

Patent No. 12,167,948
Petition for Post-Grant Review

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ASCENTCARE DENTAL PRODUCTS, INC.
Petitioner

v.

SOLMETEX, LLC
Patent Owner

Patent No. 12,167,948
Issue Date: December 17, 2024
Title: DENTAL MOUTHPIECE

Post-Grant Review No. PGR2025-00058

**PETITION FOR POST-GRANT REVIEW OF
U.S. PATENT NO. 12,167,948
UNDER 35 U.S.C. §§ 321-329 AND 37 C.F.R. § 42**

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1004	<i>Curriculum Vitae</i> for Dr. Brian P. Black
1005	U.S. Patent No. 8,911,232 to Nguyen (“Nguyen”)
1006	U.S. Patent No. 9,532,858 (“Hirsch”)
1007	U.S. Patent No. 8,029,280 (“Black”)
1008	Solmetex’s Complaint for Patent Infringement against Ascentcare (ECF No. 1), filed September 16, 2024
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1020	U.S. Patent No. 1,731,322
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LISTING OF CLAIMS

U.S. Patent No. 11,826,948 (Claims 1-11 and 13-23)

Claim Designation	Claim Language
Independent Claim 1 Preamble/ Limitation 1(a)	1. A mouthpiece comprising:
Limitation 1(b)	a main body portion comprising: a first wall that includes one or more edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall; and
Limitation 1(c)	at least one intervening wall that includes a span protruding from the one or more edges of the first wall, wherein the span is defined by a ridged edge that includes a plurality of ridges extending different distances at least partially across the distance between the first wall and the second wall;
Limitation 1(d)	a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and
Limitation 1(e)	a cheek retractor portion connected to a second end of the main body portion.
Claim 2	2. The mouthpiece of claim 1 wherein the main body portion further includes a neck that extends from the second end of the main body portion, the cheek retractor portion being connected to the neck of the main body portion, and wherein a width of the cheek retractor portion is greater than a width of the neck.
Claim 3	3. The mouthpiece of claim 1, wherein the first wall has a shape defined by the one or more edges, and wherein the second wall has a shape corresponding to the shape of the first wall.
Claim 4	4. The mouthpiece of claim 1, wherein the first wall has a shape that is different from a shape of the second wall.
Claim 5	5. The mouthpiece of claim 1, wherein the plurality of ridges includes alternating crests and troughs.

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Claim 6	6. The mouthpiece of claim 5, wherein the alternating crests include at least one flat crest.
Claim 7	7. The mouthpiece of claim 5, wherein the alternating troughs include at least one semi-circular cutout trough.
Claim 8	8. The mouthpiece of claim 1, wherein the main body portion further includes one or more perforations in one or more of the first wall or the second wall, the perforations opening into the interior space.
Claim 9	9. The mouthpiece of claim 8, wherein the perforations are located along a perimeter of one or more of the first wall or the second wall.
Claim 10	10. The mouthpiece of claim 8, wherein the main body portion further includes a neck that extends from the second end of the main body portion, and wherein the perforations are located along one or more sides of the neck.
Claim 11	11. The mouthpiece of claim 1, further comprising a bite block attached to an outside of the suction connector portion at the first end of the main body portion, wherein the bite block does not obstruct the opening into the interior space.
Claim 12	12. The mouthpiece of claim 1, wherein the suction connector portion comprises a cutout in a shape corresponding to a shape of a protrusion of a vacuum adapter, the cutout configured to interlock with the protrusion of the vacuum adapter.
Claim 13	13. The mouthpiece of claim 1, wherein the suction connector portion includes an internal stop configured to assist with sliding an adapter to a predetermined depth.
Claim 14	14. The mouthpiece of claim 1, further comprising at least one connector that connects the first wall to the second wall.
Claim 15	15. The mouthpiece of claim 14, wherein the connector includes a wall that extends within the interior space along a longitudinal axis of the main body portion.
Claim 16	16. The mouthpiece of claim 14, wherein the main body portion further includes a neck that extends from the second end of the main body portion, and wherein the connector extends through the neck at the second end of the main body portion.
Claim 17	17. The mouthpiece of claim 1, wherein the main body portion is formed of a flexible material that allows for the first wall to be pulled away from the second wall.

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Claim 18	18. The mouthpiece of claim 1, wherein the main body portion is formed of a material that includes silicone, and wherein the material is at least translucent.
Claim 19	19. The mouthpiece of claim 1, further comprising a bridge structure that includes one or more protrusions protruding from an interior surface of one of the first wall or the second wall within the interior space.
Independent Claim 20 Preamble/ Limitation 20(a)	20. A mouthpiece comprising:
Limitation 20(b)	a main body portion comprising: a first wall that includes two edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall;
Limitation 20(c)	wherein the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances partially across the distance between the first wall and the second wall,
Limitation 20(d)	the two edges of the first wall being unconnected to the second wall, the plurality of ridges forming an open-meshed configuration between the first and second walls to allow for suction of fluids from a patient's mouth into the interior space between the first and second walls; and
Limitation 20(e)	a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and
Limitation 20(f)	a cheek retractor portion connected to a second end of the main body portion.
Claim 21	21. The mouthpiece of claim 20, wherein the cheek retractor portion is connected to a neck of the main body portion, wherein the neck extends from the second end of the main body portion.
Claim 22	22. The mouthpiece of claim 21, wherein a width of the cheek retractor portion is greater than a width of the neck.

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Independent Claim 20 Preamble/ Limitation 23(a)	20. A mouthpiece comprising:
Limitation 23(b)	a main body portion comprising: a first wall that includes two edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall;
Limitation 23(c)	wherein the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances partially across the distance between the first wall and the second wall,
Limitation 23(d)	the two edges of the first wall being unconnected to the second wall, the plurality of ridges forming an open-meshed configuration between the first and second walls to allow for suction of fluids from a patient's mouth into the interior space between the first and second walls; and
Limitation 23(e)	a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and
Limitation 23(f)	a neck that extends from the second end of the main body portion.
Claim 24	24. The mouthpiece of claim 23, wherein the main body portion further includes a plurality of perforations that open into the interior space, the plurality of perforations being located in the first wall and in the neck.
Claim 25	25. The mouthpiece of claim 23, further comprising a connector wall that connects the first wall to the second wall, the connector wall extending within the interior space along a longitudinal axis of the main body portion.
Claim 26	26. The mouthpiece of claim 25, wherein the connector wall extends through the neck at the second end of the main body portion.
Claim 27	27. The mouthpiece of claim 26, wherein the main body portion is formed of a flexible material that allows for the two edges of the first wall to be pulled away from the second wall.

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Claim 28	28. The mouthpiece of claim 23, wherein the main body portion is formed of a flexible material that allows for the first wall to be pulled away from the second wall.
Claim 29	29. The mouthpiece of claim 28, further comprising a connector wall that connects the first wall to the second wall, the connector wall extending within the interior space along a longitudinal axis of the main body portion.
Claim 30	30. The mouthpiece of claim 29, wherein the connector wall extends along the longitudinal axis along a portion of the main body portion.
Claim 31	31. The mouthpiece of claim 30, wherein the main body portion further includes a plurality of perforations that open into the interior space, the plurality of perforations being located in the first wall and in the neck.

I. **FORMALITIES**

A. **Mandatory notices (37 C.F.R. § 42.8(a)(1))**

1. **Real Party in Interest (37 C.F.R. § 42.8(b)(1))**

Petitioner Ascentcare Dental Products, Inc. (“Ascentcare”) is the real party-in-interest in this petition. Ascentcare is the defendant in the related proceeding identified in Section I.A.4.

2. **Designation of Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))**

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3. **Notice of Service**

Please direct all correspondence to lead counsel at the above address. Petitioner also consents to email service at the above email addresses for lead and back-up counsel.

4. **Related Proceedings**

U.S. Patent No. 12,167,948 is presently asserted in *Solmetex, LLC v. Ascentcare Dental Products, Inc.*, Case No. 1:24-cv-00954 (W.D. Mich). An Amended Complaint asserting for the first time the '948 Patent (EX1008) was served on February 20, 2025 (EX1009)¹. Thus, this Petition is filed within one year after Ascentcare was served with a complaint for infringement. Ascentcare has not filed a separate civil action challenging the validity of the '948 Patent.

Petitioner also filed an *inter partes* review petition on four related patents (U.S. 11,589,969, 11,589,970, 11,744,686, 12,011,329) also asserted in *Solmetex, LLC v. Ascentcare Dental Products, Inc.*, Case No. 1:24-cv-00954. The proceeding numbers are IPR2025-01020, IPR2025-01057, IPR2025-01059, and IPR2025-01104.

B. **Grounds for Standing**

Petitioner hereby certifies the '948 Patent is available for post-grant review, and Petitioner is not barred from requesting a post-grant review challenging the patent claims on the Grounds identified in the petition.

C. **Procedural Statements**

This Petition is filed in accordance with 37 C.F.R. § 42.206(a). A Power of Attorney (37 C.F.R. § 42.10(b) and Exhibit List (37 C.F.R. § 42.63(e)) are filed

¹ The '948 Patent was not asserted in the original complaint; it was first asserted in the Amended Complaint that was served on February 24, 2025.

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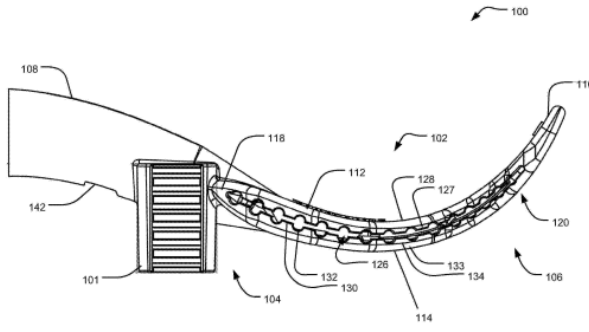
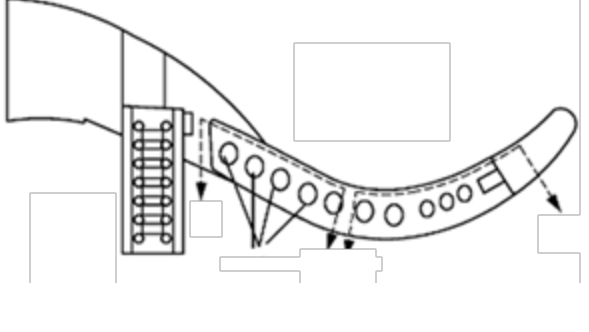
concurrently with this Petition. The fee is being paid via Deposit Acct. No. 50-0223.

The United States Patent and Trademark Office is authorized to charge any fee deficiencies, or credit any overpayment, to Deposit Acct. No. 50-0223.

II. **INTRODUCTION**

Pursuant to 35 U.S.C. §§ 321-329 and 37 C.F.R. § 42, the undersigned, on behalf of and representing Ascentcare, petitions for post-grant review of claims 1-31 of U.S. Patent No. 12,167,948, entitled “Dental Mouthpiece” (“the ‘948 Patent”), issued to Thien Nguyen and assigned to Solmetex, LLC (“Solmetex”). EX1001.

The dental mouthpiece shown and described in the ’948 Patent is nearly identical to that shown and described in an earlier-filed patent application by the same inventor (now U.S. 8,911,232, “Nguyen”). The minor, insignificant difference between these two dental mouthpieces is in the structure of the sidewalls, whereby a completely enclosed sidewall of Nguyen was turned into partial sidewalls (sometimes called “intervening walls” in the claims and herein) in the ’948 Patent. EX1001, FIG. 6; EX1005, FIG. 1D.

'948 Patent	Nguyen
 <p data-bbox="462 646 527 672">FIG. 6</p>	

This modification is suggested in the prior art, which almost universally teaches open-sided, dental isolation mouthpieces that were well-known to offer several advantages, such as increased suction, improved patient comfort, and more convenient cleaning of an autoclavable and reusable mouthpiece. EX1006, FIG. 2; EX1007, FIG. 23C, EX1017², FIG 4, EX1018, FIG. 1, EX1019, FIG. 3. As such, a person having ordinary skill in the art (“PHOSITA”) would have been instantly motivated to modify Nguyen to include open-sided sidewalls.

A petition for post-grant review must demonstrate that “it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a). The Petition meets this threshold.

² Because EX1017 is not being used as a ground herein and Petitioner is only references figures in EX1017, an official translation is not also provided.

III. **STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(A))**

Petitioner respectfully requests a final written decision that claims 1-31 of the '948 Patent are unpatentable in light of 35 U.S.C. § 103. Claims 1, 20, and 23 are independent.

Petitioner requests post-grant review of the '948 Patent based on the following references, all of which were filed, issued, or published prior to the earliest priority date of the '948 Patent, which is May 10, 2019. The prior art relevant to this Petition includes: U.S. Patent No. 8,911,232 to Nguyen ("Nguyen"), filed on December 9, 2013 and issued on December 16, 2014, U.S. Patent No. 9,532,858 to Hirsch ("Hirsch"), filed on May 31, 2016 and issued on January 3, 2017, and U.S. Patent No. 8,029,280 to Black ("Black"), filed on December 26, 2008 and issued on October 4, 2011. Nguyen, Hirsch, and Black are all prior art under 35 U.S.C. § 102(a)(1).

This Petition further relies upon the Declaration of Dr. Brian Black ("Black Decl." (EX1003); Black CV (EX1004)), which is relevant to the skill, knowledge, and expertise of a PHOSITA at the time of the invention and how that person would have understood and applied the prior art. The statutory grounds on which the challenge is based are:

(1) Claims 1-14, 17-24, and 28 are obvious under 35 U.S.C. § 103 in view of Nguyen and Black.

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(2) Claims 15-16, 25-27, and 29-31 are further obvious under 35 U.S.C. § 103 in view of Nguyen, Black, and Hirsch.

(3) Claims 1-3 and 5-31 are obvious under 35 U.S.C. § 103 in view of Nguyen and Hirsch.

(4) Claim 4 is obvious obvious under 35 U.S.C. § 103 in view of Nguyen, Hirsch, and Black.

(5) Claims 20-31 are Invalid for Lack of Written Description under 35 U.S.C. § 112.

(6) Claims 20-31 are Invalid as Indefinite under 35 U.S.C. § 112.

(7) Claim 18 is Invalid as Indefinite under 35 U.S.C. § 112.

