

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

DECLARATION OF DOUGLAS ERICKSON, D.D.S., M.S.

TABLE OF CONTENTS

I.	INTRODUCTION AND BACKGROUND	7
II.	SUMMARY OF OPINIONS	10
III.	INFORMATION CONSIDERED.....	10
IV.	LEGAL STANDARDS	12
	A. Level of Ordinary Skill in the Art	12
	B. Claim Construction.....	12
	C. Written Description	13
	D. Indefiniteness.....	14
	E. Obviousness.....	15
V.	THE '209 PATENT	18
	A. Overview of the '209 Patent	18
	B. The Prosecution History	22
	C. The Challenged Claims of the '209 Patent.....	25
VI.	LEVEL OF ORDINARY SKILL IN THE ART	29
VII.	CONSTRUCTION OF CLAIM TERMS	30
	A. “Drill guide”	31
	B. “Fixation base”	35
VIII.	OVERVIEW OF THE PRIOR ART	39
	A. Llop126 (Ex. 1006).....	39
	B. Sichuan (Exs. 1008, 1009).....	42
	C. Yau (Ex. 1010)	44
	D. Groscurth (Ex. 1011)	46
	E. Scherer (Exs. 1012, 1013).....	48
IX.	FACTS AND OPINIONS RELEVANT TO THE UNPATENTABILITY GROUNDS ASSERTED IN THE PETITION	50
X.	INVALIDITY ANALYSIS FOR PETITION.....	51
	A. Ground 1: Claims 11 and 13 Lack Written Description.....	51
	1. Claim 11 Lacks Written Description.....	52

2. Claim 13 Lacks Written Description.....	54
B. Ground 2: Claims 11 and 13 are Indefinite	58
C. Ground 3: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over Llop126 and Sichuan	62
1. Llop126 and Sichuan—Motivation to Combine.....	62
2. Llop126 and Sichuan Combine to Disclose the Limitations of the Claims 70	
(a) Element 1[pre]: Preamble	70
(b) Element 1[a]: dental prosthesis	71
(c) Element 1[b]: fixation base	72
(d) Element 1[c]: fixation base features	74
(e) Element 1[d, e, f]: mouthpiece features.....	75
(f) Element 1[g]: fixation base installation.....	80
(g) Element 1[h]: mouthpiece removal	81
(h) Element 1[i]: teeth/tissue removal.....	82
(i) Element 1[j]: bone recontouring	83
(j) Element 1[k]: drill guide	83
(k) Element 1[l]: implant hole drilling.....	85
(l) Element 1[m]: implant installation.....	85
(m) Element 1[n]: abutment installation	86
(n) Element 1[o]: prosthesis installation	86
(o) Claim 2: installing fixation base.....	87
(p) Claim 3: using preformed surface to recontour	87
(q) Element 7[pre]: Preamble	88
(r) Element 7[a]: fixation base	88
(s) Element 7[b]: fixation base properties	89
(t) Element 7[c, d]: mouthpiece	89
(u) Element 7[e]: mouthpiece removal	90
(v) Claim 10: drill guide.....	90
(w) Claim 13: fixation base composition.....	92

(x)	Claim 14: recontouring surface	93
(y)	Claim 16: prosthesis attached to fixation base.....	93
(z)	Element 17[pre]: Preamble	94
(aa)	Element 17[a]: fixation base	94
(bb)	Element 17[b]: fixation base properties.....	95
(cc)	Element 17[c, d, e]: mouthpiece.....	95
(dd)	Element 17[f]: installing fixation base	95
(ee)	Element 17[g]: mouthpiece removal	95
3.	The Claims are Obvious Over the Combination of Llop126 and Sichuan	96
D.	Ground 4: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over Llop126 and Sichuan in View of Groscurth	96
1.	Llop126, Sichuan and Groscurth—Motivation to Combine	96
2.	Llop126 and Sichuan Combine to Disclose All Elements Other Than a Metal Fixation Base and Drill Guide.....	100
3.	Groscurth Discloses a Metal Fixation Base and Drill Guide	100
4.	The Claims are Obvious Over the Combination of Llop126 and Sichuan in View of Groscurth.....	101
E.	Ground 5: Claims 1–3, 7, 10, 13–14 and 16–17 are Obvious Over Llop126 and Yau	101
1.	Llop126 and Yau—Motivation to Combine	102
2.	Llop126 and Yau Combine to Disclose the Limitations of the Claims	108
(a)	Element 1[pre]: Preamble	108
(b)	Element 1[a]: dental prosthesis	108
(c)	Element 1[b]: fixation base	108
(d)	Element 1[c]: fixation base features.....	108
(e)	Elements 1[d, e, f]: mouthpiece features	108
(f)	Element 1[g]: fixation base installation.....	110
(g)	Element 1[h]: mouthpiece removal	110
(h)	Element 1[i]: teeth/tissue removal.....	110

(i)	Element 1[j]: bone recontouring	110
(j)	Element 1[k]: drill guide	110
(k)	Element 1[l]: implant hole drilling.....	110
(l)	Element 1[m]: implant installation.....	110
(m)	Element 1[n]: abutment installation	110
(n)	Element 1[o]: prosthesis installation	111
(o)	Claim 2: installing fixation base.....	111
(p)	Claim 3: using preformed surface to recontour	111
(q)	Element 7[pre]: Preamble	111
(r)	Element 7[a]: fixation base	111
(s)	Element 7[b]: fixation base properties	111
(t)	Element 7[c, d]: mouthpiece	111
(u)	Element 7[e]: mouthpiece removal	112
(v)	Claim 10: drill guide.....	112
(w)	Claim 13: fixation base composition.....	112
(x)	Claim 14: recontouring surface	112
(y)	Claim 16: prosthesis attached to fixation base.....	112
(z)	Element 17[pre]: Preamble	112
(aa)	Element 17[a]: fixation base	112
(bb)	Element 17[b]: fixation base properties.....	113
(cc)	Element 17[c, d, e]: mouthpiece.....	113
(dd)	Element 17[f]: installing fixation base	113
(ee)	Element 17[g]: mouthpiece removal	113

3. The Claims are Obvious Over the Combination of Llop126 and Yau 113

- 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..... 114
1. Llop126, Yau and Groscurth—Motivation to Combine 114
 2. Llop126 and Yau Combine to Disclose All Elements Other Than a Metal Fixation Base and Drill Guide 117

3. Groscurth Discloses a Metal Fixation Base and Drill Guide	118
4. The Claims are Obvious Over the Combination of Llop126 and Yau in View of Groscurth.....	118
G. Ground 7: Claims 5, 6 and 12 are Obvious Over the Combination of Llop126, Sichuan and Scherer	118
1. Llop126, Sichuan and Scherer—Motivation to Combine	118
2. Llop126, Sichuan and Scherer Combine to Disclose the Limitations of the Claims.....	120
(a) Claim 5: abutment guide	120
(b) Claim 6: abutment installation	121
(c) Claim 12: abutment guide	121
3. The Claims are Obvious Over the Combination of Llop126, Sichuan, Scherer	121
H. Ground 8: Claims 5, 6 and 12 are Obvious Over the Combination of Llop126, Sichuan and Scherer in View of Groscurth	122
XI. ACKNOWLEDGMENTS	123

I, Dr. Douglas Erickson of Duluth, Minnesota, declare as follows:

I. INTRODUCTION AND BACKGROUND

1. I have been retained as a technical expert by Petitioner to study and provide my independent opinions on the technology claimed in U.S. Patent No. 11,806,209 (the “’209 Patent”) and the issue of patentability of the ’209 Patent claims. I am competent to testify under oath, and will do so if called as a witness, as follows herein.

2. I am a semi-retired board-certified prosthodontist. Prior to retirement in January 2022, I ran the Dental Implant and Reconstructive Center in Duluth, Minnesota for 26 years.

3. In 1977, I obtained a Bachelor of Arts Degree in biology from St. Olaf College. In 1981, I obtained a Doctor of Dental Surgery Degree from the University of Minnesota School of Dentistry.

4. In 1982, I obtained a certificate for general practice after attending the General Practice Residency Program at the Denver General Hospital. In 1995, I obtained a Master of Science degree in prosthodontics after receiving graduate-level training through the United States Air Force prosthodontic training program at Wilford Hall Medical Center and the University of Texas Health Sciences Medical Center at San Antonio, Texas.

5. I served 10 years as a commissioned officer in the United States Air Force, achieving the rank of Lieutenant Colonel prior to establishing a full-time prosthodontic practice in Duluth, Minnesota. While in the Air Force, I served as an educator and dental laboratory manager to over 60 enlisted dental laboratory technicians. I was also instrumental in developing and installing the Air Force Stereolithography Laboratory in 1995, making Wilford Hall likely the first medical center in the world to have a digital dental laboratory with its own stereolithography machine.

6. Since the mid-1990s, I helped beta test the original Simplant SurgiGuides for dental implant replacement. I also consulted with the Belgium company Materialise in the development of the Surgicase and Simplant softwares that are commonly used today in the pre-operative planning and the placement of dental implants based on CT data.

7. I have given a number of lectures on the topics of dental implants, digital 3D modeling and the use of computed tomography, as well as the use of surgical guides and navigational equipment in dental surgery. I also lectured several times following the achievement of my master's degree in the field of Bone Morphogenic Protein.

8. I am a Diplomat of the American Board of Prosthodontics. I am also an active member of the American Academy of Restorative dentistry, the

American College of Prosthodontics, the American College of Dentists, the International Academy of Gnathology, the American Dental Association, the Minnesota Dental Association, and the Northeastern District Dental Society. I served as a past president of the Northeastern District Dental Society and was a past program chair and president of the Minnesota Academy of Gnathological Research. Currently I volunteer for the American Dental Association as the District 10 Representative for the Council on Congressional Affairs, a delegate to the American Dental Association representing the State of Minnesota, serve on the MindenPak Board for the Minnesota Dental Association, and volunteer for the Minnesota Mission of Mercy.

9. A copy of my curriculum vitae is attached as Exhibit 1004.

10. I am being compensated at a rate of \$550 per hour for my analysis and testimony in this matter. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this investigation. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

11. My education and experience have given me specialized expertise in the fundamentals, principles, and technologies associated with dental implant procedures and surgical guides.

II. SUMMARY OF OPINIONS

12. Based on my experience, my knowledge of the art prior to the critical date of the '541 patent, my analysis of prior art references, and the understanding a person of ordinary skill in the art would have understood the claim terms, in light of the specification as of the earliest effective filing date, it is my opinion that certain claims of the '209 Patent lack adequate written description to show the inventor possessed the claimed invention. It is also my opinion that certain claims of the '209 Patent do not inform a person of ordinary skill in the art ("POSA") about the scope of the claimed invention, and thus are indefinite. It is also my opinion that all of the claims of the '209 Patent are obvious in view of the prior art references discussed below. In forming my opinions, I understand from counsel that the earliest possible effective filing date of the '209 Patent is May 18, 2017. The opinions herein referencing the general knowledge of a POSA refer to the general knowledge of a POSA at the time of the alleged invention claimed in the '207 patent, which I have been informed is the timeframe prior to May 18, 2017.

III. INFORMATION CONSIDERED

13. In forming my opinions, I have considered the '209 Patent and its prosecution history, my own knowledge and experience, the exhibits itemized in the Exhibit List filed with the petition for post-grant review (PGR) of the '209

Patent that are cited herein, as well as the other materials referenced herein. I have analyzed the following publications and materials:

Exhibit	Description
1001	U.S. Patent No. 11,806,209
1002	File History of U.S. Patent No. 11,806,209
1005	Provisional Patent Application No. 62/508,377
1006	U.S. Patent Application Publication No. 2017/0252126 to Llop (“Llop126”)
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) (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) (Part 2)
1018	Internet Archive, http://www.nsequence.com/2013/11/08/all-on-x-cases-immediate-provisionalization , archived March 10, 2016 (accessed June 28, 2024)

IV. LEGAL STANDARDS

14. I have been informed that the following legal principles apply to analysis of patentability based on 35 U.S.C. §§ 102, 103 and 112.

A. Level of Ordinary Skill in the Art

15. It is my understanding that the claims and specification of a patent are to be read and construed through the eyes of a person of ordinary skill in the art at the time the invention was made, which I have been informed is the timeframe prior to May 18, 2017. To determine the appropriate level of one of ordinary skill in the art, I have been informed that the following factors may be considered: (a) the types of problems encountered by those working in the field and prior art solutions thereto; (b) the sophistication of the technology in question, and the rapidity with which innovations occur in the field; and (c) the educational level of active workers in the field.

B. Claim Construction

16. I have also been informed that, in order to assess whether the prior art satisfies a certain claim element in an invalidity analysis, the claim element must first be construed, and then the prior art must be evaluated to determine whether it satisfies the properly-construed element of the claim. I have been informed that a patent claim is construed from the perspective of a person of ordinary skill in the

art at the time of the invention, taking into account the claim language, the teachings of the patent specification and the prosecution history.

17. Other than as specifically noted below, I have been informed that the claims in the '209 Patent should be understood based on the plain and ordinary meaning of the claim language in the context of the '209 Patent. Unless otherwise specifically noted, my opinions in this Declaration are consistent with the plain and ordinary meaning of the claim language to a person of ordinary skill in the art at the time of the invention.

C. Written Description

18. I have been informed that patents must contain a written description of the invention, which is known as the written-description requirement. I have been informed that a patent claim is invalid if any portion of the claim fails the written-description requirement. I have been told that the written-description test is the same whether the claim element is essential or auxiliary to the invention.

19. I have been informed that, to provide adequate written description, the specification must reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. I have been informed that this requires an objective inquiry into the four corners of the specification from the perspective of a POSA to determine whether the specification shows that the inventor actually invented what is claimed. I have been

informed that, while the written-description requirement does not demand any particular form of disclosure or that the specification recite the claimed invention verbatim, a description that merely renders the invention obvious does not satisfy the requirement.

D. Indefiniteness

20. I have been informed that the statutory basis for the definiteness requirement is found in 35 U.S.C. § 112(b), which provides in relevant part:

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

21. I have been informed by counsel that in litigation (i.e., when a patent owner sues another party alleging infringement), patent claims are determined to be indefinite if the “claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

22. While I understand that “the definiteness requirement must take into account the inherent limitations of language,” patents “must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them.” *Nautilus*, 572 U.S. 909. The “reasonable certainty” standard reflects

“the definiteness requirement's public-notice function” and reduces the “innovation-discouraging ‘zone of uncertainty’ against which [the Supreme] Court has warned. *Id.* at 911.

23. In particular, I understand that claims are indefinite if their “legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not.” *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

E. Obviousness

24. I have been informed that a patent claim is invalid as being obvious if the differences between the claimed subject matter and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art, which I have been informed is the timeframe prior to May 18, 2017. I also understand that in order to assess whether a claim would have been obvious in light of the prior art, I must step back in time and take the viewpoint of the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made, which I understand is the timeframe prior to May 18, 2017, in the present case. I must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person.

25. I have been informed that the following factors are considered in determining whether a claimed invention is invalid as obvious over the prior art: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art and (4) any “secondary considerations” that may serve as evidence of nonobviousness, such as commercial success, long felt but unsolved needs, and failure of others.

26. I have been informed that a person of ordinary skill in the art is presumed to know all relevant prior art. I have been informed that a reference may be modified or combined with other references or with the person of ordinary skill’s own knowledge if the person would have found the modification or combination obvious. In considering whether a claim is obvious, I understand that I can take account of inferences and creative steps that a person of ordinary skill in the art would employ, and the common knowledge of the art that such a person would possess.

27. I have been told that there is no rigid rule that a reference or combination of references must contain a “teaching, suggestion, or motivation” to combine references. However, I also have been informed that the “teaching, suggestion, or motivation” test can be a useful guide in establishing a rationale for combining elements of the prior art. I have been informed that this test poses the question as to whether there is an express or implied teaching, suggestion or

motivation to combine prior art elements in a way that realizes the claimed invention, and that it seeks to counter impermissible hindsight analysis.

28. I have also been informed that the combination of familiar elements disclosed in the prior art according to known methods is likely to be obvious when it does no more than yield predictable results. I understand that if a technique has been used to improve one product, and a person of ordinary skill in the art would recognize that it would improve similar products in the same way; using the technique is obvious unless its actual application is beyond the skill of a person of ordinary skill in the art. I have been informed that the proper analysis of obviousness determines whether a person of ordinary skill in the art would have a “reasonable expectation of success”—not an “absolute predictability” of success—in achieving the claimed invention by combining prior art references.

29. I have been informed that, while there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as filtered through the knowledge of one skilled in the art. A person of ordinary skill in the art often will be able to fit the teachings of multiple references together like the pieces of a puzzle. Any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed.

30. I have also been informed that if a person of ordinary skill in the art can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. I have been told that in many fields, there may be little discussion of obvious combinations, and in these fields market demand—not scientific literature—may drive design trends. I have been told that, when there is a design need or market pressure, and there are a finite number of predictable solutions, a person of ordinary skill in the art has good reason to pursue those known options.

V. THE '209 PATENT

A. Overview of the '209 Patent

31. I understand the '209 Patent is one of several issued U.S. patents and pending applications that claim priority to U.S. Provisional Patent Application 62/508,377 filed on May 18, 2017. (Ex. 1005).

