

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3D DIAGNOSTIX, INC.,
Petitioner,

v.

WATSON GUIDE IP LLC,
Patent Owner.

Case PGR2024-00040
U.S. Patent No. 11,806,209

**PETITION FOR POST-GRANT REVIEW OF
U.S. PATENT NO. 11,806,209**

CHALLENGING CLAIMS 1–3, 5–7, 10–14 AND 16–17

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PETITIONER’S EXHIBIT LIST

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1001	U.S. Patent No. 11,806,209
1002	File History of U.S. Patent No. 11,806,209
1003	Declaration of Douglas Erickson, DDS, MS
1004	Curriculum Vitae of Douglas Erickson, DDS, MS
1005	Provisional Patent Application No. 62/508,377
1006	U.S. Patent Application Publication No. 2017/0252126 to Llop (“Llop126”)
1007	<i>Watson Guide IP, LLC v. 3D Diagnostix, Inc.</i> , Case No. 1:24-10518-LTS, Dkt. No. 30 (D. Mass. July 8, 2024)
1008	China Patent Application Publication No. CN 105686886A to Sichuan University (“Sichuan”)
1009	Certified translation of Sichuan
1010	U.S. Patent Application Publication No. 2017/0265963 to Yau (“Yau”)
1011	U.S. Patent No. 9,504,533 to Groscurth (“Groscurth”)
1012	Scherer, “Clinical Demonstration: All-on-4 nSequence Guided Prosthetics Surgical Technique with Zest Anchors Chairside Attachment Processing Material”, https://www.youtube.com/watch?v=VOWRdFpfGI , posted October 23, 2015 (accessed May 21, 2024) (“Scherer”) (Part 1)
1013	Scherer, “Clinical Demonstration: All-on-4 nSequence Guided Prosthetics Surgical Technique with Zest Anchors Chairside Attachment Processing Material”, https://www.youtube.com/watch?v=VOWRdFpfGI , posted October 23, 2015 (accessed May 21, 2024) (“Scherer”) (Part 2)

Exhibit	Description
1014	File History of U.S. Patent No. 11,173,016 (excerpts)
1015	Declaration of Kathryn Talbot
1016	Internet Archive, http://nsequence.com , archived February 7, 2016 (accessed May 21, 2024)
1017	“Fundamentals of CHROME GuidedSmile”, downloaded from https://guidedsmile.com/get-your-introduction-to-chrome-guidedsmile-ebook-today/ on June 20, 2024
1018	Internet Archive, http://www.nsequence.com/2013/11/08/all-on-x-cases-immediate-provisionalization , archived March 10, 2016 (accessed June 28, 2024)
1019	Webpage printout: All-on-4® nSequence® Implant Surgical Technique Using Zest Chairside® Attachment Processing Material – YouTube, https://www.youtube.com/watch?v=VOWRdFpfGI , (accessed June 24, 2024)
1020	Webpage printout: “Why You Should Choose Metal Over Plastic”, https://www.youtube.com/watch?v=tlOWzK4h1Nc&t , posted April 15, 2021 (accessed July 10, 2024)

LISTING OF THE CHALLENGED CLAIMS

<i>Reference</i>	<i>Claim 1</i>
1.pre	A method of installing a multi-tooth dental prosthesis in a maxillary or mandibular position in a mouth of a patient, the method comprising:
1[a]	providing a dental prosthesis for the maxillary or mandibular positioning in the patient's mouth,
1[b]	utilizing a fixation base to serve as a mounting jig for a plurality of other dental guides comprising a first dental guide and a second dental guide, wherein the fixation base comprises
1[c]	a generally arcuate shape with a front surface that has a plurality of openings through which fasteners can be passed, a rear surface, and a horizontal surface;
1[d]	utilizing the first dental guide, wherein the first dental guide is a mouthpiece that attaches to the fixation base and
1[e]	configured and dimensioned to surround at least a portion of the teeth of the patient and
1[f]	is used to assure appropriate location to attach the fixation base to the maxillary or mandibular bone tissue of said patient;
1[g]	installing the fixation base to the maxillary or mandibular bone tissue of said patient;
1[h]	removing the mouthpiece from the installed fixation base;
1[i]	removing at least one of natural teeth, dental fixtures, and obstructive mouth tissues from the work site, to expose an underside of the maxillary or mandibular bone tissue;
1[j]	recontouring the bone tissue;
1[k]	utilizing the second dental guide, wherein the second dental guide is a drill guide that attaches to the installed fixation base to assure appropriate location and orientation of holes to be drilled for the subsequently installed implants;
1[l]	drilling the implant holes in the bone tissue using the drill guide attached to the fixation base;

1[m]	installing implants in the implant holes;
1[n]	installing the abutments to the implants; and,
1[o]	installing said dental prosthesis to the abutments.
Reference	Claim 2
2	The method of claim 1, wherein installing the fixation base to maxillary or mandibular bone tissue of the patient further comprises driving fasteners through the fixation base into the bone tissue to secure the fixation base to the maxillary or mandibular bone.
Reference	Claim 3
3	The method of claim 1, wherein the step of recontouring the bone tissue comprises using a preformed surface on the installed fixation base to assure proper recontouring of the bone tissue.
Reference	Claim 5
5	The apparatus of claim 1, further comprising the step of: utilizing a third dental guide, wherein the third dental guide is an abutment guide base that attaches to the installed fixation base to assure appropriate location for the installed abutments.
Reference	Claim 6
6	The method of claim 5, wherein installing the abutments includes adjusting the abutments to appropriate angular orientations relative to a central axis of associated implants using pre-established indicators on the abutment guide base.
Reference	Claim 7
7[pre]	An apparatus for installing a dental prosthesis to maxillary or mandibular jaw bone of a patient, the apparatus comprising:
7[a]	a fixation base for providing an attachment surface for a dental guide used during a dental prosthesis installation procedure, the fixation base further comprising
7[b]	a generally arcuate base member with a front surface that includes a plurality of openings through which fasteners can be passed, a rear surface, and a horizontal surface; and

7[c]	a first dental guide, wherein the first dental guide is a mouthpiece configured and dimensioned to surround at least a portion of the teeth of the patient and
7[d]	to attach to the fixation base and
7[e]	to be removed after the fixation base is affixed to the maxillary or mandibular bone structure of a patient.
Reference	Claim 10
10	The apparatus of claim 7, further comprising a second dental guide attachable to the fixation base, wherein the second dental guide is a drill guide for guiding the drilling of holes for implants, wherein the drill guide includes a plurality of generally vertical bores corresponding in location to and in axial registry with intended implant sites.
Reference	Claim 11
11	The apparatus of claim 10, wherein the drill guide is made from a metal, metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure and comprises a support bar, a plurality of bosses with one boss for each one of the vertical bores, the bosses located rearwardly of the support bar and attached to the support bar by arms such that voids exist between the bosses and the support bar, the voids enabling direct observation of patient anatomy and insertion of irrigation and evacuation apparatus.
Reference	Claim 12
12	The apparatus of claim 7, further comprising a third dental guide attachable to the fixation base, wherein the third dental guide is an abutment guide oriented to receive abutments and guide the abutments for placement against the implants.
Reference	Claim 13
13	The apparatus of claim 7, wherein the fixation base is made from a metal, metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure.

<i>Reference</i>	<i>Claim 14</i>
14	The apparatus of claim 7, wherein the fixation base further comprises a surface to assist in recontouring of bone tissue.
<i>Reference</i>	<i>Claim 16</i>
16	The apparatus of claim 7, further comprising a dental prosthesis, wherein the dental prosthesis attaches to the installed fixation base.
<i>Reference</i>	<i>Claim 17</i>
17[pre]	A method of installing a fixation base in a maxillary or mandibular position in a mouth of a patient, the method comprising:
17[a]	utilizing a fixation base for providing an attachment surface for a dental guide used during a dental prosthesis installation procedure, wherein the fixation base comprises
17[b]	a generally arcuate shape with a front surface that has a plurality of openings through which fasteners can be passed through, a rear surface, and a horizontal surface;
17[c]	utilizing a mouthpiece configured and dimensioned to surround at least a portion of the teeth of the patient;
17[d]	attaching the mouthpiece to the fixation base;
17[e]	installing the mouthpiece onto at least some surfaces of the maxillary or mandibular portion of the mouth of the patient to assist in positioning the fixation base appropriately prior to installing the fixation base to maxillary or mandibular bone tissue of the patient;
17[f]	installing the fixation base to the maxillary or mandibular portions of the patient using fasteners through said plurality of openings in said front surface of the fixation base; and,
17[g]	removing the mouthpiece from the fixation base.

I. INTRODUCTION

Petitioner 3D Diagnostix, Inc., requests post-grant review (“PGR”) and cancellation of claims 1–3, 5–7, 10–14 and 16–17 (“Challenged Claims”) of U.S. Patent No. 11,806,209 (“the ’209 Patent”) (EX1001), which is on its face is assigned to Watson Guide IP LLC (“Patent Owner”).

This Petition presents non-cumulative grounds of invalidity not considered during prosecution. For example, claims 11 and 13 lack written description for a “drill guide” and “fixation base” that are “made from a metal, metallic alloy, *composite, polymer*, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure” (EX1002, 74–75), which was added during prosecution. The specification discloses that metal is used for these components, and the Applicant expressly disclaimed claim scope that would cover acrylic or plastic material in the provisional application incorporated into the specification. EX1005, 20, 26–27. In addition, the language referring to “material that is sufficiently strong enough to withstand breakage” renders these claims indefinite. EX1002, 74–75.

The Challenged Claims would also have been obvious. They relate to a surgical guide and mouthpiece used in guided dental implant surgery. Numerous prior art references disclose similar guides as in the ’209 Patent claims. During

prosecution, the Applicant distinguished the claims from prior art based on use of a mouthpiece “configured and dimensioned to surround at least a portion of the teeth of the patient.” EX1002, 166–168, 181–183. In fact, closely related prior art not considered by the Patent Examiner disclosed such a mouthpiece.

A. Related Proceedings

Patent Owner, and its exclusive licensee, GuidedSmile, LLC, sued 3DDX for infringement of three related patents: the ’209 Patent; its parent, U.S. Patent No. 11,173,016 (“the ’016 patent”); and its child, U.S. Patent No. 11,576,755 (“the ’755 patent”). The Complaint was served on April 4, 2024. The ’016 patent was the subject of IPR2023-00177. Petitioner is the real party in interest in this proceeding, and was not involved in IPR2023-00177.

II. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.204(a), Petitioner certifies the ’209 Patent is available for PGR, and Petitioner is not barred or estopped from requesting PGR of the ’209 Patent on the grounds identified herein. This PGR is timely and not barred or estopped under 35 U.S.C. § 325.

III. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.204(b), Petitioner requests PGR on Grounds 1–8 and cancellation of claims 1–3, 5–7, 10–14 and 16–17 of the ’209

Patent under 35 U.S.C. § 321 and 37 C.F.R. § 42.200 *et seq.* Petitioner requests the claims be canceled as unpatentable under 35 U.S.C. §§ 103 and 112 as follows:

Ground	Statute	References	Claims
1	35 U.S.C. § 112(a) (written description)		11, 13
2	35 U.S.C. § 112(b) (indefiniteness)		11, 13
3	35 U.S.C. § 103	Llop126 and Sichuan	1–3, 7, 10, 13–14, 16–17
4	35 U.S.C. § 103	Llop126 and Sichuan and Groscurth	1–3, 7, 10, 13–14, 16–17
5	35 U.S.C. § 103	Llop126 and Yau	1–3, 7, 10, 13–14, 16–17
6	35 U.S.C. § 103	Llop126 and Yau and Groscurth	1–3, 7, 10, 13–14, 16–17
7	35 U.S.C. § 103	Llop126 and Sichuan and Scherer	5, 6, 12
8	35 U.S.C. § 103	Llop126 and Sichuan and Scherer and Groscurth	5, 6, 12

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.204(b)(4) and (5), a full statement of the reasons why the claims of the '209 Patent should be held

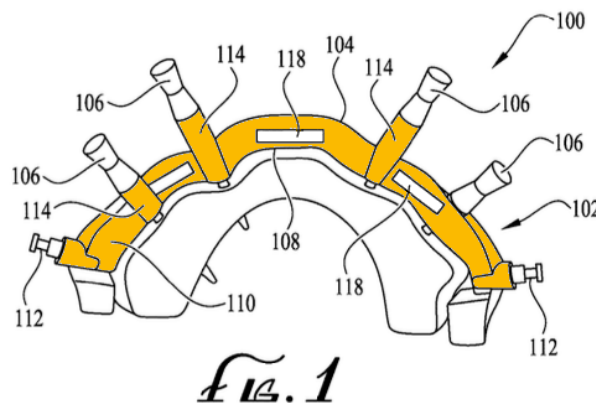
unpatentable is provided herein. Petitioner relies on the exhibits identified herein, including the prior art noted above and the expert Declaration of Dr. Douglas Erickson (EX1003, EX1004).

IV. THE '209 PATENT

The '209 Patent, entitled “Fixation Base and Guides for Dental Prosthesis Installation,” issued on November 7, 2023. As explained below, because its earliest possible effective filing date is after March 16, 2013, the AIA applies.

A. Overview

The '209 Patent is directed to apparatus and methods for installing a multi-tooth dental prosthesis in a guided oral surgery procedure. EX1001, Abstract. The dental procedure uses a “fixation base 100” (shown in gold below) that is attached to a patient’s jawbone, either of the upper or lower jaw. *Id.*, 1:37–43, 3:63–4:4, Figs. 1, 2.



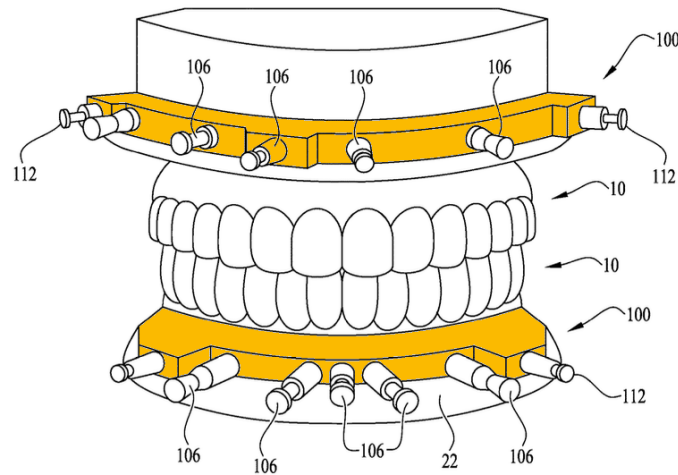


Fig. 2

The fixation base is used as a reference position for placement of subsequent guides. *Id.*, 1:38–43, 4:29–33.

The fixation base is attached to the jawbone using a “mouthpiece” (122). *Id.*, 1:43–45, Fig. 4. The mouthpiece is initially attached to the fixation base and is placed over the existing teeth to assist in locating the fixation base, and is removed after the fixation base has been installed. *Id.*, 1:43–49, 5:7–12, 8:1–18, Fig. 12c (mouthpiece shown below, in green).

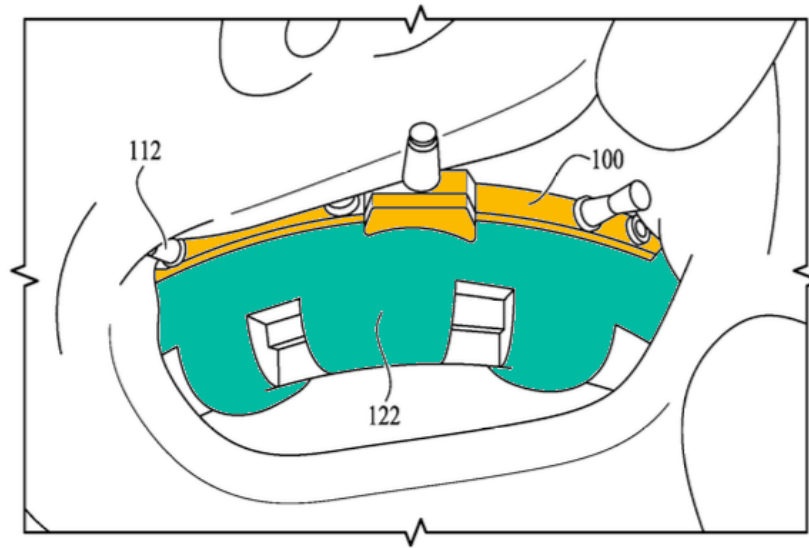


Fig. 12C

The practitioner in sequence attaches various “guides” to the installed fixation base 100. These include a “bone reduction guide” (142), a “drill guide” (124) and an “abutment guide” (136). *Id.*, 5:52–63, Fig. 7, 1:63–64, Fig. 5A, Fig. 5B, 1:57–58, Fig. 6.

Either the bone reduction guide 142 or the fixation base itself is used as a reference plane during removal of existing teeth and leveling of the bone, as shown in Fig. 12F, reproduced below. *Id.*, 1:50–56, 7:5–20, Figs. 12E, 12F.

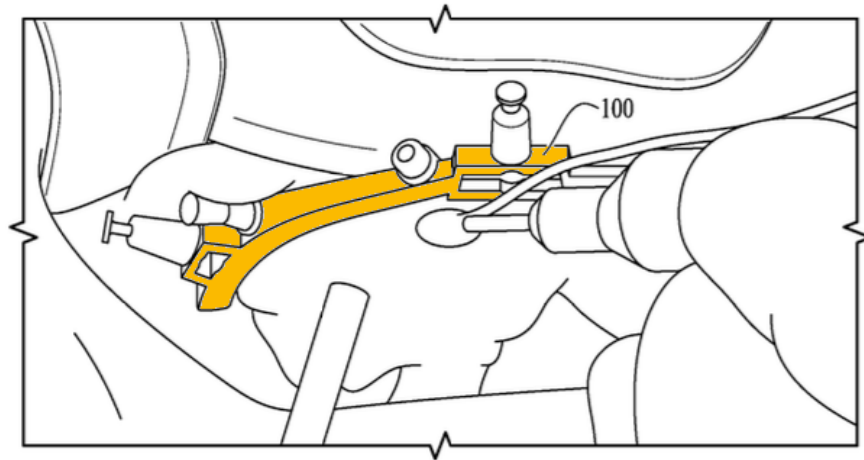


Fig. 12F

After the jawbone has been leveled, the practitioner attaches the drill guide 124 to the fixation base to confirm proper location of drill holes in the patient's mouth. *Id.*, 1:63–67, 5:18–20, Fig. 12I (drill guide shown below, in grey). The practitioner then drills and installs implants into the drilled holes. *Id.*, 1:65.

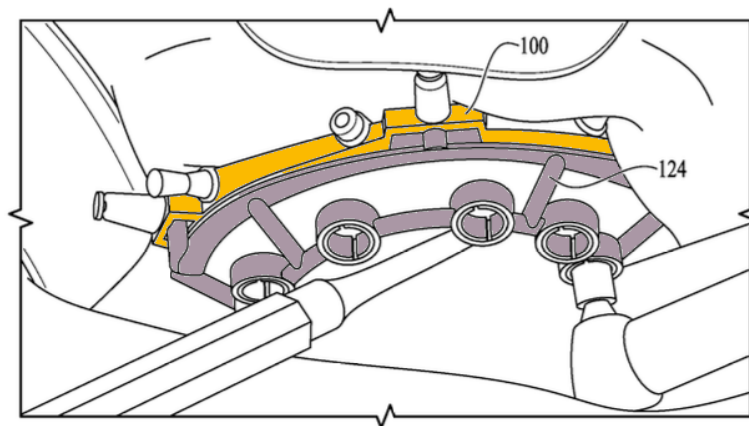


Fig. 12I

The drill guide is removed, and an abutment guide attaches to the fixation base and is used to place abutments at appropriate angles. *Id.*, Abstract, 1:57–62, 7:21–29, Fig. 12L (below, in red).