IV. **U.S. PATENT NO. 11,826,948 (THE '948 PATENT)(EX1001)**

A. **Specification and Claims**

The '948 Patent describes a dental isolation mouthpiece that attaches to a suction adapter and assists in removing fluids and debris from a patient's oral cavity during dental procedures. EX1001, Abstract. "When positioned within the mouth of a patient, the anterior wall 112 and the posterior wall 114 are capable of blocking an airway of the patient, while the bite block 101 is positioned between the patient's teeth, the suction connector portion 108 extends from one side of the patient's mouth, and the cheek retractor portion 110 presses against the cheek on the opposite side of

the patient's mouth.” EX1001, 4:8-15. The main body portion 102 also acts as a tongue isolator. EX1001, 4:49-54.

The claims of the '948 Patent recite a mouthpiece that has a main body portion 102, a cheek retractor portion 110, and a suction connector portion 108 (with the bite block 101 considered part of the suction connector portion 108). EX1001, claim 1, 2:63-67). The main body includes an anterior wall 112, a posterior wall 114, and intervening walls 127, 134 formed on edges of the anterior and posterior walls. *Id.* The intervening walls are each connected to one of the anterior or posterior wall and extend toward the other of the anterior or exterior wall. Each of the intervening walls includes a plurality of crests and troughs. *Id.*

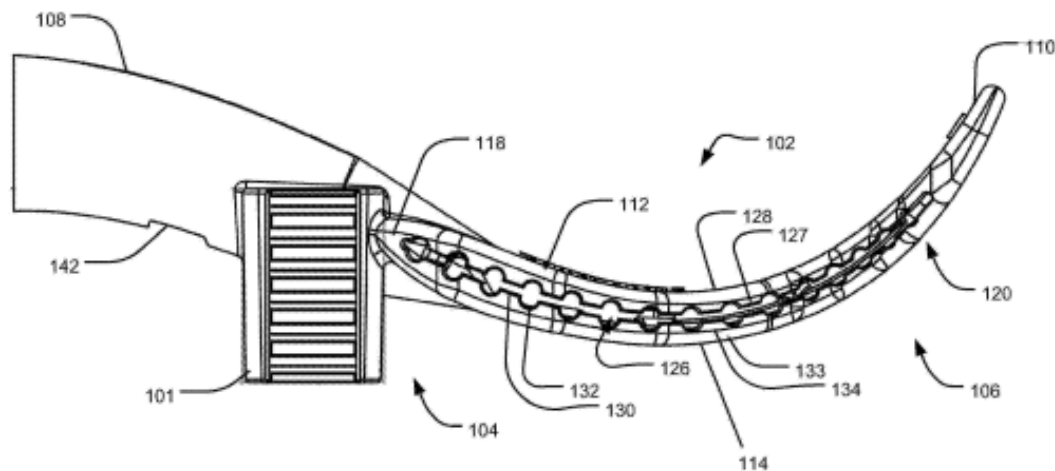
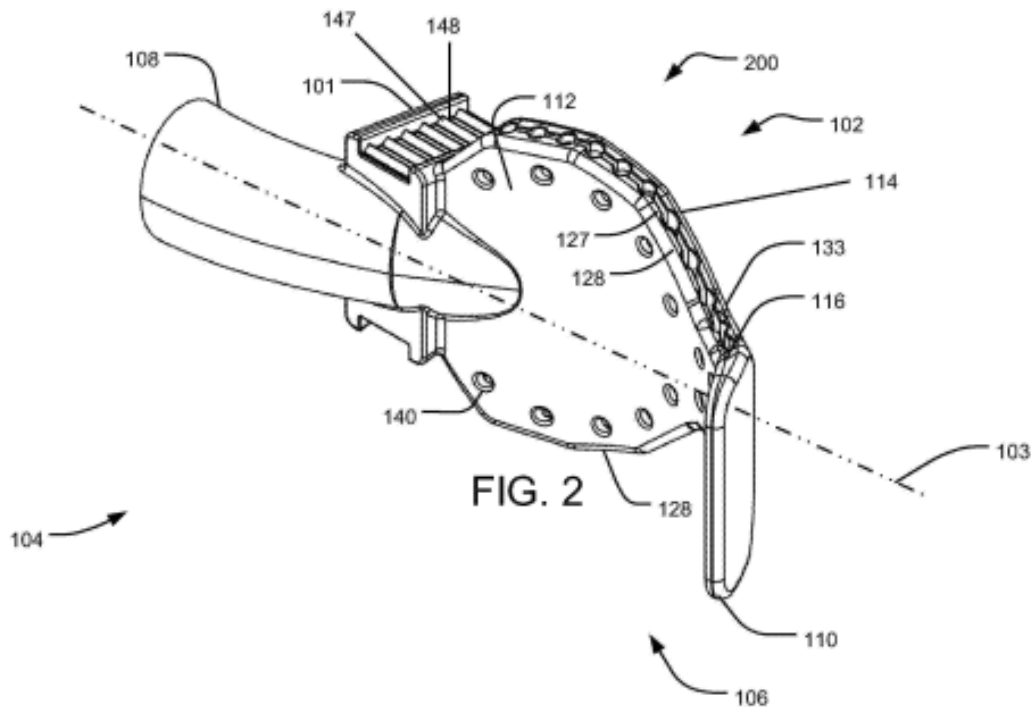


FIG. 6



The '948 Patent describes and claims other features (bridge structure 136, perforations 140, bite block 101) that are all disclosed in the prior art Nguyen patent filed by the same inventor. EX1003, ¶¶ 25-29.

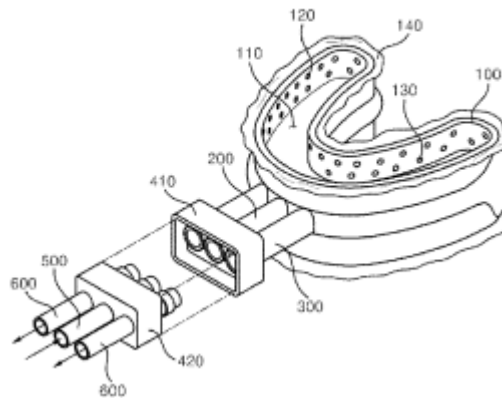
B. Prosecution History of the '948 Patent

U.S. Patent Application No. 18/376,309 was filed on October 3, 2023 claiming priority to U.S. Application No. 16/870,745 (now U.S. Patent No. 11,826,217) and to Provisional Application No. 63/846,353 filed on May 10, 2019. EX1001, (22), (63). The filed application included one independent claim that recited a main body and a suction connector. EX1002, p. 37. The original claims recited that the main body included an anterior wall, a posterior wall, at least one

intervening wall protruding from an edge of the first wall having a “ridged edge that includes a plurality of edges”. *Id.*

On December 3, 2021, the Examiner issued a non-final office action rejecting most of the claims in view of Hyun (U.S. Pub. No. 2017/0056143). EX1002, pp. 295-304.

[Figure 1]



The Examiner pointed to the sealing member 140 depicted above as the intervening wall. EX1002, p. 296. The Examiner cited Nguyen as a secondary reference against some dependent claims reciting subject matter such as the cutout and the use of flexible materials. EX1002, pp. 305-306. The Examiner also indicated that some claims were allowable, including claim 2 which was directed to a cheek retractor. *Id.* Applicant accepted the allowable subject matter and included claim 2 and introduced new independent claims. EX1015, pp. 15-20. The Examiner allowed the claims after this amendment. EX1015, p. 81; EX1003, ¶¶ 30-31.

V. **A PERSON HAVING ORDINARY SKILL IN THE ART**

The prior art and the Black Declaration demonstrate that a PHOSITA, at the time the '948 Patent was filed, would have been a person with at least a B.S. degree in mechanical engineering or a related field with at least two-years' experience designing dental devices or suction devices. Less work experience may be compensated by a higher level of education, such as a master's degree, and vice versa. EX1003, ¶¶ 1-24 and 32-41.

VI. **CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(B)(3)**

Unless otherwise addressed herein, the terms of the '948 Patent's claims are to be given their plain and ordinary meaning as understood by one of ordinary skill in the art in view of the '948 Patent's specification. *See* 37 C.F.R. § 42.200(b); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). EX1003, ¶¶ 42-43, 46. Additionally, Petitioner applies Patent Owner's implied construction for all terms in view of their assertions that Petitioner's very different product infringes the '948 Patent. For example, Patent Owner appears to assert that the same structure in Petitioner's device is both a bridge structure and an intervening wall. As such, Petitioner applies herein Patent Owner's broad construction of "intervening wall" for the purposes of demonstrating that Patent Owner's construction results in invalidity.

- A. **“partially across the distance between the first wall and the second wall”**

All of Patent Owner's independent claims specify that one intervening wall (claim 1) or ridges (claims 20 and 23) extend "partially across the distance" between the first wall and the second wall. The specification consistently uses this term to mean only partly, and not entirely. EX1001, 6:20-48, FIGs. 2, 6. Importantly, no figure or description in the '948 Patent describes or suggests an intervening wall that spans *entirely* across the distance of the interior space. Rather, the figures and description of the '948 Patent only describe two intervening walls respectively connected to *either* the anterior wall *or* the posterior wall. *Id.* Importantly, the '948 Patent describes how the two walls work together to form a "mesh", which is apparently an important feature for suction according to the '948 Patent. EX1001, 6:53-64.

The '948 Patent also uses the word "partially" in other contexts to mean only partly, and not entirely. For example, the '948 Patent explains that the bridge structure 136 partially blocks an opening between the main body 102 and the suction connector 108. EX1001, 8:31-39. Entirely blocking the suction opening would render the device inoperable for its intended purpose, which is to remove fluid and debris from the oral cavity. EX1001, 8:28-39. Put simply: the '948 Patent consistently uses the word partially according to its plain and ordinary meaning, which is only partly, not entirely.

Finally, in arguments to differentiate the prior art, Patent Owner explained to the Examiner what extending “partially across the distance of the interior space” means using Figures from the patent application. EX1011, pp. 1-2. The Examiner understood this explanation and found that Nguyen, which teaches a sidewall connected to *both* the anterior and posterior walls (*i.e.*, spanning the *entire* distance across the interior space), did not teach the claims reciting only partial extension. EX1011, pp. 3-4.

In view of the consistent use and description in the specification, as well as Patent Owner’s numerous statements about this claim term in the prosecution history, the plain and ordinary meaning of “partially across the distance of the interior space” means “only partly, and not entirely, across the distance of the interior space.” EX1003, ¶¶ 44-45.

To the extent Patent Owner argues that its claim language means “at least partially, and including entirely,” Ground 3 discussed below shows this construction.

VII. BACKGROUND OF DENTAL MOUTHPIECES AND THE PRIOR ART RELIED UPON IN THIS PETITION

A. **Dental Isolation Mouthpieces**

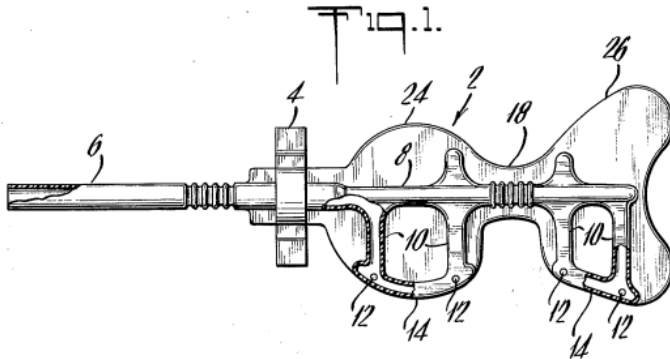
Dentists have known to isolate tissue and use suction during dental procedures for many years. EX1013, Abstract, FIGS. 1-2; EX1020; EX1003, ¶ 3, 10-11, 37.

A dental appliance integrating a suction tube, a bite block, a tongue suppressor, and a cheek retractor has been known for a very long time. EX1013,

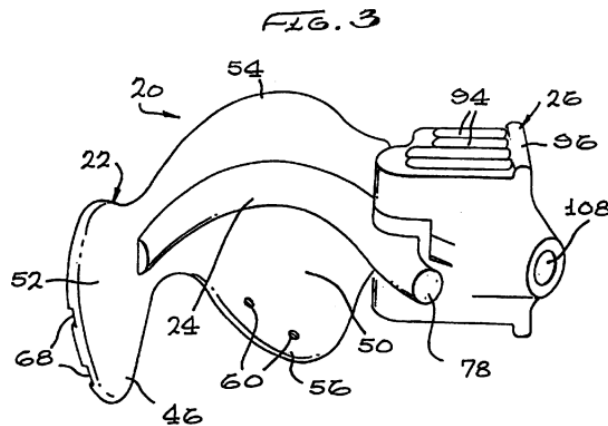
Patent No. 12,167,948

Petition for Post-Grant Review

Abstract, 2:6-23. Even the generally hour-glass shape has been known since at least 1977, as shown below.



The modern style dental isolation mouthpiece appears to have started with James Hirsch in 2001 (EX1021). Hirsch taught a suction connector, a bite block for engaging teeth on one side of the mouth, a wide main body that fits into the intraoral cavity for tongue isolation, a narrow neck for wrapping around teeth on the other side of the mouth, and a cheek retractor. EX1021, Abstract.



The dental isolation mouthpiece shown and described in the '948 Patent (and many like it) follows this same general style and structure. EX1003, ¶ 26.

Hirsch improved on his design in 2003. EX1014, FIG. 19A; EX1001, FIG. 1.

