

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TREACE MEDICAL CONCEPTS, INC.,
Petitioner,

v.

PARAGON 28, INC.,
Patent Owner.

IPR2027-00008
Patent 12,303,139

DECLARATION OF DANIEL C. FARBER, MD
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 12,303,139

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. 12,303,139 to Dacosta, et al. ("the '139 patent")
1003	Curriculum Vitae of Daniel C. Farber, M.D.
1006	U.S. Patent No. 10,575,862 to Bays et al. ("Bays")
1007	U.S. Patent No. 9,492,178 to Neal et al. ("Neal")
1008	U.S. Patent No. 8,282,645 to Lawrence et al. ("Lawrence")
1010	Hofbauer 1996 - The Lapidus procedure
1011	U.S. Patent Pub. No. US20160175089 ("Fallin")

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 '139 patent would have been anticipated by the prior art, as well as whether they 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 '139 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. With respect to anticipation of a patent claim, my understanding is that anticipation in patent law means a claimed invention lacks novelty because a single prior art reference describes every element of that claim, either expressly or inherently.

12. 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.

13. 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.

14. 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 ’139 patent is titled “Alignment Guides, Cut Guides, Systems and Methods of Use and Assembly” and the Abstract states that “[g]uides, systems, and methods for maintaining, correcting and/or fusing joint deformities are disclosed.” According to the ’139 Patent, “[t]he present disclosure relates generally to general, podiatric, and orthopaedic surgery related to joint deformities. More specifically, but not exclusively, the present disclosure relates to devices, systems, and methods for maintaining, correcting and/or fusing joint deformities.” 1:27–31. The Background of the ’139 Patent specifically discusses “the Lapidus procedure” which in turn “is commonly used to correct a hallux valgus deformity.” 1:35-37.

15. In addition, I understand 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. My understanding is 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.

16. 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.

III. LEVEL OF ORDINARY SKILL IN THE ART

17. 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.

18. The claims of the '139 Patent reference "[a] cut guide" in the preamble without further reference to cutting and have no recitations (even intended use) related to the cut guide being configured for maintaining, correcting and/or fusing joint deformities, the type of joint deformity being addressed, or any other medical or other application whatsoever.

19. It is my opinion that a POSA would have included (i) a physician with a medical degree and at least 3 years of experience performing surgery using cut guides to correct deformities, (ii) an engineer with a bachelor's degree in mechanical or biomedical engineering and at least 3 years of experience designing cut guides to correct deformities, or (iii) 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 surface and slot geometries affect cut guide use. My understanding of those features is based on my experiences using cut guides in my practice.

IV. CLAIM CONSTRUCTION

20. I understand that claim terms are to be given their plain and ordinary meaning, as they would have been understood by a person of ordinary skill in the art at the time of the invention in view of the intrinsic record (patent claims, patent specification, and file history). I have applied the plain and ordinary meaning of the terms of the '139 patent throughout my analysis unless otherwise noted.

21. To the extent Patent Owner argues that “extends into at least a portion of the extension member” in limitations 1[b][i], 18[b][i], and 20[b][i] requires a physically contiguous through-hole running entirely through the extension member, I note that the '139 Patent specification describes the opening as spanning between

opposing surfaces of the guide body and extension member, confirming that the limitation is satisfied whenever the opening is at least partially defined by the extension member. Ex. 1001, 9:10–29. The claim language is consistent with that reading. The limitation recites an opening that extends into “at least a portion of” the extension member, which a POSA would have understood to be satisfied by an opening that reaches into the extension member, whether or not the opening passes entirely through it.

V. THE ASSERTED PRIOR ART REFERENCES

BAYS

22. Bays is directed to bone preparation guides for preparing opposed bone surfaces, including for correction and fusion of joints in the foot. Figures 6A and 6C of Bays are reproduced below.

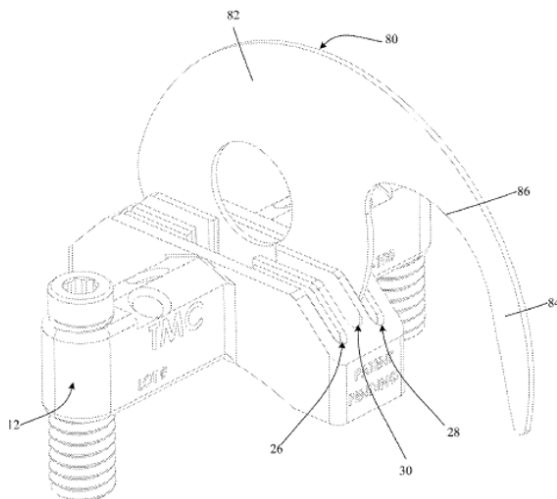


FIG. 6A

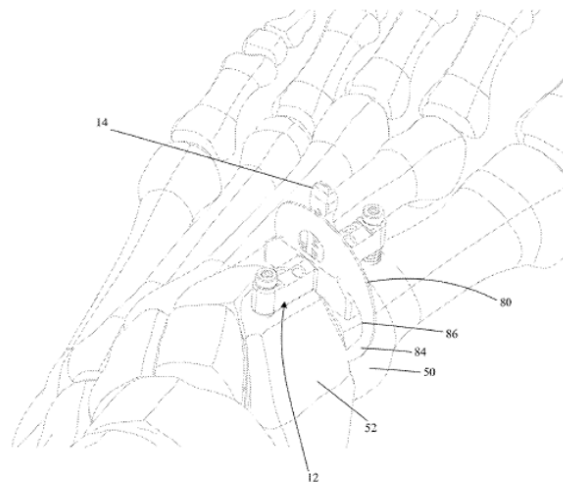
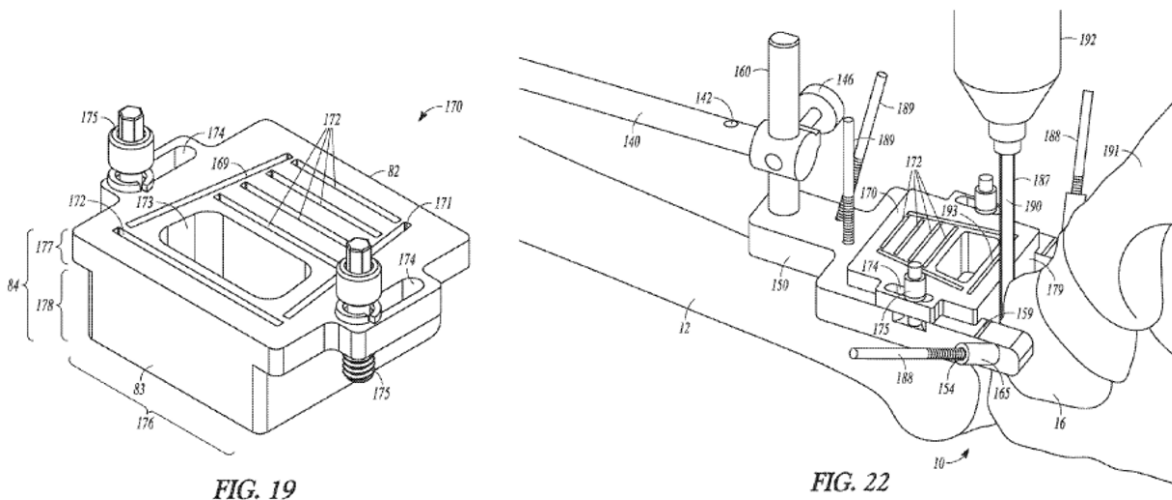


FIG. 6C

Bays discloses a bone preparation guide 12 having guide surfaces and slots for guiding a tissue-removing instrument, fixation openings, arms, and spacer or location-check structures used to position and orient the guide relative to the bones being prepared. Ex. 1006, 3:1–13, 4:20–46, 5:63–66, 19:5–11, 20:11–19.

NEAL

23. Neal is owned by Patent Owner’s parent company (Zimmer, Inc.) and was not cited during prosecution of the ’139 Patent. Neal is directed to instruments and methods for preparing bone surfaces for fusion, including resection guides used in foot and ankle procedures. Figures 19 and 22 of Neal are reproduced below.

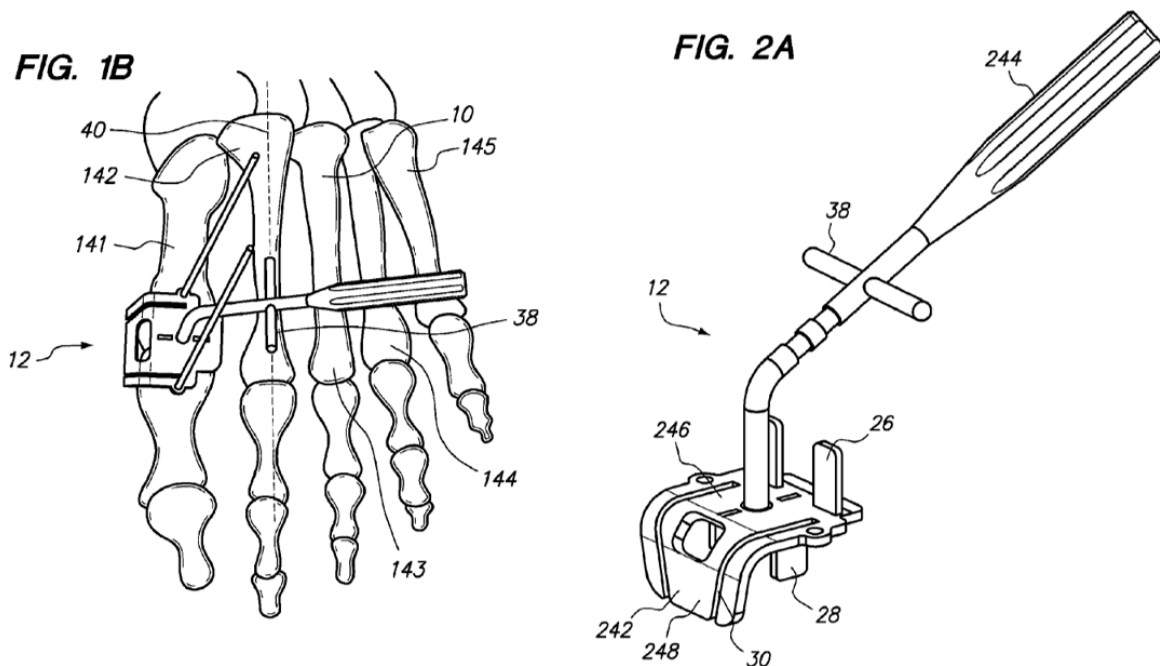


Neal discloses a resection guide 170 having a body 177, a posterior body 178, cutting slots, openings, and other guide surfaces configured to guide a cutting element during bone resection. Ex. 1007, Abstract, 22:1–32. Neal explains that its resection guide may be configured for different procedures, including resection of a first

metatarsophalangeal joint, and that slots, openings, or other interior or exterior guide surfaces may act as directional guides and supports for a bone cutting element. *Id.* at 22:1–32.

LAWRENCE

24. The publication that resulted in the issuance of the Lawrence patent is listed on the face of the '139 Patent but was not cited during prosecution. Lawrence is directed to a metatarsal bone implant cutting guide for guiding a saw blade during preparation of a metatarsal, including preparation to receive a metatarsal bone implant. Figures 1B and 2A of Lawrence are reproduced below.



Lawrence discloses a cutting guide 12 having a housing 242, housing top 246, housing side 248, alignment aperture 250, saw guides 30, alignment tabs 28,

retraction tabs 26, stabilizers 24, and a handle/aligner arrangement for positioning and aligning the saw guides relative to metatarsal anatomy. Ex. 1008, Abstract, 4:30–5:12. Lawrence teaches that the cutting guide accurately and repeatably aligns a saw blade so that a proper amount of bone may be cut and removed from the metatarsal. Id. at 3:10–23.

ANALOGOUS ART

25. Bays, Neal, and Lawrence are analogous art. First, each reference is from the same field of endeavor as the challenged patent. The '139 patent states that its disclosure relates to general, podiatric, and orthopaedic surgery, including devices, systems, and methods for maintaining, correcting, and/or fusing joint deformities. Ex. 1001, 1:27–31.

26. The '139 Patent Background specifically discusses the Lapidus procedure for correcting hallux valgus deformities (Ex. 1001, 1:35–37), which is a first tarsometatarsal joint fusion procedure. Bays, Neal, and Lawrence each disclose cut guides used in foot and ankle procedures for the same or closely related indications: Bays (first TMT joint fusion and bone preparation), Neal (first MTP joint resection), and Lawrence (metatarsal bone preparation). This specific procedural overlap further confirms each reference is in the same field of endeavor. The challenged claims are even broader, reciting generic “cut guide” structures without limiting the guide to any specific surgical procedure.

27. Bays, Neal, and Lawrence each disclose surgical cut or bone-preparation guides used in orthopedic or podiatric procedures. In my opinion, each reference falls within the same field of endeavor as the '139 patent and the challenged claims.

28. Second, Bays, Neal, and Lawrence are reasonably pertinent to the problems addressed by the '139 patent and the challenged claims. The '139 patent describes cut guides with slots and openings for positioning, alignment, and guiding cutting or fixation instruments relative to bone.

29. A POSA seeking to design or evaluate such a cut guide would naturally have looked to other orthopedic and podiatric cut guides that address the same functional problems: accurately positioning a guide relative to bone, providing slots or guide surfaces to control a cutting path, using openings or fixation features to stabilize or align the guide, and shaping guide surfaces to accommodate anatomy and the desired resection. Bays, Neal, and Lawrence each address those same problems through substantially similar mechanical guide structures. These references address the same mechanical and surgical design considerations implicated by the claimed cut guide and are, in my opinion, analogous art to the '139 patent. A POSA would have had reason to consider each of them when designing, modifying, or evaluating the claimed cut-guide structures. For example, each reference positions its guide relative to the bone and the intended cut. These are the

same positioning, cutting, and visualization functions performed by the slots and openings of the cut guide described in the '139 patent.

VI. ANTICIPATION OF CLAIMS 1-20 BY BAYS

CLAIM 1

30. Bays discloses a cut guide, as recited in the preamble of claim 1. Bays discloses each limitation of now-issued claim 1, other than the “at least one opening” extending into the base and the extension member. Bays also discloses the “at least one opening”, as demonstrated by the mappings below. Annotated versions of Figures 6A and 6D from Bays are reproduced below.

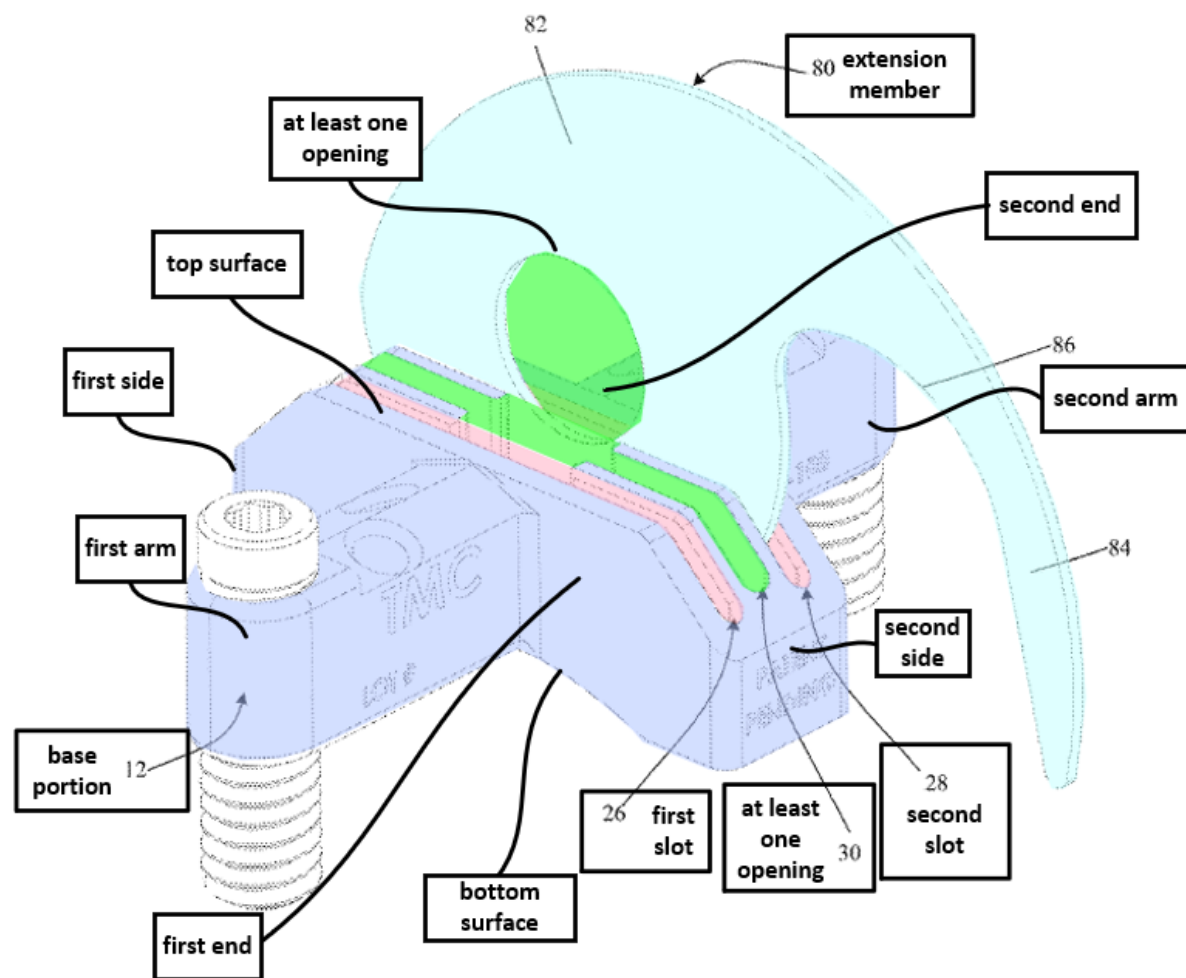


FIG. 6A

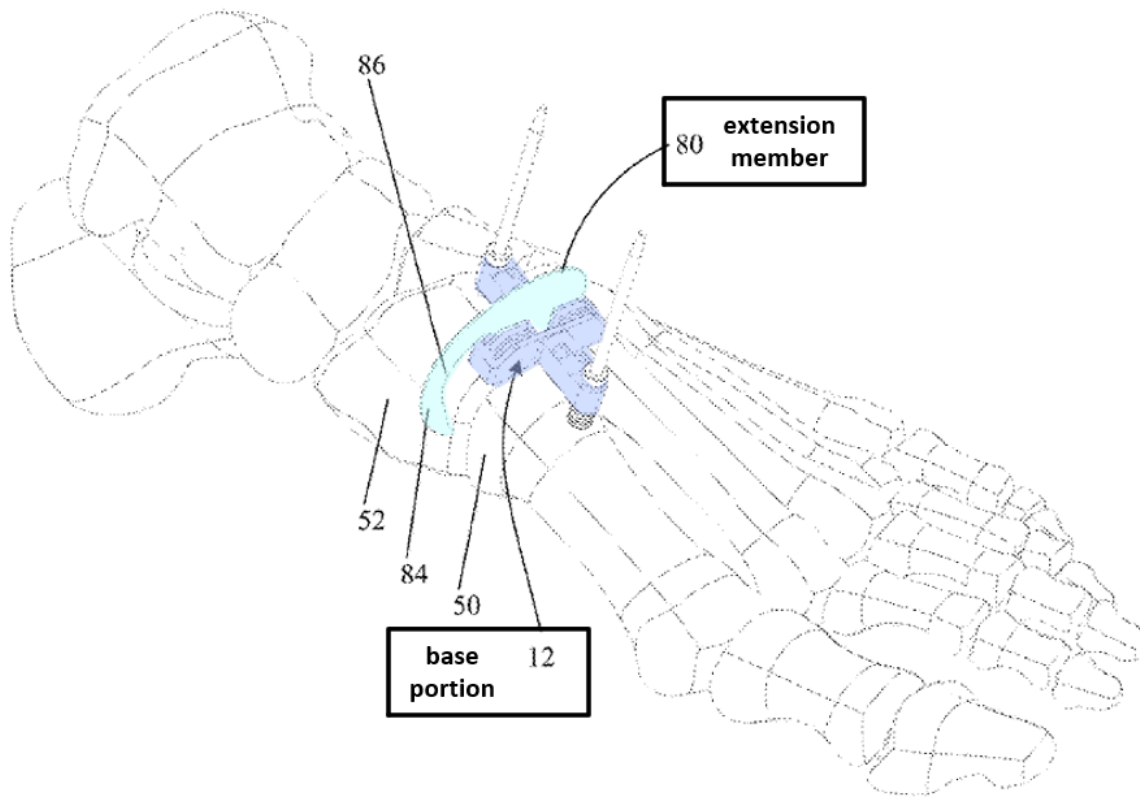


FIG. 6D

The annotated figures above provide an overview of the anticipation mapping by Bays, which will be discussed in detail below for each limitation.

Limitation 1[a]

31. Bays discloses a “base portion,” as seen in the annotated version of Figure 6A below.

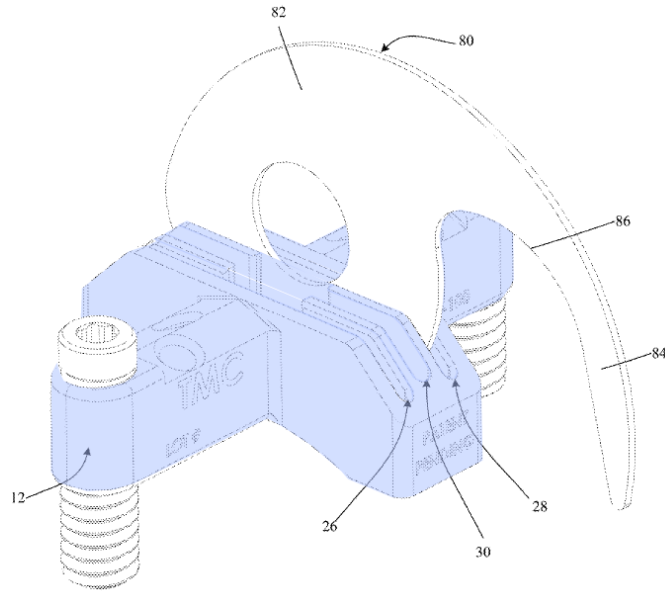
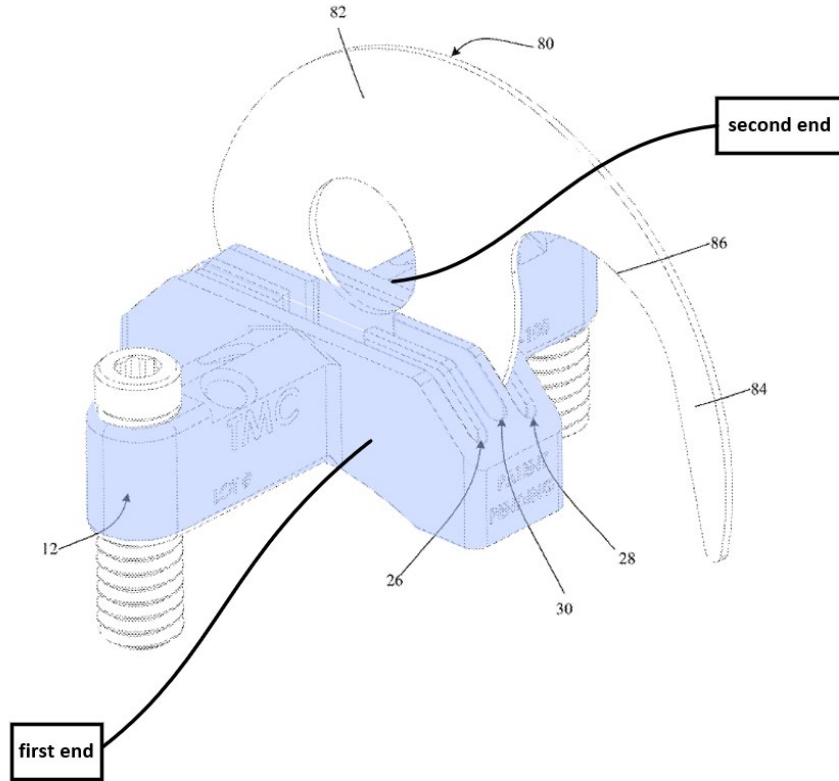


FIG. 6A

The “base portion” is the part highlighted in purple above. Bays describes a bone preparing guide 12 having a body 16. As seen in Figure 6A, body 16 is the main structure of guide 12. It defines slots 26, 28 and opening 30, and the first and second arms extend from its ends, as discussed below with respect to claims 7 and 11. A POSA would have understood body 16 to be the base portion because it is the part of guide 12 that is positioned over the bones being prepared and that carries the cutting and fixation features of the guide.