32. The '209 Patent is titled “Fixation base and guides for dental prosthesis installation.” The '209 Patent generally relates to an apparatus used to guide dental implant surgery for installing a prosthesis. Ex. 1001, Abstract, col. 1, lines 18-24, lines 47-50.

33. The system includes several components that are used to guide the surgery. A “fixation base 100” is placed in the patient’s mouth and attached to the patient’s jawbone, and is used as a reference position for the placement of

subsequent guides. *Id.* at 1:37–43, 4:29–33. Fig. 1 shows the fixation base, attached to the patient’s jawbone with fasteners, such as nails. *Id.*, 4:4–12, 29–32. “Slots” 118 in the fixation base may accept tabs from the guides to help position them. *Id.*, 4:53–55. The fixation base, subsequent guides, and prosthesis are designed and fabricated using anatomical data obtained from the patient via CT scans or other imaging techniques. *Id.*, 6:32–35.

34. The fixation base is positioned for attachment using an attached “mouthpiece.” *Id.*, 1:43–45; Fig. 4, 12c. The mouthpiece (green, below) is initially attached to the fixation base to assist in providing precision while installing the fixation base, and is removed after the fixation base has been installed. *Id.*, 1:43–49, 5:7–12, 8:1–18.

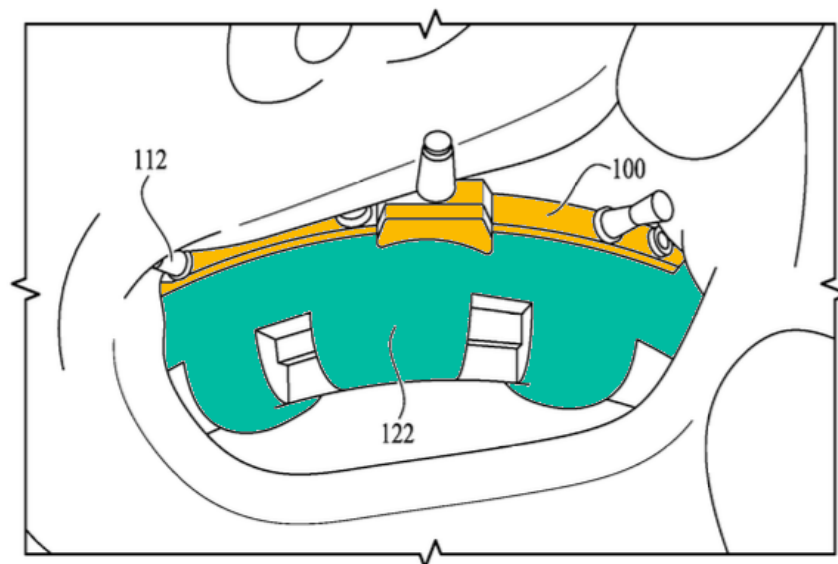


Fig. 12c

35. Once the fixation base is installed in the mouth, the teeth are removed, and the edge of the fixation base is used as a guide to remove bone with a bone removal tool such that the bone is flush with the fixation base. *Id.*, 7:5–20, Fig. 12f. A separate attachable bone reduction guide may alternatively be used.

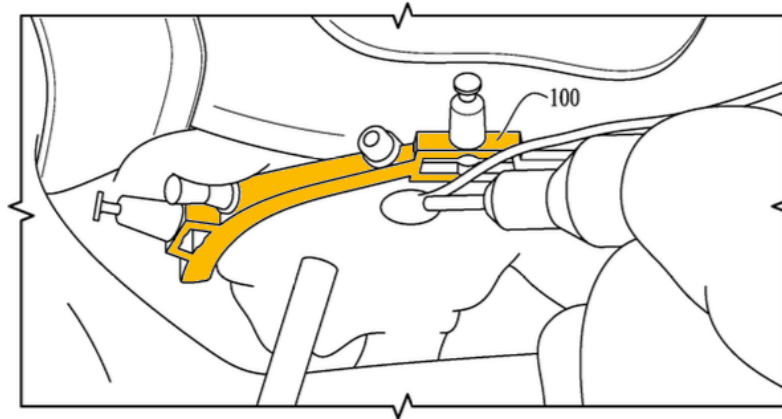


FIG. 12F

36. A drill guide is then attached to confirm proper location of drill holes in the patient's mouth. *Id.*, 1:63–67, 5:18–20. The practitioner drills and installs implants into the drilled holes. *Id.*, 1:65.

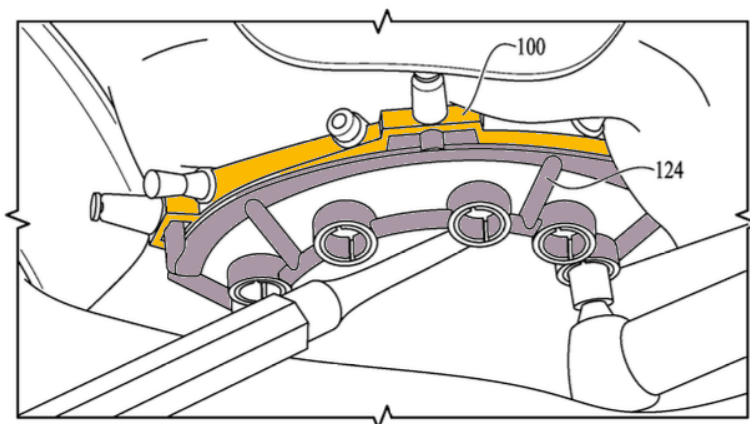


FIG. 12I

37. The drill guide is removed, and an abutment guide is then attached to assist in placing abutments onto the installed implants. *Id.*, Abstract, 1:57–62, Fig. 12L.

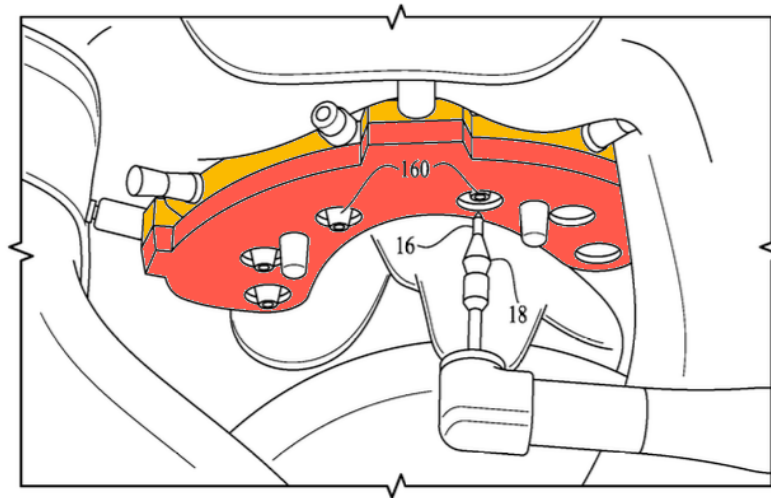


Fig. 12L

38. The prosthetic and copings are then placed onto the abutments using the abutment guide. *Id.*, 2:5–11, Fig. 12P.

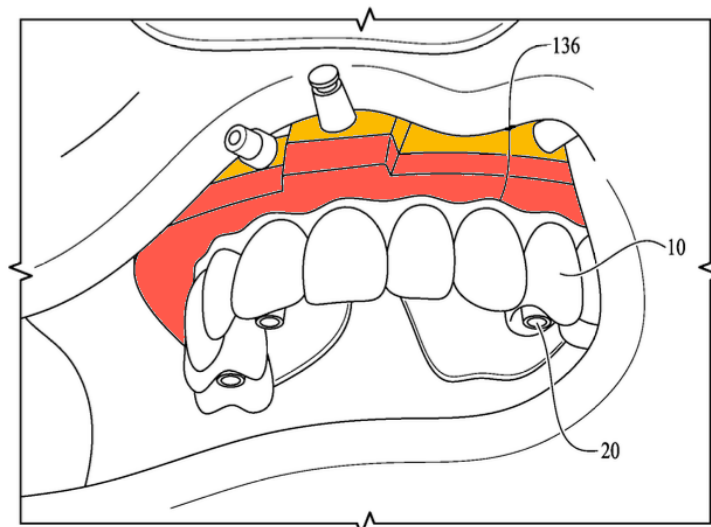


Fig. 12P

39. After the copings have been placed, the fixation base and abutment guide are removed and the practitioner can perform any necessary restorative surgery. The prosthetic is then secured.

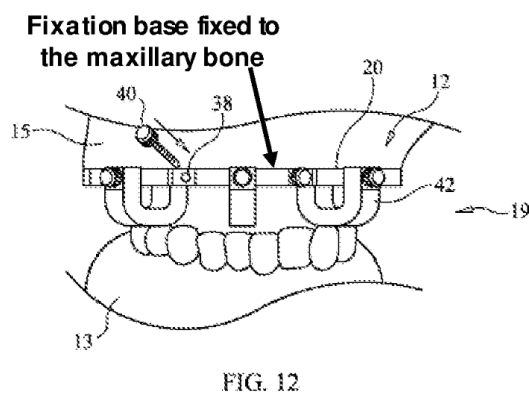
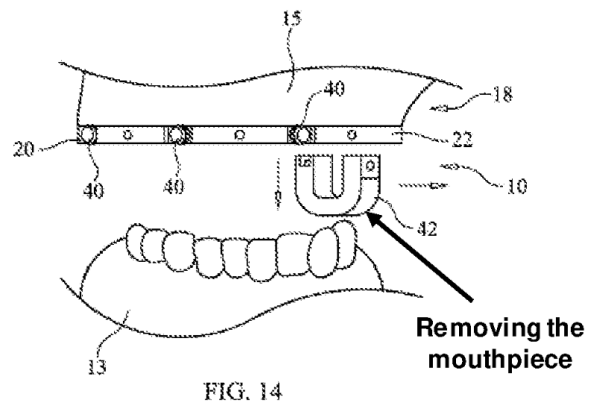
B. The Prosecution History

40. It is my understanding that the application (U.S. App. No. 17/503,359 ('359 application)) leading to the '209 Patent was filed on October 18, 2021. I further understand the application was filed as a continuation of U.S. App. No. 15/984,309 (now U.S. Patent 11,173,016), which was filed on May 18, 2018. It is also my understanding that both the '309 application and the '359 application claim the benefit of priority to U.S. Provisional App. No. 62/508,377, which was filed on May 18, 2017. I understand that the '209 Patent specification expressly incorporates the contents of the '309 application and the '377 provisional application by reference. Ex. 1001, 1:7–11.

41. I understand that after the '309 application was filed with the USPTO, but prior to receiving any office action, the applicant ("Watson") filed a preliminary amendment on February 11, 2022, amending several claims and adding others. For example, Watson amended claim 11 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." Ex. 1002, 70–76. Watson also added new claim

15 (which later became claim 13 in the issued '209 Patent) that included an identical limitation with regard to composition of the fixation base. *Id.*

42. I understand that on February 9, 2023, claims 1–3, 5–16 and 18 were rejected as anticipated by Llop126. Claims 4 and 17 were rejected as obvious over the combination of Llop126 and Llop881. Ex. 1002, 119–135. The examiner described how each claim element was present in Llop126. *Id.* With specific reference to the “mouthpiece”, 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 demonstrated this analysis with the following figures:



43. I understand that, in response to the rejection, Watson interviewed the examiner on March 21, 2023, and proposed amendments to limit the mouthpiece so as to overcome the obviousness rejection. Specifically, Watson amended the independent claims to include a limitation that the “mouthpiece” is “configured and dimensioned to surround teeth of the patient,” and later supplemented the amendment on May 15, 2023 to add “configured and dimensioned to surround at least a portion of the teeth of the patient.” Ex. 1002, 147–150.

44. In order to distinguish the claims from the prior art with regards to the “mouthpiece,” Watson argued that this was different from Llop’s anchoring strut because of the “hand and glove” relationship between the claimed mouthpiece and the patient’s existing teeth that allowed for the fixation base to be more accurately placed. Watson argued that Llop126 “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.” Ex. 1002, 167 (emphasis in original).

45. On August 3, 2023, the examiner accepted the arguments and withdrew the rejections based on Llop126. Ex. 1002, 184–191. However, the examiner added a new “double patenting” rejection. *Id.* I understand that the

examiner rejected claim 15 (now claim 13) as obvious over the combination of the parent '016 patent and U.S. Patent No. 5,320,539 to Pompa (“Pompa”). The examiner stated that 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.*, 201–218. Watson did not make any argument that the rejection was improper or that the '016 patent lacked this disclosure. Instead, Watson filed a terminal disclaimer. *Id.* The application was then allowed to issue. *Id.*, 224.

46. In the reasons for allowance, the examiner pointed to “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” as the basis of distinction over Llop126. Ex. 1002, 224. The '209 Patent issued on November 7, 2023. Ex. 1001.

C. The Challenged Claims of the '209 Patent

47. The '209 Patent includes 17 claims. In this Declaration, I have assessed the validity of claims 1–3, 5–7, 10–14 and 16–17 (the “Challenged Claims”), whose limitations are listed in the chart below:

<i>Reference</i>	<i>Claim 1</i>
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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.
Reference	Claim 14
14	The apparatus of claim 7, wherein the fixation base further comprises a surface to assist in recontouring of bone tissue.
Reference	Claim 16
16	The apparatus of claim 7, further comprising a dental prosthesis, wherein the dental prosthesis attaches to the installed fixation base.
Reference	Claim 17
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.

48. It is my opinion that the Challenged Claims of the '209 Patent are unpatentable for lack of written description, indefiniteness, or as obvious over the prior art references discussed below.

VI. LEVEL OF ORDINARY SKILL IN THE ART

49. A person of ordinary skill in the art ("POSA") pertinent to the '209 Patent as of its 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 prosthesis.

VII. CONSTRUCTION OF CLAIM TERMS

50. I understand that Petitioner has proposed constructions for two claim terms of the '209 Patent:

<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

51. In my opinion, these proposed constructions are consistent with how a POSA would understand the terms in light of the patent specification and file history. A POSA would understand that the inventor of '209 Patent disclaimed the use of traditional plastics or acrylics as materials from which the drill guide and fixation base could be made.

52. For all other claims terms than those listed above, I have applied the plain and ordinary meaning in my analysis.

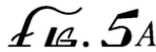
53. I have provided two sets of opinions regarding the invalidity of the claims with respect to the prior art (i.e., obviousness, in Section X.C–H, below). The first set of opinions (regarding Grounds 3, 5 and 7) assumes that the Board finds that the fixation base and drill guide do not exclude traditional plastics and acrylics. The second set of opinions (regarding Grounds 4, 6 and 8) assumes that

the Board agrees with Petitioner's proposed constructions and limits these terms so as to exclude traditional plastics and acrylics. Therefore, regardless of whether or not the Board adopts the proposed constructions, my ultimate conclusions that those Challenged Claims are obvious is unaltered.

A. "Drill guide"

54. Several claims of the '209 Patent recite a "drill guide" as an element (claims 1, 10 and 11).

55. The specification of the '209 Patent as filed contains only one statement regarding the composition of the drill guide: "the drill guide may be made from a metal or metallic alloy." Ex. 1001, 5:35–36. The patent describes that the use of metal is advantageous because it permits the guide to contain spaces that allow a dentist more visibility and accessibility to the patient's surgical site during the procedure. The patent describes these gaps as "voids 134" between the "support bar 128" and "bosses 130" supported by "arms 132" that "enable direct observation of patient anatomy and insertion of irrigation and evacuation apparatus." 5:37–43.



57. I note that the specification of the '209 Patent also incorporates by reference the entire contents of the '377 provisional application by reference. 1:9–

11. As with the '209 specification as filed, the '377 provisional also consistently refers to the drill guide as being made from metal:

- “Actual, Chrome Implant Drill Guide” (Ex. 1005, 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 does not disclose or suggest that any material other than metal is used for the drill guide.

58. The provisional not only describes the drill guide as being made only from metal, but it goes further and explains why traditional plastic is unsuitable for the claimed invention:

“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.” Ex. 1005, 26–27. (emphasis added).

It would be clear to a POSA reading this passage that the inventor disparaged the use of conventional plastic for drill guides because it was weaker and did not allow

the level of visibility to the surgeon that the metal drill guide would afford. A POSA reading this passage, along with the lack of any non-metallic description of the drill guide in the remainder of the specification, would understand that using conventional plastic for the drill guide would be outside the scope of claimed invention. A POSA would understand that the inventor did not believe or intend that his invention included drill guides made from traditionally used plastics.

59. I am aware that the passage above disclaiming the use of traditional plastic in the '377 provisional was incorporated by reference, but was not directly included in '209 Patent specification itself. A POSA would not find this fact significant in understanding the proper meaning of "drill guide." There is no other language in the '209 specification indicating that the '377 provisional application's disparagement of plastic no longer applied. As noted above, in the '209 specification itself there is only a single direct reference to the material of the drill guide in the '209 specification, and that reference is consistent with the provisional's description of the guide as being made from metal only. A POSA reading the '209 specification, even with the knowledge that the '377 provisional contained express disclaiming language that was not later directly included in the specification, would understand that the inventor did not intend to include traditional plastic and acrylic within the scope of the claims.