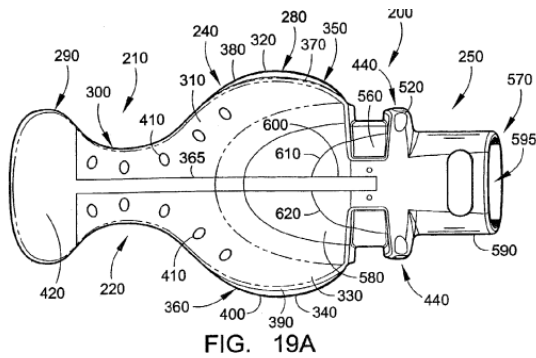
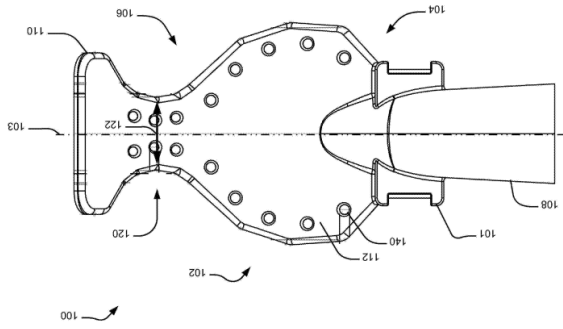


FIG. 19A

Hirsch



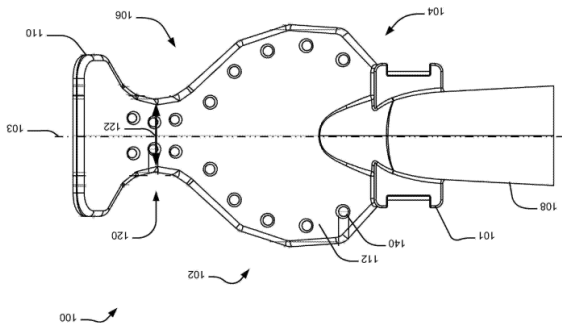
'948 Patent

This basic shape, which is very similar to the shape debuted in 1977, has prevailed since Hirsch's disclosure, and the dental isolation mouthpiece shown and described in the '948 Patent follows this same shape and concept.

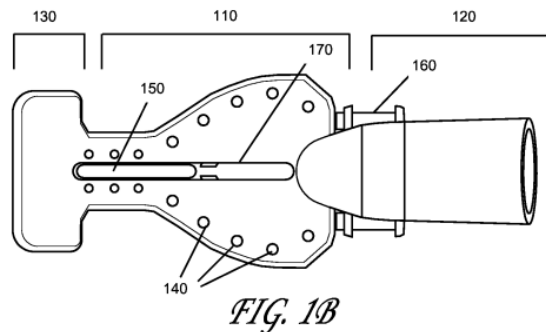
B. Prior Art Patents and Printed Publications Relied Upon

1. Nguyen

Nguyen teaches a nearly identical dental isolation mouthpiece invented by two of the four inventors of the '948 Patent. EX1005 (72); EX1001, (72).



'948 Patent



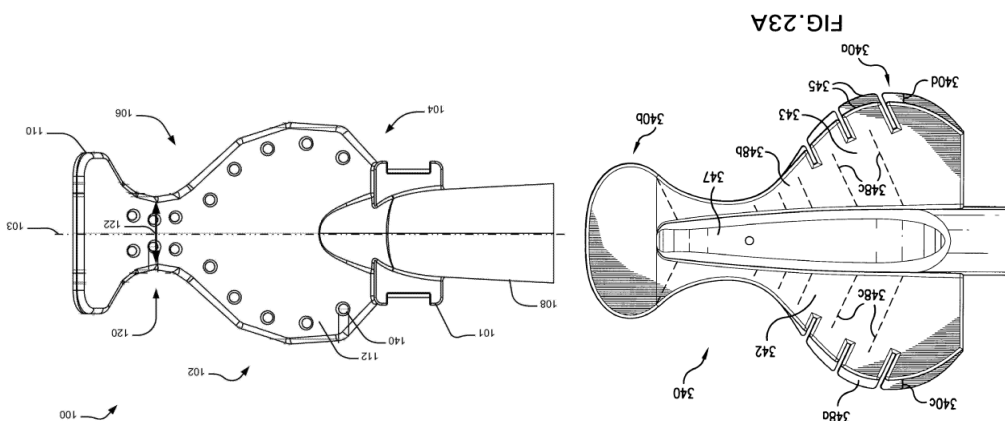
Nguyen

Like the '948 Patent, Nguyen teaches a dental isolation mouthpiece with a suction connector, a main body, and a cheek retractor. EX1005, 3:15-17. The main body of Nguyen includes an anterior wall, a posterior wall having the same shape and size as the anterior wall, and superior and inferior sidewalls that each connect to the anterior and posterior walls at the edges of the anterior and posterior walls. EX1005, 3:36-4:3, FIGs 1A-1E; EX1003, ¶ 47.

Nguyen further discloses a bridge structure formed in the center of the main body portion that ensures that the anterior and posterior wall remain separated under suction. EX1005, 4:38-56. Nguyen also discloses a bite block that is formed around the suction connector. EX1005, 5:9-22; EX1003, ¶ 48. The shape of the dental isolation mouthpiece shown and described in Nguyen is nearly identical to the shape of most dental isolation mouthpieces that predated it. *See e.g.*, EX1007.

2. Black

Black teaches a dental isolation mouthpiece having the same basic shape as that shown and described in the '948 Patent. EX1001, FIG. 1; EX1007, FIG. 23A.



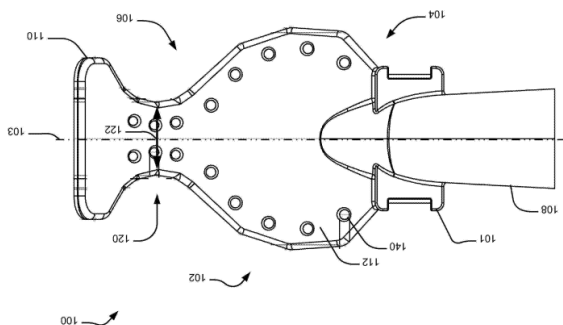
'948 Patent

Black

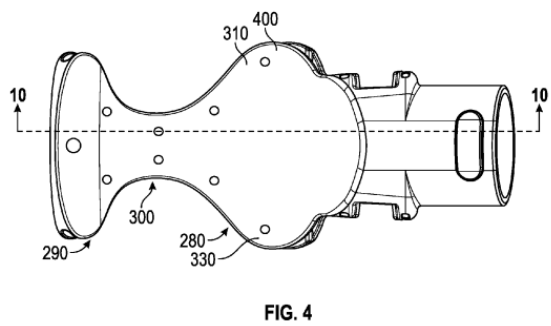
Black discloses a mouthpiece with open sides (and a wall formed near the suction connection tube). EX1007, 5:60-6:9, 14:34-15:20; EX1003, ¶ 49. Black explains that open sidewalls provide certain advantages, such as improved suction and greater flexibility for patient comfort. *Id.*

3. Hirsch

Hirsch teaches a dental isolation mouthpiece that is also of a similar shape to that shown and described in the '948 Patent and Black. EX1001, FIG. 1; EX1007, FIG. 18; EX1006, FIG. 4.



'948 Patent



Hirsch

Hirsch also discloses a mouthpiece with open sides and a spine 365 running longitudinally through the middle of the mouthpiece. EX1006, 3:17-29, FIGS. 6-14; EX1003, ¶ 50. Hirsch explains that grooves formed in walls of a dental mouthpiece wall can assist with suction. EX1006, 4:4-16, 5:2-8.

VIII. **DISCRETION UNDER § 325(D) AND § 314**

Pursuant to the guidance included in the “FAQs for Interim Processes for PTAB Workload Management”, Petitioner omits any preemptive arguments against discretionary denial. Petitioner will present arguments in an Opposition Brief, should Patent Owner file a Discretionary Denial Brief.

IX. **GROUND FOR UNPATENTABILITY**

Petitioner requests cancellation of the challenged claims on the following Grounds. EX1003, ¶¶ 51-58, 63, 129, 139, 200, 202, 211, 229.

A. **Ground 1: Claims 1-14, 17-24, and 28 are obvious under 35 U.S.C. § 103 as being unpatentable over Nguyen in view of Black**

1. **Independent Claim 1**

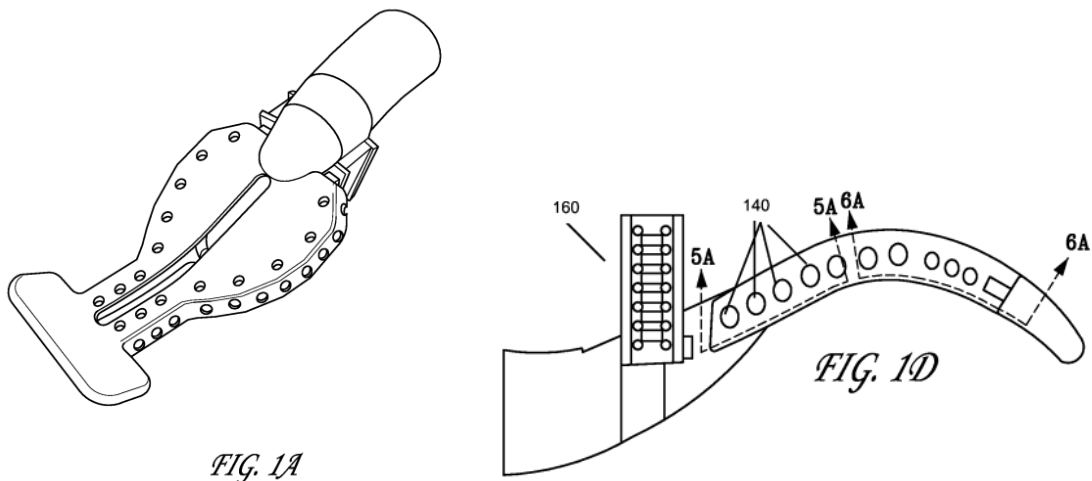
a. **Limitation 1(a)³**

Because the claim body fully sets forth the complete claimed structure, and the preamble merely describes an intended use as a dental mouthpiece, the preamble does not instill patentable weight. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *see also Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997); MPEP 2111.02(II); EX1003, ¶ 64.

³ Because Petitioner included the full claim language of the '948 Patent in the Listing of Claims, Petitioner does not reproduce the full claim language here. The Board is encouraged to reference the Listing of Claims to see the full claim language, if necessary.

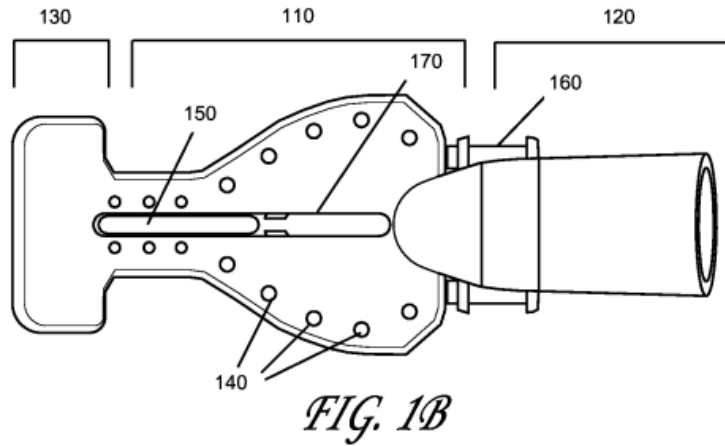
To the extent the preamble is limiting, Nguyen discloses a mouthpiece.

EX1005, Abstract, 6:2-3, FIG. 1A, 1D; EX1003, ¶ 65.



b. **Limitation 1(b)**

Nguyen discloses a main body portion 110 with a first end connected to a suction connector portion 120 and a second end connected to a cheek retractor 130. EX1005, FIG. 1B; 3:20-22. Nguyen discloses an anterior wall and a posterior wall spaced apart at a distance between the two walls. EX1005, 3:36-54, 4:6-11, 1:58-60, FIGs. 1D-1E. Nguyen discloses a pocket that is enclosed by an anterior wall, a posterior wall, and sidewalls. EX1005, 1:58-60, 3:36-54; EX1003, ¶¶ 66-69.



c. **Limitation 1(c)**

Nguyen teaches two sidewalls (inferior and superior) each connected to both the anterior and posterior walls. EX1005, 3:36-54.

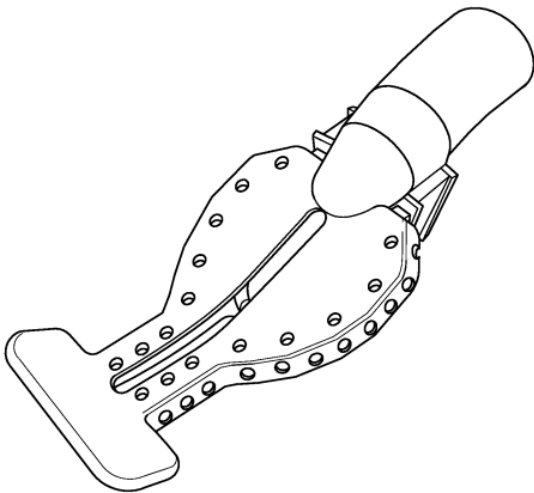


FIG. 1A

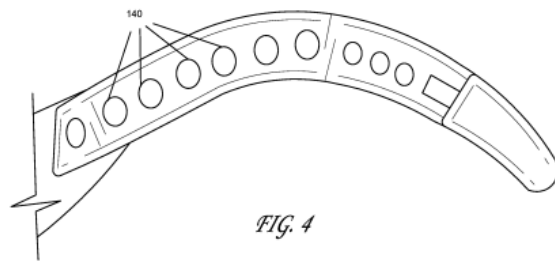


FIG. 4

Because each sidewall is connected to both the anterior wall and the posterior wall, each sidewall protrudes from the anterior wall along an edge of the anterior wall and

each also sidewall protrudes from the posterior wall along an edge of the posterior wall. *Id.*, see also, EX1005, FIG. 1A, 3:63-4:3; EX1003, ¶¶ 70-71.

To the extent Nguyen teaches that the superior and inferior walls span the entire (not “partial”) distance between the anterior and posterior walls, it would have been obvious to open the sidewalls of Nguyen in view of Black, thereby creating two intervening walls that each partially extend across the distance between the anterior and posterior walls. EX1005, 3:63-4:3, 3:40-49; EX1003, ¶ 72.

Black teaches an “open” tongue shield aspirator. EX1007, 17:47-54, 6:10-20 (all or only a portion of the sides may be open); EX1003, ¶ 73.

