

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

**PETITIONER'S REPLY TO
PATENT OWNER'S RESPONSE**

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

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1014	File History of U.S. Patent No. 11,173,016 (excerpts)
1015	Declaration of Kathryn Talbot
1016	Internet Archive, http://nsequence.com , archived February 7, 2016 (accessed May 21, 2024)
1017	“Fundamentals of CHROME GuidedSmile”, downloaded from https://guidedsmile.com/get-your-introduction-to-chrome-guidedsmile-ebook-today/ on June 20, 2024
1018	Internet Archive, http://www.nsequence.com/2013/11/08/all-on-x-cases-immediate-provisionalization , archived March 10, 2016 (accessed June 28, 2024)
1019	Webpage printout: All-on-4® nSequence® Implant Surgical Technique Using Zest Chairside® Attachment Processing Material – YouTube, https://www.youtube.com/watch?v=VOWRdFpfGI , (accessed June 24, 2024)
1020	Webpage printout: “Why You Should Choose Metal Over Plastic”, https://www.youtube.com/watch?v=tlOWzK4h1Nc&t , posted April 15, 2021 (accessed July 10, 2024)
1021	Definition of “Enclose” from Oxford English Dictionary (accessed Nov. 5, 2024)
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1024	Webpage printout: “GuidedSMILE Family of Products”, https://guidedsmile.com/guidedsmile-family-of-products , (accessed June 17, 2025)

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1025	Webpage printout: “Components of CHROME”, https://guidedsmile.com/components-of-chrome/ , (accessed June 17, 2025)
1026	Webpage printout: “GuidedSMILE Lite”, https://guidedsmile.com/guidedsmile-lite/ , (accessed June 17, 2025)
1027	Webpage printout: “GuidedSMILE Lite”, https://www.roedentallab.com/products/chrome-guidedsmile/guidedsmile-lite/ , (accessed June 22, 2025)
1028	JPEG image, https://www.roedentallab.com/hs-fs/hubfs/CHROME/Lite/Study-2/3.jpg?width=2000&height=1334&name=3.jpg , (accessed June 22, 2025)
1029	Advertising sheet, “GuidedSMILE Lite”, ROE Dental Laboratory
1030	Webpage printout and video screenshots: YouTube, Pin Guide & Fixation Base – CHROME Live Webinar Series, https://www.youtube.com/watch?v=HqxcwXUr7Os&list=PPSV , April 20, 2020 (accessed June 22, 2025)
1031	Webpage printout: Facebook, ROE Dental Laboratory, https://facebook.com/roedental , (accessed June 17, 2025)
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1036	“Dentistry Today January/February 2024” cover and selected pages, (accessed June 22, 2025)
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1038	Webpage printout: Henry Schein Dental, https://www.henryschein.com/us-en/Search.aspx?searchkeyWord=mouthpiece&subtoclevel=1&pagenumber=1 , (accessed June 10, 2025)
1039	Webpage printout: Isolite Posterior CIL0801 Mouthpiece, https://www.henryschein.com/us-en/dental/p/evacuation-products/specialty-suction-systems/isolite-posterior-mouthpiece/8010181 , (accessed June 10, 2025)
1040	Webpage printout: Isolite Anterior Mouthpiece CAM0401, https://www.henryschein.com/us-en/dental/p/evacuation-products/specialty-suction-systems/isolite-anterior-mouthpiece/1473284 , (accessed June 10, 2025)
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1043	Webpage printout: 2437 Mouthpieces, https://www.henryschein.com/us-en/dental/p/equipment-technology/equipment-accessories/mouth-prop-ster-end/6429443 , (accessed June 10, 2025)
1044	Definition of “mouthpiece” from Dictionary.com (accessed June 26, 2025)
1045	Definition of “mouthpiece” from Merriam-Webster.com (accessed June 26, 2025)
1046	Transcript, Deposition of Alan Banks, June 23, 2025
1047	Transcript, Deposition of Dr. Jeffrey A. Elo, June 26, 2025

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1048	U.S. Patent No. 11,173,016
1049	U.S. Patent No. 11,576,755
1050	Supplemental Declaration of Douglas M. Erickson, DDS, MS

In the January 28, 2025 Institution Decision on U.S. Patent No. 11,806,209 (“the ‘209 patent”), the Board found Petitioner likely to prevail in showing that at least one of claims 1–3, 5–7, 10, 12, 14, 16, and 17 (the “Challenged Claims”) is unpatentable. Nothing in Patent Owner’s¹ (“PO”) Response should disturb that conclusion.

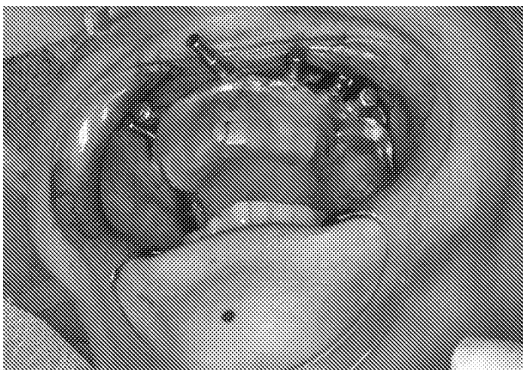
PO principally advances overly narrow constructions of “mouthpiece” and “surround at least a portion of the teeth of the patient” which are contrary to the intrinsic evidence. PO then argues an overly narrow (and legally incorrect) view of what constitutes analogous art. For secondary considerations of nonobviousness, PO fails to establish a nexus between the evidence it relies on and the Challenged Claims. Accordingly, they should be found unpatentable.