Accordingly, Bays discloses limitation 1[a].

Limitation 1[a][i]



Limitation 1[a][iii]

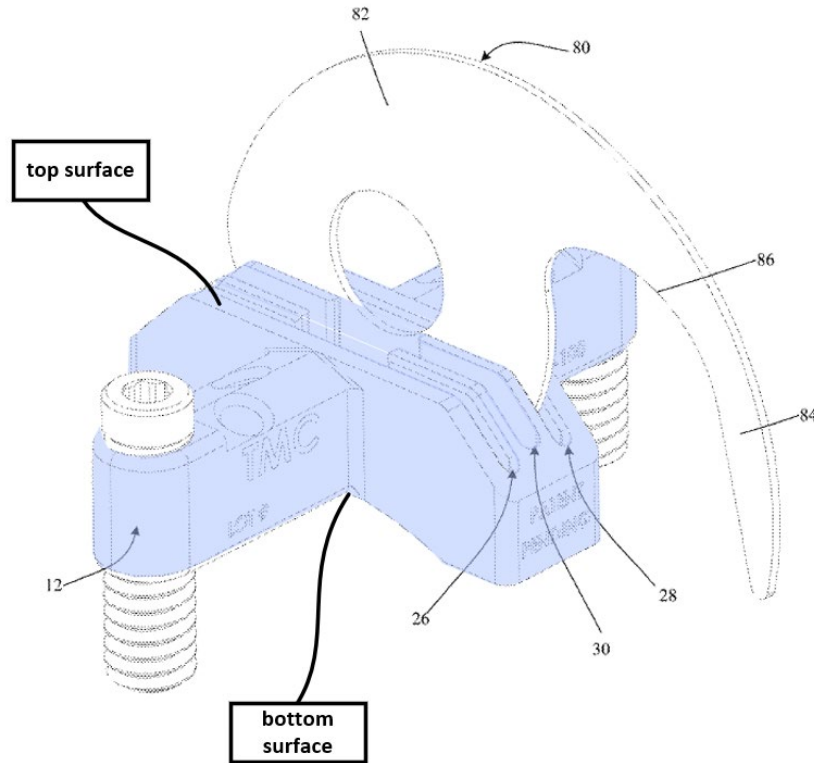


FIG. 6A

As seen above, the base portion has a top surface positioned substantially opposite a bottom surface. The bottom surface is the surface of body 16 that faces the bones when guide 12 is placed on the foot, as seen in Figures 6C and 6D, and the top surface is the opposite surface, facing away from the bones, at which the tissue-removing instrument is introduced into slots 26, 28. Accordingly, Bays discloses limitation 1[a][iii].

Limitation 1[a][iv]

35. Bays discloses its “base portion” having “at least one slot disposed between the first and second ends of the base portion and extending at least partially

between the first side and the second side of the base, wherein the slot provides fluid communication between the top and bottom surfaces of the base,” as seen in the annotated version of Figure 6A below.

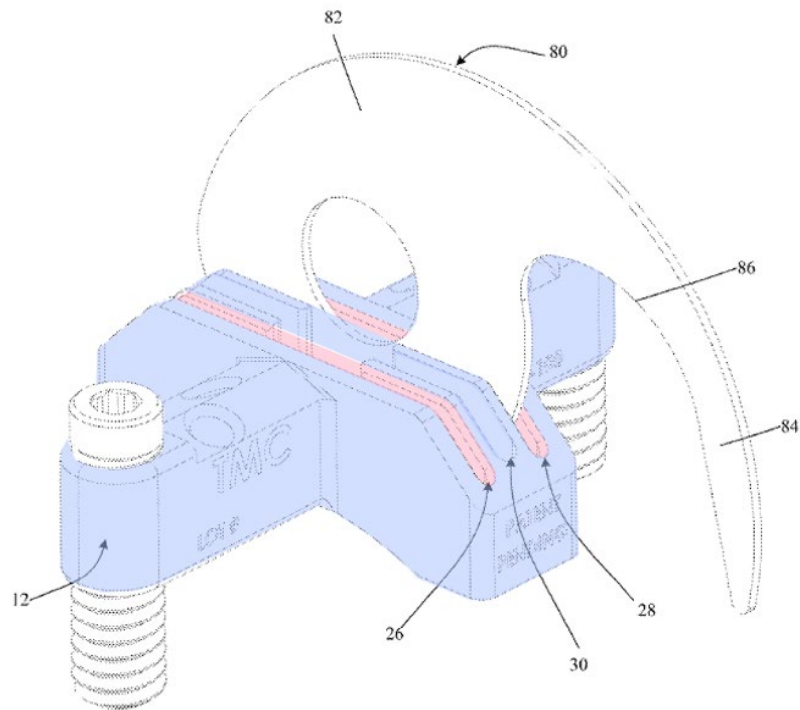


FIG. 6A

As seen above, Bays discloses multiple slots 26, 28 (pink highlighting) disposed between the first and second ends of the base portion and extending at least partially between the first side and the second side of the base.

36. Slots 26 and 28 extend entirely through the body 16 of the guide from the top surface to the bottom surface: the slots must open at both the top and bottom

of the base to allow an instrument to pass through the guide and contact the underlying bone. Ex. 1006, 4:46–48 (“Each slot 26, 28 can be sized to receive a tissue removing instrument to prepare the bone ends therethrough.”). This through-passage constitutes fluid communication between the top and bottom surfaces of the base as required by limitation 1[a][iv]. A POSA would have understood “fluid communication” between the top and bottom surfaces to describe an open passage connecting those surfaces, through which fluids present during bone preparation can pass. Each of slots 26, 28 is such a passage because it is open at the top surface, where the instrument is introduced, and at the bottom surface, where the instrument reaches the bone. Accordingly, Bays discloses limitation 1[a][iv].

Limitation 1[a][v]

37. Bays discloses its “base portion” having “at least one opening extending therethrough,” as seen in the annotated version of Figure 6A below.

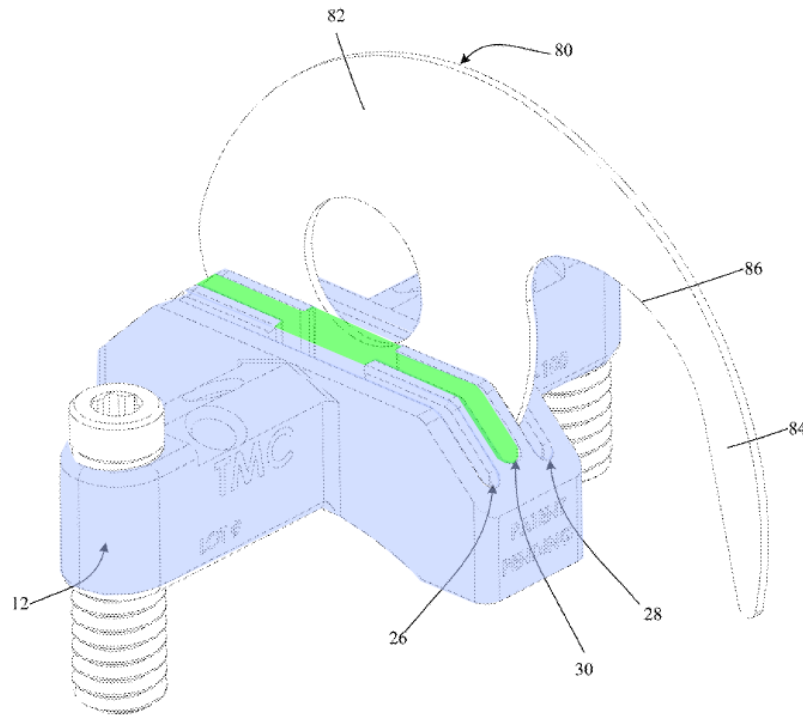


FIG. 6A

As seen above, an opening 30 (green highlighting) extends through the base portion.

38. Bays also describes the extent of the opening 30 through the base portion. Bays explains, for example, that “[t]he opening 30 can thus be an area between the slots 26, 28 useful, for instance, for allowing a practitioner to have a visual path to an osteotomy site (e.g., cartilage, bones, and / or joint space) during bone preparation and/or to receive instruments, as discussed further below.” Ex. 1006, 4:57–61. Accordingly, Bays discloses limitation 1[a][v].

Limitation 1[b]

39. Bays discloses “an extension member extending downward from the bottom surface of the base,” as seen in the annotated version of Figure 6D below.

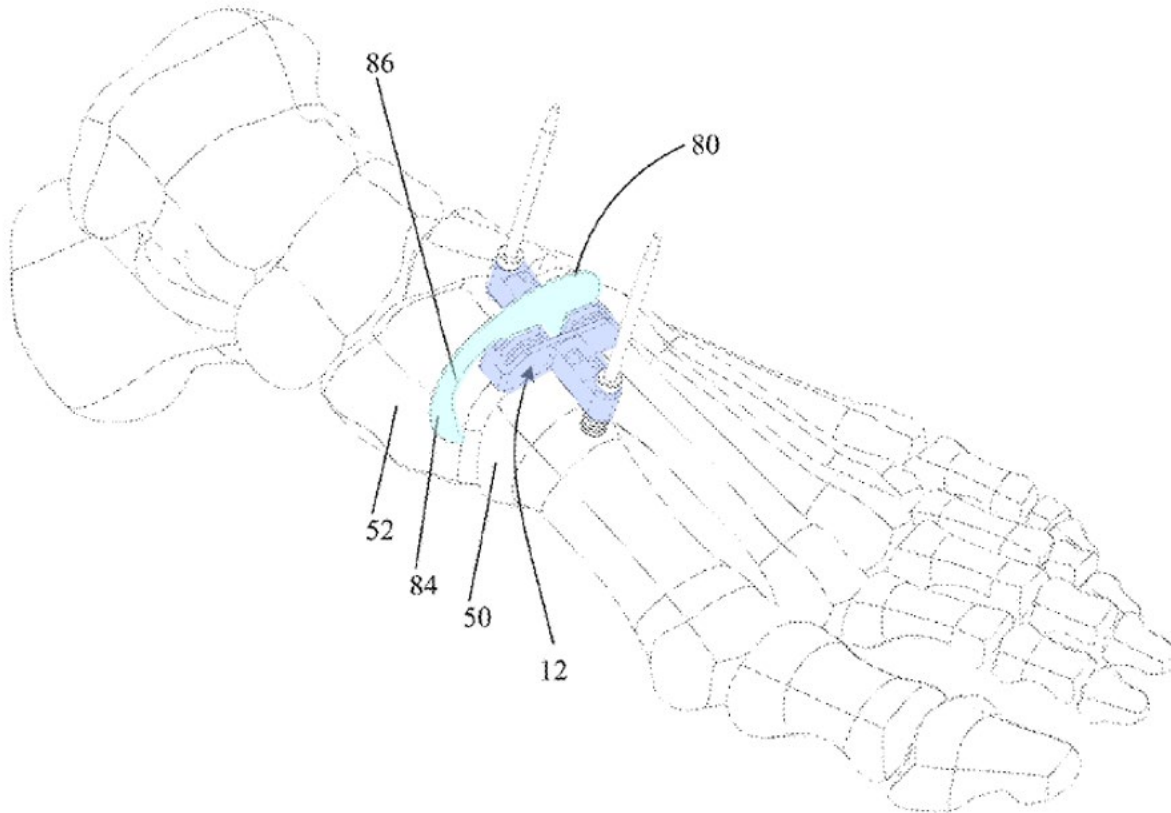


FIG. 6D

Bays discloses an “extension member” (location check member 80 in teal highlighting). Bays explains that “[t]he member 80 can be engaged with the guide 12 when the guide 12 is placed onto a foot (as shown in FIGS. 6C and 6D)” and “when the member 80 is engaged with the guide 12 on a foot, the first portion 82 can extend and contact a bone end at a same depth and location at which a cutting instrument would contact this bone end when using the guide 12 (e.g., via a slot defined in the guide).” Ex. 1006, 20:11–13, 15–19. Member 80 therefore extends

downward from the bottom surface of the base to contact the bone. Because first portion 82 extends from guide 12 to the depth and location at which the cutting instrument would contact the bone end, member 80 projects below the bottom surface of the base toward the bone. This allows the surgeon to confirm, before cutting, where the instrument will contact the bone.

40. Although shown as a separate component in the figures, Bays additionally explains that “in other embodiments the member 80 can be integral with the spacer 14 and/or guide 12.” Ex. 1006, 21:1–3. Thus, regardless of whether Patent Owner alleges any claim interpretation requiring a separate or integral extension member, Bays teaches both arrangements.

41. The disclosure of Bays therefore supports member 80 corresponding to the claimed extension member under either a separate-component or integral-component reading. Bays states that member 80 may engage guide 12 at opening 30, may extend down through the guide, and may project from the guide to show where the tissue-removing instrument will contact the bone. Ex. 1006, 19:5–11, 20:11–19, 21:1–3. Accordingly, Bays discloses limitation 1[b].

Limitation 1[b][i]

42. Bays discloses “wherein the at least one opening extends into at least a portion of the extension member,” as seen in the annotated version of Figure 6A below.

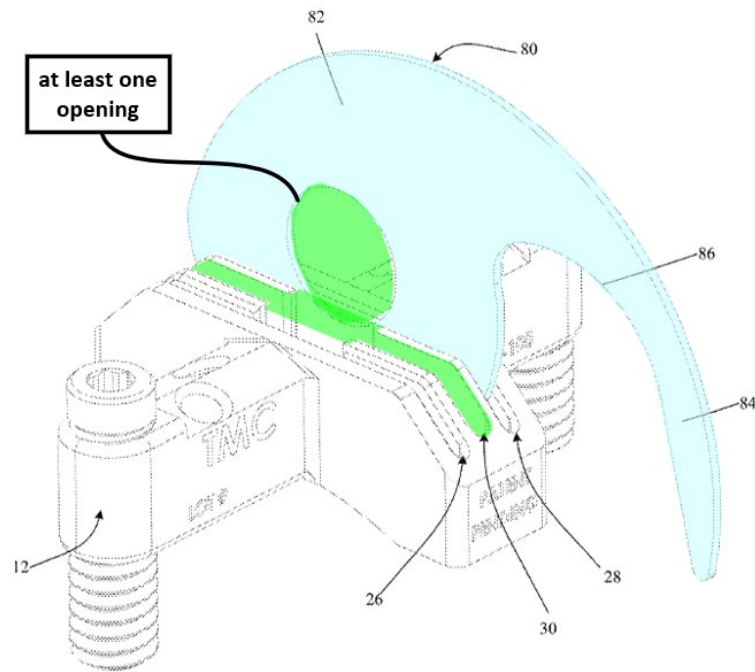


FIG. 6A

Bays discloses an opening (green highlighting) in the extension member 80 (teal highlighting). As seen above in the annotated Figure 6A, the opening in the extension member extends into both the extension member and the base portion even before the extension member is fully seated against the bone. After the extension member is seated against the bone as seen in Figure 6D above, the opening in the extension member and the opening 30 in the base portion remain in communication with one another (i.e., the same continuous opening indicated by the green highlighting above).

Bays explains:

The *member 80 can be engageable with the guide 12*, such as at a slot 26 or 28 or *opening 30*, via the first portion 82 of the member 80. As shown, the first portion 82 is engaged with the guide 12 at the slot 28 and in some cases can extend down through the slot 28. In other examples, the first portion 82 can engage the guide 12 at the slot 26 or at the opening 30.

Ex.1006, 19:5–11 (emphasis added).

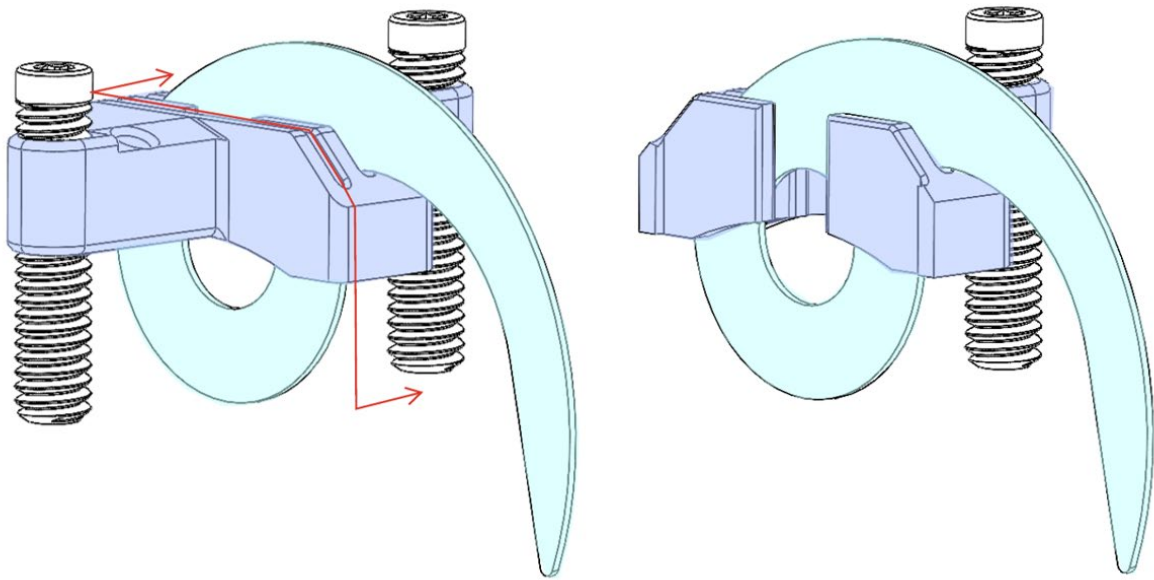
43. Bays therefore teaches that member 80 engages the guide through opening 30 and that, when engaged, the first portion 82 extends to the bone-contact depth/location corresponding to the cutting instrument. Ex. 1006, 19:5–11, 20:11–19. That disclosure supports the mapping of the combination of opening 30 and the opening in member 80 as a continuous guide/member passage corresponding to the claimed opening extending into at least a portion of the extension member. When first portion 82 is received in opening 30, the opening in member 80 and opening 30 are open to one another, so that the opening defined by the base portion continues into member 80. The opening is therefore at least partially defined by the extension member, consistent with the plain meaning of “extends into at least a portion of the extension member” discussed above in Section IV.

44. As explained above, Bays explains that “[t]he opening 30 can thus be an area between the slots 26, 28 useful, for instance, for allowing a practitioner to

have a visual path to an osteotomy site (e.g., cartilage, bones, and / or joint space) during bone preparation and/or to receive instruments, as discussed further below.” Ex. 1006, 4:57–61. The opening in extension member 80 would naturally facilitate continued visualization when inserted in opening 30 by providing a continued line of sight through the opening to the osteotomy site.

45. Furthermore, where member 80 is integral with guide 12 (as Bays expressly permits, Ex. 1006, 21:1–3), there is a single unitary opening that extends from the top surface of the guide body downward through the integral extension member, satisfying limitation 1[b][i] regardless of how Patent Owner seeks to construe “extends into at least a portion of the extension member.”

46. The “at least one opening” extending into the extension member as would be present in the integral version of Bays with the extension member extending through opening 30, as illustrated in the modified drawing from Bays provided below.



The image above is a modified version of the cut guide from Bays from Figure 6D, showing a perspective (left) and section (right) view to illustrate what the relationship between the “at least one opening” in the guide and extension member in use. Accordingly, Bays discloses limitation 1[b][i].

CLAIM 2

47. Claim 2 depends from claim 1 and recites that “the at least one slot comprises at least one first slot and at least one second slot,” as seen in the annotated version of Figure 6A below.

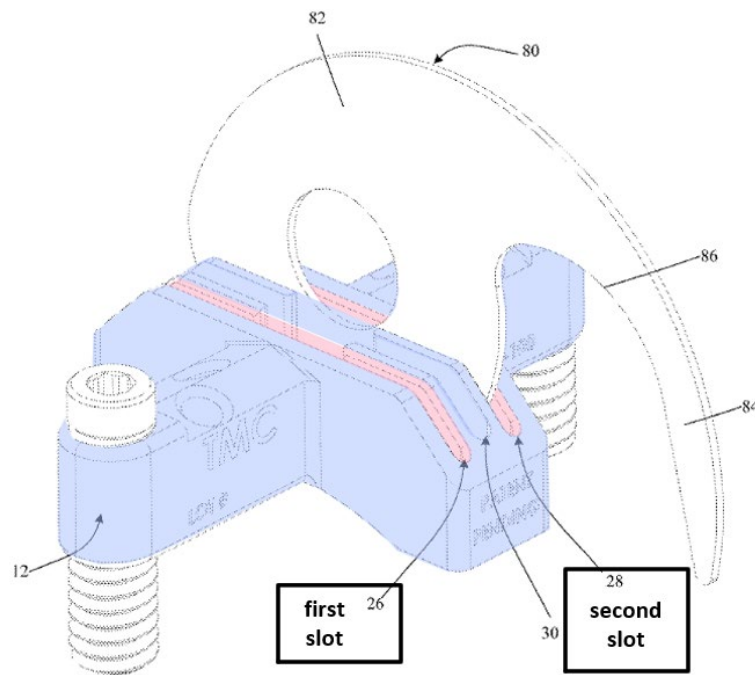


FIG. 6A

As seen above, Bays discloses a first slot 26 and a second slot 28 (pink highlighting).

Accordingly, Bays discloses the limitations recited in claim 2.

CLAIM 3

48. Claim 3 depends from claim 2 and recites that “the extension member is positioned at least partially between the at least one first slot and the at least one second slot.”

49. Although the drawings reproduced above show an embodiment where the extension member 80 is located in second slot 28, that is just one example. Bays discloses:

The *member 80 can be engageable with the guide 12*, such as at a slot 26 or 28 or *opening 30*, via the first portion 82 of the member 80. As shown, the first portion 82 is engaged with the guide 12 at the slot 28 and in some cases can extend down through the slot 28. In other examples, the first portion 82 can engage the guide 12 at the slot 26 or at the opening 30.

Ex. 1006, 19:5–11 (emphasis added). That is, Bays also discloses that extension member 80 can be disposed within opening 30. An annotated version of Bays Figure 6A is reproduced below.

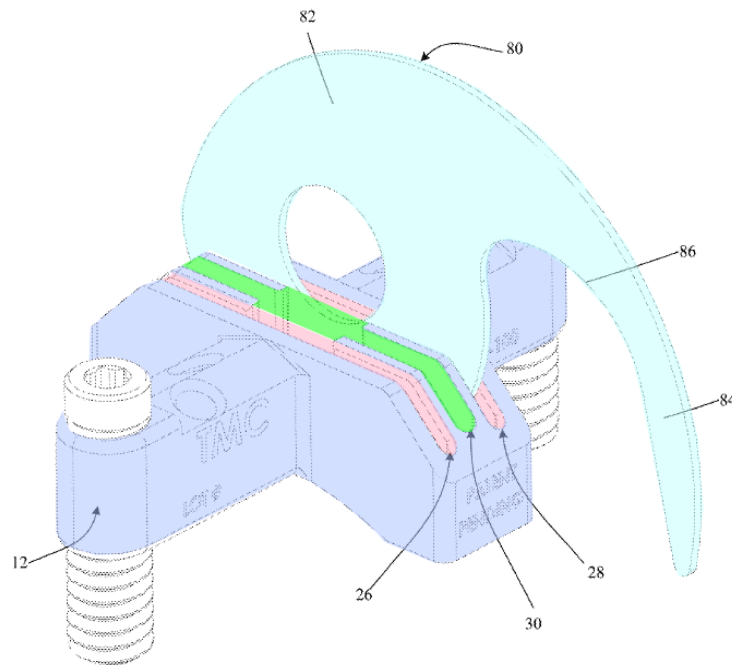


FIG. 6A

Opening 30 is between the first slot 26 and the second slot 28. Accordingly, when extension member 80 is disposed in opening 30, it is at least partially between the at least one first slot and the at least one second slot. Accordingly, Bays discloses the limitations recited in claim 3.