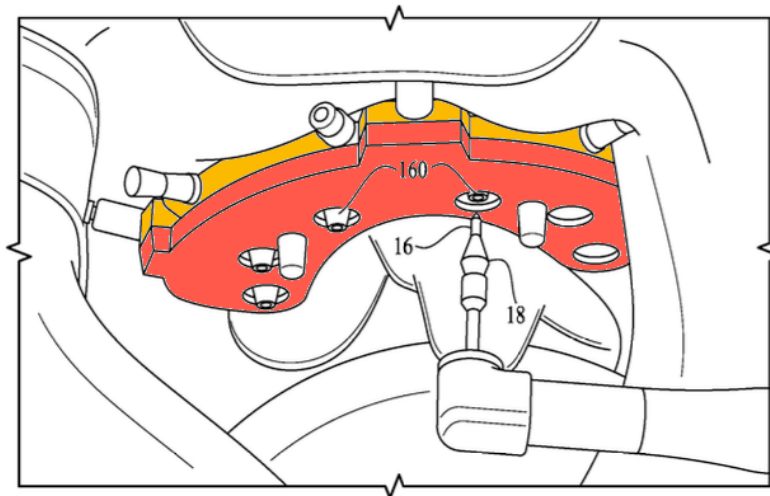
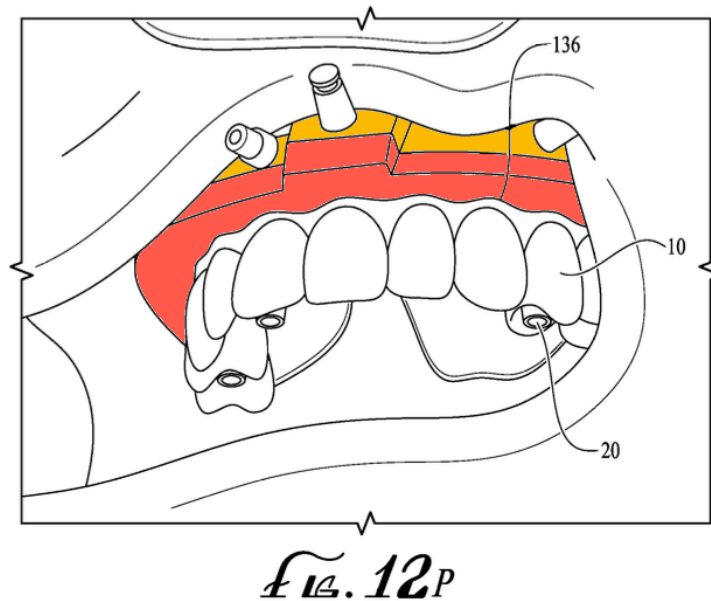


Fig. 12L

The practitioner then uses the abutments and the abutment guide to install copings and place the prosthetic in the patient's mouth. *Id.*, 2:5–11, Fig. 12P.



The fixation base and abutment guide are thereafter removed, restorative surgery steps are performed, and the prosthetic is secured in place for use. *Id.*, 2:8–14.

B. The Prosecution History

The '209 Patent issued on November 7, 2023, from U.S. Patent Application No. 17/503,359 (“the '359 application”), filed on October 18, 2021. The '359 application is a continuation of U.S. Patent No. 11,173,016 (“the ‘016 patent”), filed as U.S. Patent Application No. 15/984,309 (“the '309 application”) on May 18, 2018. The '309 application claims priority to U.S. Provisional Patent Application No. 62/508,377 (“the '377 provisional application”), filed on May 18, 2017. Both the '016 patent specification and '377 provisional application are incorporated by reference into the '209 Patent specification. EX1001, 1:7–11.

Applicant introduced new matter into amending application claim 11 (by preliminary amendment) to broaden the types of materials that could be used for the drill guide. It was amended to recite that “the drill guide is made from a metal, [[or]] metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure.” EX1002, 70–76. Applicant also presented new claim 15 (now claim 13) with a similar limitation regarding the fixation base. *Id.*

On February 9, 2023, claims 1–3, 5–16 and 18 were rejected as anticipated by U.S. Patent Application Publication No. 2017/0252126 to Llop (“Llop126”). Claims 4 and 17 were rejected as obvious over the combination of Llop126 with another Llop patent. EX1002, 119–135. In determining that Llop126 disclosed each claim element, the Examiner noted, “Regarding claim 8, Llop[126] discloses further including a first dental guide (42), wherein the first dental guide (42) is a mouthpiece configured and dimensioned to surround teeth of the patient (due to its U-shape it is capable of surround a tooth or teeth when installed in the mouth of the patient) and to releasably attach to the fixation base (20) and to be removed after the fixation base (20) is affixed to the maxillary or mandibular bone structure of a patient (see annotated Fig. 12 and 14 above).” *Id.*, 128. The Examiner’s analysis is reproduced below.

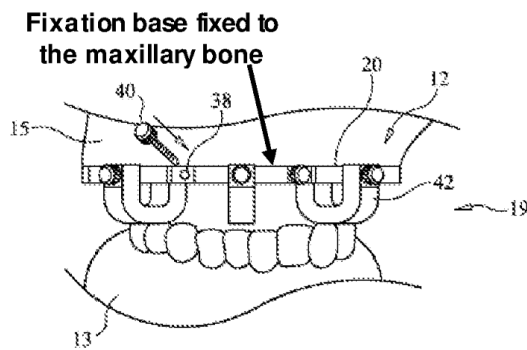


FIG. 12

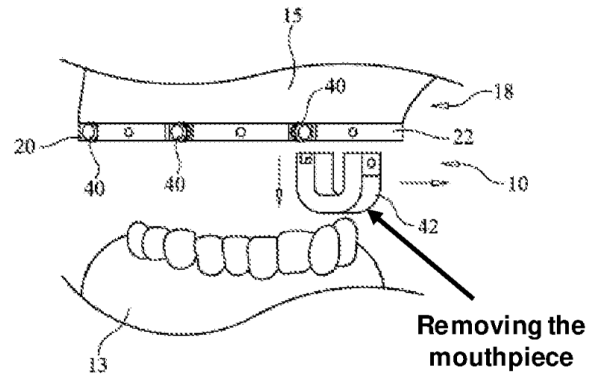


FIG. 14

In response, Applicant proposed the “mouthpiece” limitation be included in the independent claims, to require that it be “configured and dimensioned to surround teeth of the patient.” EX1002, 147–150. Applicant then explained that such amendment was “fully consistent with the term ‘mouthpiece.’” It distinguished the claimed “mouthpiece” from the Llop126 “anchoring strut” by arguing that the “hand and glove” relationship of its claimed mouthpiece to the patient’s existing teeth permits accurate placement of the fixation base. *Id.*, 166–67. According to Applicant, “In contrast, Llop ’126 removes the teeth of the patient *prior* to positioning its ‘fixation base.’ As a result, Llop ’126 does *not* utilize a mouthpiece ‘configured and dimensioned to surround teeth of the patient’ because there are no teeth to utilize. Instead, as mentioned above, Llop ’126 utilizes an ‘anchoring strut’ which is not ‘configured and dimensioned to surround teeth of the patient.’” *Id.* (emphasis in original). Applicant relied on this supposed difference to distinguish the Llop126 reference and other cited art. *Id.*, 165–168.

Applicant then attempted to broaden the “mouthpiece” by adding “configured and dimensioned to surround at least a portion of the teeth of the patient,” and reiterated the previous argument as to the updated claim language. *Id.*, 173–183.

As a result, the Examiner withdrew the anticipation and obvious rejections based on Llop ’126, but added nonstatutory double patenting rejections over the parent ’016 patent. EX1002, 184–191. Claim 15 (now claim 13) was rejected as obvious over the combination of the ’016 patent and U.S. Patent No. 5,320,539 to Pompa (“Pompa”). *Id.*, 189. Pompa was added to the combination because “U.S. Patent No. 11173016 B2 does not disclose that fixation base is made from a metal, metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure.” *Id.* Applicant filed a terminal disclaimer, thereby acquiescing in the determination of the Examiner. *Id.*, 201–218.

The Examiner stated in the reasons for allowance that “the added language in the claim,” and “specifically that the first dental guide is configured and dimensioned to surround at least a portion of the teeth of the patient” distinguished the claims over Llop126. *Id.*, 224. The ’209 Patent issued on November 7, 2023. EX1001.

V. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSA”) pertinent to the ’209 Patent as of its earliest priority date would at least have had a doctoral degree in dentistry and at least three to four years of experience working with guided dental surgery for installing dental implants and prostheses. EX1003, ¶ 49.

VI. CLAIM CONSTRUCTION

The Board generally gives claim terms their ordinary and customary meaning, as would have been understood by a POSA at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc); 37 C.F.R. § 42.200(b). Resolution of the following claim construction issues is required to resolve certain of the unpatentability grounds presented herein:

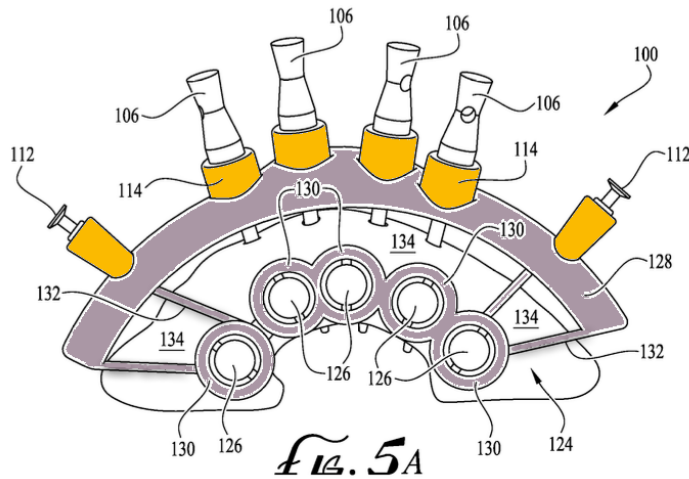
<u>Claim term</u>	<u>Claims</u>	<u>Proposed Construction</u>
“drill guide”	1, 10, 11	drill guide made from metal or metallic alloy without traditional plastic or acrylic

“fixation base”	1–5, 7–10, 12–17	fixation base made from metal, metallic alloy or other strong material without traditional plastic or acrylic
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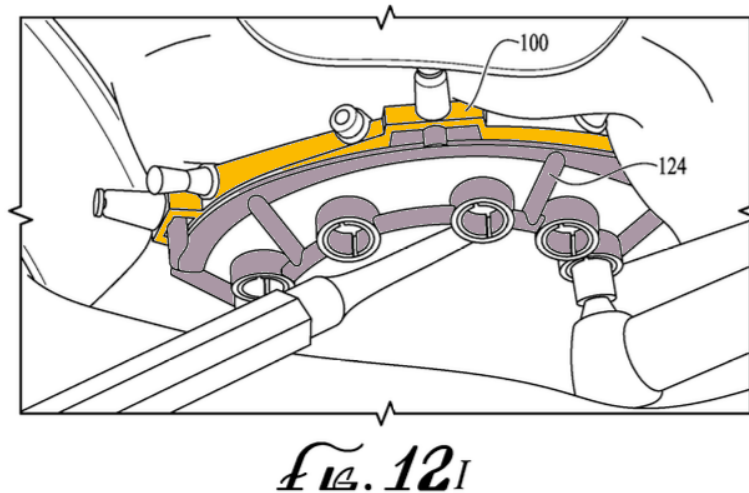
A. “Drill guide”

The term “drill guide” should be construed to be “made from metal or metallic alloy without traditional plastic or acrylic,” based on disclaimer of claim scope in the provisional application incorporated into the patent specification.

The ’209 Patent specification teaches that the composition of the drill guide is “a metal or metallic alloy.” EX1001, 5:35–36. No other alternatives are provided. Instead, the patent teaches that a metal composition for the drill guide permits the guide to contain “voids 134” (not colored in the graphic below) between the “support bar 128” and “bosses 130” supported by “arms 132.” *Id.*, 5:37–43. This allows “direct observation of patient anatomy and insertion of irrigation and evacuation apparatus.” *Id.*



Dr. Erickson explains that, while a series of struts 132 forming a web may expose a greater area between the frame and guide holes, this structure introduces undesirable weakening and flexing. EX1003, ¶¶ 54–56. That is particularly true at or near the locations where the struts connect to the respective frame and guide holes as the practitioner performs the attachment and drilling procedures. *Id.* The disclosed drill guide 124 has a specific configuration to allow the practitioner to visually observe the site at which the implants will be inserted. *Id.* The drill guide has a series of struts 132 to expose the area between the frame and guide holes. *Id.*



Consistent with the patent teachings, a POSA would have understood the particular drill guide structure would be composed of metal or other rigid material in order to withstand the flexing and weakening. *Id.*

The '377 provisional application, which is incorporated into and forms a part of the '209 Patent specification, confirms that the drill guide is composed of metal:

- “Actual, **Chrome Implant Drill Guide**” (EX1005, 13);
- “the use of 3D printed or CNC machined **chrome or similar metals** are also used for the sequential guides **for rigidity and strength**” (*Id.*, 28);
- “Guide#3 drill guide...**3D printed in Chrome cobalt.**” (*Id.*).

The provisional application contemplates no other materials to be used for the drill guide. It further explains that conventional plastic is unsuitable for the invention due to its tendency to fracture and break:

“The drill guide is also in metal to further support the invention. **Implant dentistry widely uses plastic for the implant drill guides, fixation sites are notorious for breakage with binding and flexing, under drilling pressure they could fracture and break** and because sufficient material is needed around the drill sites surgeons drill blindly into the patient's bone. **In this invention the chrome material allows the drill guide to be designed with limited material to support the drilling sites** thus allowing the surgeon to see drill to bone contact and implant insertion.”

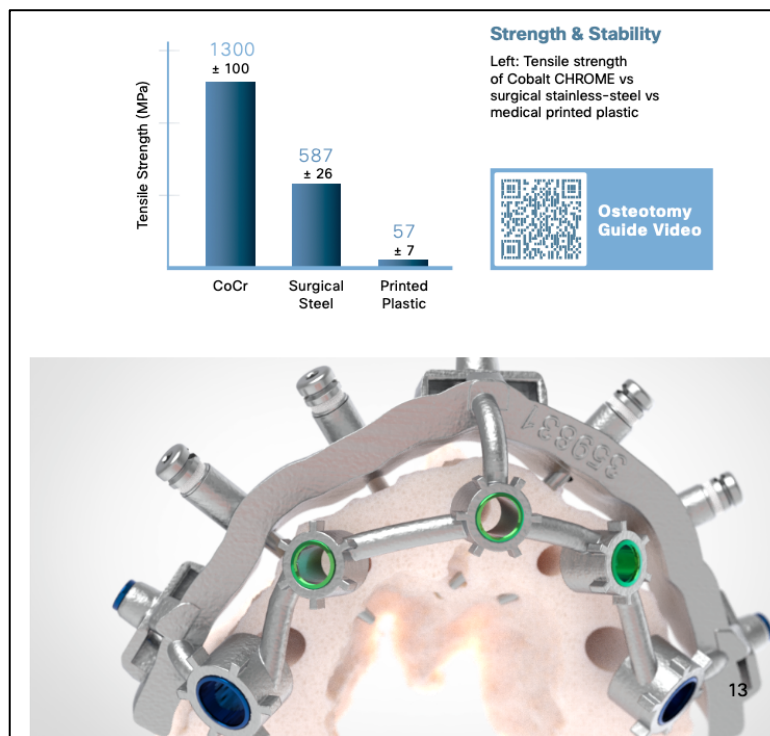
Id., 26–27 (emphasis added). That metal is required for the “invention” is set forth in terms that are unqualified and without restriction.

When the specification “makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent,” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). More recently, in *Indivior Inc. v. Dr. Reddy’s Laboratories, SA*, 930 F.3d 1325 (Fed. Cir. 2019), the court decided that a specification’s “unambiguous disparagement of conventional” methods, along with the applicant’s characterization of the invention during prosecution, resulted in a disclaimer of any claim scope that included conventional methods. *Id.* at 1338–39. See also, *Akeva L.L.C. v. Nike, Inc.*, 817 F. App’x 1005, 1009–1010 (Fed. Cir. 2020), *cert. denied* 141 S.Ct. 1386.

The ’209 Patent specification (including the incorporated ’377 provisional application) disparages plastic and limits the invention to a drill guide composed of

metal. The Applicant disclaimed any scope of a “drill guide” that would include being made from plastic, or any other traditional material other than metal or metallic alloys.

Extrinsic evidence supports such a construction. Patent Owner’s exclusive licensee markets its drill guide and fixation base products as being “unique in the industry for its strength, size and rigidity” due to their composition of metal, rather than traditional plastic. EX1017, 18. For example, the marketing literature compares tensile strength of metal to plastic:



Id. The literature identifies metal as being critical to product superiority. *Id.*, 6 (“Metal guides allow full visualization of drills and implant sites”), 7 (“Metal

guides streamline surgical and restorative processes for less chairtime”), 8 (“Core components of the CHROME GuidedSMILE system are made of strong a CoCr alloy resulting in a guide with smaller oral footprint when compared to plastic guide systems.” “...removes the significant patient discomfort caused by larger pins required by other non-metal guided systems.”), 9 (“Metal guides do not flex or break under the pressures of surgery”), 15 (“The metal alloy used for both guides (CoCr) is 20x stronger than surgical resin. It does not flex or break under pressure during surgery, resulting in accurate implant placement. Bone leveling is guided using the flat plane of the metal Fixation Base, ensuring precise bone reduction. Burs do not grind material as with plastic guides.”). Patent Owner’s licensee published a YouTube video entitled, “Why You Should Choose Metal over Plastic.” EX1020.

The present case is therefore distinguishable from *MPHJ Tech. Investments, LLC v. Ricoh Americas Corp.*, 847 F.3d 1363 (Fed. Cir. 2017). *MPHJ* involved a claim construction based on the “broadest reasonable interpretation” standard, that considered additional language added to the patent specification clarifying that the scope of the invention described in a provisional had been broadened. *Id.* at 1364, 1369 (the patent specification’s “removal of [the provisional’s] limiting clauses” was therefore “significant.”). Nor did *MPHJ* involve an *express* disclaimer, as is

present in the '377 provisional application. *See, e.g., Osteoplastics, LLC v. ConforMIS, Inc.*, No. CV 20-405 (MN) (JLH), 2022 WL 610738, at *8 (D. Del. Feb. 14, 2022). By contrast, the '209 Patent describes the drill guide as being made from “a metal or metallic alloy,” consistent with the disclaimer in the '377 provisional application. EX1001, 5:35–41. A POSA would not find significance in any differences between the '209 specification and the incorporated '377 provisional application in understanding that the drill guide is made of metal. EX1003, ¶ 59.

The patentee’s unequivocal statements and consistent representation that the drill guide is made from metal, and not from conventional plastic, amount to a disavowal of claim scope. *Techtronic Indus. v. Intl. Trade Comm.*, 944 F. 3d 901, 907 (Fed. Cir. 2019) (“[W]here the inventor...has manifested that the invention does or does not include a particular aspect, that intention ‘is regarded as dispositive’ [and] the inventor has ‘disavowed’ claim scope.”) (internal citations omitted). Accordingly, “drill guide” should be construed as “drill guide made from metal or metallic alloy, and not made from conventional plastic or acrylic.”

B. “Fixation base”

The term “fixation base” should similarly be construed to be made from metal, metallic alloy or other strong material without traditional plastic or acrylic, based on a disclaimer of claim scope.

