

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TREACE MEDICAL CONCEPTS, INC.,
Petitioner,

v.

PARAGON 28, INC.
Patent Owner.

IPR2027-00013
Patent 10,123,831

PETITION FOR *INTER PARTES* REVIEW

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Claim 1	
1[pre]	A surgical kit comprising:
1[a]	a plurality of bone anchors;
1[b]	a bone plate having bone anchor receiving portions with through openings sized to receive the bone anchors, the bone plate having a flexed configuration and an unflexed configuration;
1[c]	a plurality of elongated manipulators having distal end portions configured to be connected to the bone anchor receiving portions of the bone plate and proximal end portions opposite the distal end portions; and
1[d]	cannulas of the manipulators extending between the distal and proximal end portions thereof and being aligned with the through bores of the bone plate when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate, the cannulas being sized to permit the bone anchors to be advanced through the cannulas and into the through bores of the bone plate,
1[e]	wherein the bone anchor receiving portions of the bone plate include lips and the distal end portions of the manipulators include side walls with openings therein sized to receive the lips of the bone anchor receiving portions.

Claim 2	
2	The surgical kit of claim 1 wherein the bone anchor receiving portions of the bone plate include lobes and the distal end portions of the manipulators includes sockets sized to receive the lobes.

Claim 3	
3	The surgical kit of claim 1 wherein each of the manipulators includes a fulcrum portion and a leverage portion spaced apart from each other on opposite sides of the cannula of the manipulator, the fulcrum portion being configured to contact an upper surface of one of the bone anchor receiving portions of the bone plate and the leverage portion being configured to contact a lower surface of the one bone anchor receiving portion.

Claim 4	
4	The surgical kit of claim 1 wherein the bone plate bone anchor

	receiving portions include lobes and the manipulator distal end portions include sockets sized to receive the lobes with the lobes and sockets being configured to form a mating, non-rotatable fit when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate.
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Claim 5	
5	The surgical kit of claim 1 wherein the bone plate includes a resilient intermediate portion connecting the bone anchor receiving portions and the intermediate portion has a straight shape with the bone plate in the flexed configuration thereof and a bent shape with the bone plate in the unflexed configuration thereof.

Claim 6	
6	The surgical kit of claim 1 wherein the unflexed configuration of the bone plate orients the bone anchor receiving portions of the bone plate to extend transverse to each other and the flexed configuration of the bone plate orients the bone anchor receiving portions of the bone plate to be coplanar with each other.

Claim 7	
7[pre]	A surgical kit comprising:
7[a]	a plurality of bone anchors;
7[b]	a bone plate having bone anchor receiving portions with through openings sized to receive the bone anchors, the bone plate having a flexed configuration and an unflexed configuration;
7[c]	a plurality of elongated manipulators having distal end portions configured to be connected to the bone anchor receiving portions of the bone plate and proximal end portions opposite the distal end portions; and
7[d]	cannulas of the manipulators extending between the distal and proximal end portions thereof and being aligned with the through bores of the bone plate when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate, the cannulas being sized to permit the bone anchors to be advanced through the cannulas and into the through bores of the bone plate,
7[e]	wherein the bone plate bone anchor receiving portions include lobes

	and the bone plate includes a narrowed, intermediate portion extending between the lobes; and
7[f]	the distal end portions of the manipulators include sockets sized to receive the lobes of the bone plate and the sockets include notches that receive the intermediate portion of the bone plate.

Claim 8	
8	The surgical kit of claim 7 wherein the intermediate portion is resilient and has a straight shape with the bone plate in the flexed configuration thereof and a bent shape with the bone plate in the unflexed configuration thereof.

Claim 9	
9[pre]	A surgical kit comprising
9[a]	a plurality of bone anchors;
9[b]	a bone plate having bone anchor receiving portions with through openings sized to receive the bone anchors, the bone plate having a flexed configuration and an unflexed configuration;
9[c]	a plurality of elongated manipulators having distal end portions configured to be connected to the bone anchor receiving portions of the bone plate and proximal end portions opposite the distal end portions;
9[d]	cannulas of the manipulators extending between the distal and proximal end portions thereof and being aligned with the through bores of the bone plate when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate, the cannulas being sized to permit the bone anchors to be advanced through the cannulas and into the through bores of the bone plate; and
9[e]	a restraint having portions configured to be connected to the manipulators.

Claim 10	
10	The surgical kit of claim 9 wherein the portions of the restraint include openings sized to receive the proximal portions of the manipulators.

Claim 11	
11[pre]	A method of stabilizing a plurality of bones, the method comprising:

11[a]	pivoting manipulators connected to a bone plate to flex the bone plate;
11[b]	positioning the flexed bone plate adjacent bones;
11[c]	guiding bone anchors into through bores of the bone plate using the manipulators; and
11[d]	securing the flexed bone plate to the bones with the bone anchors.

Claim 12

12	The method of claim 11 wherein guiding the bone anchors into the through bores of the bone plate using the manipulators includes advancing the bone anchors through cannulas of the manipulators and into the through bores of the bone plate.
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Claim 13

13[a]	The method of claim 11 wherein the manipulators are connected to end portions of the bone plate having the through bores therein; and
13[b]	pivoting the manipulators to flex the bone plate includes flexing an intermediate portion of the bone plate between the end portions.

Claim 14

14	The method of claim 11 wherein pivoting the manipulators to flex the bone plate includes reconfiguring the bone plate from a bent configuration to a substantially flat configuration.
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Claim 15

15	The method of claim 11 wherein pivoting the manipulators connected to the bone plate to flex the bone plate includes engaging distal portions of the manipulators with notched profiles of the bone plate and shifting proximal handle portions of the manipulators together.
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Claim 16

16	The method of claim 11 wherein positioning the flexed bone plate adjacent the bones using the manipulators includes positioning the bone plate using the manipulators while lobes of the bone plate are received in openings of the manipulators and the bone plate lobes and manipulators form mating, non-rotatable connections therebetween.
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Claim 17

17	The method of claim 11 wherein the manipulators are elongated and pivoting the manipulators to flex the bone plate includes pivoting the manipulators from a first orientation wherein the manipulators extend transverse to each other to a second orientation wherein the manipulators extend substantially parallel to each other.
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Claim 18

18	The method of claim 11 further comprising connecting a restraint to the manipulators to fix the manipulators relative to each other while positioning the flexed bone plate adjacent the bones and guiding the bone anchors into the through bores of the bone plate using the manipulator.
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Claim 19

19	The method of claim 18 further comprising disconnecting the restraint from the manipulators to permit the manipulators to move relative to each other and be disconnected from the bone plate.
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Claim 20

20[pre]	A method of stabilizing a plurality of bones, the method comprising:
20[a]	positioning a deformed bone plate adjacent bones using manipulators connected to the deformed bone plate;
20[b]	advancing bone anchors through cannulas of the manipulators connected to the deformed bone plate and into through bores of the deformed bone plate; and
20[c]	driving the bone anchors into the bones to secure the deformed bone plate to the bones.

Claim 21

21	The method of claim 20 wherein positioning the deformed bone plate adjacent the bones using the manipulators includes keeping the cannulas of the manipulators aligned with the through bores of the deformed bone plate.
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Claim 22

22	The method of claim 20 wherein positioning the deformed bone plate adjacent the bones using the manipulators includes maintaining end
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	portions of the deformed bone plate having the through bores therein at least partially within openings of the manipulators.
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Claim 23

23	The method of claim 20 further comprising deforming the bone plate by moving the manipulators relative to each other.
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Claim 24

24	The method of claim 23 wherein deforming the bone plate includes reconfiguring the bone plate from a bent configuration to a substantially flat configuration.
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Claim 25

25	The method of claim 20 further comprising disconnecting the manipulators from the deformed bone plate and permitting the deformed bone plate to urge the bones together.
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Claim 26

26	The method claim 20 further comprising fixing the manipulators relative to each other and keeping the manipulators fixed relative to each other and connected to the deformed bone plate while positioning the deformed bone plate adjacent the bones and advancing bone anchors through the cannulas of the manipulators.
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Claim 27

27	The method of claim 26 wherein fixing the manipulators relative to each other includes connecting a restraint to the manipulators.
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Claim 28

28	The method of claim 20 wherein advancing the bone anchors through cannulas of the manipulators and into the through bores of the deformed bone plate includes connecting a driver instrument to one of the bone anchors and advancing the connected driver and bone anchor through the cannula of one of the manipulators.
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Claim 29

29	The method of claim 20 further comprising providing the deformed bone plate, wherein providing the deformed bone plate includes
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	chilling the bone plate.
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PETITIONER’S LIST OF EXHIBITS

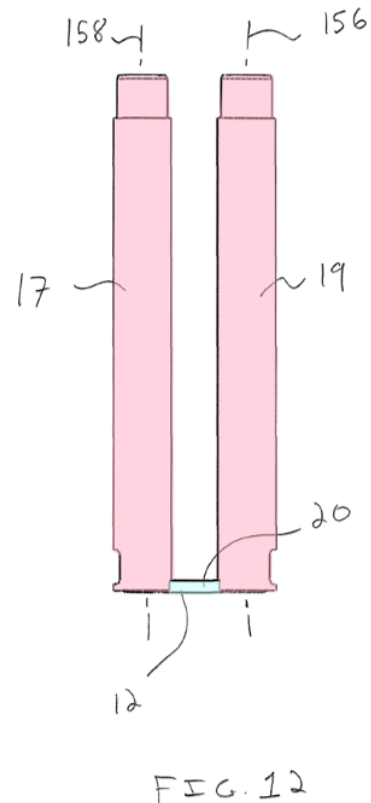
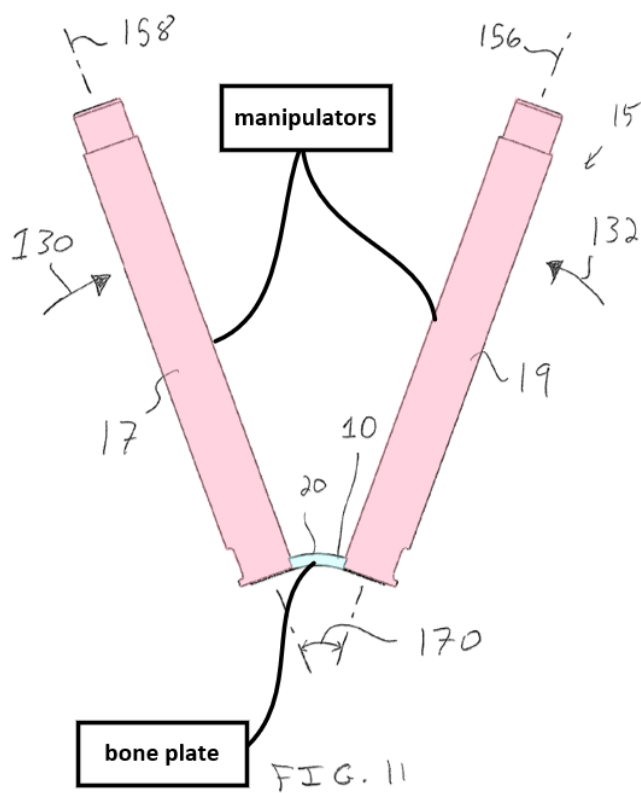
Exhibit No.	Description
1001	U.S. Patent No. 10,123,831 to Gephart (the “’831 Patent”)
1002	Declaration of Daniel C. Farber, M.D. (“Farber Declaration”)
1003	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.
1004	Prosecution History of U.S. Patent Application No. 15/058,695 (Patent No. 10,123,831)
1005	U.S. Patent Application Publication No. US 2017/0196604 A1, dated July 13, 2017 (“Hartdegen”)
1006	International (PCT) Publication No. WO 2016/007624 A1, dated January 14, 2016
1007	U.S. Provisional Application No. 62/022,811, filed July 10, 2014 (“Hartdegen provisional”)
1008	U.S. Patent Application Publication No. US 2009/0281543 A1, dated November 12, 2009 (“Orbay”)
1009	U.S. Patent No. 5,246,443 to Mai (“Mai”)

I. INTRODUCTION

Treace Medical Concepts, Inc. (“Petitioner”) requests *inter partes* review of US Patent No. 10,123,831 (Ex.1001, the “’831 Patent”) and cancellation of claims 1–29. This Petition presents new art and arguments that were not previously considered by the Office.

A. The ’831 Patent

The ’831 Patent “relates to the stabilization of bones and, more particularly, to devices for compressing bones together to encourage bone growth.” Ex.1001, 1:13–15. The ’831 Patent explains that its “bone plate 12 has an initial, unflexed configuration where an intermediate portion 20 of the bone plate 12 is curved or bent” and “may be flexed using an instrument 15 that includes a pair of manipulators 17, 19.” *Id.* at 4:4–8. Annotated versions of Figures 11 and 12 from the ’831 Patent are provided below.



Annotated Figures 11 and 12 above show bone plate 12 (teal) with its intermediate portion 20 deformed from an unflexed condition (Fig. 11) to a flexed condition (Fig. 12) using manipulators 17, 19 (pink). Ex.1002 ¶20.

The prosecution history was brief and did not involve any substantive distinction over the type of implant/insert system relied upon in this Petition. The Examiner allowed certain claims without comment, indicated certain dependent claims would be allowable if rewritten in independent form, and allowed the application after Applicant cancelled original claim 1 and placed the indicated allowable subject matter into independent form. *See* Ex.1004. The record contains

no Examiner’s reasons for allowance.

B. Evidence and Asserted Grounds

Claims 1–29 are unpatentable on the following grounds:

Ground	Reference(s)	Claims	Basis
1	Hartdegen ¹	9, 11–14, 17–21, 23–28	§102
2	Orbay ² , Hartdegen	1–8	§103
3	Hartdegen, Orbay	1–10, 13, 15, 16, 22	§103
4	Hartdegen, Mai ³	29	§103

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

II. LEVEL OF ORDINARY SKILL IN THE ART

The ’831 Patent claims recite surgical kits and methods of compressing bones together. *See* Ex.1001, 1:13–15. The ’831 Patent “relates to the stabilization of bones and, more particularly, to devices for compressing bones together to encourage bone growth.” Ex.1001, 1:13–15. In one example, the ’831 Patent explains that “a bone compression device 10 is provided having a bone plate 12 with a body 14 for being secured to bones with bone anchors, such as bone screws 16.” *Id.* at 3:45–60. The ’831 Patent describes using “elastic deformation of the bone plate 12 [to] resiliently

¹ US 2017/0196604 A1 (Ex.1005, “Hartdegen”).

² US 2009/0281543 A1 (Ex.1008, “Orbay”).

³ US 5,246,443 (Ex.1009, “Mai”).

bias[] the bone screws 16 and bones connected thereto together once the bone plate 12 has been implanted on the bones.” *Id.* at 3:49–52. The ’831 Patent includes manipulators 17, 19 engaged with the bone plate 12 to deform the bone plate 12 for installation. *Id.* at 4:9–15.

Accordingly, a person of ordinary skill in the art (POSA) would have included (i) a physician with a medical degree and at least 3 years of experience performing surgery using fixation devices to compress bone or other biological elements, (ii) an engineer with a bachelor’s degree in mechanical or biomedical engineering and at least 3 years of experience designing surgical fixation devices and related installation mechanisms, or (iii) a collaborative team combining such clinical and engineering expertise. Ex.1002 ¶¶21–22. Nevertheless, the definition of a POSA provided by Petitioner should not affect the outcome.

III. CLAIM CONSTRUCTION

In an *inter partes* review, a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citation omitted). Only those terms in controversy need to be construed, and only

to the extent necessary to resolve the controversy. *Realtime Data LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

For each term below, Petitioner does not attempt to construe the full metes and bounds of the term. Instead, Petitioner construes the terms only to the extent necessary to resolve the controversy.

A. “bone anchors”

Each of the independent claims recites “bone anchors” that are used to secure a bone plate to bone.

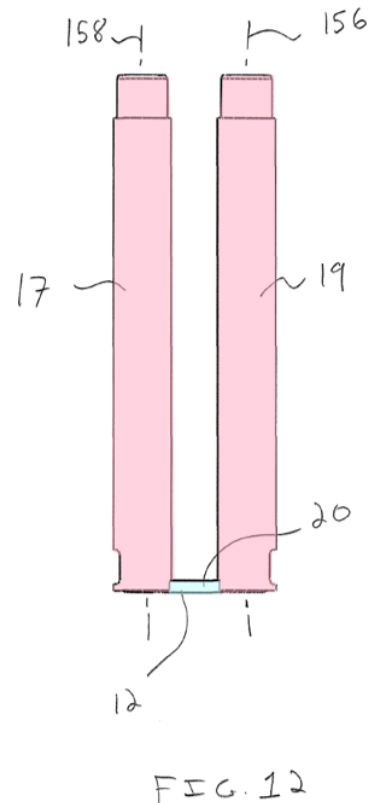
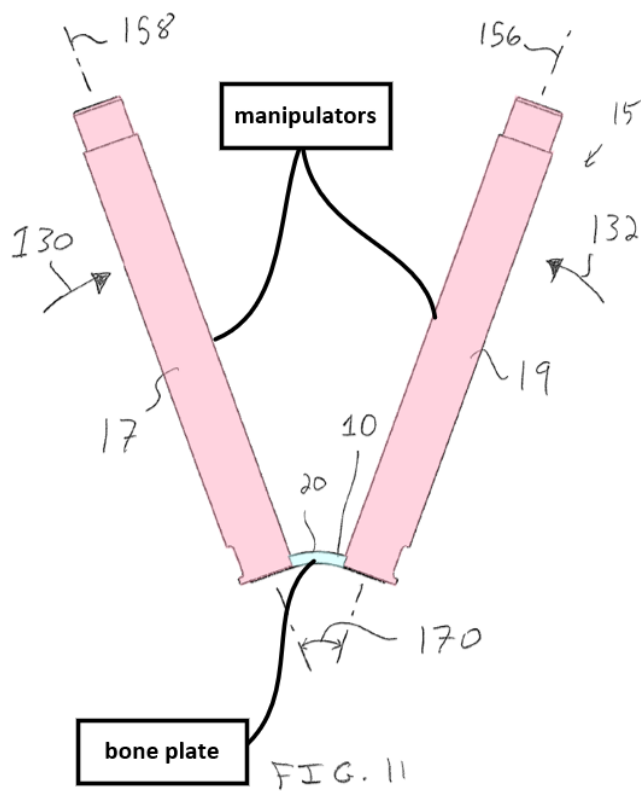
The ’831 Patent identifies bone screws 16 as examples of bone anchors. For example, the ’831 Patent explains that the bone plate is secured to bones with “bone anchors, such as bone screws 16,” and then consistently describes the bone screws as being driven into bone to secure the bone plate to the bones. Ex.1001, 3:45–50, 4:22–34, 4:51–55, 5:2–12, 8:22–30.

Consistent with the ’831 Patent, a bone screw is a bone anchor. Ex.1002 ¶24.

B. “manipulators”

Claim 1, for example, recites “a plurality of elongated manipulators.”

The ’831 Patent specification identifies tube-like members 17, 19, shown in Figures 11 and 12 below, as manipulators (pink).



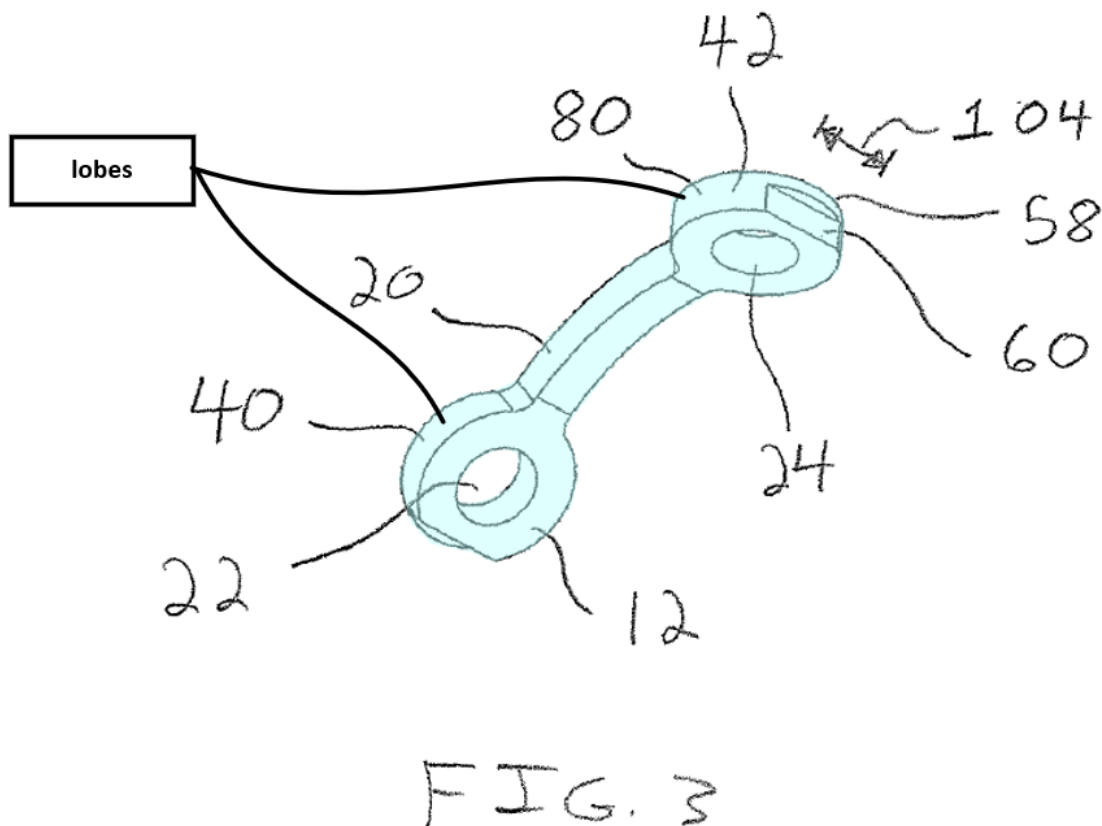
The '831 Patent explains that “[t]he manipulators 17, 19 are connected to the bone plate 12 and squeezed together . . . which bends the bone plate 12 to the flexed configuration.” Ex.1001, 4:9–15. The manipulators therefore serve as instrument members by which a surgeon flexes/deforms, positions, and fixes the bone plate during the surgical procedure.

Consistent with the '831 Patent specification, a tubular member used to bend a bone plate is a manipulator. Ex.1002 ¶¶26–27.

C. “lobes”

Claims 2, 4, 7, and 16 recite the bone plate having “lobes.”

The '831 Patent describes “bone anchor receiving portions [of the bone plate] . . . as lobes 40, 42, which include the through bores 22, 24.” Ex.1001, 4:43–45. Lobes 40, 42 are seen on the bone plate 12 (teal) in annotated Figure 3, reproduced below.



As seen above, lobes 40, 42 are rounded, enlarged regions of the bone plate relative to intermediate portion 20 and define through bores 22, 24.

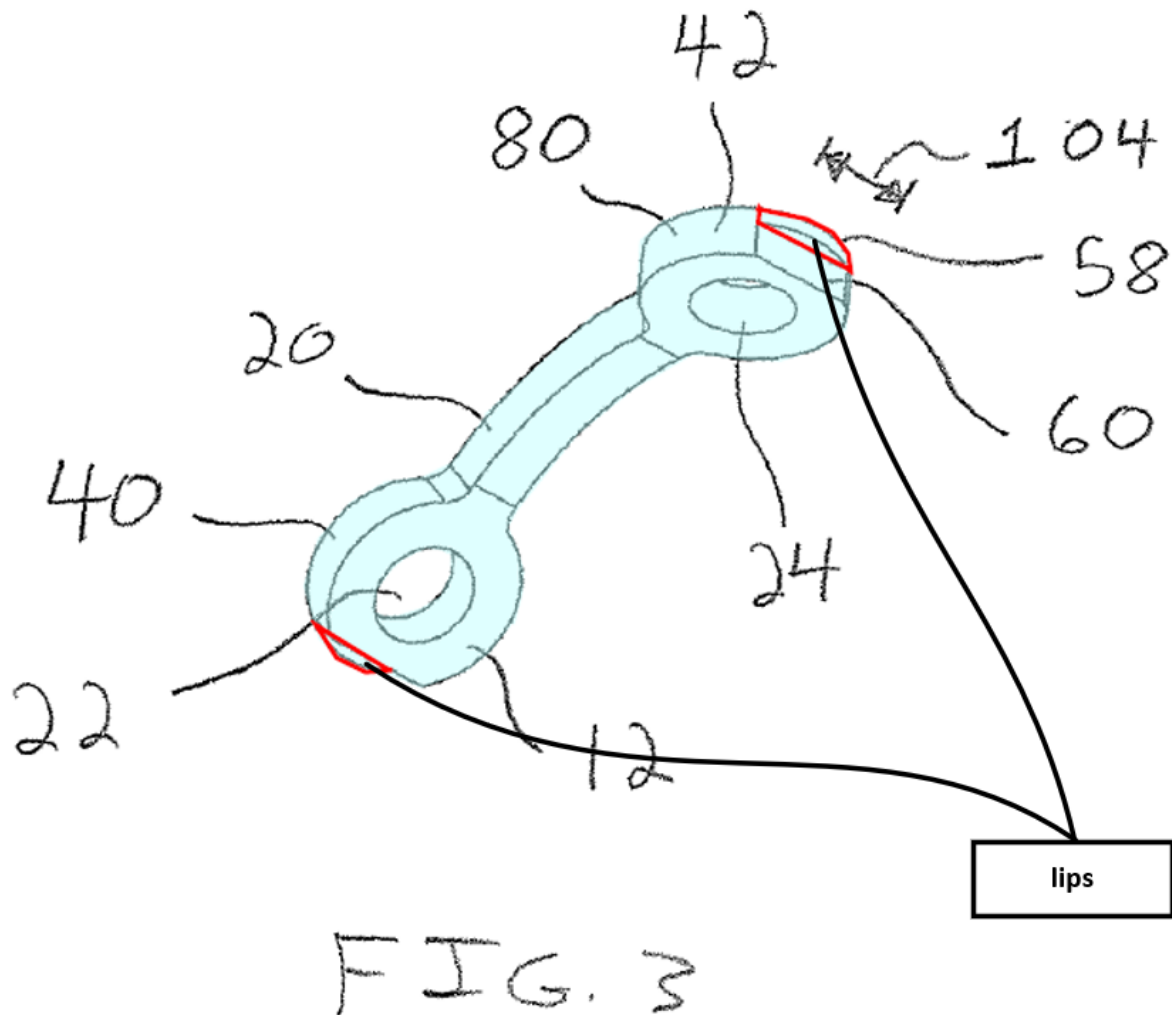
Consistent with the '831 Patent specification, a rounded portion of a bone plate, such as either of lobes 40, 42, defining a bone anchor receiving portion that is

enlarged relative to an intermediate portion connecting adjacent bone anchor receiving portions is a lobe. Ex.1002 ¶¶29–30.

