaces and portions bound an open space. Ex.1002 ¶104.

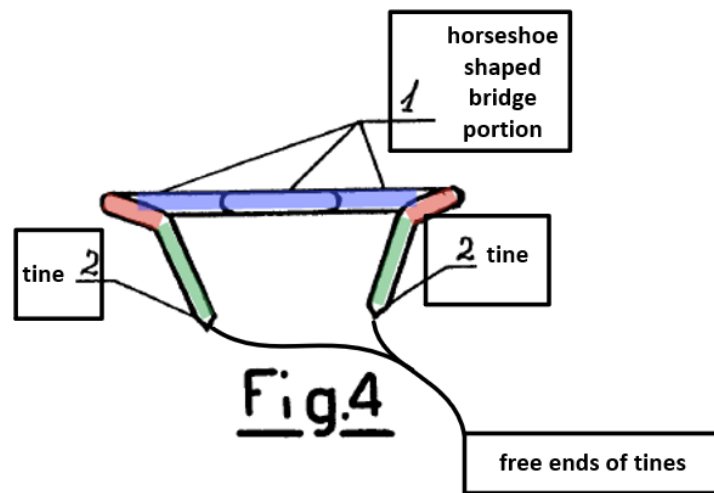
Thus, Kinmon teaches the claimed bridge geometry, and EP ’045 and Gauthier further confirm that arched, horseshoe-shaped bridge portions with open spaces were known in compression-staple osteosynthesis devices. Ex.1002 ¶105.

d. Limitation 1[d]

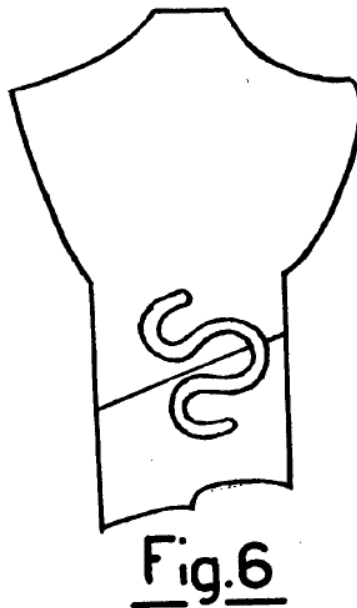
Limitation 1[d] recites “the pair of tines extending from the bridge portion and including free ends configured to be implanted into the biological elements.”

Kinmon teaches limitation 1[d] as discussed above in §V.A.1.d.

EP ’045 also teaches this limitation. An annotated version of Figure 4 from EP ’045 is reproduced below illustrating the features in limitation 1[d].



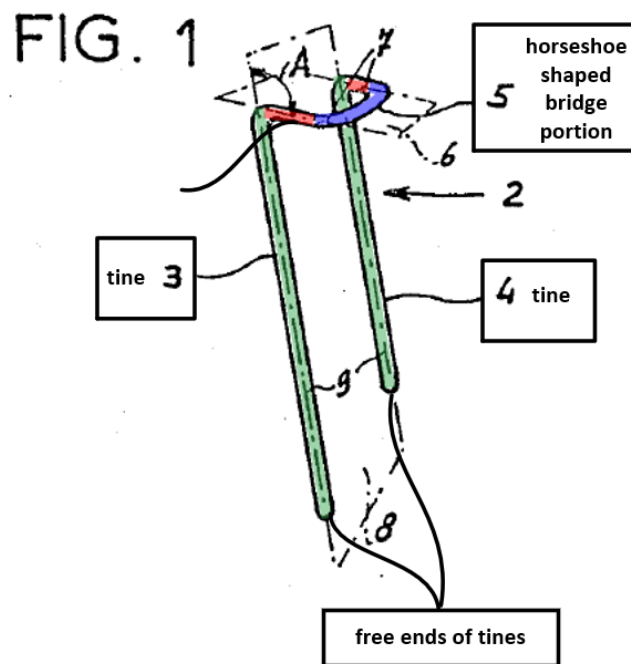
EP '045 explains, for example, that its “proposed devices can be used . . . during fracture therapy and surgical operations on the long tubular bones” (Ex.1009, 2:49–51) with “tapered plunge legs” that are inserted into bone (*id.* at 3:7). Figure 6, reproduced below, illustrates the staple in use.



EP '045 describes “surgical operations on the long tubular bones for the fixation of

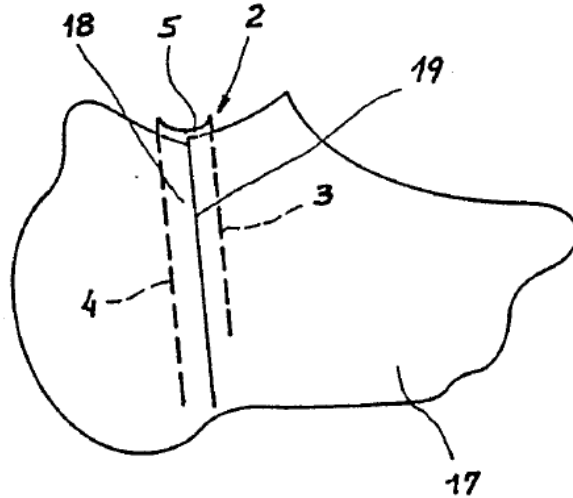
bone fragments” with “[t]he device installation layout . . . represented on fig.6.” *Id.* at 3:21–23; Ex.1002 ¶107.

Gauthier also teaches this limitation. Tines 3 and 4 extend from bridge portion 5 and are configured to be implanted into bone. An annotated version of Gauthier’s Figure 1 is reproduced below.