CLAIM 4

50. Claim 4 depends from claim 3 and recites that “the extension member extends from the bottom surface of the base portion at a substantially orthogonal angle relative to the bottom surface of the base portion.”

51. As discussed above in connection with limitation 1[b], Bays discloses its extension member 80 extending downward from the bottom surface of the base. And as seen above in the annotated Figure 6A provided in connection with claim 3, the opening 30 extends in a plane perpendicular to the bottom surface of the base.

52. Bays also describes spacer 14 extending perpendicular to the base when extending through the opening 30. See, e.g., Ex. 1006, 4:55–5:42; see also 5:63–66 (“a distal portion of the spacer can be inserted into a joint space (e.g., tarsal-metatarsal joint space) and the guide 12 positioned over the top of the spacer with a proximal portion of the spacer projecting out from the top of the guide,” confirming the upright, orthogonal orientation of the spacer/member through opening 30). A member received in opening 30, like spacer 14, is guided by the walls of opening 30, which extend perpendicular to the bottom surface of body 16. Extension member

80 would have the same orthogonal orientation when located in opening 30. Accordingly, Bays discloses the limitations recited in claim 4.

CLAIM 5

53. Claim 5 depends from claim 4 and recites that “the at least one first slot is positioned in a first plane and the at least one second slot is positioned in a second plane, wherein the first and second planes form an oblique angle.”

54. Although the drawings reproduced above show an embodiment where the first slot 26 and second slot 28 are parallel to one another, that is just one example. Bays discloses that “[t]he first and second slots 26, 28 may be parallel or skewed (e.g., non-parallel) to each other.” Ex. 1006, 4:48–49. Figure 5 of Bays illustrates an example of the skewed arrangement.

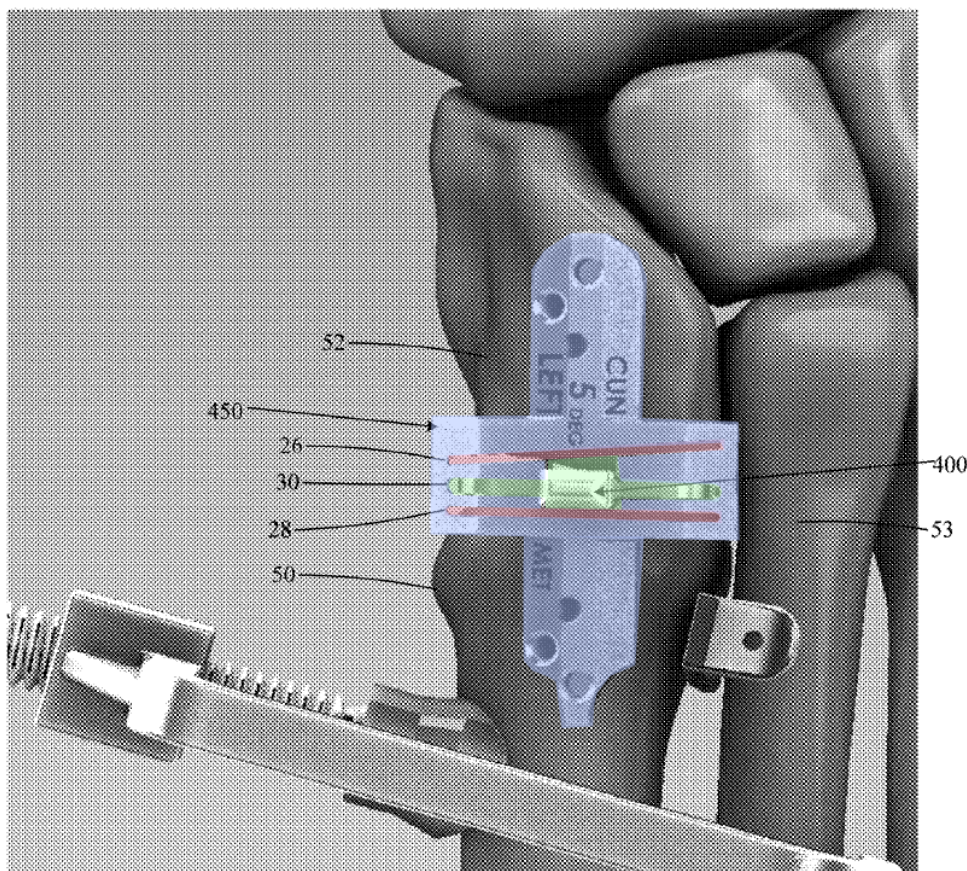


FIG. 5

Id. at 17:15–58 (discussing same).

55. Bays further discloses guides with variable skew angles and interchangeable guide bodies having different slot angles. Ex. 1006, 10:54–11:8; 17:15–58. Bays therefore discloses the first slot 26 positioned in a first plane and the second slot 28 positioned in a second plane at an oblique angle relative to the first plane. Slots positioned in planes that form an oblique angle guide two cuts that converge, so that a wedge-shaped portion of bone is removed between them. Ex.

1006, 4:1–18, 9:50–10:21. A POSA would have understood that this arrangement is used to correct an angular deformity, because closing the wedge-shaped space when the prepared bone ends are brought together changes the angle between the bones. Accordingly, Bays discloses the limitations recited in claim 5.

CLAIM 6

56. Claim 6 depends from claim 5 and recites that “the at least one opening provides fluid communication between the top and bottom surfaces of the base portion.”

57. Opening 30 extends from the top surface through the bottom surface of the base. Bays directly confirms this: opening 30 provides “a visual path to an osteotomy site (e.g., cartilage, bones, and/or joint space) during bone preparation and/or to receive instruments.” Ex. 1006, 4:57–61. A visual path to the osteotomy site below the guide means the opening extends through the guide body from the top to the bottom surface.

58. Bays also explains that “when the member 80 is engaged with the guide 12 on a foot, the first portion 82 can extend and contact a bone end at a same depth and location at which a cutting instrument would contact this bone end.” 20:11–19. For member 80 to extend from the top of the guide down to bone contact, opening 30 must extend entirely through the guide body from top surface to bottom surface. See, e.g., Ex. 1006, 5:63–66 (“a distal portion of the spacer can be inserted into a

from the same corresponding end locations of body 16. Ex. 1006, 4:35–41. The arms extend from the ends of body 16, outside the region of slots 26, 28, and include openings for fixing guide 12 to the bone. Placing the fixation openings on arms at the ends of the base allows guide 12 to be secured to the bone on either side of the cutting region without obstructing the slots. Accordingly, Bays discloses the limitations recited in claim 7.

CLAIM 8

60. Claim 8 depends from claim 7 and recites that “the first arm forms a substantially orthogonal angle with the first end of the base portion.” As discussed above and shown in the annotated Figure provided in connection with claim 7, the first arm in Bays extends generally orthogonal to the first end of the base portion. Accordingly, Bays discloses the limitations recited in claim 8.

CLAIM 9

61. Claim 9 depends from claim 8 and recites that “the first arm comprises a first opening extending therethrough from a top surface through to a bottom surface thereof,” as seen in the annotated version of Figure 6A below.

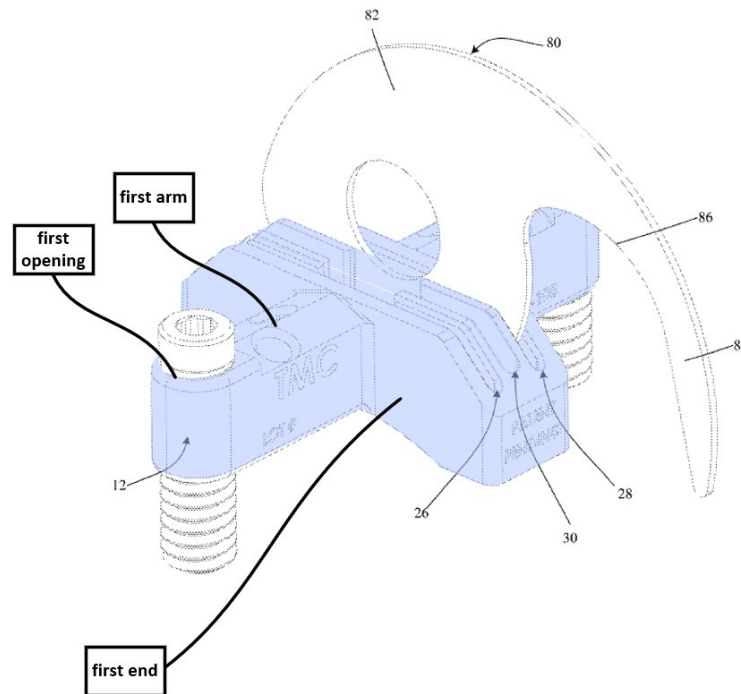


FIG. 6A

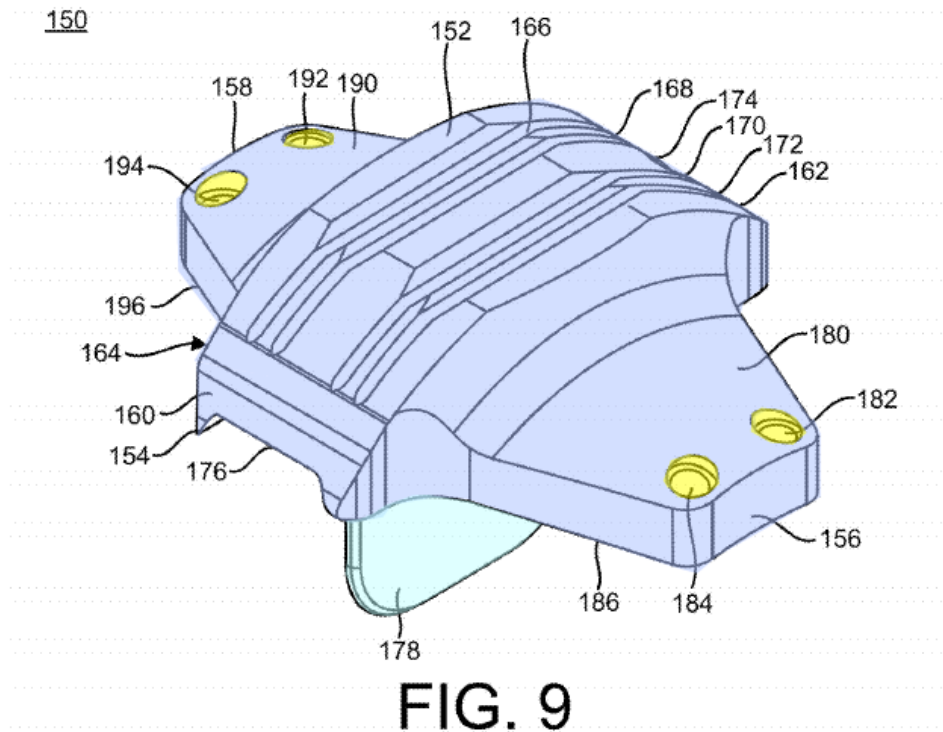
As seen above, the first arm includes a first opening extending therethrough from a top surface through to a bottom surface thereof. See Ex. 1006, 5:12–28 (discussing same). As seen in Figure 6A, the opening in the first arm receives a fixation member that passes from the top surface of the arm through its bottom surface toward the bone. Accordingly, Bays discloses the limitations recited in claim 9.

CLAIM 10

62. Claim 10 depends from claim 9 and recites that “the first opening is positioned at a terminal end of the first arm.”

63. As discussed above and shown in the annotated Figure provided in connection with claim 9, the first opening in Bays is positioned at a terminal end of the first arm. “Terminal end” does not appear in the ’139 Patent’s Specification. The

apertures in the arms of the cut guide from the '139 Patent show its openings (i.e., “the first opening”) at distal end regions of the arms, as seen in the annotated version of the Figure reproduced below.



As seen above, openings 182, 184, 192, 194 (yellow highlighting) are holes at distal ends of the arms of the cut guide like those in Bays. A POSA would have understood the “terminal end” of an arm to be its end region farthest from the base portion, consistent with the location of openings 182, 184, 192, 194 in the '139 patent. As seen in Figure 6A, the openings in the arms of Bays are likewise located at the end regions of the arms farthest from body 16. Accordingly, Bays discloses the limitations recited in claim 10.

CLAIM 11

64. Claim 11 depends from claim 10 and recites that “the cut guide further comprises a second arm extending from the second end of the base portion,” as seen in the annotated version of Figure 6A below.

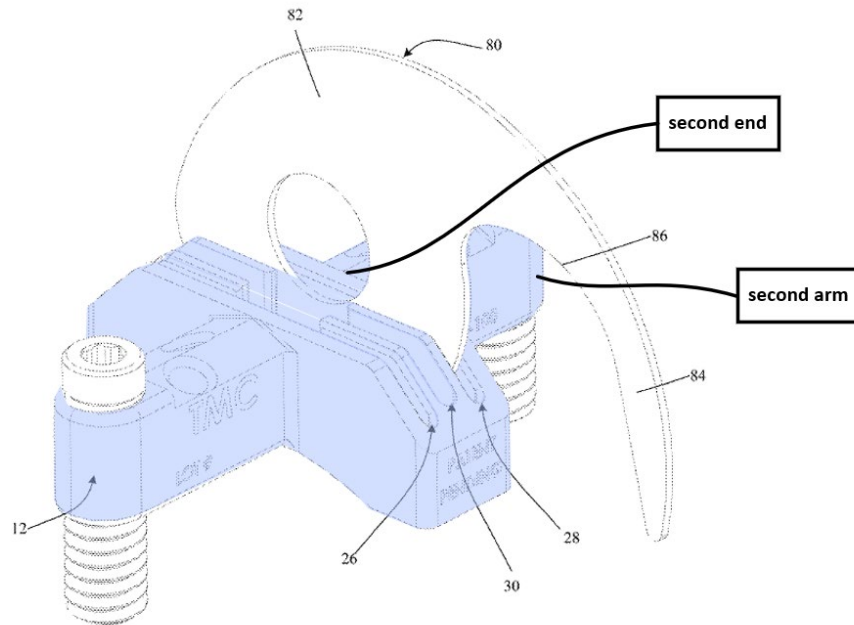


FIG. 6A

As seen above, the second arm in Bays extends from the second end of the base portion as a monolithic part. Accordingly, Bays discloses the limitations recited in claim 11.

CLAIM 12

65. Claim 12 depends from claim 11 and recites that “the second arm forms a substantially orthogonal angle with the second end of the base portion.” As discussed above and shown in the annotated Figure provided in connection with

claim 11, the second arm in Bays extends generally orthogonal to the second end of the base portion. Accordingly, Bays discloses the limitations recited in claim 12.

CLAIM 13

66. Claim 13 depends from claim 12 and recites that the “second arm comprises a second opening extending therethrough from a top surface through to a bottom surface thereof,” as seen in the annotated version of Figure 6A below.

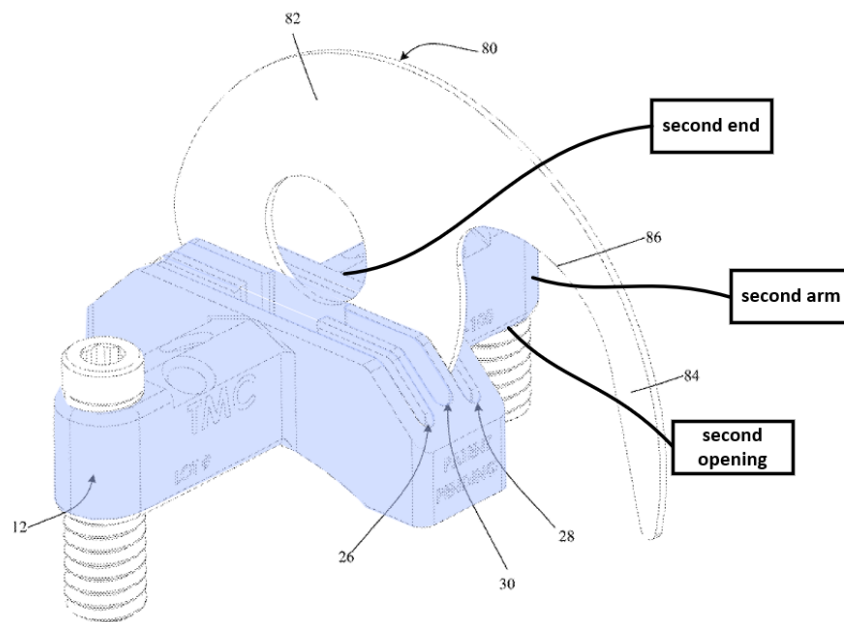


FIG. 6A

As seen above, the second arm includes a second opening extending therethrough from a top surface through to a bottom surface thereof. See Ex. 1006, 5:12–28 (discussing same). Accordingly, Bays discloses the limitations recited in claim 13.

CLAIM 14

67. Claim 14 depends from claim 13 and recites that “the second opening is positioned at a terminal end of the second arm.” As discussed above and shown in the annotated Figure provided in connection with claim 13, the second opening in Bays is positioned at a terminal end of the second arm. Accordingly, Bays discloses the limitations recited in claim 14.

CLAIM 15

68. Claim 15 depends from claim 1 and recites that “the top surface comprises a first portion and a second portion,” as seen in the annotated version of Figure 6A below.

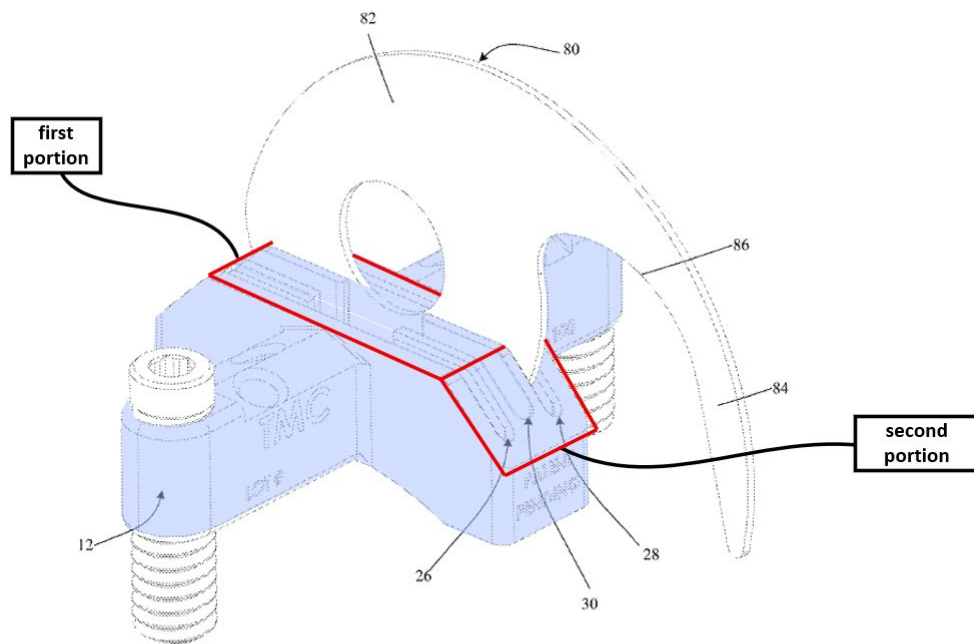


FIG. 6A

As seen above, Bays includes a first portion of the top surface (central portion outlined in red) and a second portion of the top surface (end portion outlined in red) extending at an angle from the first portion. Accordingly, Bays discloses the limitations recited in claim 15.

CLAIM 16

69. Claim 16 depends from claim 15 and recites that “the first portion is positioned in a plane which is substantial[ly] parallel to a plane of the bottom surface, and the second portion is positioned in a plane which is substantially oblique to that of the first portion and the bottom surface,” as seen in the annotated versions of Figure 6A below. One example of the planar bottom surfaces is shown in the annotated version of Figure 6A of Bays below.

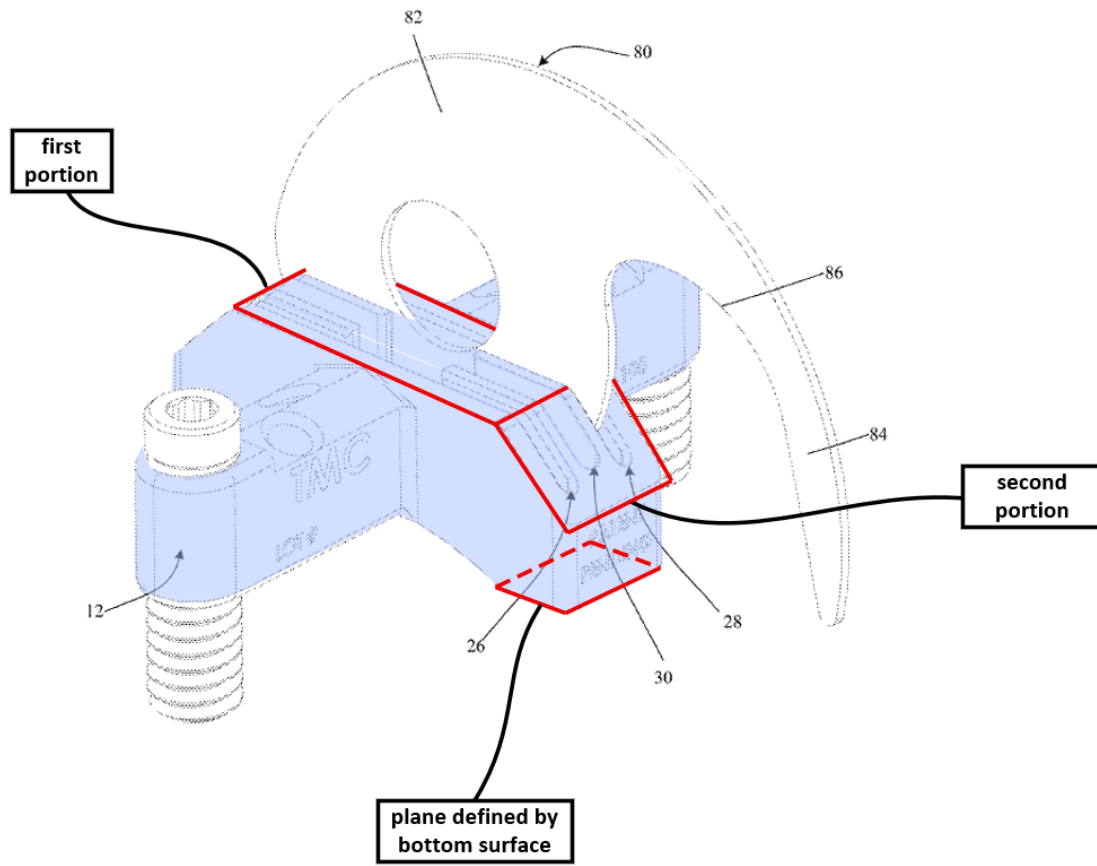


FIG. 6A

As seen above, the plane of the first portion is substantially parallel to the plane of the bottom portion. And the plane of the second portion is substantially oblique to the plane of the bottom portion.