I. PO’S CONSTRUCTIONS ARE INCORRECT AND UNNECESSARY

PO proposes overly restrictive constructions of: a) “mouthpiece”; and b) “configured and dimensioned to surround at least a portion of the teeth of the patient.” PO’s constructions are at odds with the plain meaning. EX1050, ¶¶9, 13, 15. In any event, the prior art teaches these claim elements even under PO’s construction.

¹ “Patent Owner” herein refers to both the assignee of the ’209 patent (Watson Guide IP LLC) and its exclusive licensee (GuidedSmile LLC), and its predecessor in interest (ROE Dental Laboratory).

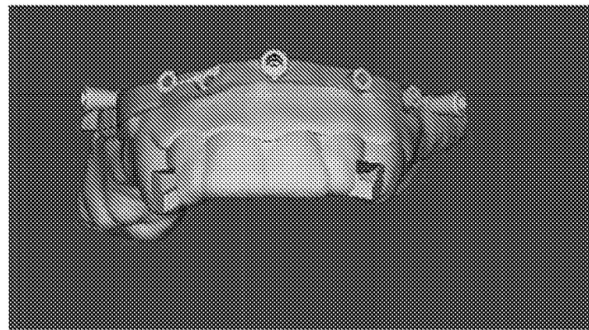
The '209 patent discloses a “mouthpiece” that is not limited to “a device that is inserted into the mouth and worn over the teeth.” The '209 patent claims priority to and incorporates by reference U.S. Provisional Application No. 62/508,377 (EX1001, 1:7-11), which discloses two mouthpiece embodiments to locate the fixation base: a partially edentulous embodiment (where the patient has some teeth remaining); and a fully edentulous embodiment (where the patient has no teeth). EX1005, 22 (“This invention uses the patients existing teeth (partially edentulous) or denture teeth for a (fully edentulous) to set the fixation base.”). The provisional specification refers to these embodiments as a “tooth borne guide” and a “tissue borne guide” (or “Denture Clone”), respectively. EX1005, 4, 6, 22, 24, 28.



EX1005, FIG. 2c (excerpt)

Tooth Borne Guide

FIG 2b.



EX1005, FIG. 2b

Tissue Borne Guide / Denture Clone

The provisional specification explains how these different “mouthpieces” are implemented: “In the design phase the first guide is designed to position over the existing teeth for the partially edentulous patient or duplicated from a tooth setup for the fully edentulous patient. The first guide must seat the teeth into the guide for the partially edentulous [patient,] or for the fully edentulous patient the copy setup guide must match the occlusion of the verified actual setup.” *Id.*, 25.

PO's proposed construction of “mouthpiece” as “a device...worn over the teeth” reads out the edentulous embodiment, where no patient teeth are used. EX1050, ¶12. There is nothing in the '209 patent specification indicating that the patentee intended to exclude the tissue borne guide from the scope of the invention. Rather, the specification states generally, without reference to teeth, “The purpose of first dental guide 122 is to assist in locating fixation base 100 with sufficient precision to assure successful installation of dental prosthesis 10. Therefore, first dental guide 122 is used when installing fixation base 100 in the mouth, but is removed thereafter and plays no further role.” EX1001, 5:7-12. This broad description encompasses both tooth borne and tissue borne guides. In contrast, the specification's lone reference to the mouthpiece surrounding teeth (4:63-67) describes only one particular embodiment in a non-limiting manner. The

patentee explains that “the present invention is not to be limited to the disclosed arrangements, but is intended to cover various arrangements...so as to encompass all modifications and equivalent arrangements which are possible.” *Id.*, 8:65-9:6.

The prosecution history also does not support PO's overly narrow construction of “mouthpiece.” In prosecuting the parent '016 patent, PO's then pending claim 4 recited a step of “designing and fabricating a mouthpiece” that “conform[s] to some surfaces of the maxillary or mandibular portion of the mouth of the patient being treated,” and claim 1 was amended to include “a mouthpiece that attaches to the fixation base and is used to assure appropriate location to attach the fixation base to the...bone tissue of the patient.” EX1014, 59, 95. Teeth are not mentioned in either of these claims regarding the mouthpiece. In contrast, then pending claim 15 recited “a mouthpiece configured and dimensioned to surround teeth of the patient.” *Id.*, 61-62, 99. Without the qualifying language of claim 15, the “mouthpiece” (as recited, e.g., in then pending claims 1 and 4) was not limited to being “worn over the teeth” as PO now argues.