Gauthier expressly describes making drilled holes to receive rods/tines 3 and 4 in the bone parts and depicts the free ends of the tines implanted in bone. Ex.1010, 3:19–21, 4:36–47. Figure 7 of Gauthier, reproduced below, provides one example illustration of its tines implanted in the biological elements.

FIG. 7



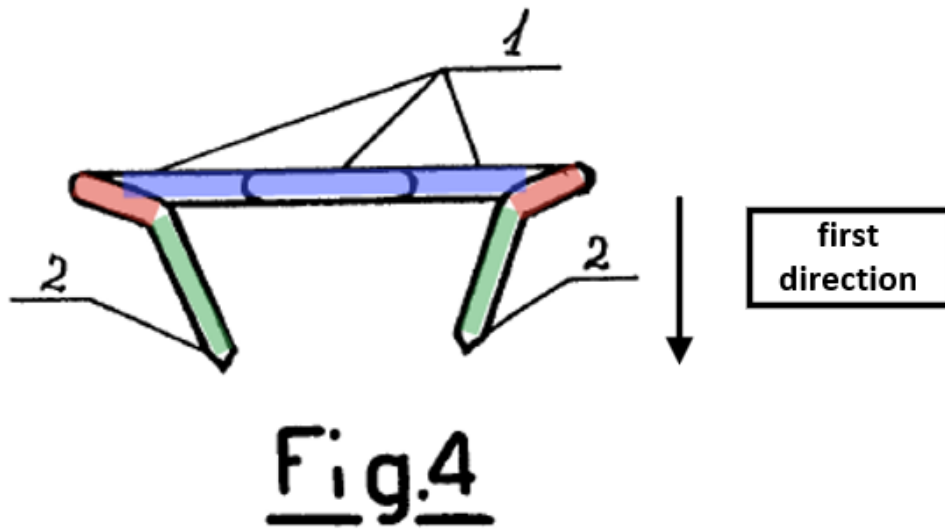
Gauthier states that “branches 3 and 4 are engaged in the bone.” *Id.* at 3:62; Ex.1002 ¶108.

e. Limitation 1[e]

Limitation 1[e] recites “each tine of the tines extending along a first direction defined between the bridge portion and a free end of the free ends thereof.”

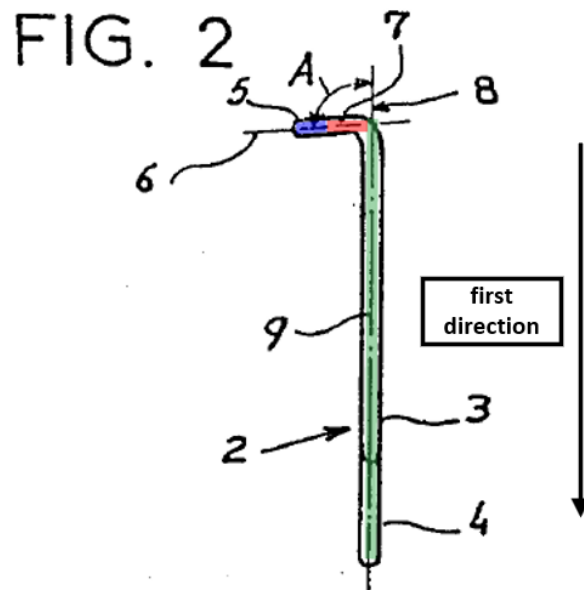
Kinmon teaches limitation 1[e] for the reasons set forth in §V.A.1.e.

EP '045 also teaches this limitation. An annotated version of EP '045's Figure 4 is provided below illustrating its teaching.



As seen above, tines 2 extend from bridge portion 1 in a first direction. Ex.1002 ¶109.

Gauthier likewise teaches this limitation. An annotated version of Gauthier's Figure 2 is provided below illustrating its teaching.



Gauthier's tines 3 and 4 extend along axes 9 from ends of bridge portion 5 to the free ends of tines 3 and 4. That direction is the first direction defined between the bridge portion and the tine free end. Ex.1002 ¶109.

f. Limitation 1[f]

Limitation 1[f] recites “maintaining the second state of the bridge portion.”

Kinmon teaches limitation 1[f] for the reasons set forth in §V.A.1.f.

Miller confirms the same maintaining step. Miller teaches opening a super-elastic staple into a splayed delivery state using an inserter and maintaining that state with a sliding lock during implantation. Ex.1008 ¶¶34–35.

EP '045 further confirms the need to maintain a deformed state until insertion. EP '045 teaches that the working part is deformed before installation to increase the distance between plunge legs, and that recovery after installation brings the legs closer together and develops compression. Ex.1009, 4:47–56; Ex.1002 ¶110.

Gauthier likewise teaches an elastic recall structure that applies contact pressure after implantation. Ex.1010, 4:36–47. A POSA would have understood that the deformed/opened state of an elastic recall clip must be maintained at least until the tines are positioned in prepared holes; otherwise, the stored recall energy would dissipate before the clip could apply contact pressure at the fracture zone. Ex.1002 ¶111.

g. Limitation 1[g]

Limitation 1[g] recites implanting the pair of tines into the pair of apertures to allow engagement of engagement mechanisms positioned on portions of the tines that substantially face the other tine.

Kinmon teaches implanting the pair of tines into apertures. Kinmon teaches that staple 1 is inserted into drilled holes while legs/tines 3 are pushed outward. Ex.1007 ¶¶92–93. Kinmon also teaches “spikes, barbs, or other similar type of projections 11 along the legs 3 of the staple 1” to stabilize staple placement in bone. Ex.1007 ¶85; Ex.1002 ¶113.