B. “Fixation base”

60. Nearly every claim of the '209 Patent, including each of the independent claims, recite a “fixation base” as an element (claims 1–5, 7–10, 12–17).

61. The specification of the '209 Patent as filed contains only a few 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.” Ex. 1001, 4:37-41. The specification describes an objective of the invention that the fixation base should “be of minimal bulk, thereby affording better viewing of the procedure by the dental personnel.” Ex. 1001, 7:2–4. A POSA would thus understand that using a stronger material, such as metal, would provide the desired strength while minimizing the bulkiness of the fixation base.

62. The specification does not provide any guidance as to what “other strong material” might be within the claim’s scope. However, a POSA reading the specification and file history would understand that “other strong material” could not include traditional plastic and acrylic, particularly because those materials could require substantially more substance than metal to achieve the same strength,

thereby increasing bulkiness, which would be inconsistent with the patent's stated goal of minimizing bulk and providing better visibility.

63. I again note that the specification of the '209 Patent incorporates by reference the entire contents of the '377 provisional application by reference. 1:9–11. Like the drill guide, the incorporated '377 provisional also consistently refers to the fixation base as being made from metal:

- “...**fixation base** and select sequential guides 3D printed or CNC milled in **chrome cobalt or similar strength metals**, its design method and system.” Ex. 1005, 4.
- “Actual, Chrome Implant Drill Guide attached to the **metal fixation base** by the locking pins.” *Id.*, 13.
- “What is claimed is: 1. **A fixation base (manufactured in metal for strength and rigidity).**” *Id.*, 28.
- “FIG. 1 illustrates the **fixation base manufactured in chrome cobalt** with locking pins (Guide1).” *Id.*, 24.
- “...bone reduction guide installed onto the **metal base.**” *Id.*
- “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.)” *Id.*, 25–26.

- “The **metal fixation base** can act as the bone reduction guide without the need to attach Guide 2.” *Id.*, 26.

64. The provisional application not only describes the fixation base as being made from metal, but it goes further and explains why traditional plastic is unsuitable for the claimed invention:

“Furthermore in this design, 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. 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.” Ex. 1005, 20 (emphasis added).

“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.” Ex. 1005, 26 (emphasis added).

It would be clear to a POSA reading these passages that the inventor disparaged the use of traditional plastic for fixation bases because it was weaker and “would surely fracture” during the surgical procedure.

65. Although the provisional application recites 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,” this would not affect a POSA’s understanding that that fixation base is not made from traditional plastic or acrylic, which the applicant expressly disclaimed due to their low rigidity and strength. Neither the provisional application nor the ’209 Patent specification provide any additional information as to what such an “engineered resin” may be. However, given that the ’209 Patent and incorporated ’377 provisional teach that the fixation base should be very thin so as to provide for minimal bulk but with increased strength (Ex. 1001, 7:2–4; Ex. 1005, 20, 26, 28), a POSA would have understood that using traditional plastic or acrylic would be inconsistent with this stated purpose. A POSA would have thus understood that, whatever an “engineered resin” may be, it cannot include traditional plastic or acrylic.

66. There is nothing in the specification itself to indicate that the inventor changed his position from the provisional application (which was expressly incorporated by reference) that traditional plastic and acrylic was unsuitable for the invention. The provisional’s statement that “**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” is very clear to a POSA, and is entirely consistent with the ’209 specification, which does not appear to contain any contradictory language.

67. Thus, for the same reasons described above with respect to the drill guide, a POSA would recognize that the use of traditional plastic and acrylic for fixation bases is outside the scope of the claimed invention. A POSA would understand that the inventor did not believe or intend that his invention included fixation bases made from traditional plastic or acrylic.

VIII. OVERVIEW OF THE PRIOR ART

A. Llop126 (Ex. 1006)

68. I understand that U.S. Patent Publication No. 2017/0252126 (Llop126) was published on September 7, 2017 from an application filed September 30, 2016. Ex. 1006. The reference is entitled “Bone Foundation Guide System and Method.” I have been informed that the Llop126 reference is available as prior art to the ’209 Patent.

69. Llop126 discloses a method and apparatus for installing a dental prosthesis, including a generally arcuate fixation base that serves as a mounting jig for other dental guides. The fixation base disclosed in Llop126 has a front surface with openings through which fasteners can be passed, a rear surface, and a

horizontal surface. Llop126 also discloses removal of the patient's teeth, recontouring the bone tissue, and using a drill guide that attaches to the fixation base to facilitate the drilling of implant holes in the bone tissue. Llop126 also discloses installing implants, abutments and a prosthesis.

70. More specifically, Llop126 discloses a system for installing dental implants using a bone foundation guide 20 that can support subsequent dental implant surgical guides 50. Ex. 1006 at [0003]. The bone foundation guide is placed with precision by first attaching a series of "anchoring struts" 42 (shown in green). *Id.* at [0098].

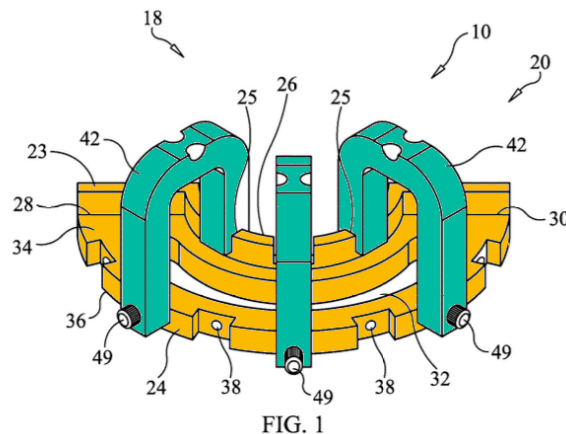


FIG. 1

The anchoring struts are used to place the bone foundation guide in the proper position, and then are removed once the bone foundation guide has been attached. The anchoring struts 42 have indentations 46 at their apices that can match portions of gum and/or dentition on the patient's opposing alveolar ridge. *Id.* The anchoring struts 42 can be patient-specific, made to have indentations at their respective apices to match various portions of the teeth. *Id.* at [0136]. The patient

clamps down on the anchoring struts, matching the indentations 46, to ensure the bone foundation guide is properly positioned. *Id.* at [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].

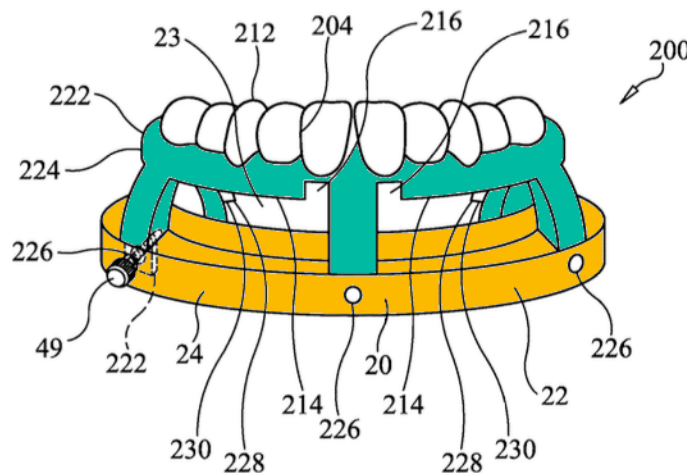


FIG. 29

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.*

71. The dental implant surgical guide 50 is then attached to the bone foundation guide and is used to guide dental drill bits to create implant channels and insert implants. *Id.* at [0034, 0102]. The dental implant surgical guide 50 is attached to the bone foundation guide by guide tabs 71 and guide pins 70 that allow a "snap-in fit." *Id.* at [0122].

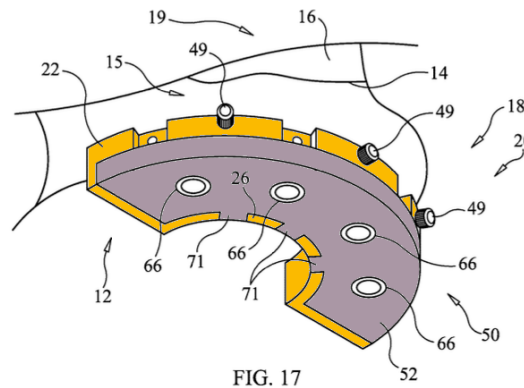


FIG. 17

72. 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. *Id.* at [0125]; Figs 20–23.

B. Sichuan (Exs. 1008, 1009)

73. I understand that Chinese patent application no. 201610012516.7 was filed on January 8, 2016, and published as Chinese publication no. CN 105686886 A on June 22, 2016 (Sichuan). Exs. 1009, 1010. Sichuan is entitled, “A subapical osteotomy locating guide plate and a manufacture method therefor.” I understand that Sichuan is available as prior art to the ’541 patent.

74. Sichuan discloses a system having fixation base having a front surface with a plurality of openings through which fasteners can be passed, the fixation base positioned and attached to the jawbone of a patient to provide a reference point for subsequent dental surgical operations. The system includes a mouthpiece attached to the fixation base, configured and dimensioned to surround at least a portion of the teeth of the patient and is used to assure appropriate location of the

fixation base. The mouthpiece of Sichuan is removed once the fixation base has been affixed.

75. In more detail, Sichuan discloses a system for positioning osteotomy guide plates for attachment to a patient's jawbone. Sichuan describes creating a positioning biteplate 1 from tooth prints 11 of the patient. Ex. 1009, e.g., Abstract, Claims 6g, 8g.3, [0007], [0027], [0038], [0066]. The biteplate 1 connects to osteotomy line guide plates 3 via connector rods 2. *Id.*, e.g., Abstract, Claims 1, 2, [0007], [0027]. 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 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].

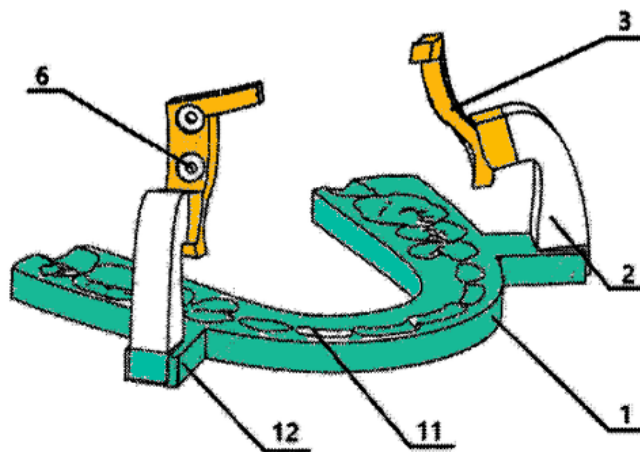


图1

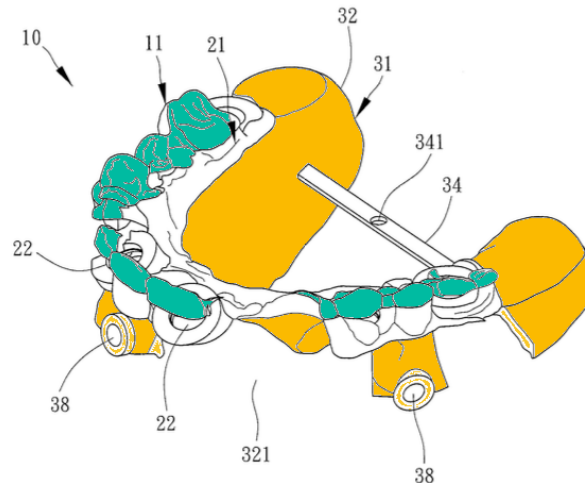
C. Yau (Ex. 1010)

76. I understand that U.S. Pat. Appl. 15/176,828 was filed on June 8, 2016 and published on September 21, 2017 as 2017/0265963 (Yau). Ex. 1010. The reference is entitled “Dental Implant Surgical Guide”. I understand that the Yau reference is available as prior art to the ’209 Patent.

77. Yau 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, comprising a generally arcuate base member with a front surface with a plurality of openings through which fasteners can be passed, a rear surface, and a horizontal surface. Yau further discloses a mouthpiece that is configured and dimensioned to surround at least a portion of the patient’s teeth and is used to assure appropriate location to attach the fixation base to the bone tissue of the patient.

78. Yau discloses an implant guide system with three members: an upper guide member including a tooth mold, and intermediate guide member including a guide portion, and a lower guide member. Ex. 1008, Abstract. 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.” *Id.* at [0007, 0017]. Yau makes clear that the tooth mold can take different forms,

either as a one-piece member or it may consist of multiple component parts. *Id.* at [0025]; Fig. 2.



79. 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.

80. The tooth mold is used for properly placing the lower guide member 31. Initially, the lower guide member 31 is mated with the patient’s gingiva. *Id.* at [0022]. The patient then bites using the tooth mold, which in turn more precisely positions the lower guide member 31 relative to the patient’s gingiva. The lower guide member is then fastened to the patient’s jawbone using mounting members 381. *Id.* Yau describes the mounting members 381 as being “plug ins or screw bolts” *Id.*, [0019]. The mounting members 381 pass through mounting portions 38 of the lower guide member 31.

81. Yau notes that attaching a surgical guide to gingiva alone can be imprecise due to sliding. *Id.*, [0004]. Yau discloses that the “tight engagement” of the upper guide with the patient’s teeth results in achieving “fine position adjustment.” *Id.*, [0022].

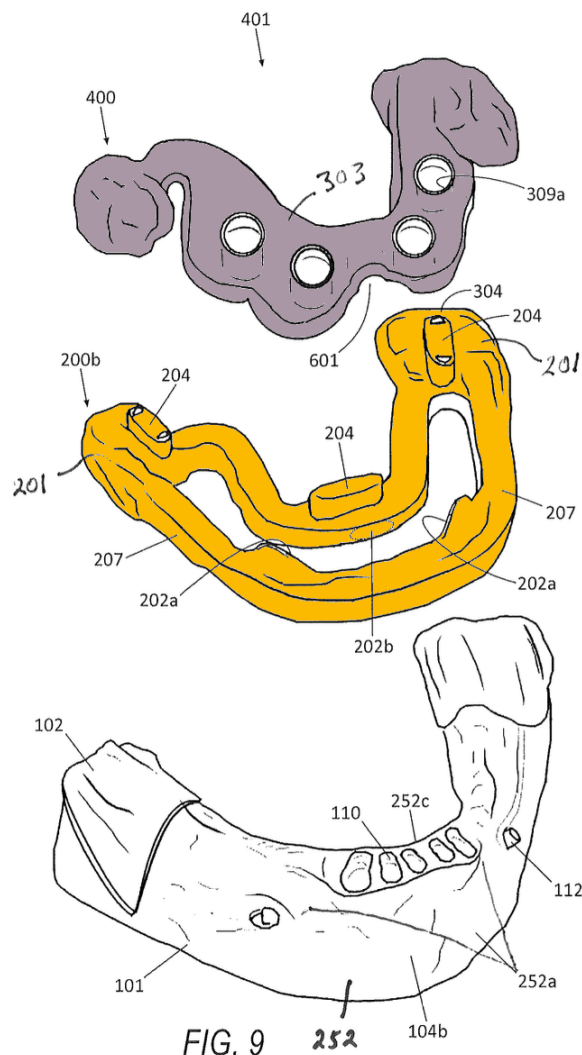
D. Groscurth (Ex. 1011)

82. I understand that U.S. Patent No. 9,504,533 issued on November 29, 2016. (Groscurth). Ex. 1011. The reference is entitled “Edentulous surgical guide.” I have been informed that the Groscurth reference is available as prior art to the ’209 Patent.

83. Groscurth discloses a stackable dental implant surgical guide system. Groscurth discloses a method and apparatus for installing a dental prosthesis, including a generally arcuate fixation base that serves as a mounting jig for a plurality of other dental guides. Groscurth discloses using a drill guide that attaches to the fixation base to drill implant holes in the bone tissue. Groscurth discloses that the fixation base may be used as a bone reduction guide, and that both the fixation base and the drill guide may be made from metal or a metallic alloy.

84. In more detail, Groscurth discloses a system for installing dental implants using a base frame 200 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. Ex. 1011, 5:10–15, 6:50–55, Figs. 1A–2D. A denture

attachment 500 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. Ex. 1011, 13:37–42, Fig. 5. The base frame 200 accepts for attachment a drill guide housing frame 300. *Id.*, 6:4–44, Figs. 3A–4D. Holes 306 on the drill guide 300 correspond with planned osteotomy sites, and are used for implant placement. *Id.*, 7:24–31.



85. Groscurth discloses that the base frame 200 may be made of metal or other material that provides sufficient rigidity and stability. *Id.*, 4:46–52.

Specifically, Groscurth says, “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 enough rigidity for stability and the right amount of flexibility in clasping areas.” *Id.*

86. Groscurth discloses that the drill guide may be made entirely of metal. *Id.*, 13:1–4 (“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.”).