D. “lips”

Claim 1 recites that “the bone anchor receiving portions of the bone plate include lips.”

The ’831 Patent describes the bone anchor receiving portions as “including a notched profile 56 with a lip 58.” Ex.1001, 5:29–30. Lip 58 (outlined in red) is shown in annotated Figure 3 below.



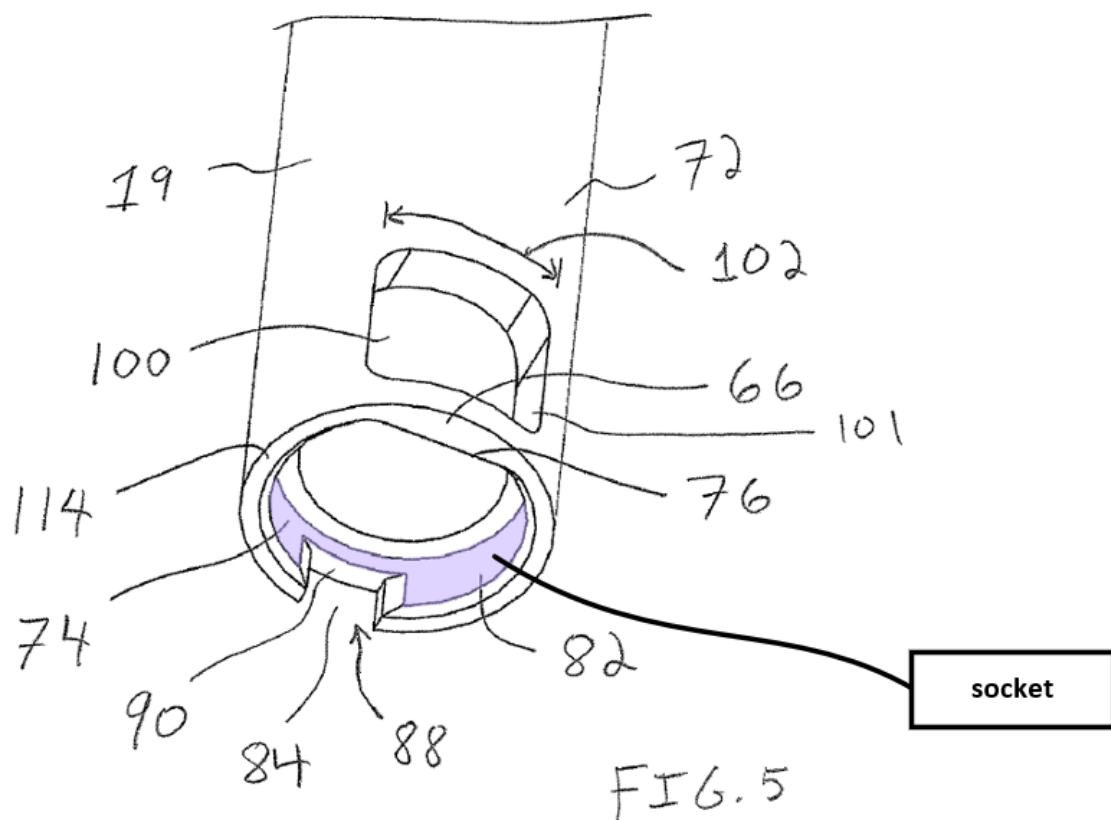
As seen above, lip 58 is a protrusion defined by a stepped profile on the bone anchor receiving portion.

Consistent with the '831 Patent specification, a protrusion defined by a stepped profile is a lip. Ex.1002 ¶¶32–33.

E. “sockets”

Claims 2, 4, and 7 recite that distal ends of the manipulators “include sockets sized to receive the lobes” of the bone plate.

The '831 Patent does not use the word “socket” in its specification, but describes a distal lobe engaging portion 82 (purple) shown in annotated Figure 5 below.



The '831 Patent explains that “the lobe 42 has a rounded outer surface 80 that fits within a rounded inner surface 82 of the lobe engaging portion 72 of the manipulator

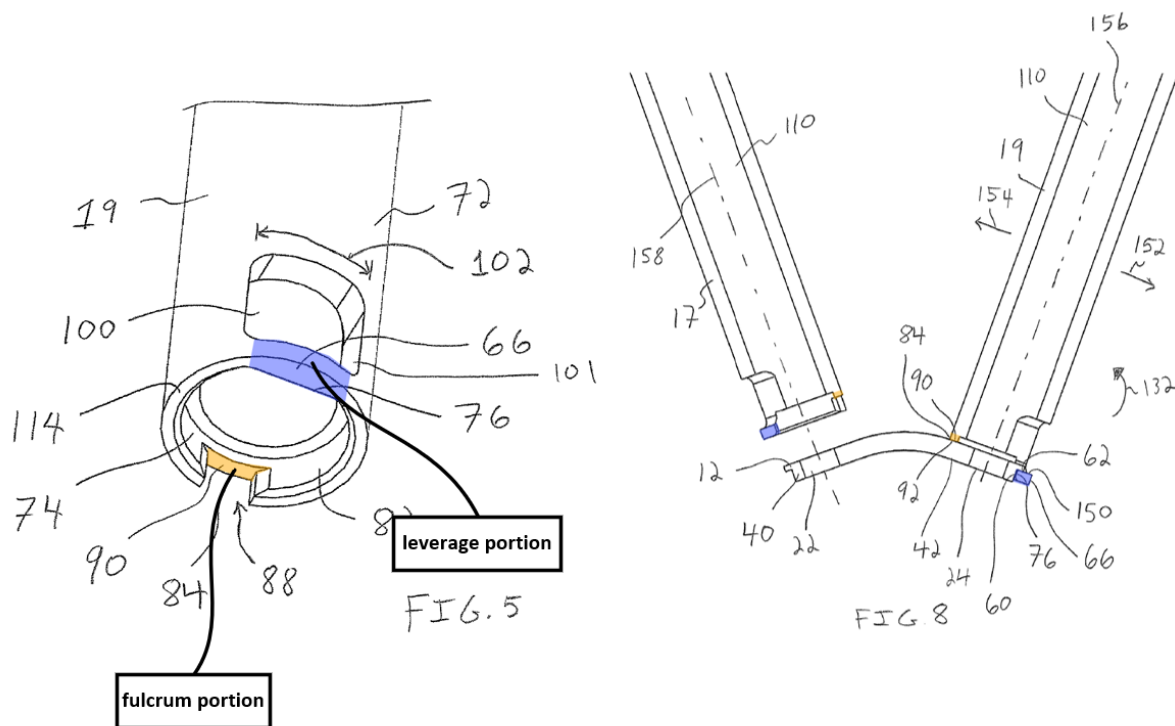
19” and is “sized to fit within openings 74 of the manipulators 17, 19.” Ex.1001, 5:38–43.

Consistent with the ’831 Patent specification, the inner surface of a lobe engaging portion of a manipulator is a socket. Ex.1002 ¶¶35–36.

F. “fulcrum portion” and “leverage portion”

Claim 3 recites that “each of the manipulators includes a fulcrum portion and a leverage portion.”

The ’831 Patent describes a fulcrum 88, which corresponds to the “fulcrum portion” recited in the claims, and a lip engaging portion 66, which corresponds to the “leverage portion” recited in the claims. The fulcrum portion (fulcrum 88—orange) and leverage portion (lip engaging portion 66—blue) are shown in annotated Figures 5 and 8 below.



The '831 Patent explains that “[t]he manipulator 19 has a fulcrum 88 for engaging the bone plate 12 as the manipulator 19 is pivoted toward the manipulator 17 to bend the bone plate 12.” Ex.1001, 5:50–53. “The fulcrum 88 includes a surface 90 that rests upon an upper surface 92 of the bone plate 12.” *Id.* at 5:53–55. The manipulator’s lip engaging portion 66 bears against the lip lower surface 62 of lobe 42, on the opposite side of the plate from fulcrum surface 90, so that “pivoting the manipulators 17, 19 . . . tends to pull upwardly on the lip 58 and pushes downwardly on the upper surface 92 of the bone plate 12 which straightens out the bone plate intermediate portion 20.” *Id.* at 6:3–15. Lip engaging portion 66 is the force-applying structure that works opposite fulcrum 88 to bend the plate.

Consistent with the '831 Patent specification, the portion of the manipulator that rests on the upper surface of the bone anchor receiving portion, such as fulcrum 88, is a “fulcrum portion” and the portion of the manipulator that engages a lower surface of the bone anchor receiving portion, such as lip engaging portion 66, is a “leverage portion.” Ex.1002 ¶¶38–40.

IV. ASSERTED REFERENCES

A. Hartdegen

Hartdegen is prior art to the '831 Patent at least under 35 U.S.C. §§ 102(a)(2) and 102(d). Hartdegen published as U.S. Patent Application Publication No. 2017/0196604 on July 13, 2017, from U.S. Application No. 15/324,393, which was filed January 6, 2017, as the U.S. national-stage application of PCT/US2015/039551, filed July 8, 2015. Hartdegen claims priority to U.S. Provisional Application No. 62/022,811, filed July 10, 2014. *See* Exs. 1005–1007. The '831 Patent, by contrast, claims priority to U.S. Provisional Application No. 62/127,609, filed March 3, 2015. *See* Ex.1001. Thus, Hartdegen’s effective filing date (July 10, 2014) predates the earliest possible effective filing date of the '831 Patent (March 3, 2015).

The Hartdegen provisional lists common inventors for the PCT application and the national-stage filing. *See* Exs. 1005–1007. Hartdegen identifies U.S.

Provisional Application No. 62/022,811, filed July 10, 2014, as its priority application, and the later PCT and U.S. national-stage filings were made within the applicable priority chain. *Id.* To the extent Patent Owner disputes Hartdegen's prior-art status, Petitioner's supporting evidence demonstrates that the disclosures relied upon in Hartdegen are described in the Hartdegen provisional.

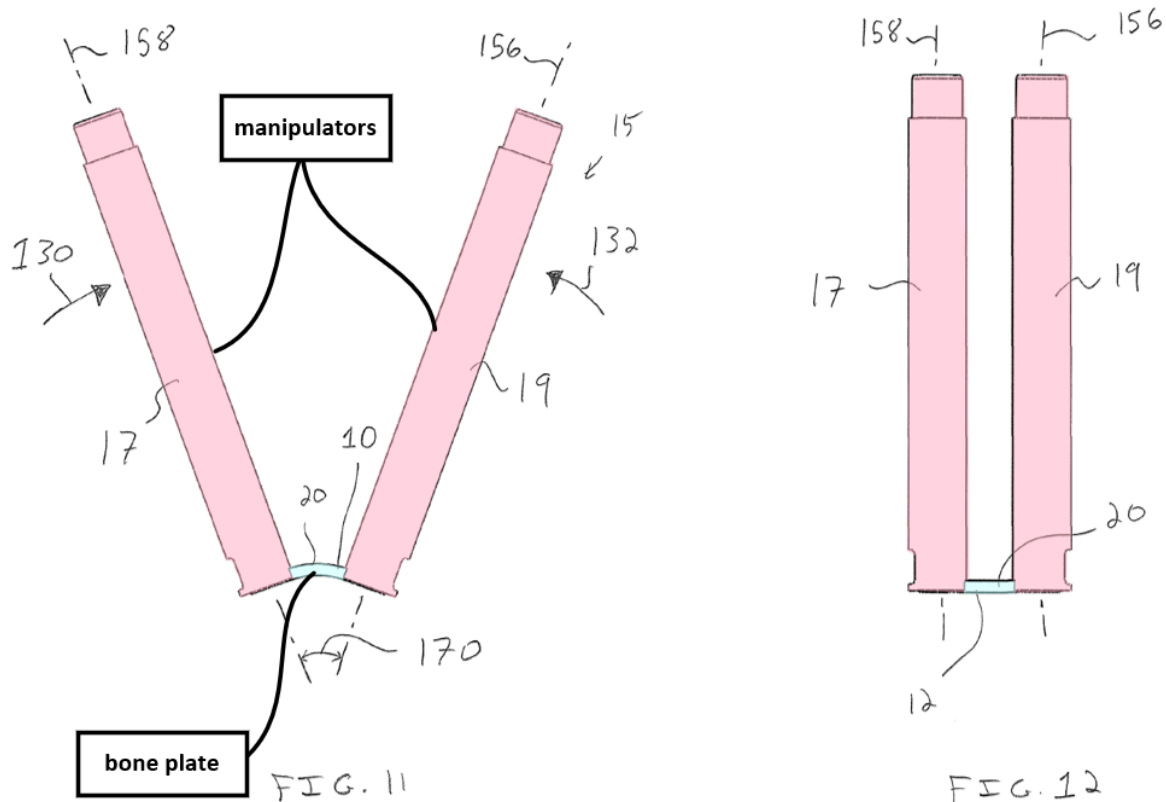
The Hartdegen provisional (Ex.1007) provides support for at least one of the claims from the Hartdegen publication (Ex.1005). For example, the Hartdegen provisional (Ex.1007) includes a claim (claim 1 on page 17) that is almost identical to claim 1 of the Hartdegen publication (Ex.1005). The provisional provides further support for published claim 1 as indicated in the table below. Ex.1002 ¶¶41–45.

Published Claim	Provisional Support
1. An assembly for delivering an implant to a surgical site for osteosynthesis comprising:	<i>See, e.g.</i> , Ex.1007, 3–5, 9–11
an implant having a first configuration when it is releasably attached to a delivery instrument and a second configuration when it is not attached to the delivery instrument,	<i>See, e.g.</i> , Ex.1007, 3–5, 9–11, FIG. 4 (first configuration), FIGS. 8 and 9 (second configuration)
the implant or a portion thereof being comprised of a material that allows the implant to have multiple configurations,	<i>See, e.g.</i> , Ex.1007, 3–4, 10–11

the implant having two or more than two means for fixation to a bone and	<i>See, e.g., Ex.1007, 10–11</i>
having means for engaging the delivery instrument, or the delivery instrument having means for engaging the implant, or both the implant and delivery instrument having means for engaging one another,	<i>See, e.g., Ex.1007, 10–11</i>
wherein the means for engaging do not impede the placement of the implant onto the bone.	<i>See, e.g., Ex.1007, 9</i>

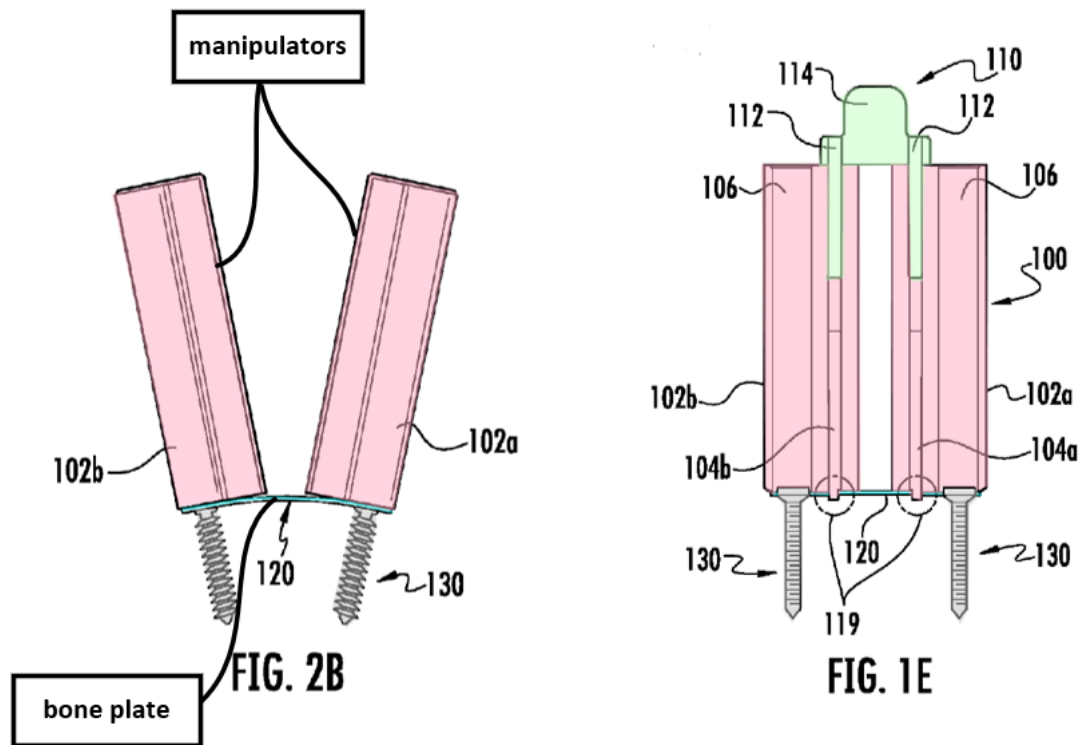
The relied-upon Hartdegen disclosures are supported nearly verbatim by the Hartdegen provisional. *Compare, e.g., Ex.1005 ¶111* (“the inserter 100 has two tube members 102a and 102b that allow the bone to be prepared through the internal diameters 106 . . . The two independent tubes are held in relative position to each other by clip 110”) *with Ex.1007, 9* (same disclosure in nearly identical language). The same is true of the disclosures relied upon at Exhibit 1005 paragraphs 7, 110, 112–117, and 125–126, each of which is supported by the corresponding pages of Exhibit 1007 (pages. 3–4, 9–14). Dr. Farber confirms that a POSA reviewing the Hartdegen provisional would understand it to disclose, in the manner required by 35 U.S.C. § 112(a), each of the foregoing teachings relied upon in this Petition. Ex.1002 ¶¶41–45.

The system disclosed in the '831 Patent (*i.e.*, a multi-configuration bone implant held by instrumentation during fixation to bones and then released to apply compression to the bones) was already disclosed by Hartdegen. Ex.1002 ¶46. This concept is illustrated below in annotated Figs. 11–12 of the '831 Patent.



The same concept is illustrated below in Figures 1E and 2B of Hartdegen.⁴

⁴ The cited figures from Ex.1005 and Ex.1007 are materially identical. *Compare* Ex.1005, Figures 1–31 *with* Ex.1007, Figures 1–31. Unless otherwise noted, citations or references in this Petition to an Ex.1005 figure number apply equally to the same-numbered figure in Ex.1007. The provisional’s written description likewise extends through the disclosure corresponding to Figure 31 using materially identical language. *See, e.g.*, Ex.1005 ¶¶7, 110–117, 125–126;



Hartdegen discloses an osteosynthesis system including a bone plate, bone screws, and an inserter having two tube members that releasably hold the implant in a first/deformed configuration while bone screws are advanced through the tube members and into the bone plate. After the bone plate is fastened to the bone and released from the inserter, the bone plate assumes another configuration that applies compression. Hartdegen further discloses a clip that fixes the tube members relative to one another, as well as inserter/plate engagement features for manipulating and maintaining the plate in the first/deformed configuration. Ex.1005 ¶¶111–112;

Ex.1007, 3–4, 9–14 (same disclosures in nearly identical language).

Ex.1007, 9–10; Ex.1002 ¶47.

However, to the extent that Patent Owner may argue that any limitation is missing from any one embodiment, Hartdegen expressly teaches “[t]he embodiments described herein may be used in connection with any type of inserter or fixation device, including but not limited to various bone staples, bone plates, etc. that have more than one implant configuration where the insertion device does not interfere with the final placement of the implant.” Ex.1005 ¶110; Ex.1007, 9. Dr. Farber confirms that a POSA reviewing Hartdegen’s disclosure would understand that the individual features and embodiments described throughout Hartdegen are interchangeable and may be combined with one another, consistent with Hartdegen’s own statement that its embodiments are not mutually exclusive. Ex.1002 ¶¶48–49.

B. Orbay

Orbay qualifies as prior art under at least 35 U.S.C. § 102(a)(1). Orbay is directed to a formable bone-plate system for reconstructive bone surgery that includes a bone plate having screw-receiving nodes separated by deformable internodes, together with manipulator instruments (clamps) configured to engage those nodes and bend or contour the plate before, during, or after fixation to bone. Ex.1008 ¶7. Orbay further teaches sockets complementary to node engagement sections. *Id.* ¶¶66–67. Orbay also discloses drill guide holes through the clamp for guiding drilling into bone for later screw placement, reinforcing that its

clamping/manipulator structures are used in connection with the screw-receiving plate portions. *Id.* Accordingly, Orbay teaches devices and steps similar to those in the '831 Patent. Ex.1002 ¶50.

C. Mai

Mai qualifies as prior art under at least 35 U.S.C. § 102(a)(1). Mai is directed to a “clip and osteosynthesis plate with dynamic compression and self-retention” made of a thermoelastic martensitic alloy (*e.g.*, a nickel-titanium or nickel-niobium shape-memory alloy) whose transformation temperatures are selected so that the device “take[s] a rectilinear shape at a temperature below the martensitic transformation temperature” and “an undulated shape at a temperature above the austenitic transformation temperature.” Ex.1009, Abstract. Mai explains that a surgeon brings the device to a temperature below its martensitic transformation temperature to render it straight for implantation, after which the warmth of the body, which exceeds the austenitic transformation temperature, causes the device to assume its final, compression-generating shape. Ex.1009, 4:10–30; Ex.1002 ¶53.

Mai further explains that the same transformation can be reversed on demand by chilling the device, stating that “it suffices to cool the clip to a temperature below the martensitic transformation temperature . . . by any suitable means” to return it to its rectilinear, low-profile configuration. Ex.1009, 5:24–29; Ex.1002 ¶54.

D. Analogous Art

Hartdegen, Orbay, and Mai are each analogous art to the challenged claims of the '831 Patent. Ex.1002 ¶¶63–64. All three references are in the same field of endeavor as the '831 Patent (*i.e.*, bone plates for orthopedic fixation). The '831 Patent discloses a bone-fixation device and method in which a bone-engaging implant is held in a first, temporary configuration for accurate placement adjacent to bone and thereafter is placed into or assumes a second configuration, different from the first, to secure adjacent bone portions. Ex.1001, Abstract, 1:13–15, 3:45–60; Ex.1002 ¶55.

Hartdegen discloses a bone fixation/osteosynthesis system including an implant maintained by an inserter in a first configuration for placement on bone, bone screws, and guide structures, the implant thereafter assuming a second configuration once released. Ex.1005, Abstract; Ex.1007, 2; Ex.1002 ¶56.

Orbay discloses a formable bone plate system including screw-receiving nodes and clamping/manipulation instruments that hold and bend the plate into a desired configuration before, during, or after fixing the plate to bones. Ex.1008, Abstract, ¶7; Ex.1002 ¶¶51–52, 57.

Mai discloses a clip/plate implant that is likewise held in a first, temporary (rectilinear) configuration for placement and thereafter assumes a second, compression-generating (undulated) configuration once implanted. Ex.1009,

Abstract; Ex.1002 ¶58.

Hartdegen, Orbay, and Mai are each also reasonably pertinent to the problem addressed by the '831 Patent: how to place and hold a bone-fixation implant in a temporary configuration suitable for accurate positioning relative to bone, and how to thereafter cause or permit that implant to assume a different configuration relative to the bone. Ex.1001, 1:13–15, 3:45–60; Ex.1002 ¶59.

Hartdegen and Orbay address this problem using instrumentation (*e.g.*, an inserter or clamps) that engages and holds the implant in its temporary configuration during positioning and fixation. Ex.1005 ¶¶111–112; Ex.1007, 9–10; Ex.1008 ¶7; Ex.1002 ¶60.

