

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

DECLARATION OF DANIEL C. FARBER, MD
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 11,304,693

I, Daniel C. Farber, do hereby declare:

1. I am making this declaration (the "Declaration") at the request of Treace Medical Concepts, Inc. ("Treace").

2. I am being compensated for my work in this matter, and I am being reimbursed at cost for any expenses. My compensation in no way depends upon the outcome of this proceeding.

3. In preparing this Declaration, I considered the following materials:

Exhibit No.	Description
1001	U.S. Patent No. 11,304,693 to Weiner, et al. ("the '693 Patent")
1007	U.S. Patent App. Publ. No. 2010/0125301 A1 to Kinmon, et al. ("Kinmon")
1008	U.S. Patent App. Publ. No. 2014/0277516 A1 to Miller, et al. ("Miller")
1009	European Patent App. Publ. No. EP0743045 A2, to Davydov et al. ("EP '045")
1010	U.S. Patent No. 4,838,254 to Gauthier ("Gauthier")
1003	Curriculum Vitae of Daniel C. Farber, M.D.

I. BACKGROUND AND QUALIFICATIONS

4. I am an orthopaedic surgeon specializing in foot and ankle surgery. My current CV is being submitted as Exhibit 1003.

5. I received my Bachelor of Arts undergraduate degree in 1992 from Dartmouth College and my Doctor of Medicine degree in 1997 from the University of Maryland School of Medicine. In 2002, I completed my residency in Orthopaedic Surgery at Penn State Milton S. Hershey Medical Center. In 2003, I held a fellowship in Orthopaedic Surgery, Foot and Ankle Surgery, at the Mayo Clinic in Jacksonville, Florida. I am board certified in Orthopaedic Surgery by the American Board of Orthopaedic Surgery.

6. My primary practice is with the Lehigh Valley Health Network where I am the Vice Chair, Academic Affairs, for the Lehigh Valley Orthopedic Institute.

7. For the past 22 years, I have performed between 250 and 350 surgeries per year, of which, roughly 50-80 per year involved bunion correction. Additionally, I have performed other podiatric and orthopaedic surgeries involving correcting and/or fusing joint deformities in the foot and ankle, including triple arthrodesis, 1st metatarsophalangeal joint fusion, midfoot (tarsal bone) fusions, osteotomies of the 1st metatarsal, cuneiforms, calcaneus, tibia, and fibula, and others.

II. NATURE OF MY ASSIGNMENT

8. I have been asked to provide my opinion as to whether the claims of the ‘693 Patent would have been obvious to a person of ordinary skill in the art (“POSA”) at the time of the alleged invention, in view of the prior art.

9. The opinions I am expressing in this Declaration are based on the application of my training and technical knowledge and experience to the evaluation of certain prior art to the '693 Patent.

10. I am not an expert in patent law. Attorneys from McCaulley Law Group and Van Hoven PC have provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of how I must apply current principles related to patent validity to my analysis.

11. It is my understanding that in determining whether a patent claim is obvious in view of the prior art, the Patent Office construes the claim by giving the claim language its ordinary and customary meaning ascribed to it by a person of ordinary skill in the art ("POSA") at the time of the invention, consistent with the descriptive language contained in the other parts of the patent. I also understand that in reading the claim, I must not add into the claim other language that appears in the description portion of the patent; in other words, I must not restrict the scope of the claim terms by adding to the claim other parts of the patent's descriptive language that are not expressed literally in the claim.

12. I understand that a claim is "obvious," and therefore unpatentable, if the claimed subject matter as a whole would have been obvious to a POSA at the time of the invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed

subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

13. In determining the scope and content of the relevant prior art, I understand that a reference is considered relevant prior art if it falls within the field of the inventor's endeavor. The '693 Patent is directed to methods of using a compressive orthopedic staple with an associated drill guide. The patent describes a familiar 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. In addition, a reference is relevant prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering their problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

14. To assess the differences between prior art and the subject matter claimed in the patent, I understand that the law requires the claimed invention to be considered as a whole. Thus it must be shown that a POSA at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have been motivated to select the elements from the

prior art and combine them in the claimed manner, and had a reasonable expectation of success in doing so.

15. I further understand that the obviousness analysis must be performed from the perspective of a POSA at the time of the invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness.

16. 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 explains that “staples are commonly used to close openings, incisions, or wounds.” Id. at 28–29. The disclosure discusses staples used in medical procedures, but does not limit to any particular field or portion of the anatomy.

LEVEL OF ORDINARY SKILL IN THE ART

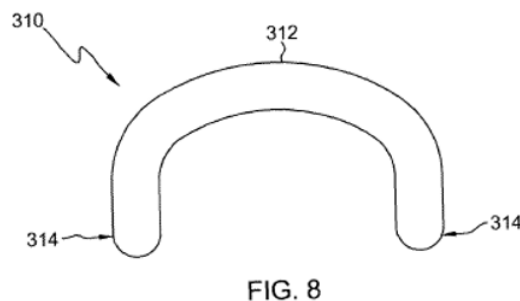
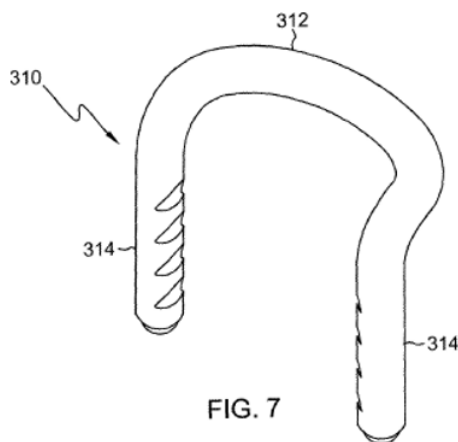
17. It is my opinion that a POSA would have had a medical degree and at least 3 years of experience performing surgery using staples to compress bone portions. It is also my opinion that a POSA could alternatively have included an engineer with a bachelor's degree in mechanical or biomedical engineering and at least 3 years of experience designing surgical fixation staples to compress bone portions and related installation mechanisms, or a collaborative team combining

such clinical and engineering expertise. My opinions expressed in this Declaration would be the same under any of these alternative articulations of the level of ordinary skill in the art. Several of my opinions below address mechanical relationships, for example, how the cross-sectional shape of a staple affects its stiffness in different directions, where a staple deforms when its legs are spread apart, and how the orientation of the bridge relative to the tines affects seating and load transfer. My understanding of those features is based on my experiences using staples in my practice.

CLAIM CONSTRUCTION

A. “substantially horseshoe shaped bridge portion”

18. Claims 1 and 9 each recite “a substantially horseshoe shaped bridge portion of a staple.” The ‘693 Patent provides examples offset bridges having the recited “horseshoe shape.” Figures 7 and 8 of the ‘693 Patent, reproduced below, provide one example of a substantially horseshoe shape.



Referring to Figures 7 and 8, the ‘693 Patent explains that “offset bridge 312 of a staple 310 according to the present discourse 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. That is, according to the ‘693 Patent, a generally C-shaped structure is considered an example of “substantially horseshoe shaped.”

B. “angled downwardly toward the free end”

19. 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 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. Another example is shown in Figures 19 and 20, reproduced below.

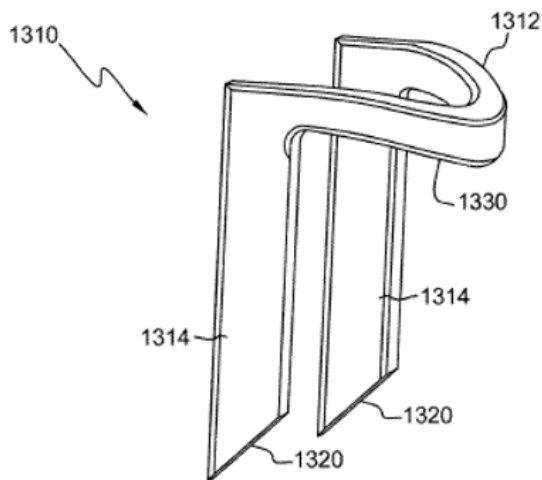


FIG. 19

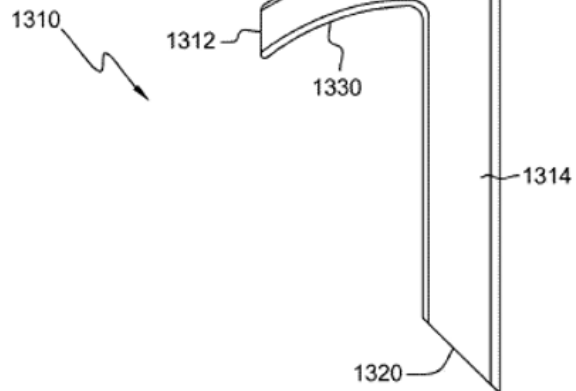


FIG. 20

“[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.” 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. Because the claim measures the angle “relative to a longitudinal dimension of a tine,” a POSA would have understood “downwardly

toward the free end” to refer to the direction along the tine’s longitudinal axis toward its free end, regardless of the orientation in which a staple is drawn. A curved portion lying in a plane perpendicular to the tine at the bridge/tine junction is not angled toward the free end; a curved portion is angled downwardly toward the free end when it is inclined relative to that plane such that it progresses toward the tine’s free end. In Figure 20, bridge 1312 extends laterally away from the top of tine 1314 and curves toward free end 1320 as it does so. In Figure 7, the portion of curved bridge 312 that descends from the crown of the bridge to the top of the right-hand tine 314 progresses toward the free end of that tine as it extends toward the top of the tine.