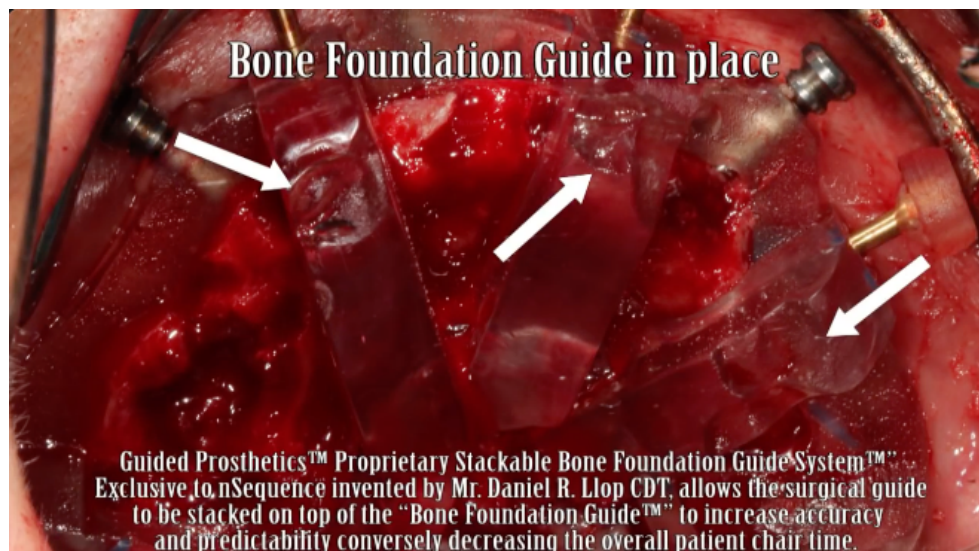
E. Scherer (Exs. 1012, 1013)

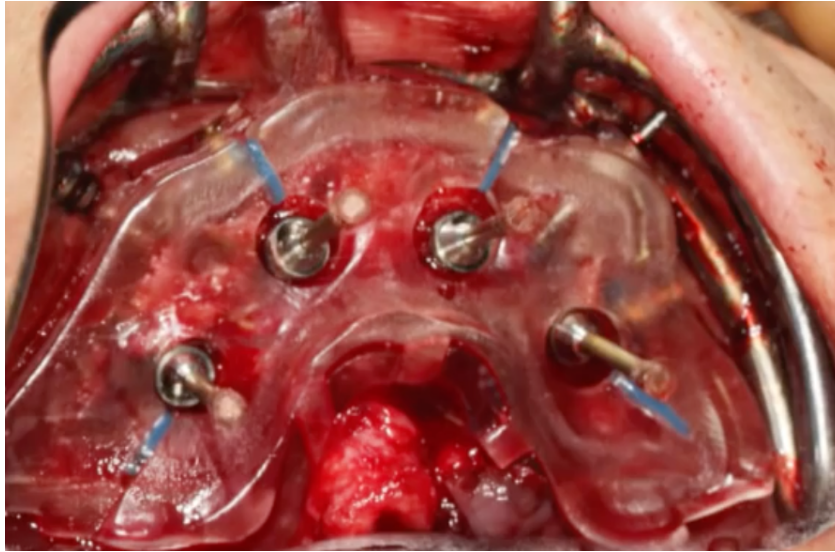
87. I understand that the video entitled, “Clinical Demonstration: All-on-4 nSequence Guided Prosthetics Surgical Technique with Zest Anchors Chairside Attachment Processing Material” was posted on YouTube on October 23, 2015, at the URL <https://www.youtube.com/watch?v=VOWRdFpfngI>. I also understand that the Scherer video was posted at the nSequence website <http://nsequence.com> no later than February 7, 2016. I have been informed that the Scherer video reference is available as prior art to the ’209 Patent.

88. Scherer is a video demonstration of an “All-on-4” procedure performed by Drs. Michael D. Scherer and Slim Bouchoucha. The video shows

the various steps of the procedure to provide a patient with a dental prosthesis using the nSequence guided system, invented by Dr. Daniel Llop.

89. Some of the various steps shown and described in the Scherer video include: placement of a bone foundation guide using a set of struts with teeth-matching indentations; removal of the struts and bone reduction using the bone foundation guide; attachment of a dental implant surgical guide to the bone foundation guide, drilling and installation of implants; removal of the dental implant surgical guide and attachment of a multi-unit abutment with rotation markings; and using the markings on the abutment guide to rotate abutments to their proper settings.





90. 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.

IX. FACTS AND OPINIONS RELEVANT TO THE UNPATENTABILITY GROUNDS ASSERTED IN THE PETITION

91. For reasons that I will address in more detail below, it is my firm belief and opinion that claims 11 and 13 of the '209 Patent are not adequately supported by the patent specification so as to convey that the named inventor possessed the claimed invention. These claims were amended or added during prosecution of the '209 Patent to claim fixation bases and drill guides made from materials including “composite” or “polymer”.

92. It is also my firm belief and opinion that claims 11 and 13, when read in light of the specification and the prosecution history, do not make clear the scope of the invention. The claims recite that that the fixation base and drill guide

are made from material that is “sufficiently strong enough to withstand breakage during a prosthesis installation procedure” but there is no description in the ’209 Patent as to how to determine whether a material is “sufficiently strong enough.”

93. It is also my firm belief and opinion that at the time of the alleged invention in the timeframe just prior to May 18, 2017, the claims of the ’209 Patent would have been obvious to a POSA. Prior to this date above, a POSA would have known that prior art dental prosthesis surgical guide systems, such as described in Llop126, could have been modified to use a mouthpiece configured and dimensioned to surround at least a portion of the patient’s teeth. A POSA at that time would have been motivated to do so because of the well-known need to accurately and precisely position a fixation base for guiding the surgery.

94. A POSA at that time would have been motivated to modify the fixation base and drill guide to be made from metal because of the need to provide a strong, rigid device that is stable in a patient’s mouth, and to avoid the need to use separate parts.

X. INVALIDITY ANALYSIS FOR PETITION

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

95. In my opinion, a POSA reading the ’209 Patent specification would not recognize that the named inventor had invented the subject matter of claims 11 and 13.

96. In fact, as discussed above in the claim construction section, a POSA would recognize that the inventor expressly did *not* possess the subject matter as his invention.

1. Claim 11 Lacks Written Description

97. Claim 11 as issued recites:

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. Ex. 1001, Claim 11.

The bold language was not included when the patent application for the '209 Patent (the '359 application) was originally filed on October 18, 2021, however. Instead, that language was added several months later, on February 8, 2022, in a Preliminary Amendment. Ex. 1002, 75–76.

98. I have examined the specification of the '209 Patent as it was filed on October 18, 2021, as well as the specification of U.S. Patent Application No. 15/984,309 (now U.S. Patent No. 11,173,016) and the contents of U.S. Provisional App. No. 62/508,377, both of which are incorporated by reference. I did not see

any support for a drill guide made from any material other than metal or metallic alloy.

99. The '209 specification makes only one reference to the material of the drill guide:

“Referring particularly to FIG. 5A, **the drill guide may be made from a metal or metallic alloy**, and comprises a support bar 128 attachable to fixation base 100 (via attachment elements 106), one boss 130 for each one of vertical bores 126, bosses 130 attached to support bar 128 by arms 132 such that voids 134 exist between bosses 130 and support bar 128. Voids 134 enable direct observation of patient anatomy and insertion of irrigation and evacuation apparatus.” Ex. 1001, 5:35-41.

100. Neither of the words “composite” and “polymer” appear in the text of the '209 Patent specification or the '309 application.

101. The '377 provisional application also discloses only a drill guide made from metal, which it describes as necessary to create the claimed “voids” for visibility, because of its strength:

“**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.” Ex. 1005, 26–27

“...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

“3D printed in Chrome cobalt” *Id.*

102. A POSA reading the '209 specification and its priority applications would not find any suggestion that the inventor possessed as his invention a drill guide made of “composite” or “polymer.” Indeed, the only language in the complete specification states affirmatively that the drill guide is metallic, and states expressly that plastic drill guides are to be avoided.

103. It is my opinion that claim 11 lacks adequate written description, and is therefore invalid.

2. Claim 13 Lacks Written Description

104. Claim 13 as issued recites:

13. 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. Ex. 1001, Claim 13.

Like the new language of claim 11, the language of claim 13 was not included when the patent application for the '209 Patent (the '359 application) was originally filed on October 18, 2021. Instead, that language was added in the February 8, 2022 Preliminary Amendment. Ex. 1002, 75.

105. I did not see any support in the '209 Patent specification or the '309 application for a fixation base made from any material other than metal or metallic alloy.

106. The '209 specification makes only one reference to the material 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**”
Ex. 1001, 4:37-41.

107. Although the '209 specification added the catch-all phrase “other strong material,” there is nothing in the '209 specification identifying or suggesting what “other” material the inventor may have thought was suitable. And there is nothing in the '209 specification indicating the inventor considered composite or polymer to be such a strong material.

108. The '377 provisional application also consistently discloses a fixation base made from metal because of its strength:

A fixation base with reference locking pins for sequential dental implant surgical guides and prosthesis, fixation base and select sequential guides 3D printed or CNC milled **in chrome cobalt or similar strength metals**, its design method and system.” Ex. 1005, 4.

Fig. 3c shows “bone reduction guide installed to **metal fixation base**.”

FIG. 3

b.) Bone Reduction Guide (installed to base by locking pins)

c.) Pictured> bone reduction guide installed to **metal fixation base** by locking pins d.) Actual, bone reduction guide installed onto locking pins.

Id., 10.

Fig. 4c shows “Drill Guide attached to the **metal fixation base.**”

FIG.4

b.) Implant Drill Guide installed to base (installed to locking pins)

c.) Actual, Chrome Implant Drill Guide attached to the **metal fixation base** by the locking pins.

Id., 13.

“a) bone reduction guide installed onto the **metal base** to the slots for easy positioning and securing by the reference locking pins.”

Id., 24.

“In addition, **The metal fixation base** can act as the bone reduction guide without the need to attach Guide 2.”

Id., 26

“What is claimed is: 1. A fixation base (**manufactured in metal for strength and rigidity**)”

Id., 28

“In this invention the first guide is designed to fit the teeth whereas the top portion of the guide where the fixation sites are located is in a non anatomical position above the tooth borne position that extends into the tissue. **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.”

Id., 25–26.

109. The ’377 provisional application confirms that the inventor did not consider plastics to be strong materials suitable for making a fixation base:

“Furthermore in this design, 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.” Ex. 1005, 20.

“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.” *Id.*, 26.

110. Reading the specification and the incorporated ’377 provisional application, a POSA would not understand the inventor to have possessed as his invention a fixation base made of traditional plastic or acrylic materials, which a POSA would understand are composites or polymers.

111. There is only one passage in the provisional application that even suggests that the fixation base may be made from a material other than metal:

“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.” (emphasis added).

However, as discussed above, a POSA reading this passage, particularly in light of the clear language cited above that disparaged the use of plastic, would understand that the phrase “engineered resins” does not include “composites” or “polymers” such as traditional plastics or acrylics that were in use at the time the ’209 Patent and ’377 provisional application were filed. A POSA reading this term in the context of the specification would understand the inventor specifically intended for the claimed invention to exclude such materials. Neither the specification nor the ’377 provisional application define “engineered resins” or suggest that such would include composites and polymers such as traditional plastic and acrylic. A POSA would not make this inference given the clarity of the inventor’s disclosure.

112. It is my opinion that claim 13 lacks adequate written description, and is therefore invalid.

B. Ground 2: Claims 11 and 13 are Indefinite

113. In my opinion, a POSA reading claims 11 and 13 in light of the ’209 Patent specification and prosecution history would not understand the scope of those claims with reasonable certainty.

114. Claim 11 depends from claim 7 and 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 procedure.” Claim 13 is also dependent on claim 7, and 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.”

115. The phrase “sufficiently strong enough” covers a category of dental devices that will withstand breakage during a prosthesis installation procedure and excludes others that will not. The ’209 Patent (including the ’377 provisional application incorporated by reference) only identifies these categories through two end points: 1) devices made of metal; and 2) devices made of traditional plastic and acrylic. The specification provides no criteria to determine where between these two end points “sufficiently strong enough” begins and ends. A POSA reading the ’209 Patent specification and prosecution history thus would not be able to recognize the boundary between these two categories.

116. The patent specification indicates that “[f]ixation base 100 is non-anatomical, being fabricated from a metal, metal alloy, or other strong material,” but does not indicate what it means to be “sufficiently strong enough.” Ex. 1001, 4:38-39. A POSA would not understand what “sufficiently strong enough” means.

For example, every practitioner may apply a different amount of pressure when drilling or performing other parts of a procedure, so what may be sufficient strength for one dentist may be insufficient for another. This could depend, for example, on the experience of the practitioner. There also could be a wide variation in the size and shape of a fixation base or drill guide depending on unique features of a patient's mouth. Different patients can open mouths more widely than others, for example, allowing for different amounts of material to stabilize or make fracture proof. This could result in guides that are weaker at particular points for some patients than for others. If the fixation base or drill guide are not reinforced at these locations, they will be susceptible to failure. From dentist to dentist, and from case to case, there are simply too many variables for a POSA to know with a reasonable degree of certainty whether a guide will be "sufficiently strong enough to withstand breakage during a prosthesis installation procedure." The '209 Patent specification does not identify any of these factors. As discussed above, this desire for strength is a reason why a POSA would have understood the drill guide of the '209 Patent to be limited to metallic material.

117. The '377 provisional application only adds to the ambiguity. As discussed above, the '377 provisional application states that widely used "plastic for the implant drill guides" are not preferable because they "are notorious for breakage with binding and flexing" and "under drilling pressure they could fracture

and break.” Ex. 1005, 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. The provisional application 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.

118. A POSA would understand that “3D printed or CNC milled acrylic” are plastic, and would know that they were widely used in performing prosthesis installation procedures by 2017, including those procedures using a fixation base or drill guide. For example, I personally used such printing and milling techniques in my own practice since the 1990s. These pre-2017 procedures were well-documented, and typically successful without breakage of the guides. See, e.g., “Stereolithography and other RP&M Technologies” by Paul F. Jacobs, PhD. (1996, Society of Manufacturing Engineers); U.S. Patent No. 5,725,376 (“Methods of manufacturing a dental implant drill guide and a dental implant superstructure.”). It is therefore unclear how the prior art dental devices used in prosthesis installation procedures would not be considered to be “sufficiently strong enough,” because they also withstand breakage. *Id.*

119. As a result of the use of the term of degree, “sufficiently strong enough to withstand breakage,” a POSA has only a subjective understanding of the claim scope of claims 11 and 13. This is particularly true when considering a dental device that may undergo some elastic bending, which often occurs in these types of procedure. The specification and prosecution history do not contain any objective points of comparison to determine whether a material is “sufficiently strong enough to withstand breakage.”

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

120. In the event that the Board determines there is no limiting construction for the “drill guide” and “fixation base”, then it is my opinion that claims 1–3, 7, 10, 13–14, and 16–17 would have been obvious to a POSA under Section 103 in view of Llop126 and Sichuan.

1. Llop126 and Sichuan—Motivation to Combine

121. In order to solve the known problem of guiding osteotomy positioning, a POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a positioning mouthpiece, like the biteplate of Sichuan, such that proper precise placement of the fixation base is ensured. Ex. 1009, [0003, 0005].

122. A POSA would have understood that there was a high likelihood of success in making the combination. Both Llop126 and Sichuan relate to the same field of endeavor as the '209 Patent and the use of surgical guides for osteotomies during dental procedures. *Compare* Ex. 1006, Title, Abstract, “Field of Invention,” Fig. 1, *with* Ex. 1009, Title, Abstract, “Field of Invention,” Figs. 1, 6. A POSA would have understood Llop126 and Sichuan are readily combinable because each concerns dental surgical guide systems. Llop126 describes a fixation base positioned and attached to the patient’s jawbone, serving as a reference for dental implant surgical guides. Ex. 1006, Abstract. Sichuan describes a set of osteotomy guide plates functionally 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. Ex. 1009, [0049].

123. It was a known problem of how to properly position a guide during an osteotomy procedure, as Sichuan recognizes. Ex. 1009, [0003–0005]. Sichuan “is intended 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” that is connected via rods to positioning guides. *Id.*, [0007, 0049]. In the same way as Llop126, Sichuan describes the use of a patient’s teeth (in Sichuan, at least a portion of all of the teeth of the patient on the same alveolar 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.

Sichuan describes that the base is then secured to the patient's jawbone using screws through "screw holes 6" of the base. *Id.*, [0011, 0012, 0063]; Figs. 1, 4.