Mai addresses the same problem through the implant's own material properties, holding the implant in its temporary configuration by chilling it below its martensitic transformation temperature and permitting the transition to its final configuration upon warming. Ex.1009, Abstract; Ex.1002 ¶61.

That Hartdegen and Orbay achieve this result through instrumentation while Mai achieves it through material properties does not diminish Mai's pertinence, since the '831 Patent itself contemplates that the transition between configurations may be achieved either through instrumentation or through the implant's own material properties. Ex.1001, 3:49–52 (elastic deformation of the bone plate “resiliently biases” the bone screws and bones “together once the bone plate . . . has

been implanted”); Ex.1002 ¶62.

V. CHALLENGES⁵

A. Anticipation of Claims 9, 11–14, 17–21, and 23–28 in view of Hartdegen

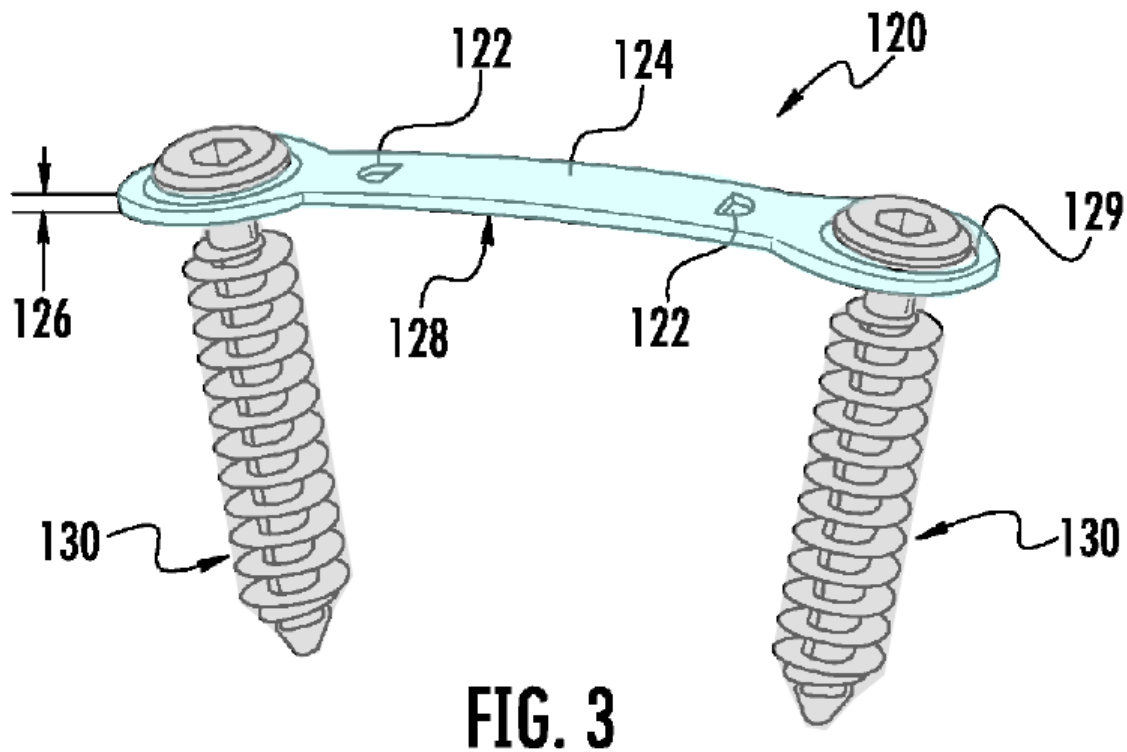
1. Claim 9

Claim 9 is directed to a surgical kit. Hartdegen discloses a surgical kit. Ex.1005, Abstract, ¶7; Ex.1007, 2, 3; Ex.1002 ¶¶65–66.

a. Limitation 9[a]

Hartdegen discloses “a plurality of bone anchors.” Hartdegen expressly discloses the use of bone screws 130 as fixation members for securing a bone plate to bone. Ex.1005 ¶¶111–115; Ex.1007, 9–11. An annotated version of Figure 3 is reproduced below.

⁵ When referencing arguments in another portion of the Petition, it is understood that those contentions are incorporated into the respective section.



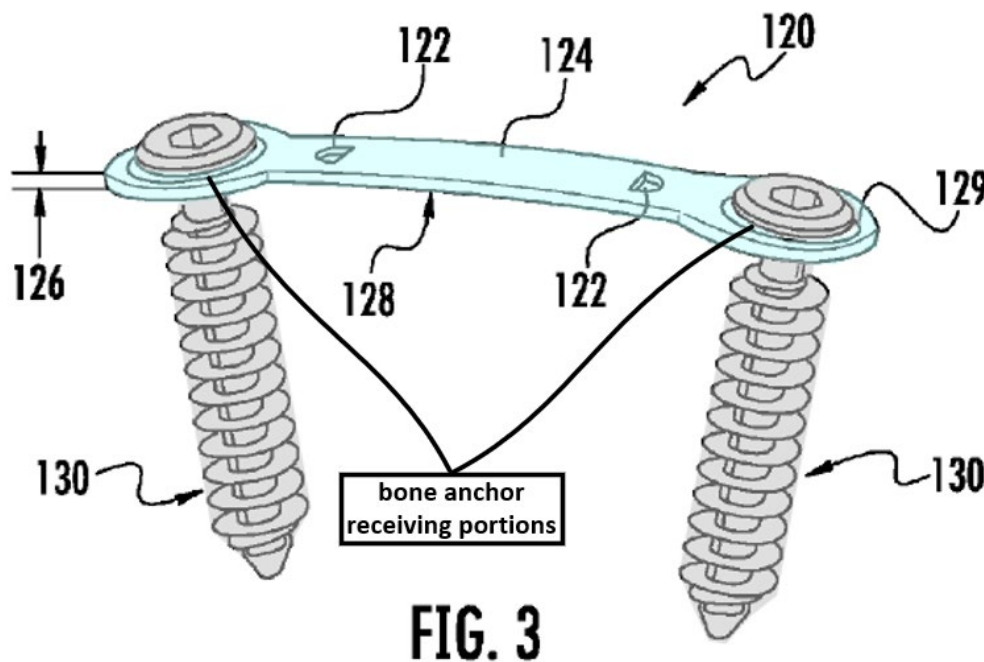
“FIG. 3 . . . shows an example of a bone attachment device 130, which in this case resembles a bone screw.” Ex.1005 ¶117; Ex.1007, 11. As seen above, Hartdegen discloses multiple screws 130 (gray).

This satisfies the claimed “bone anchors” under any reasonable construction of that term. As discussed above in the Claim Construction section, the ’831 Patent identifies bone anchors as bone screws that are driven into bone to secure the bone plate. Ex.1002 ¶67.

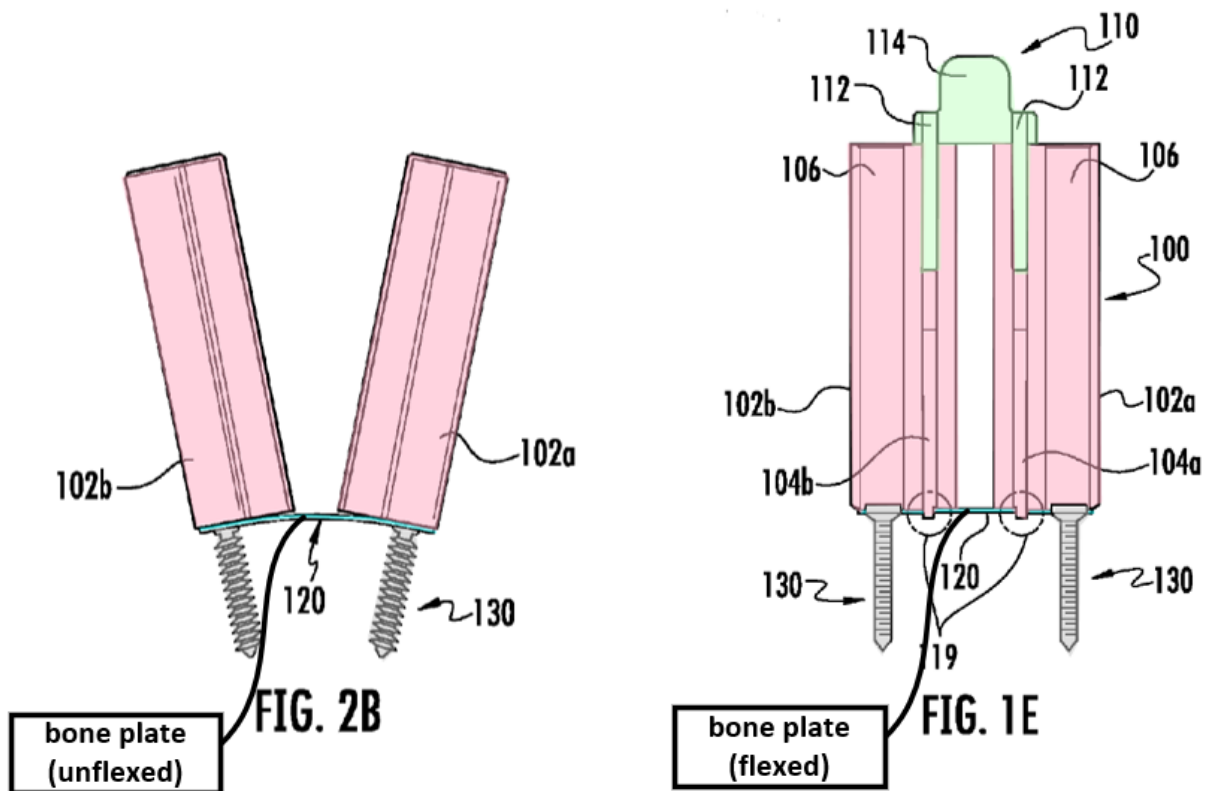
Accordingly, Hartdegen discloses limitation 9[a].

b. Limitation 9[b]

Hartdegen discloses “a bone plate having bone anchor receiving portions with through openings sized to receive the bone anchors.” As seen in annotated Figure 3 below, Hartdegen discloses that the implant 120 may be a bone plate (teal) that receives bone screws 130 through corresponding attachment features 129 (bone anchor receiving portions). Ex.1005 ¶¶111–117, Fig. 3; Ex.1007, 9–10; Ex.1002 ¶68.



Hartdegen further discloses “the bone plate having a flexed configuration and an unflexed configuration.” Annotated versions of Figures 1E and 2B are reproduced below.



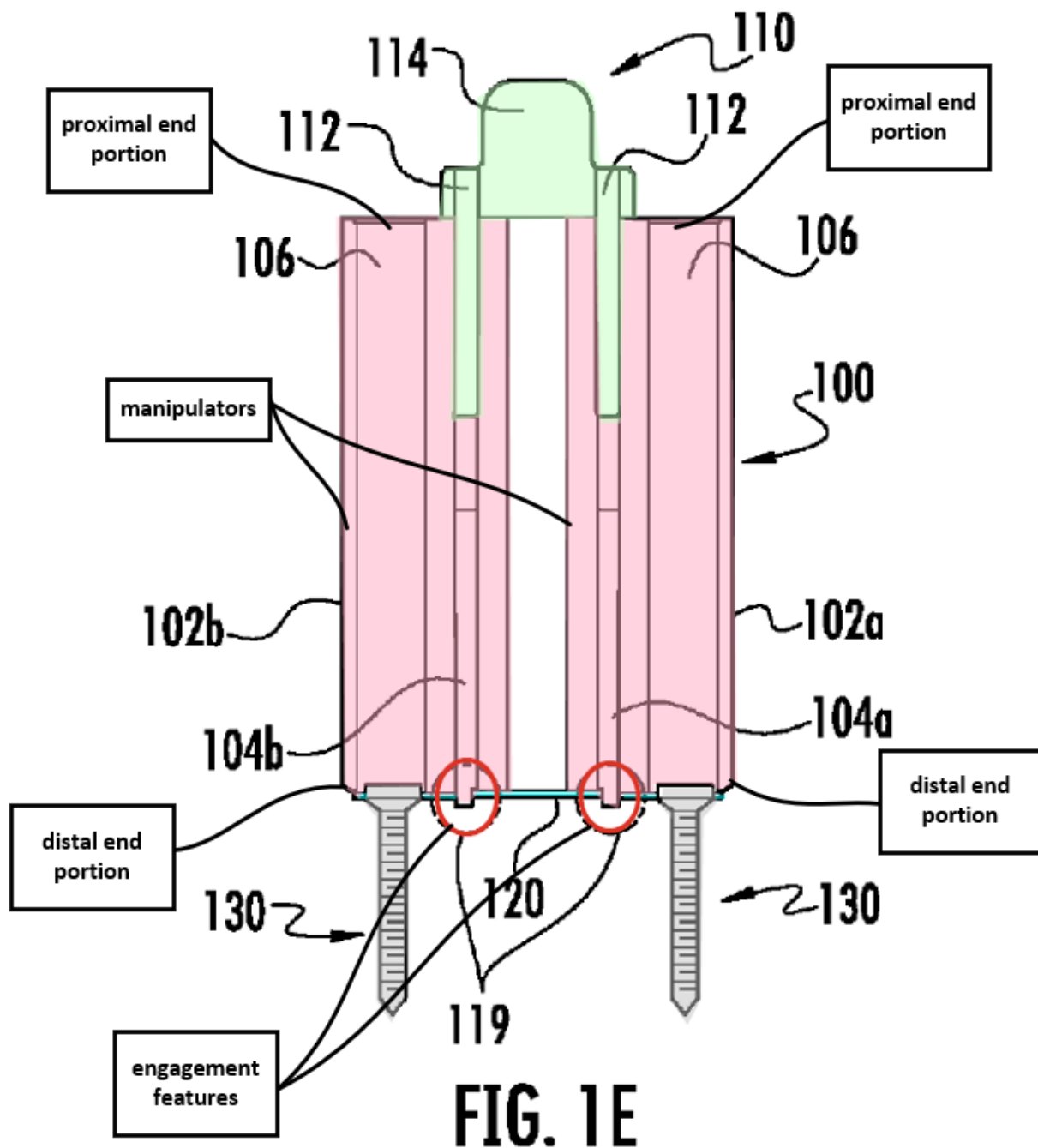
Hartdegen explains that “implant 120 is shown in a first configuration in FIGS. 1a, 1b, 1d and 1e.” Ex.1005 ¶111; Ex.1007, 10. “FIGS. 2a, 2b, 2c and 2d depict . . . [t]he implant 120 is shown in a second configuration . . . achieved either by the intrinsic mechanical properties of the material or secondary mechanical manipulation of one or more areas of the plate.” Ex.1005 ¶111; Ex.1007, 10; Ex.1002 ¶¶69–70.

The ’831 Patent describes its bone plate as having a similar initial/unflexed configuration that is shifted into a flexed configuration for insertion and that returns toward the unflexed configuration after implantation. *See* Ex.1001, 4:4–15.

Accordingly, Hartdegen discloses limitation 9[b].

c. Limitation 9[c]

Hartdegen discloses “a plurality of elongated manipulators having distal end portions configured to be connected to the bone anchor receiving portions of the bone plate and proximal end portions opposite the distal end portions.” Annotated Figure 1E of Hartdegen is shown below.



Hartdegen discloses an inserter 100 having two manipulators (pink—elongated tube members 102a and 102b), each extending from a proximal end accessible to a surgeon which are opposite to a distal end configured to be connected to the implant

120. Ex.1005 ¶¶111–112; Ex.1007, 9. Hartdegen further teaches the tube members (*i.e.*, inserter) “may be used for implant manipulation.” Ex.1005 ¶111; Ex.1007, 10; Ex.1002 ¶71.

In the embodiment shown in Hartdegen Figures 1–3, the manipulators are connected to the bridge portion of the plate with pins 104a, 104b to create engagement features 119 (circled in red above). Ex.1005 ¶111; Ex.1007, 10. “Implant 120 is temporarily connected to the tubes 102a and 102b by the engagement pins 104a and 104b.” Ex.1005 ¶111; Ex.1007, 10. Hartdegen expressly states that although the illustrated embodiment shows attachment at the bridge area of the implant, “[t]he means of attaching the plate to the inserter . . . could occur anywhere on or around the periphery of the plate.” Ex.1005 ¶111; Ex.1007, 9. A POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (*e.g.*, around the periphery of the bone anchor receiving portions). Ex.1002 ¶¶72–73.

Hartdegen’s inserter 100 satisfies “manipulators” under any reasonable construction of that term. As discussed above in the Claim Construction section, this is similar to the structure described in the ’831 Patent for its manipulators. Ex.1002 ¶74.

Accordingly, Hartdegen discloses limitation 9[c].

d. Limitation 9[d]

Hartdegen discloses “cannulas of the manipulators extending between the distal and proximal end portions thereof.”

An annotated version of Figure 1E from Hartdegen is reproduced below.

Hartdegen’s manipulators (pink) having cannulas (internal diameters 106—outlined in red).

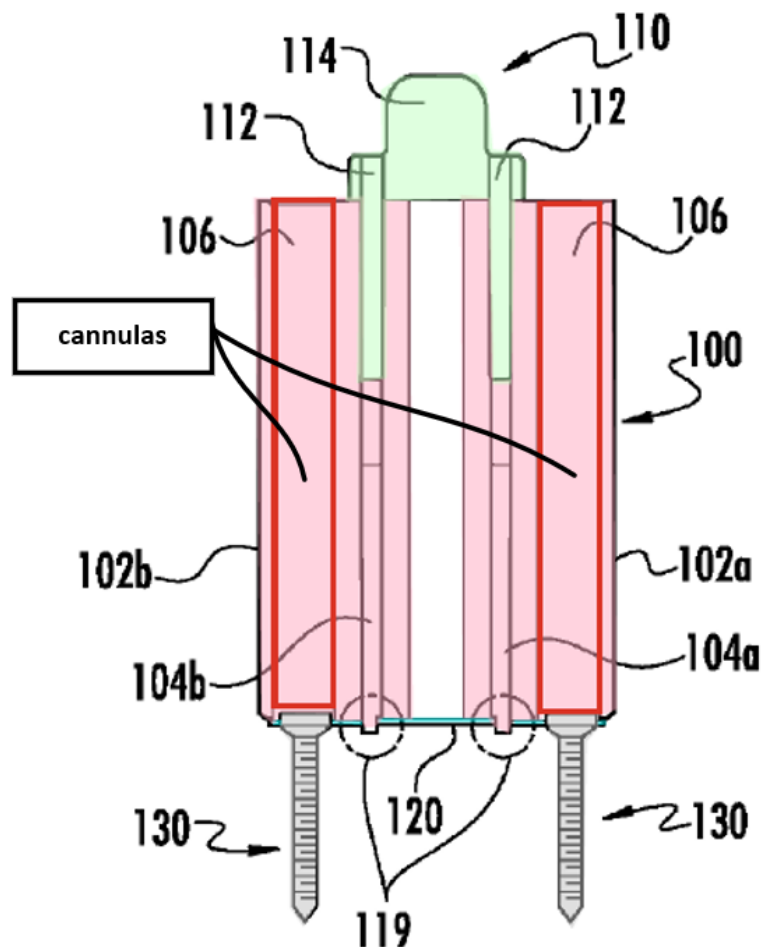


FIG. 1E

Hartdegen discloses that its “two tube members 102a and 102b . . . allow the bone to be prepared through the internal diameters 106,” and further explains that those tube members “serve as drill guides,” confirming that internal diameters 106 are cannulas extending through the elongated tube members. Ex.1005 ¶111; Ex.1007, 9; Ex.1002 ¶¶76–77.

Hartdegen also discloses its internal diameters 106 (cannulas) “being aligned with the through bores of the bone plate when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate, the cannulas being sized to permit the bone anchors to be advanced through the cannulas and into the through bores of the bone plate.” Hartdegen discloses, for example, that bone screws 130 “may be prepared and positioned through the internal diameter 106 while the inserter 100 was still attached to the implant 120.” Ex.1005 ¶111; Ex.1007, 9; Ex.1002 ¶78.

Thus, the internal diameters 106 are aligned with the screw-receiving portions of implant 120 and sized to permit screws 130 therethrough. Ex.1002 ¶79.

Accordingly, Hartdegen discloses limitation 9[d].

e. Limitation 9[e]

Hartdegen discloses “a restraint having portions configured to be connected to the manipulators.”

Hartdegen’s restraint is shown in annotated Figure 1E below.