PO's expert, Dr. Elo, equates the claimed “mouthpiece” with a “mouth guard” that is “used to protect athletes such as boxers...” EX2007, ¶39. But Dr. Elo provides no basis for his *ipse dixit* opinion that a sports definition should apply to a dental surgery patent. Rather, he points to a household dictionary of

choice, while ignoring others that do not support his position. Response, 6-7; EX2007, ¶41; EX1044; EX1045; EX1047, 31:1-33:19 (“Not always do you get an exact [dictionary] match if there’s nothing relevant under ‘mouthpiece.’”); EX1050, ¶11. Had PO wished to limit its invention to a particular “athletic mouth guard,” it could have drafted its claims to do so. PO did not.

Nor does PO address Dr. Erickson’s testimony and evidence that the term “mouthpiece” is not unique to any dental field, and that a POSA “might consider any dental device placed in the mouth to be a ‘mouthpiece.’” EX1003, ¶148; EX1050, ¶13. Indeed, a variety of “mouthpieces” are found in the industry and sold online to dental professionals. E.g., EX1038, EX1039, EX1040, EX1043; EX1050, ¶10. As Dr. Elo confirmed when presented with these samples—29 items for sale on the Henry Schein Dental website matching the search term “mouthpiece”—“I don’t see any that are consistent with my definition.” EX1047, 35:2-13. Dr. Elo could not identify that any of the mouthpieces “go over the teeth.”

PO repeats the same arguments from its POPR that “surround at least a portion of the teeth” means “enclose at least some teeth of the patient.” PO identifies patent figure 12C which, according to PO, shows the guide “completely enclosing the teeth.” Response, 8. But again, in discussing the figures the

specification makes clear that they are only “an exemplary embodiment” and that the invention “is not to be limited to the disclosed arrangements.” EX1001, 8:7-9, 8:59-60. Importing a claim limitation from a preferred embodiment is a “cardinal sin” of claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005). This is especially so here, where the proposed construction is at odds with the remaining intrinsic evidence. PO also has not addressed the criticism from Petitioner's POPR Reply or in the Institution Decision that PO's proposal “appears to only replace the disputed phrase with parallel language that is no clearer than the term itself.” Institution Decision, 15. Rather, both Dr. Elo and Dr. Erickson agree that the terms “surround” and “enclose” are synonymous to a POSA. EX1047, 38:22-41:6; EX1050, ¶¶14, 15.

II. THE CLAIMS ARE OBVIOUS UNDER LLOP + SICHUAN

A. Llop + Sichuan Disclose All Claim Elements

PO concedes that the combination of Llop and Sichuan discloses all but at most one limitation of the challenged claims, namely a mouthpiece “configured and dimensioned to surround at least a portion of the teeth of the patient.” Response, 28. Relying on its proposed claim construction, PO first argues that Llop's anchoring struts are not a “mouthpiece.” Response, 30-32. This is a

strawman. Petitioner did not argue that Llop's struts alone satisfied this claim element, but instead looked to Sichuan for this teaching. Petition, 28-29.

PO's argument that Sichuan lacks the claimed mouthpiece is unavailing. PO does not contest that Sichuan is "configured and dimensioned to surround at least a portion of the teeth," but instead argues that Sichuan's biteplate is not a "mouthpiece" under its overly narrow construction. Response, 33. But a POSA would consider Sichuan's biteplate to be a mouthpiece, particularly in light of the evidence presented above. EX1003, ¶¶ 74, 124, 125, 152. PO cites the '209 patent, col. 8, lns. 6-19, to support its argument that the claimed mouthpiece requires "a specific structure." Response, 33. But as noted above, that passage refers only to what the patentee considered "the most practical and preferred embodiment," and the specification makes clear that the invention is not so limited. EX1001, 8:58-9:6. Relying entirely on Dr. Elo, PO argues that the 1-2 mm deep tooth prints in Sichuan's biteplate disqualify it from being a "mouthpiece." Response, 34. However, given Dr. Elo's limited understanding of mouthpieces in the industry (see above), his unsupported opinion here carries little weight.

The Board found in the Institution Decision that PO provided insufficient evidence as to why Sichuan's biteplate with 2mm dental print depth is not a mouthpiece that is configured and dimensioned to surround at least a portion of a

patient's teeth. Institution Decision, 25. PO does not adequately explain anything now that should cause to Board to revisit its conclusion.