70. Another example of a planar bottom surface from Bays is shown in the annotated Figure 6A reproduced below.

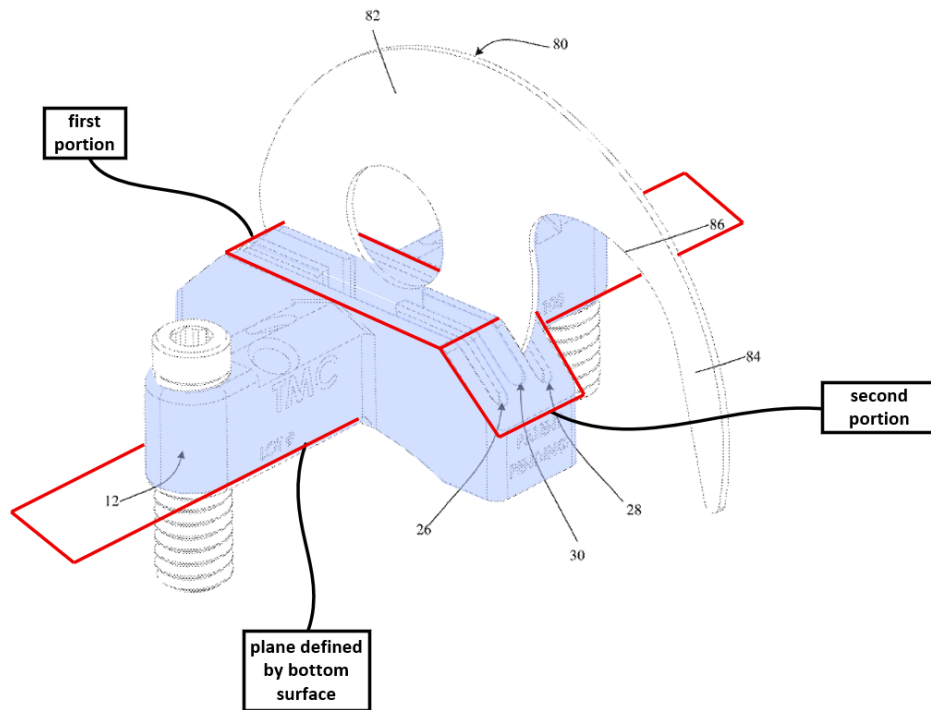


FIG. 6A

As seen above, the first portion of the top surface (the main, flat region of body 16) extends generally parallel to the bottom surface of the base portion. The second portion of the top surface (the angled region where guide surface is oriented obliquely) is disposed at an oblique angle relative to both the first portion and the bottom surface. The second portion slopes from the first portion toward the bottom surface, so that its plane intersects the planes of both the first portion and the bottom surface at an oblique angle. Accordingly, Bays discloses the limitations recited in claim 16.

CLAIM 17

71. Claim 17 depends from claim 16 and recites that “at least a portion of the at least one slot is positioned in the first portion of the top surface and the second portion of the top surface,” as seen in the annotated version of Figure 6A below.

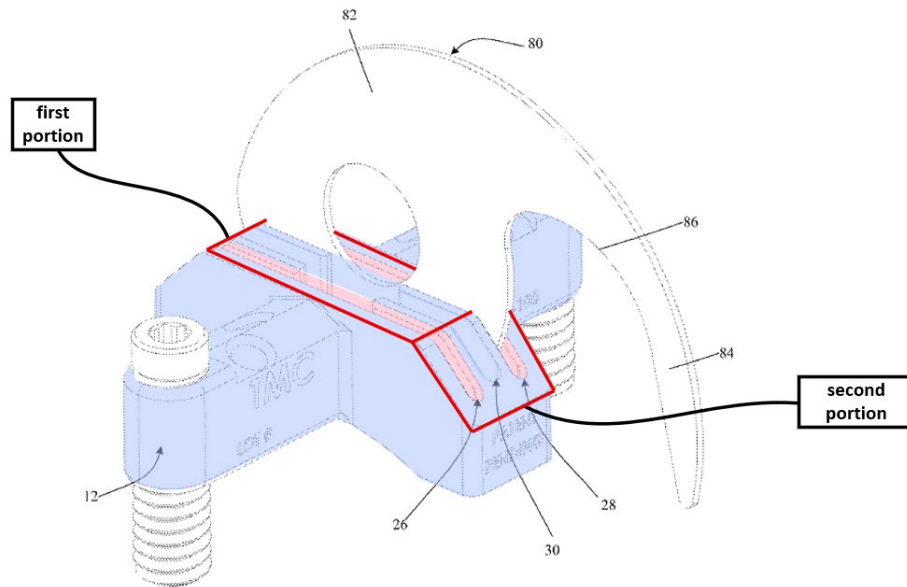


FIG. 6A

As seen above, the first and second slots 26, 28 (pink highlighting) extend along both the first and second portions of the top surface and are therefore positioned in the first portion of the top surface and the second portion of the top surface. Accordingly, Bays discloses the limitations recited in claim 17.

CLAIM 18

72. Claim 18 is an independent claim that includes limitations recited in claims 1, 15, 16, and 17 as set forth in the table below.

Claim 18		
Claim 18 Limitation	Corresponding Limitation	Claim 18
[18][pre]	1[pre]	A cut guide, comprising:
[18][a]	1[a]	a base portion, comprising:
[18][a][i]	[1][a][ii]	a first end positioned substantially opposite the base portion from a second end;
[18][a][ii]	[1][a][iii]	a top surface positioned substantially opposite the base portion from a bottom surface, comprising:
[18][a][ii][1]	15/16	a first portion positioned in a first plane; and
[18][a][ii][2]	15/16	a second portion positioned in a second plane, wherein the second plane is substantially oblique to the first plane;
[18][a][iii]	[1][a][iv]	at least one slot disposed between the first and second ends of the base portion,
[18][a][iii][1]	[1][a][iv]	wherein the at least one slot provides fluid communication between the top and bottom surfaces of the base,
[18][a][iii][2]	17	wherein at least a portion of the at least one slot is positioned in the first portion and the second portion of the top surface; and
[18][a][iv]	[1][a][v]	at least one opening extending through the base portion; and
[18][b]	[1][b]	an extension member extending downward from the bottom surface of the base,
[18][b][i]	[1][b][i]	wherein the at least one opening extends into at least a portion of the extension member.

The discussion above relative to the limitations in claim 1, 15, 16, and 17 that correspond to those in claim 18 are incorporated herein by reference. For the reasons discussed above, Bays discloses the limitations recited in claim 18.

CLAIM 19

73. Claim 19 depends from claim 18 and additionally includes limitations recited in claims 2 and 5 as set forth in the table below.

Claim 19 Limitation	Corresponding Limitation	Claim 19
19	2/5	The cut guide of claim 18, wherein the at least one slot comprises a first slot and a second slot, wherein the first and second slots are positioned in planes which form an oblique angle with one another.

The discussion above relative to the limitations in claims 2 and 5 that correspond to those in claim 19 are incorporated herein by reference. For the reasons discussed above, Bays discloses the limitations recited in claim 19.

CLAIM 20

74. Claim 20 is an independent claim that includes limitations recited in claims 1, 7–11, and 13–17 as set forth in the table below.

Claim 20 Limitation	Corresponding Limitation	Claim 20
[20][pre]	[1][pre]	A cut guide, comprising:
[20][a]	[1][a]	a base portion, comprising:
[20][a][i]	[1][a][ii]	a first side positioned substantially opposite the base portion from a second side,
[20][a][ii]	not in claim 1	wherein the first and second sides are substantially parallel to one another;
[20][a][iii]	[1][a][ii]	a first end positioned substantially opposite the base portion from a second end;

[20][a][iv]	[1][a][iii]	a top surface positioned substantially opposite the base portion from a bottom surface,
-------------	-------------	---

		comprising:
[20][a][iv][1]	15/16	a first portion positioned in a first plane; and
[20][a][iv][2]	15/16	a second portion positioned in a second plane, wherein the second plane is substantially oblique to the first plane;
[20][a][v]	[1][a][iv]	at least one slot disposed between the first and second ends of the base portion,
[20][a][v][1]	[1][a][iv]	wherein the at least one slot provides fluid communication between the top and bottom surfaces of the base,
[20][a][v][2]	17	wherein at least a portion of the at least one slot is positioned in the first portion and the second portion of the top surface; and
[20][a][vi]	[1][a][v]	at least one opening extending from the top surface through to the bottom surface;
[20][b]	[1][b]	an extension member extending downward from the bottom surface of the base,
[20][b][i]	[1][b][i]	wherein the at least one opening extends into at least a portion of the extension member.
[20][c]	7/8	a first arm extending from the first end of the base portion at a substantially orthogonal angle, comprising:
[20][c][i]	9/10	an opening positioned at a terminal end of the first arm and extending from a top surface of the first arm through to a bottom surface of the first arm; and
[20][d]	11	a second arm extending from the second end of the base portion, comprising:
[20][d][i]	13/14	an opening positioned at a terminal end of the second arm and extending from a top surface of the second arm through to a bottom surface of the second arm.

The discussion above relative to the limitations in claims 1, 7–11, and 13–17 that correspond to those in claim 20 are incorporated herein by reference.

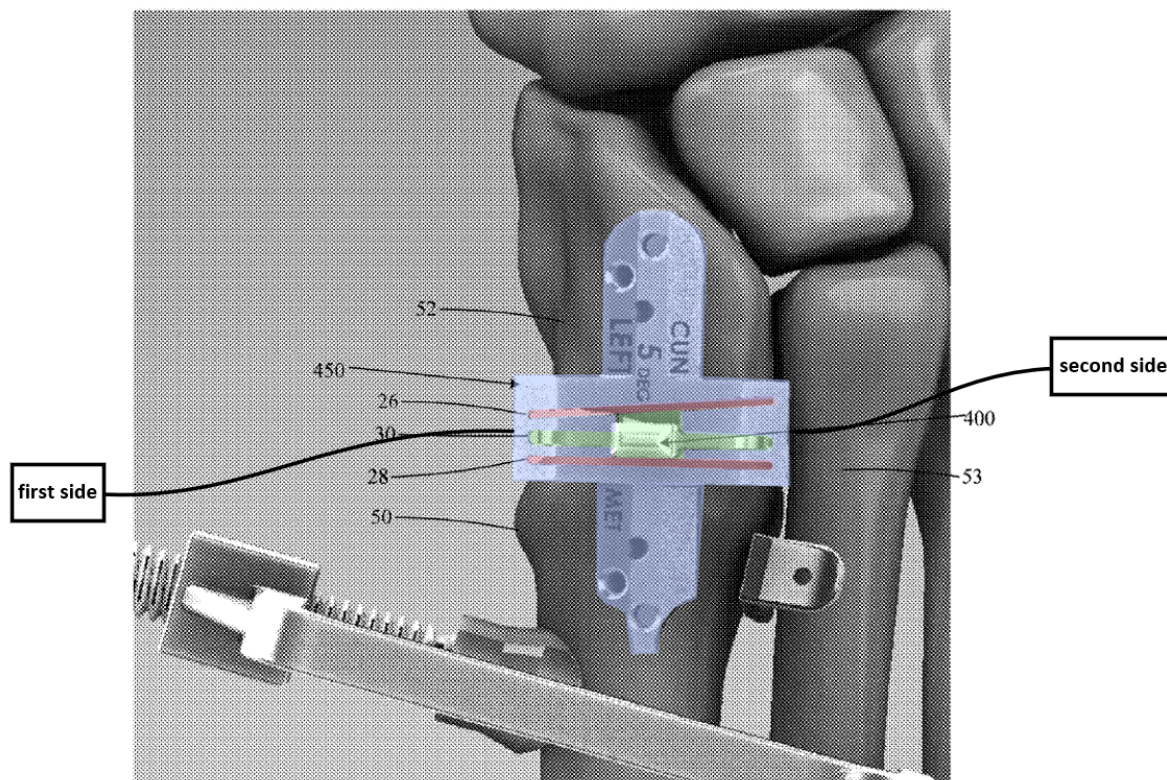


FIG. 5

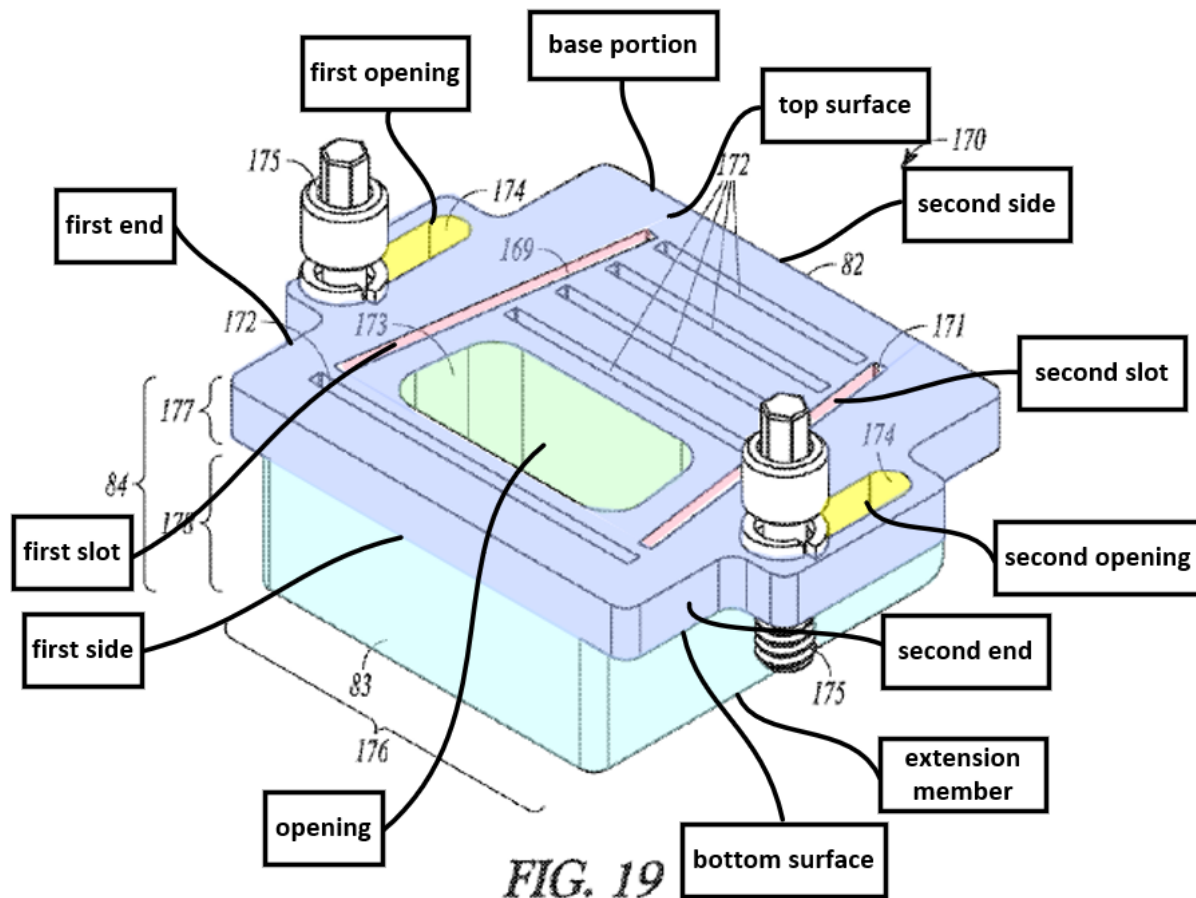
As seen above, Figure 5 shows a similar base portion of the cut guide in Bays, but with angled slots 26, 28. This top view further illustrates the parallel first and second sides. Accordingly, Bays discloses the limitations recited in claim 20.

VII. ANTICIPATION OF CLAIMS 1-15 BY NEAL

CLAIM 1

76. Neal discloses a cut guide, as recited in the preamble of claim 1. Neal discloses a cut guide used for foot and ankle fusion. Ex. 1007, Abstract. Neal teaches that the guide may provide slots, openings, or other surfaces that guide and support

the cutting element, and that the guide may be shaped/configured for anatomy and different resections. *Id.* at 22:1–19. Neal explains that “the resection guide 170 can be configured for a resection of a first metatarsophalangeal joint.” *Id.* at 22:13–15. An annotated version of Figure 19 from Neal is reproduced below.



The annotated figure above provides an overview of the anticipation mapping by Neal, which will be discussed in detail below for each limitation.

Limitation 1[a]

77. Neal discloses a “base portion,” as seen in the annotated version of Figure 19 below.

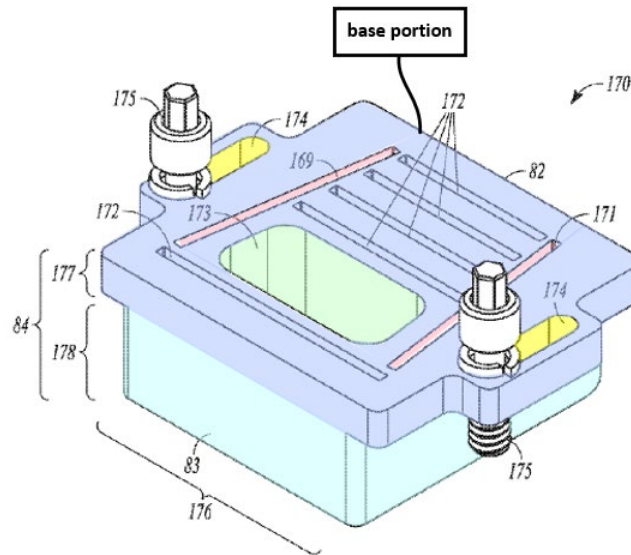
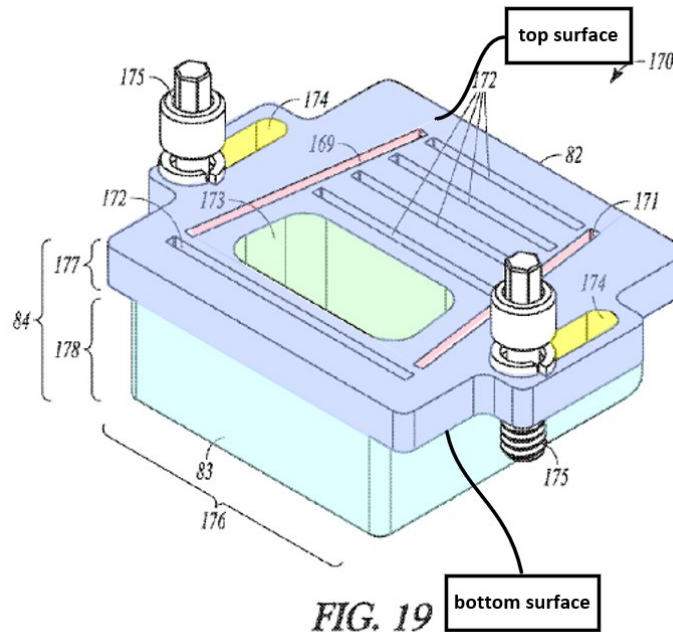


FIG. 19

The “base portion” is the anterior body 177 (highlighted in purple above). Neal describes a resection guide 170 having a body 177 (the purple highlighted part). Neal explains that guide body 84 is divided into anterior body 177 and posterior body 178. Ex. 1007, 22:21–23. As seen in Figure 19, anterior body 177 is the upper portion of guide body 84 that defines cutting slots 169, 171, 172, cut out 173, and slots 174, and that receives bolts 175 securing guide 170 to the resection frame. Id. at 22:38–57. A POSA would have understood anterior body 177 to be the base portion because it carries those cutting, viewing, and fixation features. Accordingly, Neal discloses limitation 1[a].

Limitation 1[a][i]



As seen above, the base portion has a top surface positioned substantially opposite a bottom surface. The bottom surface of anterior body 177 is the surface that faces posterior body 178 and the bone, and the top surface is the opposite surface at which the cutting element enters the cutting slots. Accordingly, Neal discloses limitation 1[a][iii].

Limitation 1[a][iv]

81. Neal discloses its “base portion” having “at least one slot disposed between the first and second ends of the base portion and extending at least partially between the first side and the second side of the base, wherein the slot provides fluid communication between the top and bottom surfaces of the base,” as seen in the annotated version of Figure 19 below.

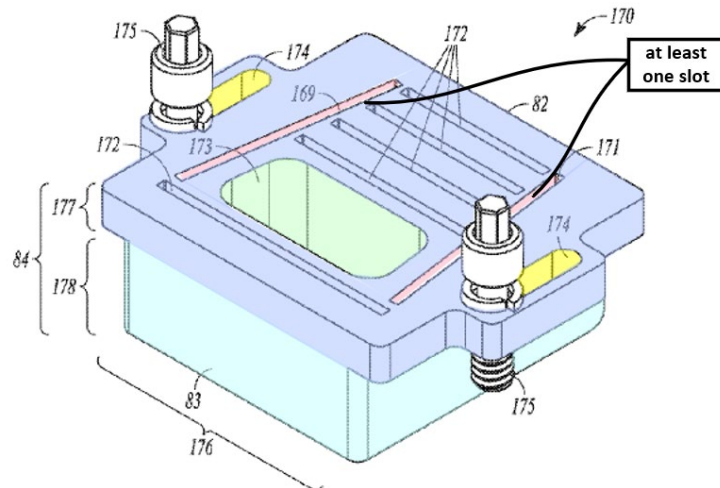


FIG. 19

Neal discloses guide body 84 with transverse cutting slots 172 and angled medial and lateral cutting slots 169, 171 for providing resection cuts. Ex. 1007, 22:38–55. As seen above, Neal discloses multiple slots 169, 171 (pink highlighting) disposed between the first and second ends of the base portion and extending at least partially between the first side and the second side of the base.

82. Neal’s cutting slots 169 and 171 provide fluid communication between the top and bottom surfaces of the base portion because to perform resection cuts, a saw blade guided by the slots must enter from the top surface and exit toward the underlying bone at the bottom, requiring the slots to be open at both surfaces. Ex. 1007, 22:38–61 (angled medial and lateral cutting slots for providing resection cuts). Each slot is therefore an open passage between the top and bottom surfaces of the base portion, which a POSA would have understood to provide fluid communication

Limitation 1[a][v]

83. Neal discloses its “base portion” having “at least one opening extending therethrough,” as seen in the annotated version of Figure 19 below.

83. Neal discloses its “base portion” having “at least one opening extending therethrough,” as seen in the annotated version of Figure 19 below.



Limitation 1[b]



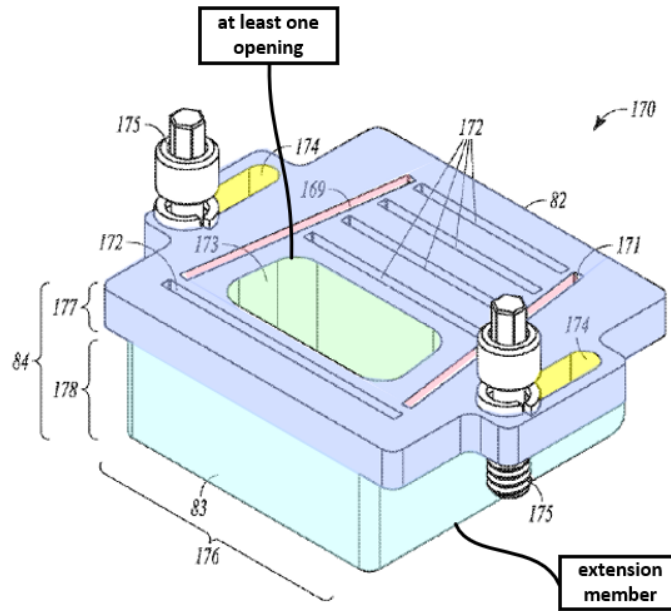


FIG. 19

Neal discloses an opening 173 (green highlighting) in the extension member 83 (teal highlighting). As seen in Figure 19, cut out 173 passes through anterior body 177 and continues downward into posterior body 178, so that the walls of posterior body 178 define part of the opening, as discussed further below with respect to claim 6. Accordingly, Neal discloses limitation 1[b][i].

CLAIM 2

86. Claim 2 depends from claim 1 and recites that “the at least one slot comprises at least one first slot and at least one second slot,” which Neal discloses as seen in the annotated version of Figure 19 below.

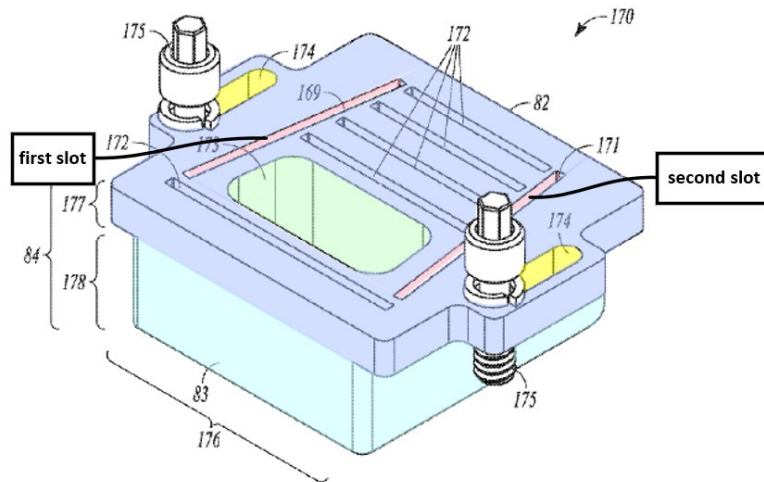


FIG. 19

As seen above, Neal discloses a first slot 169 and a second slot 171 (pink highlighting). Accordingly, Neal discloses the limitations recited in claim 2.