C. “bounding an open space”

20. 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.” The phrase “bounding an open space” does not appear in the ‘693 Patent other than the claims. The phrase “open space” is found only in the claims. The plain language of the claim requires only 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 in any way. That is, consistent with the plain and ordinary meaning of the claim language, “bounding an open space” corresponds to surrounding only a portion of the open space. I apply that understanding to each

reference below by identifying the surfaces that face the open space, the portions that bound its sides, and the side on which it remains open.

KINMON PRIOR ART REFERENCE

21. 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. In its discussion of the prior art, 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.

22. 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 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, as discussed further below with respect to limitation 1[b][ii].

MILLER PRIOR ART REFERENCE

23. Miller is directed to a bone staple storage, an inserter, and a method for use therewith, and teaches a fusion implant system for a generally horseshoe-shaped (i.e., U-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.

EP '045 PRIOR ART REFERENCE

24. 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).

GAUTHIER PRIOR ART REFERENCE

25. 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 bridgeforming central part 5,” with “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).

ANALOGOUS ART

26. Kinmon, Miller, Gauthier, and EP '045 are analogous art to the challenged claims of the '693 Patent. 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.

27. 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. Miller is in the same field because it teaches bone staple storage, 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. 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. 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.

28. The references are also reasonably pertinent to the same problem addressed by the '693 Patent: providing a compression staple having tines and a bridge portion that can be opened, inserted into prepared bone apertures, and released to apply compressive force between biological elements. Kinmon addresses the related delivery problem of 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

complete delivery method. Ex.1008 ¶¶29–37. Gauthier addresses the related structural problem of bridge shape and orientation 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. A POSA would have recognized that using a compression staple includes placing the holes at the spacing the legs will have when inserted, holding the staple open during insertion, obtaining purchase of the legs in bone so that the restoring force is transmitted to the bone, and seating the offset bridge against the cortical surface. Kinmon and Miller address the first three of those tasks, and Gauthier and EP '045 address the shape and orientation of the bridge relative to the bone surface. Ex. 1007 ¶¶ 6, 82, 85, 87–93; Ex. 1008 ¶¶ 21, 31–37; Ex. 1010, 3:6–16, 3:64–65; Ex. 1009, 3:50–56. That EP '045 describes applications including long tubular bones does not diminish its pertinence, because the teachings relied upon here, namely, the relationship between the curvature of the arched working part and the spacing of its legs and the shaping of the working part to conform to the bone surface, do not depend on the size of the bone. Ex. 1009, 3:50–56, 4:47–56. The same is true of Gauthier's teachings regarding the orientation of its bridge relative to its rods and cortical rest.

29. 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.

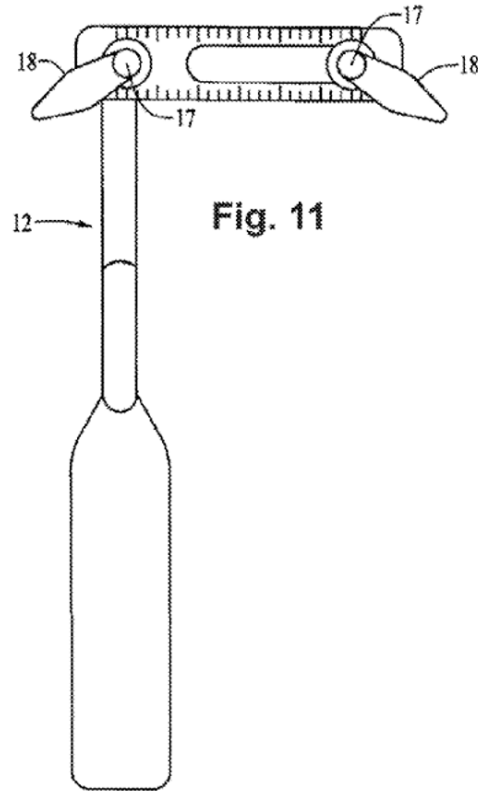
III. OBVIOUSNESS OF CLAIMS 1–9 OVER KINMON AND MILLER

CLAIM 1

30. 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 held outward and then returns to its compressed position after removal of the insertion tool. Id. ¶ 82. This is a method of compressing biological elements.

Limitation 1[a]

31. 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.” 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.

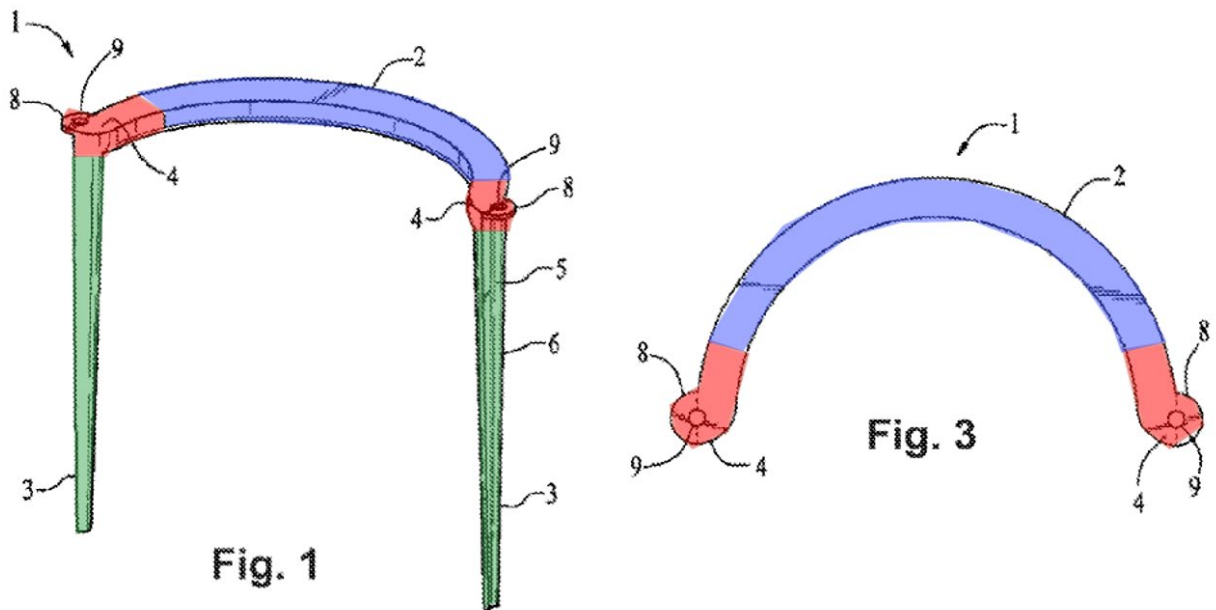
32. The opposite sides of the fractured bone in Kinmon correspond to the recited pair of biological elements. The staple is inserted into the drilled holes to compress the pair of biological elements. Id. ¶¶92–93.

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

Limitations 1[b][i]-[ii]

Limitation 1[b][i]

33. 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.” 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.

34. Kinmon’s C-shaped bridge 2 is the claimed substantially horseshoe-shaped bridge portion. 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).

35. Kinmon further explains: “Alternatively, 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. The ends of bridge 2 move closer together as the staple returns to its memorized position. Because the memorized position is the as-formed shape of bridge 2, the ends of the C are close together in the shape of the bridge itself. A POSA would have understood a C-shaped bridge whose ends are close together relative to the width of the C to extend beyond a semicircle, such that its terminal portions curve back toward one another. 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.

36. 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. Ex. 1007 ¶¶ 82–83. Because the insertion tool acts on legs 3 from under bridge 2, adjacent ends 4 (Ex. 1007 ¶ 82), separating the legs at that location pushes ends 4 apart. That separation is created by reducing the curvature of the C and increasing the distance

between its ends. That deformation is recoverable because the compressed position is the memorized shape of the memory-metal staple, to which the staple returns upon removal of the insertion tool. Id.

37. 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 the ends of C-shaped bridge 2 are close together. Kinmon then teaches that the insertion tool separates legs 3 from under bridge 2 and pushes legs 3 outward when activated. 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. Accordingly, Kinmon teaches limitation 1[b][i].

Limitation 1[b][ii]

38. 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.

39. 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. Ex. 1007 ¶¶ 82, 87–93. This follows from the order of Kinmon's steps: the width between apertures 17 is selected, the

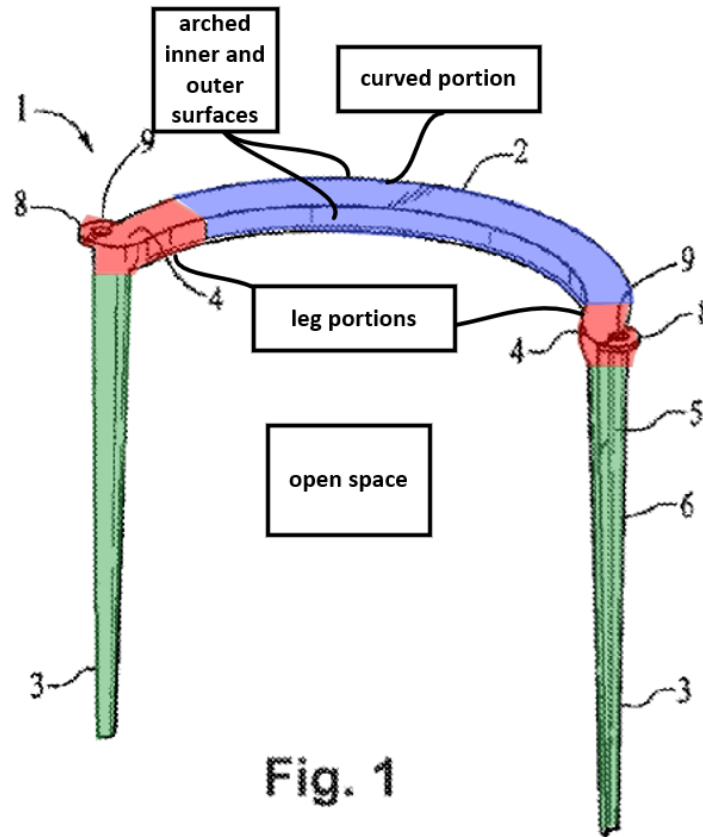
holes are drilled through apertures 17, and the staple is inserted while the insertion tool holds legs 3 outward, after which the tool is removed. Ex. 1007 ¶¶ 82, 87–88, 92–93. The relevant spacing is center-to-center, between the axes of the drilled holes and the axes of the outwardly held legs where they enter the bone. The taper of legs 3 (Figs. 1, 5) and the clearance with which holes are ordinarily drilled affect the width of each leg and its fit in the hole, not the spacing between the leg axes.