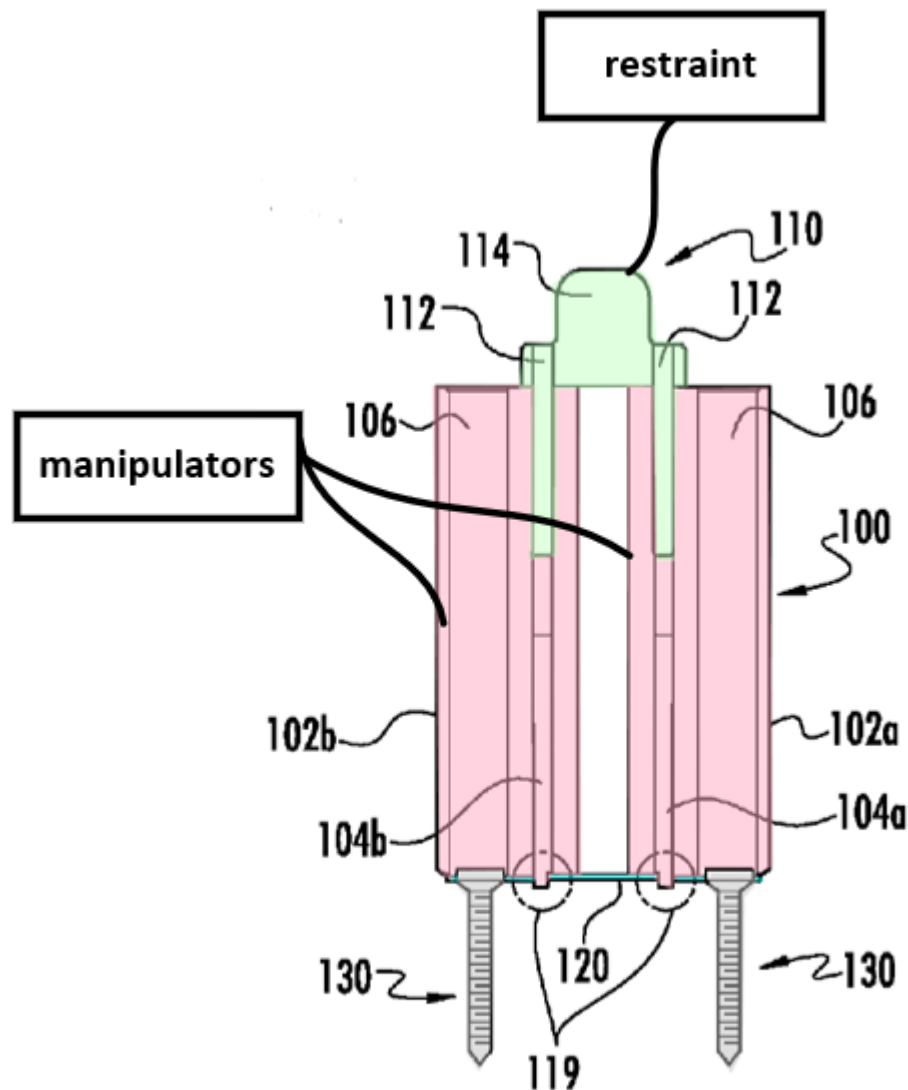


FIG. 1E

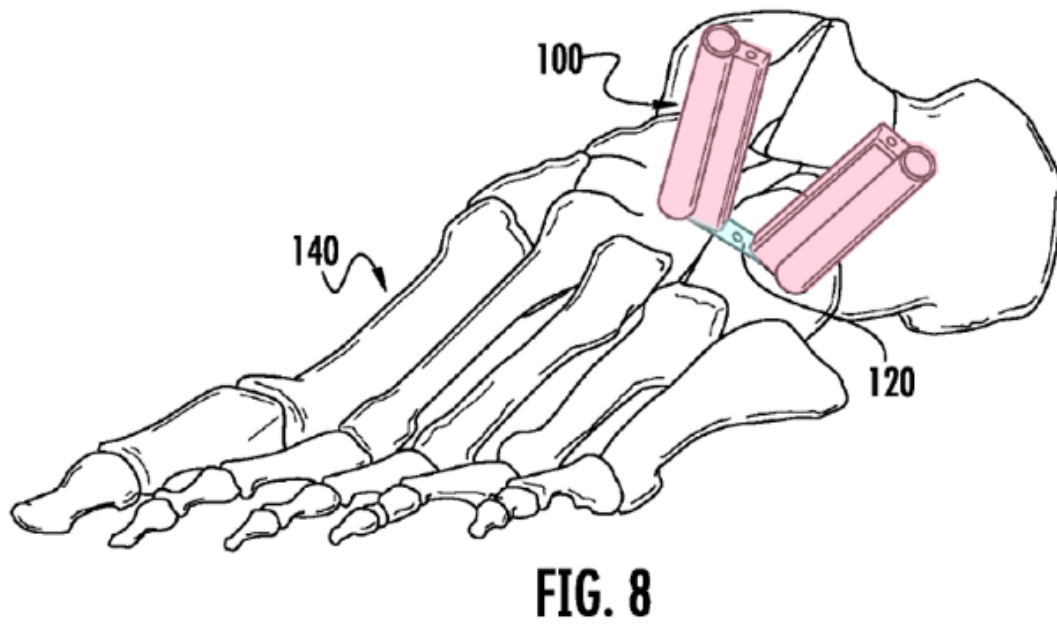
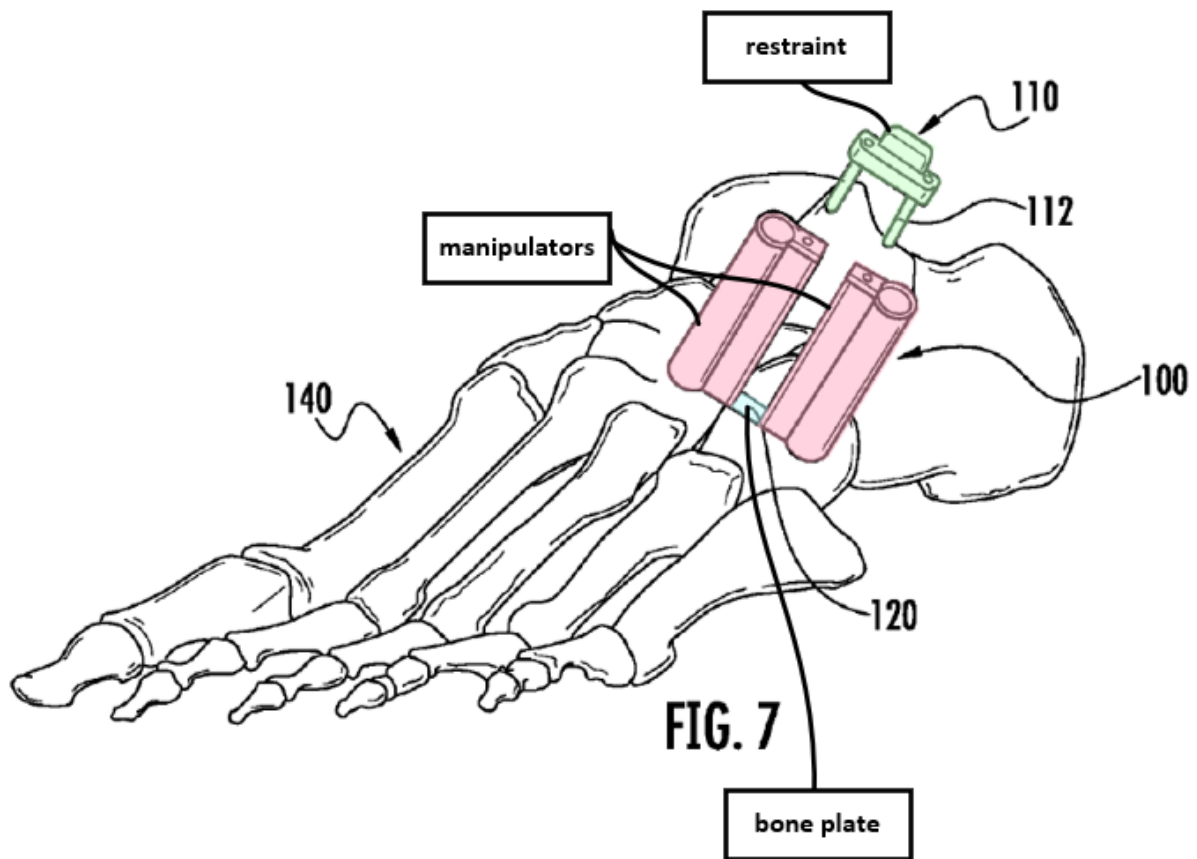
Hartdegen's clip 110 (green) is a restraint. Ex.1005 ¶¶111–116; Ex.1007, 9–11.

Hartdegen explains that its “[c]lip has . . . two engagement pins 112” that “engage the tubes 102a and 102b to hold them in relative position to each other thereby maintaining the implant 120 in its first configuration.” Ex.1005 ¶111; Ex.1007, 9;

Ex.1002 ¶81.

This is precisely the role of the claimed restraint: it has portions for connecting to the manipulators and fixes the manipulators relative to one another so that the bone plate remains in the desired flexed or first configuration during implantation.

Ex.1002 ¶82. Operation of Hartdegen's clip 110 is illustrated in annotated Figures 7 and 8 below.



As seen above, removal of clip 110 after implantation (Figure 7) permits implant 120 to adapt to a second configuration (Figure 8). Ex.1005 ¶¶114–115, Figs. 4–8; Ex.1007, 9–10, Figs. 4–8; Ex.1002 ¶83.

Accordingly, Hartdegen discloses limitation 9[e].

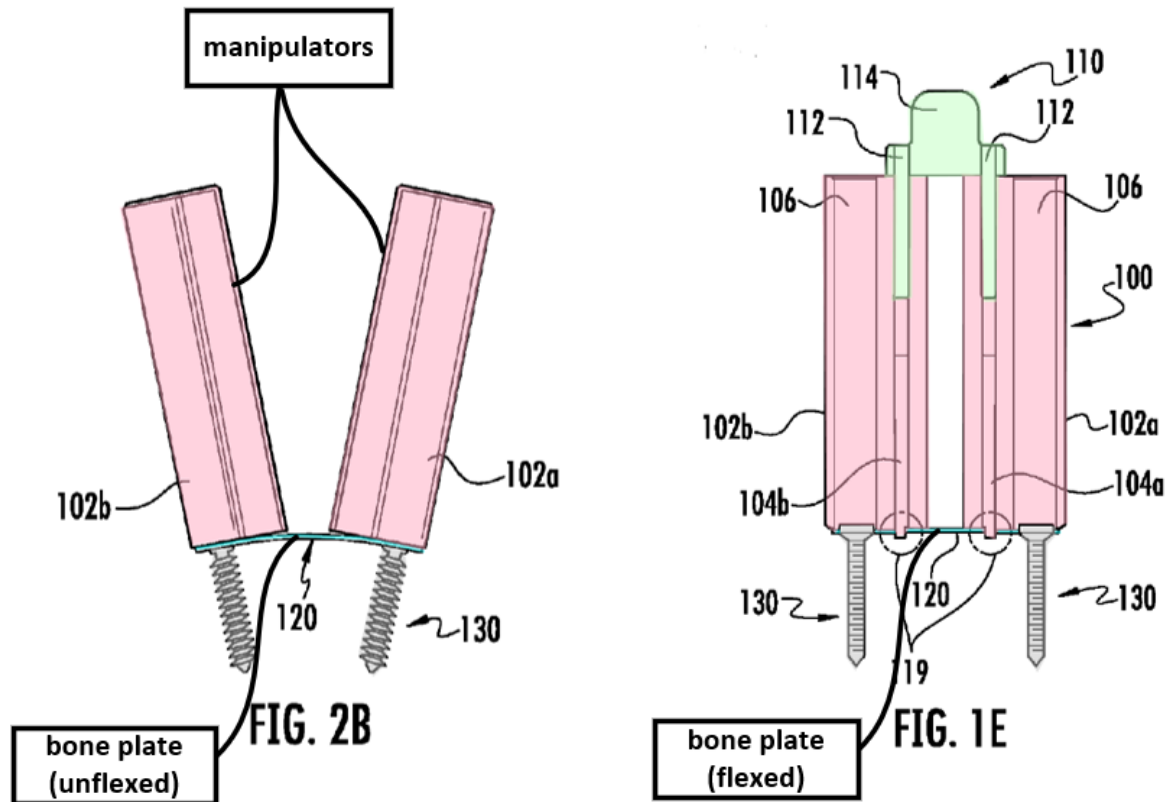
2. Claim 11

Hartdegen discloses “[a] method of stabilizing a plurality of bones.” Hartdegen discloses “a fixation system for bones of all types” comprising “an inserter and implant,” and that such systems are used in “osteosynthesis (bone fusion), wherein the implant bridges a fracture generating compression [] across the bone members.” Ex.1005 ¶2; Ex.1007, 1; Ex.1002 ¶84.

a. Limitation 11[a]

Hartdegen discloses “pivoting manipulators connected to a bone plate to flex the bone plate.”

As explained above regarding limitation 9[b], and seen in annotated Figures 1E and 2B below, Hartdegen’s implant 120 (bone plate) has a flexed (Figure 1E) and unflexed (Figure 2B) condition.



Hartdegen explains that the “two independent tubes 102a and 102b are individually connected to the implant 120 by engagement pins 104a and 104b.” Ex.1005 ¶111; Ex.1007, 9. A user pivots tube members 102a and 102b (manipulators) from an outwardly angled orientation (Figure 2B) to a substantially parallel orientation (Figure 1E), thereby flexing implant 120 from an unflexed configuration to a flexed configuration. Ex.1005 ¶¶111–114; Ex.1007, 9–11; Ex.1002 ¶87.

Hartdegen explains that “[t]he present invention may have the inserter pre-assembled to the implant or affixed to the implant at the time of use.” Ex.1005 ¶6; Ex.1007, 3. A POSA would understand Hartdegen as disclosing pivoting its tubes

102a, 102b (manipulators) to flex the implant 120 (bone plate) at least when the assembly happens at the time of use. Ex.1002 ¶¶88–89.

Accordingly, Hartdegen discloses limitation 11[a].

b. Limitation 11[b]

Hartdegen discloses “positioning the flexed bone plate adjacent bones.”

As discussed above for limitation 11[a], Hartdegen’s implant 120 is maintained in a flexed configuration by inserter 100, including tube members 102a and 102b and clip 110. Ex.1005 ¶¶111–114; Ex.1007, 9–11. As shown below in annotated Figure 4, the inserter 100 is used to position the flexed implant 120 (bone plate–teal) adjacent to bones while the inserter remains engaged. Ex.1005 ¶¶111–114; Ex.1007, 9–11; Ex.1002 ¶91.

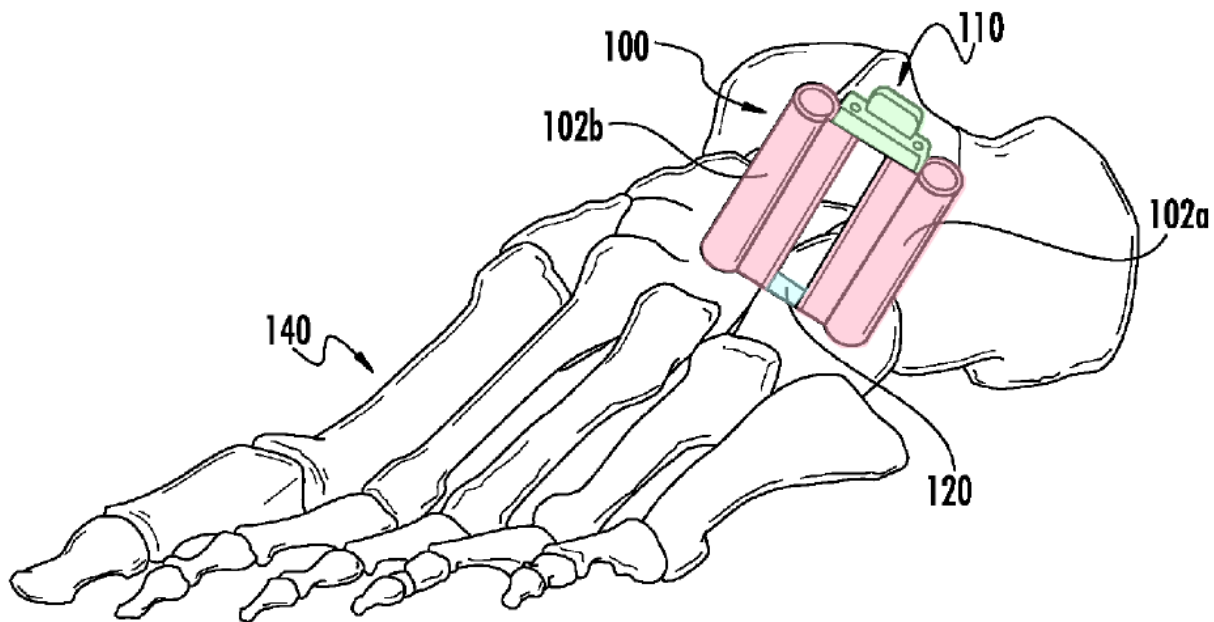


FIG. 4

Hartdegen explains, for example, that “FIG. 4 depicts one embodiment of the inserter 100 assembled to implant 120 on a foot 140” and shows the implant adjacent bones of the foot. Ex.1005 ¶114; Ex.1007, 10; Ex.1002 ¶92.

Accordingly, Hartdegen discloses limitation 11[b].

c. Limitation 11[c]

Hartdegen discloses “guiding bone anchors into through bores of the bone plate using the manipulators.”

As explained above regarding limitation 9[d], Hartdegen’s tube members 102a and 102b include internal diameters 106 that act as passages for drilling and guiding bone screws 130 into the openings of the bone plate. Ex.1005 ¶111;

Ex.1007, 9. Hartdegen explains that bone screws 130 (bone anchors) may be inserted into the implant 120 (bone plate) while it is attached to the tube members 102a, 102b (manipulators). Ex.1005 ¶111; Ex.1007, 9; Ex.1002 ¶94.

As seen above in annotated Figure 4 and discussed in connection with limitation 11[b], the inserter 100 is used to position the flexed implant 120 (bone plate—teal) adjacent to bones while the inserter remains engaged. Ex.1005 ¶¶111–114; Ex.1007, 9–11. Hartdegen explains that “FIGS. 5 and 6 depict one embodiment of the inserter 100 assembled to implant 120 on a foot 140 further showing preparation of the bone 140 with drill 150 through the internal diameter 106 to accept bone screws.” Ex.1005 ¶114; Ex.1007, 10. As shown below, Figures 5–6 of Hartdegen depict tube members 102a and 102b connected to the implant and clip 110 maintaining the relative position of the tube members while the bone is being prepared. Ex.1005 ¶¶111–115; Ex.1007, 9–11; Ex.1002 ¶95.

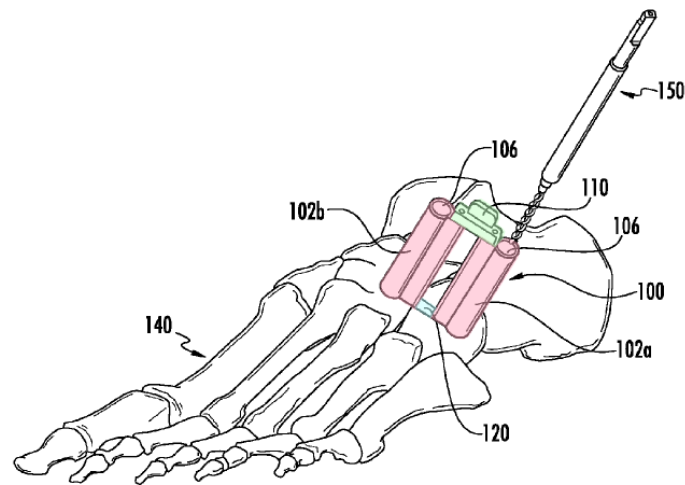


FIG. 5

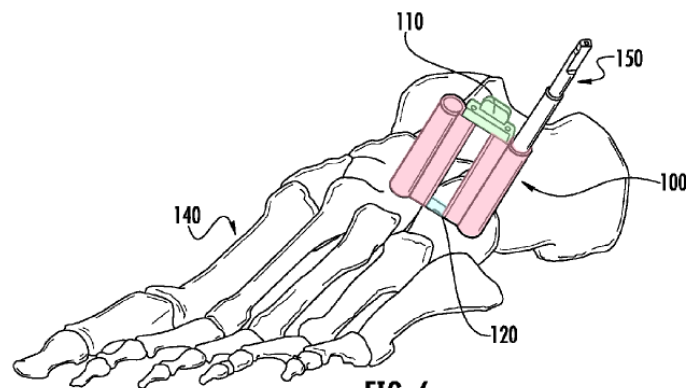


FIG. 6

Hartdegen explains that “[t]he bone screws 130 may be prepared and positioned through the internal diameter 106 while the inserter 100 was still attached to the implant 120.” Ex.1005 ¶113; Ex.1007, 10. Based on the disclosure discussed above, a POSA would have understood that Hartdegen discloses bone preparation and fixation after the implant has been positioned adjacent to the bone. Ex.1002 ¶96.

Accordingly, Hartdegen discloses limitation 11[c].

d. Limitation 11[d]

Hartdegen discloses “securing the flexed bone plate to the bones with the bone anchors.”

As discussed above regarding limitation 11[c], Hartdegen discloses bone preparation including “drilling to accept bone screws” when the implant 120 (bone plate) is in the flexed condition. Ex.1005 ¶114; Ex.1007, 10. Hartdegen explains that “bone screws 130 (not shown in FIG. 7 or 8) may . . . have been prepared and positioned while the inserter assembly was engaged with the implant.” Ex.1005 ¶115; Ex.1007, 11. An annotated Figure 9 showing screws 130 (bone anchors) securing the implant 120 (bone plate) to bone is provided below.

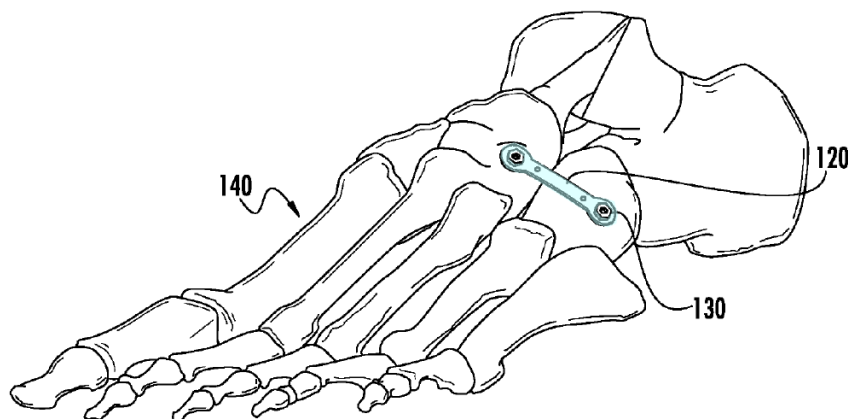


FIG. 9

“FIG. 9 shows implant 120 on bone 140 after removal of the inserter assembly 100 after the implant 120 is in its final position either before or after the implant achieves its second configuration.” Ex.1005 ¶115; Ex.1007, 11. This confirms that the screws are secured to the bone plate in its flexed condition, as the quoted portion of

Hartdegen above notes, and the implant is fixed in its final position and subsequently returns to its second configuration. Ex.1002 ¶¶98–100.

Accordingly, Hartdegen discloses limitation 11[d].

3. Claim 12

Claim 12 depends from claim 11 and recites “wherein guiding the bone anchors into the through bores of the bone plate using the manipulators includes advancing the bone anchors through cannulas of the manipulators and into the through bores of the bone plate.”

As explained above regarding limitation 9[d] (*see* §V.A.1.d), Hartdegen discloses cannulas for its manipulators, and discloses the guiding for the reasons stated above for limitations 11[c] and 11[d]. *See* §§V.A.2.c, V.A.2.d.

Hartdegen discloses, for example, that bone screws 130 (bone anchors) may be inserted into the implant 120 (bone plate) while it is attached to the tube members 102a, 102b (manipulators). Ex.1005 ¶113; Ex.1007, 10; Ex.1002 ¶¶102–103.

Accordingly, Hartdegen discloses claim 12.

4. Claim 13

Claim 13 depends from claim 11 and recites “wherein the manipulators are connected to end portions of the bone plate having the through bores therein; and pivoting the manipulators to flex the bone plate includes flexing an intermediate

portion of the bone plate between the end portions.”

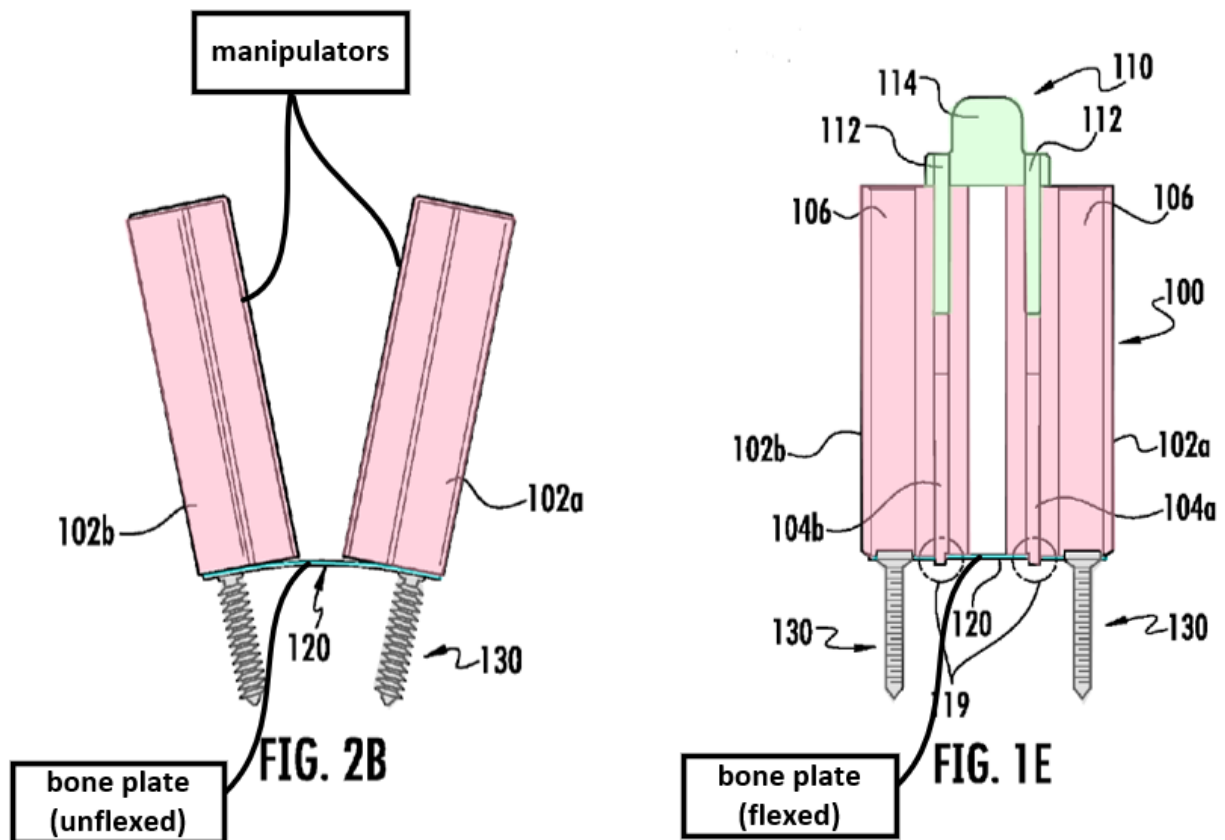
a. Limitation 13[a]

Hartdegen discloses “the manipulators are connected to end portions of the bone plate having the through bores therein,” for at least the reasons discussed above regarding limitation 9[c]. *See* §V.A.1.c; Ex.1002 ¶105.

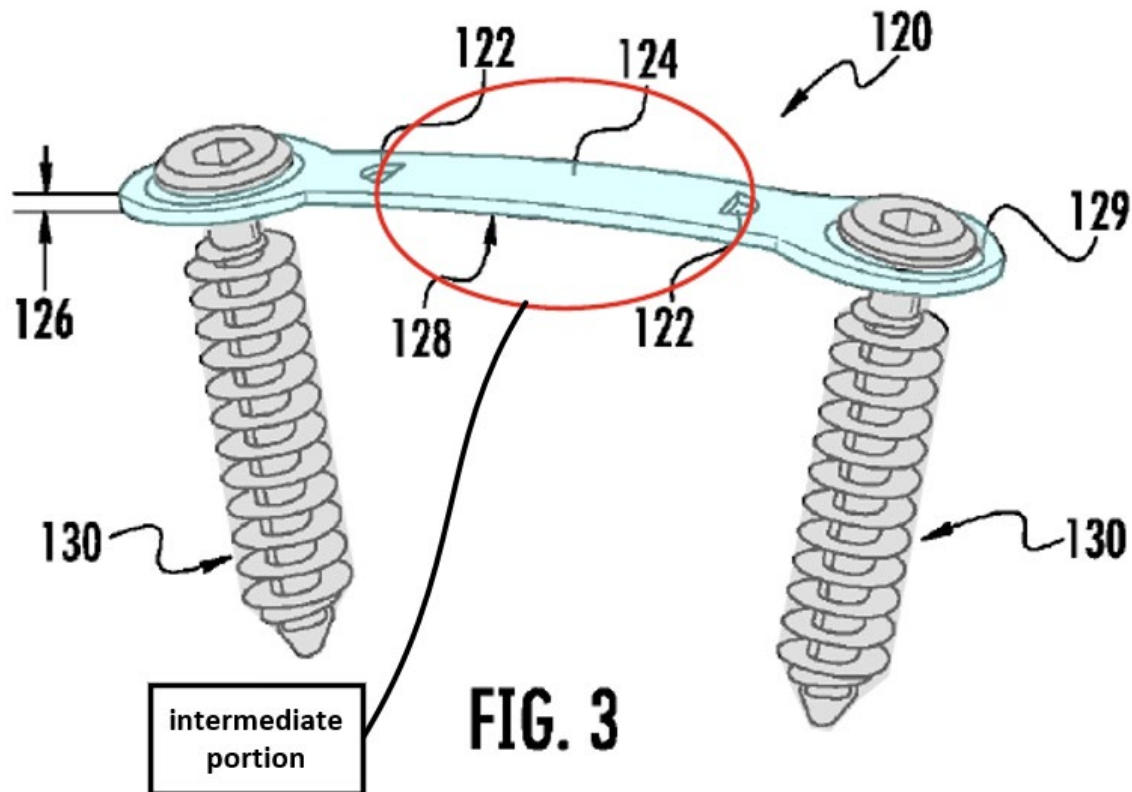
b. Limitation 13[b]

Hartdegen discloses that “pivoting the manipulators to flex the bone plate includes flexing an intermediate portion of the bone plate between the end portions.”