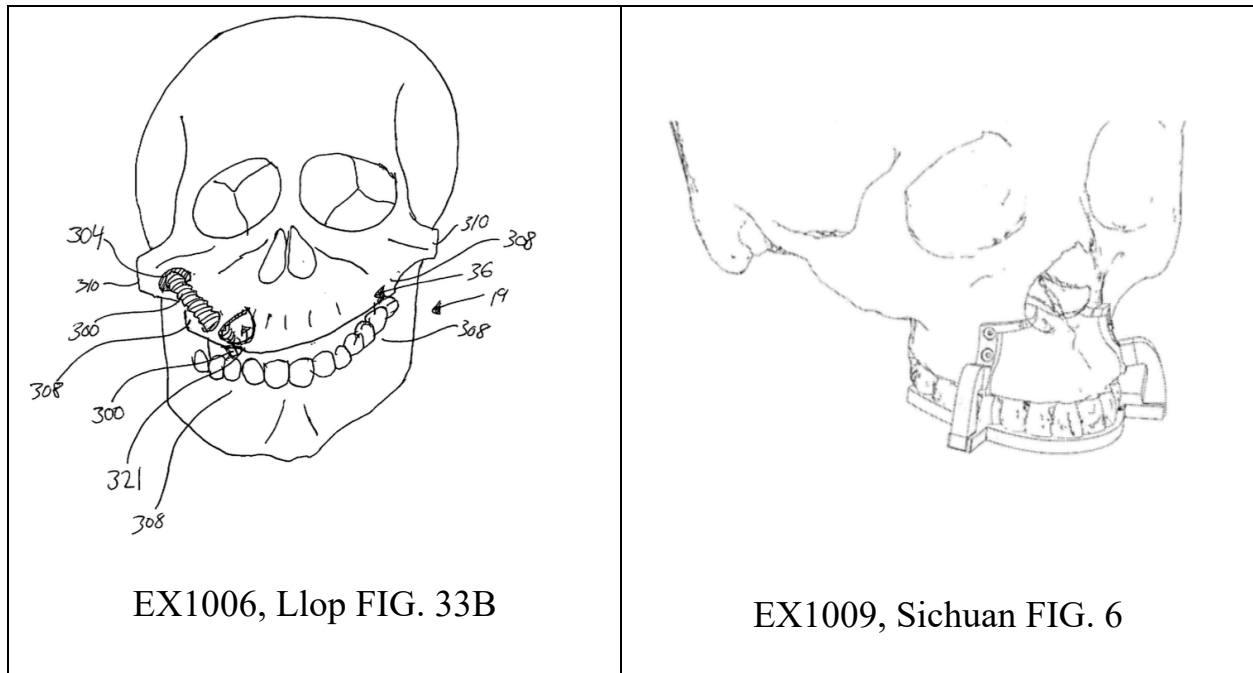
B. A POSA Would Have Been Motivated to Combine Llop + Sichuan

PO argues that a POSA would not have been motivated to combine Llop with Sichuan because Sichuan relates to a “very rare procedure...that is very different from implant installation.” Response, 35. Even if true, this would not preclude combining the references in the manner proposed, and PO cites no case law in support of its position. Sichuan is analogous art to the '209 patent because Sichuan is reasonably pertinent to the problems addressed by the '209 patent. *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374, 1379 (Fed. Cir. 2019). The '209 patent—and particularly via the use of the claimed mouthpiece—attempts to solve the problem of allowing for a precise installation of a guide (fixation base) onto a patient's jawbone structure, such that it can be used as a reference in dental surgery. EX1001, 5:7-17 (“The purpose of first dental guide 122 is to assist in locating fixation base 100 with sufficient precision to assure successful installation of dental prosthesis 10... Subsequently used dental guides use tabs corresponding to those of first dental guide 122, in the same way, and to the same end, that of precisely locating the subsequently used dental guides prior to fixing the latter using attachment elements 106.”)

Sichuan seeks to solve the same problem of allowing for precise installation of a guide (guide plate) onto a patient's jawbone structure, such that it can be used as a reference in dental surgery. EX1009, [0048] ("The present invention fills the gap of lacking an auxiliary device for positioning the bone blocks to be resected during subapical osteotomy."); EX1003, ¶¶122, 123. PO's technical expert, Dr. Elo, agrees that both the '209 patent mouthpiece and Sichuan are directed to solving this problem. EX1047, 46:16-48:4, 58:16-60:14. Sichuan is thus analogous art to the '209 patent.

Even assuming that a subapical osteotomy procedure as disclosed in Sichuan is a specialized form of dental surgery performed by oral/maxillofacial surgeons with certain training (Response, 35), neither PO nor Dr. Elo claim that an ordinarily skilled dental practitioner who performs implant surgery would not at least be *aware* of such subapical osteotomy, or would not have had access to materials and documentation on the subject in, for example, a dental school library. Both dental implant surgery and subapical osteotomy surgery involve similar areas of the patient's skull, such as the pterygoid. See, e.g., EX1006, [0015], [0019], [0112]; EX1047, 57:12-58:15. The terms "apical" and "osteotomy" are commonly understood in the dental implant field, even by non-dentists. EX1046, 28:15-29:14, *passim*. A POSA reading Llop, for example, would instantly be aware of