40. Because the drilled holes must be spaced to match the delivery state separation, in Kinmon’s disclosed sequence, the outwardly held legs could not be aligned with and seated in holes drilled at a materially narrower spacing. 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). A POSA following Kinmon’s held-open insertion sequence therefore would have set apertures 17 at the spacing of legs 3 in the second state. Thus, Kinmon teaches limitation 1[b][ii].

Limitation 1[c]

41. 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 Figure 1 from Kinmon below, Kinmon teaches the claimed bridge geometry.

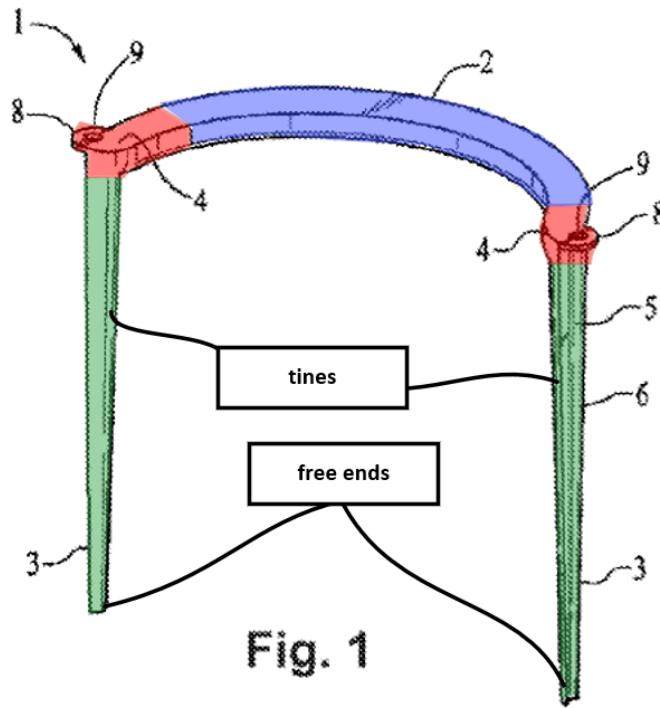


Kinmon teaches a curved bridge portion (red highlighting) connected to legs (blue highlighting). Ex. 1007 ¶ 82. Kinmon’s curved portion has an arched inner surface and an arched outer surface, and with the inner surface and leg portions bounding an open space. Id. A POSA would understand Kinmon’s C-shaped 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. The same features are shown in Kinmon’s unannotated figures. In top-view Figure 3, the

arched inner and outer surfaces are the concave and convex edges of the curved region of bridge 2, and ends 4 extend from that region to the locations at which legs 3 attach, with their inner surfaces facing each other. The open space is bounded by the inner surface and ends 4 and remains open between the ends of the C and above and below bridge 2, as Figure 1 confirms. The claimed leg portions correspond to ends 4 of bridge 2, while Kinmon's legs 3 correspond to the claimed tines. Accordingly, Kinmon teaches limitation 1[c].

Limitation 1[d]

42. 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.



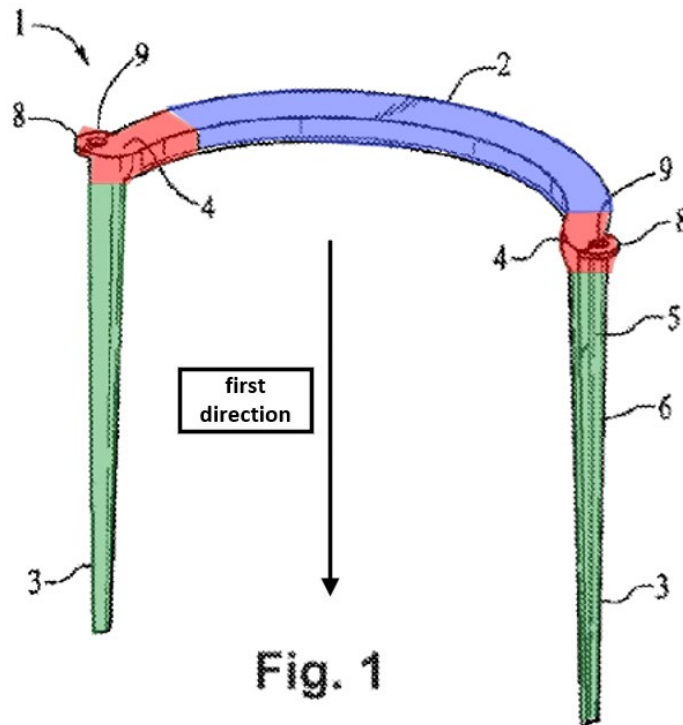
Kinmon teaches that the staple's tines are inserted into drilled holes. Id. ¶¶92–93.

Tines 3 include free ends configured to be implanted into biological elements.

Accordingly, Kinmon teaches limitation 1[d].

Limitation 1[e]

43. 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.

Accordingly, Kinmon teaches limitation 1[e].

Limitation 1[f]

44. 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 to its compressed position. Id.; see also

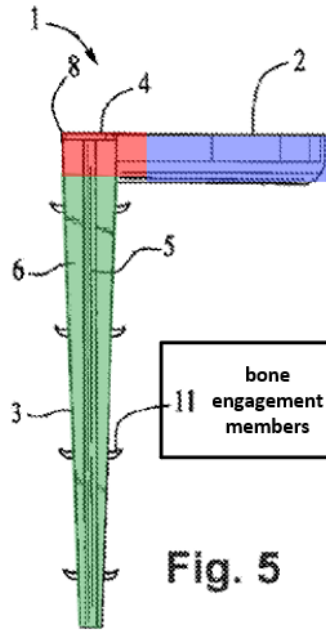
id. ¶ 92 (describing insertion of staple and subsequent activation of staple's compressive force).

45. A POSA would understand that Kinmon teaches the insertion tool maintaining the outwardly displaced second state during insertion because if the insertion tool did not maintain that state, removal of the tool would not be the event that allows the staple to return to its compressed position. In the second state, bridge 2 urges legs 3 inward. The insertion tool supplies the opposing force that prevents the staple from recovering and, because the surgeon holds the tool, also controls the alignment of legs 3 with the drilled holes during insertion.

Accordingly, Kinmon teaches limitation 1[f].

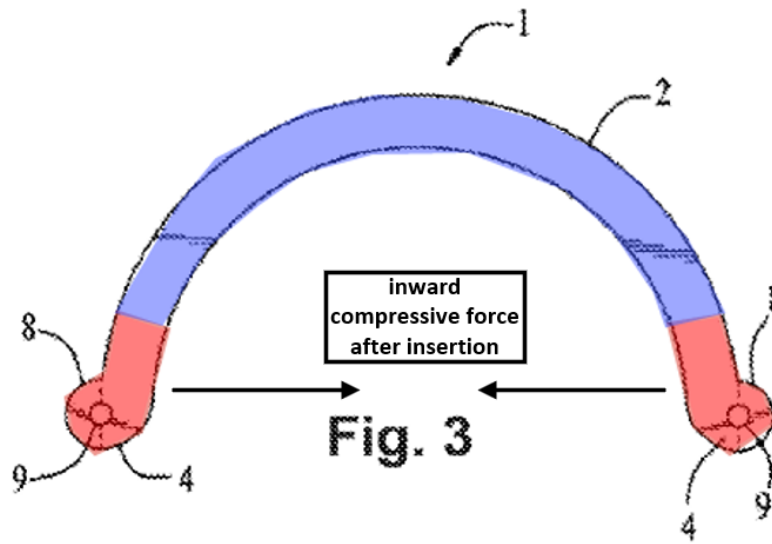
Limitation 1[g]

46. 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 teach its bone engagement members being positioned on portions of its legs 3 (tines) “that substantially face the other tine of the pair of tines along the first direction.”

47. Kinmon explains, however, in the memory-metal embodiment, 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. A POSA would understand 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. 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. Id. ¶¶ 82, 85. The compressive force would provide the engagement between projections 11 and the surrounding bone. A POSA would have distinguished two directions of movement. The recovering bridge loads each leg transversely toward the other leg, while withdrawal of the staple occurs along the longitudinal axis of the legs. The compressive force therefore presses each leg against the side of its hole nearest the other leg, which is the side the inward-facing portion of the leg faces, and drives

projections located on that portion into the bone. Once embedded, those projections resist movement of the legs along the holes, and they remain engaged for as long as the staple applies compression. Projections on outward-facing portions, by contrast, would be located on the side of each leg that is loaded away from the bone, so their engagement would depend on the fit of the leg in the hole rather than on the compressive force. The benefit a POSA would have expected is thus engagement that is driven and maintained by the staple's own compression.