CLAIM 3

87. Claim 3 depends from claim 2 and recites that “the extension member is positioned at least partially between the at least one first slot and the at least one second slot,” which Neal discloses as seen in the annotated version of Figure 19 reproduced below.

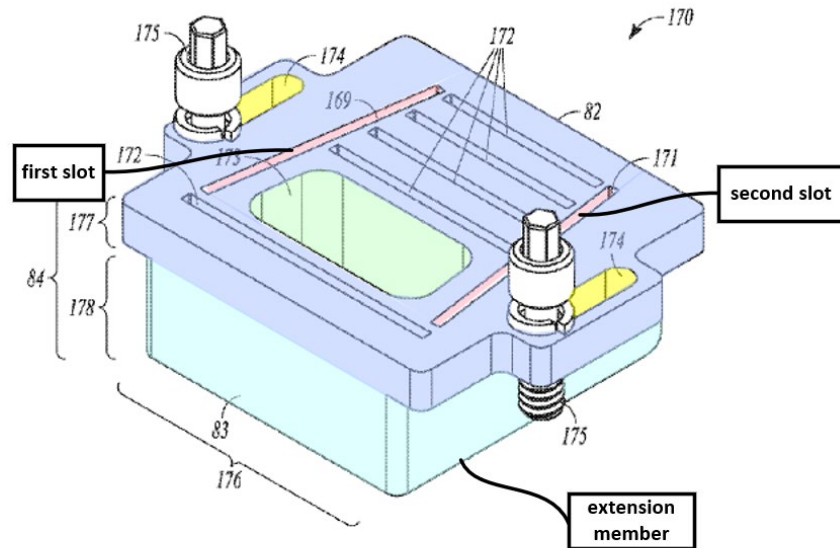


FIG. 19

As seen above, the extension member (posterior body 178, teal highlighting) spans the area between the first and second slots 169, 171. Neal discloses that lateral cutting slot 169 and medial cutting slot 171 are located on anterior body 177 on either side of the guide midline, while posterior body 178 extends downward from the midline of anterior body 177. Ex. 1007, 22:21–55. Because posterior body 178 depends from the midline and the two slots flank that midline on each side, posterior body 178 is necessarily positioned at least partially between the first and second slots. Accordingly, Neal discloses the limitations recited in claim 3.

CLAIM 4

88. Claim 4 depends from claim 3 and recites that “the extension member extends from the bottom surface of the base portion at a substantially orthogonal angle relative to the bottom surface of the base portion.” As discussed above in

connection with limitation 1[b], Neal discloses its extension member (posterior body 178, teal highlighting) extending downward from the bottom surface of the base (anterior body 177, purple highlighting) at a substantially orthogonal angle. As seen in Figure 19, the walls of posterior body 178 extend straight down from anterior body 177, perpendicular to its bottom surface. Accordingly, Neal discloses the limitations recited in claim 4.

CLAIM 5

89. Claim 5 depends from claim 4 and recites that “the at least one first slot is positioned in a first plane and the at least one second slot is positioned in a second plane, wherein the first and second planes form an oblique angle.”

90. As seen in the annotated version of Figure 19 reproduced above in connection with claim 2, the first and second slots 169, 171 are disposed at an angle relative to one another. Neal expressly states that “the lateral cutting slot 169 and the medial cutting slot 171 can be angled inwardly towards the proximal end 82 to provide resection cuts for an ankle resection system.” Ex. 1007, 22:58–61. Because slots 169 and 171 are each angled inwardly toward proximal end 82, they converge toward one another rather than extending parallel, and the planes in which they are positioned therefore form an oblique angle. Figure. 20, reproduced below, further illustrates the oblique relative orientations of the slots (pink highlighting).

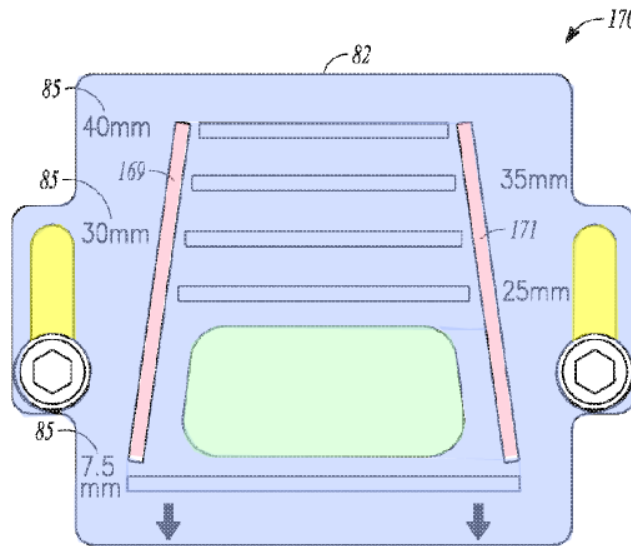


FIG. 20

Accordingly, Neal discloses the limitations recited in claim 5.

CLAIM 6

91. Claim 6 depends from claim 5 and recites that “the at least one opening provides fluid communication between the top and bottom surfaces of the base portion,” which Neal discloses as seen in the annotated version of Figure 19 below.

ends from

CLAIM 8

93. Claim 8 depends from claim 7 and recites that “the first arm forms a substantially orthogonal angle with the first end of the base portion.” As discussed above and shown in the annotated Figure provided in connection with claim 7, the first arm in Neal extends generally orthogonal to the first end of the base portion. Accordingly, Neal discloses the limitations recited in claim 8.

CLAIM 9

94. Claim 9 depends from claim 8 and recites that “the first arm comprises a first opening extending therethrough from a top surface through to a bottom surface thereof,” which Neal discloses as seen in the annotated version of Figure 19 below.

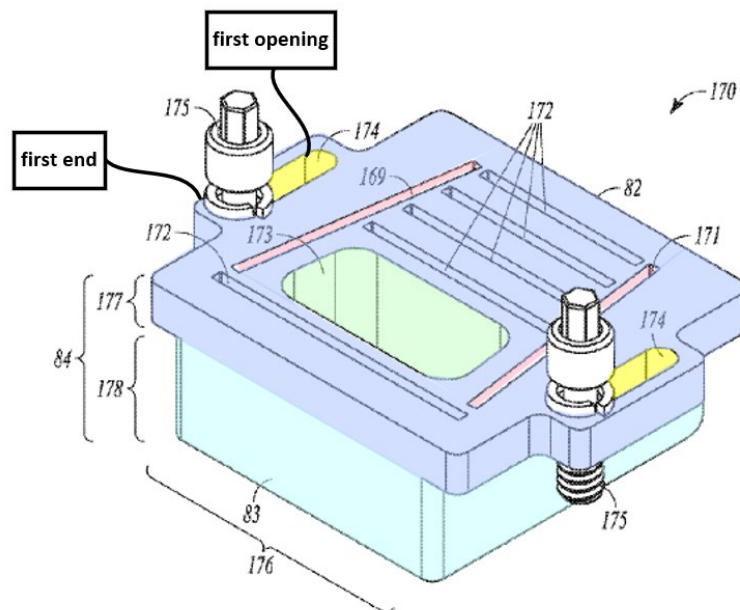


FIG. 19

As seen above, the first arm (lateral end of anterior body 177) includes a first opening extending therethrough from a top surface through to a bottom surface thereof. Neal includes bolt holes at the lateral ends of the anterior body 177 for bolts 175, and the proximal/distal adjustment slots 174 also extend through the arm from top to bottom. Ex. 1007, 22:52–57. The bolt hole or slot at the terminal end of the first arm is the recited first opening extending from the top surface through to the bottom surface. Accordingly, Neal discloses the limitations recited in claim 9.

CLAIM 10

95. Claim 10 depends from claim 9 and recites that “the first opening is positioned at a terminal end of the first arm.” As discussed above and shown in the annotated Figure 19 provided in connection with claim 9, the first opening in Neal is positioned at a terminal end of the first arm. Accordingly, Neal discloses the limitations recited in claim 10.

CLAIM 11

96. Claim 11 depends from claim 10 and recites that “the cut guide further comprises a second arm extending from the second end of the base portion,” which Neal discloses as seen in the annotated version of Figure 19 below.

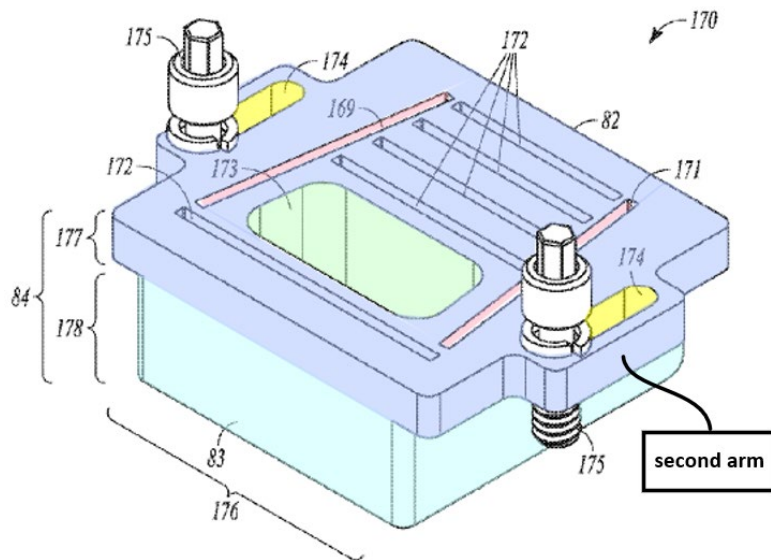


FIG. 19

As seen above, the second arm in Neal extends from the second end of the base portion as a monolithic part. The lateral end of anterior body 177 at the second end of the base portion constitutes the recited second arm extending from the second end of the base portion. Accordingly, Neal discloses the limitations recited in claim 11.

CLAIM 12

97. Claim 12 depends from claim 11 and recites that “the second arm forms a substantially orthogonal angle with the second end of the base portion.” As discussed above and shown in the annotated Figure 19 provided in connection with claim 11, the second arm in Neal extends generally orthogonal to the second end of the base portion. Accordingly, Neal discloses the limitations recited in claim 12.

CLAIM 13

98. Claim 13 depends from claim 12 and recites that the “second arm comprises a second opening extending therethrough from a top surface through to a bottom surface thereof,” which Neal discloses as seen in the annotated version of Figure 19 below.

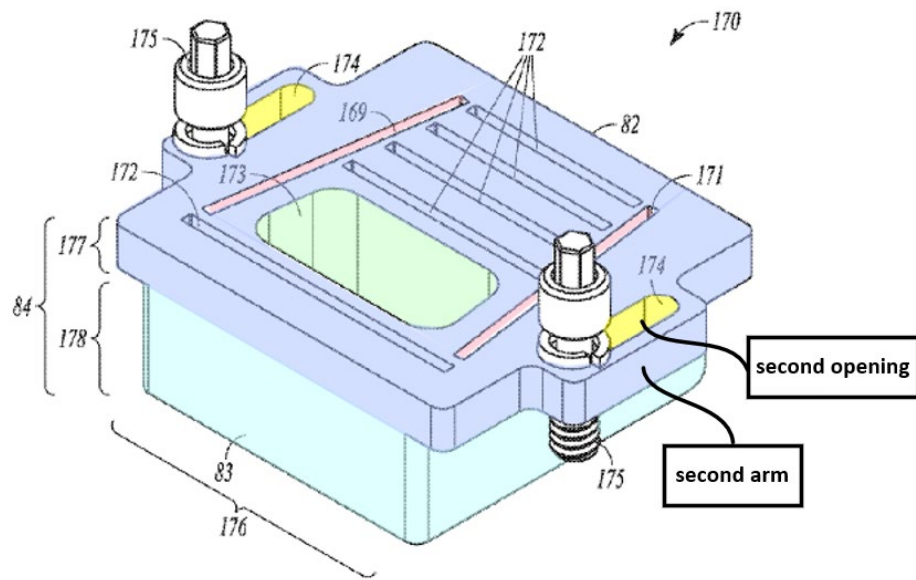


FIG. 19

As seen above, the second arm (lateral end of anterior body 177 at the second end of the base portion) includes a second opening extending therethrough from a top surface through to a bottom surface thereof. As noted above in connection with claims 9 and 11, Neal discloses bolt holes at both lateral ends of anterior body 177 for bolts 175, and proximal/distal adjustment slots 174 also extend through the arm from top to bottom. The bolt hole or slot at the terminal end of the second arm is the

recited second opening extending from the top surface through to the bottom surface. Accordingly, Neal discloses the limitations recited in claim 13.

CLAIM 14

99. Claim 14 depends from claim 13 and recites that “the second opening is positioned at a terminal end of the second arm.” As discussed above and shown in the annotated Figure provided in connection with claim 13, the second opening in Neal is positioned at a terminal end of the second arm. Accordingly, Neal discloses the limitations recited in claim 14.

CLAIM 15

100. Claim 15 depends from claim 1 and recites that “the top surface comprises a first portion and a second portion.” Claim 15 requires only that the top surface comprise a first portion and a second portion. It imposes no geometric constraint distinguishing the two portions. An annotated version of Neal’s Figure 20 is reproduced below.

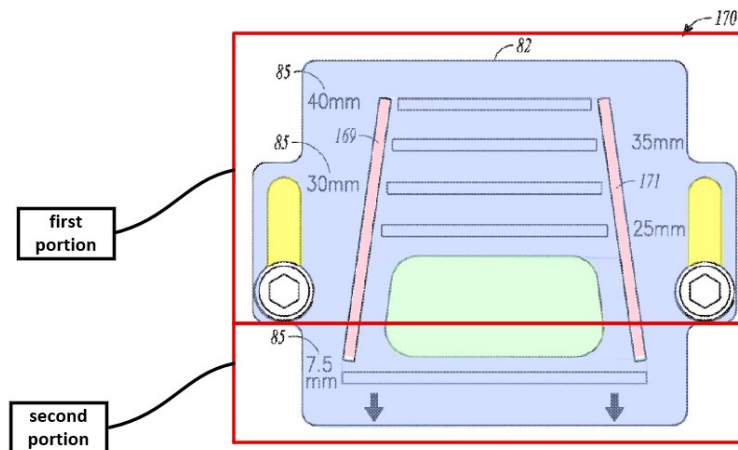


FIG. 20

As seen above, Neal discloses a top surface having first and second portions as required by claim 15. In annotated Figure 20, the first portion is the region of the top surface containing slots 169, 171 and cut out 173, and the second portion is the adjacent region of the top surface between that first portion and the end of the guide opposite proximal end 82. Accordingly, Neal discloses the limitations recited in claim 15.

VIII. OBVIOUSNESS OF CLAIMS 6–20 IN VIEW OF NEAL AND BAYS

CLAIM 6

101. Claim 6 depends from claim 5 and recites that “the at least one opening provides fluid communication between the top and bottom surfaces of the base portion.”

102. Setting aside the fact that Neal teaches the features of Claim 6, such an arrangement would have been obvious. An annotated version of Neal's Figure 19 is reproduced below.

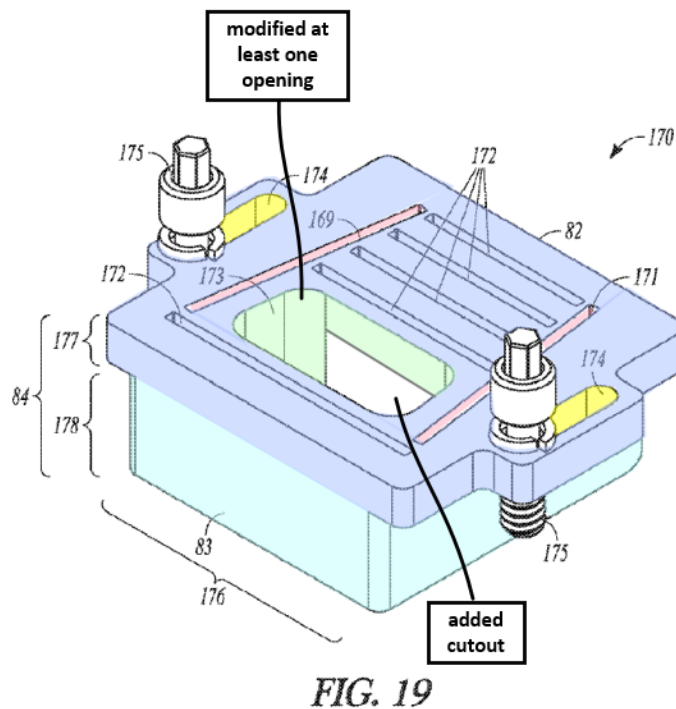


FIG. 19

As I discuss above, Neal describes cut-out 173 as a window that “can aid the surgeon in viewing anatomical features the resection guide 170 is positioned over.” Ex. 1007, 22:51–52. Additionally, as I discuss above, Bays also references the benefits of providing visualization for the surgeon and the extension member 80. Bays has an opening through its sidewall that would naturally facilitate continued visualization when inserted in opening 30 by providing a continued line of sight through the opening to the osteotomy site.

103. As seen in the modified version of Neal's Figure 19 above, it would have been obvious to provide an added cutout in the sidewall of Neal's extension member (teal highlighting) to further enhance visualization. One example cutout is illustrated, but it would have been obvious to place the cutout in a given sidewall region as appropriate for the procedure and cut location. A cutout in the sidewall of posterior body 178 would allow the surgeon to view the joint and bone surfaces from the side of the guide, in addition to viewing them from above through cut out 173, which assists in confirming the position of the guide relative to the joint before and during the resection.

104. A POSA would have understood that added visualization would have been beneficial in terms of viewing the cut site. See also Ex. 1008, 5:65–6:7 (Lawrence explaining that the alignment aperture 250 extending through its extension member's sidewall "enables the user to view the alignment tabs 28 during positioning of the cutting guide 12 relative to the metatarsal 14 and the proximal phalanx."). A POSA also would have expected the added cutout to preserve the function of Neal's guide, because the cutout can be located in a region of the sidewall of posterior body 178 spaced from the paths of cutting slots 169, 171, 172, leaving the guide body surrounding the slots in place. Accordingly, in my opinion, claim 6 would have been obvious in view of the combined teachings of Neal and Bays.

CLAIMS 7-14

105. Neal teaches the features recited in claims 7–14 for the reasons I discuss above.

CLAIM 15

106. Neal teaches the features recited in claim 15 for the reasons I have set forth above. In the event it is determined that some differentiating feature is required for the first and second portions of the top surface, such an arrangement would have been obvious in view of Neal and Bays for the reasons I discuss below in connection with claims 16 and 17, which depend from claim 15 and further define the first and second portions of the top surface. A POSA would have found claim 15 obvious in view of the combined teachings of Neal and Bays for the reasons discussed below.

CLAIM 16

107. Claim 16 depends from claim 15 and recites that “the first portion is positioned in a plane which is substantial[ly] parallel to a plane of the bottom surface, and the second portion is positioned in a plane which is substantially oblique to that of the first portion and the bottom surface.”

108. In my opinion, the combined teachings of Neal and Bays renders claim 16 obvious. Neal teaches that resection guide 170 provides “slots, openings or other interior or exterior surfaces” that act as directional guides/supports for a bone cutting element, and that both the guide and the associated cutting-element-guiding surfaces can be shaped and configured in any suitable manner to fit patient anatomy and work

with the resection frame. Ex. 1007, 22:1–15. Foot and ankle correction procedures, including the Lapidus bunionectomy specifically discussed in the '139 patent (Ex. 1001, 1:35–37), require resection cuts at defined oblique angles to the bone surface.

109. For example, the standard Lapidus correction requires a transverse-plane resection of the cuneiform at a correction angle. See Ex. 1010, 1011. Lapidus and related first TMT correction procedures require oblique resection cuts at defined angles and a POSA would have designed the guide's top-surface geometry to match.

110. A POSA designing a cut guide for such procedures would have recognized that matching the guide's top-surface geometry to the intended oblique cut angle improves blade support, reduces lateral guide deflection during the cut, and provides visual confirmation of proper guide alignment against the anatomy. A POSA would have been motivated by these anatomical and functional considerations to configure a cut guide's top surface with a planar first portion and an oblique second portion when designing a guide for angled bone resections. For example, where the second portion of the top surface is oriented in accordance with the intended oblique cut, the surgeon can compare the orientation of that surface with the anatomy to confirm the orientation of the cut before cutting. A top surface that slopes along with the bone surface beneath it also reduces the height of the guide above the bone at that location, improving the fit of the guide against the anatomy.

179 during a bone cutting procedure. Id. at 22:35–38. This teaches that exterior guide surfaces, not merely enclosed slots, may guide the cutting element.

113. In view of these teachings, I believe a POSA would have found it obvious to configure Neal's cut-guide top surface to include a first generally planar portion and a second oblique portion, with the slot extending through both, to better support and present the saw blade along the intended angled cut path. Such a configuration would predictably accommodate Neal's angled slot/cut geometry, maintain supporting guide-body structure around the slot, improve fit depending on the target anatomy, and preserve the intended resection angle. In my view, this is merely the predictable application of Neal's express teaching that guide surfaces and slots may be shaped as needed to guide a cutting element for the desired resection.

114. A POSA would have been motivated to combine the teachings of Neal and Bays in the manner described above and would have had a reasonable expectation of success in doing so.

115. Bays confirms that such angled guide-surface geometry was known and predictable in the same field. Bays teaches a bone preparation guide having first and second guide surfaces and/or slots for guiding a tissue-removing instrument, and expressly discloses that one or more guide surfaces or slots may be angled, as I have discussed above. Accordingly, claim 16 would have been obvious in view of Neal and Bays.

CLAIM 17

116. Claim 17 depends from claim 16 and recites that “at least a portion of the at least one slot is positioned in the first portion of the top surface and the second portion of the top surface.”

117. The combined teachings of Neal and Bays renders claim 17 obvious. Neal teaches that resection guide 170 may include slots, openings, and other interior or exterior surfaces that guide/support a bone cutting element, and that those guide surfaces may be shaped and configured in any suitable manner to fit patient anatomy and cooperate with the resection frame. Ex. 1007, 22:1–15.

118. Neal further teaches slots shaped for different resections and applications, including slots shaped to receive a saw or knife, and angled medial and lateral cutting slots for providing resection cuts. *Id.* at 22:15–18, 22:49–55. Based on the modifications discussed above relative to claim 16, Neal’s slots 169, 171 would extend into both the first and second portions of the top surface in at least one of the obvious configurations.

119. Further, in view of those teachings, a POSA also would have found it obvious to configure the slot so that at least a portion of the slot is positioned in both the first top-surface portion and the oblique second top-surface portion. Where an angled slot traverses a guide body, extending the slot through both top-surface portions would predictably maintain blade entry, blade support, and sufficient

surrounding guide-body material along the angled cut path. A cutting slot ordinarily extends across the width of the bone to be cut, so in a guide whose top surface includes a planar first portion and an oblique second portion, a slot guiding a cut across the full width of the bone would pass through both portions. This is a routine implementation of Neal's express teaching that guide surfaces and slot configurations may be shaped as needed to guide the cutting element for the desired resection.

120. In my opinion, a POSA would have been motivated to position the slot through both top-surface portions as recited in claim 17 and would have had a reasonable expectation of achieving the intended angled-cut result.

121. Bays confirms that this was a known and predictable guide configuration. Bays teaches guide surfaces or slots that may be angled, including a skewed guide slot for removing a wedge-shaped portion of bone. Ex. 1006, 4:1–18; 9:50–10:21.

122. Bays also teaches varying the skew angle of the guide surface/slot and providing a plurality of interchangeable guides having different slot angles selected to match the desired cut angle. *Id.* at 10:55–67; 17:35–18:35. Accordingly, positioning the slot through both a planar top-surface portion and an oblique top-surface portion would have been an obvious, predictable way to implement an angled/skewed cutting slot while preserving guide support and the intended resection

trajectory. A POSA would have found the structure recited in claim 17 obvious in view of the combined teachings of Neal and Bays.

CLAIM 18

123. Claim 18 is an independent claim that includes limitations recited in claims 1, 15, 16, and 17 as set forth in the table below.