Kinmon does not expressly state that its projections are positioned on portions of the tines that substantially face the other tine. But Miller teaches that orientation. Miller’s staple includes unidirectional barbs along the legs, described as angling outward toward the web end of the staple to help hold the staple in position in bone after implantation. Ex.1008 ¶21. Miller’s Figures 8 and 9 depict barbs on opposing staple legs positioned along the inward-facing portions of the legs, facing toward the other leg/tine. Ex.1008 ¶21, Figs. 8–9; Ex.1002 ¶114.

An annotated version of Miller’s Figure 9 illustrating barb orientation is reproduced below.

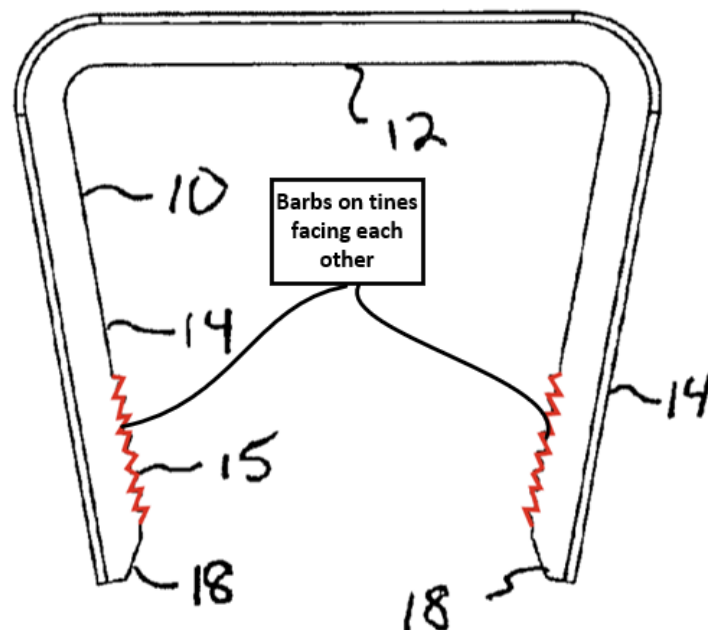


FIG. 9

As seen above, the barbs on opposite tines in Miller (outlined in red) face one another. A POSA would understand those inward-facing barbs as engagement mechanisms positioned on portions of the tines that substantially face the other tine. Ex.1002 ¶115.

A POSA would have found it obvious to implement Kinmon's spikes, barbs, or projections on the inward-facing portions of legs/tines 3, as taught by Miller. Ex.1002 ¶116. Kinmon and Miller both address compression staples inserted into bone and released to apply compression. Ex.1007 ¶¶3, 82, 85; Ex.1008 ¶¶6, 21. In Kinmon's memory-metal embodiment, legs 3 return inward toward one another after removal of the insertion tool. Ex.1007 ¶82. Placing the retention projections on the

inward-facing portions of legs/tines 3 would predictably engage bone in the direction of compression, resist withdrawal, and maintain fixation while the staple compresses the biological elements. Ex.1007 ¶¶82, 85; Ex.1008 ¶21; Ex.1002 ¶117.

h. Limitation 1[h]

Limitation 1[h] recites “releasing the potential energy of the elastic deformation of the second state of the bridge portion to apply a compressive force to the pair of biological elements via the tines and to engage the plurality of engagement mechanisms with the biological elements.”

Kinmon teaches limitation 1[h] for the reasons set forth in §V.A.1.h.

Miller confirms the same release step as taught in Kinmon. Miller teaches disengaging the inserter by releasing the sliding lock, allowing the handles to return to their original position, and releasing the staple to apply compressive force to adjacent bone segments. Ex.1008 ¶¶36–37. Miller expressly states that upon release, “the staple subsequently applies a compressive force (parallel to the web member) to the adjacent bone segments to press them into contact as the staple legs act to return to an unsplayed position.” Ex.1008 ¶6. Miller’s barbs engage the bone during and after release to inhibit withdrawal of the staple. Ex.1008 ¶21; Ex.1002 ¶119.

EP ’045 also teaches the same release of stored energy. After the working part is deformed to increase the distance between plunge legs, the working part recovers its earlier set form, the plunge legs are brought closer together, the legs are clamped

in bone, the bone fragments are clamped with one another, and the device develops compression. Ex.1009, 4:47–56; Ex.1002 ¶120.

Gauthier likewise teaches that the elasticity of bent central part 5 of clip 2 is used to assure contact pressure between the surfaces of fracture zone 19. Ex.1010, 4:45–47; Ex.1002 ¶121. A POSA would have understood that, after rods/tines 3 and 4 are implanted and the delivery-state constraint is removed, bridge 5 recovers toward its lower-energy configuration and urges rods/tines 3 and 4 toward one another. Ex.1002 ¶122.

As discussed for limitation 1[g], it would have been obvious to position Kinmon’s spikes, barbs, or projections 11 on inward-facing portions of legs/tines 3 to engage bone as the staple returns toward its compressed configuration. Ex.1007 ¶¶82, 85; Ex.1008 ¶21; Ex.1002 ¶123.

i. Combined Teachings

A POSA would have been motivated to combine the teachings of Kinmon, Miller, EP ’045, and Gauthier, and would have had a reasonable expectation of success in doing so. Ex.1002 ¶124.

The combination is obvious because it represents “the combination of familiar elements according to known methods” that “yield[s] predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Each reference addresses the same technical field and the same operative problem: how to configure and deliver a

compression staple that stores elastic energy in an open delivery state and releases that energy after implantation to apply compressive force between bone fragments. The convergence of Kinmon, Miller, EP '045, and Gauthier on the same solution confirms that the claimed method represents the predictable, expected approach in the art. *KSR*, 550 U.S. at 421 (obvious where “there are a finite number of identified, predictable solutions” and “a person of ordinary skill has good reason to pursue the known options”). Ex.1002 ¶¶124–126.