48. Such orientation of bone engaging projections on staples was well known in the art. 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.

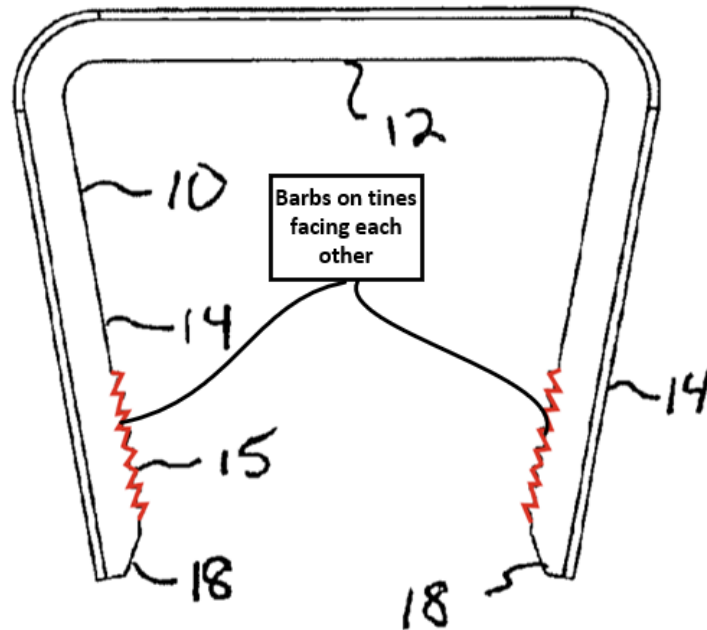


FIG. 9

As seen above the barbs on opposite tines in Miller (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. Like Kinmon, Miller describes its staple as providing an inward compressive force. See, e.g, Ex. 1008 ¶¶ 21, 34. Miller’s description of its barbs as “angling outward toward the web end” (Ex. 1008 ¶ 21) is consistent with that location. “Outward” describes the direction in which each barb projects from the surface of its leg, and “toward the web end” describes the barb’s inclination along the leg; neither describes the side of the leg on which the barbs are located, which Figures 8 and 9 show is the side facing the other leg.

49. 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. 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 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.

50. 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 on the inward-facing portions of the legs are located where the compressive force presses each leg against the bone, which drives them into engagement and maintains that engagement against withdrawal. 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).

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

Limitation 1[h]

51. 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.

52. Kinmon’s memory-metal staple is memorized in the compressed state with legs 3 and the ends of C-shaped bridge 2 close together. Ex. 1007 ¶ 82. The insertion tool pushes 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”). The staple returns toward, but not necessarily to, its compressed position, because the bone resists the inward movement of legs 3 before bridge 2 reaches its memorized shape; the remaining deformation of bridge 2 sustains the compressive force.

53. As discussed above 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. As the legs 3 move inward releasing the potential energy of the elastic deformation, they apply

a compressive force to the pair of biological elements to engage the plurality of engagement mechanisms with the biological elements. As discussed above with respect to limitation 1[g], the compressive force drives and maintains that engagement.

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

CLAIM 2

54. Claim 2 depends from claim 1 and adds that “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.” 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. That compressive force closes or reduces the space between the biological elements. For example, where a gap remains between bone fragments or prepared joint surfaces after reduction, recovery of bridge 2 urges the bone portions in which legs 3 are implanted toward one another. Where the bone portions are free to move and the staple has sufficient remaining recovery, the bone portions move together and the gap closes, after which the remaining recovery compresses the apposed surfaces. See Ex. 1007 ¶ 3.

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

CLAIM 3

55. 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 to its compressed position, the insertion tool engages the staple and maintains the outwardly displaced second state during insertion. *Id.* The insertion tool portion that engages the staple to push and maintain legs 3 outward is the claimed staple engagement portion of the guide. That portion functions as part of a guide because it holds legs 3 at the insertion spacing and directs them into the drilled holes, as discussed above with respect to limitation 1[f].

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

CLAIM 4

56. 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. Once the tool is removed, the restoring force of bridge 2 is no longer resisted by the tool and is instead transmitted through legs 3 to the bone.

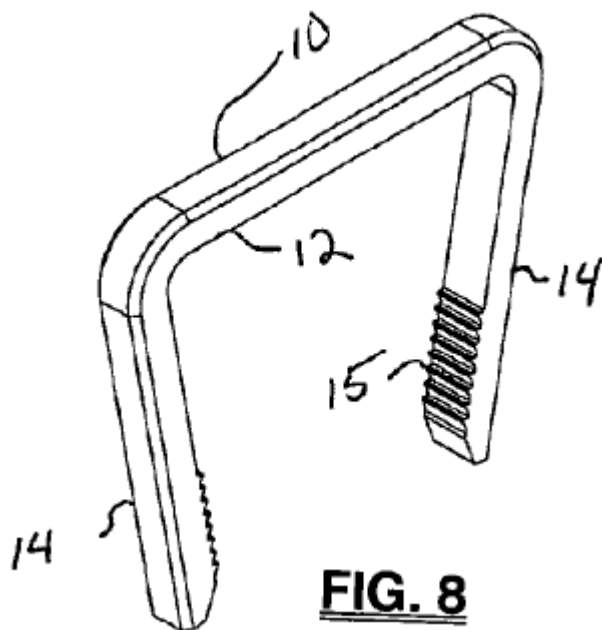
Accordingly, claim 4 would have been obvious based on the combined teachings of Kinmon and Miller.

CLAIM 5

57. 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. And as seen in Kinmon’s Figure 1, the bridge 2 has a generally rectangular cross-sectional shape. A POSA would have evaluated the cross-section of legs 3 in a plane perpendicular to each leg’s longitudinal axis, and the cross-section of curved bridge 2 in a plane perpendicular to the bridge at each location along the arc. Figure 1 depicts bridge 2 with flat faces meeting at edges that run along the arc, and Figure 5 depicts bridge 2 in side view

as a band of uniform height with straight upper and lower edges, indicating a four-sided, substantially rectangular section. Kinmon also expressly discloses flat legs. Ex. 1007 ¶ 73. Rounded corners, taper, and localized projections 11 do not change the substantially rectangular character of those sections. Accordingly, Kinmon teaches the recited “substantially rectangular cross-sections.”

58. Miller also teaches the recited “substantially rectangular cross-sections”, which was well known in the art. 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 stock as having a substantially rectangular cross-section for the web and legs. Figure 8 depicts web 12 and legs 14 with flat faces meeting at

edges that run the length of each member, and barbs 15 are localized features that do not define the cross-section of the legs.

59. A POSA would have found it obvious to use Miller's flat-sided/substantially rectangular staple-stock geometry in Kinmon's memory-metal compression staple based at least on Kinmon's own teaching of such geometry. 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. 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.

60. 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”).

Consequently, the '693 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.

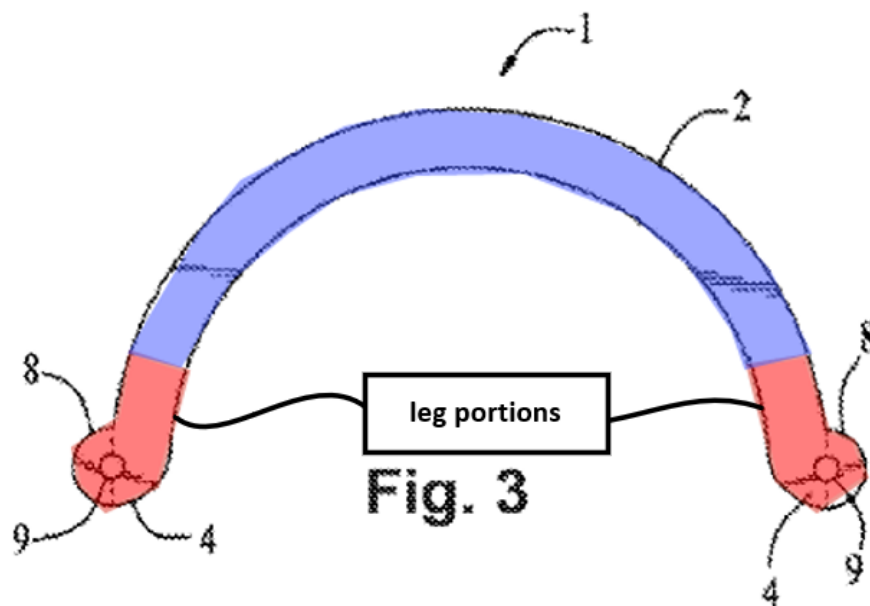
61. A POSA would have understood that the substantially rectangular cross-section is a known structural variant of staple bridge/tine geometry that can provide predictable performance compared to a circular cross-section, including directional stiffness, lower profile in one dimension, improved orientation control, and flat bearing surfaces for load transfer. This is because a flat-sided, rectangular cross-section resists bending differently in different directions, and its flat surfaces provide a larger, stable contact area for engaging insertion tooling than the continuously curved surface of a round cross-section, which contacts a mating flat surface only along a line rather than an area. In Kinmon, the benefit that would have motivated a POSA is the ability to set the stiffness of bridge 2 in the direction in which it opens and closes independently of its thickness above the bone. Kinmon's side-curved bridge opens and closes by bending in the plane of Figure 3, and the bending stiffness of a rectangular section depends on its width and on its depth in the direction of bending, so the in-plane width and the thickness of a rectangular bridge can be selected separately, whereas a round section has the same stiffness in every direction. The contact-area benefit applies to engagement with insertion

tooling; a flat-sided leg in a round drilled hole contacts the hole wall principally along its edges.