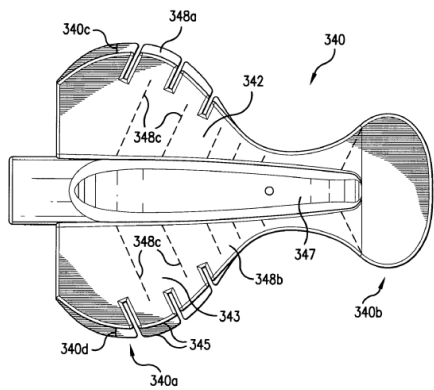


FIG. 23A

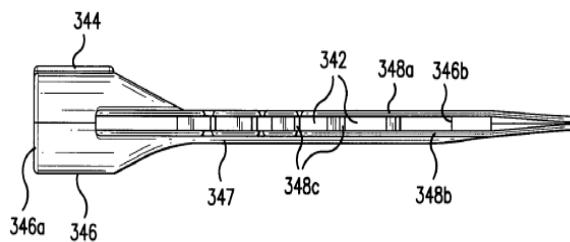


FIG. 23C

Black explains that an open-sided tongue shield aspirator, which is a dental isolation mouthpiece, facilitates enhanced fluid and debris aspiration as well as easier bending for fitting into the patient’s mouth. EX1007, 17:47-54. Because an open-sided mouthpiece increases suction, a PHOSITA would have been motivated to open the sidewalls of Nguyen to achieve these advantages. *Id.*; EX1003, ¶ 73. A PHOSITA would have also been motivated to open the sidewalls of Nguyen in order to make it

easier to clean. EX1003, ¶ 73. To this end, opening the sidewall of Nguyen would use a known technique (open sidewall on a dental isolation mouthpiece) to improve similar, known mouthpieces (the similar dental isolation mouthpiece of Nguyen) in the same way (Nguyen's mouthpiece would exhibit increased suction and easier cleaning). *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-421 (2007); EX1003, ¶ 73. Alternatively, opening the sidewalls of Nguyen would apply a known technique (opening the sidewalls of a dental isolation mouthpiece) to a known device ready for improvement (Nguyen's mouthpiece having certain downsides, discussed below) to yield predictable results (an open-sided mouthpiece with improved suction due to less suction channel narrowing and easier cleaning). *Id.*

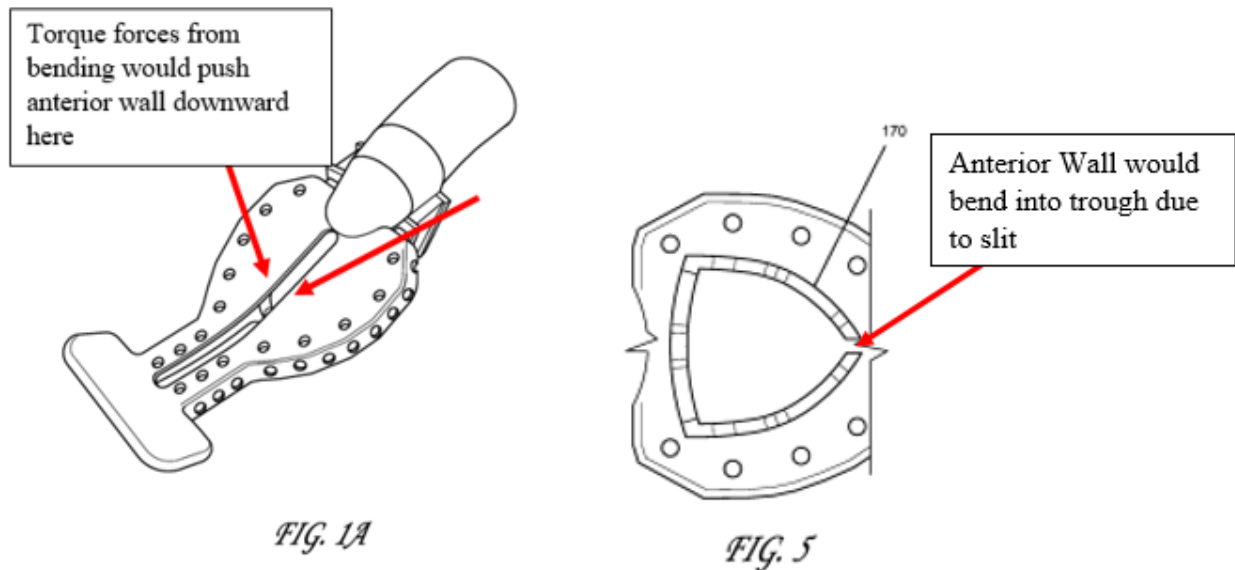
More specifically, regarding improved suction, a PHOSITA would know that, because the anterior and posterior walls comprise a flexible material, the dental mouthpiece of Nguyen would bend within the mouth due to the roof of the mouth pressing down on the superior sidewall and the floor of the mouth pressing up on the inferior sidewall. EX1005, 3:29-31, 3:42-45; EX1007, 19:33-20:47; EX1003, ¶¶ 74-75. Similarly, PHOSITA would expect that the force from the ridges of a patient's gums on the rectangular portion of Nguyen would also cause additional bending/folding. EX1005, 4:20-30, 1:52-55, 2:2-5; EX1007, 20:3-20; EX1003, ¶ 75.

A PHOSITA would understand that when two parallel walls are connected at their edges and spaced apart, any bending force from mouth tissue would force the

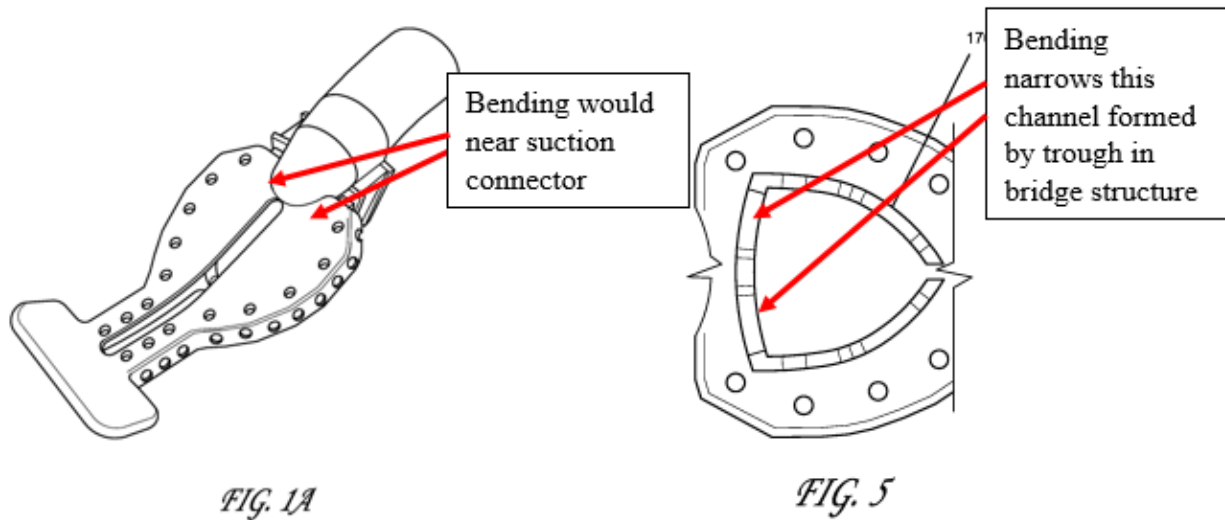
two walls to bend along different paths. The “outer” (posterior) wall would bend at a different radius than the “inner” anterior sheet. EX1003, ¶ 76; EX1007, 20:3-20. However, the anterior wall and the posterior wall cannot bend at the same radius – the geometry does not allow it. *Id.* Since the anterior and posterior wall are connected by sidewalls, one wall cannot slide or change its relative spacing, so the anterior (inner) wall will buckle from the forces acted on it from the sidewalls. *Id.* This is the basic geometric constraint of bending layered materials. *Id.* A PHOSITA would understand that the folding force caused by mouth tissue on the posterior wall would transfer through the sidewall and provide extra torque on the anterior wall in addition to the mouth tissue force, thereby causing the anterior wall to fold more than the posterior wall due to the geometric constraint of bending layered materials. EX1005, 3:36-54; EX1003, ¶ 76. Under these conditions, a PHOSITA would know that the anterior wall would crease at certain points toward the posterior wall, narrowing or partially blocking important suction channels. *Id.*

Indeed, a PHOSITA would recognize that the anterior wall would first start to bend or crease at the slit 170, as it is the weakest part of the anterior wall. EX1005, FIG. 1A, 4:31-37; EX1003, ¶ 77. This creasing would partially block one of the channels (troughs) created by the bridge structure 180 and decrease suction at the rectangular portion of the mouthpiece – an important suction location, as this is

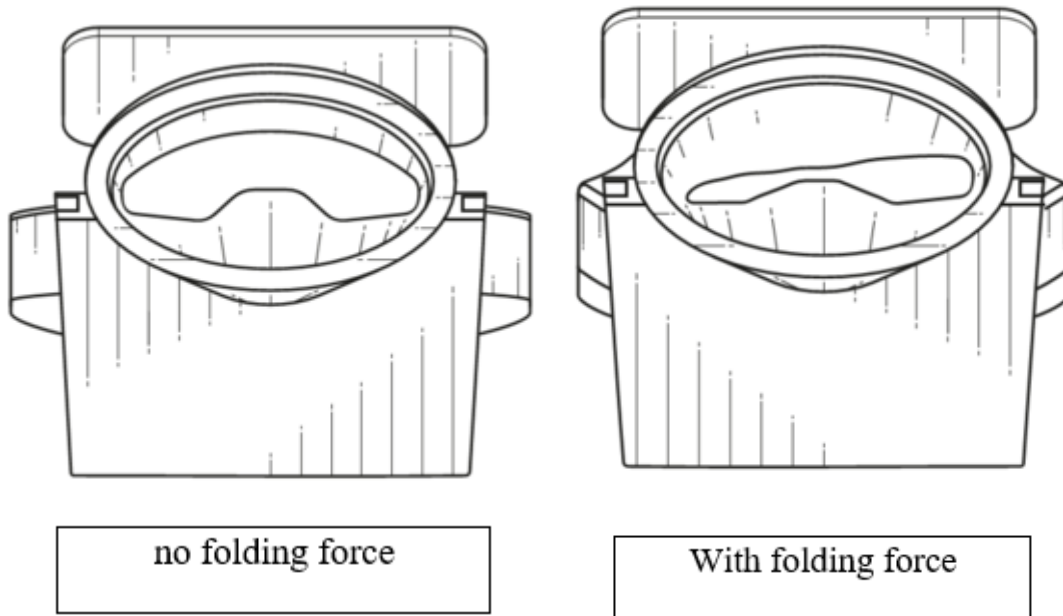
where the dental operation occurs. EX1005, 2:10-16, 4:38-56; *see also* EX1013, 2:6-41, FIG. 2; EX1003, ¶ 77.



In addition, a PHOSITA would recognize that the bending force would further cause bending at the anterior wall where the anterior wall meets the suction connector. EX1003, ¶ 78. Indeed, Nguyen teaches that the suction connector comprises a thicker material than the anterior wall, meaning the thinner, weaker anterior wall would bend short of the suction connector. EX1005, 4:57-63; EX1003, ¶ 78.



As shown above, the anterior wall would bend into a trough in the bridge structure 180 near the suction connector, thereby partially blocking one or both of the suction inlet locations at the suction connector. EX1003, ¶ 78.



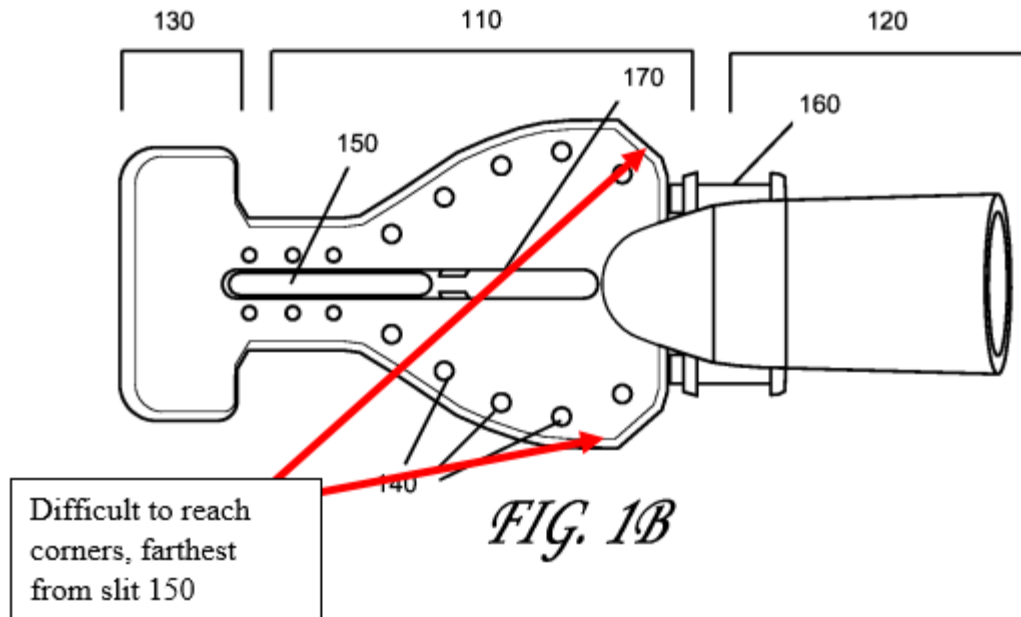
With that understanding, a PHOSITA would further understand that an unconnected edge would allow the anterior and posterior walls to bend at different

radiuses. EX1003, ¶ 79. This is because the anterior wall would not receive the posterior wall's folding force through the sidewalls (i.e., the torque) as well as any folding force it also received from mouth tissue. *Id.* Instead, with open-sides, the anterior wall would bend independent of the posterior wall, and the anterior wall would not block any suction channels (i.e. "troughs"). *Id.*

A PHOSITA would also recognize that opening the sidewalls would increase suction through the sides of the mouthpiece. EX1003, ¶ 80. Nguyen can only apply suction through the small holes 140 formed on the sidewalls. It cannot aspirate fluid, debris, etc. between the holes 140. EX1005, 3:63-4:3. Opening the sides would allow suction to occur in more places along the sides of the mouthpiece. EX1007, 17:47-54, EX1003, ¶ 80. It would also allow for the suction, and removal, of larger debris. *Id.*

A PHOSITA would have also been motivated to open the sides of Nguyen to make it easier to clean and reuse the dental mouthpiece. Nguyen teaches that the mouthpiece is autoclavable and reusable. EX1005, 3:8-10. In order to reuse a dental mouthpiece, it must be cleaned between uses and between patients. EX1005, 4:34-37; EX1003, ¶ 81. Nguyen explains that cleaning occurs through the slit 170. EX1005, 4:34-37. A PHOSITA would have known that the pocket design of Nguyen, with the slit 170, would not be conducive to easy cleaning. EX1003, ¶ 81. For example, a PHOSITA would have known that it would be difficult or awkward

for a hygienist or other dental staff to insert a cleaning brush into the slits 170 and clean the corners of Nguyen. *Id.*



A PHOSITA would have known that a dental mouthpiece with open sides, such as Black, would have been far easier to clean because a brush would remove gunk and bacteria unimpeded by any wall or material connecting the anterior and posterior walls. EX1003, ¶ 81. Indeed, an open-sided mouthpiece would simply require fitting a brush in between the anterior and posterior walls through the side openings, as opposed to folding back the anterior wall of Nguyen at the slit 170, inserting a brush through the slit 170, and attempting to reach the brush into all small corners formed on the mouthpiece of Nguyen. EX1005, 4:34-37, FIG. 1B; EX1003, ¶ 81. An open-sided mouthpiece would not have any difficult to reach corners. EX1003, ¶ 81. Most

prior art isolation mouthpieces implemented open sides. EX1006, FIG. 2; EX1007, FIG. 23C, EX1017, FIG 4, EX1018, FIG. 1, EX1019, FIG. 3.