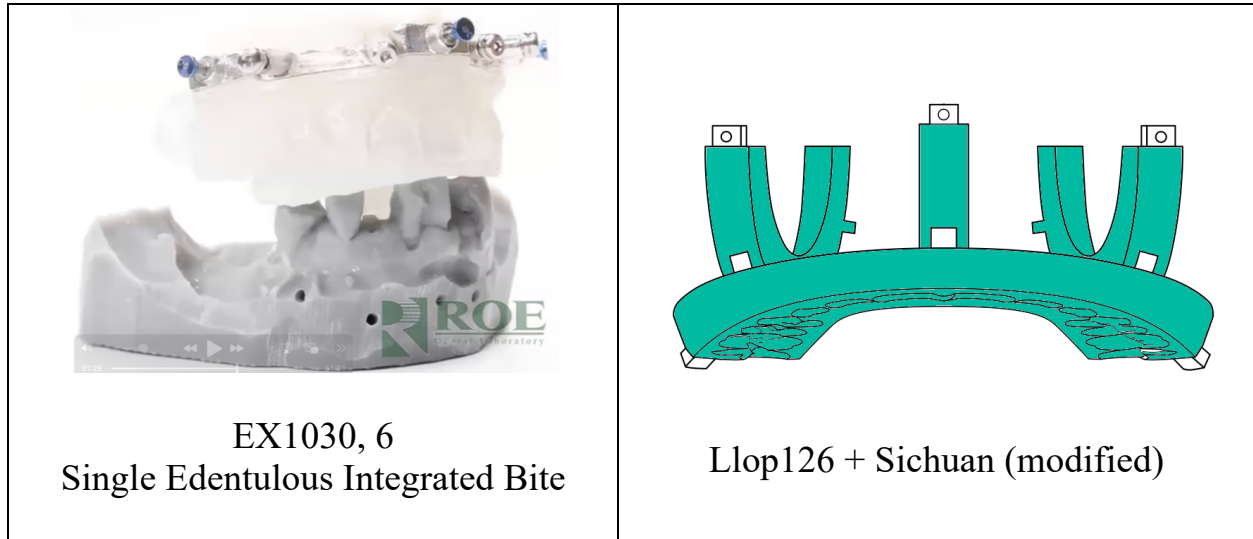
relevance of skull osteotomy procedures, such as a subapical osteotomy: nearly half of the figures in Llop relate to similar skull-based operations, as shown in the drawings reproduced below. EX1006, 19-32.



PO also argues that “there is no expectation that the biteplate of Sichuan would be more effective than the struts...that are already described in Llop.” Response, 36. However, Sichuan’s biteplate need not be a categorical improvement over Llop for an obviousness finding. Rather, there is a motivation to combine because, as shown in the Petition and as explained by Dr. Erickson (EX1003, ¶¶121-133), replacing Llop’s struts with Sichuan’s biteplate was a suitable option to address a known problem. *Intel Corp. v. PACT XPP Schweiz AG*,

61 F.4th 1373, 1381 (Fed. Cir. 2023) (“It’s enough for [Petitioner] to show that there was a known problem [] in the art, that Bauman's [teachings] helped address that issue, and that combining the teachings of Kabemoto and Bauman wasn’t beyond the skill of an ordinary artisan. Nothing more is required to show a motivation to combine under *KSR*, so we reverse the Board’s finding to the contrary.”)

The suitability of the Llop-Sichuan combination is further evidenced by PO’s own products. For partially edentulous patients who may only have a few teeth on one jaw, PO uses a “single edentulous integrated bite” pin guide, which is designed with a “negative” “impression of the lower teeth” that holds the upper mouthpiece in place. EX1030, 6; EX1046, 103:21-106:4. PO’s President describes the guide fitting the incisal edges to “make sure the lower teeth...fit into it into a predictable position” and “to ensure that there’s a good fit when there’s an occlusion.” *Id.* The similarity of PO’s single edentulous integrated bite pin guide with its “negatives” of the teeth and Petitioner’s identified Llop-Sichuan combination using the “Boolean operation” to create tooth prints is shown below:



PO's argument against suitability results from a misreading of Llop to require that "the teeth of the jaw to be operated on are removed prior to use of the struts." Response, 36. PO provides no citation for this statement, which is contradicted by Llop's own teachings: "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.*" EX1006, [0140] (emphasis added). This passage indicates that all teeth are not always removed on the jaw to be operated in Llop. Moreover, even if the teeth are removed, the Challenged Claims do not exclude mouthpieces that engage the opposite teeth as compared to the jaw being operated on, as described more fully below.

PO attacks Dr. Erickson's opinion that Sichuan's biteplate mouthpiece has advantages over taller mouthpieces, but points to unclaimed optional features in its comparison (e.g., "the claimed mouthpiece *may* be provided with windows" to increase visibility). Response, 37. PO also argues, without evidence, that "a cuspal registering biteplate is only effective in a situation...where patients typically have a lot of teeth." *Id.* Yet this statement is inconsistent with PO's own use of a single edentulous integrated bite pin guide, described above, which uses a negative to fit the incisal edges of a patient's few remaining teeth in order to position a fixation base. In any event, PO's arguments miss the point: PO does not argue that the combination of Sichuan and Llop is not *suitable* for addressing the problem of positioning a guide for attachment to a patient's jawbone. *Intel*, 61 F.4th at 1381. Petitioner and Dr. Erickson have shown the suitability of the combination.

III. THE CLAIMS ARE OBVIOUS UNDER LLOP + YAU

A. Llop + Yau Disclose All Claim Elements

PO concedes that the combination of Llop and Yau discloses all but at most one limitation of the challenged claims, namely a mouthpiece "configured and dimensioned to surround at least a portion of the teeth of the patient." For that limitation, PO's position is flawed for at least two reasons. First, PO's argument relies on its narrow claim construction of "mouthpiece," which is improper for the

reasons discussed above. Response, 40-41. As Dr. Erickson testified, a POSA would understand that Yau's upper guide member to be a "mouthpiece", particularly when configured in a "one-piece" arrangement. EX1003, ¶226.