The references collectively address the same compression-type staple. Kinmon and Miller teach the complete guide/insertor delivery sequence for opening, maintaining, implanting, and releasing a compression staple. EP '045 confirms that arched bridge deformation increases leg spacing and that recovery develops compression. Gauthier confirms that an angled curved bridge can be placed for cortical rest and can use elastic bridge recovery to apply contact pressure. Together, those teachings would have led a POSA to use known bridge-shape and bridge-orientation refinements in Kinmon's compression-staple method. Ex.1002 ¶125.

These complementary teachings would have provided a POSA with a reason to use known bridge-shape and bridge-orientation refinements in Kinmon's guide-based compression-staple method, with a reasonable expectation that the resulting method would operate as intended. Ex.1002 ¶127.

Kinmon teaches the claimed method sequence. Kinmon's memory-metal

staple has a C-shaped bridge 2 and legs/tines 3. A POSA would have found it obvious to use EP '045's arched bridge teachings in combination with Kinmon's C-shaped compression staple teachings because EP '045 teaches the same operative relationship Kinmon uses: bridge deformation increases leg spacing, and bridge recovery decreases leg spacing to apply compression. This would have been a predictable bridge-shape implementation, not a change in Kinmon's principle of operation. Ex.1002 ¶129.

A POSA also would have found it obvious to use Gauthier's angled curved bridge teachings in combination with Kinmon's teachings because Gauthier teaches that a curved bridge may be oriented relative to the tines/rods for cortical rest and elastic contact pressure. Ex.1002 ¶130. That teaching would have been directly applicable to Kinmon's bridge because Kinmon already uses a C-shaped bridge to store and release compression energy. The Gauthier teaching provided a known angled bridge orientation for seating the bridge against bone while preserving Kinmon's method of opening, holding, inserting, and releasing the staple. Ex.1002 ¶130.

This combination of teachings is not the result of reconstructing a new device from disparate references. It is the predictable use of known compression-staple bridge geometries and known delivery tools in Kinmon's already-disclosed compression-staple method. Ex.1002 ¶131.

Accordingly, claim 1 would have been obvious over Kinmon in view of Miller, EP '045, and Gauthier.

2. Claim 2

Claim 2 depends from claim 1 and adds that the compressive force applied via the tines comprises the compressive force closing a space between the biological elements.

Kinmon teaches this limitation for the reasons set forth in §V.A.2.

Miller confirms the same point. Miller teaches that, after release of the inserter, the staple applies a compressive force to adjacent bone segments to press them into contact as the staple legs return toward an unsplayed position. Ex.1008 ¶6; Ex.1002 ¶132.

EP '045 also teaches this limitation because, after the deformed working part recovers, the plunge legs are brought closer together, the legs are clamped in bone, the bone fragments are clamped with one another, and the device develops compression. Ex.1009, 4:47–56; Ex.1002 ¶133.

Gauthier likewise teaches using clip 2 as an elastic recall means and states that the elasticity of bent central part 5 assures contact pressure between the surfaces of fracture zone 19. Ex.1010, 4:36–47. Assuring contact pressure between fracture surfaces is compression that closes or reduces the space between biological elements. Ex.1002 ¶134.

Accordingly, claim 2 would have been obvious over Kinmon, Miller, EP '045, and Gauthier.

3. Claim 3

Claim 3 depends from claim 1 and recites that “maintaining the second state of the bridge portion comprises engaging the staple with a staple engagement portion of a guide.”

Kinmon teaches this limitation for the reasons set forth in §V.A.3.

Miller confirms the same tool function. Miller teaches an inserter that engages the staple, splays the staple legs outward, and maintains the splayed state with a lock while the staple legs are positioned in pilot holes. Ex.1008 ¶¶25–26, 34–35. Miller’s inserter tips constitute a staple engagement portion because they engage the staple and hold it in the splayed second state during insertion. Ex.1002 ¶136.

EP '045 teaches the underlying need to maintain the deformed state because its working part is deformed before installation so that the distance between plunge legs increases, and the device is then inserted before recovery produces compression. Ex.1009, 4:47–56; Ex.1002 ¶137.

Gauthier teaches an elastic bridge/tine structure that applies recall compression after implantation. Ex.1010, 3:6–13, 4:36–47; Ex.1002 ¶138. A POSA would have understood that Gauthier’s elastic recall clip, like the staples of Kinmon and Miller, would be maintained in an opened delivery state until its tines were

positioned in prepared holes. Ex.1002 ¶139.

The combined teachings render claim 3 obvious because Kinmon and Miller teach the claimed staple-engagement function, while EP '045 and Gauthier confirm that maintaining a deformed bridge state until insertion is the predictable way to preserve stored elastic energy for post-insertion compression. Ex.1002 ¶140.

Accordingly, claim 3 would have been obvious over Kinmon, Miller, EP '045, and Gauthier.

4. Claim 4

Claim 4 depends from claim 3 and recites that “releasing the energy of the elastic deformation of the second state of the bridge portion comprises disengaging the staple from the staple engagement portion of the guide.”

Kinmon teaches this limitation for the reasons set forth in §V.A.4.

The reason to disengage the staple engagement portion is to permit the deformed bridge to recover and apply its intended compressive force. Ex.1002 ¶141. Miller likewise teaches disengaging the inserter to release stored elastic energy. Miller explains that, to remove the inserter and tips from the staple, the sliding lock is released and the handles return, disengaging the tips from the staple. Ex.1008 ¶26; Ex.1002 ¶142. After release, the staple applies compression as the legs return toward an unsplayed position. Ex.1008 ¶6.