Thus, for all these reasons, a PHOSITA would have been motivated to open the sides of Nguyen in view of Black. EX1003, ¶¶ 72-81.

However, a PHOSITA would have been motivated to form open-sided, anti-collapse structure at the edges of Nguyen after opening the sides in view of Black. EX1003, ¶ 82. Black teaches transverse walls 348c that extend outwardly all the way to the edge of the anterior flap 348b (see dotted lines in EX1007, FIG. 23A) to act as an anti-collapse structure at the edges. EX1007, 14:21-47, FIG. 23A; EX1003, ¶¶ 82-83. Thus, Black teaches anti-collapse structure formed at the edges of the mouthpiece of Black.

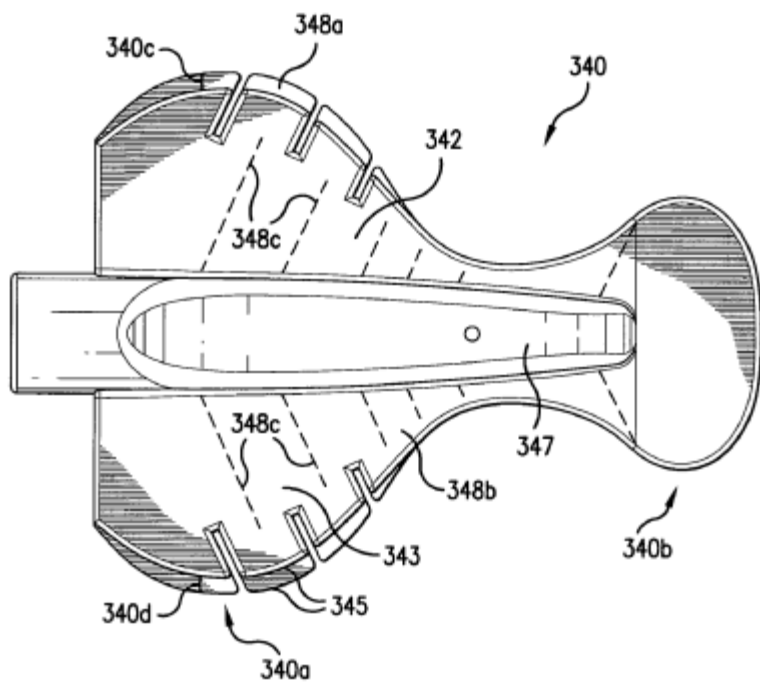
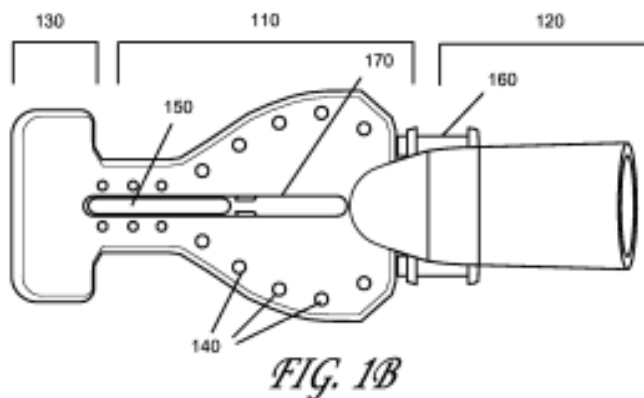


FIG. 23A

Nguyen prevents collapse under suction using a combination of sidewalls and the bridge structure 180. EX1005, 2:10-16, 4:38-56; EX1003, ¶ 83. A PHOSITA would know that removing the sidewalls in Nguyen would cause the anterior wall and posterior wall to collapse under suction at the edges of the mouthpiece near the perforations 140, which are critical to fluid removal. EX1005, 3:63-67; EX1003, ¶ 83, *see also* EX1006, 4:43-67, 4:4-6, 5:2-4. The edges of the mouthpiece would be far enough from the bridge structure 180 to not receive the benefit of the bridge structure's anti-collapse function. EX1005, FIG. 1B; EX1003, ¶ 83-84. Thus, a PHOSITA would understand that Nguyen would require some anti-collapse structure at the edges of the main body portion 110, where the perforations 140 are formed. *Id.*



Nguyen recognized the importance of anti-collapse structure and offered a suction-friendly, anti-collapse structure in the form of “crests” and “troughs” formed as a bridge structure 180. EX1005, 4:44-54. Thus, after being motivated to open the sidewalls it would have been obvious to a PHOSITA to include a second bridge

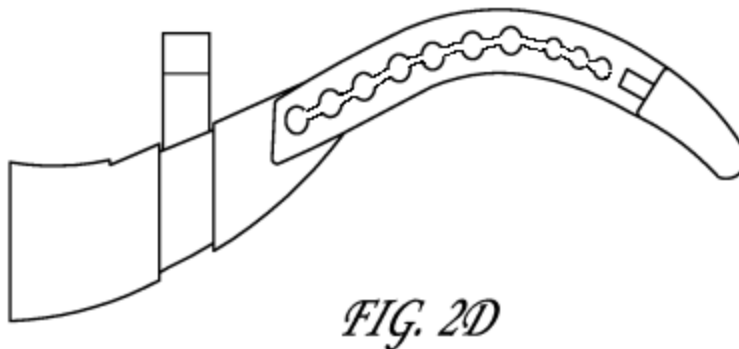
structure formed at the edges of the mouthpiece, where the mouthpiece is most likely to collapse after opening because a second bridge structure would simply be a duplication of parts. EX1003, ¶ 85; MPEP 2144.04(VI)(B). An intervening wall with “a ridged edge that includes a plurality of ridges extending different distances” is described using similar language that Nguyen used to describe the bridge structure. EX1001, 6:33-38; EX1005, 2:10-16.

Alternatively, a PHOSITA would instantly recognize that open sidewalls would be created by simply cutting open the sidewalls. EX1003, ¶ 86; MPEP 2144.04(V)(C). Cutting open the sidewalls would also create anti-collapse structure at the edges of the mouthpiece. EX1003, ¶ 86. By cutting the sidewalls of Nguyen, the sidewalls would become open *and* anti-collapse structure at the edges would remain. A PHOSITA would not even need to create a new mold to arrive at the claims of the '948 Patent. A PHOSITA need only take the existing dental mouthpiece mold of Nguyen and cut the sidewalls. *Id.*

A PHOSITA starting with Nguyen would have been motivated to open the sidewall of Nguyen in view of Black by simply cutting the material formed between the sidewall perforations 140. EX1003, ¶ 87. A PHOSITA would choose this cutting location because it is the least amount of material to cut. *Id.* Additionally, a PHOSITA would choose the middle of the sidewall for cutting because that point

provides the most leeway where there is the least chance that the cut accidentally damages the anterior or posterior wall, thereby creating a defective mouthpiece. *Id.*

Cutting at the midsection of the Nguyen sidewalls would result in suction inlets formed by cutting the circular perforations in half. EX1003, ¶ 88. Indeed, a PHOSITA would have known that U-shaped grooves can form fluid inlets. EX1006, 4:4-16, 4:67-5:8, 3:55-58. By simply cutting Nguyen along the middle of the sidewalls, the result would be two intervening walls, each protruding partially across the distance between the anterior and posterior walls. See annotated EX1005, FIG. 2D below; EX1003, ¶ 88.

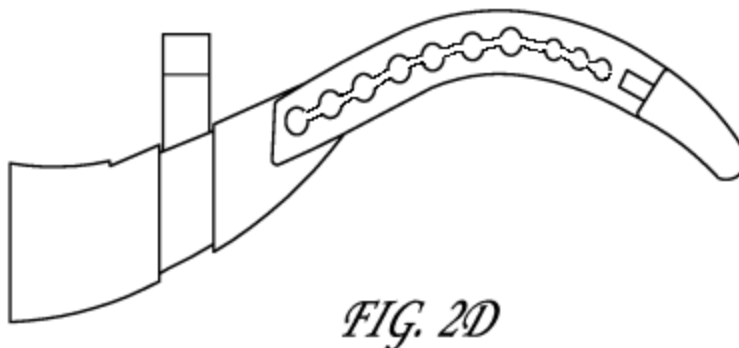


A PHOSITA would have expected success in cutting the sidewalls of Nguyen because cutting the sidewalls would be the easiest way to accomplish all the goals stated above (easier cleaning, increased suction). EX1003, ¶ 89. The simple, additional step of cutting between the perforations 140 on Nguyen in view of Black's teachings would be the simplest way to create an open-sided mouthpiece without a complete redesign (such as by adding a spine, changing the structure of the suction

connector in view of an added spine, etc.). *Id.* A PHOSITA would not even need to change the injection molding casts from Nguyen; a PHOSITA would only need to perform an additional cutting step to accomplish all of the stated goals. *Id.* The simplicity by which a PHOSITA would arrive at the claims of the '948 Patent from Nguyen demonstrates that a PHOSITA would have a reasonable expectation of success. *Id.*

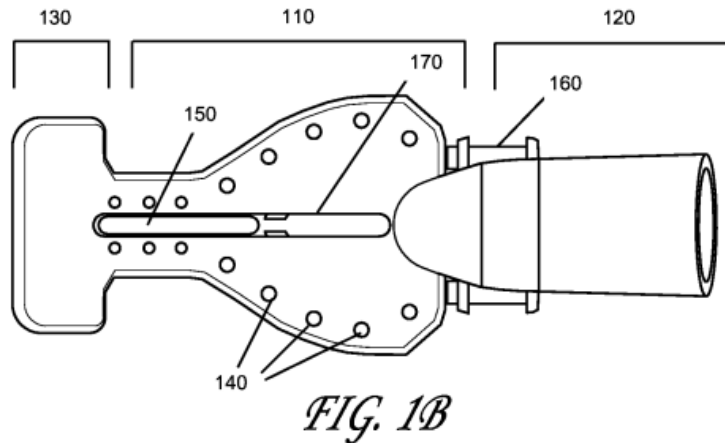
So, for all the reasons discussed above, a PHOSITA would have been motivated to modify the mouthpiece of Nguyen to cut open the fully connected sidewalls of Nguyen. EX1003, ¶¶ 86-91.

As shown below in annotated FIG. 2D, Nguyen modified by Black results in two intervening walls extending partially across the distance between the anterior wall and the posterior wall. The simple cut across the middle of the original sidewall forms two intervening walls, each with a ridged edge having a plurality of ridges extending different distances at least across the distance between the anterior and posterior walls. EX1005, FIG. 2D (annotated); EX1003, ¶ 88.



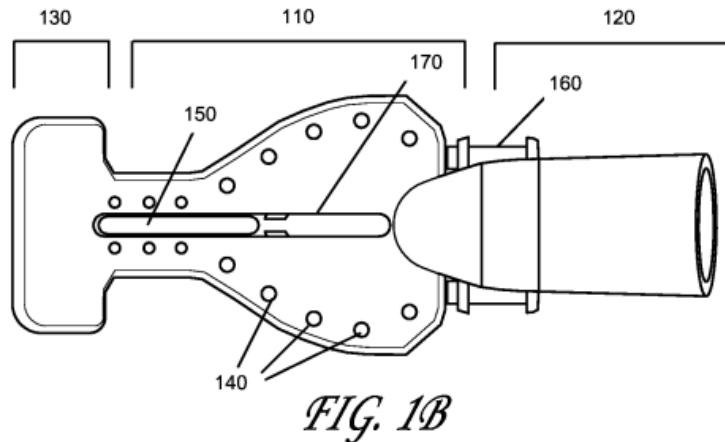
d. **Limitation 1(d)**

Nguyen teaches a suction connector portion 120 connected to the first end of the main body portion 110 configured to connect the interior space to a vacuum source. EX1005, 3:20-22, 4:57-63, 6:24-28; EX1003, ¶ 92.



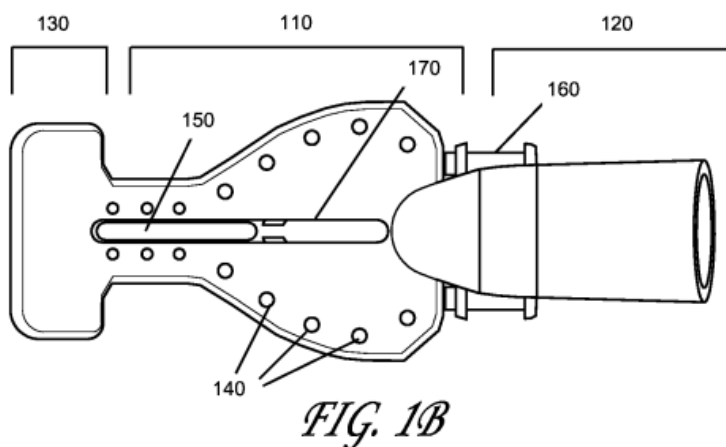
e. **Limitation 1(e)**

Nguyen teaches a cheek retractor 130 formed on a second end of the main body portion 110. EX1005, 3:20-22; EX1003, ¶ 93.



2. **Claim 2**

Nguyen teaches a rectangular portion, acting as a neck, extending from the main body portion 110 and connected to the cheek retractor portion 130. EX1005, 4:4-11. As shown in FIG. 1B, for example, the rectangular portion is narrower than the cheek retractor 130. EX1003, ¶ 94.