Hartdegen discloses flexed and unflexed conditions for its implant 120 (bone plate) as discussed above regarding limitation 9[b] (*see* §V.A.1.b) and flexing the bone plate by pivoting the manipulators for the reasons discussed regarding limitation 11[a] (*see* §V.A.2.a). Ex.1002 ¶¶106–107.

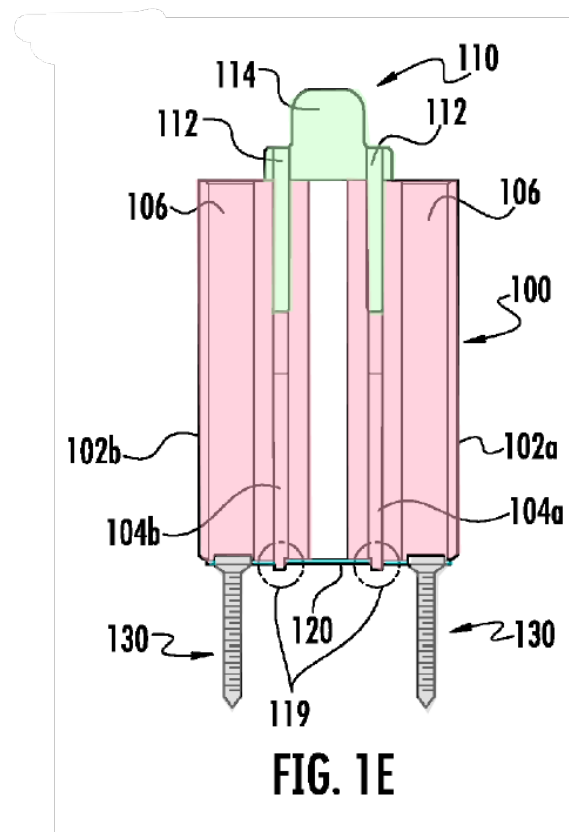


Hartdegen additionally explains that “FIG. 3 shows the implant 120 in a possible free-state or implanted-state of the device” and “shows the implant 120 having an arc or radius 128 while in its second configuration.” Ex.1005 ¶117; Ex.1007, 11. An annotated version of Figure 3 is provided below.



As seen above, the “arc or radius 128” is located at the bridge portion 124 (intermediate portion). The bridge portion 124 is curved in its free condition as shown in Figure 3.

Hartdegen further explains that when “the inserter 100 is assembled to the implant 120,” it “may . . . be flat,” as seen in annotated Figure 1E below. Ex.1005 ¶111; Ex.1007, 9.



Hartdegen therefore discloses flexing the intermediate portion in view of the manipulation of the implant 120 from the free state where the bridge portion 124 is curved (Figure 3) to the flexed state where the implant (including the bridge portion 124) is flat (Figure 1E). Ex.1002 ¶¶108–110.

Accordingly, Hartdegen discloses claim 13.

5. Claim 14

Claim 14 depends from claim 11 and recites “wherein pivoting the manipulators to flex the bone plate includes reconfiguring the bone plate from a bent configuration to a substantially flat configuration.”

These features are disclosed for the reasons set forth regarding claim 13. *See*

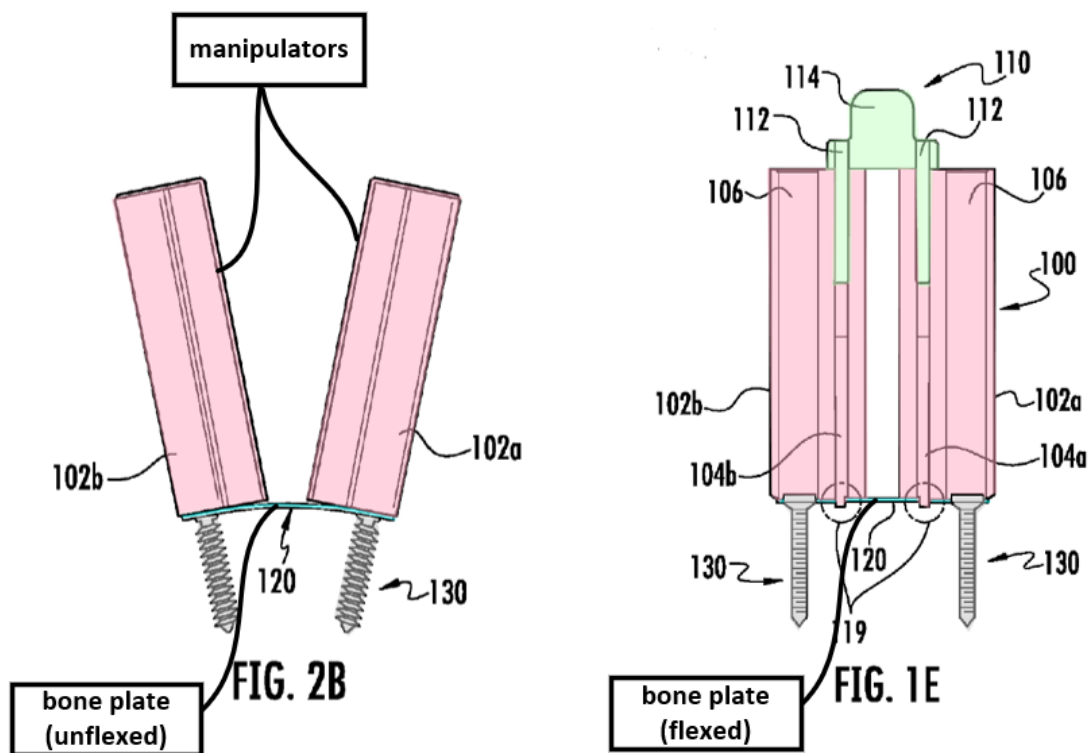
§V.A.4; Ex.1005 ¶¶111, 117; Ex.1007, 9, 11; Ex.1002 ¶112.

Accordingly, Hartdegen discloses claim 14.

6. Claim 17

Claim 17 depends from claim 11 and recites “wherein the manipulators are elongated and pivoting the manipulators to flex the bone plate includes pivoting the manipulators from a first orientation wherein the manipulators extend transverse to each other to a second orientation wherein the manipulators extend substantially parallel to each other.”

As can be seen below in annotated Figures 1E and 2B, Hartdegen discloses the first and second orientations.



As explained above regarding limitation 11[a] (*see* §V.A.2.a), a POSA would understand Hartdegen as disclosing pivoting its tubes 102a, 102b (manipulators) to flex the implant 120 (bone plate) at least when the assembly happens at the time of use. A user pivots tube members 102a and 102b (manipulators) from an outwardly angled orientation (first orientation—Figure 2B) to a substantially parallel orientation (second orientation—Figure 1E), thereby flexing the implant 120 from an unflexed configuration (Figure 2B) to a flexed configuration (Figure 1E). Ex.1005 ¶¶111–114; Ex.1007, 9–11; Ex.1002 ¶¶114–115.

Accordingly, Hartdegen discloses claim 17.

7. Claim 18

Claim 18 depends from claim 11 and recites “connecting a restraint to the manipulators to fix the manipulators relative to each other while positioning the flexed bone plate adjacent the bones and guiding the bone anchors into the through bores of the bone plate using the manipulator.”

Hartdegen discloses “connecting a restraint to the manipulators to fix the manipulators relative to each other” for the reasons discussed above regarding limitation 9[e]. *See* §V.A.1.e; Ex.1002 ¶117.

Hartdegen additionally discloses that the restraint is in place “while positioning the flexed bone plate adjacent the bones and guiding the bone anchors into the through bores of the bone plate using the manipulator” for the reasons

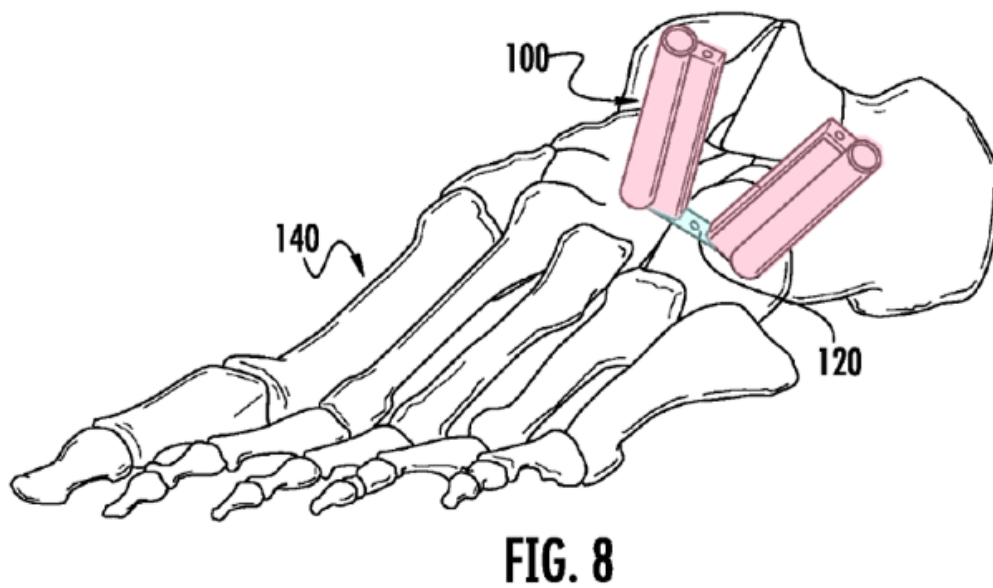
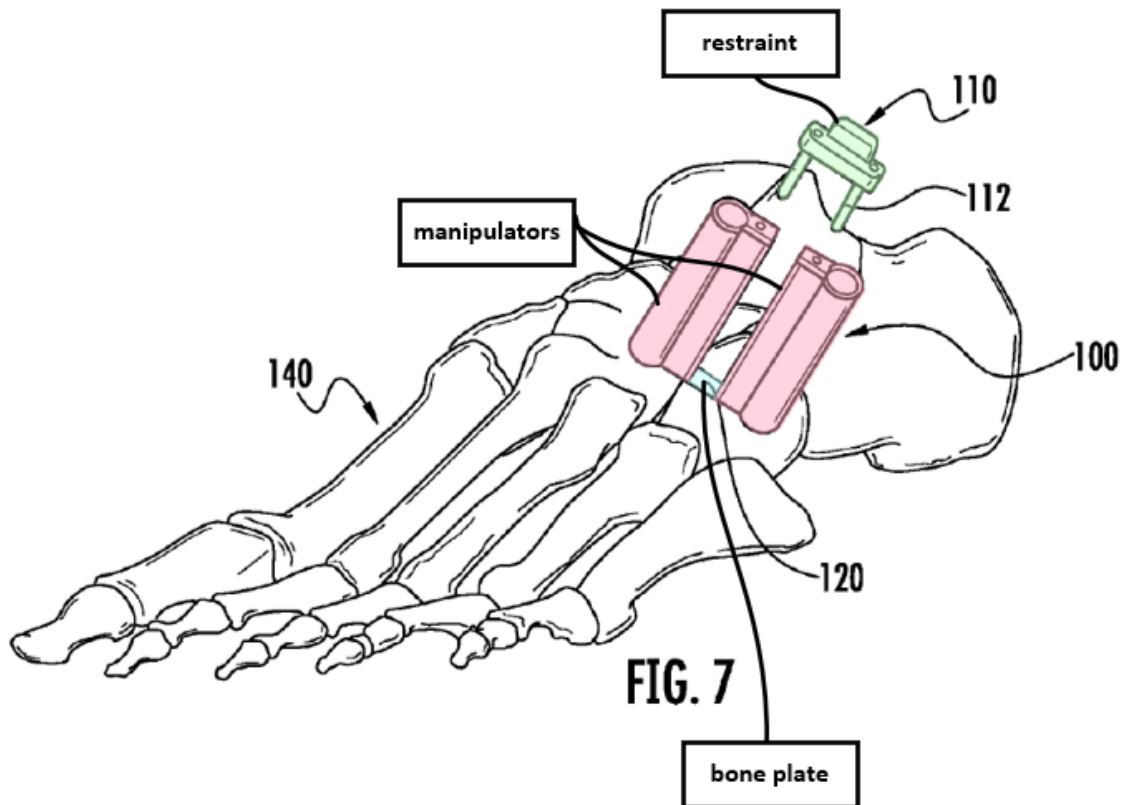
discussed above regarding limitations 11[b] and 11[c]. *See* §§V.A.2.b, V.A.2.c; Ex.1005 ¶¶111–115; Ex.1007, 9–11 (insertor 100 is used to position the flexed implant 120 adjacent to bones while the insertor remains engaged and tube members 102a and 102b remain connected to the implant and with clip 110 maintaining the relative position of the tube members while the bone is being prepared); Ex.1002 ¶118.

Accordingly, Hartdegen discloses claim 18.

8. Claim 19

Claim 19 depends from claim 18 and recites “disconnecting the restraint from the manipulators to permit the manipulators to move relative to each other and be disconnected from the bone plate.”

As discussed above regarding limitation 9[e], and seen in annotated Figures 7 and 8 below, removal of clip 110 (restraint–green) after implantation (Figure 7) permits implant 120 to adapt to a second configuration (Figure 8). Ex.1005 ¶¶114–115, Figs. 4–8; Ex.1007, 9–10, Figs. 4–8.



As seen above, Hartdegen discloses removing clip 110 (restraint–green) from inserter 100, as can be seen in Figures 7 and 8. Ex.1002 ¶120.

Hartdegen also discloses disconnecting the tube members 102a, 102b (manipulators) from implant 120 after clip 110 is removed. As seen below in annotated Figure 9, Hartdegen describes implant 120 (teal) on bone after removal of the inserter assembly 100 from the implant. Ex.1005 ¶115, Fig. 9; Ex.1007, 11, Fig. 9; Ex.1002 ¶121.

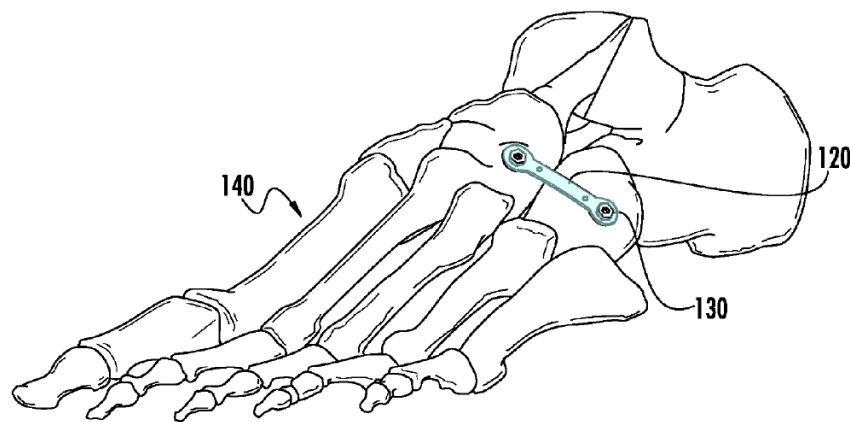


FIG. 9

“FIG. 9 shows implant 120 on bone 140 after removal of the inserter assembly 100 after the implant 120 is in its final position either before or after the implant achieves its second configuration.” Ex.1005 ¶115; Ex.1007, 11; Ex.1002 ¶122.

Accordingly, Hartdegen discloses claim 19.

9. Claim 20

The preamble of claim 20 is disclosed by Hartdegen for the reasons set forth for claim 11’s preamble.

a. Limitation 20[a]

Hartdegen discloses “positioning a deformed bone plate adjacent bones using

manipulators connected to the deformed bone plate[.]” Ex.1002 ¶124.

The claimed “deformed bone plate” in limitation 20[a] corresponds to the “flexed bone plate” recited in limitations 11[a] and 11[b] because both refer to the bone plate while it is held in an insertion configuration before release toward another configuration. *See* Ex.1001, 3:52–56 (describing elastic deformation as a form of deformation). Accordingly, for the same reasons discussed above regarding the flexed bone plate in limitations 11[a] and 11[b] (*see* §§V.A.2.a, V.A.2.b), Hartdegen discloses positioning a deformed bone plate adjacent bones using manipulators connected to the deformed bone plate, including by positioning implant 120 on bone while inserter 100 and tube members 102a/102b remain connected to the implant and maintain it in its first configuration. Ex.1005 ¶¶111–115; Ex.1007, 9–11; Ex.1002 ¶125.

Hartdegen additionally explains that implant 120’s “second configuration after removal of the inserter 100” can be “achieved either by the intrinsic mechanical properties of the material or secondary mechanical manipulation of one or more areas of the plate,” which it describes as “mechanical manipulation/deformation.” Ex.1005 ¶¶112–113; Ex.1007, 10. That is, to the extent Patent Owner asserts something different than flexing is required by “deformed,” Hartdegen contemplates

both elastic and mechanical deformation of its bone plate. Ex.1002 ¶126.

Accordingly, Hartdegen discloses limitation 20[a].

b. Limitation 20[b]

Hartdegen discloses limitation 20[b] for the reasons discussed above regarding claim 12. *See* §V.A.3; Ex.1002 ¶¶127–128.

c. Limitation 20[c]

Hartdegen discloses “driving the bone anchors into the bones to secure the deformed bone plate to the bones.” Ex.1002 ¶129.

Hartdegen discloses limitation 20[c] for the reasons discussed above regarding limitations 11[c] and 11[d]. *See* §§V.A.2.c, V.A.2.d; Ex.1002 ¶130.

10. Claim 21

Hartdegen discloses claim 21 for at least the same reasons discussed above regarding limitations 9[d] and 20[c]. *See* §§V.A.1.d, V.A.9.c; Ex.1002 ¶132.

11. Claim 23

Hartdegen discloses claim 23 for the reasons discussed above regarding limitation 11[a]. *See* §V.A.2.a; Ex.1002 ¶134.

12. Claim 24

Hartdegen discloses claim 24 for the reasons discussed above regarding claim 14. *See* §V.A.5; Ex.1002 ¶136.

13. Claim 25

Hartdegen discloses claim 25 for the reasons discussed above regarding claim 19. *See* §V.A.8; Ex.1005 ¶115, Ex.1007, 11 (“removal of the clip 110 from the inserter 100 after completing the appropriate bone preparation allows the implant 120 to adapt to a second configuration while the implant 120 is in its final implant position.”). The second configuration of the implant urges the bones together. Ex.1005 ¶115; Ex.1007, 11; Ex.1002 ¶¶138–139.

14. Claim 26

Hartdegen discloses claim 26 for the reasons discussed above regarding claim 18. *See* §V.A.7; Ex.1002 ¶141.

15. Claim 27

Hartdegen discloses claim 27 for the reasons discussed regarding claim 18. *See* §V.A.7; Ex.1002 ¶143.

16. Claim 28

Claim 28 depends from claim 20 and recites “wherein advancing the bone anchors through cannulas of the manipulators and into the through bores of the deformed bone plate includes connecting a driver instrument to one of the bone anchors and advancing the connected driver and bone anchor through the cannula of one of the manipulators.”

Hartdegen discloses that the inserter (tubes 102a, 102b—the manipulators) may

include guide means for “drivers” while the inserter remains attached to the implant. Ex.1005 ¶7; Ex.1007, 4. Hartdegen further explains that bone screws 130 “may be prepared and positioned through the internal diameter 106 while the inserter 100 was still attached to the implant 120.” Ex.1005 ¶¶111–113; Ex.1007, 9–10; Ex.1002 ¶145.

A POSA would understand this disclosure as positioning or driving bone screws through the internal diameter 106 using a driver connected to the screw. Ex.1005 ¶7; Ex.1007, 4; Ex.1002 ¶¶146–147.

Accordingly, Hartdegen discloses claim 28.

17. Summary

For at least these reasons, claims 9, 11–14, 17–21, and 23–28 are anticipated by Hartdegen.

B. Obviousness of Claims 1-8 over Orbay and Hartdegen

1. Claim 1

Claim 1 is directed to a surgical kit. Orbay explains that its “invention relates to a formable bone plate, a clamping apparatus, an osteotomy system” that provide a surgeon with implants and instruments necessary to perform reconstructive bone surgery (osteotomies and fusions) of the small bones of the upper extremity or other parts of the human body.” Ex.1008 ¶3; Ex.1002 ¶148.

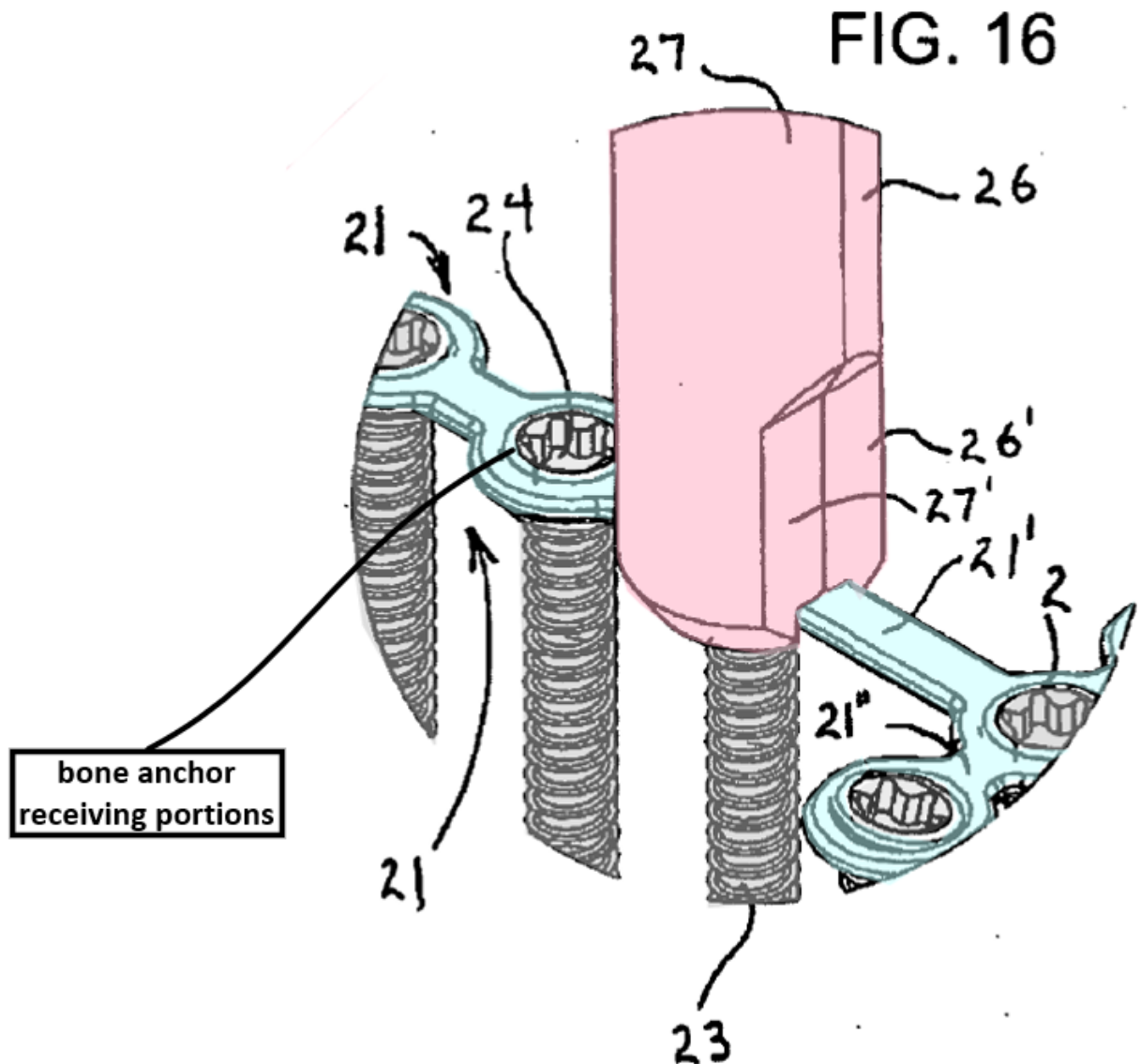
a. Limitation 1[a]

Orbay teaches “a plurality of bone anchors.” As discussed in the claim construction section above, a bone screw is a bone anchor. Orbay’s kit includes a plurality of bone screws 23. *See* Ex.1008 ¶¶66–67, Figs. 15, 16; Ex.1002 ¶149.

b. Limitation 1[b]

Orbay teaches “a bone plate having bone anchor receiving portions with through openings sized to receive the bone anchors, the bone plate having a flexed configuration and an unflexed configuration.”