EP '045 teaches that the deformed working part recovers its earlier set form

and brings the plunge legs closer together, thereby clamping the bone fragments together and developing compression. Ex.1009, 4:47–56. Gauthier similarly teaches that the elasticity of bent central part 5 assures contact pressure between fracture surfaces. Ex.1010, 4:45–47; Ex.1002 ¶143–144.

Accordingly, claim 4 would have been obvious over Kinmon, Miller, EP '045, and Gauthier.

5. Claim 5

Claim 5 depends from claim 1 and recites that the bridge and the pair of tines comprise substantially rectangular cross-sections.

Kinmon teaches that the legs 3 of staple 1 can be formed in different shapes, including flat or circular shapes. Ex.1007 ¶73. That disclosure confirms that cross-sectional shape was a selectable design parameter in compression-staple construction. Ex.1002 ¶146.

Miller teaches flat-sided staple geometry. Miller's Figures 8 and 9 show flat-sided web and leg structures, and Miller describes staple dimensions including web length, leg length, and thickness. Ex.1008 ¶21; Figs. 8–9. A POSA would have understood Miller's flat-sided staple stock as corresponding to a substantially rectangular cross-section for the bridge/web and legs/tines. Ex.1002 ¶147.

EP '045 and Gauthier confirm that the operative compression function depends on elastic deformation and recovery of the bridge/working part, not on a

uniquely required circular cross-section. EP '045 teaches deformation and recovery of an arched working part to bring plunge legs closer together and generate compression. Ex.1009, 4:47–56. Gauthier teaches that the elasticity of bent central part 5 provides contact pressure between bone surfaces. Ex.1010, 4:36–47. Neither reference limits elastic compression to a cross-section that would exclude known flat or rectangular staple stock. Ex.1002 ¶148.

A POSA would have understood the substantially rectangular cross-section as a known structural variant providing predictable tradeoffs, including directional stiffness, flat bearing surfaces for tool engagement, and ease of forming barbs or projections. Ex.1002 ¶149. The '693 Patent itself treats circular and rectangular cross-sections as alternative staple geometries rather than as altering the claimed method. Ex.1001, 2:14–18, 9:12–16.

Accordingly, claim 5 would have been obvious over Kinmon in view of Miller, EP '045, and Gauthier.

6. Claim 6

Claim 6 depends from claim 1 and recites that the leg portions comprise linear portions extending opposite the open space relative to each other.

Kinmon teaches or renders obvious this limitation because its C-shaped bridge 2 includes terminal regions adjacent legs/tines 3 on opposite sides of the open space for the reasons set forth in §V.A.6. Ex.1007 ¶82; Ex.1002 ¶151. A POSA would

have understood the ends of Kinmon's C-shaped bridge as the claimed opposite leg portions or, at minimum, would have found it obvious to implement those terminal regions as linear portions to provide a predictable transition between the curved bridge and the tines. Ex.1002 ¶152.

EP '045 further teaches arched working parts connected to plunge legs and depicts bridge portions having curved portions and terminal portions extending linearly toward the legs on opposite sides of an open space. Ex.1002 ¶153. EP '045 explains that the middle part of the device is arch-shaped and that the working part deforms to increase the distance between plunge legs before recovering to apply compression. Ex.1009, 1:50–51, 4:47–56.

Gauthier also teaches the limitation. Gauthier's bridge 5 includes opposite portions extending from the curved central portion toward rods/tines 3 and 4, and those portions lie on opposite sides of the open space bounded by the bridge and tines and extend linearly. Ex.1010, 3:6–13; Figs. 1–2; Ex.1002 ¶154.

Further, linear terminal portions would have been a predictable bridge-shape implementation because they preserve the same compression function while providing defined load paths from the curved bridge into the tines. The claimed linearity does not change the method steps of forming apertures, deforming the bridge, maintaining the deformed state, implanting the tines, and releasing stored energy. It merely specifies a known geometry for the staple structure used in that

method. Ex.1002 ¶155.

Accordingly, claim 6 would have been obvious over Kinmon in view of Miller, EP '045, and Gauthier.

7. Claim 7

Claim 7 depends from claim 1 and recites that “the curved portion is angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines.”

Kinmon teaches that bridge orientation relative to the staple legs was a design consideration. Kinmon states that bridge 2 may be curved to the side so that its axis is substantially perpendicular to the staple legs, or curved upward so that its axis is substantially parallel to the staple legs. Ex.1007 ¶81; Ex.1002 ¶157. A POSA would have understood Kinmon as recognizing that the bridge orientation relative to the tines could be selected to achieve the desired compression and seating characteristics. Ex.1002 ¶158.

Gauthier supplies the specific angled-bridge teaching. As shown in the annotated Gauthier Figure 2 below, bridge portion 5 is angled downward toward the free ends of tines 3 and 4, consistent with the '693 Patent's examples of a bridge curved or angled toward the tine free ends, including the example discussed in §III.B and shown in Figure 20 of the '693 Patent, reproduced below.