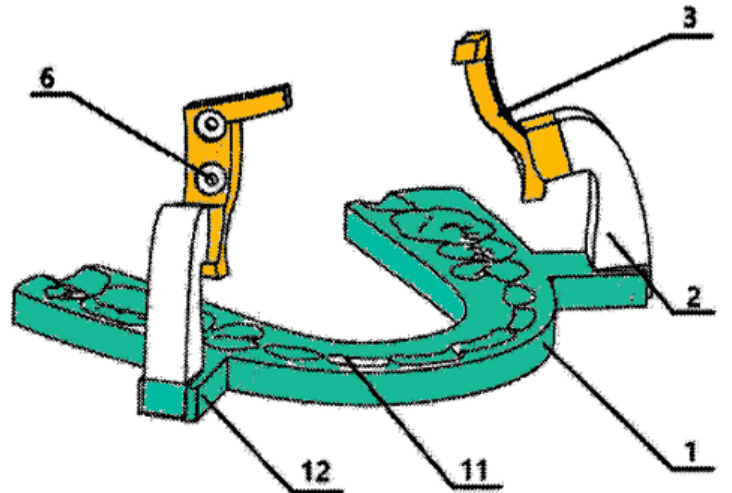


图1

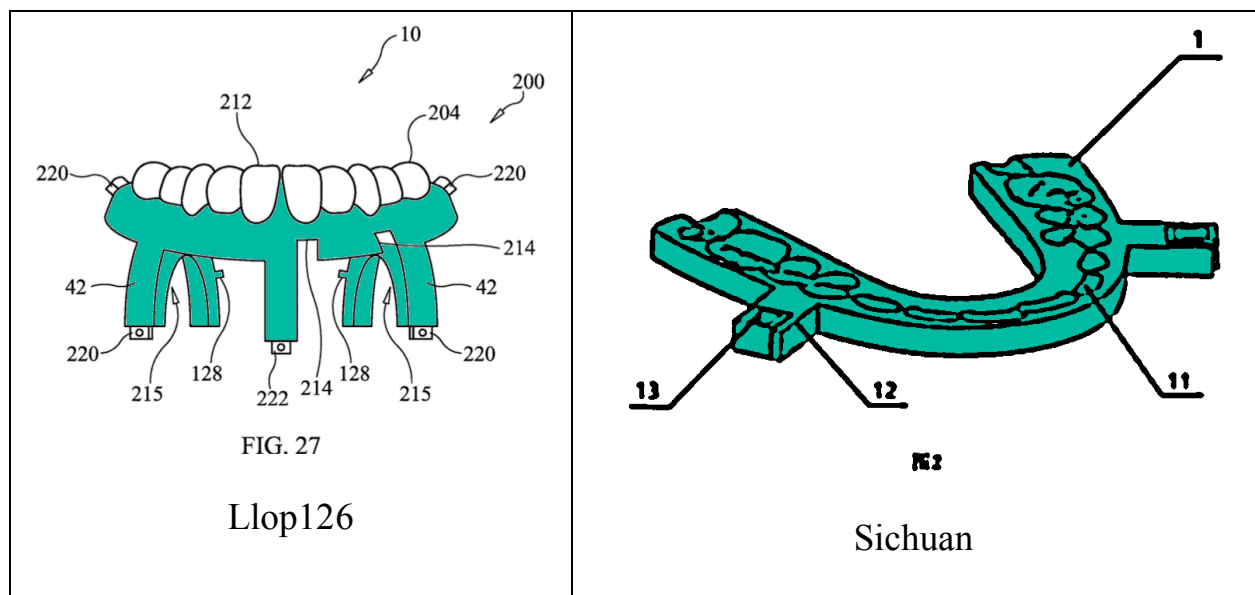
124. A POSA would have understood from Sichuan the benefits of modifying the anchoring struts of Llop126 to include a mouthpiece, in order to improve the positioning of the bone foundation guide for attachment to a patient's jawbone. For example, there was a known problem of sliding when using surgical guides, particularly when guides are making contact with a patient's gums (gingiva) or other soft tissue. Without using a "hard" reference point, such as teeth, it can be difficult to fixate a guide precisely in a proper location, as the guide is more likely to slide along the soft tissue. A POSA would have also understood that this modification furthered the objective of Llop126 to "control[] and refine[]

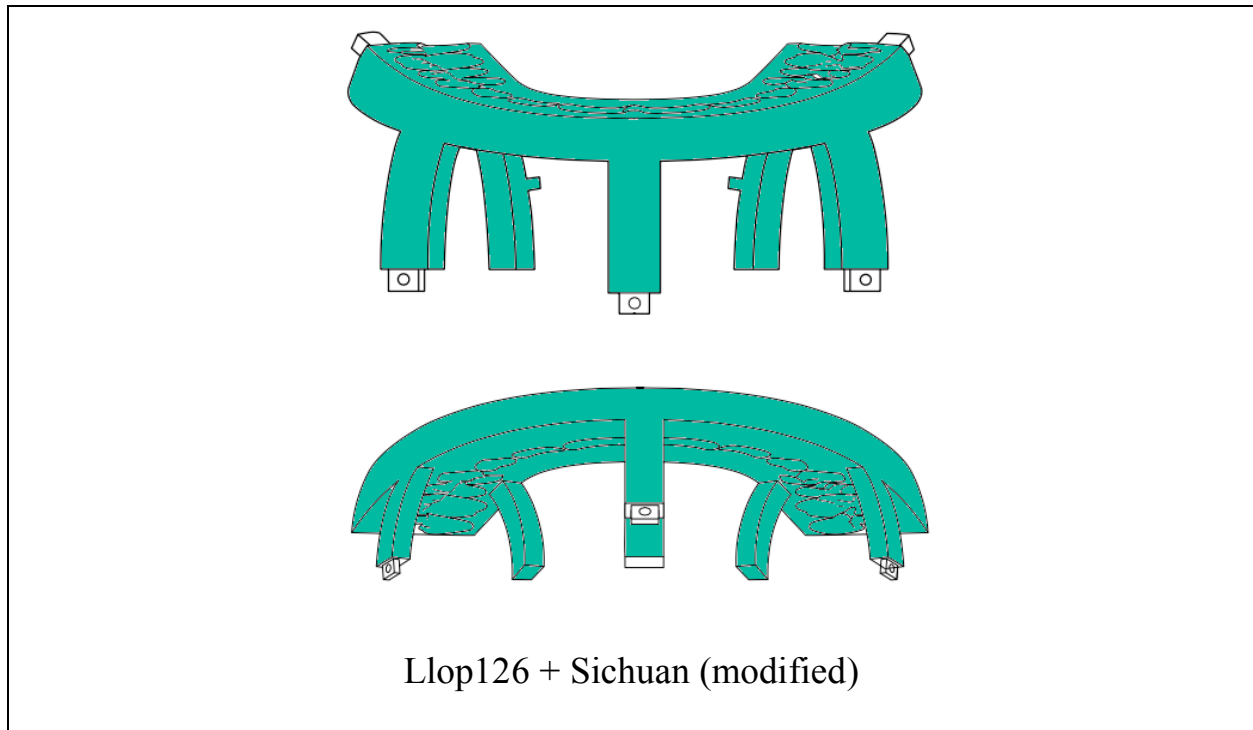
the accuracy” of the stackable guide system by ensuring more precise placement of the bone foundation guide. Ex. 1006, [0029].

125. Sichuan discloses a biteplate that is configured and dimensioned to surround the teeth on both the maxillary and mandibular jaws, such that it forms a mouthpiece having a “hand and glove” relationship with the patient’s teeth. Ex. 1009, [0088] (“positioning biteplate 1 is provided with initial dental prints 11 disposed on the upper and lower surfaces thereof.”). The Sichuan mouthpiece includes precise recesses for the cusps of each tooth, thereby surrounding them. Using such a cuspal registering mouthpiece for positioning purposes, as in the ’209 Patent, achieves equally accurate results as mouthpieces that are taller and which extend further up the tooth, and has advantages over them. The thinner mouthpiece of Sichuan is less bulky, and thus easier to manipulate in a patient’s mouth and allows for greater visibility. Additionally, a tall mouthpiece designed to engage with the entire tooth may be difficult to place and prone to getting stuck, whereas a cuspal registering mouthpiece as in Sichuan is easy to remove and place.

126. A POSA would thus have understood that the modification to the Llop126 anchoring struts could be made to engage with teeth on either the same or opposing alveolar ridge as that being operated on. For example, a POSA could have easily modified Llop126 to combine the teachings of Sichuan for the biteplate to engage with teeth on either same or opposite alveolar ridge as being

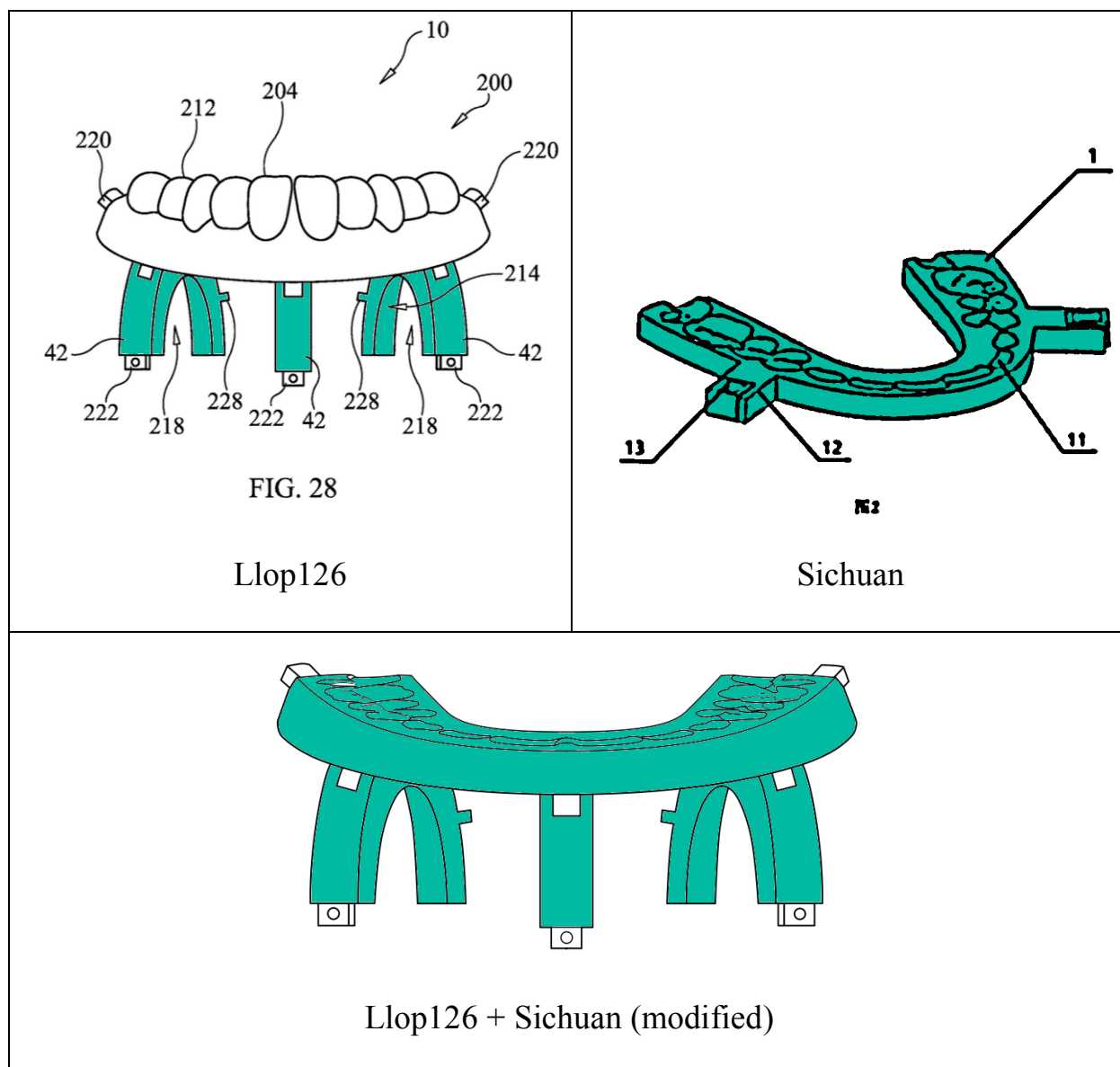
operated on. Llop126 discloses that a device (“prosthesis 200”) can be unitary with or removably attached to the ends of the struts 42, to facilitate positioning of the bone foundation guide. Ex. 1006, [0074, 0075, 0133], Figs. 27, 28. Llop126 acknowledges that teeth may be present at the surgical site at the time the bone foundation guide is placed. Ex. 1006, [0140]. In such a case, a POSA would have been motivated to use those teeth with a mouthpiece apparatus such as that in Sichuan, to allow for greater precision in placement of the bone foundation guide. A POSA could have modified the “unitary” embodiment of Llop126 to replace the prosthesis portion with Sichuan’s positioning biteplate. Sichuan discloses that the biteplate may conform to both upper and lower teeth. Ex. 1009, [0088]. It would have been a simple matter for a POSA to substitute a biteplate for the prosthesis 200 in the “unitary” embodiment of Fig. 27, as shown below.





Such a modification would permit the biteplate to engage with the teeth on either the mandibular or maxillary arches of the patient's mouth, providing an even more accurate placement than could be obtained with the Llop126 prosthesis.

127. It would also have been straightforward for a POSA to modify Llop126 to be used even in edentulous cases, when teeth are not present on the same ridge as the surgical site but are present on only the opposing alveolar ridge. It would have been straightforward for a POSA to substitute a biteplate for the prosthesis 200 in the “non-unitary” embodiment of Llop126 Fig. 28, as shown below.



128. A POSA would have seen that the Sichuan biteplate is applicable to Llop126's anchoring struts. For instance, the biteplate could be attached at the apexes of the struts in the same manner as Llop's prosthesis is attached. This would permit the biteplate's dental imprints to engage with the teeth on the opposite ridge.

129. For either the unitary or removable embodiments, these modifications would not have been difficult for a POSA, and would have been a simple matter of slightly redesigning the manufacturing specifications for the milling or 3D printing equipment that would have otherwise made the Llop126 devices. For instance, Llop126 describes the prosthesis 200 is attached to the bone foundation guide via “friction fit based tab-slot coupling means,.” Ex. 1006, [0133]. Replacing the prosthesis 200 with the Sichuan biteplate (which is disclosed as having its own tab-rod connecting mechanism) would have been a simple matter to make compatible with the tab-slot mechanism of Llop126. A POSA would have had a reasonable expectation of success in making these modifications.

130. A POSA also would have been motivated to apply the Sichuan biteplate and connecting rods to interact with the bone foundation guide of Llop126. Like the anchoring struts of Llop126, the connecting rods of Sichuan are removably attached to a guide that is to be fastened to the patient’s jawbone (i.e., the guide plates in Sichuan, and the bone foundation guide of Llop126). The connecting rods and biteplate of Sichuan could easily be adapted such that they could be attached to the bone foundation guide of Llop126 in the same manner as the anchoring struts.

131. In these ways, such a modification would permit the biteplate to engage with the teeth on either or both arches of the patient’s mouth, as needed.

Llop126 modified to include a biteplate, as taught by Sichuan, satisfies the “mouthpiece...configured and dimensioned to surround at least a portion of the teeth of the patient” limitation found in independent claims 1, 7 and 17 of the ’209 Patent. A POSA would have understood that this modification had a high likelihood of success and was obvious.

132. A POSA would have been motivated to modify the anchoring strut system of Llop126 by using a biteplate as taught by Sichuan to achieve the benefits as described above. Modifying Llop126 to use a mouthpiece such as the biteplate of Sichuan would not alter its operating principles. Placing the biteplate on top of, under, or in place of the apexes of the Llop126 struts is entirely consistent with the struts’ operation in Llop126, and does not affect any other aspect of the Llop126 system. The Sichuan biteplate would be removed along with the anchoring struts after the bone foundation guide has been set.

133. The combination of Llop126 and Sichuan is a predictable use of interchangeable prior art elements according to their established functions. This combination is not innovative but the product of ordinary skill and common sense.

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

(a) Element 1[pre]: Preamble

134. The preamble recites “[a] method of installing a multi-tooth dental prosthesis in a maxillary or mandibular position in a mouth of a patient, the method

comprising.” It is my opinion that Llop126 discloses a method of installing a multi-tooth dental prosthesis in a maxillary or mandibular position in a mouth of a patient.

135. 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. Ex. 1006, [0026–0043, 0125]; Figs. 23, 26–30. The prosthesis is multi-tooth, and is installed in either a maxillary or mandibular position. *Id.*, e.g., [0098].

136. Llop discloses a method of installing a multi-tooth dental prosthesis in a maxillary or mandibular position in a mouth of a patient, and hence the preamble of claim 1.

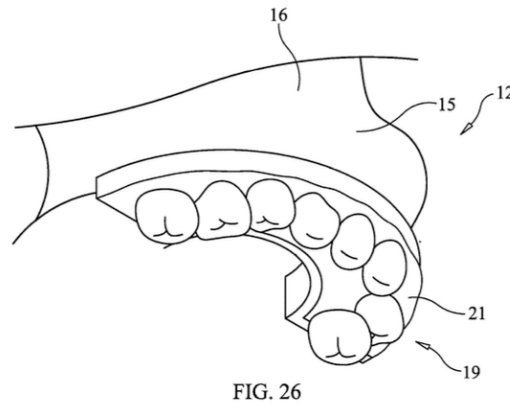
(b) Element 1[a]: dental prosthesis

137. Element 1[a] recites a step of “providing a dental prosthesis for the maxillary or mandibular positioning in the patient’s mouth.”

138. In my opinion, Llop126 discloses a step of providing a dental prosthesis, which is positioned in either the maxillary or mandibular portion of the patient’s mouth, and therefore this element of claim 1.