The '209 specification contains two sentences regarding the composition of the fixation base: “Fixation base 100 is non-anatomical, being fabricated from a metal, metal alloy, or other strong material. Fixation base 100 may be fabricated for example by three dimensionally printing using a chromium cobalt alloy.”

EX1001, 4:37-41. The specification provides no guidance as to what “other strong material” may suffice for the fixation base.¹ However, such “other strong material” excludes traditional plastic or acrylic.

The '377 provisional application consistently refers to the fixation base as being made from metal:

¹ Although claims 11 and 13 include limitations that the drill guide and fixation base, respectively, can be made from materials including “composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation,” this language was added by amendment during prosecution, after the original filing of the '209 Patent, and thus is not part of its specification. 37 C.F.R. § 1.115(a)(2). For this reason, these claims are invalid for lack of written description. See Ground 1 (Section VIII.A), *infra*.

<u>EX1005</u> <u>Citation</u>	<u>Metal Description of Fixation Base</u>
4	“... fixation base and select sequential guides 3D printed or CNC milled in chrome cobalt or similar strength metals , its design method and system.”
13	“Actual, Chrome Implant Drill Guide attached to the metal fixation base by the locking pins.”
28	“What is claimed is: 1. A fixation base (manufactured in metal for strength and rigidity). ”
24	“FIG. 1 illustrates the fixation base manufactured in chrome cobalt with locking pins (Guide1).”
24	“...bone reduction guide installed onto the metal base. ”
25–26	“The fixation base is created from the top end (non anatomical) part of the tooth borne reference guide. It is from here that all sequential guides are attached via the locking pins to complete all necessary steps. In this invention, the top portion of Guide 1 is designed in metal and the tooth borne area in a 3D printed acrylic. The two parts are conjoined by the locking pins and act as one unit in the first phase of the procedure. After this position is

	properly installed and fixated, the acrylic portion is then detached from the fixation base by the locking pins. (See FIG.2d.)”
26	“The metal fixation base can act as the bone reduction guide without the need to attach Guide 2.”

The provisional application expressly disclaims from the invention a fixation base made from traditional plastics and acrylics for the fixation base:

- “The fixation base is manufactured in a **very rigid material like metal** since this area is very thin and must support the forces being applied during the procedure. **This invention could not use traditional materials such as 3D printed or CNC milled acrylic widely used to produce full arch implant guides in the dental industry.** Within the thin tolerances needed it would surely fracture.” EX1005, 26 (emphasis added); see also *id.* at 20.

While the provisional application indicates that the fixation base may be made from “engineered resins that have sufficient strength at this minimal thickness to manufacture the base for rigidity and strength” (EX1005, 20–21), neither the provisional application nor the ’209 Patent specification provide any

additional information regarding “engineered resins.”² Nevertheless, a POSA would have understood that “engineered resins” do *not* include traditional plastics and acrylics that were in use at the time of the purported invention, because the Applicant expressly disclaimed those due to their *low* rigidity and strength. EX1003, ¶¶ 61–65. This is consistent with the patent teachings that a very thin fixation base should be utilized, and that it should provide increased visibility and access to the surgical site. EX. 1001, 7:2–4; EX1005, 20, 26; EX1003, ¶¶ 61–65. A POSA would not find significance in any differences between the ’209 specification and the incorporated ’377 provisional application in understanding that the fixation base is made without traditional plastic or acrylic. EX1003, ¶ 66.

The extrinsic evidence, including Patent Owner’s marketing materials, supports a construction that excludes traditional plastic or acrylic. EX1017, 18 (describing fixation base products as being “unique in the industry for its strength, size and rigidity” due to their composition of metal, rather than traditional plastic); see also EX1020.

² As discussed above, the ’377 provisional application was *not* incorporated into the parent ’016 patent. EX1014, 1. Any claim relying on material only now incorporated into the ’209 Patent from the provisional—including a fixation base made from an “engineered resin”—is thus not entitled to the benefit of any priority claim. *Hollmer v. Harari*, 681 F.3d 1351, 1355–58 (Fed. Cir. 2012). Instead, the effective filing date of such claims is the ’209 Patent’s filing date of October 18, 2021.

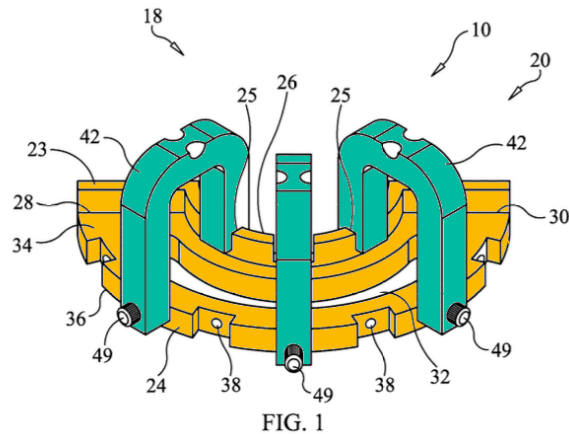
VII. DESCRIPTION OF THE PRIOR ART UPON WHICH THE CHALLENGE IS BASED

A. Llop126 (EX1006)

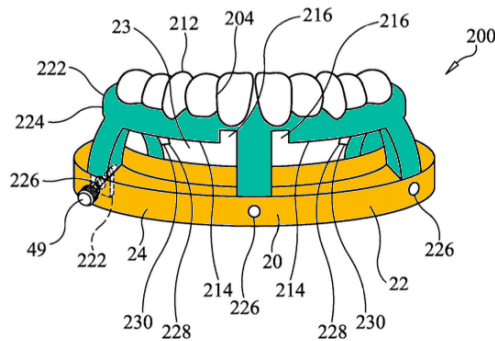
Llop126 qualifies as prior art to the '209 Patent under at least 35 U.S.C. § 102(a)(2) (AIA). Llop126 published under 35 U.S.C. § 122(b) on September 7, 2017. EX1006, Cover (43). Llop126 was filed on September 30, 2016, which is before the earliest effective filing date of the '209 Patent. *Id.*, (22).

Llop126, entitled “Bone Foundation Guide System and Method,” discloses a stackable dental implant surgical guide system. Llop126 discloses a method and apparatus for installing a dental prosthesis, including a generally arcuate fixation base (or bone foundation guide 20, shown in gold below) that is a mounting jig to support a plurality of subsequent dental implant surgical guides 50. EX1006, [0003]; EX1003, ¶ 69. The fixation base has a front surface with openings through which fasteners can be passed, a rear surface, and a horizontal surface. EX1003, ¶ 69.

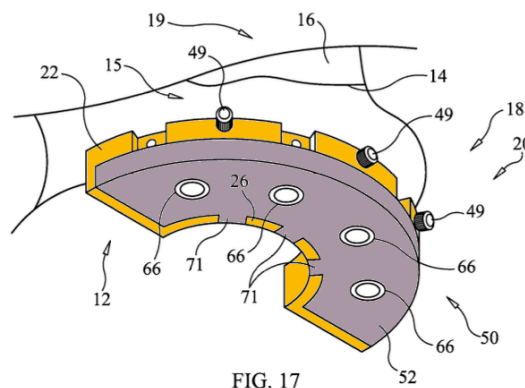
Llop126 discloses a set of “anchoring struts 42” (shown in green) that attaches to the fixation base. They are used to locate the fixation base to the bone tissue of the patient, and then are removed. EX1006, [0098]; EX1003, ¶ 70.



The anchoring struts 42 have indentations 46 at their apexes that match one or more portions of gum, dentition or both of the patient's first or opposing alveolar ridge. EX1006, [0098]. The anchoring struts 42 and indentations can be patient-specific. *Id.*, [0136]. The patient clamps down on the anchoring struts, matching the indentations 46, to ensure the bone foundation guide is properly positioned. *Id.*, [0099]. Alternatively, the bone foundation guide is removably attached to an initial prosthesis 200, and the patient bites on the prosthesis with the opposing alveolar ridge to place the bone foundation guide. *Id.*, [0128], Fig. 29.



Once the bone foundation guide 20 is properly positioned, it is secured to the patient's bone by body fasteners 40, and the anchoring struts 42 (or prosthesis 200) are removed. *Id.*, [0099]. The dental implant surgical guide 50 is then attached to the bone foundation guide and used to guide dental drill bits to create implant channels and insert implants. *Id.*, [0034], [0101], Fig. 17; EX1003, ¶ 71.



The dental implant surgical guide 50 is removed, and a tissue spacing gasket 80 is then mounted to the bone foundation guide 20, to allow proper spacing for placement of the prosthesis. EX1006, [0125], Figs 20–23; EX1003, ¶ 72.

The Examiner determined that Llop126 discloses the limitations of the Challenged Claims, except for a “mouthpiece” that “is configured and dimensioned to surround at least a portion of the teeth of the patient.” EX1002, 224. As explained below, it would have been obvious to modify Llop126’s anchoring struts (with indentations that conform to teeth) to include a mouthpiece configured and dimensioned to surround at least a portion of the patient’s teeth, as disclosed by

Sichuan or Yau, to provide greater stability to register a fixation base (or bone foundation guide).

B. Sichuan (EX1008, EX1009)

Sichuan qualifies as prior art to the '209 Patent under at least 35 U.S.C. § 102(a)(1) (AIA). Sichuan published on June 22, 2016, prior to the earliest effective filing date of the '209 Patent. EX1009, Cover (43). Sichuan was filed as Chinese patent application 201610012516.7 on January 8, 2016. *Id.*, Cover (21, 22). Sichuan was not submitted during the examination of the '209 Patent. EX1002.

Sichuan, entitled, “A subapical osteotomy locating guide plate and a manufacture method therefor,” discloses a system for positioning osteotomy guide plates for attachment to a patient’s jawbone, which provide a reference point for subsequent dental surgical operations. EX1003, ¶¶ 73–74. Sichuan teaches a positioning biteplate 1 (or mouthpiece) that is formed from tooth prints 11 of the patient. EX1009, *e.g.*, Abstract, Claims 6g, 8g.3, [0007], [0027], [0038], [0066]; see also EX1003, ¶ 75. The mouthpiece is configured and dimensioned to surround at least a portion of the teeth of the patient. EX1003, ¶¶ 74–75.

The biteplate 1 connects to osteotomy line guide plates 3 via connector rods 2. EX1009, *e.g.*, Abstract, Claims 1, 2, [0007], [0027], Fig. 1.

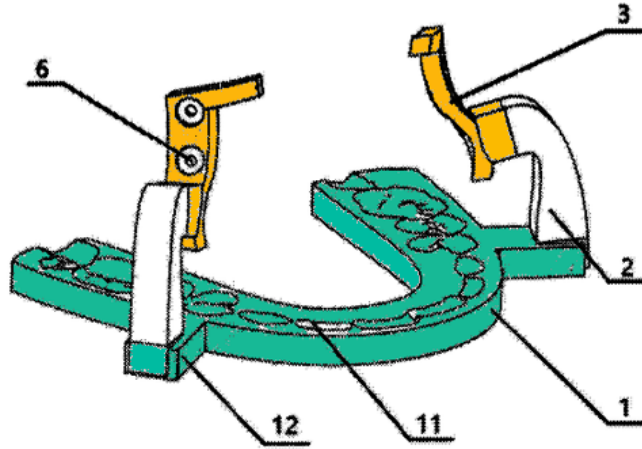


图1

Once positioned with the biteplate, the guide plates 3 are affixed to the patient's jawbone using screws through screw holes 6 in the guide plates. *Id.*, e.g., Abstract, Claims 1, 2, [0007], [0012]. The biteplate is attached to the guide plates via connecting rods 2, used to assure appropriate location of the guide plates. *Id.*, e.g., Abstract.

Once the guide plates have been affixed, the connector rods and biteplate can then be removed, leaving the guide plates in place to facilitate the osteotomy operation with cutting of the jawbone. *Id.*, [0049]; EX1003, ¶¶ 74–75. With the guide plates precisely fixed to the jawbone, the surgeon performs the osteotomy.

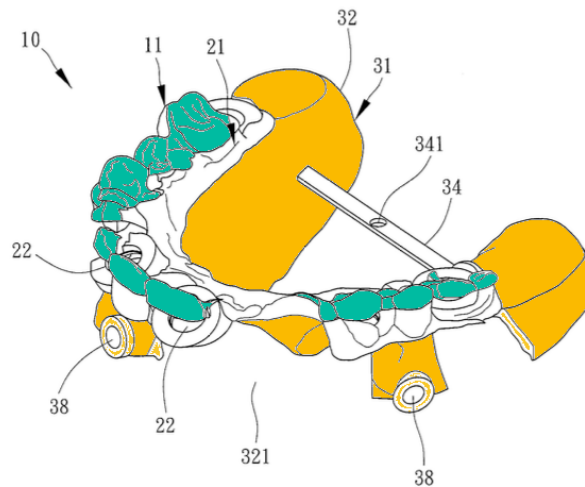
As explained below, it would have been obvious to modify Llop's system to include a mouthpiece as disclosed by Sichuan.

C. Yau (EX1010)

Yau qualifies as prior art to the '209 Patent under at least 35 U.S.C. § 102(a)(2) (AIA). Yau published under 35 U.S.C. § 122(b) on September 21, 2017. EX1010, Cover (43). Yau was filed on June 8, 2016, which is before the earliest possible effective filing date of the '209 Patent. *Id.*, (22). Yau was not submitted during the examination of the '209 Patent. EX1002.

Yau is entitled, “Dental Implant Surgical Guide,” and discloses a stackable set of components for use in installing dental implants. Yau discloses a fixation base providing an attachment surface for a dental guide, and a mouthpiece configured and dimensioned to surround a portion of the patient’s teeth. The mouthpiece assures appropriate location to attach the fixation base to the bone tissue of the patient. EX1003, ¶¶ 76–77.

Yau discloses an implant guide system with three members: an upper guide member including a tooth mold (shown in green below), and intermediate guide member including a guide portion (not colored below), and a lower guide member. EX1010, Abstract, Fig. 1; EX1003, ¶¶ 78–80.



The upper guide member 11 comprises a “tooth mold 12 [] adapted for tight engagement with the natural teeth or temporary dentures of the opposite jaw when the patient bites.” EX1010, [0007], [0017]. The upper guide member tooth mold 11 is formed as a one-piece member or may include multiple component parts. *Id.*, [0025], Fig. 2. The upper guide member 11 is secured to the intermediate guide member 21, which consists of holes (“guide portion 22”), which provide guidance during drilling or implant installation. *Id.*, [0007], [0023]. The intermediate guide is in turn secured to the lower guide member 31. *Id.*, [0007]. The lower guide member 31 is initially mated with the patient’s gingiva. *Id.*, [0007], [0022]. The patient then bites using the teeth mold, which in turn more precisely positions the lower guide member 31 relative to the patient’s gingiva. *Id.*, [0022]; EX1003, ¶ 80. The lower guide member is then fastened by means of friction resistance between mounting members 381 and the patient’s jawbone. EX1010, [0022]. The mounting

members 381 pass through mounting portions 38 of the lower guide member 31.

EX1003, ¶ 80.

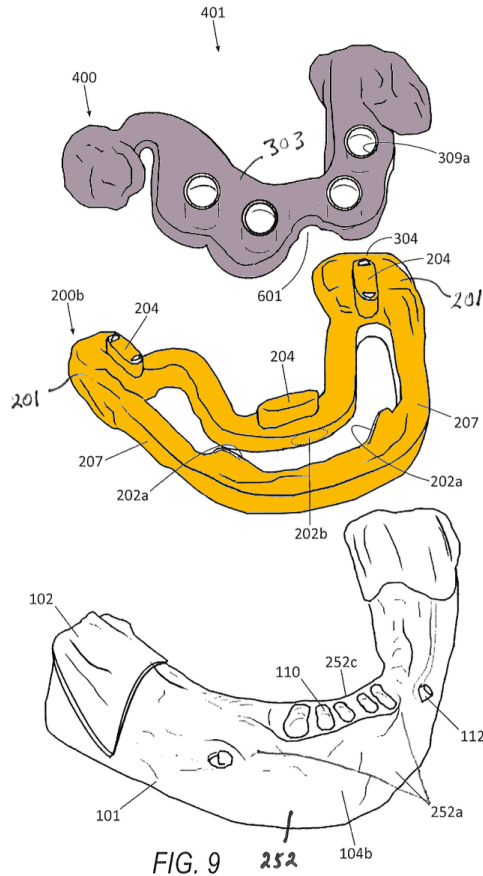
It would have been obvious to modify Llop's system to include a mouthpiece, as disclosed by Yau.

D. Groscurth (EX1011)

Groscurth qualifies as prior art to the '209 Patent under at least 35 U.S.C. § 102(a)(1) (AIA). Groscurth issued as a patent on November 29, 2016, which is before the earliest effective filing date of the '209 Patent. EX1011, Cover (45). Groscurth published under 35 U.S.C. § 122(b) as U.S. Patent Publication No. 2013/00071811 on March 21, 2013, and was filed as application 13/621,146 on September 15, 2012. EX1011, Cover (65, 21, 22).

Groscurth is entitled "Edentulous surgical guide" and discloses a stackable dental implant surgical guide system. *Id.*, (54), Abstract. Groscurth discloses a system for installing dental implants using a base frame 200 (shown in gold below) which is contoured to match the patient's exposed surgical area, and which may be anchored to the patient's jawbone using pins or fastening devices. EX1011, 5:5–14, 6:50–55, Figs. 1A–2D. The base frame thus is a fixation base. EX1003, ¶¶ 82–84. A denture attachment (not shown below) can be used on the base frame 200 to verify its position by biting while the base frame 200 is secured, and then the

attachment 500 is removed. EX1011, 13:37–42, Fig. 5. The base frame 200 accepts for attachment a drill guide housing frame 300 (shown in grey below). EX1011, 6:4–44, Figs. 3A–4D, Fig. 9.



Holes 306 on the drill guide 300 correspond with planned osteotomy sites, and are used for implant placement. EX1011, 7:24–31. Groscurth discloses that the base frame 200 may be made of metal or other material that provides sufficient rigidity and stability, and that the drill guide 300 may be made entirely of metal. *Id.*, 4:46–52, 13:1–4; EX1003, ¶¶ 85–86.

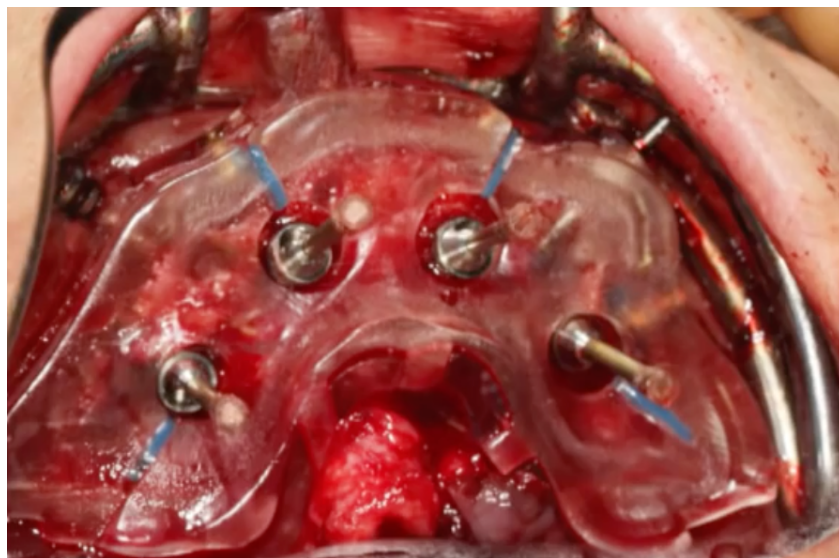
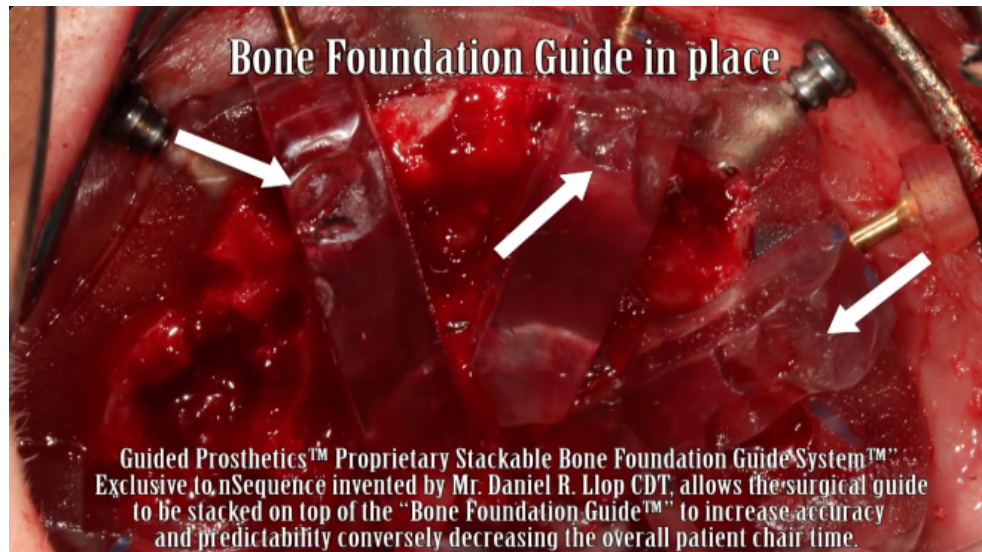
As explained below, it would have been obvious to compose the drill guide and fixation base of Llop126 of metal as disclosed by Groscurth.