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

CLAIM 6

62. 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 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. An annotated version of Kinmon’s Figure 3 is reproduced below.



As seen above, Kinmon's leg portions (red highlighting) are substantially linear. 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. In Figure 3, each end 4 extends from the end of the curved arc of bridge 2, where the blue highlighting ends, to the rounded end at which leg 3 attaches, and the edges of end 4 are drawn as straight lines along that extent. Making the leg portions of Kinmon's bridge linear would have been a predictable way to implement the same bridge geometry. 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.

63. 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. Purely linear end portions do not change the claimed method. 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.

64. 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. This is because the principal deformation that opens and closes the bridge occurs in its curved portion, and a straight terminal segment provides a single, constant-direction load path from the curved portion into the tine. Straight terminal segments do affect the overall compliance of the bridge, because they transmit the closing force and moment of the curved portion to the tines and themselves bend to some degree. A POSA would have accounted for those effects by sizing the terminal segments and the curved portion so that the bridge opens to the insertion spacing within its recoverable range. A POSA would have been motivated to use straight terminal segments to set the distance by which the curved portion is offset from the tines without enlarging the radius of the curved portion, and to provide a defined transition from the bridge into the tines.

65. 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. 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. Further use of linear ends of a staple bridge would have been obvious to provide greater offset as needed for placement based on specific bone geometry. See, e.g., Ex. 1010, Figs. 3, 5, 7.

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

CLAIM 7

66. 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.

67. A POSA would have appreciated that the use of “substantially” in Kinmon indicates that the disposition of bridge 2 need not be perfectly parallel or perpendicular, and, read with the remainder of Kinmon ¶ 81, indicates that Kinmon treats the orientation of bridge 2 relative to legs 3 as a design choice. A POSA would have understood the “axis” of C-shaped bridge 2 to be its axis of symmetry, extending from the crown of the C through its open side. When bridge 2 is curved “to the side” (Figs. 1, 3), the C lies in a plane perpendicular to legs 3 and its axis is perpendicular to the legs; when bridge 2 is curved “upward,” the C lies in a plane

containing legs 3, arching above them, and its axis is parallel to the legs. Kinmon thus identifies the orientation of the plane of the bridge relative to the legs as a choice to be made based on practical considerations, such as whether the bridge is to lie against the bone surface or arch above it.

68. At a minimum, a POSA also would have found orienting Kinmon's bridge at an angle that is not perpendicular to its legs obvious. This is because Kinmon already discloses that its bridge orientation is a design choice between an axis substantially parallel and an axis substantially perpendicular to the legs, and a POSA would have selected an orientation between those alternatives for a specific reason, namely, seating the offset bridge against the bone surface, as discussed below.

69. The '693 Patent's own disclosure confirms that the claimed "curved portion angled downwardly toward the free end" is satisfied where a curved bridge includes a region that progresses toward the tine free ends, as discussed above. In Figures 7 and 8 discussed above, the '693 Patent depicts a curved bridge that arches above the tines and descends from its crown toward the tops of the tines, and thus toward their free ends.

70. Kinmon teaches that same relationship in the embodiment where its C-shaped bridge 2 is substantially vertically oriented relative to legs/tines 3, and in that configuration the portions of curved bridge 2 that descend from the crown of the C

to ends 4 progress along legs/tines 3 toward their free ends, similar to the Figure 7, 8 embodiment in the '693 Patent. Ex. 1007 ¶ 81.

71. 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." That upward-curved configuration is disclosed in Kinmon. Alternatively, as discussed below, a POSA would have found it obvious to incline the plane of the side-curved bridge shown in Kinmon's Figures 1 and 3 so that its offset curved region extends toward the free ends of legs 3, as in Figure 20 of the '693 Patent.

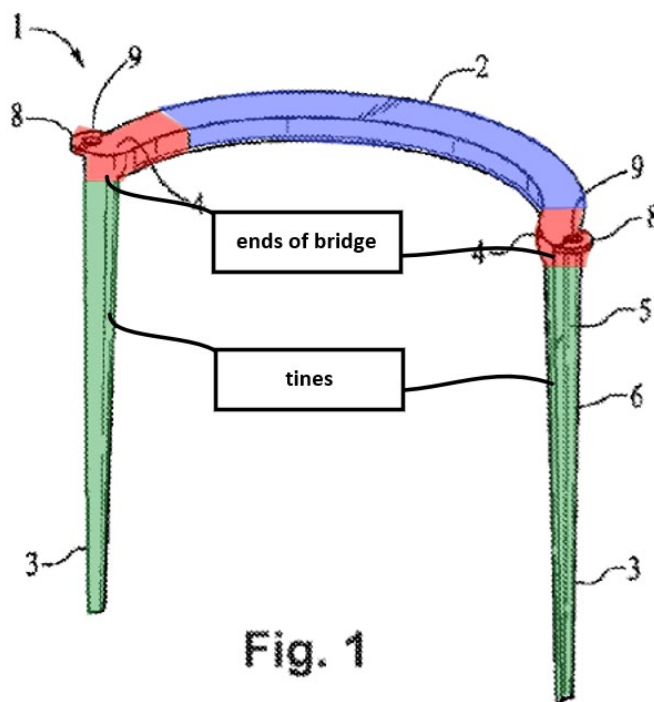
72. Even if Kinmon did not expressly disclose this orientation, it would have been obvious to a POSA to orient the curved bridge portion downward toward the tine free ends in order to seat the bridge against the bone surface while the tines apply the compressive force. A bridge lying in a plane perpendicular to the legs stands off the bone where the cortical surface is convex and falls away from the line between the tine entry sites, as on the dorsal or medial surface of a metatarsal or on the "curved metaphysis surface" described in EP '045. Ex. 1009, 3:50–56. Inclining the offset curved region of Kinmon's bridge toward the free ends of legs 3 brings it onto or near the cortex, reducing its prominence beneath the soft tissue and supporting it against the bone. That seating function is distinct from the compressive force, which is applied through the tines, and a POSA would have had reason to

incline the bridge in this way where the bone surface falls away from the tine entry sites.

73. Seating the bridge against bone was a recognized design objective 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. Where the bone surface falls away from the tine entry sites, inclining the offset curved region toward the free ends is a direct way to meet that objective. Accordingly, claim 7 would have been obvious based on the combined teachings of Kinmon and Miller.

CLAIM 8

74. 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 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. Those inner surfaces and the open space between them are identified above with respect to limitation 1[c].

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

CLAIM 9

75. 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.

Limitation 9[a]

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

Limitation 9[b][i]-[ii]

77. 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].

Limitation 9[c]

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

Limitation 9[d]

79. 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].

Limitation 9[e]

80. 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].

Limitation 9[f]

81. 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.

Limitation 9[g]

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

Limitation 9[h]

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

Limitation 9[i]

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

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

REASONABLE EXPECTATION OF SUCCESS

86. A POSA would have had a reasonable expectation of success in applying Miller's inward-facing barb orientation and flat-sided/substantially rectangular staple-stock 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 set to a desired width and insertion into drilled holes while the legs are pushed outward. Id. ¶¶ 87–93.

87. Miller’s inward-facing barb orientation would have predictably worked 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. The inward-facing orientation places the barbs where the compressive force presses the legs against the bone, as discussed above with respect to limitation 1[g].

88. A POSA also would have expected Miller’s flat-sided/substantially rectangular staple-stock geometry to work in Kinmon. 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. A POSA would have expected this to work because the compressive function of Kinmon’s staple is produced by elastic deformation and recovery of the bridge and by the outward/inward movement of the legs, and that mechanism is available with either cross-section. A rectangular section changes the force required to open the staple and the compression it delivers, and a POSA would have sized the section so that the staple still opens to the insertion spacing without permanent deformation.

89. 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. The modifications are also compatible with one another. Inward-facing projections inclined toward the bridge present a sloped face during insertion, and the holes would be sized to accommodate them, as with any barbed staple leg. The projections are located along

the portions of legs 3 that enter the bone, away from the insertion tool's engagement with the staple beneath bridge 2. Ex. 1007 ¶ 82. The rectangular bridge would be sized for the required opening, and the hole diameter would account for the cross-sectional dimensions of a rectangular leg. Kinmon's memorized configuration, C-shaped bridge, guide device 12, insertion tool, and delivery sequence remain unchanged, and the only accommodations are dimensional choices within the ordinary skill of a POSA. Accordingly, a POSA would have reasonably expected the Kinmon/Miller combination to successfully deliver, retain, and compress the biological elements as claimed.

IV. OBVIOUSNESS OF CLAIMS 1–9 OVER KINMON, MILLER, EP '045, AND GAUTHIER

90. 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.

91. 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.

92. As discussed below, the ground relies on the combined teachings of the references. The references provide complementary teachings that would have led a POSA to the claimed method. 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. The specific combination is described below in the section addressing the combined teachings.

CLAIM 1

93. 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]). Ex. 1008 ¶ 6; Ex. 1009, 2:55–3:4, 4:47–56; Ex. 1010, 4:36–47.

Limitation 1[a]

94. 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. 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. 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.

95. 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.

Limitation 1[b][i]-[ii]

Limitation 1[b][i]

96. 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. EP ’045 additionally teaches this limitation. Figures 3 and 4 of EP ’045 are reproduced below.