139. 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 (or mandibular) ridge of a patient. Ex. 1006, [0070, 0073, 0026–0043, 0125]; Figs. 23, 26.



140. Therefore, in my opinion Llop126 describes providing a dental prosthesis for the maxillary or mandibular positioning in the patient’s mouth, and therefore element 1[a].

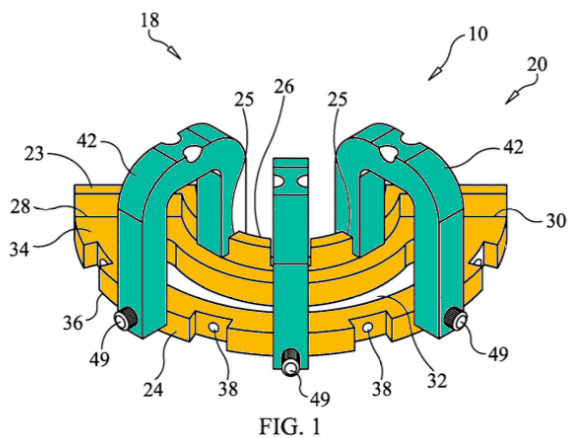
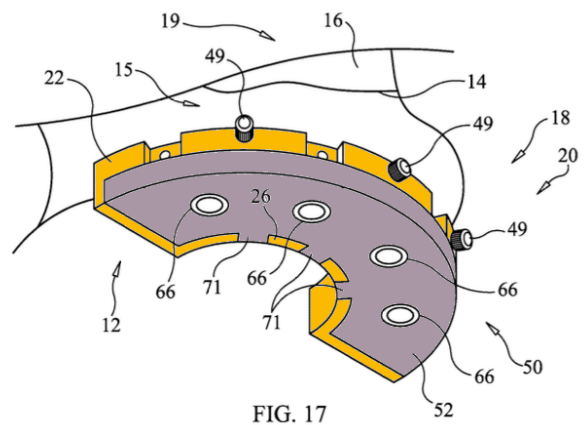
(c) Element 1[b]: fixation base

141. Element 1[b] recites a step of utilizing a “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.”

142. In my opinion, Llop126 discloses a step of utilizing a fixation base, which serves as a mounting jig for at least two other dental guides, and therefore this element of claim 1.

143. Llop126 discloses a bone foundation guide 20 (shown in gold, below) that serves as a mounting jig for other dental guides. Ex. 1006, [0026–30]; Figs. 4, 5 and 19. 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.”); Figs. 1, 17. Llop126 describes that the guides have tabs (e.g., tab 45 in the struts, guide tabs 71, gasket tabs 88) that engage with cutouts 25 in the bone foundation guide for a secure attachment. *Id.*, [0098], [0122], [0127].



144. For these reasons, in my opinion Llop describes a step of 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 and therefore Element 1[b].

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

145. Llop126 discloses a fixation base having 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, as recited in Element 1[c] of claim 1.

146. Llop126 discloses a bone foundation guide with a generally arcuate shape with a front surface that has a plurality of openings (38) through which fasteners (40) can be passed (see annotated Fig. 4 and 12 below). Ex. 1006, [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.”). Bone foundation guide 20 has a horizontal surface (top 34), and a rear surface (lingual wall 26).

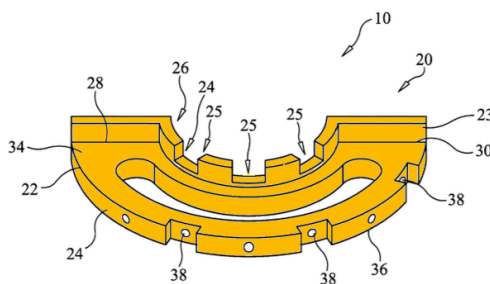


FIG. 4

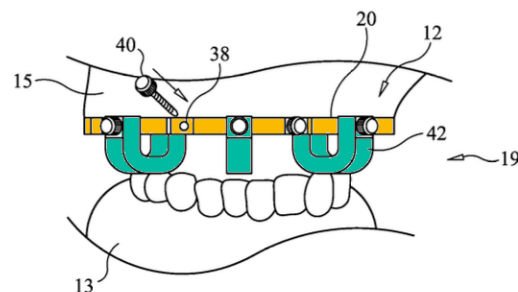


FIG. 12

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

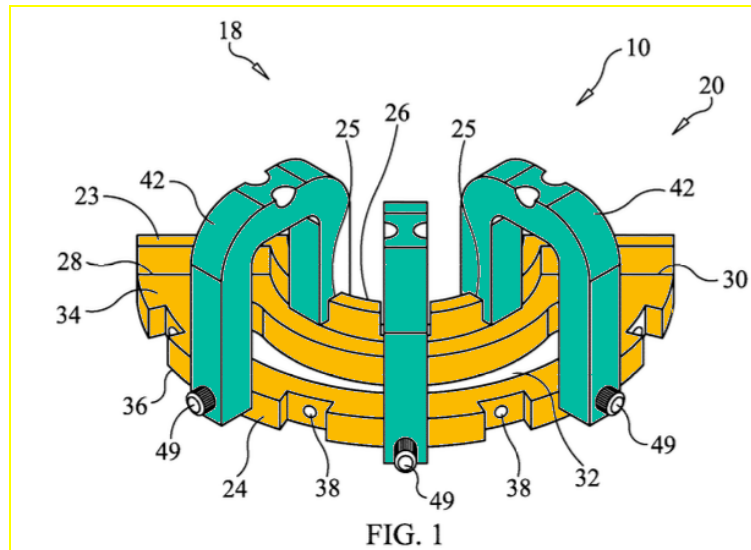
147. Llop126 discloses utilizing the first dental guide, wherein the first dental guide are anchoring struts that attach to the fixation base and engage with the patient's teeth to assure appropriate location to attach the fixation base to the maxillary or mandibular bone tissue of said patient, as recited in Elements 1[d], [e] and [f] of claim 1.

148. Llop126 discloses a set of anchoring struts 42 that attaches to the fixation base through the use of strut fasteners 49. Ex. 1006, [0136], [0098]; 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."). A POSA would understand that the anchoring struts 42 form a "mouthpiece" as that term is commonly understood. For example, Webster's defines "mouthpiece" as "a part (as of an instrument) that goes in the mouth or to which the mouth is applied" or "something placed at or forming a mouth" ("Mouthpiece." Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/mouthpiece>. Accessed 18 Jul. 2024.) Other dictionaries I have seen have similar definitions. I am not aware of a definition of "mouthpiece" unique to the dental field In my experience, a dental practitioner might consider any dental device placed in the mouth to be a "mouthpiece." Nevertheless, I

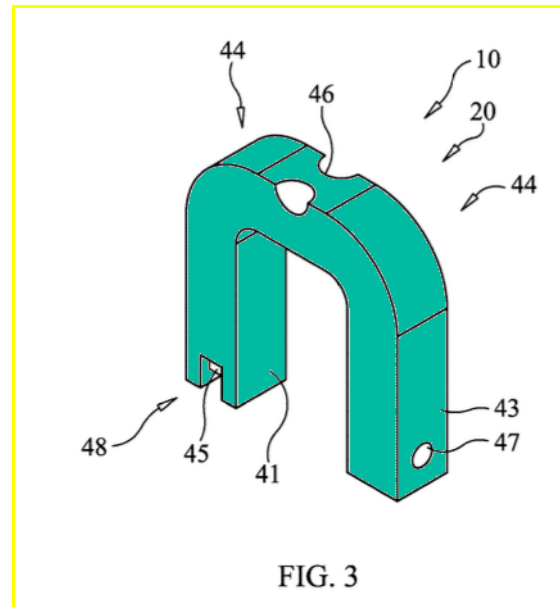
understand that the Examiner for the '209 Patent found that Llop126 did not disclose a “mouthpiece” as claimed. Ex. 1002, 224 (“the added language in the claim is not found in the prior art of Llop’126 and Llop’881 used in the Office Action of 9 February 2023.”)

149. The set of anchoring struts 42 are used to register the bone foundation guide in its appropriate location like the mouthpiece described in the '209 Patent. Ex. 1001, 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 form a mouthpiece that “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.” Ex. 1006, [0099]. The set of anchoring struts assures appropriate location of the bone foundation guide. *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.”) The bone foundation guide is set upon the bone tissue of the patient. *Id.*, Abstract

(“...the bottom contoured to removably affix the bone foundation guide body to the bone of a dental implant surgical site...”)



150. The anchoring struts engage with the patient's teeth. In particular, the anchoring struts 42 have, “at 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.” Ex. 1006, [0098] (emphasis added); Fig. 3. The indentations are specifically configured to match the contours of the patient's teeth. *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.”)



151. The language of claim 1 does not necessitate that the indentations of the Llop126 mouthpiece match teeth on the same alveolar ridge of the patient's mouth (*i.e.*, maxillary or mandibular) as being operated on. There is no language in the '209 Patent claims or specification limiting the mouthpiece to engage only with a particular ridge. I understand that claim element 1[g] includes mouthpieces that are configured and dimensioned to surround at least a portion of teeth on the opposing ridge from the surgical site, and is not limited to mouthpieces that fit teeth only on the same ridge.

152. Sichuan discloses a mouthpiece that is 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. *Id.*, [0007, 0049]. Sichuan, like Llop126, 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, 6. Sichuan's biteplate thus engages with teeth on the same ridge as the surgical site.

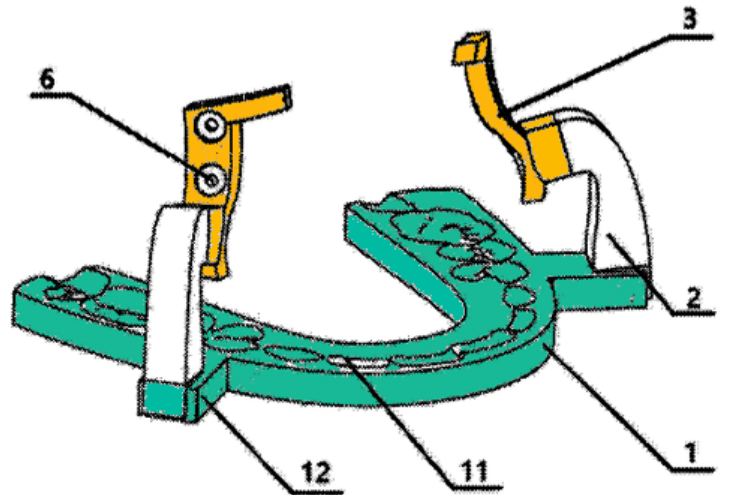


图1

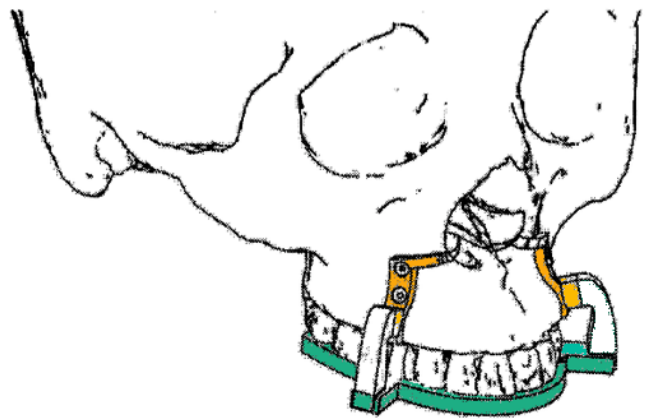


图6

153. Sichuan discloses that the biteplate is created from tooth prints 11 of the patient, e.g., Ex. 1009, Abstract, Claims 6g, 8g.3, [0007], [0027], [0038],

[0066]. The design of the tooth prints is obtained from digital data obtained by scanning a plaster model or “scanning directly with an intraoral scanner to obtain the patient’s data.” *Id.*, [0021], [0041], [0068]. This permits a “Boolean operation” to be used for designing the tooth prints onto the surfaces of the biteplate. *Id.*, e.g., [0027]. The Boolean operation is well-known in the field of digital dentistry and design, and would result in tooth prints on the biteplate that conform precisely to the shape of the teeth, and that they would thus surround each of the patient’s teeth.

154. Sichuan further discloses that the biteplate may conform to both upper and lower teeth. Ex. 1009, [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.

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

155. Llop126 discloses installing the fixation base to the maxillary or mandibular bone tissue of said patient, as recited in Element 1[g] of claim 1.

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 set of anchoring struts mouthpiece 42. Ex. 1006, [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.”)

157. 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.

(g) *Element 1[h]: mouthpiece removal*

158. Llop126 and Sichuan disclose removing the mouthpiece from the installed fixation base as recited in Element 1[h].

159. Llop126 discloses that once the bone foundation guide has been installed, the set of anchoring struts 42 that form the mouthpiece may be removed. Ex. 1006, [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.”)

160. Sichuan also describes that the mouthpiece is removed after the positioning guide plates have been installed. 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. *Id.* [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

161. 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 recited in Element 1[i].

162. Llop126 discloses using the bone foundation guide “to substantially modify (e.g., reduce, augment or both) the bone 14 of the dental surgical site 12 as needed for a successful surgery.” Ex. 1006, [0096, 0061]; Fig. 15.

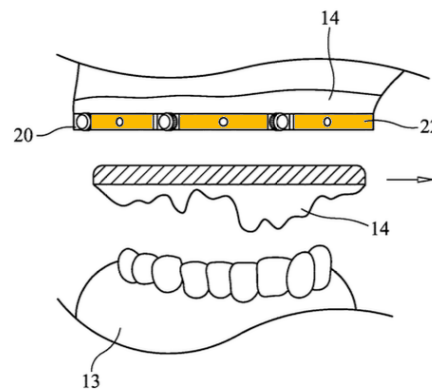


FIG. 15

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

163. Llop126 discloses recontouring the bone tissue, as recited in Element 1[l].

164. Llop126 discloses using the bone foundation guide “to substantially modify (e.g., reduce, augment or both) the bone 14 of the dental surgical site 12 as needed for a successful surgery.” Ex. 1006, [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

165. Llop126 discloses utilizing a 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, as recited in Element 1[k] of claim 1

166. Llop126 discloses utilizing a dental implant surgical guide 50, which is a drill guide that attaches to the installed fixation base. Ex. 1006, [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).”)

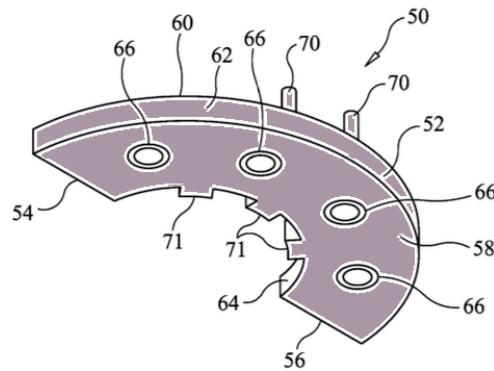


FIG. 16

167. Guide 50 is used to assure 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.”)

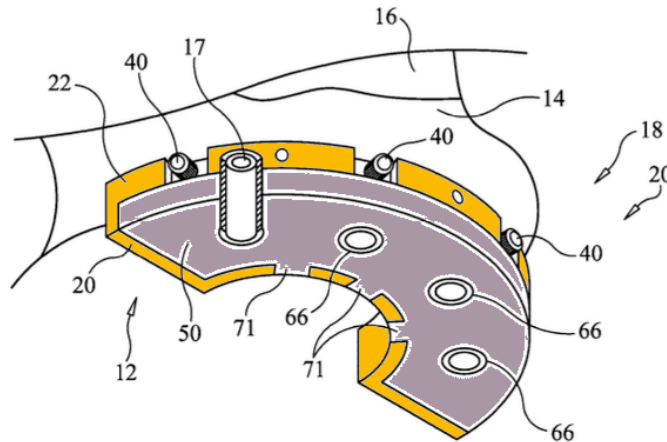


FIG. 19

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

168. Llop126 discloses drilling the implant holes in the bone tissue using the drill guide attached to the fixation base, as recited in Element 1[l] of claim 1. See, generally, Element 1[m]. *E.g.*, Ex. 1006, [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

169. Llop126 discloses installing implants in the implant holes, as recited in Element 1[m] of claim 1. See, generally, Element 1[k]. *E.g.*, Ex. 1006, [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.