E. Scherer (EX1012, EX1013)

Scherer qualifies as prior art to the '209 Patent under at least 35 U.S.C. § 102(a)(1) (AIA). Scherer is a video published on YouTube as of October 23, 2015, which is before the earliest effective filing date of the '209 Patent. EX1012, EX1013, EX1019, EX1015. Scherer was also available for viewing on the nSequence website no later than February 7, 2016. EX1016, EX1015; M.P.E.P. § 2128(II)(E). Accordingly, Scherer qualifies as prior art under 35 U.S.C. § 102(a). *See, e.g., Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1379-83 (Fed. Cir. 2018) (vacating Board's finding that a video was not sufficiently accessible to constitute a printed publication); *MerchSource, LLC v. DODOcase VR, Inc.*, PGR2018-00020, Paper 11, *18-19 (P.T.A.B. Aug. 22, 2018) (finding YouTube video to be a printed publication).

Scherer discloses a dental prosthesis installation procedure using the nSequence Guided Prosthetics Proprietary Stackable Bone Foundation Guide System, invented by Daniel Llop. EX1012, 1:58; EX1003, ¶¶ 87–88. Scherer discloses a bone foundation guide installed using removable struts with teeth-

matching indentations, a drill guide, and a marked abutment guide used for rotating abutments to their proper orientations. *Id.*, 1:58, 2:30, 4:30; EX1003, ¶¶ 89–90.



As explained below, it would have been obvious to implement the teachings of Scherer with those of Llop126.

VIII. DETAILED EXPLANATION OF GROUNDS FOR CHALLENGE

A. Ground 1: Claims 11 and 13 Lack Written Description

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that “clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (cleaned up). The disclosure of the application must reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter *as of the filing date*. *Id.* (emphasis added).

1. Claim 11

Claim 11 as originally presented indicated that “the drill guide is made from a metal or metallic alloy.” Applicant amended the claim as follows:

“The apparatus of claim 10, wherein the drill guide is made from a metal, ~~or~~ metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure...”. EX1002, 74.

There is no description for a drill guide that is composed of materials other than metal. The words “composite” and “polymer” do not appear in the specification. Instead, the specification teaches that the drill guide is “**made from a metal or metallic alloy**.” EX1001, 5:35-41; EX1003, ¶¶ 97–100.

As described above in Section VI regarding claim construction, the '377 provisional application, incorporated by reference into the '209 Patent specification in its entirety, similarly discloses a metal drill guide, and that the use of metal permits the guide to be constructed with “voids” to allow greater surgical visibility. *See, e.g.*, EX1005, 26–27 (“The drill guide is also in metal to further support the invention...In this invention the chrome material allows the drill guide to be designed with limited material to support the drilling sites thus allowing the surgeon to see drill to bone contact and implant insertion.”). The '377 provisional application consistently describes a metallic drill guide. EX1003, ¶ 101.

As discussed above, not only does the '209 Patent specification fail to disclose a “composite” or “polymer” drill guide, but the '377 provisional application disclaims the use of such materials. A POSA would have understood that such “plastic” materials are excluded from the scope of the invention. EX1003, ¶ 102. A POSA would have understood that the inventor did not possess a drill guide other than a metallic one. *Id.* Because claim 11 lacks written description for at least a composite or polymer drill guide, it is invalid under § 112(a).

2. Claim 13

Claim 13 was not presented in the '359 application as originally filed.

Rather, Applicant submitted that claim (as application claim 15) in a preliminary amendment:

“The apparatus of claim 6, wherein the fixation base is made from a metal, metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure.” EX1002, 75.

As with the drill guide in claim 11, the specification lacks description for a fixation base that is made from a “composite” or “polymer.” The specification instead discloses that the “[f]ixation base 100 is non-anatomical, being fabricated from a metal, metal alloy, or other strong material. Fixation base 100 may be fabricated for example by three dimensionally printing using a chromium cobalt alloy.” EX1001, 4:37–41. The specification provides no indication as to what “other strong materials” would qualify, and it does not provide “blaze marks” to indicate that the inventor considered composites or polymers to be within the scope of the claimed invention. *Purdue Pharm. LP v. Collegium Pharm., Inc.*, 86 F.4th 1338, 1346; EX1003, ¶¶ 104–107.

The incorporation by reference of the '377 provisional application confirms the exclusion of materials other than metal. The provisional consistently describes

the fixation base as being made from metal, and explains why metal is advantageous over other materials. *See* Section VI, *supra*; EX1003, ¶¶ 108–110. And, as discussed above, the '377 provisional application expressly warns against the use of traditional plastic materials for the fixation base, making clear that such materials are excluded from the claimed invention. *E.g.*, EX1005, 26 (“The fixation base is manufactured in a **very rigid material like metal** since this area is very thin and must support the forces being applied during the procedure. **This invention could not use traditional materials such as 3D printed or CNC milled acrylic** widely used to produce full arch implant guides in the dental industry. Within the thin tolerances needed it would surely fracture.”)

The provisional application does indicate that “3D printing using Selective Laser Sintering also known as SLS or CNC milling of chrome cobalt, titanium or similar metals or *engineered resins* that have sufficient strength at this minimal thickness to manufacture the base for rigidity and strength is being applied to this invention.” EX1005, 20 (emphasis added). However, as discussed above, the express disclaimer language in the provisional application dictates that “engineered resins” are to exclude *traditional or conventional* plastic or acrylic materials that were in use at the time of the '209 Patent’s effective filing date. A POSA would have understood the inventor intended to exclude such materials from the scope of

the invention. Neither the specification nor the '377 provisional application define “engineered resins” or suggest that such would include conventional composites and polymers.³ A POSA would not make this inference given the clarity of the inventor’s disclaimer. EX1003, ¶ 111.

The specification and the incorporated '377 provisional application indicate that the inventor did not possess a fixation base made of traditional plastic or acrylic materials, which are composites or polymers. EX1003, ¶ 110. Claim 13 is therefore invalid for lack of written description under § 112.

B. Ground 2: Claims 11 and 13 are Indefinite

The definiteness requirement focuses on whether “a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1260 (Fed. Cir. 2014) (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014)). Patent claims that do not are invalid under 35 U.S.C. § 112(b) for indefiniteness.

Dependent claim 11 has a term of degree that requires the drill guide to be “made from a metal, metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation

³ See FN2, *supra*, re the effective filing date of claims relying on the provisional application’s recitation of “engineered resins.”

procedure.” Dependent claim 13 similarly requires that “the fixation base is made from a metal, metallic alloy, composite, polymer, or any other material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure.” EX1001.

Claim language employing such terms of degree is definite only when “objective boundaries” are provided to one skilled in the art when read in the context of the patent specification. *Interval Licensing, LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). The phrase “sufficiently strong enough” covers a category of dental appliances that will withstand breakage during a prosthesis installation procedure and excludes others that will not. But the intrinsic record does not inform skilled artisans of any boundary between the two categories. The patent specification indicates that “[f]ixation base 100 is non-anatomical, being fabricated from a metal, metal alloy, or other strong material.” EX1001, 4:38-39. It further excludes such materials as traditional plastic or acrylic. EX1003, ¶¶ 60–67.

Dr. Erickson identifies the problem with use of such a term of degree, such as “sufficiently strong enough,” when only the end-points (metal vs. traditional plastic/acrylic) are identified. EX1003, ¶¶ 113–115. Whether a drill guide or fixation base will “withstand breakage during a prosthesis installation procedure”

depends on numerous factors, none of which are identified in the patent specification. *Id.*, ¶ 116. These include the size and shape of the fixation base and drill guide themselves, including the manner in which any build-up of material is provided at locations that are susceptible for failure. *Id.* Additional factors include the manner in which the particular prosthesis installation procedure is performed, depending on the experience and skill of the practitioner. *Id.* That is why, for example, a POSA would have understood the disclosed drill guide structure (made with struts that connect a frame to drill holes) to be limited to a metal composition. *Id.*

The ambiguity is compounded by the disclosure in the provisional application incorporated into the patent specification. It states that widely used “plastic for the implant drill guides” are to be excluded because they “are notorious for breakage with binding and flexing” and “under drilling pressure they could fracture and break.” EX1005, 26–27. The disclosure indicates that, because the fixation base is “very thin, traditional methods of 3D printing in plastic materials for dental surgical guides is not ideal because of low strength and high fracture probabilities at this thickness of design of the Fixation Base.” *Id.*, 20. Consistent with this disclosure, the Applicant explains that “a very rigid material like metal” must be used for the fixation base because “traditional materials such as 3D printed

or CNC milled acrylic” would “surely fracture.” *Id.*, 26. But the disavowed materials such as “3D printed or CNC milled acrylic,” have differing rigidity based on material choice, thickness and structural features. EX1003, ¶¶ 117–118. This creates an unresolved ambiguity as to what materials should be considered as “sufficiently strong enough” to withstand breakage. *Id.*, ¶ 119.

The intrinsic record illustrates the problem with a term of degree, such as “sufficiently strong enough to withstand breakage.” A skilled artisan is left with little more than a highly subjective understanding of the claim scope, particularly in evaluating a dental appliance that may undergo some elastic bending, which often occurs in these types of procedures. *Id.* Other than the end points, the specification and prosecution history contain no point of comparison for a skilled artisan to determine an objective boundary of “sufficiently strong enough to withstand breakage.” See *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1364 (Fed. Cir. 2018) (no points of comparison for “minimal” redundancy where example provided in patent specification exhibited no redundancy).

A claim is indefinite where it contains “a term that is ‘completely dependent on a person’s subjective opinion.’” *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) (finding the term “fragile gel” to be indefinite). Here, neither the specification or prosecution history provides any

guidance for whether a particular material can qualify as “sufficiently strong enough to withstand breakage during a prosthesis installation procedure.”

C. Ground 3: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over Llop126 and Sichuan

If the Board decides that “drill guide” and “fixation base” should not be limited according to Patent Owner’s express disclaimer of claim scope (*see* Section VI, *supra*)⁴, then claims 1–3, 7, 10, 13–14, and 16–17 would have been obvious to a POSA based on Llop126 in view of Sichuan. EX1003, ¶¶ 120–198.

1. Llop126 and Sichuan—Motivation to Combine

A POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a positioning mouthpiece as in Sichuan, to ensure proper placement of the fixation base relative to the surgical site. EX1009, [0003], [0005], EX1003, ¶¶ 121–133.

Llop126 and Sichuan are analogous to the subject matter of the ’209 Patent. *See Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335 (Fed. Cir. 2015); *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). Llop126 and Sichuan are in the

⁴ The Petition presents two alternative sets of obviousness grounds. Grounds 3, 5 and 7 are based on a construction of “drill guide” and “fixation base” that does not include the disclaimer of subject matter. Grounds 4, 6 and 8 are based on a claim construction that includes Patent Owner’s disclaimer of traditional plastic and acrylic.

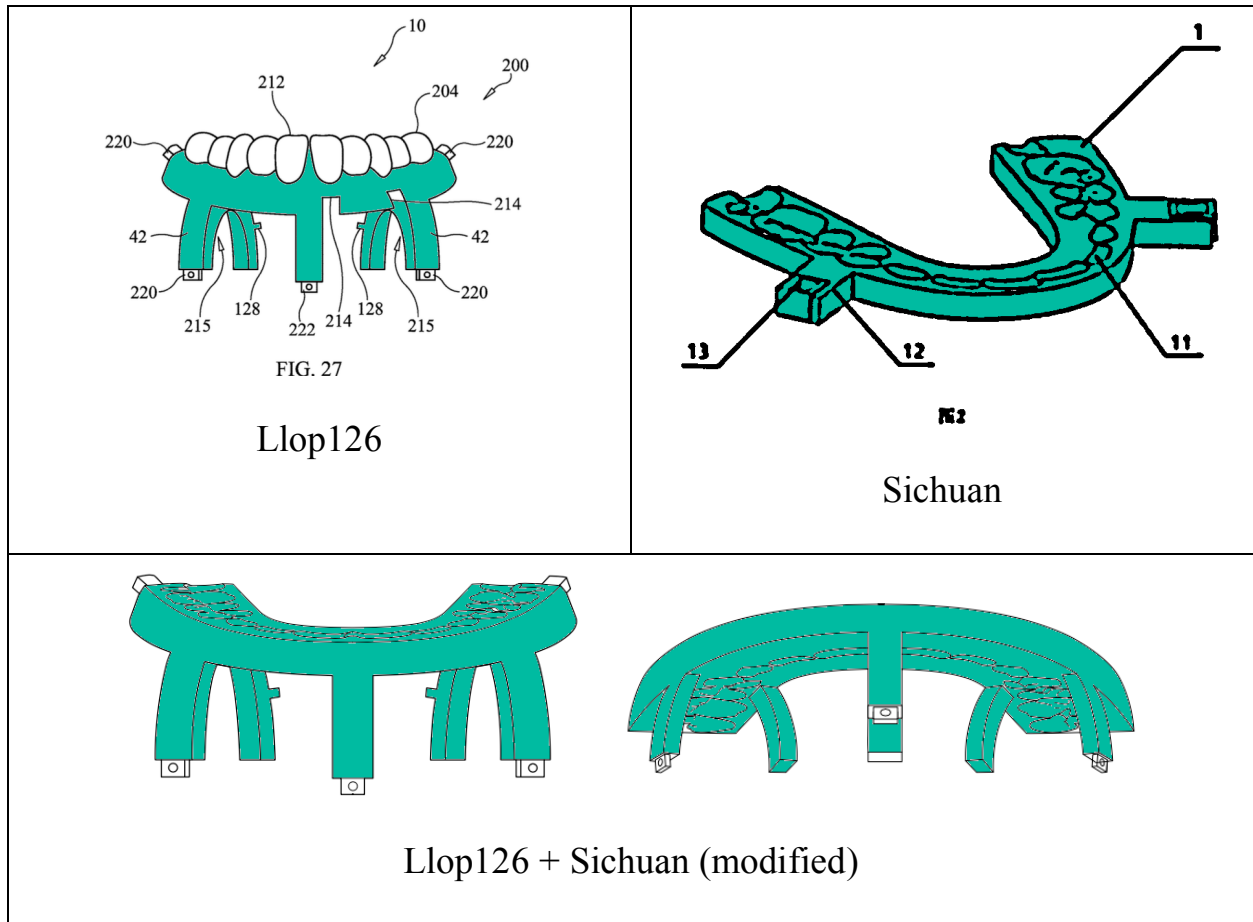
same field of endeavor as the '209 Patent, relating to surgical guides for osteotomies. *Compare* EX1006, Title, Abstract, “Field of Invention,” Fig. 1, *with* EX1009, Title, Abstract, “Field of Invention”, Figs. 1, 6; EX1003, ¶ 122.

Sichuan identifies the problem of properly positioning a guide for an osteotomy procedure. EX1009, [0003]–[0005]; EX1003, ¶ 123. Sichuan seeks to “fill the gap of lacking a device for guiding osteotomy positioning during subapical osteotomy.” *Id.* Sichuan solves this problem by using a removable “positioning biteplate,” which is a mouthpiece connected via rods to positioning guides. EX1009, [0007], [0049]; EX1003, ¶ 123. Similar to Llop126, Sichuan describes the use of a patient’s teeth (here, at least a portion of all of the teeth of the patient on the same ridge as the surgical site) to precisely position a base (maxillary osteotomy line guide plates 3 and/or positioning plate 4) in the patient’s mouth, and securing the base to the patient’s jawbone using screws through “screw holes 6” of the base. *Id.*, [0011], [0012], [0063], Figs. 1, 4.

A POSA would have understood from Sichuan the benefits of modifying the anchoring struts of Llop126 to include a mouthpiece, in order to improve the positioning of a fixation base for attachment to a patient’s jawbone. EX1003, ¶¶ 124–125 (explaining the problem of sliding). Llop126 is not limited to fully edentulous cases, and acknowledges that teeth may be present at the surgical site at

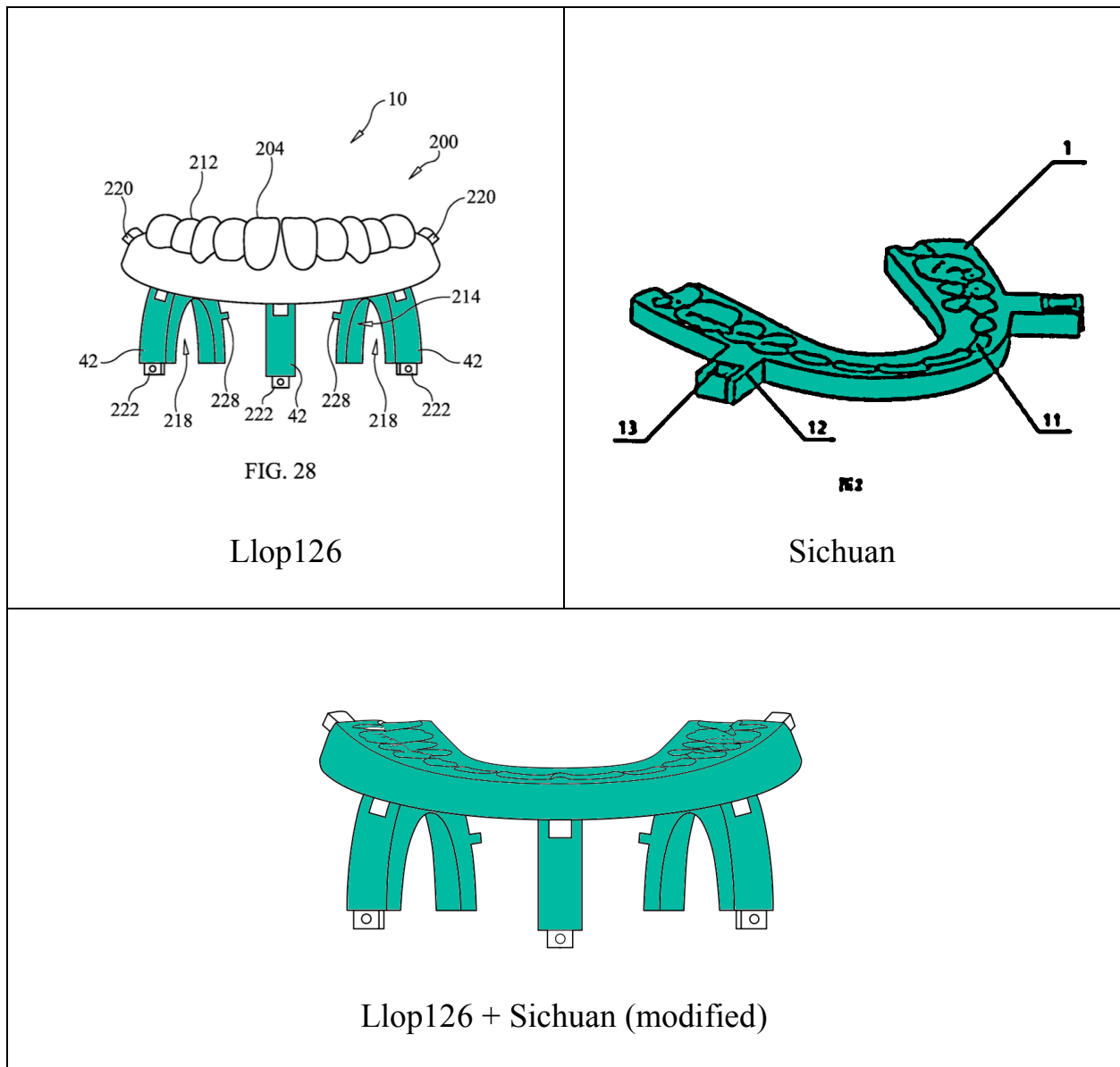
the time its fixation base is placed. EX1006, [0140]. For at least non-edentulous cases where teeth remain, a POSA would have been motivated to modify the anchoring strut system of Llop126 by using a biteplate as taught by Sichuan. EX1003, ¶ 126.