Claim 18		
Claim 18 Limitation	Corresponding Limitation	Claim 18
[18][pre]	1[pre]	A cut guide, comprising:
[18][a]	1[a]	a base portion, comprising:
[18][a][i]	[1][a][ii]	a first end positioned substantially opposite the base portion from a second end;
[18][a][ii]	[1][a][iii]	a top surface positioned substantially opposite the base portion from a bottom surface, comprising:
[18][a][ii][1]	15/16	a first portion positioned in a first plane; and
[18][a][ii][2]	15/16	a second portion positioned in a second plane, wherein the second plane is substantially oblique to the first plane;
[18][a][iii]	[1][a][iv]	at least one slot disposed between the first and second ends of the base portion,
[18][a][iii][1]	[1][a][iv]	wherein the at least one slot provides fluid communication between the top and bottom surfaces of the base,
[18][a][iii][2]	17	wherein at least a portion of the at least one slot is positioned in the first portion and the second portion of the top surface; and
[18][a][iv]	[1][a][v]	at least one opening extending through the base portion; and
[18][b]	[1][b]	an extension member extending downward from the bottom surface of the base,
[18][b][i]	[1][b][i]	wherein the at least one opening extends into at least a portion of the extension member.

My discussion above relative to the limitations in claims 1, 15, 16, and 17 that correspond to those in claim 18 are incorporated herein by reference. A POSA would have found the limitations of claim 18 obvious in view of the combined teachings of Neal and Bays for the reasons I set out above.

CLAIM 19

124. Claim 19 depends from claim 18 and includes limitations recited in claims 2 and 5 as set forth in the table below.

Claim 19 Limitation	Corresponding Limitation	Claim 19
19	2/5	The cut guide of claim 18, wherein the at least one slot comprises a first slot and a second slot, wherein the first and second slots are positioned in planes which form an oblique angle with one another.

My discussion above relative to the limitations in claims 2 and 5 that correspond to those in claim 19 are incorporated herein by reference. A POSA would have found the limitations of claim 19 obvious in view of the combined teachings of Neal and Bays for the reasons I explain above.

CLAIM 20

125. Claim 20 is an independent claim that includes limitations recited in claims 1, 7–11, and 13–17 as set forth in the table below.

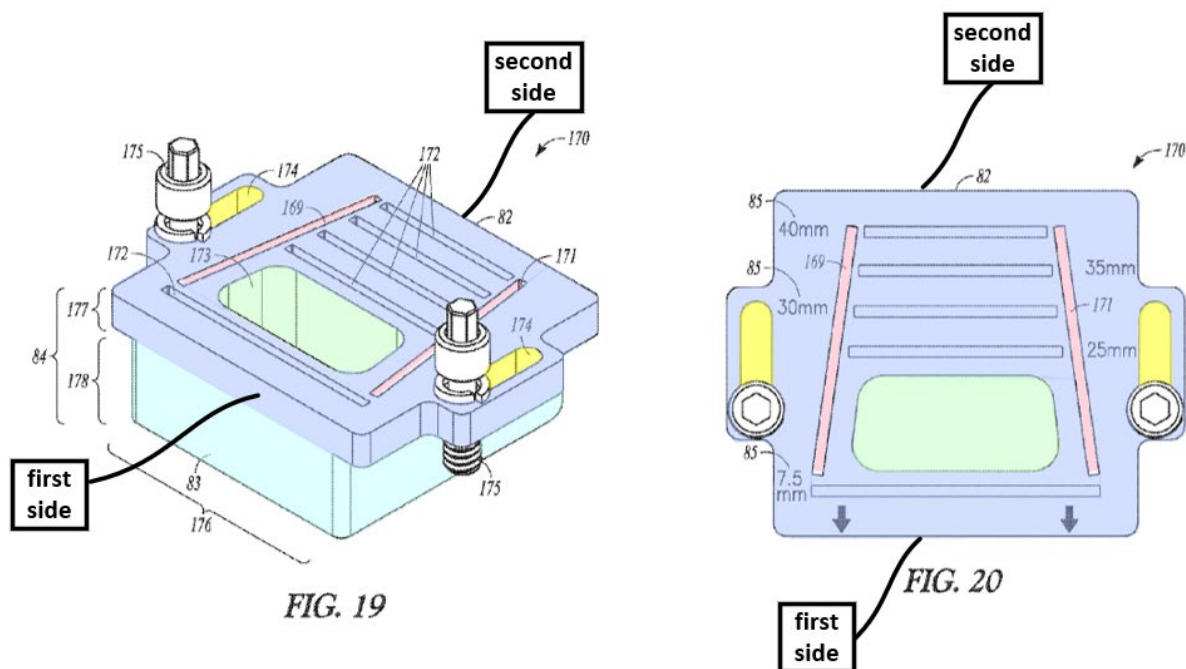
Claim 20 Limitation	Corresponding Limitation	Claim 20
[20][pre]	[1][pre]	A cut guide, comprising:

[20][a]	[1][a]	a base portion, comprising:
[20][a][i]	[1][a][ii]	a first side positioned substantially opposite the base portion from a second side,
[20][a][ii]	not in claim 1	wherein the first and second sides are substantially parallel to one another;
[20][a][iii]	[1][a][ii]	a first end positioned substantially opposite the base portion from a second end;
[20][a][iv]	[1][a][iii]	a top surface positioned substantially opposite the base portion from a bottom surface, comprising:
[20][a][iv][1]	15/16	a first portion positioned in a first plane; and
[20][a][iv][2]	15/16	a second portion positioned in a second plane, wherein the second plane is substantially oblique to the first plane;
[20][a][v]	[1][a][iv]	at least one slot disposed between the first and second ends of the base portion,
[20][a][v][1]	[1][a][iv]	wherein the at least one slot provides fluid communication between the top and bottom surfaces of the base,
[20][a][v][2]	17	wherein at least a portion of the at least one slot is positioned in the first portion and the second portion of the top surface; and
[20][a][vi]	[1][a][v]	at least one opening extending from the top surface through to the bottom surface;
[20][b]	[1][b]	an extension member extending downward from the bottom surface of the base,
[20][b][i]	[1][b][i]	wherein the at least one opening extends into at least a portion of the extension member.
[20][c]	7/8	a first arm extending from the first end of the base portion at a substantially orthogonal angle, comprising:
[20][c][i]	9/10	an opening positioned at a terminal end of the first arm and extending from a top surface of the first arm through to a bottom surface of the first arm; and
[20][d]	11	a second arm extending from the second end of the base portion, comprising:
[20][d][i]	13/14	an opening positioned at a terminal end of the second arm and extending from a top surface of

		the second arm through to a bottom surface of the second arm.
--	--	---

My discussion above relative to the limitations in claims 1, 7–11, and 13–17 that correspond to those in claim 20 are incorporated herein by reference.

126. In limitation 20[a][ii], claim 20 additionally recites that “the first and second sides [of the base portion] are substantially parallel to one another.” As seen in the annotated versions of Figures 19 and 20 from Neal below, the first and second sides of the base portion are substantially parallel to one another.



Accordingly, the limitations recited in claim 20 would have been obvious in view of Neal and Bays.

REASONABLE EXPECTATION OF SUCCESS

127. A POSA would have had a reasonable expectation of success in modifying Neal's cut guide as recited in claims 6–20. Neal already discloses a resection guide having openings, slots and other interior or exterior guide surfaces for visualization and guiding/supporting a bone cutting element. Further, Neal teaches that those guide surfaces and slots may be shaped and configured as suitable for the anatomy and desired resection. Ex. 1007, 22:1–18. Neal also discloses angled cutting slots for providing resection cuts. Id. at 22:33–65. Thus, the proposed modifications would not change Neal's basic operating principle. The modifications would merely enhance the visualization taught by Neal and implement Neal's disclosed guide-shaping and angled-slot concepts through a predictable guide-body geometry. The modifications also would not affect how Neal's guide is positioned and secured. Guide 170 would still be secured to the resection frame by bolts 175 at the lateral ends of anterior body 177, and cutting slots 169, 171, 172 would retain their positions and angles relative to the bone, so the surgeon would place and use the modified guide in the same manner as Neal's guide.

128. Bays further confirms the predictability of the modification. Bays teaches bone-preparation guides with angled guide surfaces or slots, including skewed guide slots for producing wedge-shaped bone removal, and further teaches guides with different skew angles selected to achieve the desired cut angle. Ex. 1006, 3:63–4:19; 9:49–10:22; 10:54–11:8; 17:35–18:25.

129. Because surgical cut guides operate by mechanically constraining the cutting instrument along guide surfaces or slots, a POSA would have expected that forming Neal's top surface with planar and oblique portions, and positioning the slot through those portions, would successfully guide the blade along the intended angled resection path. The saw blade is guided by the walls of the slot, and changing the shape of the top surface around the slot changes the entry region of the slot, not the orientation of the slot walls that define the cut path.

130. The combination therefore involves only a predictable variation in the shape of a known mechanical guide, using known angled/skewed guide-surface and slot geometry for the same purpose taught by Neal and Bays: guiding a tissue-removing instrument to make a desired bone cut.

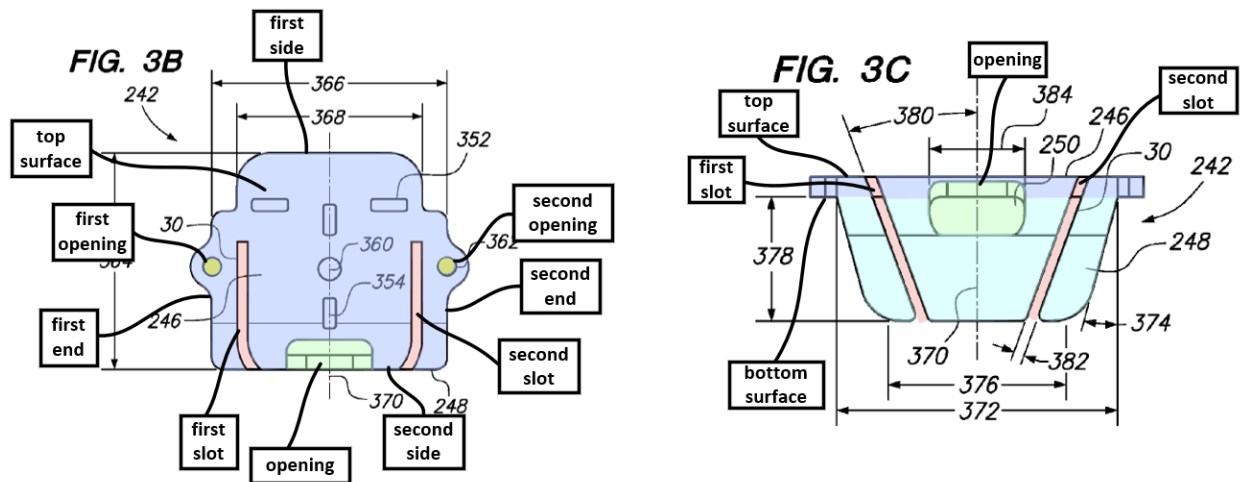
131. A POSA would have expected the modified guide to maintain blade support, preserve the intended cut angle, and provide the desired resection without undue experimentation. A POSA would have had a reasonable expectation of success in modifying Neal's cut guide as described above to arrive at the subject matter of claims 6–20, and that the proposed modifications are the type of routine design choices within the ordinary skill of a POSA working with surgical cut guides.

IX. ANTICIPATION OF CLAIMS 1-15 BY LAWRENCE

CLAIM 1

132. Lawrence discloses a cut guide, as recited in the preamble of claim 1. For example, Lawrence describes cutting guide 12 as a guide that accurately and repeatably aligns a saw blade so that a proper amount of metatarsal bone may be cut and removed. Ex. 1008, 3:10–21, 5:1–12.

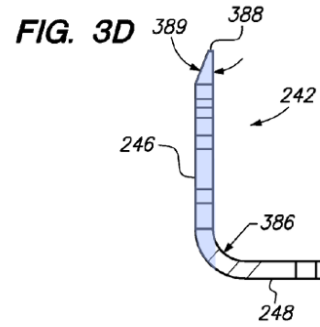
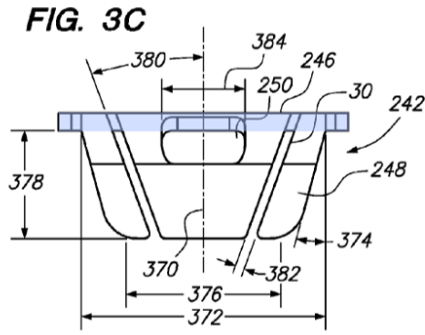
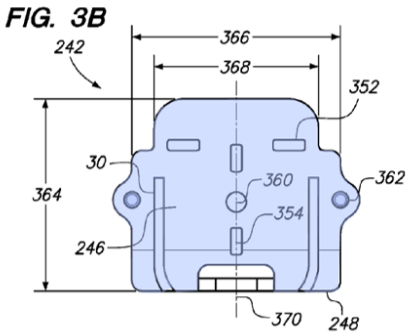
133. Annotated versions of Figures 3B and 3C from Lawrence are reproduced below.



The annotated figures above provide an overview of the anticipation mapping by Lawrence, which will be discussed in detail below for each limitation.

Limitation 1[a]

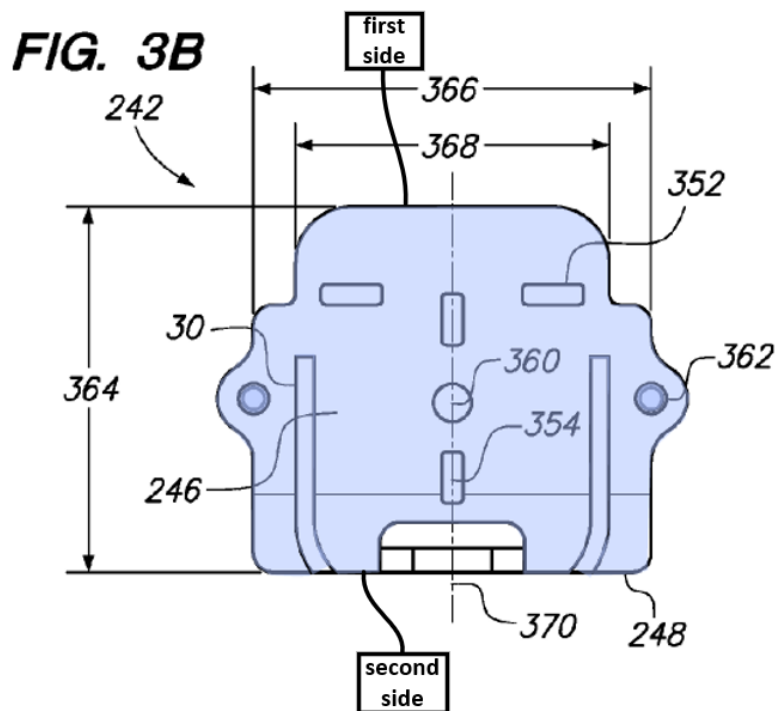
134. Lawrence discloses a “base portion,” as seen in the annotated version of Figures 3B–D below.



The “base portion” is the part highlighted in purple above. Lawrence describes a housing 242 (the purple highlighted part) with housing top 246, housing side 248, and saw guides 30. Ex. 1008, 7:31–9:48. As seen in Figures 3B–3D, the base portion is housing top 246, from which housing side 248 extends, as discussed below with respect to limitation 1[b]. Accordingly, Lawrence discloses limitation 1[a].

Limitation 1[a][i]

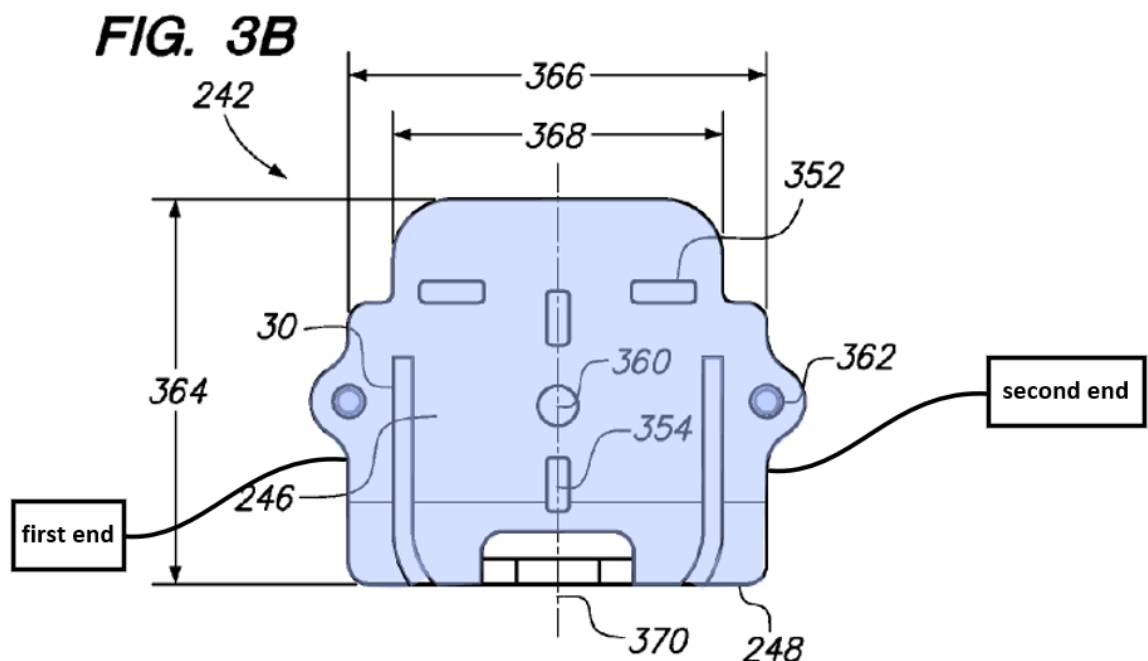
135. Lawrence discloses its “base portion” having “a first side positioned substantially opposite the base portion from a second side,” as seen in the annotated version of Figure 3B below.



As seen above, the first and second sides are the sides of the body portion at opposite ends of the slots. Saw guides 30 extend from one side of housing top 246 toward the other and are located between its ends, consistent with limitation 1[a][iv]. Accordingly, Lawrence discloses limitation 1[a][i].

Limitation 1[a][ii]

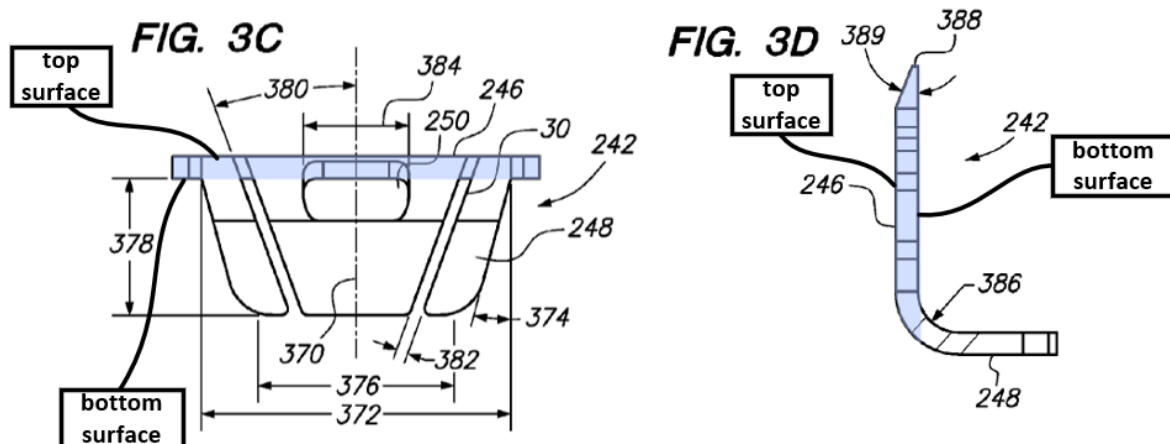
136. Lawrence discloses its “base portion” having “a first end positioned substantially opposite the base portion from a second end,” as seen in the annotated version of Figure 3B below.



As seen above, the first and second ends are the ends of the base portion at opposite sides of the slots. Accordingly, Lawrence discloses limitation 1[a][ii].

Limitation 1[a][iii]

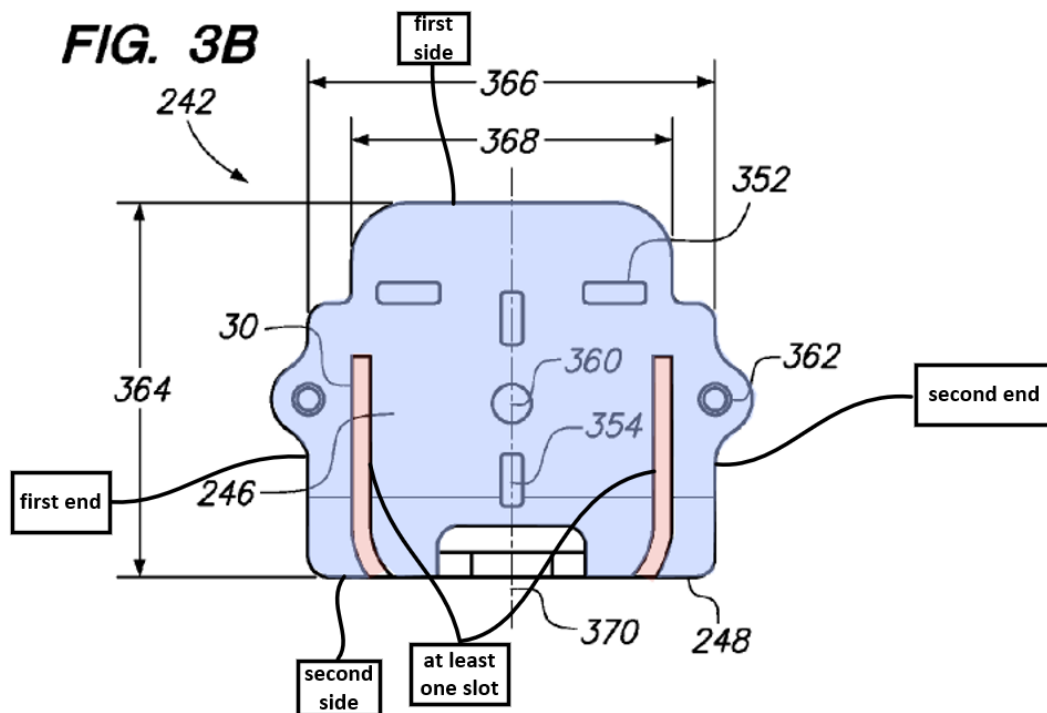
137. Lawrence discloses its “base portion” having “a top surface positioned substantially opposite the base portion from a bottom surface,” as seen in the annotated version of Figures 3C and 3D below.



As seen above, the base portion has a top surface positioned substantially opposite a bottom surface. The bottom surface of housing top 246 faces the metatarsal and is the surface from which housing side 248 extends, and the top surface is the opposite surface, facing away from the bone. Accordingly, Lawrence discloses limitation 1[a][iii].

Limitation 1[a][iv]

138. Lawrence discloses its “base portion” having “at least one slot disposed between the first and second ends of the base portion and extending at least partially between the first side and the second side of the base, wherein the slot provides fluid communication between the top and bottom surfaces of the base,” as seen in the annotated version of Figure 3B below.