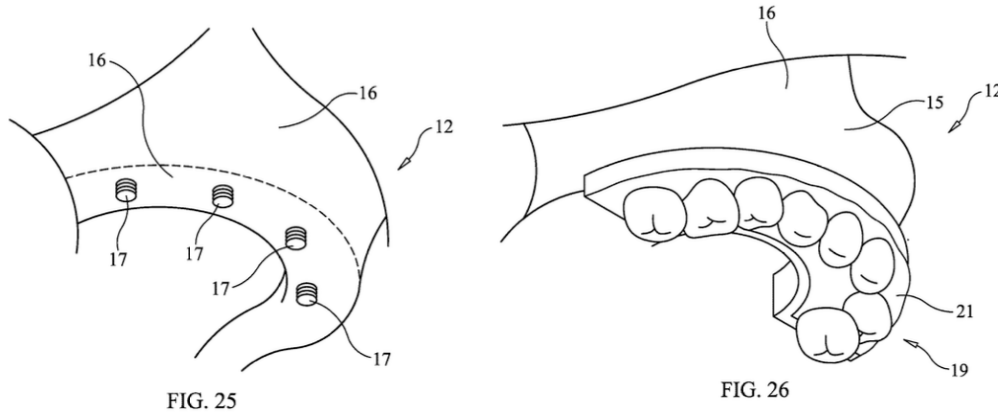
(m) Element 1[n]: abutment installation

170. Llop126 discloses installing the abutments to the implants, as recited in Element 1[n] of claim 1. Llop126 discloses the common practice of installing abutments to implants, which are then used to install a dental prosthesis. Ex. 1006, [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

171. Llop126 discloses installing said dental prosthesis to the abutments, as recited in Element 1[o] of claim 1. Llop126 discloses a prosthesis “can be placed over the tissue spacer gasket to come into contact the temporary abutments.” Ex. 1006, [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

172. Llop126 discloses installing the fixation base by driving fasteners through openings in its front surface, as recited in claim 2. See, generally, Element 1[c] above. *E.g.*, Ex. 1006, [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

173. Llop126 discloses using a preformed surface on the fixation base to assure proper recontouring of the bone tissue, as recited in claim 3. See, generally, Element 1[j] above. *E.g.*, Ex. 1006, [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.”)

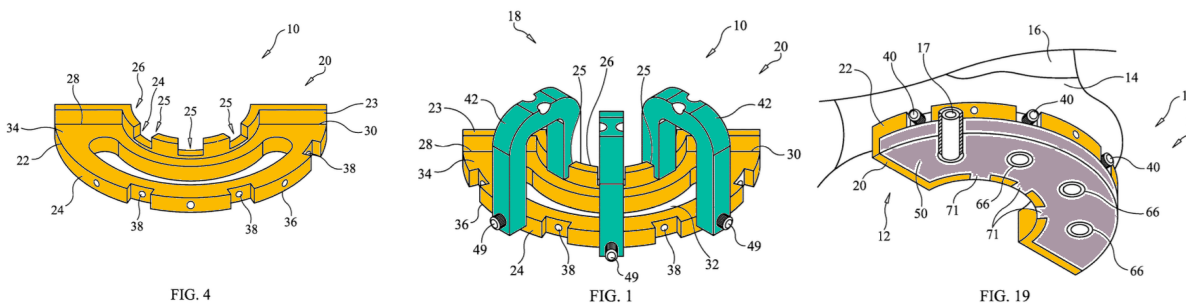
(q) Element 7[pre]: Preamble

174. Llop126 discloses an apparatus for installing a dental prosthesis to a jaw bone of a patient. 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. Ex. 1006, [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

175. 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]. Llop126 discloses a bone foundation guide 20 that serves as a mounting jig for other dental guides. Ex. 1006, [0026–30], e.g., Figs. 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). *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.



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

176. See Element 1[c] above.

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

177. See Element 1[d, e, f] above. As noted, the set of anchoring struts 42 have at their outer apices indentations 42 that match dentition on the patient’s opposing alveolar ridge. Ex. 1006, [0098, 0136].

178. 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. Ex. 1009, [0007, 0049]. 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.

(u) Element 7[e]: mouthpiece removal

179. Llop126 discloses installing the anchoring struts to be removed after the fixation base is affixed, as recited in Element 7[g] of claim 7. Llop126 discloses that once the bone foundation guide has been installed, the set of anchoring struts 42 that form the mouthpiece may be removed. Ex. 1006, [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.”)

180. Sichuan also describes removal of the mouthpiece after the positioning guide plates have been installed. 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. *Id.* [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

181. Llop126 discloses a drill guide attachable to the fixation base as recited in Element 10. 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. Ex. 1006, [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).”)

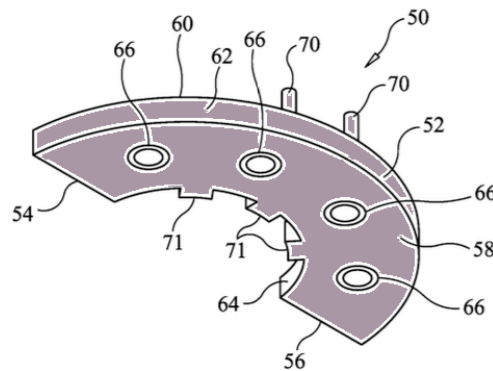


FIG. 16

182. 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. 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.”). Guide 50 includes a plurality of generally vertical bores corresponding in location to and in axial registration with intended implant sites. Ex. 1006, [0122] (The drill guide body 52 includes “implant

(w) *Claim 13: fixation base composition*

92

Llop126 would need a bone foundation guide to be made of a material that was sufficiently strong enough to withstand breakage during the prosthesis installation procedure.

(x) Claim 14: recontouring surface

184. Llop126 discloses a fixation base including a surface to assist in bone recontouring, as recited in claim 14. See generally Element 3, above. E.g., Ex. 1006, [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

185. Llop126 discloses a dental prosthesis that attaches to the fixation base, as recited in claim 16. 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. Ex. 1006, [0128]; Figs. 27–30.

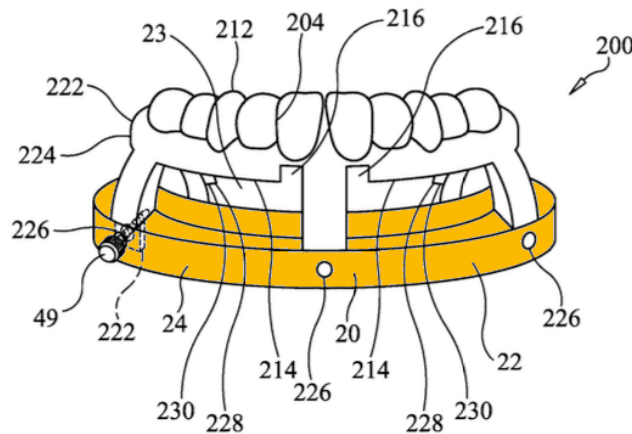


FIG. 29

(z) Element 17[pre]: Preamble

186. See Element 1[pre].

(aa) Element 17[a]: fixation base

187. See Element 7[a].

188. 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].

189. Llop126 discloses a bone foundation guide 20 that serves as a mounting jig for other dental guides. Ex. 1006, 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

190. See Element 1[c].

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

191. See Element 1[d, e, f].

192. 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 opposing alveolar ridge. Both Llop126 and Sichuan disclose attaching the mouthpiece to the fixation base, and installing the mouthpiece to assist in positioning the fixation base properly before it is installed to the patient’s bone tissue.

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

193. See claim 2.

194. Llop126 discloses installing the fixation base by driving fasteners through openings in its front surface. See, e.g., Ex. 1006, [0097].

(ee) Element 17[g]: mouthpiece removal

195. See Element 1[h].

196. Llop126 discloses removing the anchoring struts from the installed fixation base as in Element 1[h]. Ex. 1006, [0099–0101], Figs. 13–15.

197. Sichuan also describes removal of the mouthpiece after the positioning guide plates have been installed. Ex. 1009, [0049].

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

198. 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. It is my opinion that these claims are obvious, and not patentable under 35 U.S.C. § 103.

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

199. Assuming the claims are construed to limit the material of the drill guide and fixation base (Section VII), 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.

1. Llop126, Sichuan and Groscurth—Motivation to Combine

200. As I discuss above (Section X.C.1), a POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a

positioning bite plate, such that proper precise placement of the fixation base is ensured. Ex. 1009, [0003, 0005].

201. A POSA would further have been motivated to modify the Llop126/Sichuan system such that the fixation base and drill guide are made of metal, to increase rigidity and stability.

202. It would have been an obvious modification for a POSA to make the fixation base and drill guide from a metallic material. It was known in the field that surgical guides needed to be strong and withstand breakages. In order to address the known problem of providing strong dental surgical guides, a POSA would have been motivated to modify the Llop126 bone foundation guide—which does not specify the material used—and a drill guide made from metal as disclosed by Groscurth. Ex. 1011, 2:46–52, 13:1–4. It was commonly known that metal was a strong material and less susceptible to breakage than plastic.

203. A POSA would have understood that there was a high likelihood of success in making the combination. Llop126 and Groscurth are both in the same field of endeavor as the '209 Patent, providing surgical guide systems for performing osteotomies, and installing dental implants and prostheses. *Compare* Ex. 1006, Title, Abstract, “Field of Invention,” Fig. 1, *with* Ex. 1011, Title, Abstract, “Field of Invention”, Figs. 2, 6.

204. Groscurth discloses the known problem of a fixation base that is not of appropriate rigidity or stability. Ex. 1011, 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. Groscurth also discloses that the type of material and material thicknesses chosen will allow the different rigidity and flexibility of the base frame and drill guide as desired. For example, Groscurth discloses that the base frame is rigid in some areas, but can be more flexible than the surgical guide in other areas because “the surgical drill guide section placed on top of [the base frame] can solidify the whole drill guide assembly and the flexibility allows the device to clasp on to the undercut easily.” *Id.*, 4:55–59. Groscurth thus discloses the use of different materials and material thicknesses including an embodiment in which the fixation base (base frame 200) and the drill guide are made of metal. *Id.*, 4:46–52, 13:1–4. In particular, Groscurth identifies metal as “provid[ing] the base frame 200 with enough rigidity for stability and the right amount of flexibility in clasping areas.” *Id.*, 4:46–52. A POSA would have recognized that such clasping was commonly achieved using metal that is flexible in parts so as to snap into undercuts in the bone, such as with the use of removable partial dentures. Davenport, J et al. (Jan. 2001). Prosthetics: Clasp design. *British Dental Journal* (190), pp. 71-81 (describing standards for metal alloy clasp tips to

ensure appropriate flexibility and stability). Groscurth also discloses an embodiment where “the patient’s oral structure does not allow the [base frame] device to have enough retention”, and thus calls for “placing a temporary anchor directly into the jawbone.” *Id.*, 5:34–37, 6:50–55 (describing “fastening anchor devices such as screws and pins that are used to fasten the base frame 200 onto the jawbones 103 and 104 without engaging with the drill guide housing frame 300.”). A POSA would have understood that Groscurth’s use of a metal base frame in this structure would be advantageous.

205. Groscurth also suggests that using an entirely metal drill guide can be advantageous over other materials since it would not require any additional parts for bushings or adhesive material. *Id.*, 13:1–4. (“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.”) A POSA would understand that using metal for the fixation base and drill guide, as disclosed by Groscurth, would provide for stronger guides and make them less susceptible to breakage. It would have been obvious to modify Llop126 to use metal for the fixation base and drill guide as disclosed by Groscurth.

206. Similarly, Sichuan does not describe any particular material to be used for its components, but says they “are made into physical objects using three-dimensional printing materials through three-dimensional printing rapid

prototyping.” Ex. 1009, [0086]. A POSA would understand that these techniques could be used for metallic material as described in Groscurth. 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. Ex. 1009, [0083] (“a thickness of 3mm”).

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

207. 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 IX.C.2), above.

3. **Groscurth Discloses a Metal Fixation Base and Drill Guide**

208. Groscurth discloses a fixation base and drill guide that is made of metal, consistent with Petitioner’s proposed construction of “fixation base.” 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 clasp areas.**” Ex. 1011, 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.

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

209. The combination of Llop126 and Sichuan and Groscurth discloses all of the features of Claims 1–3, 7, 10, 13–14, and 16–17. 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, it would have been obvious for a POSA to combine those references as claimed. It is my opinion that these claims are obvious, and not patentable 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

210. 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 VII), then in my opinion, claims 1–3, 7, 10, 13–14, and 16–17 would have been obvious to a POSA under Section 103 based on Llop126 in view of Yau.

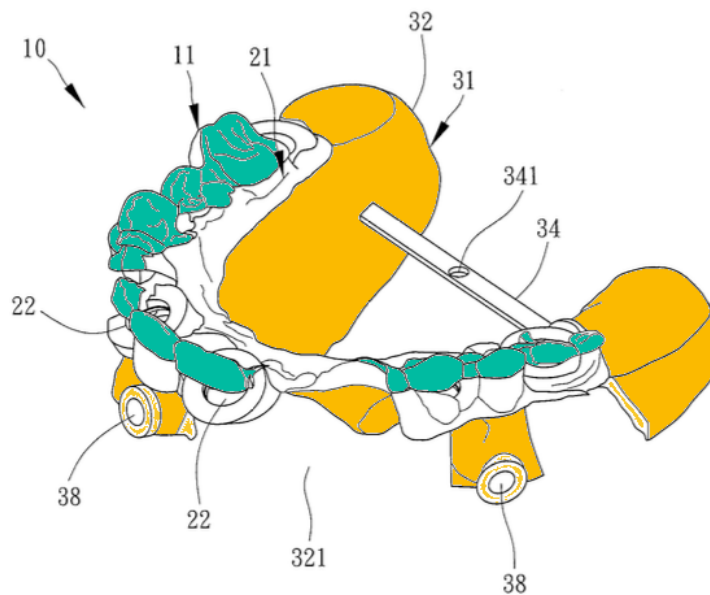
1. Llop126 and Yau—Motivation to Combine

211. In order to solve the known problem of positioning inaccuracies using gingiva alone, a POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a tooth mold for “tight engagement with the natural teeth,” such that proper precise placement of the fixation base is ensured. Ex. 1010, [0004, 0007].

212. A POSA would have understood that there was a high likelihood of success in making the combination. Llop126 and Yau are both in the same field of endeavor as the '209 Patent, namely surgical guides for dental implant and prosthesis installation. *Compare* Ex. 1006, Title, Abstract, “Field of Invention,” Fig. 1, *with* Ex. 1008, Title, Abstract, “Field of Invention”, Figs. 1–3. A POSA would have understood Llop126 and Yau are readily combinable because each concerns stackable dental implant surgical guide systems. Llop126 describes a fixation base positioned and attached to the patient’s jawbone, serving as a reference for dental implant surgical guides. Ex. 1006, 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. Ex. 1010.

213. It was a known 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.” Ex. 1010, [0004]. “Such positioning inaccuracy may lead to incorrect location of implant,” particularly for patients with too many missing teeth. *Id.* Yau solves this problem by 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. *Id.*, [0007, 0008, 0016–0025]. In the same way as 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.*, [0020]; Figs. 1, 4.



Yau discloses that the tooth mold can be multiple components (as shown), or a single component. *Id.*, [0025] (“...in actual application, the upper guide member

can be a one-piece member.”) A POSA would consider either the multiple component tooth mold or the single member tooth mold to be a mouthpiece.

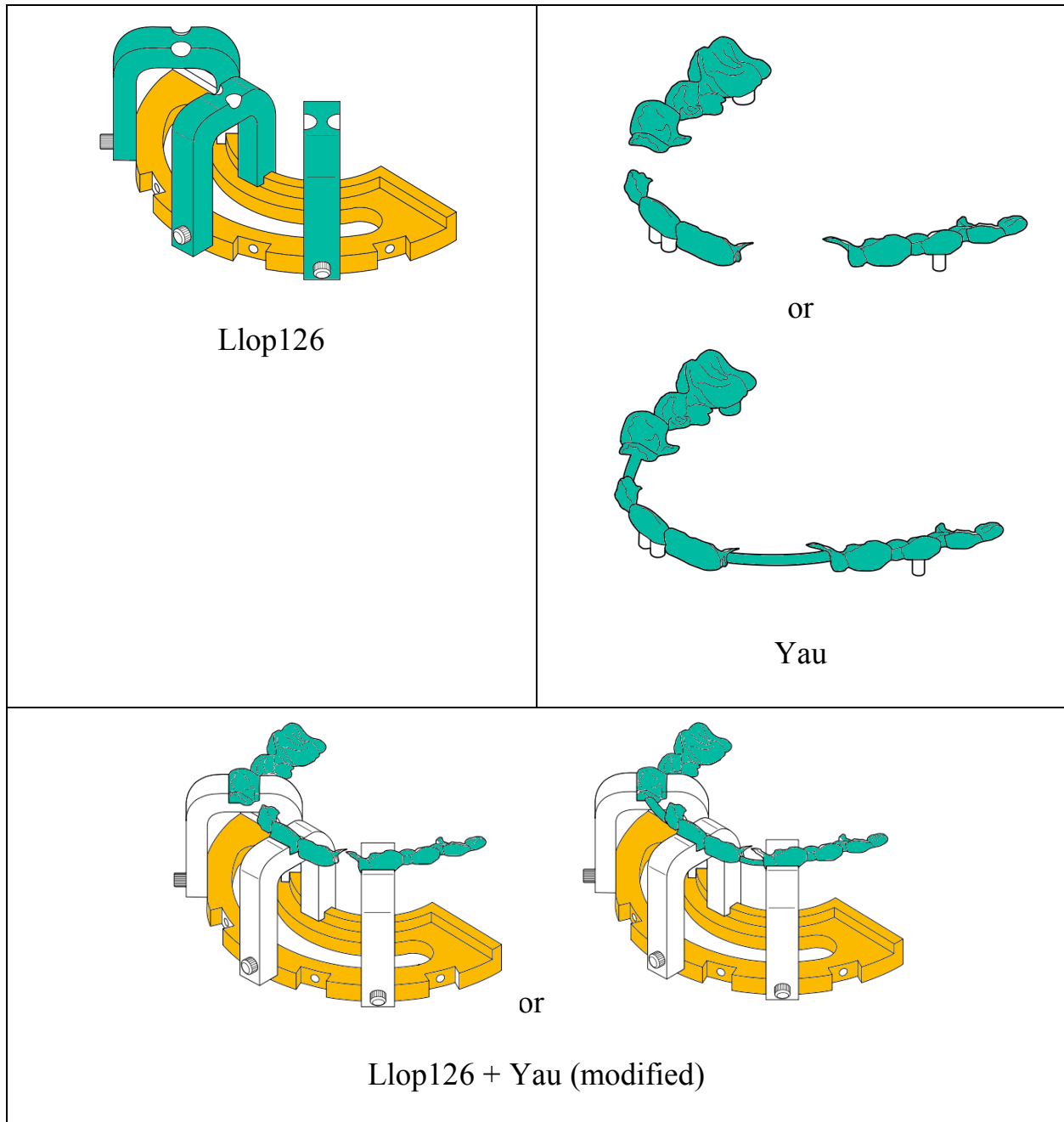
214. A POSA would have understood from Yau the benefits of modifying the anchoring struts of Llop126 to include a mouthpiece, in order to improve the positioning of the bone foundation guide for attachment to a patient’s jawbone. For example, Yau explains about the known problem of sliding when using surgical guides, particularly when guides are making contact with a patient’s gums (gingiva) or other soft tissue. Without using a “hard” reference point, such as teeth, it can be difficult to fixate a guide precisely in a proper location, as the guide is more likely to slide along the soft tissue. A POSA would have also understood that this modification furthered the objective of Llop126 to “control[] and refine[] the accuracy” of the stackable guide system by ensuring more precise placement of the bone foundation guide. Ex. 1006, [0029].