For example, Llop126 discloses that a device (“prosthesis 200”) can be unitary with or removably attached to the ends of the struts 42, to facilitate positioning of the bone foundation guide. EX1006, [0074], [0075], [0133], Figs. 27, 28. Sichuan discloses that the biteplate may conform to both upper and lower teeth (EX1009, [0088]) such that it forms a mouthpiece having a “hand and glove” relationship with the teeth of the patient. EX1003, ¶ 125. A POSA would have been motivated to substitute Sichuan’s mouthpiece for the prosthesis 200 in the “unitary” embodiment of Fig. 27, as shown below. EX1003, ¶ 126. Such a modification would permit the biteplate to engage with the teeth on either the mandibular or maxillary arches of the patient’s mouth. *Id.*



A POSA would have further understood the benefit of modifying Llop126 to use the Sichuan mouthpiece in edentulous cases, where teeth are not present on the ridge of the surgical site, but are present only on the opposite alveolar ridge.

EX1003, ¶ 127. A POSA would have been motivated to substitute a biteplate for the prosthesis 200 in the “non-unitary” embodiment of Llop126 (EX1006, Fig. 28, as shown below). EX1003, ¶ 127.



A POSA would have seen the applicability of Sichuan's mouthpiece to Llop126's anchoring struts by, e.g., attaching the biteplate at the apexes of the struts, to engage with the teeth on the opposing ridge. EX1003, ¶ 128.

Sichuan discloses an obvious solution (a mouthpiece that attaches to the guide plate via connecting rods) to overcome the problem, encountered by a user, of precisely positioning an osteotomy guide plate. EX1003, ¶¶ 121–133. A POSA would have been motivated to modify Llop126’s anchoring struts to include a mouthpiece, as in the claims of the ’209 Patent. *Id.*

A POSA would have had a reasonable expectation of success in making such combination. EX1003, ¶ 129. Llop126 discloses a fixation base positioned and attached to the patient’s jawbone, serving as a reference for dental implant surgical guides. EX1006, Abstract; EX1003, ¶ 122. Sichuan discloses a set of osteotomy guide plates that function similar to the Llop126 base as it is positioned and attached to the patient’s jawbone and used as a reference for subsequent surgical osteotomy procedures. EX1009, [0049]; EX1003, ¶ 122.

A POSA also would have recognized that the modification Llop126’s design to include the Sichuan mouthpiece was straightforward. EX1003, ¶¶ 126–130. Llop126 discloses an embodiment that includes a bone foundation guide prosthesis 200 removably attached to (or unitary with) the “one or more anchor struts 42” via, e.g., “[f]riction fit based tab-slot coupling means,” and which is used for positioning the bone foundation guide. EX1006, [0133]. A POSA would have

understood that the prosthesis 200 would advantageously be replaced by the Sichuan mouthpiece. EX1003, ¶ 126–130.

The modification of Llop126’s anchoring strut assembly to include a mouthpiece would not alter the operating principles of Llop126. *Id.*, ¶ 132. Rather than the indentations 46 at the apexes of the anchoring struts that match one or more portions of gum, dentition or both of the patient, the result of the combination would include a mouthpiece that surrounds a portion of the patient’s teeth to thereby provide a more robust registration of the bone foundation guide. *Id.*, ¶¶ 131–132. The result is a “combination of familiar elements according to known methods” that “does no more than yield predictable results.” *KSR Intern. Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

Thus, it would have been obvious to combine the teachings of Llop126 with the “mouthpiece” of Sichuan.

2. Llop126 and Sichuan Combine to Disclose the Limitations of the Claims

(a) Element 1[pre]: Preamble

Llop126 discloses a method of installing a dental prosthesis in the mouth of a patient. EX1003, ¶¶ 134–136. Llop126 discloses a dental implant surgical

guide, bone foundation guide, and/or tissue spacing gasket to properly place a dental implant-retained prosthesis to a dental surgical site. EX1006, [0026]–[0043], [0125]; Figs. 23, 26–30. The prosthesis is installed in either a maxillary or mandibular position. *Id.*, e.g., [0098].

(b) Element 1[a]: dental prosthesis

Llop126 discloses providing a dental prosthesis for the maxillary or mandibular positioning in the patient’s mouth. EX1003, ¶¶ 137–140. Llop126 discloses a “prosthesis applied to the bone foundation guide and tissue gasket combination” and then “the prosthesis relocated upon the implants” on the maxillary ridge of a patient. EX1006, [0070], [0073], [0026]–[0043], [0125], Figs. 23, 26. See Fig. 26 below:

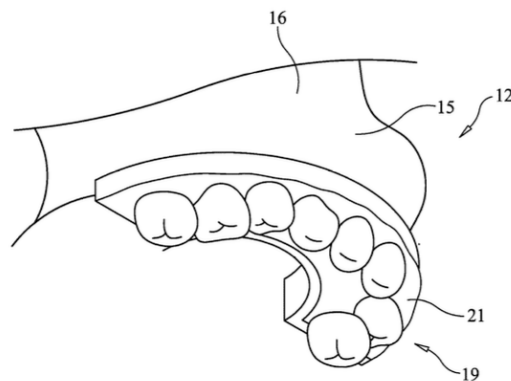
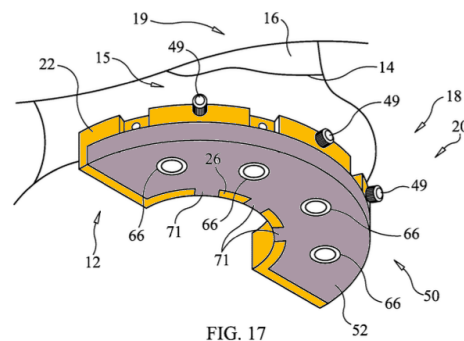
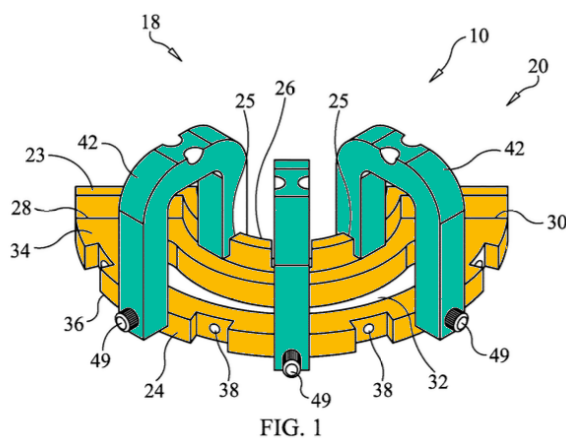


FIG. 26

(c) Element 1[b]: fixation base

Llop126 discloses a fixation base that provides a mounting jig for a plurality of other dental guides, including a first dental guide and a second dental guide as recited in Element 1[b]. EX1003, ¶¶ 141–144; EX1006, [0026]–[0030], Figs. 4, 5 and 19, identifying bone foundation guide 20 (shown in gold in Figs. 1, 17, below). The other dental guides include a first dental guide (set of anchoring struts 42, acting as a mouthpiece, shown in green) and a second dental guide (dental implant surgical guide 50, shown in grey). EX1006, [0028]–[0029], [0064], [0095], [0098], [0139] (“This stacking capability allows the bone foundation guide, once removably secured to the dental surgical site by the dental health care profession, to generally act as a foundation for the dental implant surgical guide or the spacing tissue gasket to secure them alternatively to the dental surgical site.”), Figs. 1, 17.



(d) Element 1[c]: fixation base features

Llop126's bone foundation guide has the structural features recited in Element 1[c]. EX1003, ¶¶ 145–146. Llop126 discloses a bone foundation guide 20 with a generally arcuate shape that includes a front surface with a plurality of openings (38) through which fasteners (40) can be passed (see annotated Fig. 4 and 12 below). EX1006, [0097] (“The bone foundation guide body 22 may be further penetrated by one or more attachment apertures 38 that may be oriented to pass through a buccal 24 wall. Body fasteners 40 may pass through the attachment apertures 38 to into the bone 14 of the dental surgical site 12 to removably secure the bone foundation guide body 22 to dental surgical site 12.”). The bone foundation guide 20 also has a horizontal surface (top 34), and a rear surface (lingual wall 26). EX1003, ¶ 146.

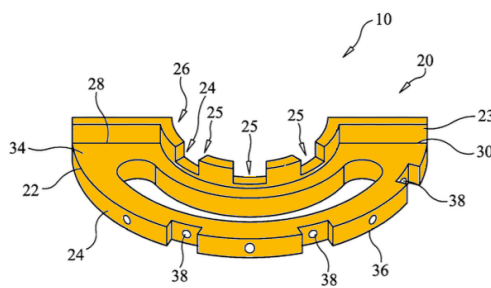


FIG. 4

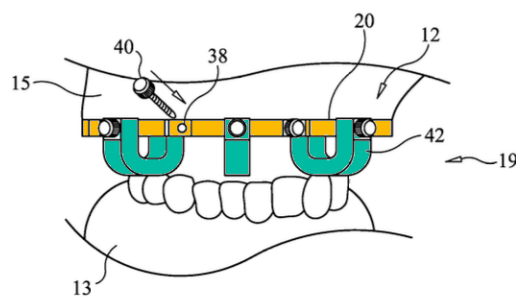


FIG. 12

(e) Elements 1[d, e, f]: mouthpiece features

Llop126 discloses anchoring struts 42 that attach to the fixation base, used to assure appropriate location to attach the fixation base to the maxillary or

mandibular bone tissue of the patient, as in Elements 1[d], [e] and [f]. EX1003, ¶¶ 147–154. The anchoring struts 42 attach to the bone foundation guide through the use of strut fasteners 49. EX1006, [0098], [0136]; Fig. 1 (“Some embodiments of the bone foundation guide body 22 may further comprise of a one or more anchoring struts 42 that may be removably attached to the buccal wall 24 and the lingual wall 26 between the first end 38 and the second end 30.”) Although the anchoring struts 42 form a “mouthpiece” according to its commonly understood meaning (EX1003, ¶ 148), the Examiner determined that Llop126 did not disclose a “mouthpiece” as claimed. EX1002, 224 (“the added language in the claim is not found in the prior art of Llop’126 and Llop’881 used in the Office Action of 9 February 2023.”)

The anchoring struts register the bone foundation guide in its appropriate location. EX1003, ¶ 149 (referring to EX1001, 1:45–48) (the anchoring struts are “formed to more of the maxillary or mandibular structure than that contacted by the fixation base from the images, and assists in appropriately setting the fixation base in appropriate location.”). The anchoring struts 42 “may allow the patient itself press at least a portion of gum tissue, dentition or both of the opposing alveolar ridge 13 upon at least one anchoring strut 42 of the bone foundation guide 20 to generally hold the bone foundation guide 20 in place upon the dental surgical

site 12.” EX1006, [0099]. They assure appropriate location of the bone foundation guide when the bone foundation guide is set upon the bone tissue of the patient. *Id.* (“The patient’s action (e.g., substantially clamping down with patient’s mouth upon the bone foundation guide 20 in situ could allow the patient to temporarily and removably hold the bone foundation dental upon the dental surgical site while the dental health care professional (not shown) is free to use both hands to attach the bone foundation guide 20 in place with body fasteners.”); *see also* Abstract (“...the bottom contoured to removably affix the bone foundation guide body to the bone of a dental implant surgical site...”).

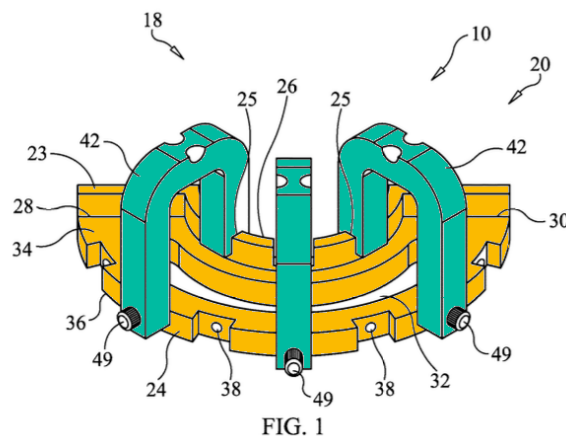


FIG. 1

The anchoring struts 42 have indentations that are matched with the patient’s teeth or gum. EX1003, ¶ 150; EX1006, [0098] (“[A]t its outer apex 44 one or more indentation 46 that can match one or more portions of gum, *dentition* or both the patient’s first or opposing alveolar ridge 28.” (emphasis added)), Fig. 3; *see also id.*, [0136] (“The anchoring struts can also be patient-specific made to have

indentations at their respective apices to match various portions of the *dentition*, tissue or both of the opposing alveolar ridge.”).

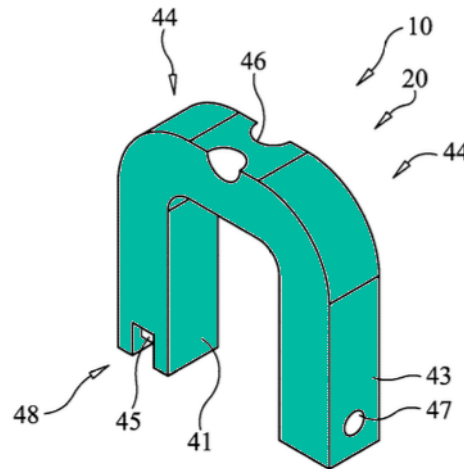


FIG. 3

The indentations formed in the anchoring struts match teeth on the *opposing* ridge. Element 1[e], however, allows for mouthpieces that are configured and dimensioned to surround at least a portion of teeth on the opposing alveolar ridge from the surgical site. EX1003, ¶ 151.

Sichuan discloses a mouthpiece configured and dimensioned to surround a portion of the teeth that is used to assure appropriate location to attach a guide to the patient’s maxillary or mandibular bone tissue. Sichuan describes using a removable “positioning biteplate” that is connected via rods to positioning guides. EX1009 [0007], [0049]. Like Llop126, Sichuan describes the use of a patient’s teeth (here, on the same maxillary ridge as the surgical site) to precisely position a

base (maxillary osteotomy line guide plates 3 and/or positioning plate 4) in the patient's mouth, and securing the base to the patient's jawbone using screws through "screw holes 6" of the base. *Id.*, [0011], [0012], [0063], [0066], Figs. 1, 4, 6; EX1003, ¶ 152.

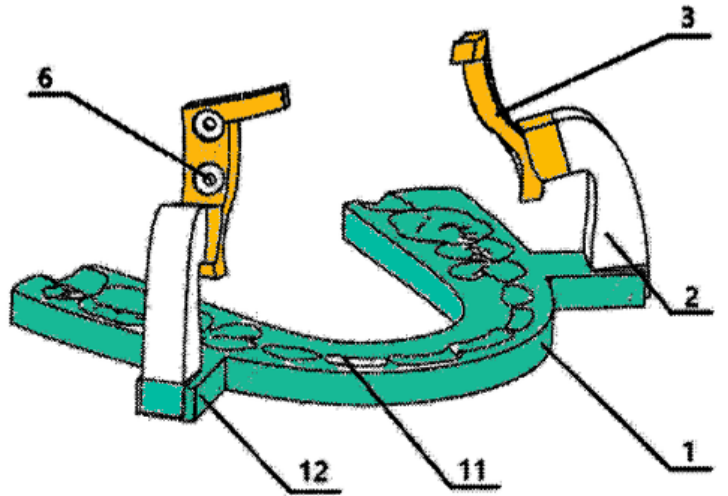


图1

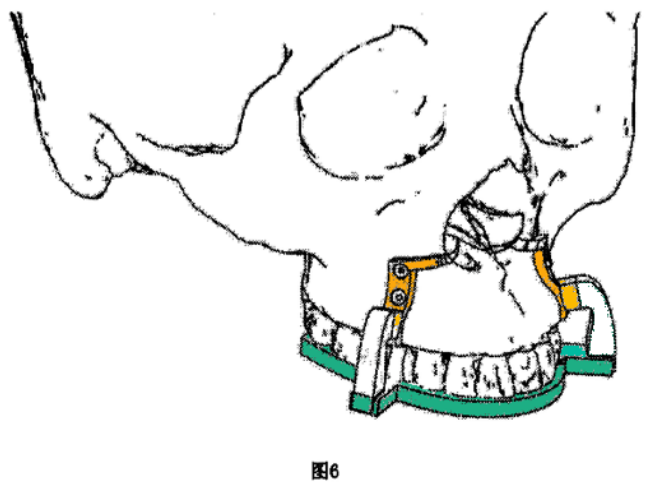


图6

Sichuan discloses that the biteplate is created from tooth prints 11 of the patient with dentition data obtained from, e.g., an intraoral scanner. E.g., EX1009, Abstract, Claims 6g, 8g.3, [0007], [0027], [0038], [0066], [0021]. The “Boolean operation” is used to design the tooth prints onto the surfaces of the biteplate. *Id.* A POSA would understand that the Boolean operation would result in tooth prints on the biteplate that conform precisely to the shape of the teeth, and that they would thus be configured and dimensioned to surround at least a portion of the teeth of the patient. EX1003, ¶ 153.

Sichuan further discloses that the biteplate may conform to both upper and lower teeth. EX1009, [0088]. In this way, the teeth on the same or opposing alveolar ridge from the surgical site may engage with the biteplate to aid in positioning the guides. EX1003, ¶ 154.

(f) Element 1[g]: fixation base installation

Llop126 discloses installing the fixation base to the maxillary or mandibular bone tissue of the patient, as in Element 1[g]. EX1003, ¶¶ 155–156. Llop126 discloses that the practitioner installs the bone foundation guide 20 while it is held in place through the patient’s biting down on the mouthpiece formed by anchoring struts 42. EX1006, [0097]–[0099]. (“The patient's action (e.g., substantially clamping down with patient's mouth upon the bone foundation guide 20 in situ

could allow the patient to temporarily and removably hold the bone foundation dental upon the dental surgical site while the dental health care professional (not shown) is free to use both hands to attach the bone foundation guide 20 in place with body fasteners.”)