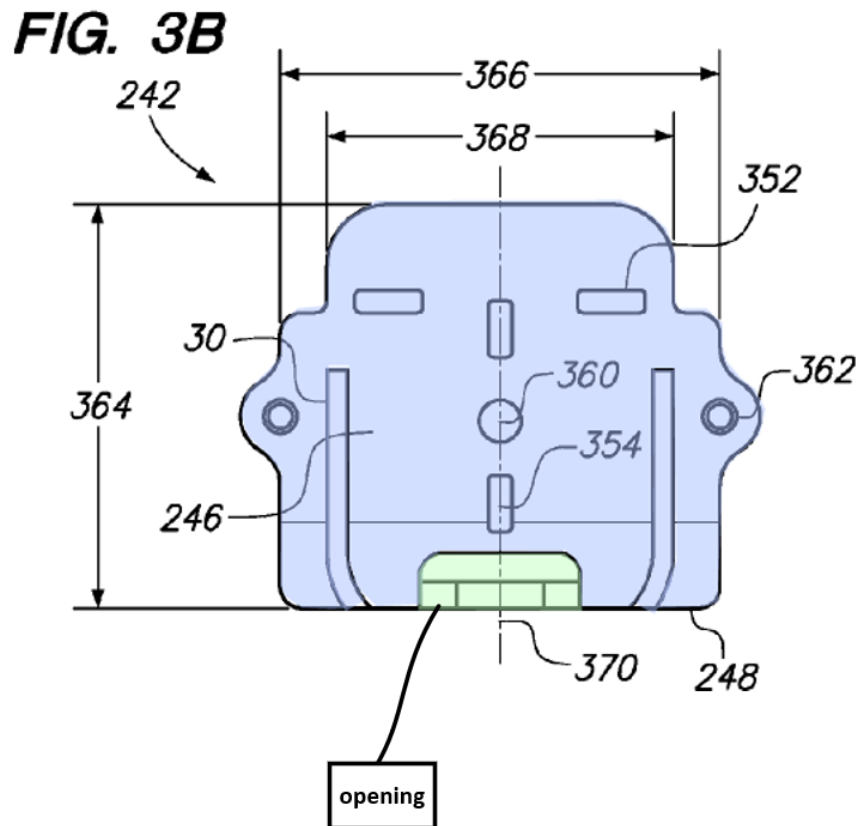


139. As seen above, Lawrence discloses multiple slots 30 (pink highlighting) disposed between the first and second ends of the base portion and extending at least partially between the first side and the second side of the base. Lawrence expressly discloses that saw guides 30 have a guide width sufficient to receive saw blade 54, Ex. 1008, 8:35–45, and that the saw blade passes through the guide to perform the bone resection. Ex. 1008, 3:10–23 (guide “accurately and repeatably align[s] a saw blade so that a proper amount of bone may be cut and removed from the metatarsal”). The saw guides therefore extend entirely through housing top 246 from the top surface to the bottom surface, providing fluid communication between the top and bottom surfaces as required by limitation 1[a][iv]. Each saw guide 30 is therefore an open passage between the top and bottom surfaces of the base portion, which a POSA

would have understood to provide fluid communication between those surfaces, as discussed above with respect to Bays. Accordingly, Lawrence discloses limitation 1[a][iv].

Limitation 1[a][v]

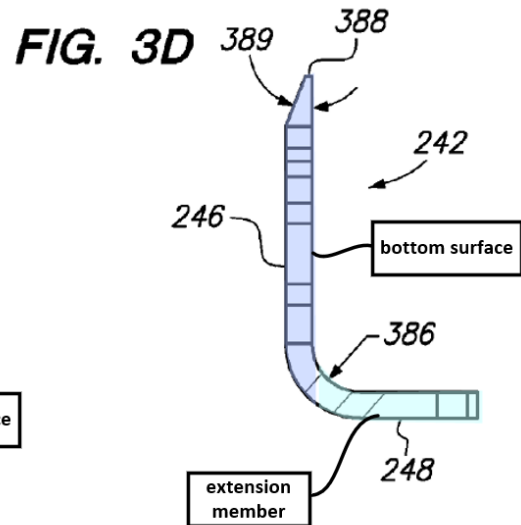
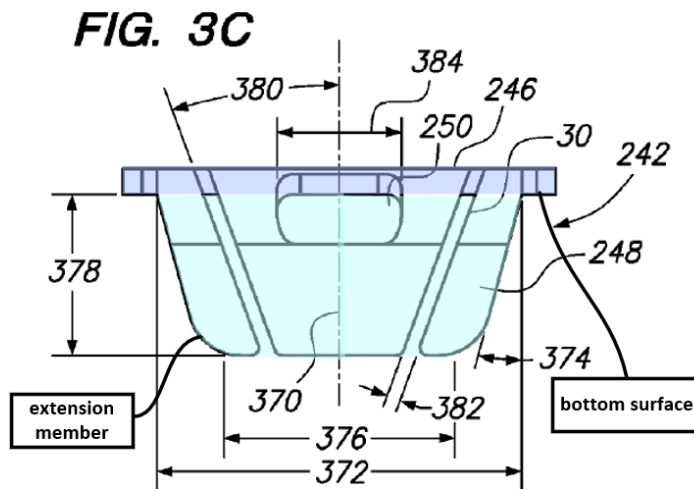
140. Lawrence discloses its “base portion” having “at least one opening extending therethrough,” as seen in the annotated version of Figure 3B below.



As seen above, Figure 3B shows an opening (green highlighting) extending through the base portion. Accordingly, Lawrence discloses limitation 1[a][v].

Limitation 1[b]

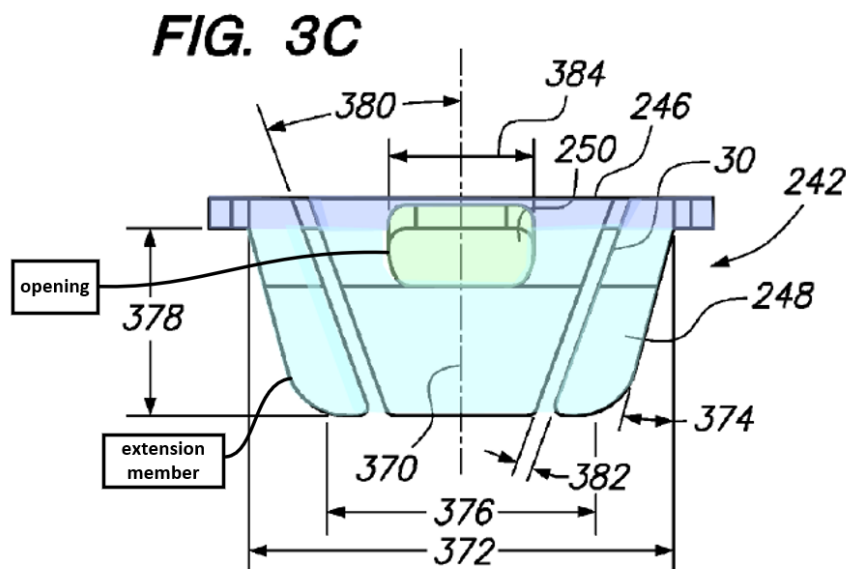
141. Lawrence discloses “an extension member extending downward from the bottom surface of the base,” as seen in the annotated version of Figures 3C and 3D below.



Lawrence discloses an “extension member” (housing side 248 in teal highlighting). Lawrence explains that housing side 248 “cantilevers away from the housing top 246” and is “approximately perpendicular to the housing top 246.” Ex. 1008, 5:1–12. Housing side 248 therefore extends downward from the bottom of housing top 246 (the “base portion”) and constitutes the recited extension member. As seen in Figure 3C, saw guides 30 continue from housing top 246 through housing side 248, so that housing side 248 guides the saw blade toward the bone as it extends toward the metatarsal. Accordingly, Lawrence discloses limitation 1[b].

Limitation 1[b][i]

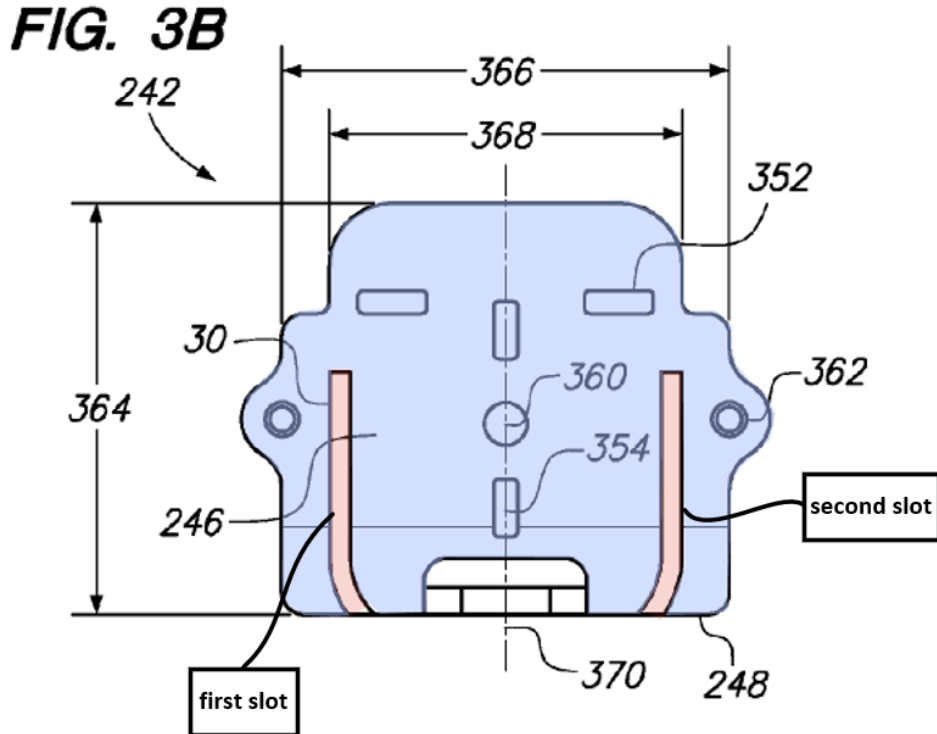
142. Lawrence discloses “wherein the at least one opening extends into at least a portion of the extension member,” as seen in the annotated version of Figure 3C below.



143. Lawrence discloses an opening (green highlighting) in the extension member 248 (teal highlighting). As seen above in the annotated Figure 3C, the alignment aperture 250 extends along a portion of both housing top 246 (the base portion) and housing side 248 (the extension member), and is openly accessible from both. Ex. 1008, 9:12–20 (“the alignment aperture 250 extends along a portion of both the housing top 246 and the housing side 248”). Lawrence further explains that aperture 250 “enables the user to view the alignment tabs 28 during positioning of the cutting guide,” confirming it provides a through-passage from the top surface of the base into the extension member. Id. at 5:65–6:7. Accordingly, Lawrence discloses limitation 1[b][i].

CLAIM 2

144. Claim 2 depends from claim 1 and recites that “the at least one slot comprises at least one first slot and at least one second slot,” as seen in the annotated version of Figure 3B below.

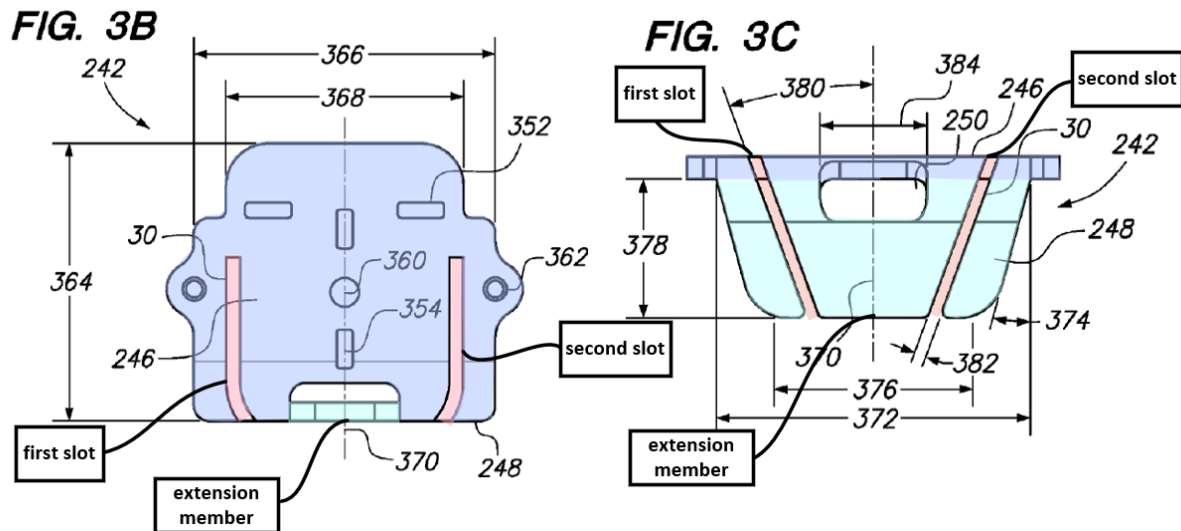


As seen above, Lawrence discloses first and second slots 30 (pink highlighting). Accordingly, Lawrence discloses the limitations recited in claim 2.

CLAIM 3

145. Claim 3 depends from claim 2 and recites that “the extension member is positioned at least partially between the at least one first slot and the at least one

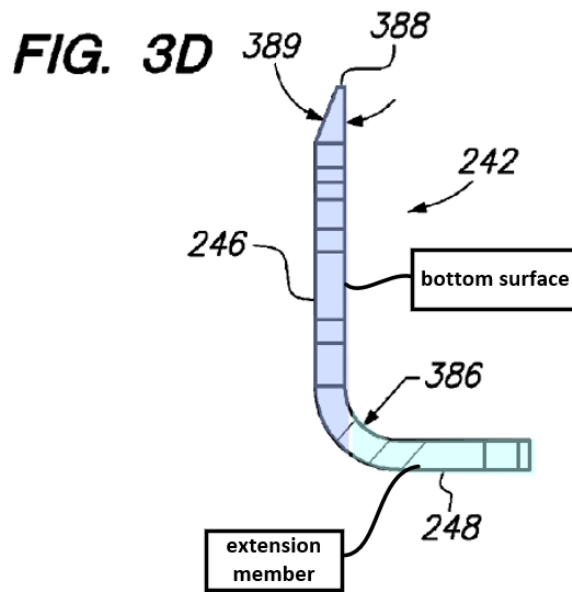
second slot.” An annotated version of Lawrence Figures 3B and 3C is reproduced below.



As seen above, Lawrence also discloses extension member 248 (teal highlighting) disposed at least partially between first and second slots 30 (pink highlighting). As seen in Figure 3C, saw guides 30 are located on opposite sides of housing axis 370, and housing side 248 extends across the region between them. Accordingly, Lawrence discloses the limitations recited in claim 3.

CLAIM 4

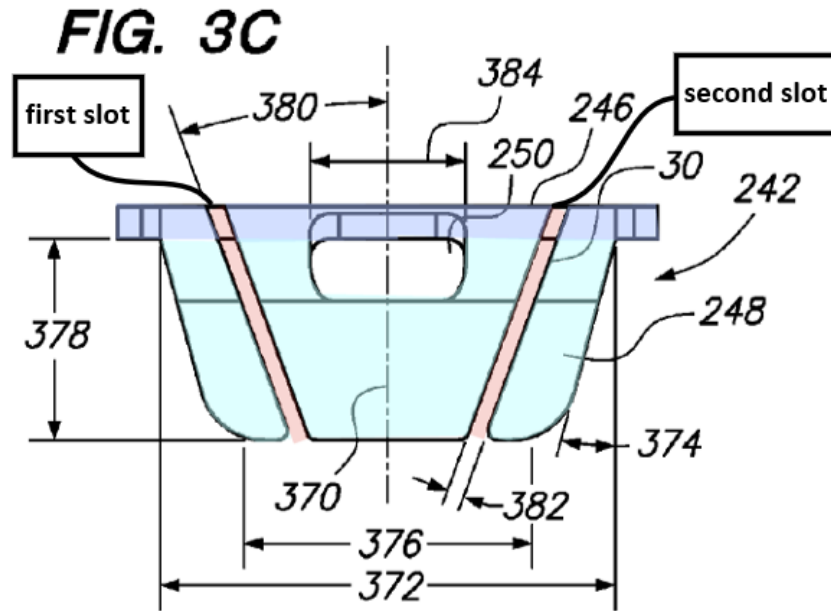
146. Claim 4 depends from claim 3 and recites that “the extension member extends from the bottom surface of the base portion at a substantially orthogonal angle relative to the bottom surface of the base portion,” as seen in the annotated version of Figure 3D below.



As discussed above in connection with limitation 1[b], Lawrence discloses its extension member 248 (teal) extending downward from the bottom surface of the base (purple) at a substantially orthogonal angle. Lawrence states that housing side 248 is “approximately perpendicular to the housing top 246,” Ex. 1008, 5:1–12, directly confirming the orthogonal angle required by claim 4. Accordingly, Lawrence discloses the limitations recited in claim 4.

CLAIM 5

147. Claim 5 depends from claim 4 and recites that “the at least one first slot is positioned in a first plane and the at least one second slot is positioned in a second plane, wherein the first and second planes form an oblique angle,” as seen in the annotated version of Figure 3C below.

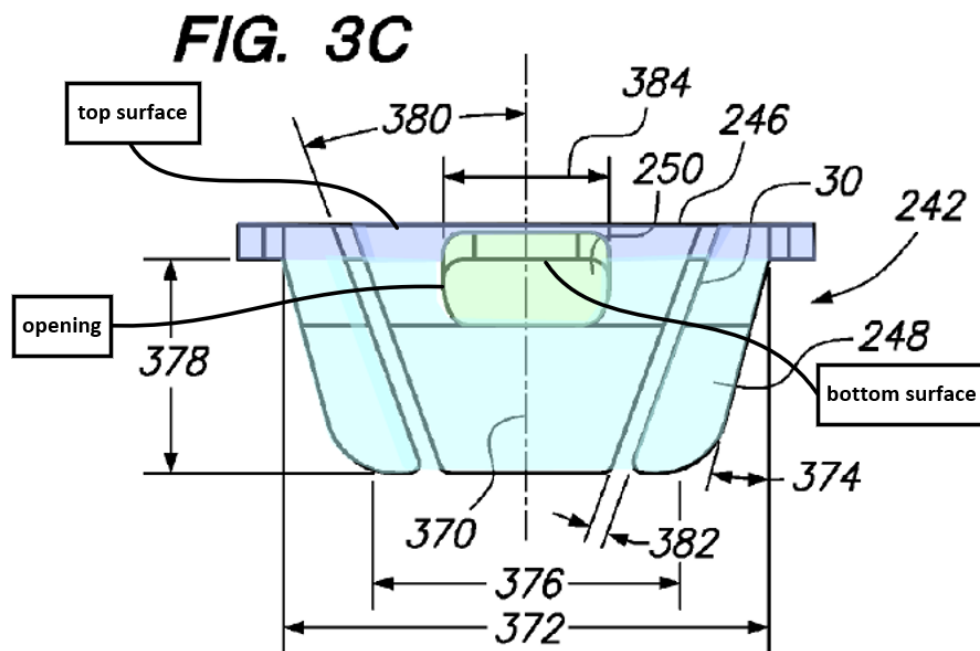


As seen above, Lawrence discloses that saw guides 30 “extend through both the housing top and the housing side” and that the saw guide “extends through the housing side at a guide angle of between approximately 12 degrees and 25 degrees relative to the housing axis.” Ex. 1008, 2:4–11; see also 8:35–45. Lawrence further discloses that the saw guides “can be positioned at a guide angle 380 of between approximately 12 degrees and 25 degrees” and expressly illustrates the saw guides 30 at approximately 18 degrees relative to the housing axis 370. Ex. 1008, 8:61–9:10, Fig. 3C. Because the two saw guides 30 are on opposite sides of the housing axis 370, they are positioned in planes that form an oblique angle with one another. As shown in Figure 3C, the two saw guides 30 are inclined toward one another in mirror image on opposite sides of housing axis 370, converging toward the lower edge of housing side 248. Because each saw guide is inclined relative to housing

axis 370, the angle between the planes of the two saw guides is approximately the sum of their guide angles, which is neither parallel nor perpendicular. Accordingly, Lawrence discloses the limitations recited in claim 5.

CLAIM 6

148. Claim 6 depends from claim 5 and recites that “the at least one opening provides fluid communication between the top and bottom surfaces of the base portion,” as seen in the annotated version of Figure 3C below.

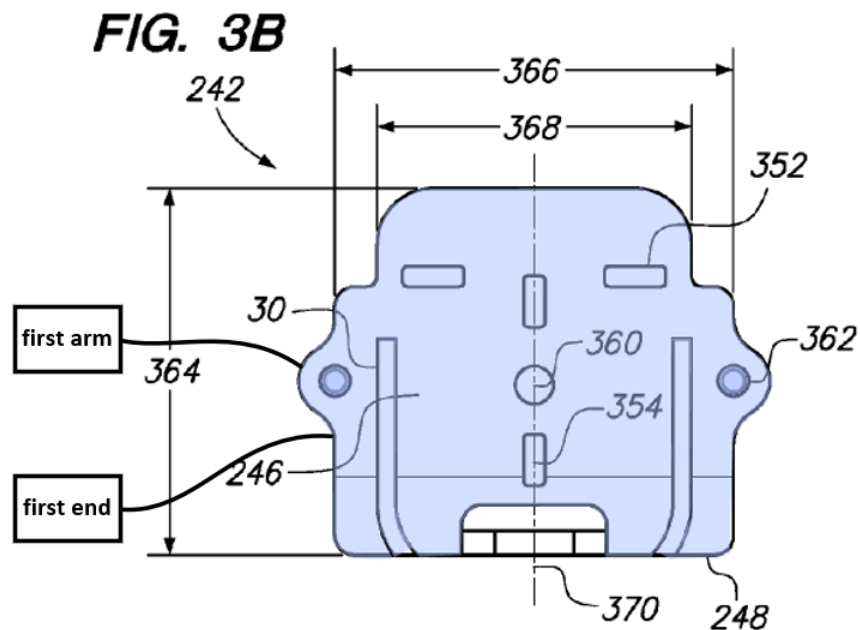


Opening 250 extends from the top surface through the bottom surface of the base as seen in Figure 3C. Lawrence explains that the alignment aperture 250 “enables the user to view the alignment tabs 28 during positioning of the cutting guide 12 relative to the metatarsal 14 and the proximal phalanx.” Ex. 1008, 5:65–6:7. Opening 250 thus extends along a portion of both housing top 246 and housing side 248 and

provides fluid communication between the top and bottom surfaces of the base portion, as the aperture is openly accessible from both the top surface (housing top 246) and the bottom/interior of the base (housing side 248). Ex. 1008, Fig. 3B–3C. Accordingly, Lawrence discloses the limitations recited in claim 6.

CLAIM 7

149. Claim 7 depends from claim 6 and recites that “the cut guide further comprises a first arm extending from the first end of the base portion,” as seen in the annotated version of Figure 3B below.



As seen above, the first arm in Lawrence extends from the first end of the base portion as a monolithic part. The lateral end of housing top 246 at the first end of the base portion extends outward as an integral part of housing top 246, carrying stabilizer aperture 362, and constitutes the recited first arm. Ex. 1008, 7:31–45, Fig.

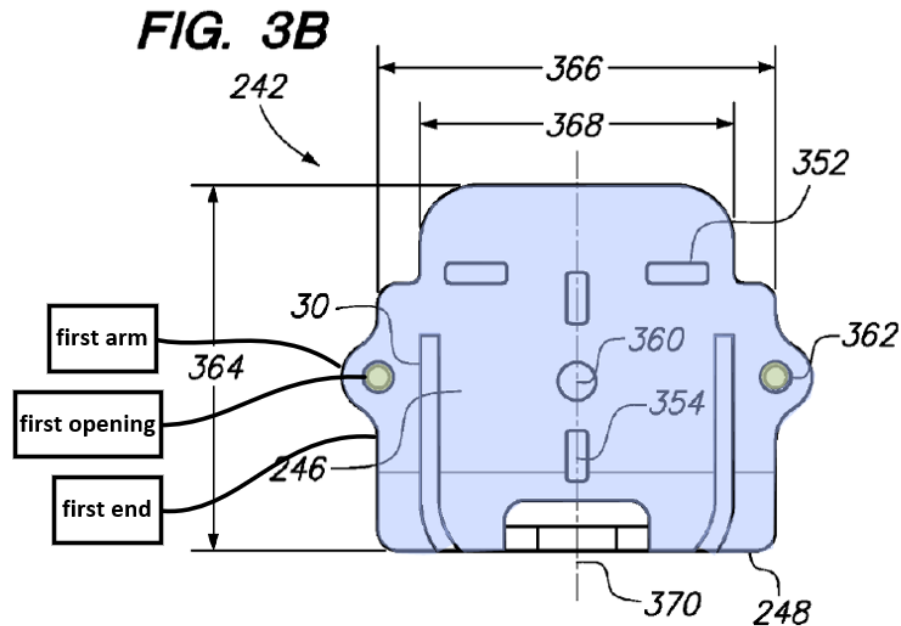
3B. Stabilizer aperture 362 receives a stabilizer that holds cutting guide 12 in position on the bone, and locating the aperture on the lateral end of housing top 246 places it outside the region of saw guides 30. Accordingly, Lawrence discloses the limitations recited in claim 7.