3. **Claim 3**

Nguyen teaches that the anterior wall and the posterior wall are identical in shape and each defined by inferior and superior edges. EX1005, 3:36-54, 3:67-4:1, FIG. 1A-1E; EX1003, ¶¶ 95.

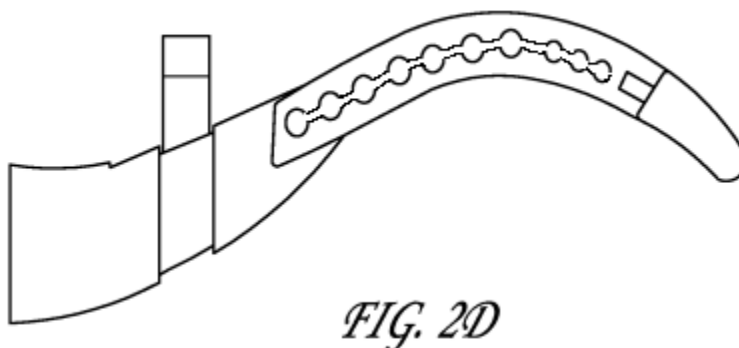
4. **Claim 4**

Nguyen teaches that the anterior wall and the posterior wall are identical in shape and each defined by inferior and superior edges. EX1005, 3:36-54, 3:67-4:1; EX1003, ¶¶ 96-97. However, after opening the sides in view of Black, it would have been obvious to change the shape of the anterior or posterior wall. In fact, Black

teaches an embodiment where the anterior wall is different in size and shape from the posterior wall. EX1007, FIG. 25A, 17:32-38. Black explains that, by changing the shape of the anterior layer to include indentations, enhanced fluid and debris aspiration from the patient's cavity may occur. EX1007, 17:66-18:7. Thus, a PHOSITA would have been motivated to change the shape of the anterior layer in view of Black to increase debris and fluid aspiration. *Id.* Moreover, a change in anterior wall shape is an obvious change in shape. MPEP 2144.04(IV)(A).

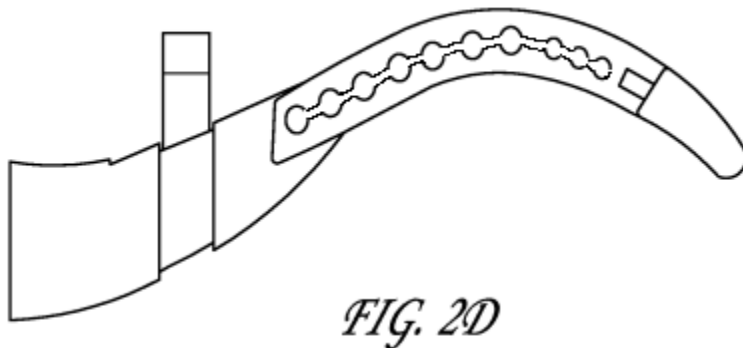
5. **Claim 5**

As shown below in annotated FIG. 2D, Nguyen modified by Black results in two intervening walls extending partially across the distance between the anterior wall and the posterior wall. The simple cut across the middle of the original sidewall forms two intervening walls, each with alternating crests and troughs. EX1005, FIG. 2D (annotated); EX1003, ¶ 98.



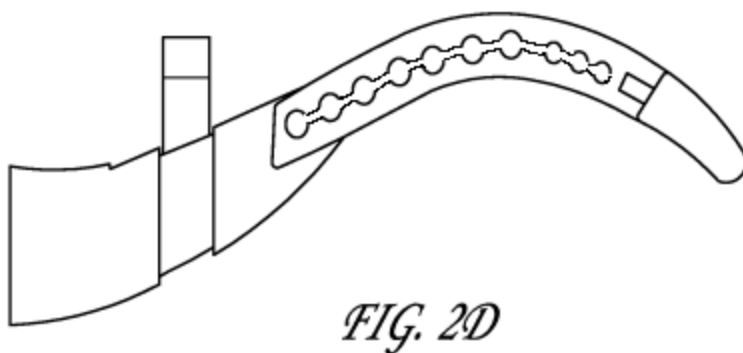
6. **Claim 6**

As shown below in annotated FIG. 2D, Nguyen modified by Black results in two intervening walls each with alternating crests and troughs, and at least one of the crests is flat. EX1005, FIG. 2D (annotated); EX1003, ¶ 99.



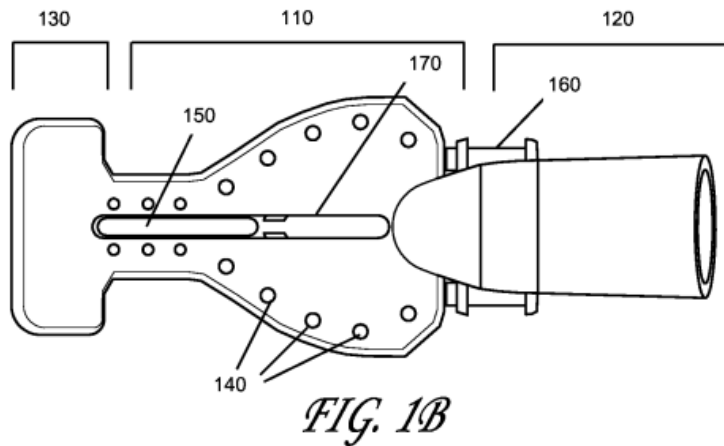
7. **Claim 7**

As shown below in annotated FIG. 2D, Nguyen modified by Black results in two intervening walls each with alternating crests and troughs, and at least one of the troughs is semi-circular. EX1005, FIG. 2D (annotated); EX1003, ¶ 100.



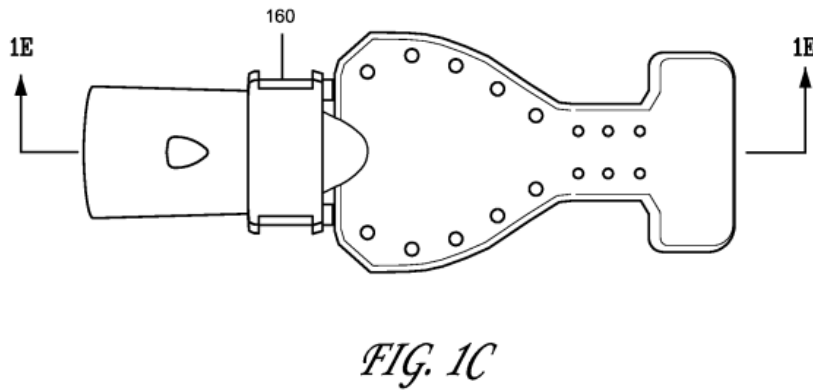
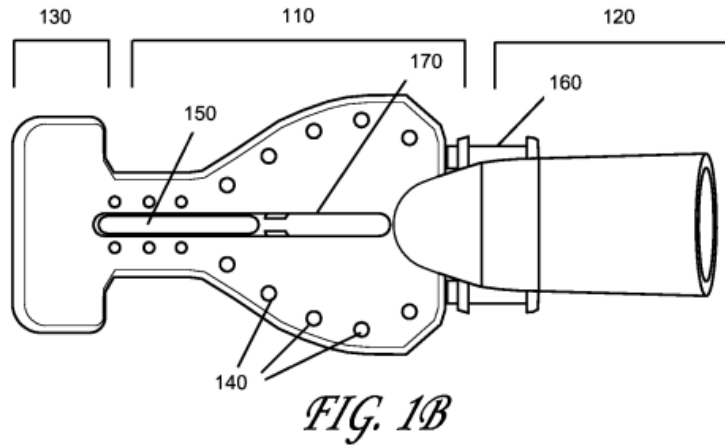
8. **Claim 8**

Nguyen teaches perforations 140 formed on both the anterior and posterior wall. EX1005, 3:63-67, FIG. 1B-1C; EX1003, ¶ 101. The perforations open into the pocket of the main body 110. *Id.*



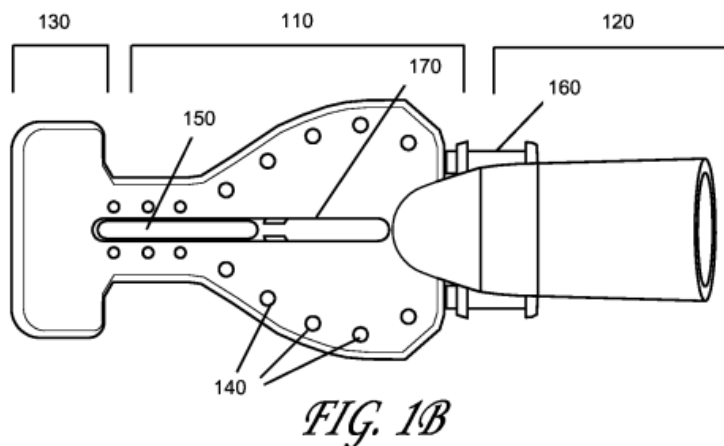
9. **Claim 9**

Nguyen teaches perforations 140 formed on both the superior and inferior sides of the anterior and posterior wall. EX1005, 3:63-67, FIG. 1B-1C; EX1003, ¶ 102.



10. **Claim 10**

See Section IX.A.2. As shown in FIG. 1B, Nguyen illustrates that the perforations 140 are formed on narrow, rectangular portion. EX1005, FIG. 1B-1C; EX1003, ¶ 103.



11. **Claim 11**

Nguyen teaches a mouth prop that engages a patient's teeth to prop open a patient's mouth. EX1005, 5:9-38; EX1003, ¶ 104. Nguyen teaches that the mouth prop 160 includes a strap that wraps around a suction connector. EX1005, 4:65-5:2. Thus, the mouth prop attaches to the outside of the suction connector and does not obstruct any suction opening. *Id.*

12. **Claim 12**

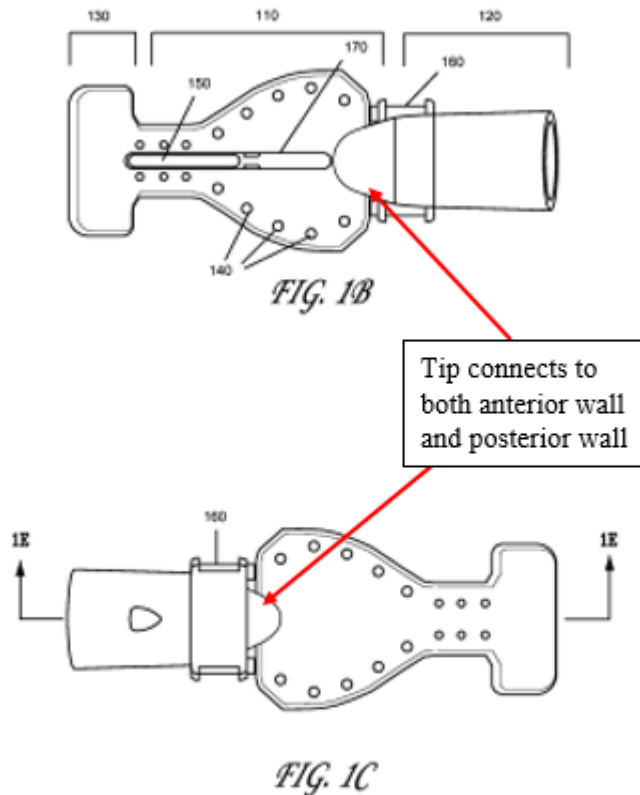
Nguyen teaches a cut out that interlocks with a vacuum adapter, and that the cutout has a shield shape that matches a shape on the vacuum adapter. EX1005, 5:22-27; EX1003, ¶ 105.

13. **Claim 13**

Nguyen teaches an internal stop that assists in sliding the mouthpiece onto an adapter to the desired depth. EX1005, 4:63-65; EX1003, ¶ 106.

14. **Claim 14**

Nguyen teaches a tip in front of the suction connector that connects the anterior wall to the posterior wall. E.g., EX1005, FIGs. 1B, 1C, 1E. Therefore, the tip in front of the suction connector is a connector connecting the anterior wall to the posterior wall. EX1003, ¶ 107.



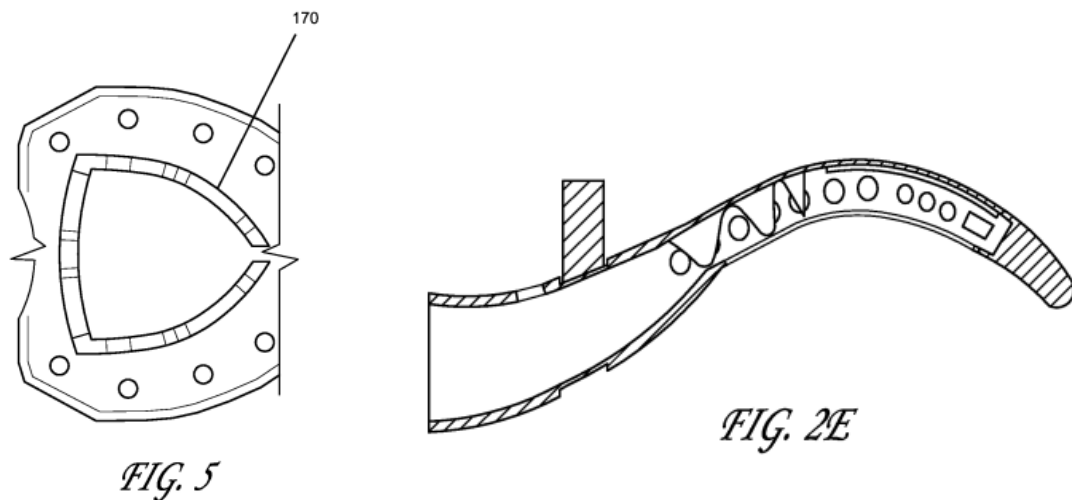
15. **Claims 17-18**

Nguyen teaches a mouthpiece formed of a flexible, translucent, high-heat resistant, autoclavable, silicone-based material. EX1005, Abstract; EX1003, ¶ 108. A PHOSITA would understand that such flexibility would allow the anterior wall to be pulled away from the posterior wall once the sidewalls were opened in view of

Black. EX1003, ¶ 109. Regardless, this portion of the limitation is nothing more than an intended use. MPEP 2114(II).

16. **Claim 19**

Nguyen teaches the exact same bridge structure as described in the '948 Patent. EX1005, 4:38-56; EX1003, ¶ 110.