Sichuan also discloses installing the fixation base to the maxillary or mandibular bone tissue of the patient. Sichuan describes the use of a patient’s teeth to precisely position a base (maxillary osteotomy line guide plates 3 and/or positioning plate 4) in the patient’s mouth, and securing the base to the patient’s jawbone using screws through “screw holes 6” of the base. *Id.*, [0011], [0012], [0063], [0066], Figs. 1, 4; EX1003 ¶ 157

(g) Element 1[h]: mouthpiece removal

Llop126 discloses removing the mouthpiece from the installed fixation base as in Element 1[h]. EX1003, ¶¶ 158–159. After the bone foundation guide has been installed, the anchoring struts 42 are removed. EX1006, [0099]–[0101], Figs. 13–15.

Sichuan also describes removal of the mouthpiece after the positioning guide plates have been installed. EX1003, ¶ 160. The connector rods and biteplate can be removed after installation, leaving the guide plates in place to facilitate the osteotomy operation with cutting of the jawbone. EX1009, [0049] (“When the

positioning plate is fixed with screws, the connector rods and the positioning biteplate can be removed to facilitate cutting operation of the jawbone.”)

(h) Element 1[i]: teeth/tissue removal

Llop126 discloses removing at least one of natural teeth, dental fixtures, and obstructive mouth tissues from the work site, to expose an underside of the maxillary or mandibular bone tissue, as in Element 1[i]. EX1003, ¶¶ 161–162. In Llop126, the bone foundation guide is used “to substantially modify (e.g., reduce, augment or both) the bone 14 of the dental surgical site 12 as needed for a successful surgery.” EX1006, [0096], [0061]; Fig. 15.

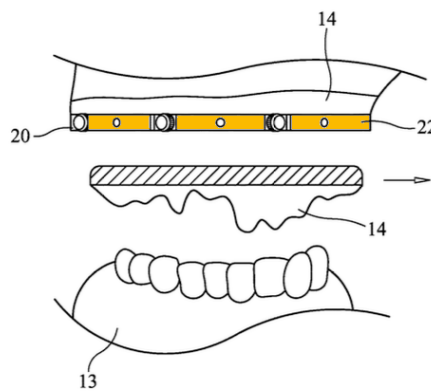


FIG. 15

Llop126 further discloses the removal of natural teeth to expose an underside of bone tissue. *Id.*, [0140] (“If needed the tissue can be peeled [sic] back further to expose at least a portion of the posterior maxilla’s bone (e.g., on the posterior maxilla’s buccal side for sinus augmentation.) Any teeth at the dental implant surgical site can be removed. If the patient’s dental health has declined

enough, the alveolar ridge supporting the dental surgical site could be made edentulous.”)

(i) Element 1[j]: bone recontouring

Llop126 discloses recontouring the bone tissue, as in Element 1[j]. EX1003, ¶¶ 163–164. The bone foundation guide is used “to substantially modify (e.g., reduce, augment or both) the bone 14 of the dental surgical site 12 as needed for a successful surgery.” EX1006, [0096], [0061], [0146]; Fig. 15 (“...the bone foundation guide top to be used to guide a cutting implement (e.g., a blade saw) to reduce the dental implant surgical site’s bone structure.”)

(j) Element 1[k]: drill guide

Llop126 discloses utilizing a second dental guide that attaches to the installed fixation base to assure appropriate location and orientation of holes to be drilled for the subsequently installed implants, as in Element 1[k]. EX1003, ¶¶ 165–167. Llop126 discloses utilizing a dental implant surgical guide 50, which is a drill guide that attaches to the installed fixation base. EX1006, [0034], [0121]–[0124], [0149], Figs. 16, 40 (“The dental healthcare professional could use the bone foundation guide and the dental implant surgical guide stacked or otherwise combined together to substantially direct and operate implant preparation implements (e.g., drills, reamers, and the like), implant components, or both by

space to properly prepare the dental surgical site to receive the implant(s).”)

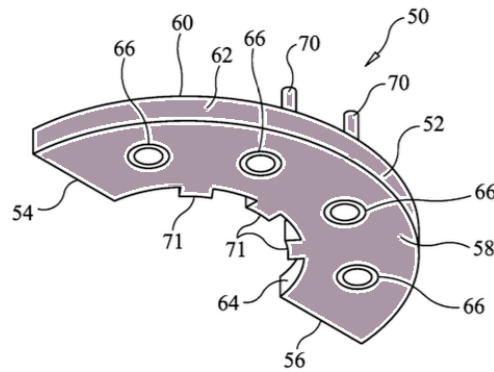


FIG. 16

Guide 50 assures the appropriate location and orientation of holes for subsequently installed implants. *Id.*, [0121]-[0125], [0149], Fig. 19 (showing abutment 17, attached to installed implant) (“This implant preparation could ensure there was proper orientation and telemetry of the implant components and implants into the generally exposed bone of the dental surgical site. Once the bone is properly prepared to receive the implants, the implant(s) could then pass through the combination to be anchored into the bone.”)

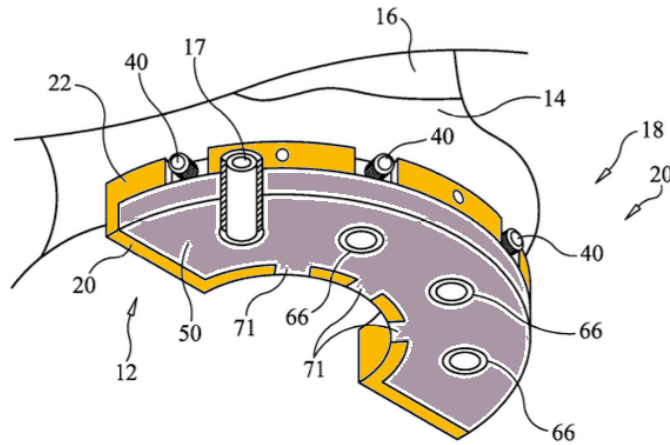


FIG. 19

(k) Element 1[l]: implant hole drilling

Llop126 discloses drilling the implant holes in the bone tissue using the drill guide attached to the fixation base, as in Element 1[l]. EX1003, ¶ 168. See, generally, Element 1[k]. E.g., EX1006, [0034], [0149] (“the ability place [sic] a dental drill through a set of guiding cylinders held by a combination of bone foundation guide and dental implant surgical guide, the dental surgical guide guiding the entrance into and the bone foundation guiding the exit out of a placement channel.”)

(l) Element 1[m]: implant installation

Llop126 discloses installing implants in the implant holes, as in Element 1[m]. EX1003, ¶ 169. See, generally, Element 1[k], above. E.g., EX1006, [0007], [0123] (“When so combined together, the dental implant surgical guide 50 generally surrounds the bone foundation guide's open surgical space 32 to allow

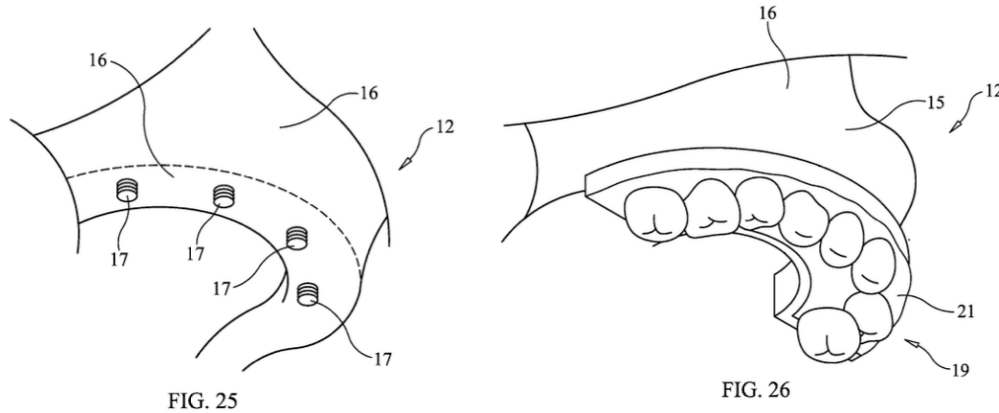
implant components, implants or both to pass through the dental implant surgical guide's implant aperture(s) 66 and on through the [sic] of the open surgical space 32.”), [0149] (“Once the bone is properly prepared to receive the implants, the implant(s) could then pass through the combination to be anchored into the bone.”), Fig. 19.

(m) Element 1[n]: abutment installation

Llop126 discloses installing the abutments to the implants, as in Element 1[n]. EX1003, ¶ 170. Llop126 discloses the common practice of installing abutments to implants, which are then used to install a dental prosthesis. EX1006, [0008], [0125] (“When the prosthesis 21 is generally fixed about the implants (e.g., to the abutments 17 attached to the implants), dental acrylic could be injected into the prosthesis to secure implant abutments to the prosthesis.”), [0156] (“In one possible embodiment, once the tissue spacing gasket is removably attached to the bone foundation guide then temporary abutments can be placed upon the implants.”)

(n) Element 1[o]: prosthesis installation

Llop126 discloses installing a dental prosthesis to the abutments, as in Element 1[o]. EX1003, ¶ 171.



Llop126 discloses a prosthesis “can be placed over the tissue spacer gasket to come into contact the temporary abutments.” EX1006, [0156], [0125] (“When the prosthesis 21 is generally fixed about the implants (e.g., to the abutments 17 attached to the implants), dental acrylic could be injected into the prosthesis to secure implant abutments to the prosthesis.”), Figs. 25, 26.

(o) Claim 2: installing fixation base

Llop126 discloses installing the fixation base by driving fasteners through openings in its front surface, as recited in Element 2 of claim 2. EX1003, ¶ 172. See, generally, Element 1[c] above. E.g., EX1006, [0097] (“The bone foundation guide body 22 may be further penetrated by one or more attachment apertures 38 that may be oriented to pass through a buccal 24 wall. Body fasteners 40 may pass through the attachment apertures 38 to into the bone 14 of the dental surgical site 12 to removably secure the bone foundation guide body 22 to dental surgical site 12.”).

(p) Claim 3: using preformed surface to recontour

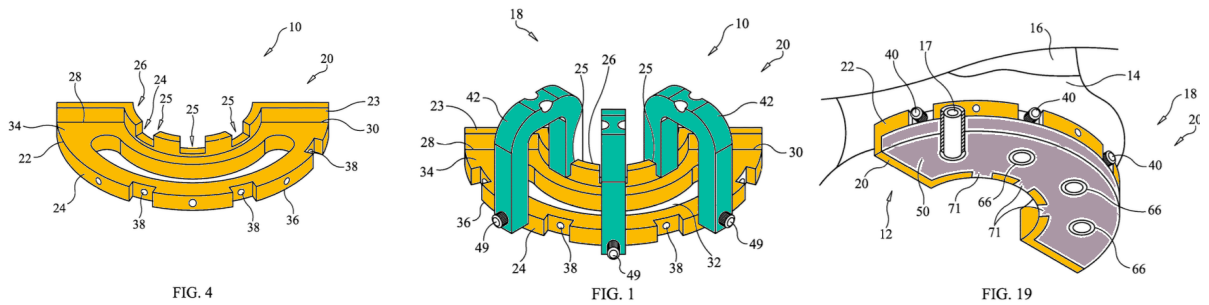
Llop126 discloses using a preformed surface on the fixation base to assure proper recontouring of the bone tissue, as recited in claim 3. EX1003, ¶ 173. See, generally, Element 1[j] above. E.g., EX1006, [0096], [0061], [0146], Fig. 15 (“...the bone foundation guide top to be used to guide a cutting implement (e.g., a blade saw) to reduce the dental implant surgical site’s bone structure.”)

(q) Element 7[pre]: Preamble

Llop126 discloses an apparatus for installing a dental prosthesis to a jaw bone of a patient. EX1003, ¶ 174. Llop126 discloses the provision of a dental implant surgical guide, bone foundation guide, and/or tissue spacing gasket to properly place a dental implant-retained prosthesis to a dental surgical site. EX1006, [0026]–[0043], [0125]; Figs. 23, 26–30. The prosthesis is installed in either a maxillary or mandibular position to the jaw bone. *Id.*, e.g., [0098].

(r) Element 7[a]: fixation base

Llop126 discloses a fixation base for providing an attachment surface for a dental guide used during a prosthesis installation procedure as recited in Element 7[a]. EX1003, ¶ 175. Llop126 discloses a bone foundation guide 20 that serves as a mounting jig for other dental guides. EX1006, e.g., [0095], Figs. 1, 4, 5 and 19.



For example, the other dental guides include a first dental guide (set of anchoring struts 42, shown in green) and a second dental guide (dental implant surgical guide 50, shown in grey). *Id.*, [0028]–[0029], [0064], [0095], [0098], [0139] (“This stacking capability allows the bone foundation guide, once removably secured to the dental surgical site by the dental health care profession, to generally act as a foundation for the dental implant surgical guide or the spacing tissue gasket to secure them alternatively to the dental surgical site.”) The first dental guide is attached to the bone foundation guide by securing struts to the surface of buccal wall 24 of the guide.

(s) Element 7[b]: fixation base properties

See Element 1[c] above.

(t) Element 7[c, d]: mouthpiece

See Element 1[d, e, f] above. As noted, Llop126 includes a set of anchoring struts 42 that have at their outer apexes indentations that match dentition on the patient’s opposing alveolar ridge. EX1006, [0098], [0136].

Sichuan describes a mouthpiece in the form of a biteplate designed with tooth prints that are configured and dimensioned to surround a portion of the teeth of the patient. EX1009, [0007], [0049]; EX1003, ¶ 178. Like Llop126, Sichuan describes the use of a patient's teeth to precisely position a base in the patient's mouth, and securing the base to the patient's jawbone using screws through "screw holes 6" of the base. *Id.*, [0011], [0012], [0063], Figs. 1, 4. As explained above, it would have been obvious to include Sichuan's mouthpiece in Llop126's system, such as by attaching to the anchoring struts of Llop126.

(u) Element 7[e]: mouthpiece removal

Llop126 discloses installing the anchoring struts to be removed after the fixation base is affixed, as recited in Element 7[e] of claim 7. EX1003, ¶ 179. Llop126 discloses that once the bone foundation guide has been installed, the set of anchoring struts 42 may be removed. EX1006, [0099]–[0101], Figs. 13–15. ("The dental health care professional can then proceed with the removal of the strut fasteners 49 from the bone foundation guide 20 so as to be able to lift the anchoring struts 46 [sic 42] free and clear from the body 22.")

Sichuan also describes removal of the mouthpiece after the positioning guide plates have been installed. EX1003, ¶ 180. The connector rods and biteplate can be removed after installation, leaving the guide plates in place to facilitate the

osteotomy operation with cutting of the jawbone. EX1009 [0049] (“When the positioning plate is fixed with screws, the connector rods and the positioning biteplate can be removed to facilitate cutting operation of the jawbone.”)

(v) Claim 10: drill guide

Llop126 discloses a drill guide attachable to the fixation base as recited in Claim 10. EX1003, ¶ 181–182. See, generally, Elements 1[m, n], above. Llop126 discloses utilizing a dental implant surgical guide 50, which is a drill guide that attaches to the installed fixation base. EX1006, [0034], [0121]–[0124], [0149]; Figs. 16, 40 (“The dental healthcare professional could use the bone foundation guide and the dental implant surgical guide stacked or otherwise combined together to substantially direct and operate implant preparation implements (e.g., drills, reamers, and the like), implant components, or both by passing them through the dental implant surgical guide and into the open surgical space to properly prepare the dental surgical site to receive the implant(s).”).

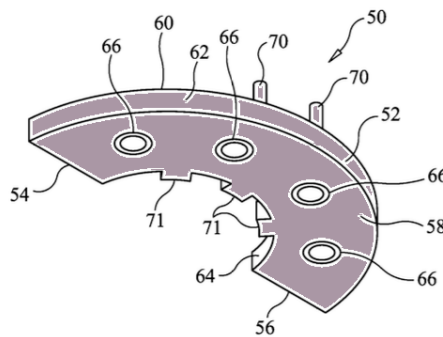


FIG. 16

Guide 50 is used to guide the drilling of holes for subsequently installed implants. *Id.*, [0121]-[0125], [0149], Fig. 19 (showing abutment 17, attached to installed implant) (“This implant preparation could ensure there was proper orientation and telemetry of the implant components and implants into the generally exposed bone of the dental surgical site.”). Guide 50 includes a plurality of generally vertical bores corresponding in location to and in axial registration with intended implant sites. EX1006, [0122] (The drill guide body 52 includes “implant apertures 66 that could continuously connect the top side 58 to the bottom side 60 to guide implant preparation and attachment”), Fig. 19.

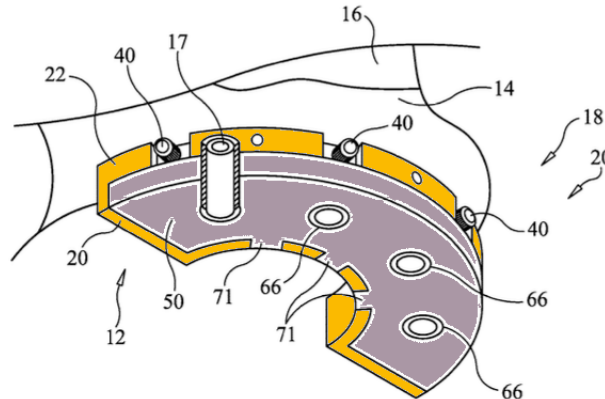


FIG. 19

(w) Claim 13: fixation base composition

Llop126 discloses a fixation base made from a material that is sufficiently strong enough to withstand breakage during a prosthesis installation procedure, as recited in Claim 13. EX1003, ¶ 183. Llop126 discloses that bone foundation guide

20 is used throughout the entirety of a prosthesis installation procedure, including being installed via an attached mouthpiece, fixing an attached drill and implant guide, and holding an abutment guide in place. A POSA would have understood that bone foundation guide in Llop126 must withstand breakage. *Id.*

(x) Claim 14: recontouring surface

Llop126 discloses a fixation base including a surface to assist in bone recontouring, as recited in Claim 14. EX1003, ¶ 184. See generally Element 3, above. *E.g.*, EX1006, [0096], [0061], [0146], Fig. 15 (“...the bone foundation guide top to be used to guide a cutting implement (e.g., a blade saw) to reduce the dental implant surgical site’s bone structure.”).

(y) Claim 16: prosthesis attached to fixation base

Llop126 discloses a dental prosthesis that attaches to the fixation base, as recited in Claim 16. EX1003, ¶ 185.

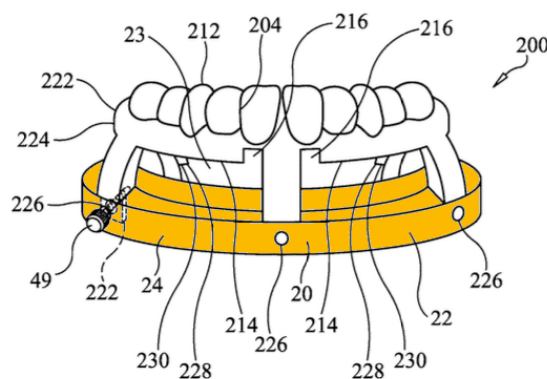


FIG. 29

Llop126 discloses an embodiment that includes a “bone foundation guide prosthesis 200 that can be removably combined with the body 22 of the bone foundation guide to form a bone foundation guide prosthesis-body combination,” which can be used, e.g., in placing the bone foundation guide. EX1006, [0128], Figs. 27–30.

(z) Element 17[pre]: Preamble

See Element 1[pre]. Llop126 discloses a method of installing a fixation base in the mouth of a patient. EX1003, ¶ 186. Llop126 discloses a bone foundation guide that is installed in either a maxillary or mandibular position. EX1006, e.g., [0098]–[0100], Figs. 1, 5, 29, 30.