Second, while PO admits that the Yau tooth molds 12 "are adapted for tight engagement" with the patient's teeth or dentures, PO does not address Dr. Erickson's conclusion that this "tight engagement" of the mouthpiece surrounds at least a portion of the patient's teeth, as claimed in the '209 patent. EX1003, ¶¶215-217, 225-226. Rather, PO and Dr. Elo improperly compare Yau's mouthpiece *to the alleged disclosure of a tooth-surrounding mouthpiece in Llop*, which is not at issue in this proceeding.² That the Examiner during prosecution of the '209 patent allowed the claims over *Llop* is a red herring, and is immaterial to the present analysis of *Yau* and the proper inquiry of whether *Yau*'s disclosure satisfies the claim elements. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (second factor for determining obviousness is ascertaining "differences between the prior art and the claims at issue.") PO and Dr. Elo do not

² PO mischaracterizes Dr. Erickson's testimony as "believ[ing]" that the struts in *Llop* are not "configured and dimensioned to surround at least a portion of the teeth of the patient." Response, 41, 43. Dr. Erickson provides no such opinion, and PO cites to none. Rather, Dr. Erickson opines that a POSA would understand that *Llop*'s struts "form a 'mouthpiece' as that term is commonly understood," and "engage with a patient's teeth." EX1003, ¶¶148, 150.

explain why Yau does not disclose the claimed mouthpiece, except to conclude that “there is little difference” between Yau’s tooth molds and Llop’s struts.

Response, 41; EX2007, ¶78.

B. A POSA Would Have Been Motivated to Combine Llop + Yau

PO’s arguments that a POSA would not have been motivated to combine Llop with Yau fail for similar reasons as described above with respect to the Llop-Sichuan combination. Llop and Yau address the same problem as in the ’209 patent, namely assuring an appropriate location to attach a surgery guide (fixation base) to the bone tissue of the patient. EX1003, ¶¶ 76-77. Because Yau provides known way of addressing that problem, and combining the teachings of Llop and Yau was well within the skill of a POSA to result in a “suitable” solution, a POSA would have been motivated to make the combination. EX1003, ¶216; *Intel*, 61 F.4th at 1381. This is true even if the combination does not result in an improvement to Llop. *Id.* Thus, Dr. Elo’s opinion that Yau’s mouthpiece is “no better” than Llop’s (Response, 43; EX2007, ¶97) is irrelevant. Moreover, PO cites no evidence to refute Dr. Erickson’s opinion that modifying Llop’s struts with the Yau mouthpiece *is* an improvement that “further[s] the objective of Llop126...by ensuring more precise placement of the bone foundation guide.” EX1003, ¶214.

IV. SECONDARY INDICIA DO NOT SUPPORT NONOBVIOUSNESS

PO argues that objective indicia show that the Challenged Claims are not obvious. Response, 49-64. However, to be relevant, “there must be a nexus between the merits of the claimed invention and the objective evidence.” *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed. Cir. 2023). PO has failed to show any such nexus here. PO is not entitled to a presumption of nexus, and PO has not shown that “the evidence is a direct result of the unique characteristics of the claimed invention.” *Id.*

A nexus can be presumed “when the patentee shows that the asserted objective evidence is tied to a specific product and that product embodies the claimed features, and is coextensive with them.” *Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*, 24 F.4th 1406, 1417 (Fed. Cir. 2022) (internal quotations omitted). For coextensiveness, the patentee must demonstrate that “the product is essentially the claimed invention” and that unclaimed features of the product are not significant. *Id.* at 1418.

PO presents, without support, a claim chart mapping a “product known as CHROME GuidedSmile” to the ’209 patent claims to argue coextensiveness. Response, 49-61. In contrast to cases where a presumption was found, however, PO has not “provided ‘ample evidence’ that its commercial products ‘embody the

full scope of the claimed invention, and that the claimed invention is not merely a subcomponent of those products.” *Quanergy*, 24 F.4th at 1418. For example, PO’s expert here has not “provided a detailed analysis” mapping the ’209 patent claims to the descriptions in PO’s product literature. *Id.* This absence of evidence alone suffices to deny PO a presumption of nexus.

PO’s unsupported conclusion of coextensiveness is easily rebutted. First, PO refers to “CHROME GuidedSmile” as if it were a single product. Not true. CHROME GuidedSmile is the label for an entire *family* of products, as confirmed by GuidedSmile’s President, Mr. Alan Banks. EX1046, 13:16-16:3; EX1024; EX1050, ¶17. PO’s evidence of supposed objective indicia is thus not “tied to a specific product.” *Quanergy*, 24 F.4th at 1418.

The GuidedSmile product family includes products and variations that are not covered by the ’209 patent. EX1050, ¶¶18-21. Notably, the GuidedSmile family of products includes multiple types of “pin guides,” only some of which would be considered by PO to be a “mouthpiece” that is “configured and dimensioned to surround at least a portion of the teeth of the patient” under PO’s proposed construction. EX1025, 9; EX1030; EX1050, ¶¶19-20. For example, GuidedSmile can include an “edentulous pin guide,” which is used when a patient has no teeth over which to mount a dentate pin guide. In that instance, the

GuidedSmile edentulous pin guide is used as a copy of the patient's denture which is adapted to be attached to a fixation base, placed in the mouth, and the fixation base is then positioned when the patient bites onto the denture copy with proper occlusion. EX1046, 50:6-11, 52:13-54:22; EX1025; EX1030; EX1050, ¶19. In PO's words used to distinguish prior art, the edentulous pin guide "does *not* utilize a mouthpiece 'configured and dimensioned to surround at least a portion of the teeth of the patient' because there are no teeth to utilize." EX1002, 167. Accordingly, PO cannot now argue (and does not argue) that the edentulous pin guide satisfies the "mouthpiece configured to..." limitation of the '209 patent claims. EX1050, ¶20.