17. **Independent Claim 20**

a. **Limitation 20(a)**

See Section IX.A.1.a; EX1003, ¶ 111.

b. **Limitation 20(b)**

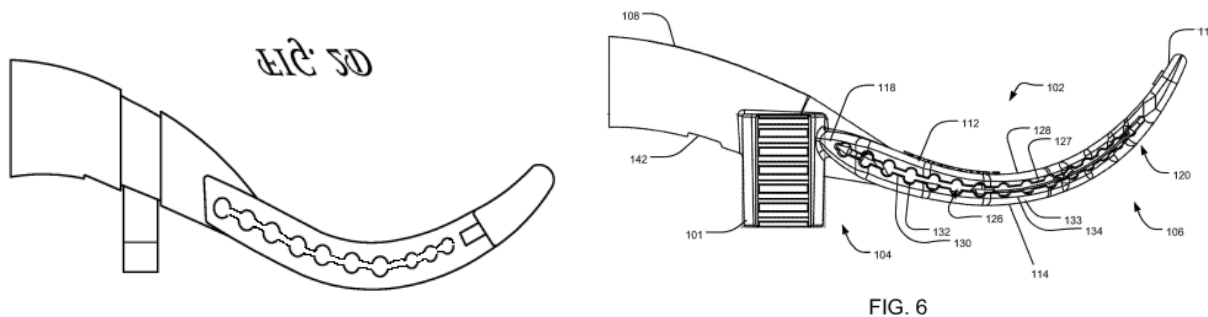
See Section IX.A.1.b; EX1003, ¶ 112.

c. **Limitation 20(c)**

To the extent this limitation is supported by the specification, see Section IX.A.1.c; EX1003, ¶ 113.

d. **Limitation 20(d)**

Notwithstanding the confusing and unsupported claim language, once modified by Black, the plurality of ridges of the ridged configuration would “not connect to the second wall” in the same way shown in the '948 Patent. Moreover, to the extent that “open meshed configuration” can be understood, Nguyen as modified by Black results in nearly identical sides as shown in FIG. 6 of the '948 Patent, which the '948 Patent describes as an “open-meshed configuration”. EX1001, 6:50-64; EX1003, ¶¶ 114-116, 228.



e. **Limitation 20(e)**

See Section IX.A.1.d; EX1003, ¶ 117.

f. **Limitation 20(f)**

See Section IX.A.1.e; EX1003, ¶ 118.

18. **Claim 21-22**

See Section IX.A.2; EX1003, ¶¶ 119-120.

19. **Independent Claim 23**

a. **Limitation 23(a)**

See Section IX.A.1.a; EX1003, ¶ 121.

b. **Limitation 23(b)**

See Section IX.A.1.b; EX1003, ¶ 122.

c. **Limitation 23(c)**

To the extent this limitation is supported by the specification, *See* Section IX.A.1.c; EX1003, ¶ 123.

d. **Limitation 23(d)**

See Section IX.A.17.d; EX1003, ¶ 124.

e. **Limitation 23(e)**

See Section IX.A.1.d; EX1003, ¶ 125.

f. **Limitation 23(f)**

See Section IX.A.2; EX1003, ¶ 126.

20. **Claim 24**

See Section IX.A.10; EX1003, ¶ 127.

21. **Claim 28**

See Section IX.A.15; EX1003, ¶¶ 128.

B. Ground 2: Claims 15-16, 25-27, 29-31 are further obvious under 35 U.S.C. § 103 by Nguyen in view of Black and Hirsch

1. **Claim 15**

As explained above, the tip in front of the suction connector includes a wall within the interior space that exists along or substantially near a longitudinal axis of the mouthpiece. *See* Section IX.A.14; EX1005, FIG. 1E.

Alternatively, Nguyen discloses a stability bar that includes a wall within the interior space along a longitudinal axis of the main body portion. EX1005, 4:6-30. The stability bar, which Nguyen also calls a reinforcing bar, assists in providing cheek retraction force to retract a patient's cheek away from the dental procedure area. EX1005, 3:29-35, 4:28-30; EX1003, ¶ 130.

While the stability bar is described as a thickened area (EX1005, 4:12-15, FIG. 6B), a PHOSITA would have known that a thicker stability bar would provide enhanced cheek retraction forces. EX1003, ¶¶ 130-131; *see also* EX1007, 17:55-65. A PHOSITA would further know that the thickest and strongest cheek retraction force would come from a stability bar that connects the anterior wall to the posterior wall. EX1003, ¶¶ 130-131. Hirsch teaches such a spine that connects anterior flaps to posterior flaps and provides added rigidity, which a PHOSITA would know provided added cheek retraction force. EX1006, 4:22-27, 2:62-64, FIG. 14; EX1003, ¶¶ 130-131.

Thus, it would have been obvious to a PHOSITA to replace or extend the stability bar 150 in Nguyen with a spine 365 at least in the rectangular portion to provide enhanced cheek retraction. EX1005, 3:29-35. A PHOSITA would have expected success in thickening walls to help with cheek retraction because mouthpieces with spines were known and mouthpieces with thickened areas on the area between a tongue retractor and a cheek retractor were also known. EX1006,

4:22-27, FIG. 14; EX1007, 17:55-65; EX1003, ¶¶ 130-131. The extended stability bar may close at least a portion of the slit, but as mentioned in Section IX.C.1.c, the slit is optional after opening the sides. EX1003, ¶¶ 130-131.

2. **Claim 16**

Hirsch teaches that the spine extends through the neck, and the stability bar extends through the rectangular portion of Nguyen. After replacing the stability bar with a spine, the connector would extend through the rectangular area (neck) of Nguyen. EX1003, ¶ 132.

3. **Claim 25**

See Section IX.B.1; EX1003, ¶ 133.

4. **Claim 26**

See Section IX.B.2; EX1003, ¶ 134.

5. **Claim 27**

See Section IX.A.15; EX1003, ¶ 135.

6. **Claim 29**

See Section IX.B.1; EX1003, ¶ 136.

7. **Claim 30**

See Section IX.B.2; EX1003, ¶ 137.

8. **Claim 31**

See Section IX.A.10; EX1003, ¶ 138.

C. **Ground 3: Claims 1-3 and 5-31 are obvious under 35 U.S.C. § 103 by Nguyen in view of Hirsch**

1. **Independent Claim 1**

a. **Limitation 1(a)**

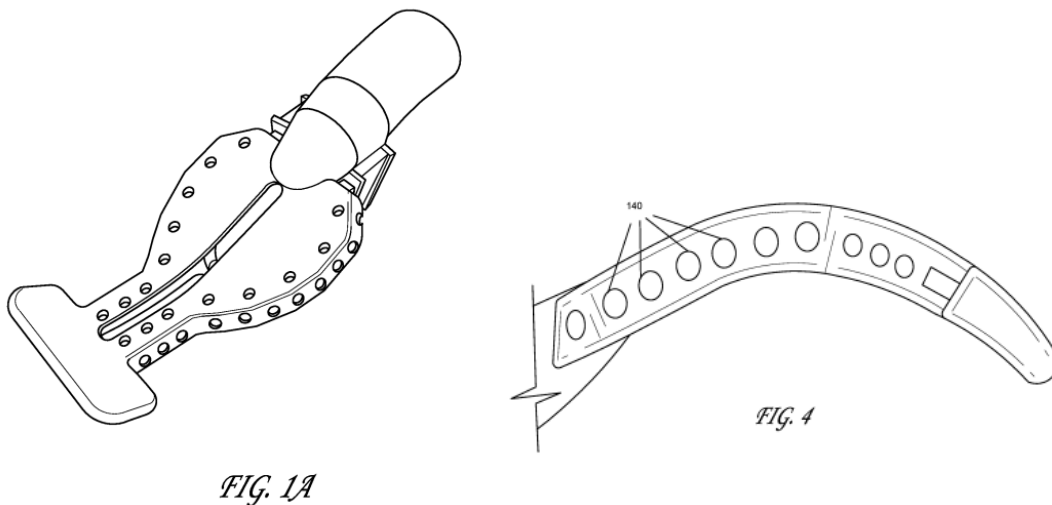
See Section IX.A.1.a; EX1003, ¶ 140.

b. **Limitation 1(b)**

See Section IX.A.1.b; EX1003, ¶ 141.

c. **Limitation 1(c)**

Nguyen teaches two sidewalls (inferior and superior) each connected to both the anterior and posterior walls. EX1005, 3:36-54.



Because each sidewall is connected to both the anterior wall and the posterior wall, each sidewall protrudes from the anterior wall along an edge of the anterior wall and each also sidewall protrudes from the posterior wall along an edge of the posterior wall. *Id.*, *see also*, EX1005, FIG. 1A, 3:40-49, 3:63-4:3; EX1003, ¶¶ 142-1143.

Nguyen teaches that the superior and inferior sidewalls span the entire distance between the anterior and posterior walls (not “partially”). EX1005, 3:40-

49, 3:63-4:3. Nevertheless, it would have been obvious to open the sidewalls of Nguyen in view of Hirsch, thereby creating at least one intervening wall that partially extends across the distance between the anterior and posterior walls. EX1003, ¶ 131.

Hirsch teaches a retractor 240 having gaps 350, 360. EX1006, 3:17-21. Hirsch explains that the upper gap 350 engages the roof of the patient's mouth, and the lower gap 360 engages the lingual or floor of the patient's mouth. EX1006, 4:43-67. Hirsch further explains that the mouth tissue bends the flaps 310, 320, 330, 340 forward. *Id.*; EX1003, ¶ 144.

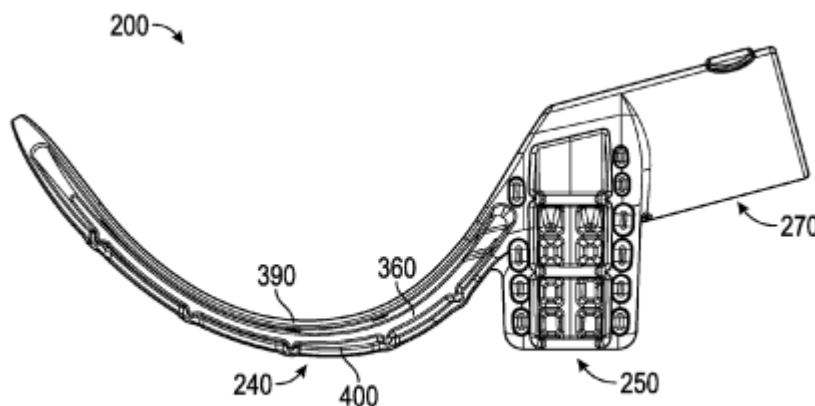
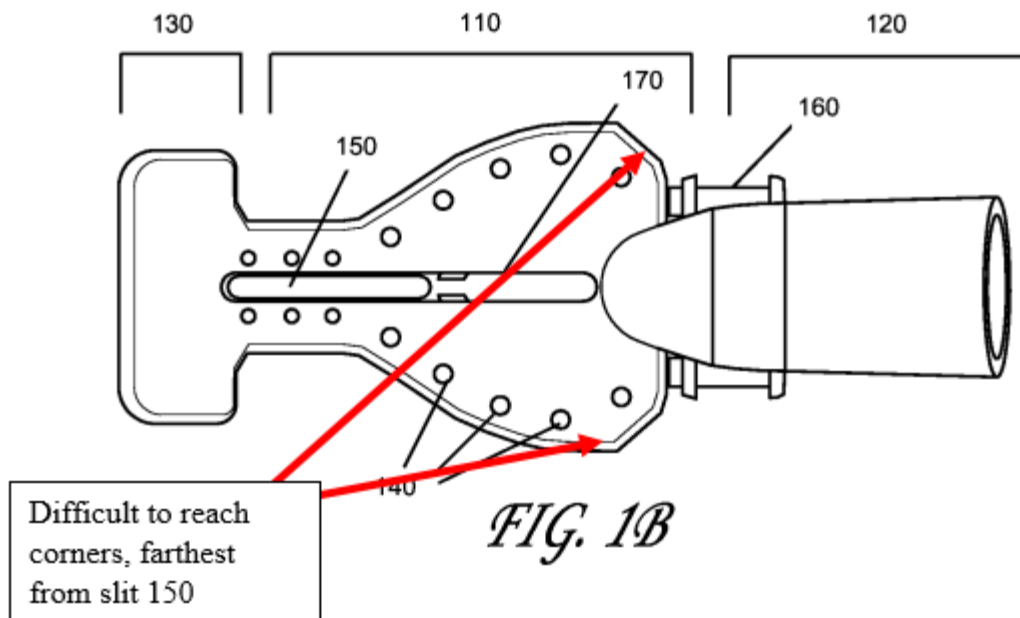


FIG. 6

A PHOSITA would have been also motivated to open the sidewalls of Nguyen in view of Hirsch to improve suction through the mouthpiece. EX1003, ¶¶ 145-147. Petitioner fully explained how the mouth tissue applies bending forces on the anterior wall and posterior walls, and how the sidewall prevents the anterior wall from bending along an independent radius, which leads to anterior wall buckling and

suction channel blockage/narrowing in Section IX.A.1.c. The same rationale applies again here. EX1003, ¶ 147.

Third, a PHOSITA would have been motivated to open the sides of Nguyen in view of Hirsch to make it easier to clean and reuse the dental mouthpiece of Nguyen. Nguyen teaches that the mouthpiece is autoclavable and reusable. EX1005, 3:8-10. In order to reuse a dental mouthpiece, it must be cleaned between uses and between patients. EX1005, 4:34-37; EX1003, ¶ 148. Nguyen explains that cleaning occurs through the slit 170. EX1005, 4:34-37. However, a PHOSITA would have known that the pocket design of Nguyen, with the slit 170, would not be conducive to easy cleaning. EX1003, ¶ 148. For example, a PHOSITA would have known that inserting a cleaning brush into the corners of Nguyen would be difficult or awkward to reach for a hygienist or other dental staff trying to clean the product. *Id.*



A PHOSITA would have known that a dental mouthpiece with open sides, such as Hirsch, would have been far easier to clean because a brush would remove gunk and bacteria unimpeded by any wall. EX1003, ¶ 149. Indeed, an open-sided mouthpiece would simply require fitting a brush in between the upper flap 310/320 and lower flap 330/340 through the gaps 350, 360, as opposed to folding back the anterior wall of Nguyen at the slit 170, inserting a brush through the slit 170, and attempting to reach the brush into all small corners formed on the mouthpiece of Nguyen. EX1005, 4:34-37, FIG. 1B; EX1003, ¶ 149. An open-sided mouthpiece would not have any difficult to reach corners. EX1003, ¶ 149. Most prior art isolation mouthpieces implemented open sides. EX1006, FIG. 2; EX1007, FIG. 23C, EX1017, FIG 4, EX1018, FIG. 1, EX1019, FIG. 3.