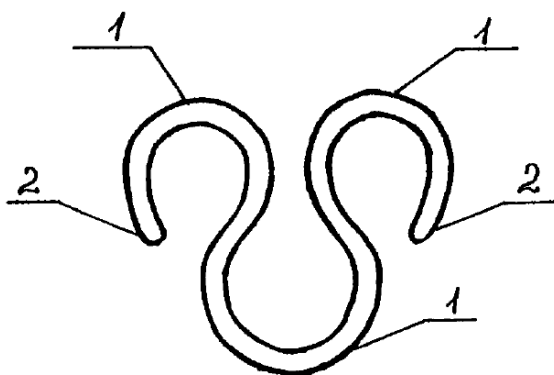


Fig. 3

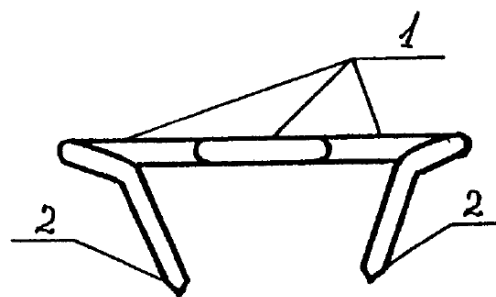


Fig. 4

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.

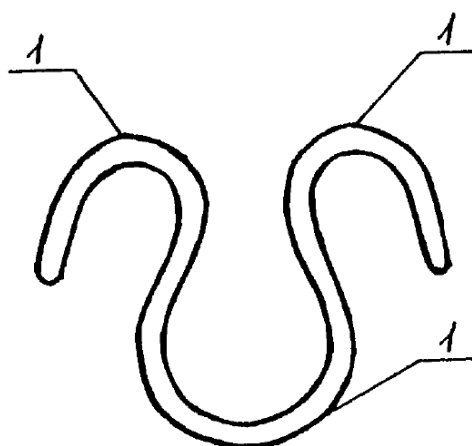
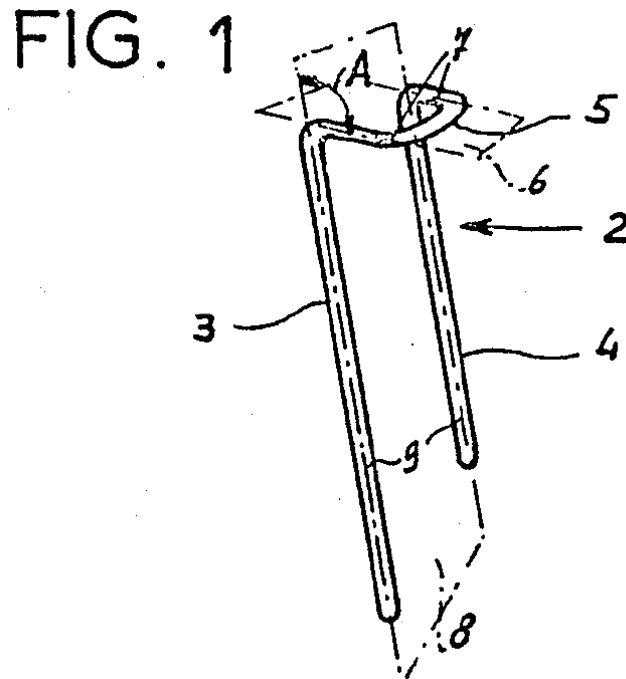


Fig. 5

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. Comparing Figure 5 with Figure 3, the arched regions of working part 1 lie in series between legs 2, so reducing their curvature lengthens the distance each spans, and those increases combine to increase the distance between legs 2. A POSA would have relied on EP ’045 for that geometric relationship; in the proposed combination, the restraint of the deformed staple during insertion and its release are supplied by Kinmon’s insertion tool, as discussed above with respect to limitations 1[f] and 1[h].

97. Gauthier also teaches a staple having a horseshoe-shaped bridge portion, as seen in Figure 1, reproduced below.



Gauthier describes clip 2 as including two lateral rods 3 and 4 connected by bridge-forming central part 5, and states that “the central part forming bridge 5 is curved.” Ex. 1010, 3:6–10. Gauthier also teaches the elastic deformation of that bridge portion, explaining that the elasticity of bent part 5 is used to obtain coaptation of bone parts and assure contact pressure at the fracture zone. *Id.* at 4:36–47.

98. A POSA would have understood from Gauthier’s disclosure of an “elastic recall means” and the “elasticity of bent part 5” that bridge 5 is elastically displaced from a lower-energy configuration into a delivery configuration. This is because a structure cannot exhibit an “elastic recall” back to a given shape unless it was first displaced away from that shape; the recall function Gauthier describes necessarily includes displacement from bridge 5’s lower-energy, at-rest

configuration. That disclosure establishes that bridge 5 is elastically deformed before it applies recall. To the extent Gauthier does not describe the manner in which rods/tines 3 and 4 are displaced before implantation, the opening, holding, and release steps of the proposed combination come from Kinmon, and Gauthier is relied upon for the orientation of its bridge and to confirm that the elasticity of a curved bridge can apply contact pressure between bone surfaces. Ex. 1010, 4:36–47.

Limitation 1[b][ii]

99. 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. 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.

100. 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.

101. 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. The same center-to-center relationship discussed above for Kinmon applies to Miller's pilot holes and to Gauthier's drilled holes when used in Kinmon's held-open delivery sequence.

Limitation 1[c]

102. 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.

103. EP '045 also teaches limitation 1[c]. EP '045 specifically states that “the middle part of the device is made arch-shaped.” *Id.* at 1:50–51. Annotated versions of EP '045's Figures 3 and 4 are provided below illustrating the features of limitation 1[c].

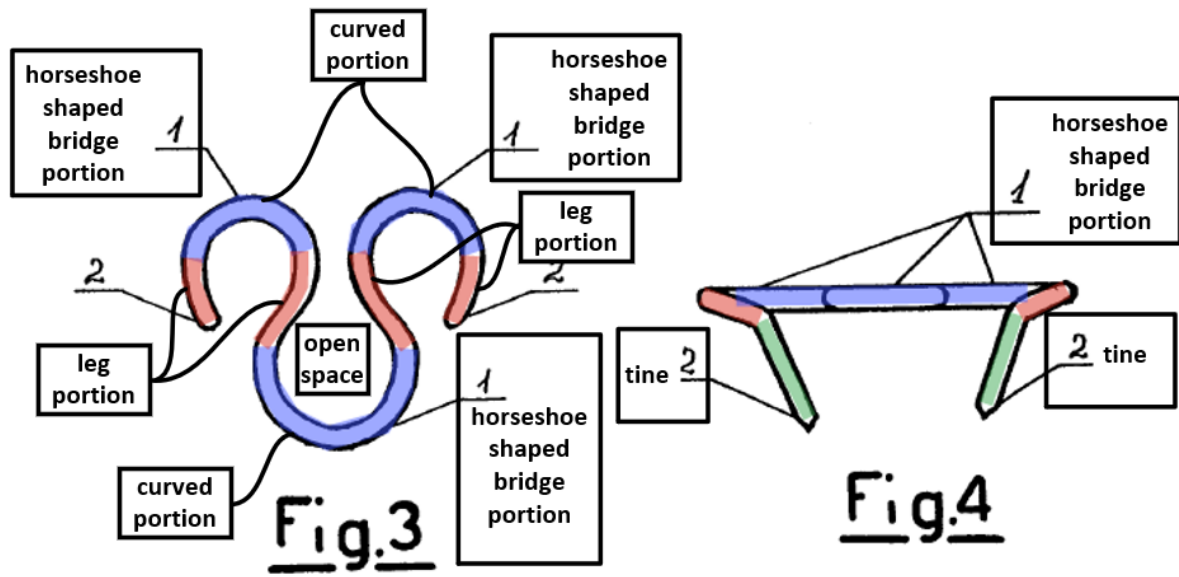


Figure 3 is a top view of EP '045's staple in a compressed (working) state and Figure 4 is a side view of the staple in a compressed state. Ex.1009, 3:5–6. As seen in those Figures, ends of the bridge portions (red highlighting) connect to the tines (green highlighting). The bridge portion includes curved 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. And as seen in the annotated figures, the inner surface and the leg portions bound an open space. Working part 1 is a continuous strip connecting the two plunge legs 2 and forms the claimed bridge portion. Within it,

the central arched region (blue highlighting, labeled “curved portion” at the bottom of annotated Figure 3) and the two segments rising from it (red highlighting) bound the labeled open space, and each of those segments leads, through the adjacent upper arched region, to one of the plunge legs 2.

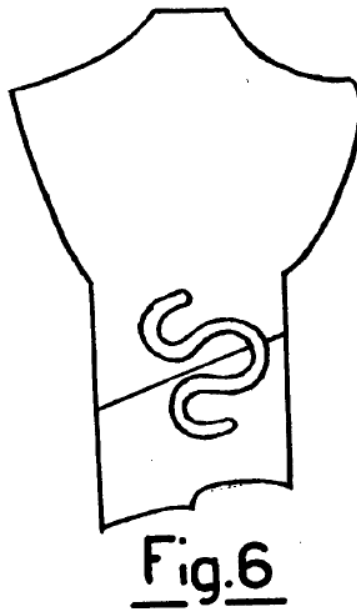
104. Gauthier also teaches limitation 1[c]. Gauthier explains that clip 2 includes “two lateral rods 3 and 4, approximately parallel, connected together by a bridge-forming central part 5,” and that “the central part forming bridge 5 is curved.” Ex. 1010, 3:6–10. Gauthier’s curved bridge portion 5 includes 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. 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.

105. 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.

Limitation 1[d]

106. 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.