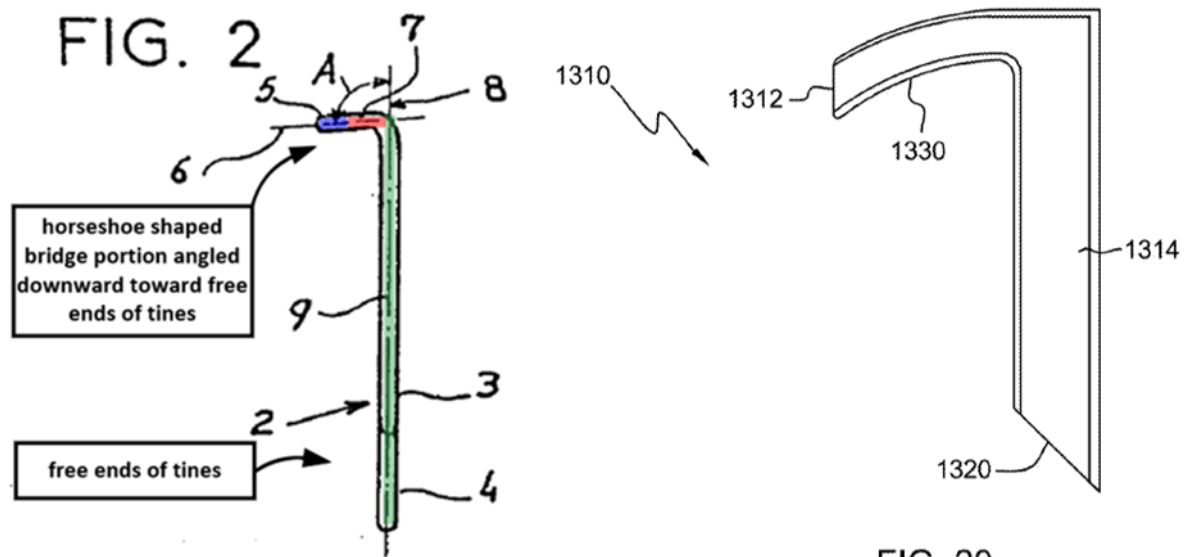
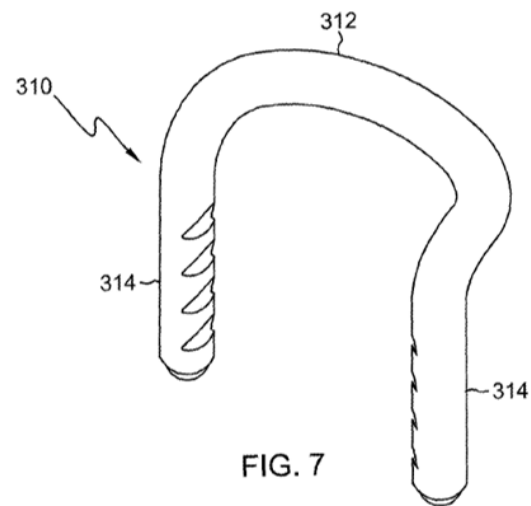
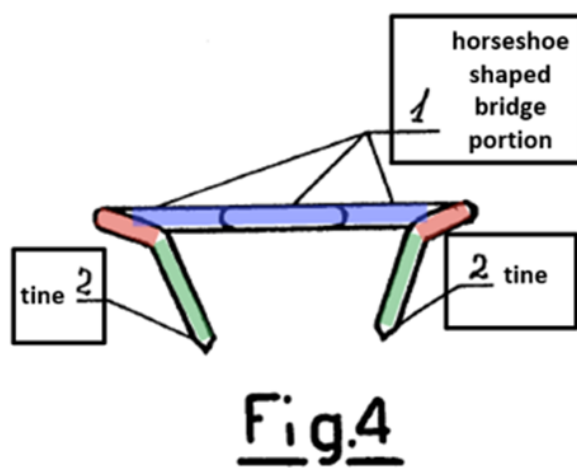


FIG. 20

Gauthier teaches a curved bridge-forming central part 5 arranged so that the plane containing the bridge's median axis 6 forms a large angle (A), slightly greater than 90 degrees, with the plane containing the median axes 9 of rods/tines 3 and 4. Ex.1010, 3:6–16. Gauthier also teaches bringing the bridge-forming part to cortical rest and using the elasticity of bent central part 5 to assure contact pressure between fracture surfaces. *Id.* at 3:64–65, 4:45–47. Because Gauthier's bridge plane forms an angle greater than 90 degrees relative to the tine axis, the curved bridge portion extends angled downward toward the bone and toward the free ends of the tines rather than being perpendicular to or directed away from them. A POSA would therefore have understood Gauthier's bridge geometry as disclosing a curved portion angled downwardly toward the tine free ends as recited in the claim. Ex.1002 ¶¶159–

160.

EP '045 corroborates that downward or bone-conforming bridge orientation was applicable to compression-staple bridge design. An annotated version of Figure 4 from EP '045 is reproduced below, consistent with the '693 Patent's examples of a bridge curved or angled toward the tine free ends, including the example discussed in §III.B and shown in Figure 7 of the '693 Patent, reproduced below.



As seen above in Figure 4, EP '045's horseshoe shaped bridge portion (red and blue highlighting), including the curved portion (blue highlighting) is shown extending at a downward angle relative to its tines (green highlighting). *See* Ex.1009, 3:6 (describing Figure 4 as a side view). EP '045 teaches arched working parts and explains that tight adjoining of the device to the bone surface is achieved by an arched component shaped according to the curved metaphysis surface. Ex.1009, 3:50–56. EP '045 also teaches deforming the working part to increase leg spacing

and then recovering the working part to bring the legs closer together and develop compression. *Id.* at 4:47–56; Ex.1002 ¶161.