Additionally, PO has made at least one GuidedSmile product that used sequential, rather than stackable, guides. EXS1027-1029; EX1046, 67:6-69:11, 69:17-71:2. In this version, the pin guide is not attached to the fixation base, and therefore is not covered by Challenged Claims. EX1050, ¶ 18. With respect to any of the proffered evidence for secondary considerations, PO makes no attempt to distinguish those particular products of the CHROME GuidedSmile family that may be covered by the '209 patent claims from those products that are not.³

³ The GuidedSMILE product family also includes the "GuidedSMILE Lite" product, which uses a fixation base and drill guide made of traditional plastic,

In addition to its overly broad identification of products, PO fails to acknowledge the presence of “critical unclaimed feature[s] that [are] claimed by a different patent and that materially affects the product’s functionality.” *Quanergy*, 24 F.4th at 1418 (internal quotations omitted). For example, the claims of the ’209 patent’s parent, U.S. Patent No. 11,173,016 and child U.S. Patent No. 11,576,755, contain a limitation that “the fixation base is configured and dimensioned to fit only in front of the maxillary or mandibular bone structure...and itself does not include any portion which would otherwise extend in back of the maxillary or mandibular bone structure” of the patient. EX1048, 9:9-15, 10:13-19, 11:11-16; EX1049, 9:23-28, 10:18-22, 12:3-7. When adding this language in an amendment during prosecution of the ’016 patent, PO described this as a “key difference” over the cited prior art, which disclosed a fixation base that “sandwich[ed] the exposed bone for the remainder of the procedure, all while taking up limited space in an

rather than metal. EX1046, 15:20-16:1; EX1024; EX1026; EX1027; EX1050, ¶21. Petitioner contends that the “fixation base” and “drill guide” as recited in the ’209 patent claims exclude the use of traditional plastic or acrylic. Petition, 13-24. Following PO’s disclaimer of erstwhile claims 11 and 13 of the ’209 patent, the Board declined to “explicitly construe [these] claim terms...for purpose of this [Institution] Decision.” Institution Decision, 13. However, in light of PO’s raising secondary indicia of nonobviousness and Petitioner’s right to rebut PO’s arguments as to nexus, Petitioner respectfully submits that the question of these terms’ scope is again ripe, and requests that the Board now rule on their proper construction as it deems appropriate.

already crowded surgical field. This is not desirable and is an issue that Applicant's invention avoids." EX1014, 65-66. This 'only in front of the bone' limitation is for a critical feature that materially affects the product's functionality and is claimed by other patents, yet is entirely absent from the '209 patent claims, and is unaccounted for in PO's proffered evidence.

The parent '016 patent also contains a claim limitation that "the drill guide is made from a metal or metallic alloy." EX1048, 10:49-50. As noted in the Petition, the use of metal has been a critical point in marketing GuidedSmile's alleged superiority. Petition, 18-19. This fact was confirmed by Mr. Banks, who further acknowledged that it was a reason why the name "CHROME" was chosen. EX1046, 13:12-15, 44:15-17, 59:2-19, 65:3-10, 96:14-97:5. The use of metal for the drill guide and fixation base was also claimed in the '755 patent. EX1049, 10:50-51, 10:66-67. Yet the Challenged Claims of the '209 patent (now) contain no express limitation on the material of the drill guide or fixation base. Again, PO fails to acknowledge this critical feature in its presentation.

Also notably absent from PO's argument is any expert analysis comparing the '209 patent claims to the CHROME GuidedSmile products. Unlike cases such as *Polaris Industries, Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1073 (Fed. Cir. 2018) where the patent owner's expert performed a full and complete analysis of

coextensiveness by examining the patent, commercial products and product literature, here PO's expert Dr. Elo performed no first-hand analysis whatsoever. Instead, he relied entirely on Mr. Banks's description of an unidentified CHROME Guided Smile product, and never inspected a physical product himself. EX1047, 22:2-23:1. The evidence presented above shows that PO's overly general identification includes products not covered by the '209 patent claims, and that PO's GuidedSmile products include critical unclaimed features. They are thus not coextensive, and any presumption of nexus is rebutted.

In addition, there can be no presumption of nexus (and no nexus) because "the proffered objective evidence was 'due to extraneous factors other than the patented invention.'" *Quanergy*, 24 F.4th at 1418. As shown above, there were additional unclaimed features that were essential to PO's products. With respect to specific secondary indicators of supposed nonobvious, PO's evidence again fails to establish a nexus or that one should be presumed.