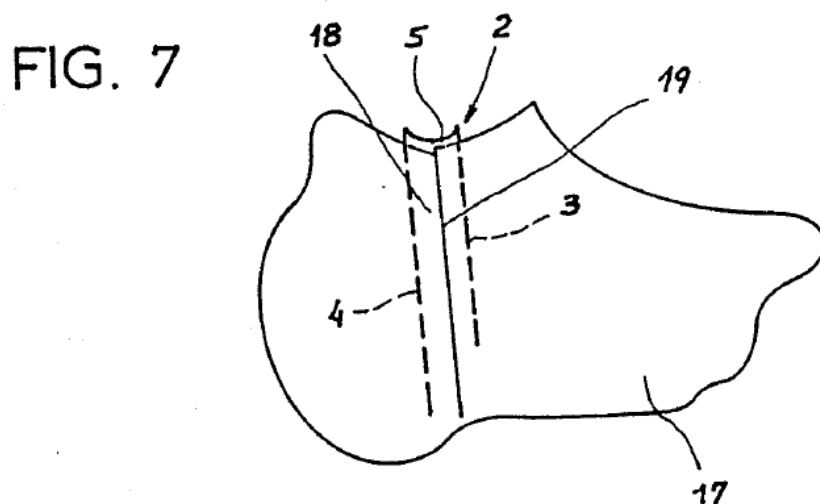
107. EP '045 also teaches this limitation. EP '045 explains, for example, that its “proposed devices can be used . . . during fracture therapy and surgical operations on the long tubular bones” (Ex.1009, 2:49–51) with “tapered plunge legs” that are inserted into bone (id. at 3:7). Figure 6, reproduced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

108. Gauthier also teaches this limitation. Tines 3 and 4 extend from bridge portion 5 and are configured to be implanted into bone. 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.



Gauthier states that “branches 3 and 4 are engaged in the bone.” Id. at 3:62.

Limitation 1[e]

109. 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 above. EP ’045 also teaches this limitation; tines 2 extend from bridge portion 1 in a first direction. Gauthier likewise teaches this limitation. 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.

Limitation 1[f]

110. Limitation 1[f] recites “maintaining the second state of the bridge portion.” Kinmon teaches limitation 1[f] as discussed above. 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. Gauthier likewise teaches an elastic recall structure that applies contact pressure after implantation. Ex. 1010, 4:36–47.

111. 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. A deformed staple can be held in that state by mechanical restraint, as with Kinmon’s insertion tool (Ex. 1007 ¶ 82) and Miller’s inserter and sliding lock (Ex. 1008 ¶¶ 34–35), or, for some shape-memory alloys, by a material condition in which the deformed shape is retained until the alloy is warmed. In the proposed combination, the restraint is supplied by Kinmon’s insertion tool, and the combination does not depend on EP ’045 or Gauthier for a restraint mechanism. If the restraint were released before the tines were seated, the

staple would begin to recover, the tines would no longer match the spacing of the holes, and the stored energy would be spent before the tines engaged bone.

Limitation 1[g]

112. 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.

113. 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.

114. 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. “Outward” in that description refers to the direction in which each barb projects from the surface of its leg, not to the side of the leg on which the barb is located.

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

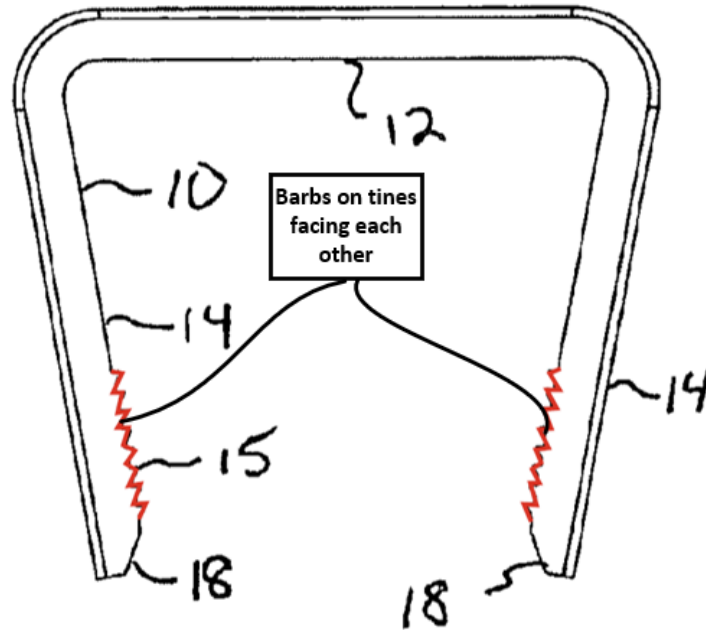


FIG. 9

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.

116. 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.

117. 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. That is because the compressive force presses the legs against the bone at their inward-facing portions, as discussed above in Section III with respect to limitation 1[g]. Kinmon in view of Miller renders limitation 1[g] obvious.

Limitation 1[h]

118. 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 above.

119. 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.

120. 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. In the proposed combination, the release step is performed by removal of Kinmon’s insertion tool, and EP ’045 is relied upon for the relationship between recovery of the working part and movement of its legs.

121. 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.

122. 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. This is because, as explained above with respect to limitation 1[b][i], an elastically deformed structure stores energy and moves toward its lower-energy configuration when the force holding it in its deformed state is removed. In the proposed combination, that holding force is applied and removed by Kinmon’s insertion tool.

123. 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. Accordingly, Kinmon in view of Miller, EP '045, and Gauthier renders limitation 1[h] obvious.

COMBINED TEACHINGS

124. 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. In the combination, Kinmon supplies the memory-metal staple memorized in its compressed position, with C-shaped bridge 2, legs 3, and projections 11, together with guide device 12, the insertion tool, and the sequence of setting the guide, drilling, opening the staple, inserting it while held open, and removing the tool. Ex. 1007 ¶¶ 81–93. Miller supplies the placement of projections 11 on the inward-facing portions of legs 3 (claim 1) and flat-sided, substantially rectangular staple stock (claim 5), and its drill guide, inserter, and lock confirm Kinmon's delivery steps. Ex. 1008 ¶¶ 21, 31–37. EP '045 supplies arched bridge geometry, including an arched component extending beyond 180 degrees so that the bridge ends converge and shaped to conform to the bone surface, and confirms the deformation and recovery relationship Kinmon already uses. Ex. 1009, 3:9–10, 3:50–56, 4:47–56. Gauthier supplies the inclination of the curved bridge

relative to the tines, at an angle slightly greater than 90 degrees, for cortical rest (claims 7 and 9). Ex. 1010, 3:6–16, 3:64–65. A POSA would have arrived at this combination by addressing two issues presented by Kinmon’s staple. Kinmon does not specify where on legs 3 projections 11 are located, and Miller places its barbs on the inward-facing portions, where the compressive force presses the legs against the bone. And Kinmon’s offset bridge stands off a bone surface that falls away from the tine entry sites, while Gauthier inclines its bridge toward the free ends of its rods for cortical rest. Neither modification changes Kinmon’s tool engagement, guide, or recovery mechanism, and inclining the bridge about the line joining ends 4 does not change the direction in which legs 3 move.

125. 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.

126. The references are also governed by the same technical constraints. In each, an elastically deformed bridge loads two implantable members so that the bone

bears the restoring force, the shape and section of the bridge govern how far it can be deformed and how much force it returns, and the position of the bridge relative to the bone governs whether it is prominent or supported. In Kinmon and Miller, an instrument holds the deformed state until the members are seated. Because those relationships are common to the references, a POSA would have expected teachings regarding projection placement, bridge section, and bridge orientation to apply predictably from one reference to another.

127. 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.

128. Accordingly, claim 1 would have been obvious based on the combined teachings of Kinmon, Miller, EP '045, and Gauthier. Kinmon teaches the claimed method sequence. Kinmon's memory-metal staple has a C-shaped bridge 2 and legs/tines 3.

129. 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. In the combination, EP '045 is relied upon for arched bridge geometry, while the restraint and release of the staple are supplied by Kinmon's insertion tool.

130. 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. 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.

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

CLAIM 2

132. 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 above.

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.

133. 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.

134. 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 presupposes that those surfaces are in contact; where a gap exists, the same recovery first closes it, as discussed above in Section III with respect to claim 2.

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

CLAIM 3

135. 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 above.

136. 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.

137. 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.

138. Gauthier teaches an elastic bridge/tine structure that applies recall compression after implantation. Ex. 1010, 3:6–13, 4:36–47.

139. 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. This is because, as explained above, releasing an elastic recall structure before its tines are seated in the prepared holes would allow the bridge to spring back and dissipate its stored energy without the tines engaged in bone, so that the tines would no longer match the spacing of the holes and the stored energy would be spent before the tines engaged bone.

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

CLAIM 4

141. 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 above. The reason to disengage the staple engagement portion is to permit the deformed bridge to recover and apply its intended compressive force.

142. 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. After release, the staple applies compression as the legs return toward an unsplayed position. Ex. 1008 ¶ 6.

143. 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.

144. Gauthier similarly teaches that the elasticity of bent central part 5 assures contact pressure between fracture surfaces. Ex. 1010, 4:45–47.

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

CLAIM 5

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

146. 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.

147. Miller teaches flat-sided staple-stock 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.

148. 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.

149. 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. 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.

CLAIM 6

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

151. 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 above. Ex. 1007 ¶ 82.

152. 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. This is because, as explained

above, the principal opening and closing deformation occurs in the curved portion of the bridge, and linear terminal segments provide a fixed, single-direction load path into the tines, with any effect on the compliance of the bridge accounted for in sizing the bridge.

153. EP '045 further teaches arched working parts connected to plunge legs and depicts bridge portions having curved portions and terminal portions extending toward the legs on opposite sides of an open space. 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.

154. 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.

155. 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.