To the extent any modification is necessary, a POSA would have found it obvious to angle Kinmon’s curved bridge downward toward the free ends of the tines based on Gauthier’s bridge-orientation teaching, as well as EP ’045’s teaching. Ex.1002 ¶162. Kinmon already uses bridge deformation and recovery to apply compression. Gauthier teaches that an angled curved bridge can be placed for cortical rest and used to apply elastic contact pressure. Ex.1010, 3:64–65, 4:45–47. EP ’045 teaches that the “working part can have any shape depending on specific osteosynthesis.” Ex.1009, 4:5–9. Applying a downwardly angled bridge orientation to Kinmon would have been a predictable way to improve bridge seating against the bone depending on bone geometry while maintaining the same open–hold–insert–release compression method, particularly where Kinmon already expressly contemplates orientations of its bridge ranging from perpendicular to parallel relative to its tines. Ex.1002 ¶163. A POSA would have used Gauthier’s bridge-orientation teaching for the same purpose Gauthier discloses (*i.e.*, cortical rest and elastic contact pressure) while preserving Kinmon’s delivery sequence and compression mechanism. Ex.1002 ¶164.

A POSA would have had a reasonable expectation of success because the modification would not alter Kinmon’s delivery sequence or compression principle.

Ex.1002 ¶165. The staple would still be opened by separating the tines, held in the opened state, inserted into prepared holes, and released so the bridge drives the tines toward one another. The only change would be the known orientation of the curved bridge relative to the tines, as taught by Gauthier and corroborated by EP '045.

Ex.1002 ¶165. Because Gauthier's bridge plane is angled relative to the plane of the rods/tines and is brought to cortical rest, a POSA would have understood the curved bridge portion as angled toward the tine free ends when applied in Kinmon's method for cortical rest, with the curved portion directed toward the tine free ends and the bone surface below. Ex.1002 ¶166.

Accordingly, claim 7 would have been obvious over Kinmon in view of Miller, EP '045, and Gauthier.

8. Claim 8

Claim 8 depends from claim 1 and recites that the pair of tines extend from opposing ends of the bridge portion, the ends having inner surfaces opposite each other about the open space.

Kinmon teaches this limitation for the reasons set forth in §V.A.8.

EP '045 also teaches the limitation because plunge legs 2 extend from opposite sides of the arched working part 1, with the inner surfaces of the opposite bridge ends facing one another about the open space bounded by the arched bridge. Ex.1009, 3:5–10; Figs. 3–4; Ex.1002 ¶168.

Gauthier also teaches the limitation. Gauthier explains that lateral rods 3 and 4 are connected together by curved bridge-forming central part 5. Ex.1010, 3:6–10. The rods/tines extend from opposing ends of bridge 5, and the bridge ends have inner surfaces opposite each other about the open space bounded by the bridge and adjacent portions. Ex.1002 ¶169.

Accordingly, claim 8 would have been obvious over Kinmon in view of Miller, EP '045, and Gauthier.

9. Claim 9

Claim 9 is an independent claim that recites a method of compressing biological elements and includes limitations corresponding to claim 1, but it does not require that the drill-guide openings be spaced the second distance. The combined teachings of Kinmon, Miller, EP '045, and Gauthier render claim 9 obvious for the same reasons discussed for claim 1 and claim 7. Ex.1002 ¶170.

a. Limitation 9[a]

Limitation 9[a] recites forming a first pair of apertures within a pair of biological elements. Gauthier teaches making drilled holes to receive rods/tines 3 and 4 in the bone parts to be held. Ex.1010, 3:19–21. Miller and Kinmon confirm that such holes were conventionally formed using drill guides for staple insertion. Ex.1008 ¶¶31–32; Ex.1007 ¶¶6, 87–88. Thus, limitation 9[a] is taught or rendered obvious for the reasons stated for limitation 1[a]. Ex.1002 ¶171.

b. Limitations 9[b][i]–[ii]

Limitations 9[b][i] and 9[b][ii] correspond to limitations 1[b][i] and 1[b][ii]. These limitations are taught or rendered obvious for the reasons stated for limitations 1[b][i]–[ii]. Ex.1002 ¶172.

c. Limitation 9[c]

Limitation 9[c] corresponds to limitation 1[c]. This limitation is taught or rendered obvious for the reasons stated for limitation 1[c]. Ex.1002 ¶173.

d. Limitation 9[d]

Limitation 9[d] corresponds to limitation 1[d]. This limitation is taught or rendered obvious for the reasons stated for limitation 1[d]. Ex.1002 ¶174.

e. Limitation 9[e]

Limitation 9[e] corresponds to limitation 1[e]. This limitation is taught or rendered obvious for the reasons stated for limitation 1[e]. Ex.1002 ¶175.

f. Limitation 9[f]

Limitation 9[f] corresponds to claim 7. This limitation is taught or rendered obvious for the reasons stated for claim 7. Ex.1002 ¶176.

g. Limitation 9[g]

Limitation 9[g] corresponds to limitation 1[f]. This limitation is taught or rendered obvious for the reasons stated for limitation 1[f]. Ex.1002 ¶177.

h. Limitation 9[h]

Limitation 9[h] corresponds to limitation 1[g]. This limitation is taught or

rendered obvious for the reasons stated for limitation 1[g]. Ex.1002 ¶178.

i. Limitation 9[i]

Limitation 9[i] corresponds to limitation 1[h]. This limitation is taught or rendered obvious for the reasons stated for limitation 1[h]. Ex.1002 ¶179.

10. Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in applying the bridge-shape teachings of EP '045 and Gauthier, together with inward-facing barb teachings of Miller, to Kinmon's compression-staple method. Ex.1002 ¶180.

Kinmon already teaches the operative method. Its memory-metal staple is memorized in a compressed position, an insertion tool pushes the legs outward, the staple is inserted into drilled holes while held outward, and removal of the insertion tool allows the staple to return toward its compressed position. Ex.1007 ¶¶82, 87–93; Ex.1002 ¶181.