(aa) Element 17[a]: fixation base

See Element 7[a]. Llop126 discloses a fixation base for providing an attachment surface for a dental guide used during a prosthesis installation procedure as recited in Element 17[a]. EX1003, ¶¶ 187–189. Llop126 discloses a bone foundation guide 20 that serves as a mounting jig for other dental guides. EX1006, e.g., [0095], Figs. 4, 5 and 19. For example, The other dental guides include a first dental guide (set of anchoring struts 42, acting as a mouthpiece, shown in green) and a second dental guide (dental implant surgical guide 50, shown in grey). *Id.*, [0028]–[0029], [0064], [0095], [0098], [0139] (“This stacking capability allows the bone foundation guide, once removably secured to the dental

surgical site by the dental health care profession, to generally act as a foundation for the dental implant surgical guide or the spacing tissue gasket to secure them alternatively to the dental surgical site.”) The first dental guide is attached to the bone foundation guide by securing struts to the surface of buccal wall 24 of the guide using fasteners.

(bb) Element 17[b]: fixation base properties

See Element 1[c].

(cc) Element 17[c, d, e]: mouthpiece

See Element 1[d, e, f]. EX1003, ¶¶ 191–192. As discussed above, Sichuan discloses using a mouthpiece (biteplate) that is configured and dimensioned to surround at least a portion of the teeth of the patient. Llop126 discloses using a set of anchoring struts with indentations matching dentition on the patient’s opposite alveolar ridge. Both Llop126 and Sichuan disclose attaching the mouthpiece to the base, and installing the mouthpiece to assist in positioning the base properly before it is installed to the patient’s bone tissue.

(dd) Element 17[f]: installing fixation base

See claim 2. Llop126 discloses installing the fixation base by driving fasteners through openings in its front surface. EX1003, ¶¶ 193–194. *See, e.g.*, EX1006, [0097].

(ee) Element 17[g]: mouthpiece removal

See Element 1[h]. Llop126 discloses removing the anchoring struts from the installed fixation base as in Element 1[h]. EX1003, ¶¶ 195–196; EX1006, [0099]–[0101], Figs. 13–15.

Sichuan also describes removal of the mouthpiece after the positioning guide plates have been installed. EX1003, ¶ 197; EX1009, [0049].

3. The Claims are Obvious Over the Combination of Llop126 and Sichuan

The combination of Llop126 and Sichuan discloses all of the features of Claims 1–3, 7, 10, 13–14, and 16–17. As shown above, it would have been obvious for a POSA to combine those references as claimed. Accordingly, these claims should be found not patentable as obvious under 35 U.S.C. § 103.

D. Ground 4: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over the Combination of Llop126 and Sichuan in View of Groscurth

Assuming the claims are construed to limit the material of the drill guide and fixation base (Section VI), then claims 1–3, 7, 10, 13–14, and 16–17 would have been obvious to a POSA based on the combination of Llop126 and Sichuan in view of Groscurth. EX1003, ¶¶ 199–209.

1. Llop126, Sichuan and Groscurth—Motivation to Combine

As explained above (Section VIII.C.1), a POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a positioning mouthpiece as in Sichuan, to ensure proper alignment of the fixation base.

EX1009, [0003, 0005]; EX1003, ¶ 200. A POSA would have been motivated to further modify the Llop126/Sichuan system to form the fixation base and drill guide of metal, to increase rigidity and stability. EX1003, ¶ 201.

Llop126, Sichuan and Groscurth are analogous to the subject matter of the '209 Patent. *See Circuit Check Inc.*, 795 F.3d at 1335; *In re Deminski*, 796 F.2d at 442. These references are in the same field of endeavor as the '209 Patent namely surgical guide systems for performing osteotomies, and installing dental implants and prostheses. *Compare* EX1006, Title, Abstract, “Field of Invention,” Fig. 17, *with* EX1011, Title, Abstract, “Field of Invention”, Fig. 9; EX1003, ¶ 203.

Groscurth describes the problem of a fixation base that is not rigid or stable. EX1011, 1:56–2:10. Groscurth acknowledges the need for a fixation base / drill guide system that has “great rigidity so that it is very stable in the patient’s mouth as well as on the physical anatomical diagnostic model.” *Id.*, Abstract, 2:1–11, 6:35–40. To solve this problem, Groscurth discloses an embodiment in which a drill guide and fixation base are made of metal. EX1011, 2:46–52, 13:1–4;

EX1003, ¶¶ 202–205 (explaining that Groscurth teaches an embodiment in which metal is used to provide a strong dental surgical guides which are advantageous for surgical procedures). A POSA would have been motivated to modify the Llop126 bone foundation guide and drill guide—in which the material used is not specified—to be made of metal as disclosed by Groscurth. *Id.*

Similarly, Sichuan teaches that the surgical components “are made into physical objects using three-dimensional printing materials through three-dimensional printing rapid prototyping.” EX1009, [0086]. A POSA would understand that these techniques could be used for metallic material as described in Groscurth. EX1003, ¶ 206. A POSA would further understand that using such metallic material for at least the positioning guide plates and connector rods is not only consistent with the teachings of Sichuan, but would be preferable to plastic given the stated thin dimensions of the guide plates. *Id.*; EX1009, [0083] (“a thickness of 3mm”).

It would have been obvious to modify Llop126 to use metal for the fixation base and drill guide as disclosed by Groscurth.

2. Llop126 and Sichuan Combine to Disclose All Elements Other Than a Metal Fixation Base and Drill Guide

All elements of claims 1–3, 7, 10, 13–14 and 16–17 are present in the combination of Llop and Sichuan, for the reasons set forth in Ground 3 (Section VIII.C.2) above. EX1003, ¶ 207.

3. Groscurth Discloses a Metal Fixation Base and Drill Guide

Groscurth discloses a fixation base and drill guide that is made of metal, consistent with Petitioner’s proposed construction of “fixation base.” EX1003, ¶ 208. Groscurth discloses **“The base frame 200 may be made of a transparent or semi-transparent resin or other composite material that gives the surgeon maximum visibility of the surgical site, but it may also be made of a colored resin and other composite material or metal that provides the base frame 200 with enough rigidity for stability and the right amount of flexibility in clasping areas.”** EX1011, 4:46–52. Groscurth also discloses, “The drill guide may also be created with built-in drill guide holes or slots without any separate parts **if the device is made of an appropriate harder material such as metal.**” *Id.*, 13:1–4. There is nothing in Groscurth suggesting that traditional plastic or acrylic must be used. *WAG Acquisition, LLC v. WebPower, Inc.*, 781 F. App’x 1007, 1013 (Fed. Cir. 2019).

4. The Claims are Obvious Over the Combination of Llop126 and Sichuan in View of Groscurth

The combination of Llop126 and Sichuan and Groscurth discloses all of the features of Claims 1–3, 7, 10, 13–14, and 16–17. EX1003, ¶ 209. As shown above, Llop126 and Sichuan together disclose every claim element other than a metallic fixation base and drill guide. The combination of Llop126 and Sichuan with Groscurth includes this limitation and thus discloses all of the claim elements. As shown above, it would have been obvious for a POSA to combine those references as claimed. Accordingly, these claims should be found not patentable as obvious under 35 U.S.C. § 103.

E. Ground 5: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over Llop126 and Yau

If the Board decides that “drill guide” and “fixation base” should not be limited according to Patent Owner’s express disclaimer of claim scope (*see* Section VI), then claims 1–3, 7, 10, 13–14, and 16–17 would have been obvious to a POSA based on Llop126 in view of Yau. EX1003, ¶¶ 210–257.

1. Llop126 and Yau—Motivation to Combine

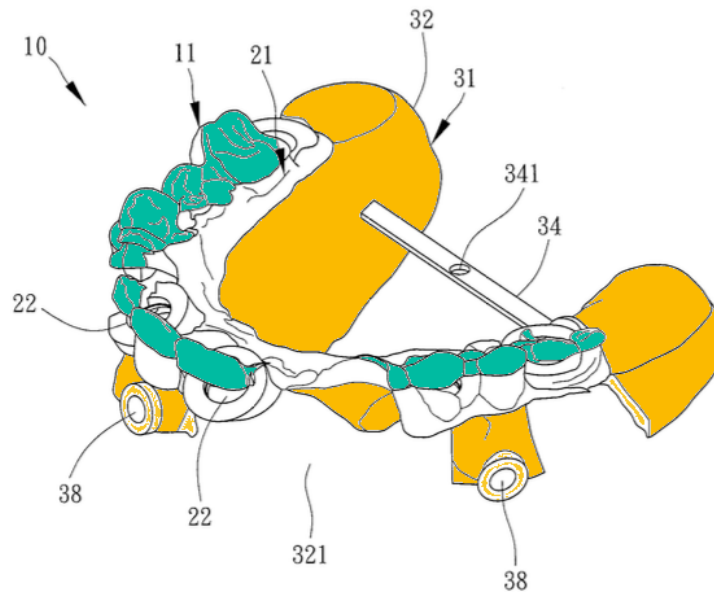
A POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a tooth mold mouthpiece as in Yau, which

mouthpiece provides “tight engagement with the natural teeth,” to ensure proper placement of the fixation base. EX1010, [0004], [0007]; EX1003, ¶ 211.

Llop126 and Yau are analogous to the subject matter of the ’209 Patent. *See Circuit Check Inc.*, 795 F.3d at 1335; *In re Deminski*, 796 F.2d at 442. Llop126 and Yau are both in the same field of endeavor as the ’209 Patent, relating to surgical guides for dental implant and prosthesis installation. *Compare* EX1006, Title, Abstract, “Field of Invention,” Fig. 1, *with* EX1010, Title, Abstract, “Field of Invention”, Figs. 1–3; EX1003, ¶ 212. Llop126 and Yau both disclose a stackable dental surgical guide system for the installation of implants. *Id.*

Yau identifies the problem that “using a bite to install a dental implant surgical guide in a patient’s gingival has poor positioning effects, and the dental implant surgical guide can slide.” EX1003, ¶ 213; EX1010, [0004]. According to Yau, “[s]uch positioning inaccuracy may lead to incorrect location of implant,” particularly for patients with too many missing teeth. EX1010, [0004]. Yau addresses this problem with a “tooth mold” or mouthpiece (shown in green below), used as an “upper guide member” that attaches to a “middle” and “lower” guide member so that they may be fixed to the patient’s gingiva. *Id.*, [0007], [0008], [0016]–[0025]. Like Llop126, Yau discloses using opposing teeth to precisely position a base (lower member 31 shown in gold below) in the patient’s mouth,

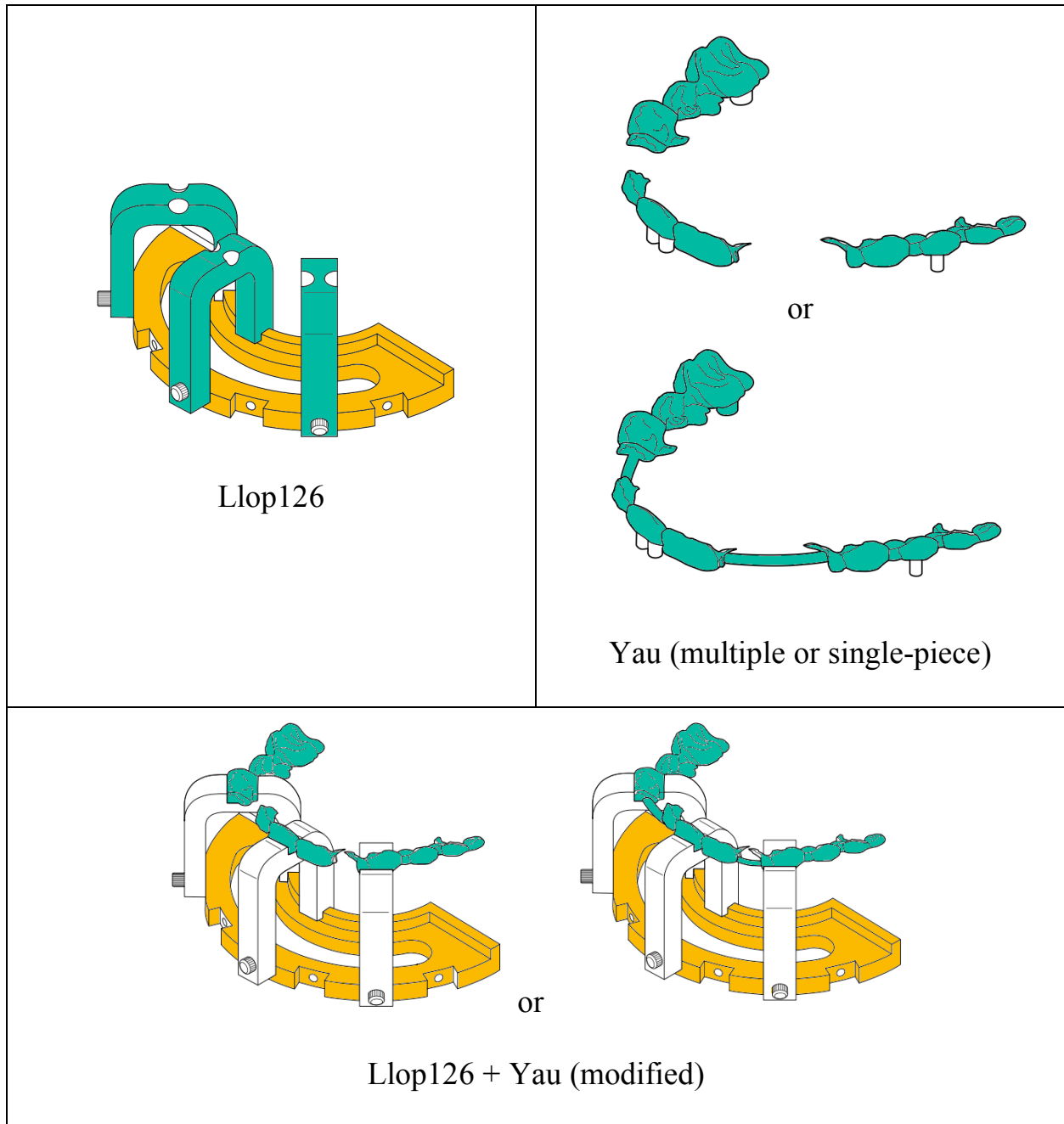
and securing the base to the patient's jawbone using "plug pins or screw bolts" through apertures 38 of the base. *Id.*, [0019], Figs. 1, 4; EX1003, ¶ 213.



Yau also discloses that the tooth mold mouthpiece 11 may be made of a single piece, rather than three components as shown. EX1010, [0025] (disclosing that "in actual application, the upper guide member 11 can be a one-piece member"). A POSA would consider either a one-piece tooth mold or multi-piece tooth mold to be a "mouthpiece." EX1003, ¶ 213.

A POSA would have understood from Yau the benefits of modifying the anchoring struts of Llop126 to include a mouthpiece, in order to improve on the solution to the known problem of sliding when positioning a fixation base for attachment to a patient's jawbone. EX1003, ¶¶ 214–216. A POSA would have

been motivated to modify the anchoring struts relative to the apex indentations, which match the teeth or gums, by using a mouthpiece as taught by Yau, and as shown below. *Id.*



Yau discloses use of a mouthpiece that is configured to surround the patient's teeth in order to prevent sliding when positioning a surgical guide base. EX1010, [0004]. Yau discloses an obvious solution (a mouthpiece that attaches to the base) to overcome the problem, encountered by a user, of precisely positioning a fixation base. EX1003, ¶ 219 A POSA would have been motivated to construct the Llop126 anchoring struts with tooth molds, including as recited in the claims of the '209 Patent. *Id.* Such modification to include a tooth mold mouthpiece, as taught by Yau, satisfies the “mouthpiece...configured and dimensioned to surround at least a portion of the teeth of the patient” limitation in independent claims 1, 7 and 17. *Id.*

A POSA would have had a reasonable expectation of success in combining Llop126 and Yau as each concerns dental implant surgical guide systems. EX1003, ¶ 212. Llop126 discloses a fixation base positioned and attached to the patient's jawbone, serving as a reference for dental implant surgical guides. *Id.*; EX1006, Abstract. Yau describes a fixation base substantially like the Llop126 base as it is positioned and attached to the patient's jawbone and used as a reference for subsequent implant-related drilling and installation. EX1010, [0023]. EX1003, ¶ 212. When the prior art identifies a problem and provides express guidance on how to fix the problem as in Yau, a skilled artisan would have had a reasonable

expectation of success in combining the prior art. *See, e.g., In re Inland Steel Co.*, 265 F.3d 1354, 1364 (Fed. Cir. 2001).

A POSA also would have recognized that the modification Llop126's design to include the Yau tooth mold was easy to implement. EX1003, ¶ 216. For example, a POSA would either replace or modify the apexes of Llop126's anchoring struts to accept Yau's tooth mold as individual components (or as one piece), which could be either fabricated as a single strut-mold unit through, e.g., 3D printing, or designed for attachment through other standard means known in the art (e.g., plug pins and holes, as taught by Yau). *Id.* Replacing or modifying the anchoring struts with the Yau tooth mold components would have been straightforward, with a reasonable expectation of success.

A POSA would have also understood that modifying the Llop126 anchoring struts assembly to include tooth molds would not alter the operating principles of Llop126. *Id.*, ¶ 217. Rather than the indentations 46 at the apexes of the anchoring struts that match one or more portions of gum, dentition or both of the patient, the result of the combination would include a mouthpiece that surrounds a portion of the patient's teeth to thereby provide a more robust registration of the bone foundation guide. *Id.*

Thus, it would have been obvious to combine the teachings of Llop126 with the “mouthpiece” of Yau.

2. Llop126 and Yau Combine to Disclose the Limitations of the Claims

(a) Element 1[pre]: Preamble

See Ground 3 (Section VIII.C.2.(a)), above.

(b) Element 1[a]: dental prosthesis

See Ground 3 (Section VIII.C.2.(b)), above.

(c) Element 1[b]: fixation base

See Ground 3 (Section VIII.C.2.(c)), above.

(d) Element 1[c]: fixation base features

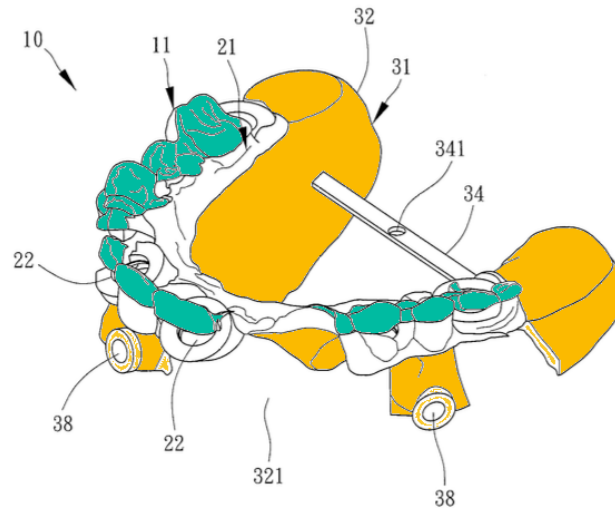
See Ground 3 (Section VIII.C.2.(d)), above.

(e) Elements 1[d, e, f]: mouthpiece features

See Ground 3 (Section VIII.C.2.(e)), above re Llop126.

Yau discloses a mouthpiece configured and dimensioned to surround a portion of the teeth that is used to assure appropriate location to attach a guide to the patient’s maxillary or mandibular bone tissue. EX1003, ¶ 225. Yau describes using a “tooth mold” as an “upper guide member” that attaches to a “middle” and “lower” guide member so that they may be fixed to the patient’s gingiva. EX1010, [0007], [0008], [0016]–[0025]. Like Llop126, Yau describes the use of opposing teeth to precisely position a base (lower member 31) in the patient’s mouth, and

securing the base to the patient's jawbone using "plug pins or screw bolts" through apertures 38 of the base. *Id.*, [0019], [0022], [0029], Figs. 1, 4.