An annotated version of Figure 16 from Orbay is reproduced below.



Orbay teaches a bone plate (teal) with bone anchor receiving portions that have openings that receive bone screws (gray). Ex.1008 ¶62 (“a bone plate 1 . . . having a plate body with . . . nodes . . . and may be linear, T-shaped, L-shaped, Y-shaped, arched, curved or any combination of shapes.”). Orbay explains that “[t]he nodes 2 each have an inner surface 4, which can be . . . shape[d] as required for seating or

engaging the complementarily shaped head of a screw, surrounding a hole 5 for permitting passage of the shaft of a screw 23.” *Id.*; Ex.1002 ¶¶150–152.

Orbay’s bone plate has a flexed configuration and an unflexed configuration. Ex.1008 ¶73 (“Rotating or torqueing [sic] the second clamp generates bending forces which cause bending or formation of the plate in the direction of any of the X, Y, and/or Z axes.”), ¶74 (“The plates . . . have the advantage of being able to be formed by the surgeon to match the patient’s anatomical circumstances before application, during application or after being partially or fully affixed in-situ” and “fit common reconstructive clinical needs and present dedicated deformable sections for correction adjustment.”); Ex.1002 ¶153.

Orbay’s unflexed configuration corresponds to the plate before being deformed by the surgeon and its flexed configuration corresponds to the plate after being deformed by the surgeon. Ex.1002 ¶154.

To the extent Patent Owner contends that flexed and unflexed require some elastic property that provides compression between adjacent bone portions, Hartdegen teaches a bone plate with such features as explained above regarding limitation 9[b]. *See* §V.A.1.b; Ex.1002 ¶¶155–156.

It would have been obvious to use a bone plate with an elastic bridge structure as taught by Hartdegen as a simple substitution of one known bone plate structure for another, with Hartdegen’s resilient bridge providing the benefit of compression

to bone fragments. Ex.1005 ¶2; Ex.1007, 1; Ex.1002 ¶¶157, 160–162.

Hartdegen additionally describes the interchangeability of elastically and mechanically deformable bone plates. *See* Ex.1005 ¶¶112–113 (describing the bone plate’s installed configuration being “achieved either by the intrinsic mechanical properties of the material or secondary mechanical manipulation of one or more areas of the plate,” which it describes as “mechanical manipulation/deformation”); Ex.1007, 10. Orbay’s plate is itself a formable, mechanically deformable bone plate, including screw-receiving nodes and internodes that provide “an area more easily deformed.” Ex.1008 ¶5; Ex.1002 ¶158.

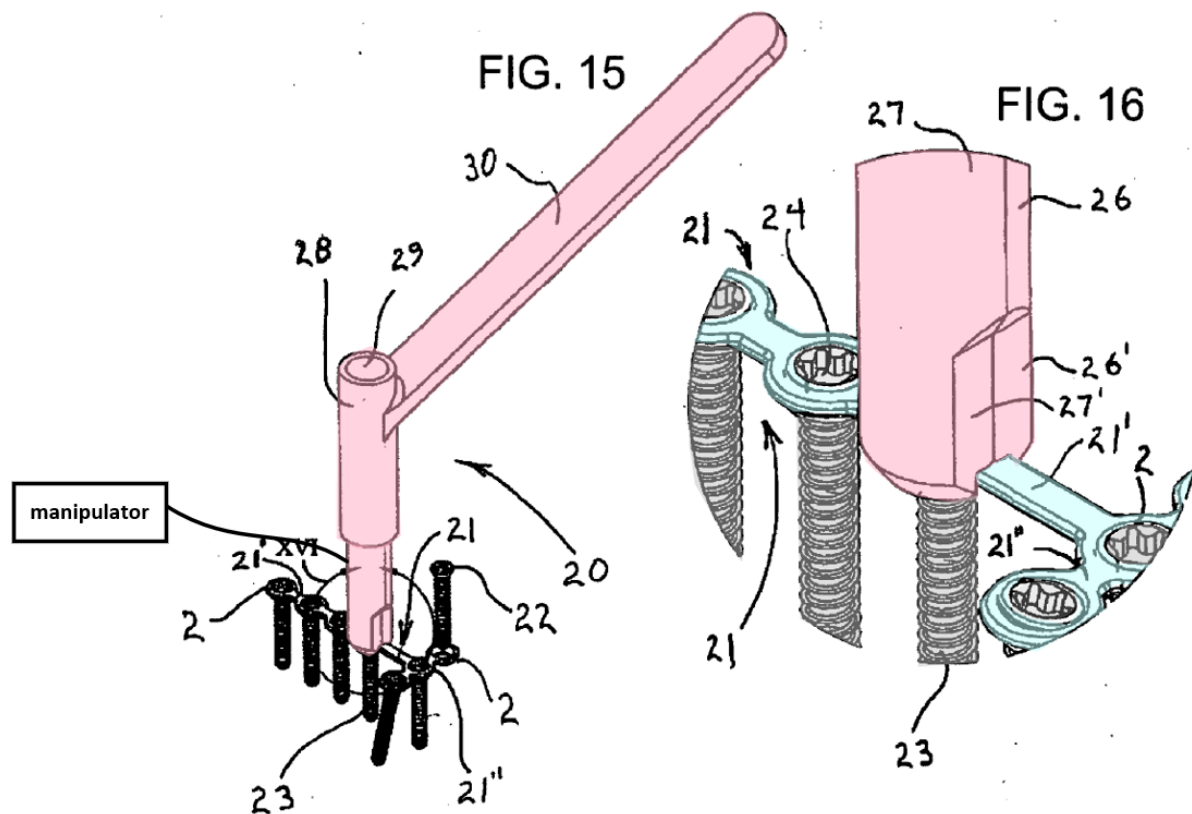
Given Hartdegen’s teaching that formable and elastically deformable bone plates are known, interchangeable alternatives for achieving the same plate-configuration function, a POSA would have found it obvious to substitute Hartdegen’s elastically deformable bridge structure for Orbay’s mechanically formable internode structure. Ex.1002 ¶¶159–162.

c. Limitation 1[c]

Orbay teaches “a plurality of elongated manipulators having distal end portions configured to be connected to the bone anchor receiving portions of the bone plate and proximal end portions opposite the distal end portions.”

Orbay explains that “first clamp 20, 40, 50 is opened, then placed circumferentially around a node” and “[t]hen, a second clamp 20, 40, 50 is opened

and secured in a similar way to a second node.” Ex.1008 ¶73. The clamps are the plurality of manipulators. Annotated Figures 15 and 16 below provide one example of the manipulators (clamp–pink).



As seen above, the distal end of the clamp 20 (pink) is connected to the bone plate 21 (teal) at the bone anchor receiving portion. The clamp has a proximal end (near reference numerals 28, 30) opposite the distal end. Ex.1002 ¶¶164–165.

The connection between the distal end and bone plate is further illustrated in annotated Figure 20 below.

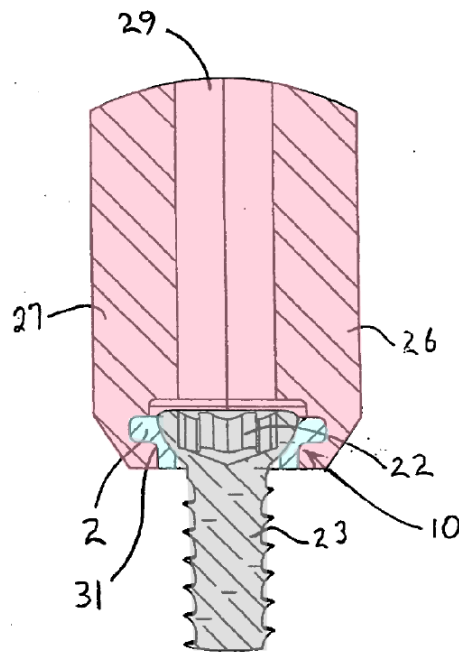


FIG. 20

Orbay explains that “clamp 20 . . . is placed over, and engages with, a node 2, thus receiving a head 22 of a screw 23 passing through a hole 5 in one of the nodes 2.”

Ex.1008 ¶65; Ex.1002 ¶167.

d. Limitation 1[d]

Orbay teaches “cannulas of the manipulators extending between the distal and proximal end portions thereof and being aligned with the through bores of the bone plate when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate.”

An annotated version of Orbay’s Figure 20 is provided below.

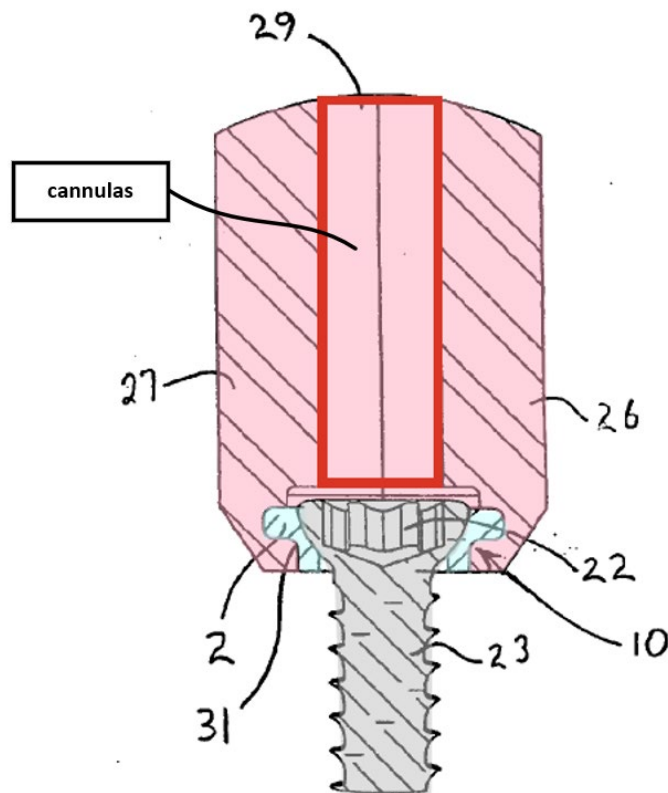


FIG. 20

Orbay has a drill guide hole 29 (cannula—outlined in red). “The drill guide hole 29 continues through the clamping jaws 26, 27 to permit drill access to the bone.” Ex.1008 ¶65; Ex.1002 ¶170.

Orbay does not expressly teach “the cannulas being sized to permit the bone anchors to be advanced through the cannulas and into the through bores of the bone plate.” Hartdegen discloses these features as explained above regarding limitation 9[d]. *See* §V.A.1.d. Hartdegen explains that its “inserter may have a feature or features such as guide means that allow use of drills, screws, drivers, depth gages,

etc. while the inserter is still attached to the implant.” Ex.1005 ¶7; Ex.1007, 4. Hartdegen further explains that bone screws 130 “may be prepared and positioned through the internal diameter 106 while the inserter 100 was still attached to the implant 120.” Ex.1005 ¶¶111–113; Ex.1007, 9–10; Ex.1002 ¶171.

Orbay explains that “[a]fter a clamp 20, 40 has been clamped into place, the surgeon inserts a drill into the guide hole 29, 49 of the clamp 20, 40 and proceeds to drill through the bone. The hole created by such drilling then serves as a pilot hole for a screw 23 to be placed later.” Ex.1008 ¶74. It would have been obvious to configure the cannula in Orbay as taught by Hartdegen to allow for bone screw installation without requiring removal of the clamp 20 between the drilling stage and the fastening stage. Ex.1002 ¶¶173–176.

e. Limitation 1[e]

Orbay teaches “the bone anchor receiving portions of the bone plate include lips and the distal end portions of the manipulators include side walls with openings therein sized to receive the lips of the bone anchor receiving portions.”

An annotated Figure 20 of Orbay is provided below labeling the lips of the bone anchor receiving portion on the bone plate.

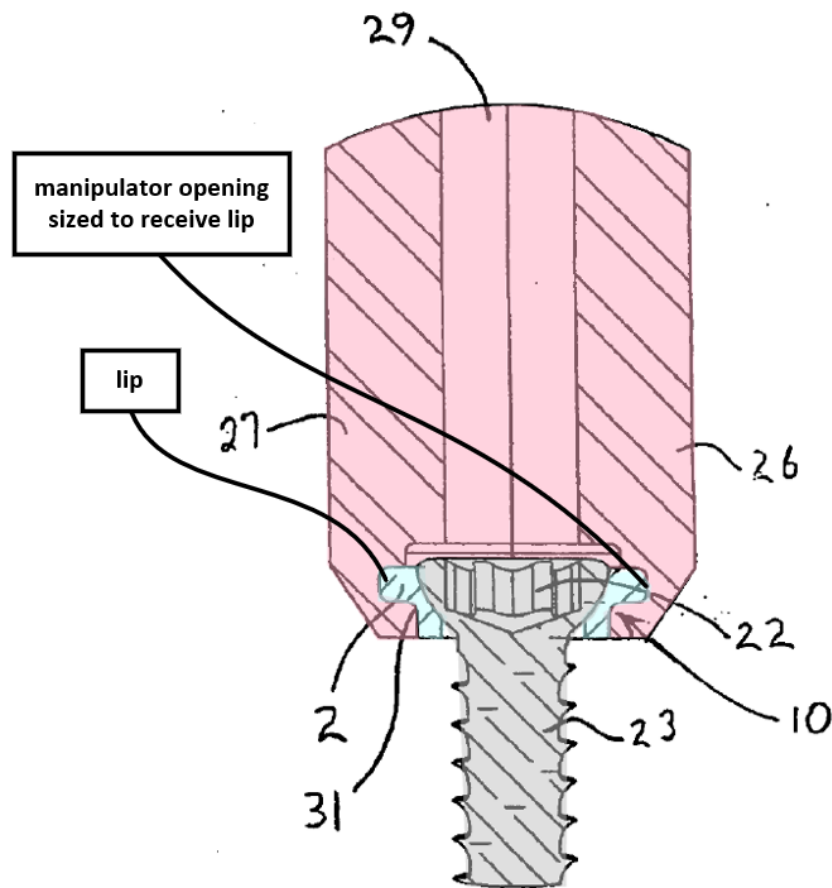
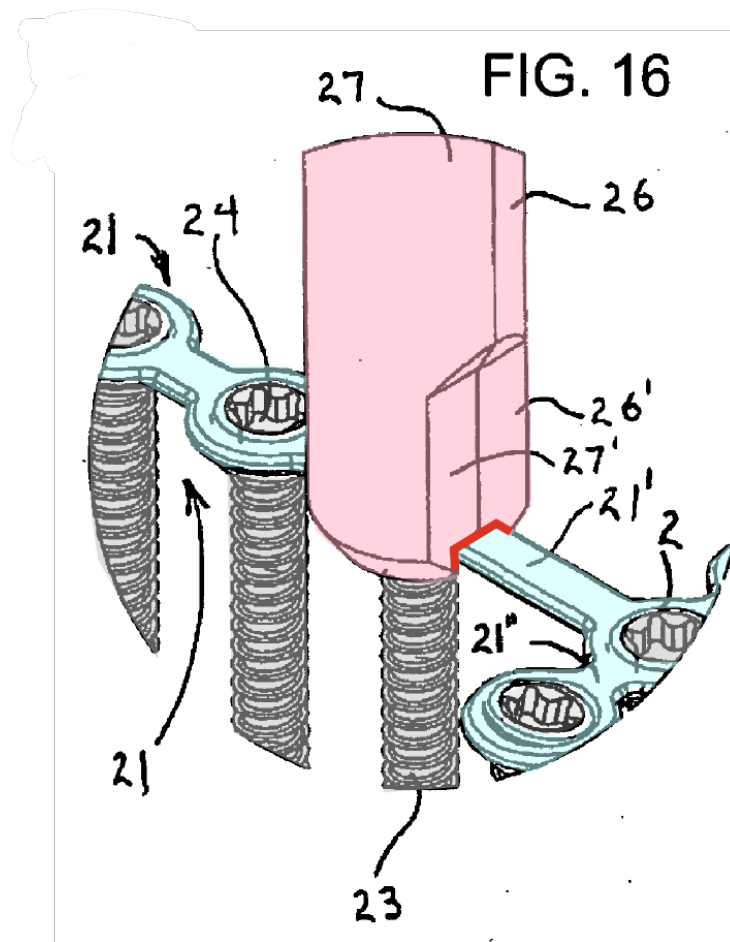


FIG. 20

As seen above, Orbay's bone plate lips reside in openings defined in the sidewalls of distal ends of the clamp 20 (manipulator—pink). Ex.1002 ¶178.

To the extent Patent Owner contends that openings must extend through the sidewall, Orbay's Figure 16, provided below, shows such an arrangement.



As seen above, the red outlined portion of the manipulator end forms a part of Orbay's opening that receives the lips and extends completely through its sidewall.

Ex.1002 ¶179.

Moreover, it would have been obvious to modify the distal ends of the manipulators to have the openings extend completely through the sidewall at other regions around the manipulator distal end to allow visualization to ensure proper seating of the bone plate in the manipulator. Ex.1002 ¶¶180–182.

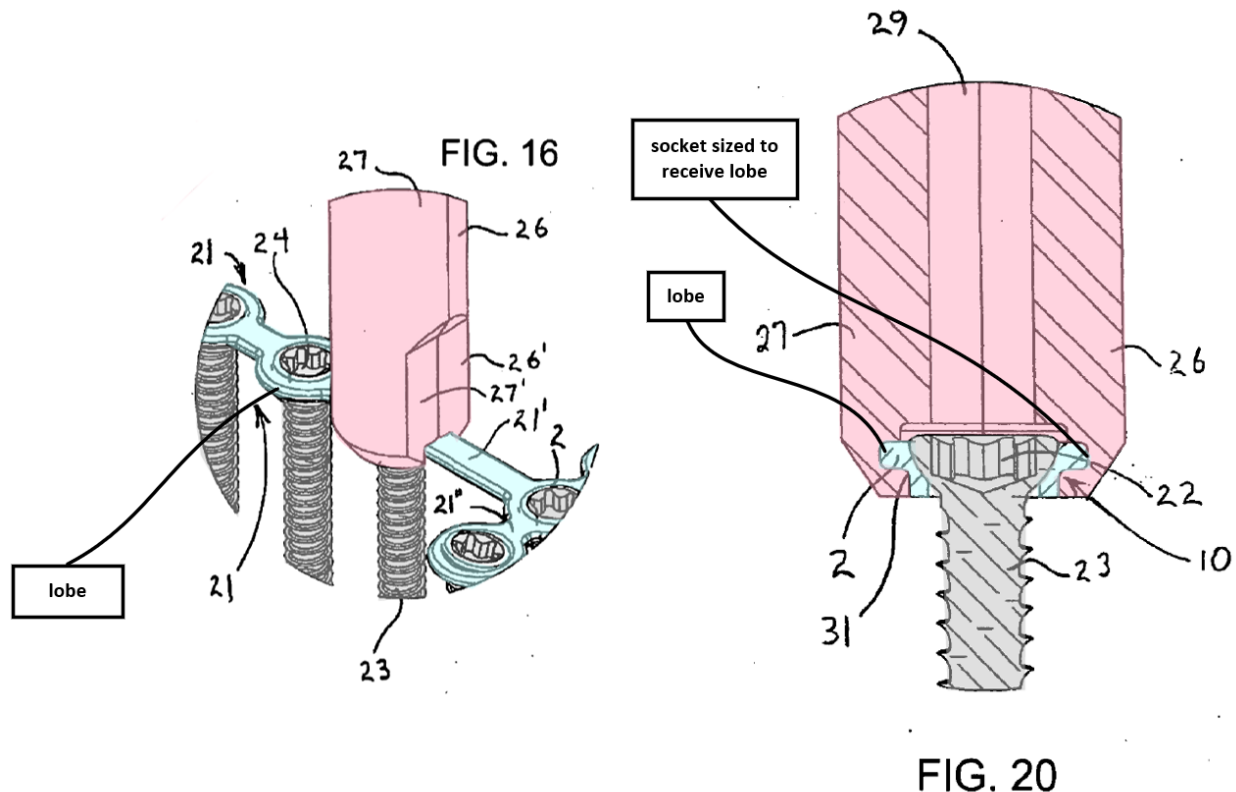
Accordingly, claim 1 would have been obvious in view of Orbay and

Hartdegen.

2. Claim 2

Claim 2 depends from claim 1 and recites that “the bone anchor receiving portions of the bone plate include lobes and the distal end portions of the manipulators includes sockets sized to receive the lobes.”

As discussed above regarding limitation 1[e], Orbay’s lobes are the portions of the bone plate receiving the screws and are shown in the socket defined by clamp 20 in annotated Figures 16 and 20 below. Ex.1002 ¶184.



Orbay explains that “clamping jaws 26, 27 engage a node 2 nested therein by gripping the annular or circumferential step 10 of the engagement section.” Ex.1008

¶67. Orbay specifically describes its “socket 31 [as] shaped to engage a node 2 [that] is nested in the step 10.” *Id.*; Ex.1002 ¶185.

Accordingly, claim 2 would have been obvious in view of Orbay and Hartdegen.

3. Claim 3

Claim 3 depends from claim 1 and recites that

each of the manipulators includes a fulcrum portion and a leverage portion spaced apart from each other on opposite sides of the cannula of the manipulator, the fulcrum portion being configured to contact an upper surface of one of the bone anchor receiving portions of the bone plate and the leverage portion being configured to contact a lower surface of the one bone anchor receiving portion.

Orbay explains that “[r]otating or torqueing [sic] the second clamp generates bending forces which cause bending or formation of the plate in the direction of any of the X, Y, and/or Z axes.” Ex.1008 ¶73. An annotated version of Orbay’s Figure 20 is provided below.

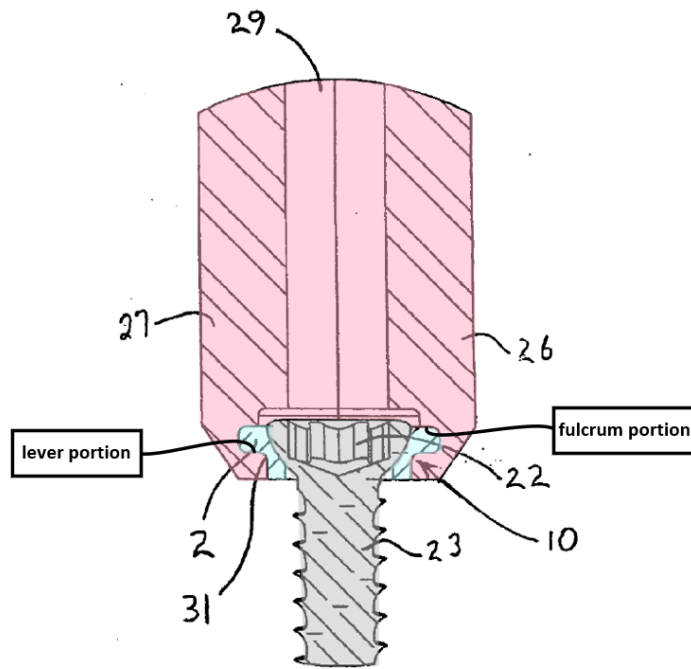


FIG. 20

As seen above, Orbay includes a fulcrum portion and a leverage portion similar to those described in the '831 Patent and discussed in the Claim Construction section. The fulcrum portion and leverage portion are on opposite sides of the cannula from one another and engage upper and lower surfaces of the bone plate during the bending or formation of the plate discussed above. The fulcrum portion and leverage portion locations are determined by the action imparted on the bone plate (*i.e.*, how the manipulator is being pivoted) but are located opposite one another. Ex.1002 ¶¶187–189.

Accordingly, claim 3 would have been obvious in view of Orbay and Hartdegen.