EP '045 would have given a POSA reason to use arched bridge geometry (*i.e.*, the arched-surface, horseshoe-shaped bridge geometry required by limitation 1[c]) in Kinmon's method because EP '045 teaches the same deformation-and-recovery mechanics: the bridge is deformed to increase leg spacing, and recovery brings the legs closer together to develop compression. Ex.1009, 4:47–56; Ex.1002 ¶182.

Gauthier would have given a POSA reason to use angled curved bridge geometry (*i.e.*, the vertically angled bridge orientation required by claim 7's "angled

downwardly toward the free end” limitation) in Kinmon’s method because Gauthier teaches a curved bridge-forming central part angled relative to the rods/tines, positioned for cortical rest, and used to apply elastic contact pressure between fracture surfaces. Ex.1010, 3:6–16, 3:64–65, 4:45–47; Ex.1002 ¶183.

Applying those teachings to Kinmon would not have required changing Kinmon’s principle of operation. Kinmon’s staple would still be opened, held, inserted, and released. The guide holes would still be formed at the delivery spacing. Ex.1002 ¶184. The bridge would still store elastic energy in the opened state and release that energy after implantation. EP ’045 and Gauthier would merely provide known bridge-shape and bridge-orientation refinements for the same compression-staple function. Ex.1002 ¶184.

For the same reasons stated in Ground 1’s Reasonable Expectation of Success section (§V.A), a POSA would have had a reasonable expectation of success in applying Miller’s inward-facing barb orientation and substantially rectangular staple geometry to Kinmon’s compression-staple method. Ex.1002 ¶185. The expectation of success for the Miller-based aspects of the combination is the same in Ground 2 as in Ground 1.

The proposed combination therefore involves predictable use of known compression-staple components according to their established functions. Ex.1002 ¶186. Kinmon supplies the compression-staple method. Miller supplies known

delivery-tool, lock, barb, and flat-sided staple teachings. EP '045 supplies arched bridge deformation/recovery teachings. Gauthier supplies angled bridge orientation, cortical-rest, and elastic-contact-pressure teachings. A POSA would have expected the combined method to work for its intended purpose: delivering a compression staple in an opened state, maintaining the opened state during insertion, and releasing stored elastic energy after implantation to compress biological elements. Ex.1002 ¶186.

For at least these reasons, claims 1–9 would have been obvious over Kinmon, Miller, EP '045, and Gauthier.

11. Summary

Claims 1–9 would have been obvious over Kinmon, Miller, EP '045, and Gauthier. Kinmon teaches the primary claimed method sequence, including forming apertures with guide openings, elastically deforming a C-shaped bridge to increase tine spacing, maintaining the opened state, implanting the tines, and releasing stored energy to compress bone. Miller confirms conventional guide/inserters/lock delivery and supplies inward-facing barb and flat-sided staple teachings. EP '045 confirms arched bridge deformation and recovery to apply compression. Gauthier confirms angled curved bridge geometry for cortical rest and elastic contact pressure. The combination preserves Kinmon's principle of operation and uses the secondary references for directly applicable, predictable compression-staple teachings.

Ex.1002 ¶187.

VI. STANDING

Petitioner is not barred or estopped from requesting *inter partes* review on these grounds.

VII. STIPULATION

Petitioner stipulates that, if this Petition is instituted, it will not pursue in district court the grounds identified in this Petition or that could have been reasonably raised in this IPR (*i.e.*, any ground that reasonably could have been raised under 35 U.S.C. §§102 or 103 on the basis of prior art patents or printed publications) with regard to the claims subject to institution. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (PTAB Dec. 1, 2020) (precedential as to §II.A).

VIII. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. If Patent Owner identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

IX. MANDATORY NOTICES

A. Real Party-In-Interest

Petitioner identifies Treace Medical Concepts, Inc. as the real party-in-interest.

B. Related Matters

To the best of Petitioner's knowledge, other judicial or administrative matters that would affect, or be affected by, a decision in the proceeding include:

Paragon 28, Inc. et al v. Treace Medical Concepts, Inc. et al, C.A. No. 1-25-cv-01092 (Dist. Del.); and

Inter partes review filed concurrently herewith directed to U.S. Patent No. 12,303,139.

C. Lead and Backup Counsel Information

Petitioner provides the following designation of counsel, all of whom are identified in Petitioner's Power of Attorney.

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D. Service Information

Please direct all communication to lead counsel and back-up counsel at the addresses above. Petitioner also consents to electronic service at:

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X. CONCLUSION

Petitioner respectfully requests the Board grant *inter partes* review and find all challenged claims unpatentable.

IPR2027-00007
Patent 11,304,693

Dated: October 6, 2026

Respectfully Submitted,

/Jeremy Plenzler/

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 14,000 words provided in 37 C.F.R. § 42.24(a)(1)(i). The word processing program used to prepare the Petition indicates that it contains 13,993 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a), (that is, the word count does not include the table of contents, table of authorities, the exhibit list, the claim listing, the certificate of service, or the certificate of compliance).

Dated: October 6, 2026

/Jeremy Plenzler/
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Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that on the 6th of October 2026, a complete and entire copy of the foregoing “PETITION FOR *INTER PARTES* REVIEW,” including any exhibits, was served to the below counsel of record for Patent Owner via FedEx Standard Overnight.

Heslin Rothenberg Farley & Mesiti PC
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A courtesy copy was sent to Patent Owner’s litigation counsel Ali S. Razai at: ali.razai@morganlewis.com.

Dated: October 6, 2026

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