CLAIM 8

150. Claim 8 depends from claim 7 and recites that “the first arm forms a substantially orthogonal angle with the first end of the base portion.” As discussed above and shown in the annotated Figure 3B provided in connection with claim 7, the first arm (lateral end of housing top 246) extends generally orthogonal to the first end of the base portion. As seen in Figure 3B, housing top 246 extends laterally on each side of the handle aperture 360, with the lateral ends projecting perpendicularly from the long axis of the guide. Accordingly, Lawrence discloses the limitations recited in claim 8.

CLAIM 9

151. Claim 9 depends from claim 8 and recites that “the first arm comprises a first opening extending therethrough from a top surface through to a bottom surface thereof,” as seen in the annotated version of Figure 3B below.



As seen above, the first arm (lateral end of housing top 246) includes a first opening extending therethrough from a top surface through to a bottom surface thereof. Lawrence expressly discloses that “stabilizer apertures 362 can be substantially circular in shape and can be positioned between approximately 0.40 and 0.47 inches from the housing side 248 of the housing 242 and can be evenly spaced on either side of the handle aperture 360.” Ex. 1008, 7:40–50, Fig. 3B. The stabilizer aperture 362 at the terminal end of the first arm receives a stabilizer (e.g., K-wire) that extends from the top surface through to the bottom surface, constituting the recited first opening. Accordingly, Lawrence discloses the limitations recited in claim 9.

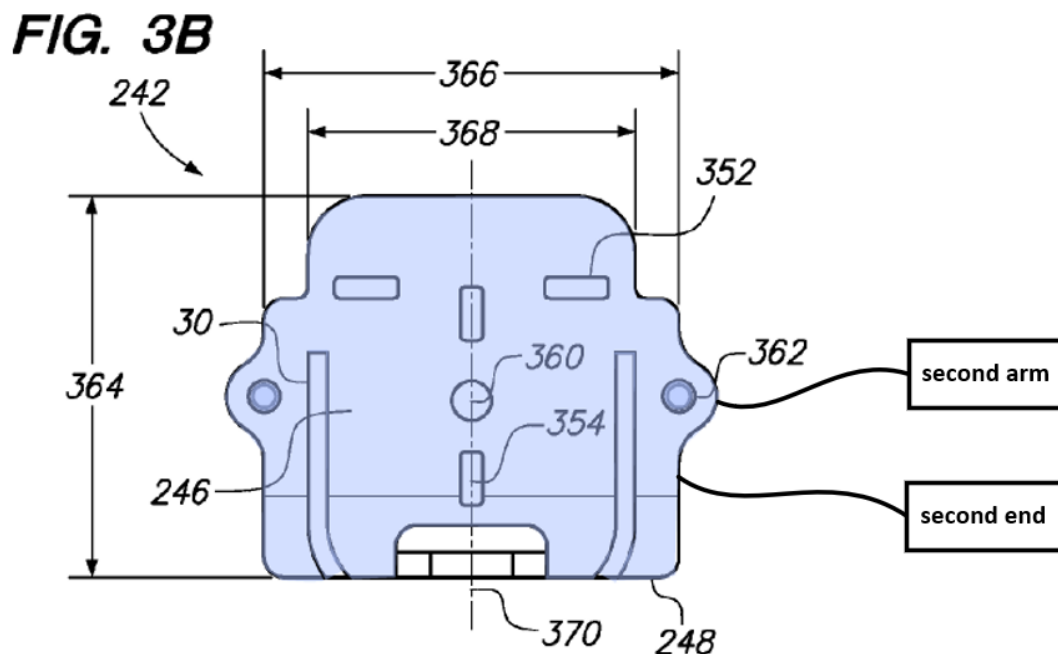
CLAIM 10

152. Claim 10 depends from claim 9 and recites that “the first opening is positioned at a terminal end of the first arm.” As discussed above and shown in the

annotated Figure provided in connection with claim 9, the first opening in Lawrence is positioned at a terminal end of the first arm. As explained above, the terminal end is the distal end region of the arm. Stabilizer aperture 362 in Lawrence is located at the distal end region of the arm. Stabilizer aperture 362 in Lawrence is located at the distal end region of the lateral arm projection of housing top 246. Ex. 1008, 7:40–50, Fig. 3B. Accordingly, Lawrence discloses the limitations recited in claim 10.

CLAIM 11

153. Claim 11 depends from claim 10 and recites that “the cut guide further comprises a second arm extending from the second end of the base portion,” as seen in the annotated version of Figure 3B below.



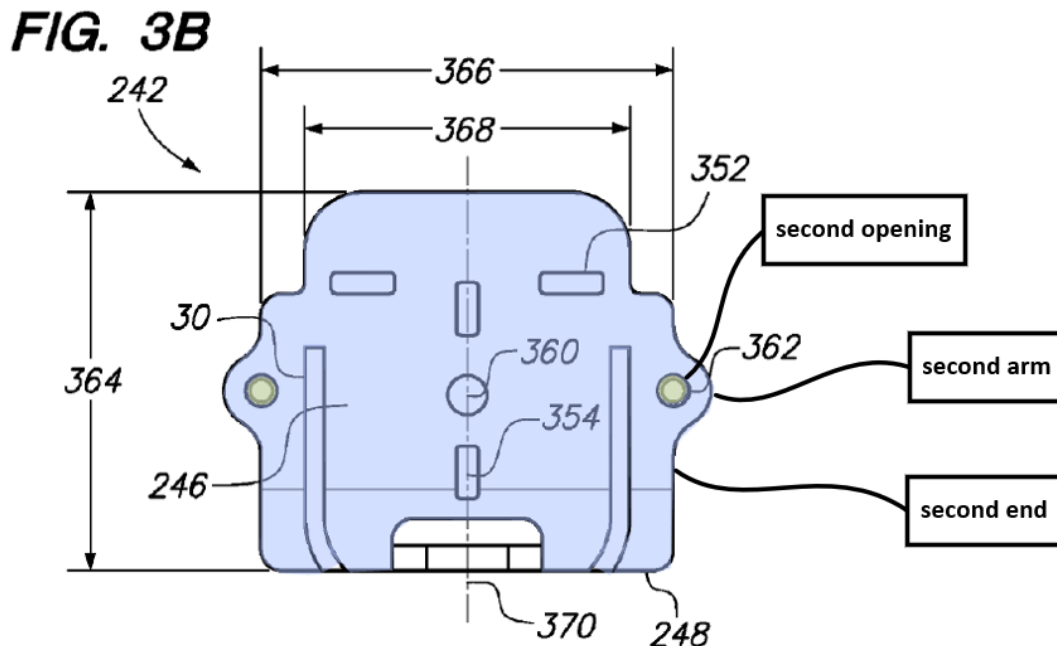
As seen above, the second arm in Lawrence extends from the second end of the base portion as a monolithic part. Accordingly, Lawrence discloses the limitations recited in claim 11.

CLAIM 12

154. Claim 12 depends from claim 11 and recites that “the second arm forms a substantially orthogonal angle with the second end of the base portion.” As discussed above and shown in the annotated Figure provided in connection with claim 11, the second arm in Lawrence extends generally orthogonal to the second end of the base portion. Accordingly, Lawrence discloses the limitations recited in claim 12.

CLAIM 13

155. Claim 13 depends from claim 12 and recites that the “second arm comprises a second opening extending therethrough from a top surface through to a bottom surface thereof,” as seen in the annotated version of Figure 3B below.



As seen above, the second arm (lateral end of housing top 246 at the second end of the base portion) includes a second opening extending therethrough from a top surface through to a bottom surface thereof. As noted above in connection with claims 9 and 11, Lawrence discloses stabilizer apertures 362 at both lateral ends of housing top 246, each receiving a stabilizer that extends from the top surface through to the bottom surface. Ex. 1008, 7:40–58, Fig. 3B. The stabilizer aperture 362 at the terminal end of the second arm is the recited second opening. Accordingly, Lawrence discloses the limitations recited in claim 13.

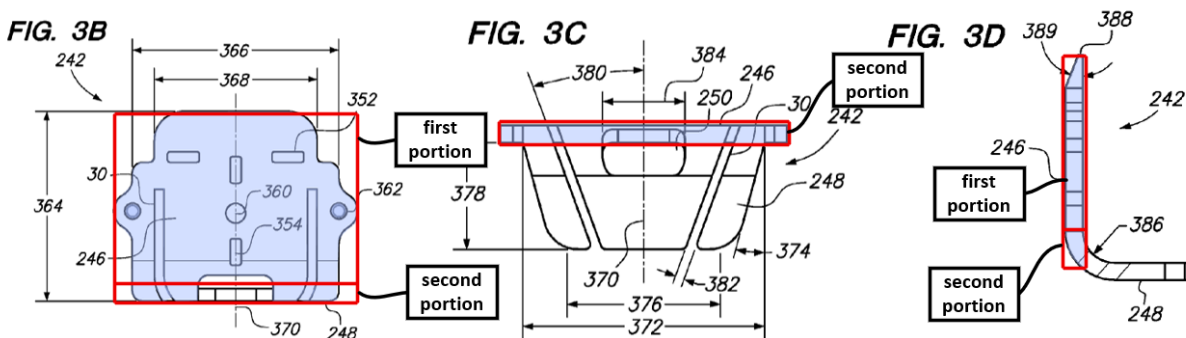
CLAIM 14

156. Claim 14 depends from claim 13 and recites that “the second opening is positioned at a terminal end of the second arm.” As discussed above and shown in the annotated Figure provided in connection with claim 13, the second opening in

Lawrence is positioned at a terminal end of the second arm. Accordingly, Lawrence discloses the limitations recited in claim 14.

CLAIM 15

157. Claim 15 depends from claim 1 and recites that “the top surface comprises a first portion and a second portion,” as seen in the annotated Figures 3B, 3C, and 3D below.



As seen above, Lawrence includes a first portion of the top surface (the main flat region of housing top 246, labeled “first portion” in annotated Figures 3B and 3D) and a second portion of the top surface at an angle from the first portion. The curved transition portion 386 (curving downward from housing top 246) provides a second portion of the top surface, as shown in annotated Figure 3D.

158. Alternatively, Lawrence discloses a “flat tapered portion 388” at an end of housing top 246 having “a taper angle 389 of approximately 16 degrees.” Ex. 1008, 9:37–46, Fig. 3D. This flat tapered portion 388 is the second portion of the top surface: it is a discrete, planar section of housing top 246 positioned in a plane that

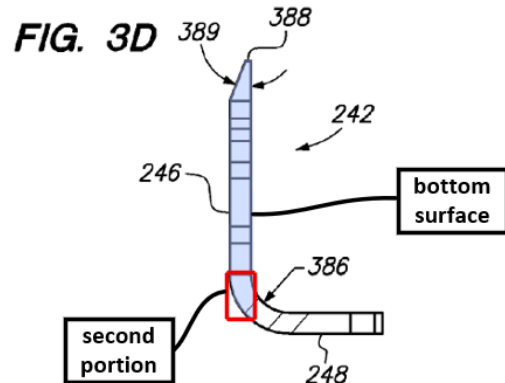
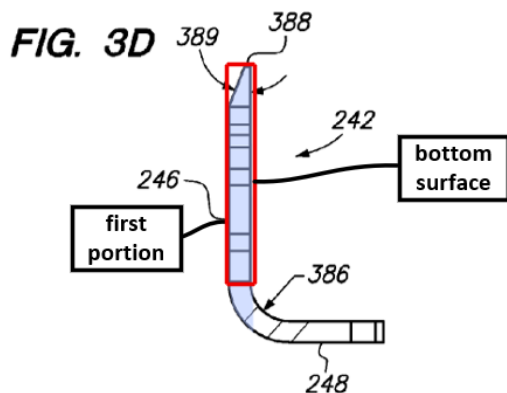
is oblique to the main flat region of housing top 246. The two portions (main flat region and tapered portion 388) together comprise the top surface of the base portion with a first portion and a second portion as required by claim 15. Accordingly, Lawrence discloses the limitations recited in claim 15.

X. OBVIOUSNESS OF CLAIMS 16–20 IN VIEW OF LAWRENCE

CLAIM 16

159. Claim 16 depends from claim 15 and recites that “the first portion is positioned in a plane which is substantial[ly] parallel to a plane of the bottom surface, and the second portion is positioned in a plane which is substantially oblique to that of the first portion and the bottom surface.”

160. Claim 16 would have been obvious based on Lawrence. Annotated versions of Figure 3D are reproduced below.



As seen above, the first portion of the top surface extends generally parallel to a bottom surface defined by the base portion. The second portion of the top surface is

curved downward relative to the first portion of the top surface and the bottom surface defined by the base portion.

161. Lawrence expressly teaches varying the top/side transition geometry. Lawrence discloses that housing side 248 and housing top 246 can be joined by curved portion 386 having a radius of approximately 0.125 inches, but alternatively the housing 242 can be designed without that curved portion, or the radius of curved portion 386 can be greater than or less than 0.125 inches. Ex. 1008, 9:25–36. Thus, Lawrence teaches that the curvature and transition geometry are design variables. In my opinion, selecting a different radius, including reducing the curvature or omitting the curved portion, would have been an obvious matter of design choice to achieve the desired fit, profile, manufacturability, and saw-guide support.

162. I believe it also would have been obvious to replace or approximate the curved transition with a flat oblique surface. Lawrence itself discloses a flat tapered portion 388 at an end of housing top 246, with taper angle 389 of approximately 16 degrees, and further states that the housing top 246 may be provided with or without that tapered portion. Ex. 1008, 9:37–46. This teaches that planar angled/tapered surfaces were known and acceptable features on Lawrence's housing top. In my opinion, a POSA therefore would have understood that the curved transition 386 could predictably be modified to a flat tapered or chamfered oblique portion,

analogous to tapered portion 388/angle 389, while retaining the same basic cutting-guide function.

163. The modification would have been straightforward and predictable. Lawrence's guide operates by positioning housing 242 adjacent the metatarsal and guiding the saw blade through saw guide 30. Changing the outer transition/top-surface geometry from a curved radius to a planar oblique taper would not change that operating principle. Rather, it would merely substitute one known housing-surface geometry for another to provide a low-profile, manufacturable guide surface while preserving the intended guide-slot orientation and saw-blade guidance. A planar oblique surface also presents a flat, defined surface that the surgeon can readily see, and Lawrence's own tapered portion 388 shows that such a planar surface was compatible with housing top 246.

164. A POSA would have been motivated to select the flat oblique/tapered top-surface geometry recited in claim 16 as an obvious design alternative to Lawrence's curved transition, and would have had a reasonable expectation of achieving the same saw-guiding function. Accordingly, claim 16 would have been obvious in view of Lawrence.

CLAIM 17

165. Claim 17 depends from claim 16 and recites that “at least a portion of the at least one slot is positioned in the first portion of the top surface and the second portion of the top surface.”

166. As discussed above in connection with claim 16, replacing or approximating the curved transition 386 with a flat oblique/tapered portion would have been obvious in view of Lawrence. Because the first and second slots 30 pass through that region of the housing, the resulting slot in modified version of Lawrence would also naturally extend through both the generally planar top portion and the oblique/tapered portion. A POSA would have found claim 17 obvious in view of Lawrence for the reasons I discuss above.

CLAIM 18

167. Claim 18 is an independent claim that includes limitations recited in claims 1, 15, 16, and 17 as set forth in the table below.

Claim 18		
Claim 18 Limitation	Corresponding Limitation	Claim 18
[18][pre]	1[pre]	A cut guide, comprising:
[18][a]	1[a]	a base portion, comprising:
[18][a][i]	[1][a][ii]	a first end positioned substantially opposite the base portion from a second end;
[18][a][ii]	[1][a][iii]	a top surface positioned substantially opposite the base portion from a bottom surface, comprising:
[18][a][ii][1]	15/16	a first portion positioned in a first plane; and
[18][a][ii][2]	15/16	a second portion positioned in a second plane, wherein the second plane is substantially

		oblique to the first plane;
[18][a][iii]	[1][a][iv]	at least one slot disposed between the first and second ends of the base portion,
[18][a][iii][1]	[1][a][iv]	wherein the at least one slot provides fluid communication between the top and bottom surfaces of the base,
[18][a][iii][2]	17	wherein at least a portion of the at least one slot is positioned in the first portion and the second portion of the top surface; and
[18][a][iv]	[1][a][v]	at least one opening extending through the base portion; and
[18][b]	[1][b]	an extension member extending downward from the bottom surface of the base,
[18][b][i]	[1][b][i]	wherein the at least one opening extends into at least a portion of the extension member.

My discussion above relative to the limitations in claims 1, 15, 16, and 17 that correspond to those in claim 18 are incorporated herein by reference. In my opinion, a POSA would have found the limitations of claim 18 obvious in view of Lawrence for the reasons I discuss above.

CLAIM 19

168. Claim 19 depends from claim 18 and includes limitations recited in claims 2 and 5 as set forth in the table below.

Claim 19 Limitation	Corresponding Limitation	Claim 19
19	2/5	The cut guide of claim 18, wherein the at least one slot comprises a first slot and a second slot, wherein the first and second slots are positioned in planes which form an oblique angle with one another.

My discussion above relative to the limitations in claims 2 and 5 that correspond to those in claim 19 are incorporated herein by reference. A POSA would have found the limitations of claim 19 obvious in view of Lawrence for the reasons I discuss above.

CLAIM 20

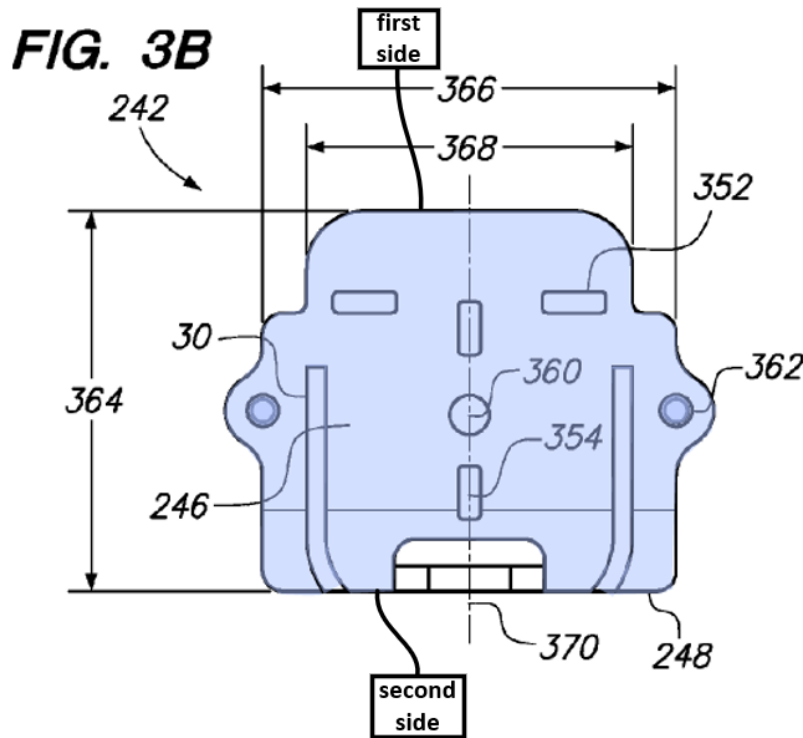
169. Claim 20 is an independent claim that includes limitations recited in claims 1, 7–11, and 13–17 as set forth in the table below.

Claim 20 Limitation	Corresponding Limitation	Claim 20
[20][pre]	[1][pre]	A cut guide, comprising:
[20][a]	[1][a]	a base portion, comprising:
[20][a][i]	[1][a][ii]	a first side positioned substantially opposite the base portion from a second side,
[20][a][ii]	not in claim 1	wherein the first and second sides are substantially parallel to one another;
[20][a][iii]	[1][a][ii]	a first end positioned substantially opposite the base portion from a second end;
[20][a][iv]	[1][a][iii]	a top surface positioned substantially opposite the base portion from a bottom surface, comprising:
[20][a][iv][1]	15/16	a first portion positioned in a first plane; and
[20][a][iv][2]	15/16	a second portion positioned in a second plane, wherein the second plane is substantially oblique to the first plane;
[20][a][v]	[1][a][iv]	at least one slot disposed between the first and second ends of the base portion,
[20][a][v][1]	[1][a][iv]	wherein the at least one slot provides fluid communication between the top and bottom surfaces of the base,
[20][a][v][2]	17	wherein at least a portion of the at least one slot is positioned in the first portion and the second portion of the top surface; and

[20][a][vi]	[1][a][v]	at least one opening extending from the top surface through to the bottom surface;
[20][b]	[1][b]	an extension member extending downward from the bottom surface of the base,
[20][b][i]	[1][b][i]	wherein the at least one opening extends into at least a portion of the extension member.
[20][c]	7/8	a first arm extending from the first end of the base portion at a substantially orthogonal angle, comprising:
[20][c][i]	9/10	an opening positioned at a terminal end of the first arm and extending from a top surface of the first arm through to a bottom surface of the first arm; and
[20][d]	11	a second arm extending from the second end of the base portion, comprising:
[20][d][i]	13/14	an opening positioned at a terminal end of the second arm and extending from a top surface of the second arm through to a bottom surface of the second arm.

My discussion above relative to the limitations in claims 1, 7–11, and 13–17 that correspond to those in claim 20 are incorporated herein by reference.

170. In limitation 20[a][ii], claim 20 additionally recites that “the first and second sides [of the base portion] are substantially parallel to one another,” which Lawrence teaches as seen in the annotated version of Figure 3B below.



As seen above, Lawrence's first and second sides of the base portion are parallel to one another. A POSA would have found the limitations of claim 20 obvious in view of Lawrence for the reasons I discuss above.

REASONABLE EXPECTATION OF SUCCESS

171. In my opinion, a POSA would have had a reasonable expectation of success in making the proposed modifications to Lawrence. Lawrence's cutting guide operates by positioning housing 242 adjacent the metatarsal and using saw guide 30 to receive and guide the saw blade. Lawrence already discloses that saw guide 30 extends through housing top 246 and housing side 248, and that the saw guide may be angled relative to housing axis 370. Ex. 1008, 2:4–11; 8:35–45; 8:61–

9:10. The proposed modification would not change that basic operation. It would merely alter the exterior housing-surface geometry around the guide.

172. Lawrence also expressly identifies the top/side transition geometry as variable. Lawrence teaches curved portion 386 with a radius of approximately 0.125 inches, but further states that the housing may omit the curved portion or use a radius greater than or less than 0.125 inches. Ex. 1008, 9:25–36. Lawrence separately discloses a flat tapered portion 388 on housing top 246 at taper angle 389, and states that the housing top may alternatively be designed without that tapered portion. *Id.* at 9:37–46. Thus, Lawrence confirms that curved, non-curved, and flat tapered housing surfaces were predictable design options.

173. A POSA therefore would have expected that replacing or approximating the curved portion 386 with a flat oblique/tapered surface would successfully preserve Lawrence’s saw-guide function while maintaining blade lead-in, structural support around the slot, and the desired angled cutting path. The modification would involve only routine mechanical design and manufacturing choices, not a change in principle of operation. In my view, a POSA would have had a reasonable expectation of success in modifying Lawrence as described above, and that doing so would have been within the routine skill of a person familiar with orthopedic cut-guide design. Housing 242 would still be positioned relative to the metatarsal using alignment tabs 28 viewed through alignment aperture 250 and held

with stabilizers placed through apertures 362, and saw guides 30 would retain their guide angle relative to housing axis 370, so the surgeon would use the modified guide in the same manner as Lawrence's guide.

XI. CONCLUSION

174. For the foregoing reasons, it is my opinion that Claims 1-20 of the '139 patent are anticipated by the Bays prior art reference.

175. For the foregoing reasons, it is my opinion that Claims 1-15 of the '139 patent are anticipated by the Neal and Lawrence prior art references.

176. Additionally, for the foregoing reasons, it is my opinion that as of December 2017, a POSA would have found Claims 6–20 of the '139 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.

177. 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.

178. 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: September 28, 2026

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