Yau also discloses that the tooth mold upper guide member 11 may be made of a single piece, rather than three components as shown. *Id.*, [0025] (“...in actual application, the upper guide member 11 can be a one-piece member, or consists of multiple component parts.”). A POSA would consider such a one-piece member to be a “mouthpiece.” EX1003, ¶ 226. A POSA would understand from Yau’s description of a “tooth mold adapted for tight engagement with the natural teeth” and the accompanying figures that the tooth mold is configured and dimensioned to surround at least a portion of the patient’s teeth. *Id.*

(f) *Element 1/g[: fixation base installation*

See Ground 3 (Section VIII.C.2.(f)), above re Llop126.

Yau also discloses installing a fixation base to the maxillary or mandibular bone tissue of the patient. Yau describes the use of opposing teeth to precisely position a base (lower member 31) in the patient's mouth, and securing the base to the patient's jawbone using "plug pins or screw bolts" through apertures 38 of the base. EX1010, [0019], Figs. 1, 4; EX1003, ¶ 228.

(g) Element 1[h]: mouthpiece removal

See Ground 3 (Section VIII.C.2.(g)), above re Llop126.

(h) Element 1[i]: teeth/tissue removal

See Ground 3 (Section VIII.C.2.(h)), above.

(i) Element 1[j]: bone recontouring

See Ground 3 (Section VIII.C.2.(i)), above.

(j) Element 1[k]: drill guide

See Ground 3 (Section VIII.C.2.(j)), above.

(k) Element 1[l]: implant hole drilling

See Ground 3 (Section VIII.C.2.(k)), above.

(l) Element 1[m]: implant installation

See Ground 3 (Section VIII.C.2.(l)), above.

(m) Element 1[n]: abutment installation

See Ground 3 (Section VIII.C.2.(m)), above.

(n) Element 1[o]: prosthesis installation

See Ground 3 (Section VIII.C.2.(n)), above.

(o) Claim 2: installing fixation base

See Ground 3 (Section VIII.C.2.(o)), above.

(p) Claim 3: using preformed surface to recontour

See Ground 3 (Section VIII.C.2.(p)), above.

(q) Element 7[pre]: Preamble

See Ground 3 (Section VIII.C.2.(q)), above.

(r) Element 7[a]: fixation base

See Ground 3 (Section VIII.C.2.(r)), above.

(s) Element 7[b]: fixation base properties

See Ground 3 (Section VIII.C.2.(s)), above.

(t) Element 7[c, d]: mouthpiece

See Ground 3 (Section VIII.C.2.(t)), above re Llop126.

Yau discloses a mouthpiece configured and dimensioned to surround a portion of the teeth and to attach to the fixation base. EX1003, ¶ 243–244. Yau describes using a “tooth mold” as an “upper guide member” that attaches to a “middle” and “lower” guide member so that they may be fixed to the patient’s gingiva. EX1010, [0007], [0008], [0016]–[0025].

Yau discloses that the tooth mold upper guide member 11 may be made of a single piece, rather than three components as shown. *Id.*, [0025] (“...in actual application, the upper guide member 11 can be a one-piece member, or consists of multiple component parts.”). A POSA would consider such a one-piece member to be a “mouthpiece.” EX1003, ¶ 244. A POSA would understand from Yau’s description of a tooth mold “adapted for tight engagement with the natural teeth” and the accompanying figures that the tooth mold is configured and dimensioned to surround at least a portion of the patient’s teeth. *Id.*

(u) Element 7[e]: mouthpiece removal

See Ground 3 (Section VIII.C.2.(u)), above re Llop126.

(v) Claim 10: drill guide

See Ground 3 (Section VIII.C.2.(v)), above.

(w) Claim 13: fixation base composition

See Ground 3 (Section VIII.C.2.(w)), above.

(x) Claim 14: recontouring surface

See Ground 3 (Section VIII.C.2.(x)), above.

(y) Claim 16: prosthesis attached to fixation base

See Ground 3 (Section VIII.C.2.(y)), above.

(z) Element 17[pre]: Preamble

See Ground 3 (Section VIII.C.2.(z)), above.

(aa) Element 17[a]: fixation base

See Ground 3 (Section VIII.C.2.(aa)), above.

(bb) Element 17[b]: fixation base properties

See Ground 3 (Section VIII.C.2.(bb)), above.

(cc) Element 17[c, d, e]: mouthpiece

See Ground 3 (Section VIII.C.2.(cc)), above re Llop126.

See Element 1[d, e, f]. As discussed above, Yau discloses using a mouthpiece (tooth mold) that is configured and dimensioned to surround at least a portion of the teeth of the patient. EX1003, ¶ 254. Llop126 discloses using a set of anchoring struts with indentations matching dentition on the patient's opposite alveolar ridge. Both Llop126 and Yau disclose attaching the mouthpiece to the base, and installing the mouthpiece to assist in positioning the base properly before it is installed to the patient's bone tissue. *Id.*

(dd) Element 17[f]: installing fixation base

See Ground 3 (Section VIII.C.2.(dd)), above.

(ee) Element 17[g]: mouthpiece removal

See Ground 3 (Section VIII.C.2.(ee)), above re Llop126.

3. The Claims are Obvious Over the Combination of Llop126 and Yau

The combination of Llop126 and Yau discloses all of the features of claims 1–3, 7, 10, 13–14 and 16–17. As shown above, it would have been obvious for a

POSA to combine those references as claimed. Accordingly, these claims should be found not patentable as obvious under 35 U.S.C. § 103.

F. Ground 6: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over the Combination of Llop126 and Yau in View of Groscurth

Assuming the claims are construed to limit the material of the drill guide and fixation base (Section VI), then 1–3, 7, 10, 13–14, and 16–17 would have been obvious to a POSA based on Llop126 in view of Yau and Groscurth. EX1003, ¶¶ 258–268.

1. Llop126, Yau and Groscurth—Motivation to Combine

As described above in Ground 4 (Section VIII.E.1) and incorporated herein, a POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a tooth mold as in Yau, to ensure proper alignment of the fixation base. EX1010, [0007], [0017], [0022]; EX1003, ¶ 259. A POSA would have been motivated to further modify the Llop126/Yau system to form the fixation base and drill guide of metal, to increase rigidity and stability. EX1003, ¶ 260.

Llop126, Yau and Groscurth are analogous to the subject matter of the '209 Patent. *See Circuit Check Inc.*, 795 F.3d at 1335; *In re Deminski*, 796 F.2d at 442. These references are in the same field of endeavor as the '209 Patent namely

surgical guide systems for performing osteotomies, and installing dental implants and prostheses. *Compare* EX1006, Title, Abstract, “Field of Invention,” Fig. 17, *with* EX1011, Title, Abstract, “Field of Invention”, Fig. 9; EX1003, ¶ 262.

Groscurth describes the problem of a fixation base that is not rigid or stable. EX1011, 1:56–2:10. Groscurth acknowledges the need for a fixation base / drill guide system that has “great rigidity so that it is very stable in the patient’s mouth as well as on the physical anatomical diagnostic model.” *Id.*, Abstract, 2:1–11, 6:35–40. To solve this problem, Groscurth discloses an embodiment in which a drill guide and fixation base are made of metal. EX1011, 2:46–52, 13:1–4; EX1003, ¶¶ 261–264 (explaining that Groscurth teaches an embodiment in which metal is used to provide a strong dental surgical guides which are advantageous for surgical procedures). A POSA would have been motivated to modify the Llop126 bone foundation guide and drill guide—in which the material used is not specified—to be made of metal as disclosed by Groscurth. EX1003, ¶¶ 261–264.

Yau does not describe any particular material to be used for its components, but notes the provision of a “support bar” connected to the body of the base “for providing support to enhance the overall structural rigidity of the lower guide member 31.” EX1010, [0019]. Yau further describes that the support bar may include an “inspection hole 341 for allowing the dentist to visually check whether

the lower guide member 31 has been closely attached...” *Id.*, [0029]. A POSA would recognize that these stated goals from Yau of structural rigidity and improved visibility could be met through the use of a metallic material for the base, as described in Groscurth. EX1003, ¶ 265.

2. Llop126 and Yau Combine to Disclose All Elements Other Than a Metal Fixation Base and Drill Guide

All elements of claims 1–3, 7, 10, 13–14 and 16–17 are present in the combination of Llop and Yau, for the reasons set forth in Ground 5 (Section VIII.E.2) above.

3. Groscurth Discloses a Metal Fixation Base and Drill Guide

See Ground 4 (Section VIII.D.3), above.

4. The Claims are Obvious Over the Combination of Llop126 and Yau in View of Groscurth

The combination of Llop126 and Yau and Groscurth discloses all of the features of Claims 1–3, 7, 10, 13–14, and 16–17. EX1003, ¶ 268. As shown above, Llop126 and Yau together disclose every claim element other than a metallic fixation base and drill guide. The combination of Llop126 and Yau with Groscurth includes this limitation and thus discloses all the claim elements. As shown above, it would have been obvious for a POSA to combine those references as claimed. *Id.* Accordingly, these claims should be found not patentable as obvious under 35 U.S.C. § 103.

G. Ground 7: Claims 5, 6 and 12 are Obvious Over the Combination of Llop126, Sichuan and Scherer

If the Board decides that “drill guide” and “fixation base” should not be limited according to Patent Owner’s express disclaimer of claim scope (see Section VI), then claims 5, 6 and 12 would have been obvious to a POSA under Section 103 in view of Llop126 and Sichuan with Scherer. EX1003, ¶¶ 269–275.

1. Llop126, Sichuan and Scherer—Motivation to Combine

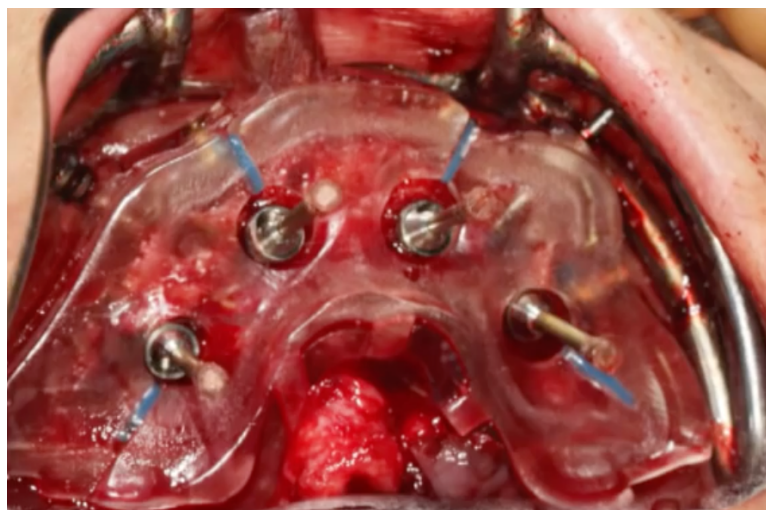
In order to solve the known problem of aligning abutments to proper angular orientation, a POSA would have been motivated to use an attachable abutment guide as disclosed in Scherer. A POSA would have understood that the nSequence system shown by Scherer is similar or identical to the system described in Llop126, and thus there was a high likelihood of success in making the combination. EX1003, ¶ 270; EX1012, 1:58; EX1018, 4–5 (identifying U.S. Provisional App. 61/784,029, to which the Llop126 application claims priority). Scherer describes an abutment guide used for orienting the abutments that attaches to the bone foundation guide. EX1012, 4:30–5:10. The Scherer abutment guide uses the same or similar tabs/cutout mechanism to attach to the foundation guide as what is described and shown in Llop126 for attaching the implant surgical guide (drill guide) and tissue gasket of Llop126. *Id.*; EX1006, [0122], [0126]; EX1003,

¶ 271. There is thus complete compatibility between the abutment guide of Scherer and the surgical guide system of Llop126. EX1003, ¶ 271. The operating principles of Llop126 are not affected by the use of Scherer’s abutment guide, nor by the use of a mouthpiece as from Sichuan. *Id.* A POSA would have understood the advantages of using a fully compatible abutment guide, as disclosed in Scherer, with the system of Llop126 in order to ensure that abutments were properly aligned, so that a proper prosthesis fit could be attained. *Id.*

2. Llop126, Sichuan and Scherer Combine to Disclose the Limitations of the Claims

(a) Claim 5: abutment guide

Scherer discloses utilizing an abutment guide that attaches to the fixation base, as recited in claim 5. EX1003, ¶ 272. Scherer shows “a multi-unit rotation guide that goes on top of the bone foundation guide which will assist the surgeon to orient the multi-unit abutments properly. The blue line assists with that alignment.” EX1012, 4:30–5:15.



Scherer demonstrates how the blue line indicators on the abutment guide are used to align abutments to appropriate angular rotation for placement against the implants. *Id.* (17 degree abutments in the interior, 30 degree abutments in the posterior). As seen in and described by Scherer, each blue line on the abutment guide corresponds to an orientation for the abutment relative to the central axis of the associated implant. EX1003, ¶ 272.

(b) Claim 6: abutment installation

See Claim 5, above.

(c) Claim 12: abutment guide

See Claim 5, above.

3. The Claims are Obvious Over the Combination of Llop126, Sichuan and Scherer

The combination of Llop126 and Sichuan with Scherer discloses those limitations and thus discloses all the elements of claims 5, 6 and 12 of the '209 Patent.

H. Ground 8: Claims 5, 6 and 12 are Obvious Over the Combination of Llop126, Sichuan and Scherer in View of Groscurth

Assuming the claims are construed to limit the material of the drill guide and fixation base (Section VI), then claims 5, 6 and 12 would have been obvious to a POSA based on Llop126, Sichuan and Scherer in view of Groscurth. EX1003, ¶¶ 276–277.

As shown above, Groscurth discloses a metal drill guide and fixation base, and it would have been obvious for a POSA to combine Llop126 and Sichuan with Scherer (Section VIII.G, above). None of the advantages of using Scherer's abutment guide are mitigated by the further combination with Groscurth for a metallic fixation base and drill guide.

I. Secondary Considerations

At the institution phase, the Board has repeatedly determined that evidence of secondary considerations should be addressed in a trial where the parties may develop, and the Board may consider, a full record. *See, e.g., Tristar Products, Inc. v. Choon's Design, LLC*, IPR2015-01883, Paper No. 6 at 26 (P.T.A.B. Mar. 9, 2016) (“The issue of secondary considerations is highly fact specific, and at this stage of the proceeding, the record regarding such secondary considerations is incomplete.”).

That is the appropriate course here, given that “the inventions represent[] no more than ‘the predictable use of prior art elements according to their established functions,’” and, thus any secondary considerations do not establish nonobviousness as a matter of law. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *KSR*, 550 U.S. at 417); *see, e.g., Leapfrog Enterprises Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (“[G]iven the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion [of obviousness].”).

IX. THE BOARD SHOULD INSTITUTE TRIAL UNDER §§ 324 AND 325

A. Institution Should Not Be Denied Based on Parallel Litigation

The Massachusetts litigation should not be used to deny institution because that case was only recently filed and served, and the parties have made little or no investment there. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 13-14 (P.T.A.B. Mar. 20, 2020). The parties have jointly represented that they may request a stay of that litigation pending the resolution of this Post Grant Review. EX1007.

B. The Petition Relies on Different Prior Art and Arguments

In evaluating a petition under § 325(d), the Board uses a two-part framework: “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential).

The first prong of the *Advanced Bionics* framework is not satisfied here because there are new grounds and arguments based on lack of written description and indefiniteness under 35 U.S.C. § 112. The Examiner did not consider the

adequacy of description for drill guides and fixation bases made from “composite or polymer” materials. Nor was definiteness of “sufficiently strong enough to withstand breakage during a prosthesis installation procedure” considered.

EX1002. These are new arguments and grounds. *Forte Biosciences, Inc. v. Univ. of Mass.*, PGR2023-00014, Paper 10 at 13 (P.T.A.B., July 3, 2023). (In the absence of any rejection or analysis of § 112 issues during prosecution, “the same or substantially the same arguments presented in the Petition could not have been presented previously to the Office.”)

Petitioner also presents prior art not considered by the Office that discloses the element found to be missing—a mouthpiece “configured and dimensioned to surround at least a portion of the teeth.” EX1002, 224. As explained above, the Examiner found the mouthpiece element to be missing in the prior art of record. *Id.*, 224–225 (“[T]he added language in the claim is not found in the prior art of Llop'126 and Llop'881 used in the Office Action of 9 February 2023.”) Both Sichuan and Yau, however, disclose a mouthpiece that is “configured and dimensioned to surround at least a portion of the teeth of the patient” as required by claim elements 1[e], 7[c], 17[c]. EX1003, ¶¶ 77, 125. These references—which are used in the Petition’s obviousness grounds—thus provide compelling new evidence of obviousness that should be considered by the Office. This new

evidence is not cumulative or overlapping with prior art or arguments presented earlier.

X. CONCLUSION

For the reasons set forth above, Petitioner respectfully requests post-grant review of claims 1–3, 5–7, 10–14 and 16–17 of the '209 Patent.

XI. MANDATORY NOTICES

A. Real Party-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that the real party-in-interest is 3D Diagnostix, Inc., of Boston, Massachusetts. Petitioner further certifies that 30% of the stock of 3D Diagnostix, Inc. is held by Straumann Manufacturing, Inc., which has no control, input or participation in the preparing or filing of this Petition.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), the '209 Patent is currently the subject of litigation in *Watson Guide IP, LLC v. 3D Diagnostix, Inc.*, No. 1:24-cv-10158-LTS (D. Mass.), filed on February 29, 2024 and served on April 4. Other than the pending prosecution of continuation patent applications from the '209 Patent, Petitioner is unaware of any other judicial or administrative matter which would

affect, or be affected by, a decision in this proceeding. The parent '016 patent was the subject of IPR2023-00177.

C. Lead and Back-Up Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner designates the following counsel:

Lead Counsel: Aaron R. Feigelson, Reg. No. 59,022

Backup Counsel: Wesley O. Mueller, Reg. No. 33,976

Pursuant to 37 C.F.R. § 42.10(b), Petitioner has filed a power of attorney appointing the practitioners associated with Leydig, Voit & Mayer, Ltd., Customer Number 23460, which include the aforementioned lead and backup counsel.

D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), Petitioner provides the following service information for the designated counsel. Petitioner consents to electronic service by email at the email addresses provided below.

Mailing Address:

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XII. PAYMENT OF FEES

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.15(a) and 42.203. If any additional fees are due at any time during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 12-1216.

Respectfully Submitted,

Date: July 19, 2024

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CERTIFICATE OF WORD COUNT UNDER 37 C.F.R. § 42.24(a)

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that this Petition complies with the type-volume limits of 37 C.F.R. § 42.24(a)(1)(ii). As calculated by the word count feature of the word-processing system used to prepare this Petition, it contains no more than 17,332 words, excluding the parts of this Petition that are exempted by 37 C.F.R. § 42.24(a).

Date: July 19, 2024

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing petition for Post-Grant Review of U.S. Patent No. 11,806,209, including all Exhibits, was served on July 19, 2024, via UPS delivery directed to the attorney of record for the patent at the following address:

James Italia
Italia IP
3500 West Olive Ave., Suite 300
Burbank, CA 91505

Additionally, a courtesy copy of the foregoing petition for Post-Grant Review of U.S. Patent No. 11,806,209, and the accompanying Declaration of Dr. Erickson, was sent on July 19, 2024, to Watson Guide IP, LLC's litigation counsel via Electronic-Mail delivery, addressed as follows:

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Date: July 19, 2024

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