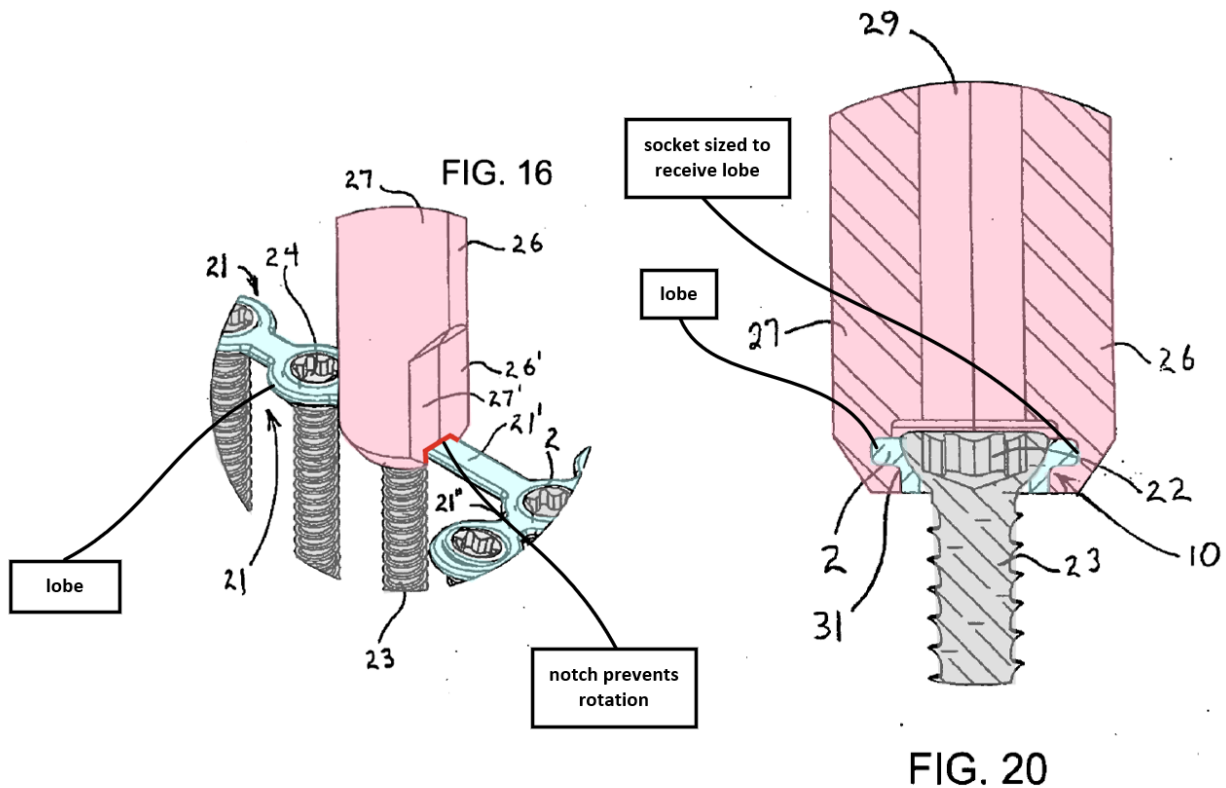
4. Claim 4

Claim 4 depends from claim 1 and recites that

the bone plate bone anchor receiving portions include lobes and the manipulator distal end portions include sockets sized to receive the lobes with the lobes and sockets being configured to form a mating, non-rotatable fit when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate.

Orbay teaches the recited lobes and sockets for the reasons discussed above regarding claim 2. *See* §V.B.2. Orbay's node 2 corresponds to the recited lobe and its "socket 31, shaped to engage a node 2 is nested in the step 10." Ex.1008 ¶67; Ex.1002 ¶191.

As seen in annotated Figure 6 below, Orbay's nodes 2 (lobes) and sockets are configured to form a mating, non-rotatable fit when the distal end portions of the manipulators are connected to the bone anchor receiving portions of the bone plate.



As seen above, the interface between the node 2 and socket 31 (red outlined region) provides a non-rotatable fit. This is consistent with Orbay’s discussion that “[r]otating or torqueing [sic] the second clamp generates bending forces which cause bending or formation of the plate in the direction of any of the X, Y, and/or Z axes.” Ex.1008 ¶73; Ex.1002 ¶¶192–194.

Accordingly, claim 4 would have been obvious in view of Orbay and Hartdegen.

5. Claim 5

Claim 5 depends from claim 1 and recites that “the bone plate includes a

resilient intermediate portion connecting the bone anchor receiving portions and the intermediate portion has a straight shape with the bone plate in the flexed configuration thereof and a bent shape with the bone plate in the unflexed configuration thereof.”

Orbay does not expressly teach its bone plate having a resilient intermediate portion. As explained above regarding limitation 1[b], Hartdegen teaches a bone plate having a resilient intermediate portion. *See* §V.B.1.b. And as explained regarding limitation 13[b], Hartdegen teaches its intermediate bone plate portion having a straight shape with the bone plate in the flexed configuration and a bent shape with the bone plate in the unflexed configuration. *See* §V.A.4.b.

Using a bone plate in Orbay with features recited in claim 5 would have been obvious as discussed regarding limitation 1[b]. *See* §V.B.1.b; Ex.1002 ¶¶196–197.

Accordingly, claim 5 would have been obvious in view of Orbay and Hartdegen.

6. Claim 6

Claim 6 depends from claim 1 and recites “the unflexed configuration of the bone plate orients the bone anchor receiving portions of the bone plate to extend transverse to each other and the flexed configuration of the bone plate orients the bone anchor receiving portions of the bone plate to be coplanar with each other.”

Orbay teaches these features. Orbay explains that its bone plate “may be

linear, T-shaped, L-shaped, Y-shaped, arched, curved or any combination of shapes.” Ex.1008 ¶62. When starting with an initial (unflexed) condition of a bone plate having an arched or curved configuration, the bone anchor receiving portions of the bone plate extend transverse to each other. A POSA would understand that after the bending operation discussed in Orbay, one option for the subsequent (flexed) condition would be orienting the bone anchor receiving portions of the bone plate to be coplanar with each other. Ex.1002 ¶¶199–201.

To the extent there is any dispute as to whether Orbay teaches this limitation, it would have been obvious in view of Hartdegen as explained above regarding claim 5. *See* §V.B.5. As discussed above, Hartdegen’s bent shape in the unflexed configuration provides the transverse orientation of the bone anchor receiving portions and Hartdegen’s straight shape in the flexed configuration provides the coplanar bone anchor receiving portions. Ex.1002 ¶202.

Accordingly, claim 6 would have been obvious in view of Orbay and Hartdegen.

7. Claim 7

Claim 7 is an independent claim directed to a surgical kit that includes limitations recited in claims 1 and 2.

Orbay teaches a surgical kit for the reasons discussed above regarding claim 1. *See* §V.B.1; Ex.1002 ¶204.

a. Limitation 7[a]

Limitation 7[a] is the same as limitation 1[a]. *See* §V.B.1.a; Ex.1002 ¶205.

b. Limitation 7[b]

Limitation 7[b] is the same as limitation 1[b]. *See* §V.B.1.b; Ex.1002 ¶206.

c. Limitation 7[c]

Limitation 7[c] is the same as limitation 1[c]. *See* §V.B.1.c; Ex.1002 ¶207.

d. Limitation 7[d]

Limitation 7[d] is the same as limitation 1[d]. *See* §V.B.1.d; Ex.1002 ¶208.

e. Limitation 7[e]

Limitation 7[e] is similar to limitation 1[e]. Limitation 1[e] includes all of the features recited in limitation 7[e], except for the recitation of the lobes, which are included in claim 2, and a narrowed, intermediate portion extending between the lobes, which is addressed below in the discussion of limitation 7[f]. Accordingly, the discussion of limitation 1[e] and claim 2 addresses limitation 7[e]. *See* §§V.B.1.e, V.B.2; Ex.1002 ¶209.

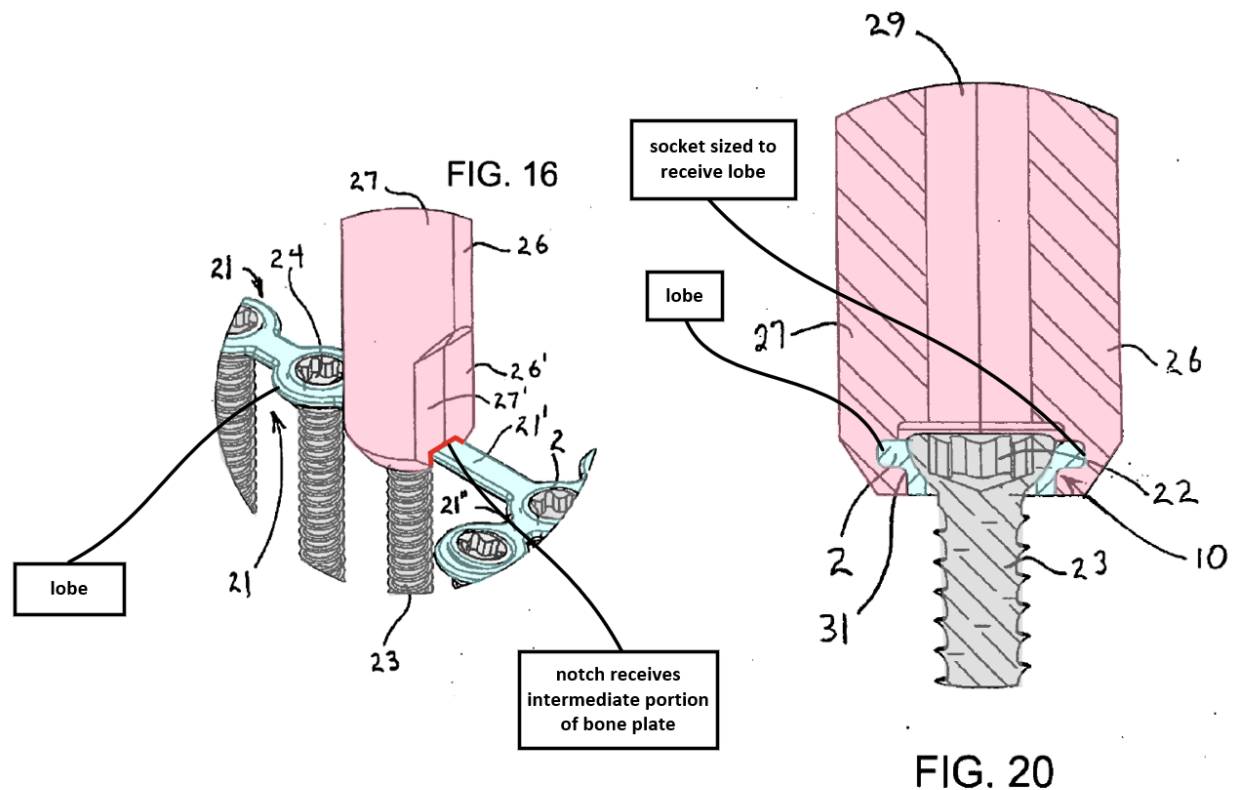
f. Limitation 7[f]

Limitation 7[f] recites that “the distal end portions of the manipulators include sockets sized to receive the lobes of the bone plate and the sockets include notches that receive the intermediate portion of the bone plate.”

Claim 2 recites the lobes and sockets, similar to limitation 7[f]. Orbay teaches

those features for the reasons discussed regarding claim 2. *See* §V.B.2.

Orbay also teaches that the sockets 31 include notches that receive the narrowed intermediate portion of the bone plate, as seen in annotated Figures 16 and 20 below.



As seen above, the distal end of Orbay's manipulator (pink) includes a notch (outlined in red) that receives leg 21' (intermediate portion). Ex.1002 ¶¶212–214.

Accordingly, claim 7 would have been obvious in view of Orbay and Hartdegen.

8. Claim 8

Claim 8 depends from claim 7 and recites that “the intermediate portion is resilient and has a straight shape with the bone plate in the flexed configuration thereof and a bent shape with the bone plate in the unflexed configuration thereof.”

The features recited in claim 8 are similar to those in claim 5. The features recited in claim 8 would have been obvious for the reasons discussed above regarding claim 5. *See* §V.B.5; Ex.1002 ¶216.

Accordingly, claim 8 would have been obvious in view of Orbay and Hartdegen.

9. Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in combining the teachings of Orbay and Hartdegen. The combination includes bone plates and manipulators of bone plates in devices having similar operating characteristics and involves no more than routine skill in the art. Ex.1002 ¶217.

Both Orbay and Hartdegen are directed to bone plate osteosynthesis systems that use a manipulator instrument to hold a bone plate in a first configuration, position it against bone, and secure it with bone anchors, and each discloses the same basic mechanical elements (a plate with anchor-receiving portions and an instrument that grips those portions). Ex.1005, Abstract; Ex.1007, 1; Ex.1008 ¶7. Because Orbay itself expressly contemplates that its bone plate may take a variety of shapes

and be formed by a range of mechanisms (Ex.1008 ¶¶62, 74), a POSA would have had no difficulty substituting or supplementing Orbay's plate and manipulator structure with the analogous, art-recognized structure Hartdegen discloses for achieving the first/second-configuration functionality, with predictable results. Ex.1002 ¶¶218–220.

10. Summary

For at least these reasons, claims 1–8 would have been obvious in view of Orbay and Hartdegen.

C. Obviousness of Claims 1–10, 13, 15, 16, and 22 over Hartdegen and Orbay

1. Claim 1

Hartdegen teaches a surgical kit for the reasons set forth above regarding claim 9. *See* §V.A.1; Ex.1002 ¶221.

a. Limitation 1[a]

Limitation 1[a] is taught by Hartdegen for the reasons stated above for limitation 9[a]. *See* §V.A.1.a; Ex.1002 ¶222.

b. Limitation 1[b]

Limitation 1[b] is taught by Hartdegen for the reasons stated above for limitation 9[b]. *See* §V.A.1.b; Ex.1002 ¶223.

c. Limitation 1[c]

Limitation 1[c] is taught by Hartdegen for the reasons stated above for limitation 9[c]. *See* §V.A.1.c; Ex.1002 ¶224.

d. Limitation 1[d]

Limitation 1[d] is taught by Hartdegen for the reasons stated above for limitation 9[d]. *See* §V.A.1.d; Ex.1002 ¶225.

e. Limitation 1[e]

As discussed above regarding the challenge to claim 1 based on Orbay in Ground 2, Orbay teaches limitation 1[e]. *See* §V.B.1.e; Ex.1002 ¶227.

With respect to the lips of the bone anchor receiving portions, Orbay explains that “[a]n additional benefit of the presently described embodiment is that the smaller surface area of the plate, created by the undercut, may minimize tissue damage of the periosteum.” Ex.1008 ¶8. Accordingly, it would have been obvious to use a similar arrangement in Hartdegen to provide the minimization of tissue damage described. Ex.1002 ¶228.

It also would have been obvious to carry over the mating socket structure from Orbay to provide “side walls with openings therein sized to receive the lips of the bone anchor receiving portions” as discussed above regarding limitation 1[e] in Ground 2. *See* §V.B.1.e. As discussed above regarding claim 3 in Ground 2, Orbay’s engagement structure provides the same fulcrum/lever arrangement as Hartdegen’s

manipulators and those described in the '831 Patent. When using Orbay's stepped lip bone anchor receiving portion structure in Hartdegen, it would have been obvious to carry over the manipulator structure as a known manner of providing a secure grip to bend Hartdegen's bone plate. Ex.1002 ¶229.

Hartdegen also expressly contemplates that "[t]he means of attaching the plate to the inserter is shown on the bridge area of the plate, but could occur anywhere on or around the periphery of the plate." Ex.1005 ¶111; Ex.1007, 9. Hartdegen also contemplates a sidewall receiving structure in another embodiment, seen in Figure 30 below, that would be compatible with Orbay's stepped bone plate structure.

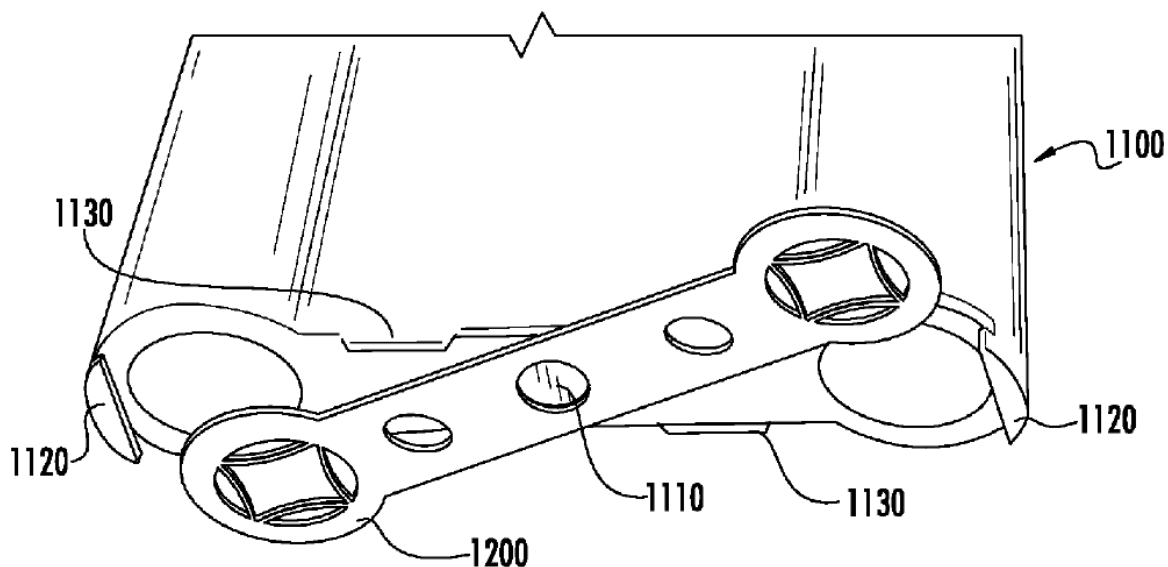
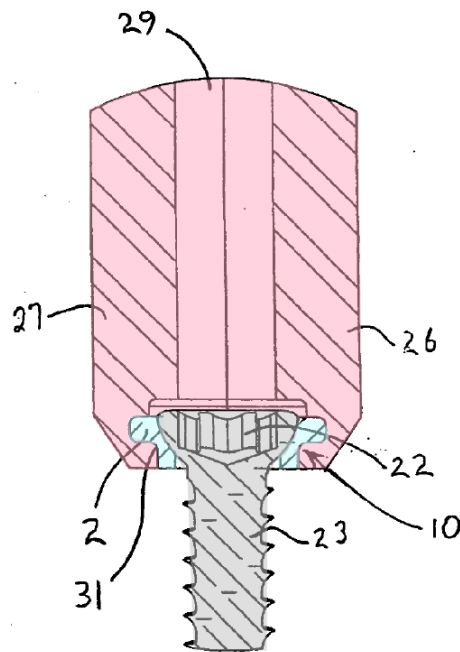


FIG. 30

The “means 1120 . . . for attaching to the implant” (Ex.1005 ¶133; Ex.1007, 16) has a similar stepped structure as Orbay's manipulator as seen in annotated Figure 20

below.



In one example arrangement, it would have been obvious to include features like Hartdegen's "means 1120" on each of its inserter tubes 102a, 102b as a known alternate attachment means that would facilitate use of the stepped profile bone plate to incorporate its benefits of minimizing tissue damage while also taking advantage of the engagement structure enabling bone plate forming as taught by Orbay. Ex.1002 ¶¶230–233.

Accordingly, claim 1 would have been obvious in view of the combined teachings of Hartdegen and Orbay.

2. Claim 2

Claim 2 depends from claim 1. As discussed above regarding Ground 2, Orbay teaches these additional features. *See* §V.B.2. As explained above in the modifications to Hartdegen based on Orbay in connection with limitation 1[e], a similar mating socket structure from Orbay (or modified version thereof with engagement features like Hartdegen's means 1120) would have been obvious to implement when using its stepped bone plate configuration. *See* §V.C.1.e; Ex.1002 ¶235.

Accordingly, claim 2 would have been obvious over the combined teachings of Hartdegen and Orbay.

3. Claim 3

Claim 3 depends from claim 1. As discussed above regarding Ground 2, Orbay teaches these additional features. *See* §V.B.3. As explained above regarding limitation 1[e], a similar mating socket structure from Orbay (or modified version thereof with engagement features like Hartdegen's means 1120) would have been obvious to implement when using its stepped bone plate configuration. *See* §V.C.1.e; Ex.1002 ¶237.

Accordingly, claim 3 would have been obvious over the combined teachings of Hartdegen and Orbay.

4. Claim 4

Claim 4 depends from claim 1. As discussed above regarding Ground 2, Orbay teaches these additional features. *See* §V.B.4. As explained above regarding limitation 1[e], a similar mating socket structure from Orbay (or modified version thereof with engagement features like Hartdegen's means 1120) would have been obvious to implement when using its stepped bone plate configuration. *See* §V.C.1.e; Ex.1002 ¶239.

Accordingly, claim 4 would have been obvious over the combined teachings of Hartdegen and Orbay.

5. Claim 5

Claim 5 depends from claim 1. As explained above regarding limitation 1[b] in Ground 2, Hartdegen teaches a bone plate having a resilient intermediate portion. *See* §V.B.1.b. And as explained regarding limitation 13[b], Hartdegen teaches a bone plate having a resilient bridge portion having a straight shape with the bone plate in the flexed configuration and a bent shape with the bone plate in the unflexed configuration. *See* §V.A.4.b; Ex.1002 ¶241.

Accordingly, claim 5 would have been obvious over the combined teachings of Hartdegen and Orbay.

6. Claim 6

Claim 6 depends from claim 1. Hartdegen teaches these features for the

reasons discussed above regarding claim 5. *See* §V.C.5. Hartdegen's bent shape in the unflexed configuration provides the transverse orientation of the bone anchor receiving portions and Hartdegen's straight shape in the flexed configuration provides the coplanar bone anchor receiving portions. Ex.1002 ¶243.

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

7. Claim 7

Claim 7 is an independent claim directed to a surgical kit that includes limitations recited in claims 1 and 2.

Hartdegen teaches a surgical kit for the reasons discussed above regarding claim 9. *See* §V.A.1; Ex.1002 ¶245.

a. Limitation 7[a]

Limitation 7[a] is the same as limitation 1[a]. *See* §V.C.1.a; Ex.1002 ¶246.

b. Limitation 7[b]

Limitation 7[b] is the same as limitation 1[b]. *See* §V.C.1.b; Ex.1002 ¶247.

c. Limitation 7[c]

Limitation 7[c] is the same as limitation 1[c]. *See* §V.C.1.c; Ex.1002 ¶248.

d. Limitation 7[d]

Limitation 7[d] is the same as limitation 1[d]. *See* §V.C.1.d; Ex.1002 ¶249.

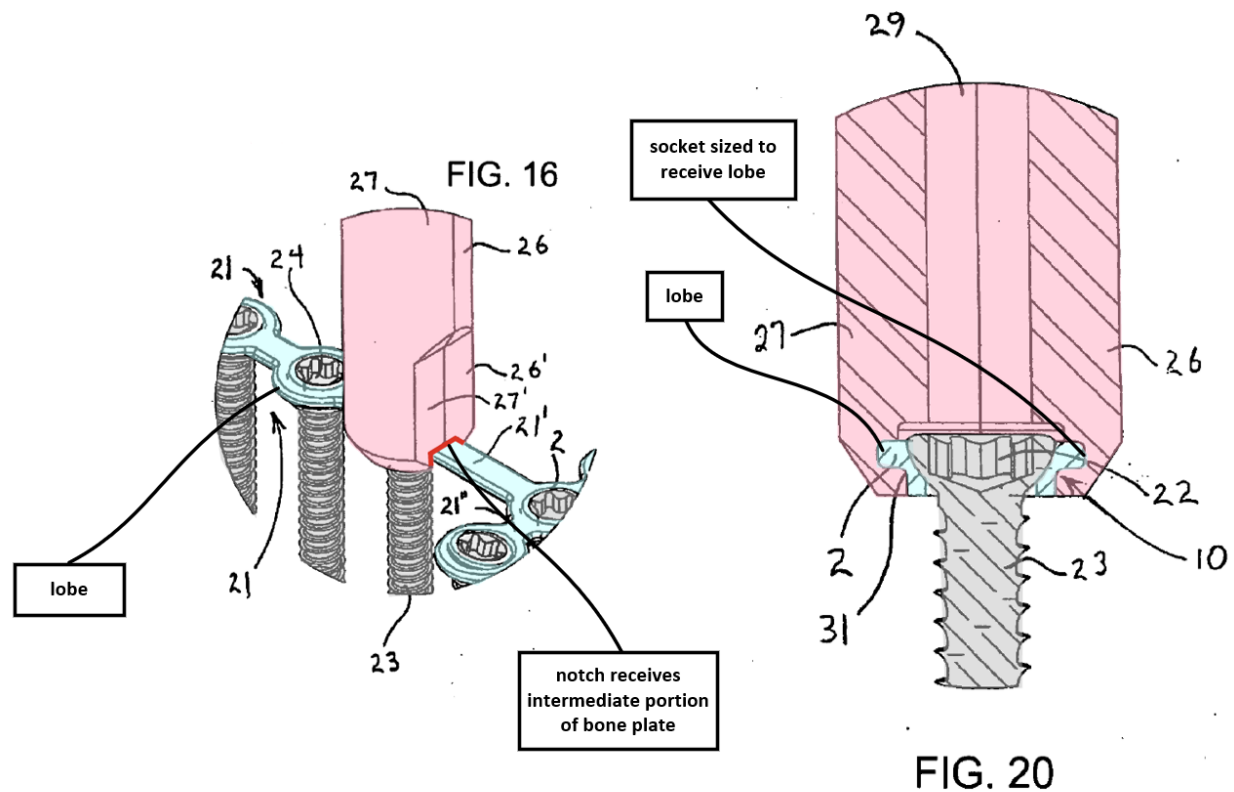
e. Limitation 7[e]

Limitation 7[e] is similar to limitation 1[e]. Limitation 1[e] includes all of the features recited in limitation 7[e], except for the recitation of the lobes, which are included in claim 2, and a narrowed, intermediate portion extending between the lobes, which is addressed below in the discussion of limitation 7[f]. Accordingly, the discussion of limitation 1[e] and claim 2 addresses limitation 7[e]. *See* §§V.C.1.e, V.C.2; Ex.1002 ¶250.

f. Limitation 7[f]

Claim 2 recites the lobes and sockets, similar to limitation 7[f]. Orbay teaches those features for the reasons discussed regarding claim 2. *See* §V.C.2.