215. Yau discloses use of a tooth mold that is configured to surround the patient’s teeth, such that it forms a “hand and glove” relationship with the patient’s teeth. in order to prevent sliding when positioning a surgical guide base. Ex. 1010, [0007], [0017], [0022]. The Yau mouthpiece includes a tooth mold that is “adapted for tight engagement with natural teeth or temporary dentures of the opposite jaw when the patient bites.” *Id.*, [0017], Figs. 1, 2. A POSA would also understand that Yau’s upper guide member 11 may alternatively and/or in addition

represent occlusal tables for the patient's opposing natural teeth, adapted for tight engagement. The Yau mouthpiece includes precise recesses for the cusps of each tooth, thereby surrounding them. *Id.* Using such a cuspal registering mouthpiece for positioning purposes, as in the '209 Patent, achieves equally accurate results as mouthpieces that are taller and which extend further up the tooth, and has advantages over them. The thinner mouthpiece of Yau is less bulky, and thus easier to manipulate in a patient's mouth and allows for greater visibility. Additionally, a tall mouthpiece designed to engage with the entire tooth may be difficult to place and prone to getting stuck, whereas a cuspal registering mouthpiece as in Yau is easy to remove and place. Moreover, the component nature of the Yau mouthpiece allows for still easier manipulation.

216. Modifying Llop126's anchoring struts to include Yau's tooth molds would not have been difficult for a POSA, and would have been a simple matter of slightly redesigning the manufacturing specifications for the milling or 3D printing equipment that would have otherwise made the Llop126 devices. For instance, the anchoring struts of Llop126 could be manufactured to have the Yau tooth molds at their apexes, rather than indentations. Replacing the apexes of Llop126 with Yau tooth molds would have been a simple matter to make each strut-tooth mold individually, or as a single device, consistent with Yau's teaching that the tooth molds could be one more multiple components. Ex. 1010, [0025]. A POSA would

also recognize that the Llop126 anchoring struts could be made with holes so as to accept the “plug pins” from Yau’s tooth molds for simple attachment, or other standard attachment means could be employed.



217. 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. Placing the Yau tooth mold at the apexes of the Llop126 anchoring struts is entirely consistent with the struts' operation in Llop126, and does not affect any other aspect of the Llop126 system. The Yau tooth mold would be removed along with the anchoring struts after the bone foundation guide has been set. The "tight engagement" of the mouthpiece surrounds at least a portion of the patient's teeth for an improved registration of the bone foundation guide.

218. The combination of Llop126 and Yau is a predictable use of interchangeable prior art elements according to their established functions. This combination is not innovative but the product of ordinary skill and common sense.

219. A POSA would have understood from Yau the benefits of modifying the anchoring struts of Llop126, to improve on the solution to the known problem of sliding when positioning a fixation base for attachment to a patient's jawbone. A POSA would have been motivated to modify the anchoring struts' apex indentations by using a single or multiple-piece mouthpiece as taught by Yau, and as shown above. Llop126 modified 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 found in independent claims 1,

7 and 17 of the '209 Patent. A POSA would have understood that this modification had a high likelihood of success and was obvious.

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

(a) Element 1[pre]: Preamble

220. See Ground 3, above (¶¶ 134–136).

(b) Element 1[a]: dental prosthesis

221. See Ground 3, above (¶¶ 137–140).

(c) Element 1[b]: fixation base

222. See Ground 3, above (¶¶ 141–144).

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

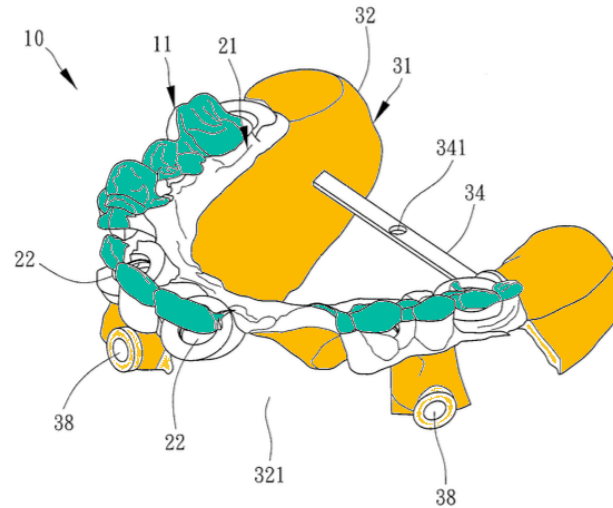
223. See Ground 3, above (¶¶ 145–146).

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

224. See Ground 3, above re Llop126 (¶¶ 147–151).

225. 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. 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. *Id.*, [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.*, [0020]; Figs. 1, 4.



226. 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.” A POSA would also understand that Yau’s upper guide member 11 may alternatively and/or in addition represent occlusal tables for the patient’s opposing natural teeth, adapted for tight engagement. A POSA would understand from Yau’s description of a “tooth mold adapted for tight engagement with the natural teeth” of the patient and the accompanying figures that the tooth mold is configured and dimensioned to surround at least a portion of the patient’s teeth.

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

227. See Ground 3, above re Llop126(¶¶ 155–156).

228. 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. *Id.*, [0020], Figs. 1, 4.

(g) Element 1[h]: mouthpiece removal

229. See Ground 3, above re Llop126 (¶¶ 158–159).

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

230. See Ground 3, above (¶¶ 161–162).

(i) Element 1[j]: bone recontouring

231. See Ground 3, above (¶¶ 163–164).

(j) Element 1[k]: drill guide

232. See Ground 3, above (¶¶ 165–167).

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

233. See Ground 3, above (¶ 168).

(l) Element 1[m]: implant installation

234. See Ground 3, above (¶¶ 169).

(m) Element 1[n]: abutment installation

235. See Ground 3, above (¶ 170).

(n) Element 1[o]: prosthesis installation

236. See Ground 3, above (¶ 171).

(o) Claim 2: installing fixation base

237. See Ground 3, above (¶ 172).

(p) Claim 3: using preformed surface to recontour

238. See Ground 3, above (¶ 173).

(q) Element 7[pre]: Preamble

239. See Ground 3, above (¶ 174).

(r) Element 7[a]: fixation base

240. See Ground 3, above (¶ 175).

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

241. See Ground 3, above (¶ 176).

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

242. See Ground 3, above re Llop126 (¶ 177).

243. Yau discloses a mouthpiece configured and dimensioned to surround a portion of the teeth and to attach to the fixation base. 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. *Id.*, [0007, 0008, 0016–0025].

244. 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.” A POSA would understand from Yau’s description of a “tooth mold for tight engagement” and the accompanying figures that the tooth mold is configured and dimensioned to surround at least a portion of the patient’s teeth.

(u) Element 7[e]: mouthpiece removal

245. See Ground 3, above re Llop126 (¶ 179).

(v) Claim 10: drill guide

246. See Ground 3, above (¶¶ 181–182).

(w) Claim 13: fixation base composition

247. See Ground 3, above (¶ 183).

(x) Claim 14: recontouring surface

248. See Ground 3, above (¶ 184).

(y) Claim 16: prosthesis attached to fixation base

249. See Ground 3, above (¶ 185).

(z) Element 17[pre]: Preamble

250. See Ground 3, above (¶ 186).

(aa) Element 17[a]: fixation base

251. See Ground 3, above (¶¶ 187–189).

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

252. See Ground 3, above (¶ 190).

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

253. See Ground 3, above re Llop126 (¶ 191).

254. 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. 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.

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

255. See Ground 3, above (¶¶ 193–194).

(ee) Element 17[g]: mouthpiece removal

256. See Ground 3, above re Llop126 (¶¶ 195–196).

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

257. 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. It is my opinion that these claims are obvious, and not patentable 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

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

1. Llop126, Yau and Groscurth—Motivation to Combine

259. As I discuss above (Section X.E.1) with regards to Ground 4 and incorporated herein, a POSA would have been motivated to modify the Llop126 anchoring strut system by constructing it with a tooth mold, such that proper precise placement of the fixation base is ensured. Ex.1010, [0007, 0017, 0022].

260. A POSA would further have been motivated to modify the Llop126/Yau system such that the fixation base and drill guide are made of metal, to increase rigidity and stability.

261. It would have been an obvious modification for a POSA to make the fixation base and drill guide from a metallic material. It was known in the field that surgical guides needed to be strong and withstand breakages. In order to address the known problem of providing strong dental surgical guides, a POSA would have been motivated to modify the Llop126 bone foundation guide—which

does not specify the material used—and a drill guide made from metal as disclosed by Groscurth. Ex. 1011, 2:46–52, 13:1–4.

262. A POSA would have understood that there was a high likelihood of success in making the combination. Llop126 and Groscurth are both in the same field of endeavor as the '209 Patent, providing surgical guide systems for performing osteotomies, and installing dental implants and prostheses. *Compare* Ex. 1006, Title, Abstract, “Field of Invention,” Fig. 1, *with* Ex. 1011, Title, Abstract, “Field of Invention”, Figs. 2, 6.

263. Groscurth describes the known problem of a fixation base that is not of appropriate rigidity or stability. Ex. 1011, 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. Groscurth solves this problem by suggesting the use of hard material, such as metal, for the fixation base (base frame 200) and the drill guide. *Id.*, 4:46–52, 13:1–4. Groscurth also discloses that the type of material and material thicknesses chosen will allow the different rigidity and flexibility of the base frame and drill guide as desired. For example, Groscurth discloses that the base frame is rigid in some areas, but can be more flexible than the surgical guide in other areas because “the surgical drill guide section placed on top of [the base frame] can solidify the whole drill guide assembly and the

flexibility allows the device to clasp on to the undercut easily.” *Id.*, 4:55–59.

Groscurth thus discloses the use of different materials and material thicknesses including an embodiment in which the fixation base (base frame 200) and the drill guide are made of metal. *Id.*, 4:46–52, 13:1–4. In particular, Groscurth identifies metal as “provid[ing] the base frame 200 with enough rigidity for stability and the right amount of flexibility in clasping areas.” *Id.* 4:46–52. A POSA would have recognized that such clasping was commonly achieved using metal that is flexible in parts so as to snap into undercuts in the bone, such as with the use of removable partial dentures. See, e.g., Davenport, J et al. (Jan. 2001). Prosthetics: Clasp design. *British Dental Journal* (190), pp. 71-81 (describing standards for metal alloy clasp tips to ensure appropriate flexibility and stability). Groscurth also discloses an embodiment where “the patient’s oral structure does not allow the [base frame] device to have enough retention”, and thus calls for “placing a temporary anchor directly into the jawbone.” *Id.*, 5:34–37, 6:50–55 (describing “fastening anchor devises such as screws and pins that are used to fasten the base frame 200 onto the jawbones 103 and 104 without engaging with the drill guide housing frame 300.”). A POSA would have understood that Groscurth’s use of a metal base frame in this structure would be advantageous.

264. Groscurth also suggests that using an entirely metal drill guide can be advantageous over other materials since it would not require any additional parts

for bushings or adhesive material. *Id.*, 13:1–4. (“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.”) A POSA would understand that using metal for the fixation base and drill guide, as disclosed by Groscurth, would provide for stronger guides and make them less susceptible to breakage. It would have been obvious to modify Llop126 to use metal for the fixation base and drill guide as disclosed by Groscurth.

265. 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.” Ex. 1010, [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.

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

266. 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 IX.E.2), above.

3. Groscurth Discloses a Metal Fixation Base and Drill Guide

267. See Ground 4 (Section IX.D.3, ¶ 208), above.

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

268. The combination of Llop126 and Yau and Groscurth discloses all of the features of Claims 1–3, 7, 10, 13–14, and 16–17. 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 of the claim elements. As shown it would have been obvious for a POSA to combine those references as claimed. It is my opinion that these claims are obvious, and not patentable under 35 U.S.C. § 103.

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

269. 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 VII), then in my opinion, claims 5, 6 and 12 would have been obvious to a POSA under Section 103 based on Llop126 and Sichuan with Scherer.

1. Llop126, Sichuan and Scherer—Motivation to Combine

270. 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

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. Ex. 1012, 1:58 (identifying “Guided Prosthetics™ Proprietary Stackable Bone Foundation Guide System™, Exclusive to nSequence invented by Mr. Daniel R. Llop CDT.”); 1018, 4–5 (identifying U.S. Provisional App. 61/784,029, to which the Llop126 application claims priority).

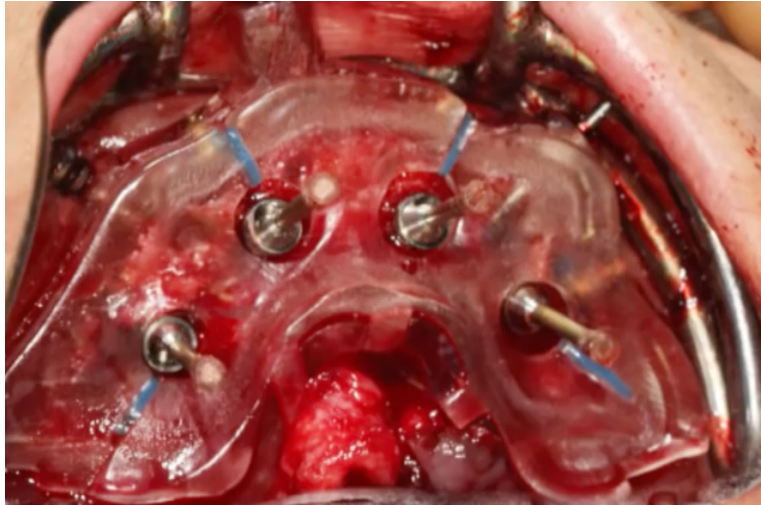
271. Scherer describes an abutment guide used for orienting the abutments that attaches to the bone foundation guide. Ex. 1012, 4:30–5:10. The Scherer abutment guide uses the same or similar tabs/cutout mechanism to attach to the foundation guide as what is described and shown in Llop126 for attaching the implant surgical guide (drill guide) and tissue gasket of Llop126. *Id.*; Ex. 1006, [0122, 0126]. The abutment guide of Scherer and the surgical guide system of Llop126 are thus completely compatible. 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, or the use of a metal base as from Groscurth. 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.

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

(a) Claim 5: abutment guide

272. Scherer discloses utilizing an abutment guide that attaches to the fixation base, as recited in claim 5. 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.” Ex. 1012, 4:30–5:15. Scherer demonstrates how the blue line indicators on the abutment guide are used to align abutments to appropriate angular rotation *Id.* (17 degree abutments in the interior, 30 degree abutments in the posterior). Ex. 1012, 4:30–5:15. 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.





(b) Claim 6: abutment installation

273. See Claim 5, above.

(c) Claim 12: abutment guide

274. See Claim 5, above.

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

275. The combination of Llop126 and Sichuan with Scherer discloses all of the features of claims 5, 6 and 12. As shown, it would have been obvious for a POSA to combine those references as claimed. It is my opinion that these claims are obvious, and not patentable under 35 U.S.C. § 103.

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

276. 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.

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 (Ground 7). 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.

XI. ACKNOWLEDGMENTS

I, Douglas M. Erickson, declare under penalty of perjury under the laws of the United States of America that the foregoing is true and current.

DocuSigned by:
Douglas M. Erickson, D.D.S., M.S.
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Executed on 7/18/2024