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

CLAIM 7

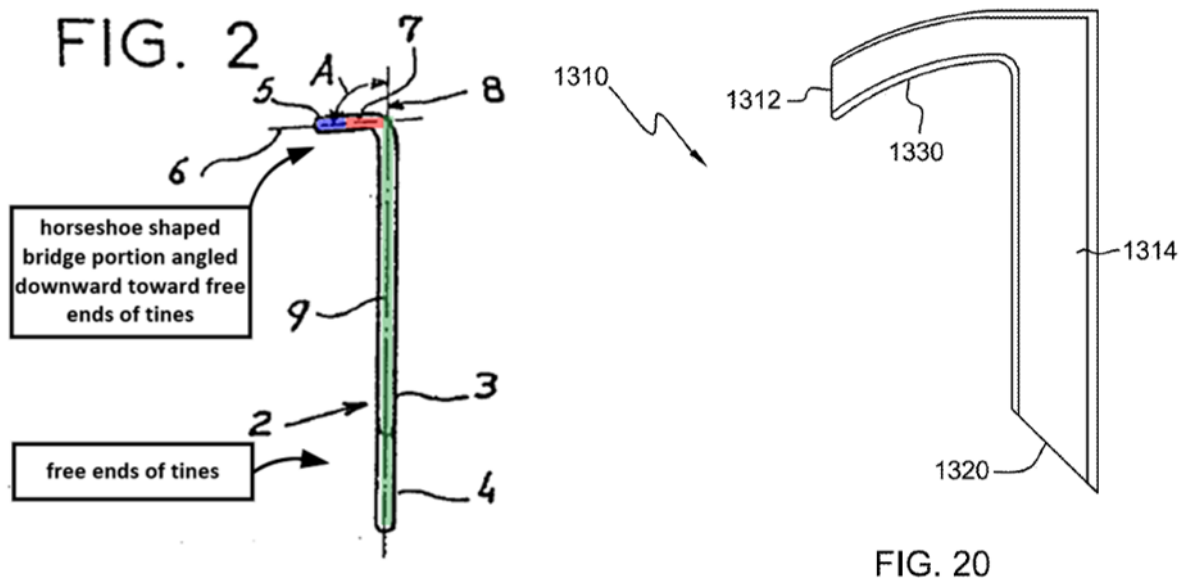
156. Claim 7 depends from claim 1 and recites that “the curved portion is angled downwardly toward the free end relative to a longitudinal dimension of a tine of the pair of tines.”

157. 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.

158. 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. This is because Kinmon itself discloses a range of bridge orientations, from substantially parallel to substantially perpendicular relative to the legs, as alternative configurations, indicating that orientation was understood in the art as a selectable parameter rather than a fixed, single-choice feature.

159. 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 above and shown in Figure 20 of the '693 Patent, reproduced below.



Gauthier teaches a curved bridge-forming central part 5 arranged so that the plane containing the bridge's median axis 7 forms a large angle, 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. As shown in Figures 1 and 2, angle A is formed between plane 6, containing median axis 7 of bridge 5, and the portion of plane 8 that extends above the junction of bridge 5 with rods/tines 3 and 4, away from their free ends. If angle A were 90 degrees, bridge 5 would extend perpendicular to the

tines. Because angle A is slightly greater than 90 degrees, bridge 5 lies on the free-end side of that perpendicular, forming an angle slightly less than 90 degrees with the direction toward the free ends of the tines. The curved bridge portion thus extends angled downward toward the bone and toward the free ends of the tines as it extends away from them, as in Figure 20 of the '693 Patent, consistent with Gauthier's teaching that the bridge is brought to cortical rest. Ex. 1010, 3:64–65.

160. 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.

161. 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 above and shown in Figure 7 of the '693 Patent, reproduced below.

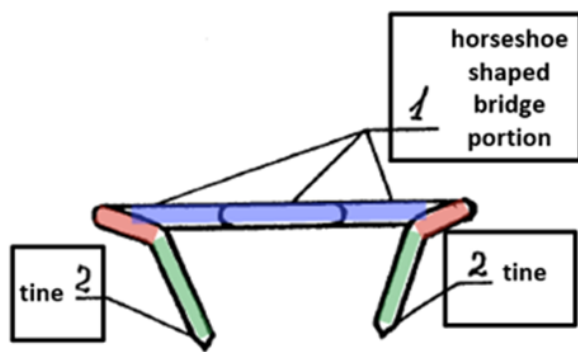


Fig.4

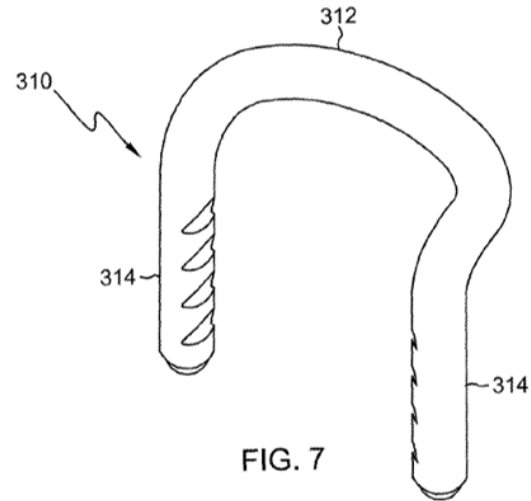


FIG. 7

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. Measured against the longitudinal dimension of each leg 2, as the claim requires, the curved central region of working part 1 extends from each leg at less than 90 degrees to the direction toward that leg's free end, because legs 2 are inclined toward one another. EP '045's teaching that the arched component

is shaped according to the curved metaphysis surface (Ex. 1009, 3:50–56) further provides a reason to orient the bridge toward the bone surface.

162. 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. Inclining the plane of Kinmon's C-shaped bridge about the line joining ends 4, which is perpendicular to legs 3, lowers the offset curved region toward the bone without moving ends 4. The bridge still opens and closes along that line, so legs 3 move apart for insertion and toward one another on recovery as before, and the closing force is still transmitted through ends 4 to legs 3, with only a small twisting component introduced at the bridge/leg junction. Contact between the curved region and the cortex would not materially impede recovery, because the curved region moves generally along the bone surface and is not driven into the bone, and that contact supports and stabilizes the bridge rather than generating compression. The insertion tool's engagement with the staple beneath bridge 2 is likewise unchanged, requiring only ordinary clearance for the lowered curved region.

163. 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.

164. 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.

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

166. 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.

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

CLAIM 8

167. 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 above.

168. 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.

169. Gauthier 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.

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

CLAIM 9

170. 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.

Limitation 9[a]

171. 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. Limitation 9[a] is taught or rendered obvious for the reasons stated for limitation 1[a].

Limitation 9[b][i]–[ii]

172. 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].

Limitation 9[c]

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

Limitation 9[d]

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

Limitation 9[e]

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

Limitation 9[f]

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

Limitation 9[g]

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

Limitation 9[h]

178. Limitation 9[h] corresponds to limitation 1[g]. This limitation is taught or rendered obvious for the reasons stated for limitation 1[g].

Limitation 9[i]

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

REASONABLE EXPECTATION OF SUCCESS

180. 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.

181. 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.

182. EP '045 would have given a POSA reason to use arched bridge geometry in Kinmon's method because EP '045 teaches the same deformation-and-recovery mechanics: the working part is deformed to increase leg spacing, and recovery brings the legs closer together to develop compression. Ex. 1009, 4:47–56.

183. Gauthier would have given a POSA reason to use angled curved bridge geometry 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.

184. 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.

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.

185. For the same reasons stated in the Reasonable Expectation of Success section above in paragraphs 86-89, a POSA would have had a reasonable expectation of success in applying Miller's inward-facing barb orientation and substantially rectangular staple-stock geometry to Kinmon's compression-staple method. The expectation of success for the Miller-based aspects of the combination is the same as discussed above in Section "IV. OBVIOUSNESS OF CLAIMS 1-9 OVER KINMON, MILLER, EP '045, AND GAUTHIER", and as above in Section "III. OBVIOUSNESS OF CLAIMS 1-9 OVER KINMON AND MILLER." That expectation applies to the combination as a whole. The bridge section, any linear terminal segments, and the inclination of the bridge each affect the compliance of the bridge, and a POSA would have sized the bridge so that it opens to the insertion spacing within its recoverable range. The guide apertures would still be set to the spacing of the outwardly held legs, which inclining the bridge about the line joining ends 4 does not change. Neither the inward-facing projections nor the inclined bridge would obstruct insertion or the insertion tool, given ordinary hole and tool clearances. Upon release, the bridge would still load legs 3 toward one another and drive the projections into the bone, and the inclined bridge would seat against the

cortex without materially impeding recovery. The adjustments involved, including the bridge section, the inclination angle, the hole diameter, and the tool clearance, are dimensional choices a POSA would have made through routine design, and a POSA would have expected the combined staple to be opened, held open, implanted, and released to compress the biological elements as claimed.

186. The proposed combination therefore involves predictable use of known compression-staple components according to their established functions. Kinmon supplies the compression-staple method. Miller supplies known delivery-tool, lock, barb, and flat-sided staple-stock 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.

187. 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/insertion/lock delivery and supplies inward-facing barb and flat-sided staple-

stock 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.

V. CONCLUSION

188. For the foregoing reasons, it is my opinion that, as of May 2014, a POSA would have found claims 1–9 of the '693 Patent unpatentable as obvious in view of the prior art discussed above and the knowledge of one of ordinary skill in the art at the time of the alleged invention.

189. I reserve the right to supplement my opinions in the future to respond to any arguments or positions that Patent Owner Paragon may raise, taking account of new information as it becomes available to me.

190. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on: October 4, 2026

By: /s/ Daniel C. Farber
Dr. Daniel C. Farber