Orbay also teaches that the sockets 31 include notches that receive the narrowed intermediate portion of the bone plate, as seen in annotated Figures 16 and 20 below.



As seen above, the distal end of Orbay's manipulator (pink) includes a notch (outlined in red) that receives leg 21' (intermediate portion). As explained above regarding limitation 1[e], it would have been obvious to carry over Orbay's manipulator structure as a known manner of providing a secure grip to bend Hartdegen's bone plate. *See* §V.C.1.e; Ex.1002 ¶¶252–255.

Accordingly, claim 7 would have been obvious in view of Hartdegen and Orbay.

8. Claim 8

Claim 8 depends from claim 7. The features recited in claim 8 are similar to

those in claim 5. The features recited in claim 8 would have been obvious for the reasons discussed above regarding claim 5. *See* §V.C.5; Ex.1002 ¶257.

Accordingly, claim 8 would have been obvious in view of Hartdegen and Orbay.

9. Claim 9

Hartdegen teaches the limitations of claim 9 for the reasons discussed above in Section V.A.1. As discussed above regarding limitation 9[c], however, to the extent Patent Owner contends that Hartdegen's engagement features 119 are outside of the bone anchor receiving portions and/or that a direct connection is required at the bone anchor receiving portions of the implant 120, Hartdegen expressly states that "[t]he means of attaching the plate to the inserter . . . could occur anywhere on or around the periphery of the plate." Ex.1005 ¶111; Ex.1007, 9. A POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (*e.g.*, around the periphery of the bone anchor receiving portions). Ex.1002 ¶¶258–259.

To the extent this does not disclose a connection at bone anchor receiving portions, such an arrangement would have been obvious, as Hartdegen discloses that the attachment location is a design choice that can be made anywhere on or around the plate's periphery, and a POSA would have recognized the bone anchor receiving portions as one of a finite number of identified, predictable locations for this

attachment, with a reasonable expectation that doing so would successfully enable the inserter to flex and manipulate the plate as intended. The modification would have been the application of a known technique (attaching the inserter at a peripheral location) to a known device (the bone plate) in an obvious manner to achieve a predictable result. Ex.1002 ¶¶260–261. This also would have been obvious because selecting the bone anchor receiving portions as the attachment point, rather than another peripheral location, amounts to no more than a predictable design choice among a limited set of known options expressly contemplated by Hartdegen, yielding no unexpected results. Ex.1002 ¶¶261–262.

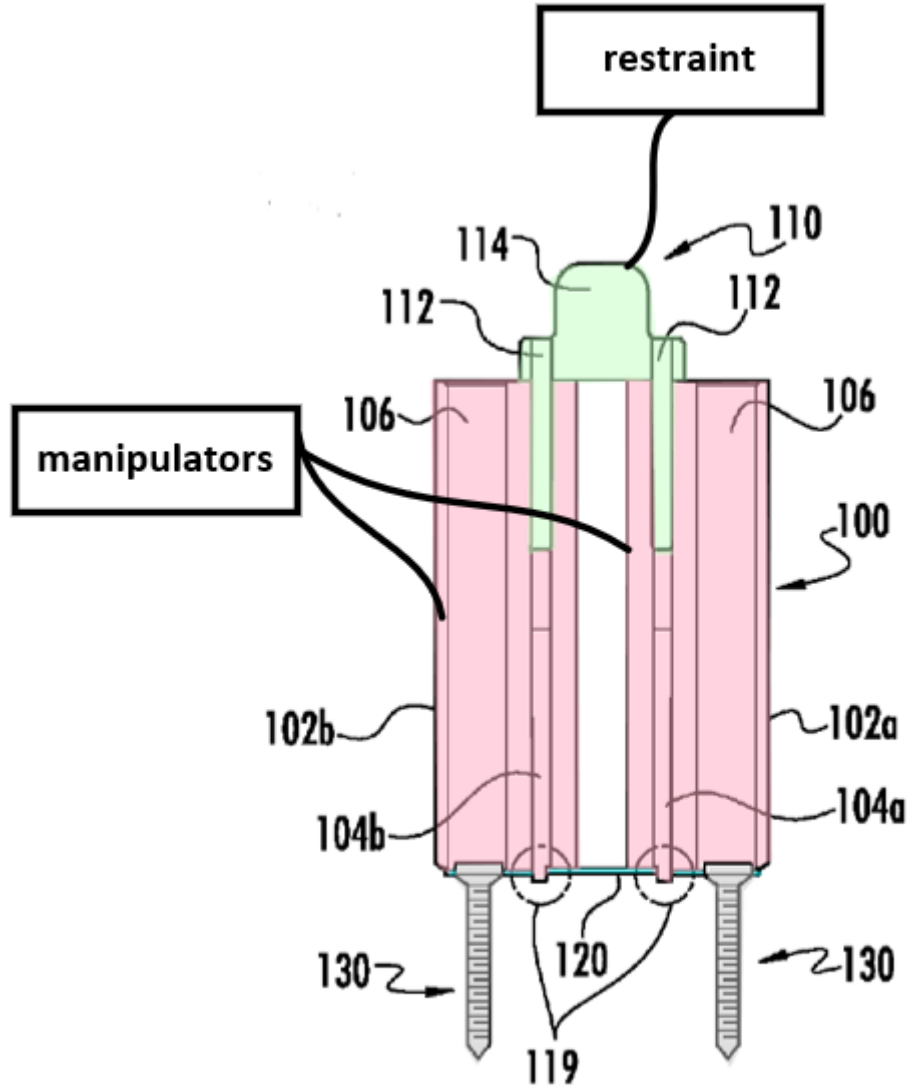
Such an arrangement also would have been obvious in view of Orbay, as explained above in Ground 2 regarding limitation 1[c]. *See* §V.B.1.c; Ex.1002 ¶263.

Thus, claim 9 would have been obvious in view of the combined teachings of Hartdegen and Orbay.

10. Claim 10

Claim 10 depends from claim 9 and recites that “the portions of the restraint include openings sized to receive the proximal portions of the manipulators.”

Hartdegen teaches a restraint as explained in §V.A.1.e above. Hartdegen’s restraint is shown in annotated Figure 1E below.



Hartdegen's clip 110 (green) is a restraint. Ex.1005 ¶¶111–116; Ex.1007, 9–11. Hartdegen's restraint extends into the manipulators via engagement pins, rather than including openings sized to receive the proximal portions of the manipulators. There are a finite number of ways to connect a restraint to manipulators (*e.g.*, extending

into them, as in Hartdegen, or surrounding them via openings, as in Orbay's clamping tubes 28, which surround and lock clamping jaws 26, 27 in place). Ex.1008 ¶65. Selecting Orbay's opening-based structure over Hartdegen's pin-based structure would have been an obvious, predictable substitution of one known connecting means for another serving the identical purpose—temporarily holding the manipulators in position. Ex.1002 ¶¶265–266.

Modifying Hartdegen's clip 110 to adopt Orbay's opening-based connecting structure would not disturb the function Hartdegen's restraint already performs. Hartdegen's clip 110 fixes tubes 102a and 102b "in relative position to each other" (Ex.1005 ¶111; Ex.1007, 9). That bridging function depends on the restraint spanning between and connecting to both manipulators, not on whether its connecting portions take the form of pins extending into the manipulators or openings surrounding them. A POSA modifying Hartdegen's clip 110 to use openings sized to receive the manipulators, as taught by Orbay's clamping tubes 28, would therefore have had a reasonable expectation of success in retaining Hartdegen's already-disclosed function of fixing the manipulators in relative position, since only the form of the connecting portions changes and not the overall structure bridging the two manipulators. Ex.1002 ¶267.

Accordingly, claim 10 would have been obvious in view of Hartdegen and Orbay.

11. Claim 13

Claim 13 depends from claim 11. Hartdegen teaches the limitations recited in claim 13 for the reasons discussed above relative to Ground 1. *See* §V.A.4. As discussed above regarding limitation 13[a], however, to the extent Patent Owner contends that Hartdegen's engagement features 119 are outside of the bone anchor receiving portions and/or that a direct connection is required at the bone anchor receiving portions of the implant 120, Hartdegen expressly states that "[t]he means of attaching the plate to the inserter . . . could occur anywhere on or around the periphery of the plate." Ex.1005 ¶111; Ex.1007, 9. A POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (*e.g.*, around the periphery of the bone anchor receiving portions). Ex.1002 ¶269.

To the extent this does not disclose a connection at bone anchor receiving portions, such an arrangement would have been obvious, as Hartdegen discloses that the attachment location is a design choice that can be made anywhere on or around the plate's periphery, and a POSA would have recognized the bone anchor receiving portions as one of a finite number of identified, predictable locations for this attachment, with a reasonable expectation that doing so would successfully enable the inserter to flex and manipulate the plate as intended. The modification would have been the application of a known technique (attaching the inserter at a peripheral

location) to a known device (the bone plate) in an obvious manner to achieve a predictable result. Ex.1002 ¶270. This also would have been obvious because selecting the bone anchor receiving portions as the attachment point, rather than another peripheral location, amounts to no more than a predictable design choice among a limited set of known options expressly contemplated by Hartdegen, yielding no unexpected results. Ex.1002 ¶270.

Such an arrangement also would have been obvious in view of Orbay, as explained above in Ground 2 regarding limitation 1[c]. *See* §V.B.1.c; Ex.1002 ¶270.

Thus, claim 13 would have been obvious in view of the combined teachings of Hartdegen and Orbay.

12. Claim 15

Claim 15 depends from claim 11 and recites that pivoting the manipulators includes “engaging distal portions of the manipulators with notched profiles of the bone plate and shifting proximal handle portions of the manipulators together.”

As discussed above in connection with limitation 1[e], Orbay explains that “[a]n additional benefit of the presently described embodiment is that the smaller surface area of the plate, created by the undercut, may minimize tissue damage of the periosteum.” Ex.1008 ¶8. Accordingly, it would have been obvious to use a similar arrangement in Hartdegen to provide the minimization of tissue damage described. Ex.1002 ¶272.

It also would have been obvious to carry over the mating socket structure from Orbay to provide “side walls with openings therein sized to receive the lips of the bone anchor receiving portions” as discussed above regarding limitation 1[e] in Ground 2. *See* §V.B.1.e. As discussed above regarding claim 3 in Ground 2, Orbay’s engagement structure provides the same fulcrum/lever arrangement as Hartdegen’s manipulators and those described in the ’831 Patent. When using Orbay’s stepped lip bone anchor receiving portion structure in Hartdegen, it would have been obvious to carry over the manipulator structure as a known manner of providing a secure grip to bend Hartdegen’s bone plate. Ex.1002 ¶273.

Hartdegen also expressly contemplates that “[t]he means of attaching the plate to the inserter is shown on the bridge area of the plate, but could occur anywhere on or around the periphery of the plate.” Ex.1005 ¶111; Ex.1007, 9. Hartdegen contemplates a sidewall receiving structure in another embodiment, for example, seen in Figure 30 below, that would be compatible with Orbay’s stepped bone plate structure. Ex.1002 ¶274.

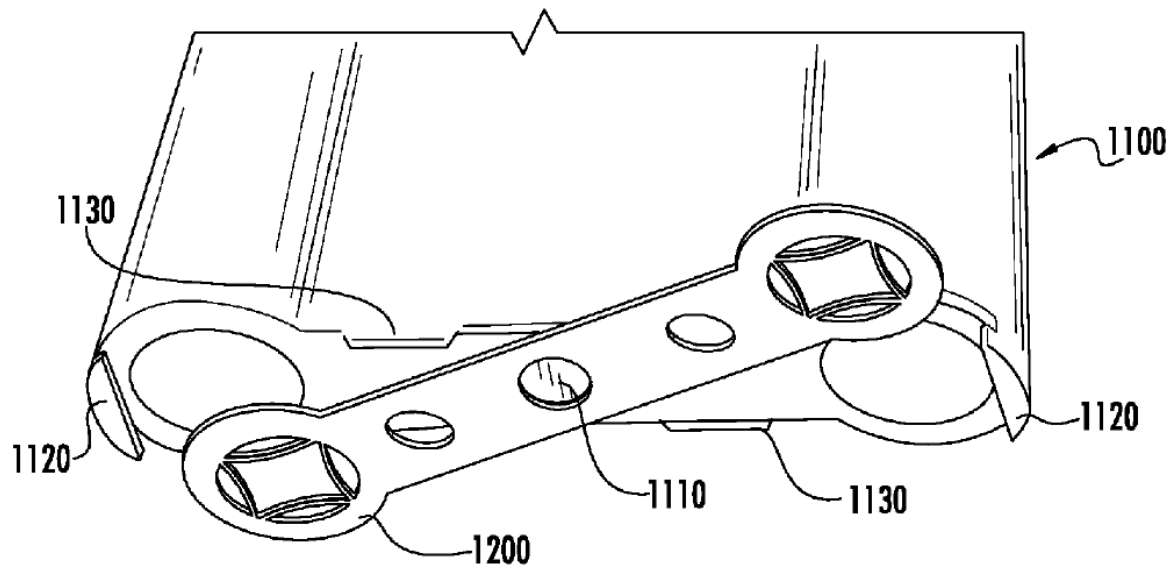


FIG. 30

The “means 1120 . . . for attaching to the implant” has a similar stepped structure as Orbay’s manipulator as seen in annotated Figure 20 below.

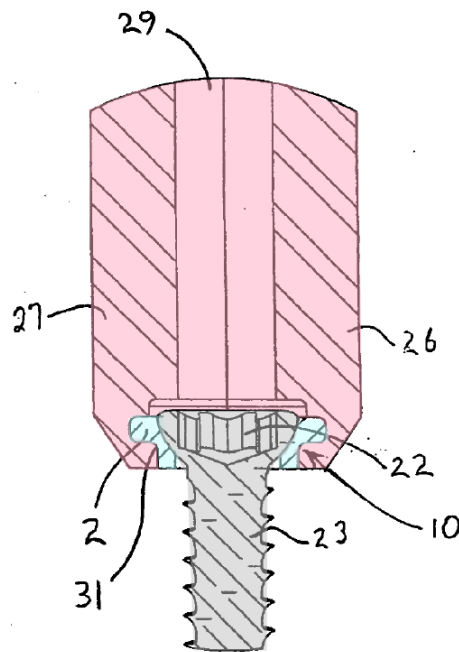


FIG. 20

In one example arrangement, it would have been obvious to include features like Hartdegen's "means 1120" on each of its inserter tubes 102a, 102b as a known alternate attachment means that would facilitate use of the stepped profile bone plate to incorporate its benefits of minimizing tissue damage while also taking advantage of the engagement structure enabling bone plate forming as taught by Orbay. Ex.1002 ¶¶275–276.

As explained in the combined teachings described above, distal portions of Hartdegen's manipulators would be engaged with notched profiles on the bone plate. Ex.1002 ¶277.

Claim 15 also recites "shifting proximal handle portions of the manipulators

together.” Hartdegen discloses this. As explained above regarding limitation 11[a] and claim 17, the tubes are pivoted from the orientation of Figure 2B, in which their proximal ends diverge, to the parallel orientation of Figure 1E. See §§V.A.2.a, V.A.6. That pivoting moves the proximal portions of the tubes, which are the portions the surgeon holds, toward each other. Ex.1005 ¶¶111–114; Ex.1007, 9–11. The combination with Orbay does not change this: Orbay’s engagement geometry would be used at the distal ends of Hartdegen’s tubes, and the tubes would still be pivoted by bringing their proximal portions together. Ex.1002 ¶278.

Accordingly, claim 15 would have been obvious in view of the combined teachings of Hartdegen and Orbay.

13. Claim 16

Claim 16 depends from claim 11 and recites, in relevant part, “positioning the bone plate using the manipulators while lobes of the bone plate are received in openings of the manipulators and the bone plate lobes and manipulators form mating, non-rotatable connections therebetween.”

This limitation would have been obvious for the reasons discussed above regarding claim 4, which recites similar features. See §V.C.4; Ex.1002 ¶280.

Accordingly, claim 16 would have been obvious over the combined teachings of Hartdegen and Orbay.

14. Claim 22

Claim 22 depends from claim 20 and recites that “positioning the deformed bone plate adjacent the bones using the manipulators includes maintaining end portions of the deformed bone plate having the through bores therein at least partially within openings of the manipulators.”

It would have been obvious to include a socket arrangement like Orbay’s for the reasons discussed above regarding claim 2. *See* §V.C.2. When using the socket arrangement, Hartdegen’s end portions of the deformed bone plate would be at least partially within openings of the manipulators. Obviousness of this arrangement is also supported for the reasons stated above regarding limitations 1[e], 7[f] and claim 4, for example. Ex.1002 ¶282.

Accordingly, claim 22 would have been obvious over the combined teachings of Hartdegen and Orbay.

15. Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in combining the teachings of Hartdegen and Orbay. The combination includes modifications of bone plate and mating manipulator geometries in devices having similar operating characteristics and involves no more than routine skill in the art. Ex.1002 ¶283.

As explained above, Hartdegen already discloses a plate-and-manipulator system that positions and secures a bone plate through cannulated tube members,

and Orbay discloses a stepped lip-and-socket engagement geometry performing the function of retaining and aligning a bone plate within a manipulator. Ex.1005 ¶111; Ex.1007, 9–10; Ex.1008 ¶¶65, 67. Because both structures are similar components that interface at the same bone-anchor-receiving portion of a bone plate, incorporating Orbay’s stepped/lip engagement geometry onto Hartdegen’s tube members would have amounted to no more than the use of a known engagement geometry to improve a similar device in the same way, yielding the predictable result of a secure, visualizable connection. Ex.1002 ¶284.

16. Summary

For at least these reasons, claims 1–10, 13, 15, 16, and 22 would have been obvious in view of Hartdegen and Orbay.

D. Obviousness of Claim 29 over Hartdegen and Mai

1. Claim 29

Claim 29 depends from claim 20 and recites “providing the deformed bone plate, wherein providing the deformed bone plate includes chilling the bone plate.”

The features of claim 20 are taught by Hartdegen for the reasons discussed above regarding claim 20. *See* §V.A.9; Ex.1002 ¶286. Hartdegen additionally explains that “[t]he ability of the implant to have multiple configurations may be a result of the material properties that have shape memory or super elastic properties or it may be a result of manipulation (mechanical, physical, chemical or otherwise)

of the implant to create a second configuration.” Ex.1005 ¶7; Ex.1007, 3; Ex.1002 ¶286.

A temperature-dependent change in a bone plate’s shape relates to a physical or thermomechanical property and would have been understood as one of the manipulations contemplated by Hartdegen. Moreover, deforming bone plates via chilling was well-known in the art as taught by Mai. Ex.1002 ¶287.

Mai teaches an osteosynthesis plate/clip “made of a thermoelastic martensitic alloy whose transformation temperatures are: martensitic transformation temperature M_s below 10°C [,] . . . austenitic transformation temperature A_s above 15°C ,” and which “is educated to take a rectilinear shape at a temperature below the martensitic transformation temperature M_s . . . and an undulated shape at a temperature above the austenitic transformation temperature A_s .” Ex.1009, Abstract; Ex.1002 ¶288.

Mai explains that “[f]or its positioning, the clip assembly is brought to a temperature below the martensitic transformation temperature[,]
[a]t this temperature, the connection base . . . and the two lateral branches . . . are rendered rectilinear,” after which “[t]he clip is then implanted in the rectilinear position,” and because “the temperature of the human body is above the austenitic transformation temperature, the clip deforms and adopts a shape defined by the shape memory already acquired.” Ex.1009, 5:5–16; Ex.1002 ¶289.

Mai further explains that to reverse this process, “it suffices to cool the clip to a temperature below the martensitic transformation temperature,” accomplished “by any suitable means.” Ex.1009, 5:24–29. Thus, Mai expressly teaches chilling a bone-fixation device made of a thermoelastic, shape-memory alloy below its transformation temperature to place it in a deformed, rectilinear (straight) configuration for insertion, and allowing the device to warm above that temperature to cause it to assume its final, compression-generating configuration (*i.e.*, the “chilling” step recited in claim 29). Ex.1002 ¶290.

It would have been obvious to include the known temperature deformation process of Mai as one of the manipulations contemplated by Hartdegen, and a POSA would have had reason to combine Mai’s teaching with Hartdegen’s implant with a reasonable expectation of success. Hartdegen already discloses that its implant may be made of a material having “shape memory or super elastic properties” and may be deformed to its first (deformed) configuration by “manipulation (mechanical, physical, chemical or otherwise).” Ex.1005 ¶¶7, 126; Ex.1007, 3, 14. Mai discloses that chilling is a known, art-recognized technique for placing a thermoelastic shape-memory bone-fixation device into its deformed, insertion-ready configuration. Ex.1009, Abstract. Applying Mai’s known chilling technique to Hartdegen’s shape-memory-capable implant would have amounted to the application of a known technique to a known device (method) ready for improvement to yield predictable

results, and would have required nothing more than routine skill because both references address the identical problem of placing a deformable orthopedic implant into a temporary configuration for insertion. Ex.1002 ¶¶291–293.

Moreover, a POSA would also have understood, independent of Mai, that shape-memory orthopedic implants of this era were commonly engineered with transformation temperatures selected to permit exactly this kind of chill-to-insert, warm-to-activate handling, which is a standard design and handling practice for shape-memory bone-fixation devices generally. Ex.1002 ¶294. Mai’s teaching of chilling the device below its martensitic transformation temperature to hold it in a deformed configuration therefore reflects conventional practice for shape-memory orthopedic implants, further confirming that a POSA would have expected to apply the same handling technique to Hartdegen’s shape-memory-capable implant as a simple substitution of one bone plate deformation technique for another and/or as a matter of routine design choice.

Accordingly, claim 29 would have been obvious over the combined teachings of Hartdegen and Mai.

2. Reasonable Expectation of Success

A POSA would have had a reasonable expectation of success in combining the teachings of Hartdegen and Mai. Both references address the same problem (*i.e.*, using the material properties of an implant to hold it in a temporary, deformed

configuration for insertion) and both recognize that a shape-memory or thermoelastic material can be manipulated between two configurations. Ex.1005 ¶¶7, 126; Ex.1007, 3–4, 14; Ex.1009, Abstract. Applying Mai’s well-known chilling technique to Hartdegen’s shape-memory-capable implant requires no more than routine skill, involves predictable results (a temperature-induced, reversible change in the implant’s configuration), and does not require any change in the basic function or principle of operation of either reference. Ex.1002 ¶295.

3. Summary

For at least these reasons, claim 29 would have been obvious in view of Hartdegen and Mai.

VI. STANDING

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

VII. STIPULATION

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

§II.A).

VIII. SECONDARY CONSIDERATIONS

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

IX. MANDATORY NOTICES

A. Real Party-In-Interest

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

B. Related Matters

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

Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and MIOS Marketing, LLC d/b/a RedPoint Medical 3D, C.A. No. 1:25-cv-01092-GBW (Dist. Del.);

IPR2027-00007;

IPR2027-00008; and

An *inter partes* review filed concurrently herewith directed to US Patent No. 10,932,833.

C. Lead and Backup Counsel Information

Petitioner provides the following designation of counsel, all of whom are

identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
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D. Service Information

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

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plavanway@fredlaw.com;

aarrubla@treace.net; and

rfredeking@treace.net.

X. CONCLUSION

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

Dated: October 14, 2026

Respectfully Submitted,

/Jeremy Plenzler/

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Counsel for Petitioner

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 14,000 words provided in 37 C.F.R. § 42.24(a)(1)(i). The word processing program used to prepare the Petition indicates that it contains 13,972 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a), (that is, the word count does not include the table of contents, table of authorities, the exhibit list, the claim listing, the certificate of service, or the certificate of compliance).

Dated: October 14, 2026

/Jeremy Plenzler/
Jeremy Plenzler (Reg. No. 56,432)

Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that on the 14th of October 2026, a complete and entire copy of the foregoing “PETITION FOR *INTER PARTES* REVIEW,” including any exhibits, was served to the below counsel of record for Patent Owner via USPS Priority Mail Express.

Fitch Even Tabin & Flannery, LLP
120 South Lasalle Street, Suite 200
Chicago, IL 60603

A courtesy copy was sent to Patent Owner’s litigation counsel Ali S. Razai at: ali.razai@morganlewis.com.

Dated: October 14, 2026

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