Regarding a supposed long felt need, PO relies on the testimony of Mr. Banks, who recalled anecdotally that some doctors who created denture prosthetics—not doctors who actually performed dental implant surgery—were looking for "more precision" than what came from "freehand" surgery. EX1046, 18:8-20:1. But PO provides no documentation, and Mr. Banks was not aware of

any, to corroborate his recollection. Nor does PO or Mr. Banks present any evidence supporting his bare assertion that the previous “CombiGuide” was not a success. *Id.*, 18:8–20:1; *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (Fed. Cir. 2004) (“Iron Grip has presented no evidence of a long-felt need for three-grip weight plates or the failure of others. Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.”). Mr. Banks also admits that at least some of the industry’s “initial guided surgical products” that pre-date the ’209 patent were ultimately successful, and are still in use today. EX2006, ¶5; EX1046, 26:5-20 (The nSequence product is “still producing today, you know, years later so I -- -- I think they have a successful product, yeah.”)

PO points to alleged commercial success of its CHROME GuidedSmile family in the form of a single sales chart. Response, 62. However, as discussed above, this chart includes sales of products that are not covered by the ’209 patent claims, such as the GuidedSmile products using an edentulous pin guide and the plastic GuidedSmile Lite. And PO does not provide any sales data for the earlier CombiGuide product for comparison. EX1046, 40:16-22. There is thus no way to discern that any sales increase is attributable to features claimed in the ’209 patent.

Moreover, Mr. Banks's unsupported statement that the "same marketing effort" was used to promote GuidedSMILE as was used in the previous CombiGuide (EX2006, ¶15) is contradicted by the evidence: for the CombiGuide, there was virtually no social media marketing, while for GuidedSMILE there was an abundance of it. PO posted at most three times *total* to Facebook to market CombiGuide, but PO posted over three *dozen* times to Facebook to market GuidedSMILE in 2017 and 2018 alone. EX1031; EX1046, 72:9-73:8. Similarly, PO posted no YouTube videos related to CombiGuide, but published dozens of videos for GuidedSMILE in 2017 and 2018. EX1032; EX1046, 73:9-75:21. As Mr. Banks admits regarding the failed CombiGuide product, PO "hardly did any social media stuff back then. ...Should have been more tech savvy, huh?" EX1046, 40:2-15. Unsurprisingly, on deposition Mr. Banks qualified his statement regarding the "same marketing effort" to "I would say initially." EX1046, 71:9-14.

PO's claims of industry praise for its GuidedSmile product are similarly unsupported. For example, PO and Mr. Banks cite to eleven "awards" that Dentistry Today "gave" for CHROME GuidedSmile. Response, 63; EX2006, ¶17. These so-called "awards" are either paid advertisements or are based on the number of readers who circled a magazine feedback card to request additional information. E.g., EX1033, 2 ("Dentistry Today's 37th Annual Top 100 Products

are selected based on lead generation.”); EX1036, 2 (“Dentistry Today’s Eighth Annual Top Innovative Products are selected based on lead generation.”). PO itself wrote the text that describes the product in the Dentistry Today entries.

EX1046, 82:12-83:3; 89:20-90:2. The “Innovation Spotlight” is not an award to be “won,” but is rather merely a more prominently featured placement of the same PO-written text describing its product. EX1034; EX1046, 87:10-90:15. Mr. Banks did not dispute that Dentistry Today is a free publication provided to dental professionals, and is an advertising tool. *Id.*, 80:2-14.

Lastly, PO’s allegation of copying appears to be based on 3DDX’s alleged inclusion of a patented feature—a “mouthpiece that attached to the fixation base to locate the fixation base.” Response, 63-64; EX2006, ¶18. This comparison of a competitor’s product to the patent claims, however, is not the proper inquiry here. Rather, a copying analysis requires “comparison of the competitor’s product with the allegedly copied patented product.” *Medtronic, Inc. v. Teleflex Innovations S.a.r.l.*, 70 F.4th 1331, 1340 (Fed. Cir. 2023). Mr. Banks admits that there are key differences between the CHROME GuidedSmile and 3DDX products. EX1046, 97:7-99:7 (e.g., 3DDX product does not use a floating fixation base, does not use metal, and uses magnets rather than locking pins). PO has not put forth any “actual

evidence of copying efforts as opposed to mere allegations regarding similarities between the accused product and a patent.” *Medtronic*, 70 F.4th at 1340.

In sum, PO has not established that there is any nexus or that it is entitled to a presumption of nexus, and Petitioner has rebutted PO's arguments with ample evidence. Accordingly, there are no secondary indicia of nonobviousness for the Board to consider.

V. CONCLUSION

Petitioner has shown that the Challenged Claims of the '209 patent are obvious over the prior art. Patent Owner's Response does not refute the Petition's evidence and argument, and the narrow claim construction positions should be rejected. Petitioner respectfully requests the cancellation of the Challenged Claims.

Respectfully Submitted,

Date: July 16, 2025

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

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that this Reply Brief complies with the type-volume limits of 37 C.F.R. § 42.24(c)(1). As calculated by the word count feature of the word-processing system used to prepare this Petition, it contains no more than 5,535 words, excluding the parts of this Petition that are exempted by 37 C.F.R. § 42.24(c).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petitioner's Reply to Patent Owner's Response, including all Exhibits, was served on July 16, 2025, on the following correspondence address of record via email:

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