Thus, for all these reasons, a PHOSITA would have been motivated to open the sides of Nguyen in view of Hirsch. EX1003, ¶¶ 131-139.

However, a PHOSITA would have been motivated to form open-sided, anti-collapse structure at the edges of Nguyen after opening the sides in view of Hirsch. EX1003, ¶ 150. Hirsch explains that mouth tissue bends the anterior and posterior flaps forward to create a seal, thereby preventing suction through the sealed gaps 350, 360. EX1006, 4:43-67. The lack of anti-collapse structure at the edges in Hirsch is what causes the seal. EX1003, ¶ 150.

Nguyen prevents collapse under suction using a combination of sidewalls and the bridge structure 180. EX1005, 2:10-16, 4:38-56; EX1003, ¶ 150. A PHOSITA would know that removing the sidewalls in Nguyen would cause the anterior wall and posterior wall to collapse under suction at the edges of the mouthpiece near the perforations 140, which are critical to fluid removal. EX1006, 4:43-67; EX1003, ¶ 150. The edges of the mouthpiece would be far enough from the bridge structure 180 to not receive the benefit of the bridge structure's anti-collapse function, and would create the undesirable seal at the edges like Hirsch teaches. EX1006, 4:43-67; EX1003, ¶ 150. Thus, a PHOSITA would understand that Nguyen would require some anti-collapse structure at the edges of the main body portion 110, where the perforations 140 are formed. EX1003, ¶ 151.

Nguyen recognized the importance of anti-collapse structure and offered a suction-friendly, anti-collapse structure in the form of "crests" and "troughs" formed as a bridge structure 180. EX1005, 4:44-54. Thus, after being motivated to open the sidewalls in view of Hirsch it would have been obvious to a PHOSITA to include a second bridge structure formed at the edges of the mouthpiece, where the mouthpiece is most likely to collapse after opening, as such a second bridge structure would simply be a duplication of parts. EX1003, ¶ 152; MPEP 2144.04(VI)(B). An intervening wall with "alternating crests and troughs" is described using very similar

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language that Nguyen used to describe the bridge structure. EX1001, 6:33-38; EX1005, 2:10-16.

Alternatively, a POSA would recognize that Hirsch's grooved wall would function as an anti-collapse structure that could replace Nguyen's sidewalls. EX1003, ¶ 153. Hirsch teaches V-shaped grooves 416 formed on the edge of a wall that become fluid inlets for drawing in fluid. EX1006: FIG. 8, 4:67-5:8. A projecting wall with groves 416 as shown in Hirsch connected to only the posterior wall would generate an open-sided mouthpiece with anti-collapse structure formed at the edges of the mouthpiece. EX1003, ¶ 153. As such, Nguyen in view of Hirsch is a simple substitution of one known element (a sidewall connected to two walls) for another element (a wall having V-shaped grooves for suction at the edges of the posterior wall) to obtain predictable results (a mouthpiece having a sidewall connected to only the posterior wall and having V-shaped groves at the edge of the span of the sidewall). See annotated EX1005, FIG. 1A and 1D. EX1003, ¶ 153.

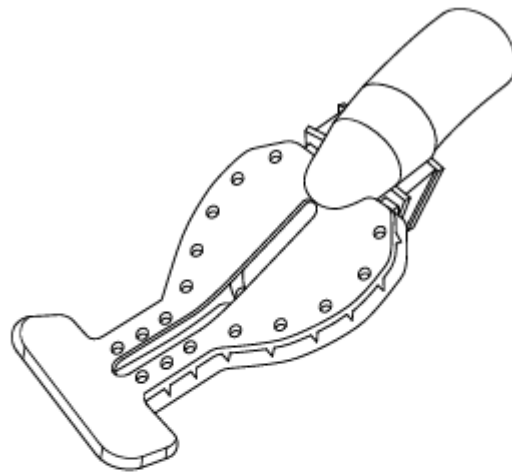


FIG. 1A

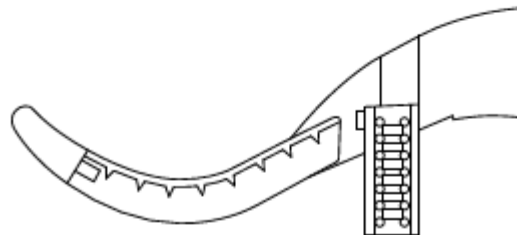


FIG. 1D

A PHOSITA would have expected success in modifying Nguyen in view of Hirsch as proposed above because Hirsch explains that a wall having V-shaped grooves assists in suction. EX1006, 3:51-55, 4:4-16; EX1003, ¶ 154. Nguyen in view of Hirsch would still allow for suction on the superior and inferior sides, while also preventing suction blockages and making the mouthpiece easier to clean. EX1005, 3:63-4:3; EX1003, ¶ 154. Additionally, substituting the sidewalls connected to both the anterior and posterior walls with an upward projecting wall having grooves connected only to the posterior wall would function as anti-collapse structure at the edges. EX1003, ¶ 154.

To the extent Patent Owner argues that a PHOSITA would not have been motivated to implement the grooves 416 of Hirsch on a sidewall because the grooves 416 are located on a posterior flap of Hirsch, such an argument would greatly diminish the common sense of a PHOSITA. As described above, a PHOSITA would have been motivated to maintain anti-collapse structure at the edges of the mouthpiece to avoid the undesirable seal taught by Hirsch. EX1006, 4:43-67; EX1003, ¶ 155. However, a PHOSITA would know that there must be some inlet for suction to occur, lest the sidewall completely block suction through the superior and inferior sides. EX1006, 3:51-55, 4:4-16; EX1003, ¶ 155. Hirsch describes one such fluid inlet in the form of V-shaped (or U-shaped) grooves. EX1006, 3:51-55, 4:4-16. A PHOSITA would instantly recognize that grooves of this shape would function as inlets in either a posterior, anterior, or sidewall configuration. Indeed, U-shaped grooves are nothing more than half of the circular perforations described by Nguyen. EX1003, ¶ 155. Or alternatively, it would have been equally obvious to duplicate the bridge structure 180 at the edges of the mouthpiece. MPEP 2144.04(VI)(B); EX1003, ¶ 155.

Finally, a PHOSITA may be further motivated to remove the slit 170. The slit 170 primarily operates as an opening into the pocket of Nguyen for cleaning purposes. EX1005, 4:31-37. The open sides of modified Nguyen in view of Hirsch would remove the need for the slit because cleaning would most easily occur through

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the sides. EX1003, ¶ 156-157. The slit 170 can stay because Nguyen mentions that it assists in suction. EX1005, 4:35-37. If the slit 170 were removed, the collapse issues mentioned above may be rectified, so a PHOSITA would also be motivated to remove the slit 170, but this removal is of little consequence to the claim language of the claim 1.

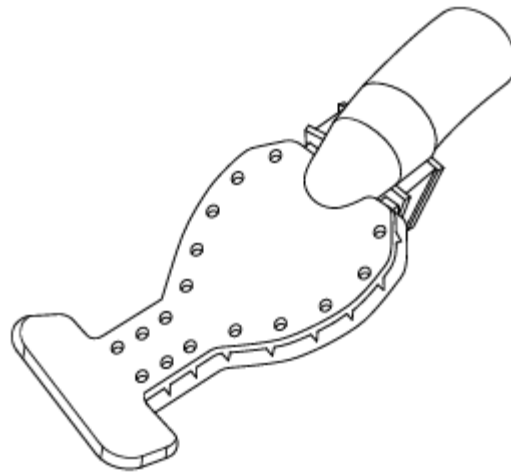


FIG. 1A

d. **Limitation 1(d)**

See Section IX.A.1.d; EX1003, ¶ 158.

e. **Limitation 1(e)**

See Section IX.A.1.e; EX1003, ¶ 159.

2. **Claim 2**

See Section IX.A.2; EX1003, ¶ 160.

3. **Claim 3**

See Section IX.A.3; EX1003, ¶ 161.

4. **Claim 5**

As shown below in annotated FIG. 1D, Nguyen modified by Hirsch results in an intervening wall extending partially across the distance between the anterior wall and the posterior wall. Substituting Nguyen's sidewalls with the wall taught by Hirsch forms an intervening wall with alternating crests and troughs. EX1005, FIG. 1D (annotated); EX1003, ¶ 162.

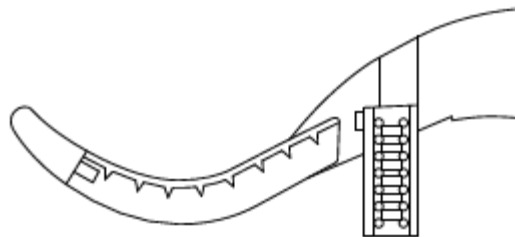


FIG. 1D

5. **Claim 6**

As shown below in annotated FIG. 1D, Nguyen modified by Hirsch results in an intervening wall with alternating crests and troughs, and at least one of the crests is flat. EX1005, FIG. 1D (annotated); EX1003, ¶ 163.

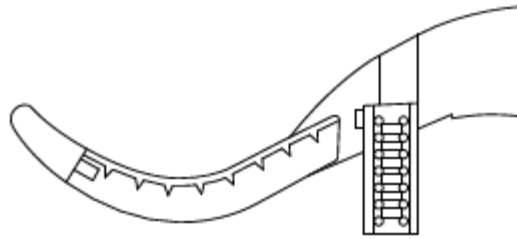


FIG. 1D

6. **Claim 7**

As shown below in annotated FIG. 1D, Nguyen modified by Hirsch results in two intervening walls each with alternating crests and troughs, and at least one of the troughs is semi-circular. EX1005, FIG. 1D (annotated); EX1003, ¶ 164. Hirsch explains that the grooves may be U-shaped, which is a semi-circle. EX1006, 3:56-60.

7. **Claim 8**

See Section IX.A.8; EX1003, ¶ 165.

8. **Claim 9**

See Section IX.A.9; EX1003, ¶ 166.

9. **Claim 10**

See Section IX.A.10; EX1003, ¶ 167.

10. **Claim 11**

See Section IX.A.11; EX1003, ¶ 168.

11. **Claim 12**

See Section IX.A.12; EX1003, ¶ 169.

12. **Claim 13**

See Section IX.A.13; EX1003, ¶ 170.

13. **Claim 14**

See Sections IX.B.1-2; EX1003, ¶ 171.

14. **Claims 15-16**

See Sections IX.B.1-2; EX1003, ¶¶ 172-173.

15. **Claims 17-18**

See Section IX.A.15; EX1003, ¶¶ 174-175.

16. **Claims 19**

See Section IX.A.16; EX1003, ¶ 176.

17. **Independent Claim 20**

a. **Limitation 20(a)**

See Section IX.A.17.a; EX1003, ¶ 177.

b. **Limitation 20(b)**

See Section IX.A.17.b; EX1003, ¶ 178.

c. **Limitation 20(c)**

To the extent this limitation is supported by the specification, *See* Section IX.C.1.c; EX1003, ¶ 179.

d. **Limitation 20(d)**

Notwithstanding the confusing and unsupported claim language, once modified by Hirsch, the plurality of ridges of the ridged configuration would not

connect to the second wall. Moreover, to the extent that “open meshed configuration” can be understood, Nguyen as modified by Hirsch results in grooves that allow for suction of fluids. EX1006, 4:4-16; EX1003, ¶¶ 180-181.

e. **Limitation 20(e)**

See Section IX.A.1.d; EX1003, ¶ 182.

f. **Limitation 20(f)**

See Section IX.A.1.e; EX1003, ¶ 183.

18. **Claim 21-22**

See Section IX.A.2; EX1003, ¶¶ 184-185.

19. **Independent Claim 23**

a. **Limitation 23(a)**

See Section IX.A.1.a; EX1003, ¶ 186.

b. **Limitation 23(b)**

See Section IX.A.1.b; EX1003, ¶ 187.

c. **Limitation 23(c)**

To the extent this limitation is supported by the specification, *See* Section IX.A.1.c; EX1003, ¶ 188.

d. **Limitation 23(d)**

See Section IX.C.17.d; EX1003, ¶ 189.

e. **Limitation 23(e)**

See Section IX.A.1.d; EX1003, ¶ 190.

f. **Limitation 23(f)**

See Section IX.A.2; EX1003, ¶ 191.

20. **Claim 24**

See Section IX.A.10; EX1003, ¶ 192.

21. **Claim 25**

See Section IX.B.3; EX1003, ¶ 193.

22. **Claim 26**

See Section IX.B.4; EX1003, ¶ 194.

23. **Claim 27**

See Section IX.B.5; EX1003, ¶ 195.

24. **Claim 28**

See Section IX.A.21; EX1003, ¶¶ 196.

25. **Claim 29**

See Section IX.B.6; EX1003, ¶¶ 197.

26. **Claim 30**

See Section IX.B.7; EX1003, ¶¶ 198.

27. **Claim 31**

See Section IX.B.8; EX1003, ¶¶ 199.

D. **Ground 4: Claim 4 is obvious under 35 U.S.C. § 103 by Nguyen in view of Hirsch and Black**

1. **Claim 4**

See Section IX.A.4; EX1003, ¶¶ 201.

E. **Ground 5: Claims 20-31 are Invalid for Lack of Written Description under 35 U.S.C. § 112**

35 U.S.C. § 112 at ¶ 1 states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The test for written description “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1251 (Fed. Cir. 2010). “Based on the inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Id.* The level of detail required to satisfy the written description requirement depends on a number of factors such as the nature and scope of the claims, the complexity and predictability of the relevant technology, existing knowledge in the field, the extent and content of the prior art, and the maturity of the technology. *Capon v. Eshhar*, 418 F.3d 1349, 1357-59 (Fed. Cir. 2005); EX1003, ¶¶ 59-60.

1. **“[A] main body portion comprising ... the two edges of the first wall being unconnected to the second wall”**

Independent claims 20 and 23 are invalid for a lack of adequate written description regarding edges of the first wall being unconnected to the second wall. EX1003, ¶ 202. The specification provides no support for the **edges** of the first wall being **unconnected** to a second wall **in the main body portion** of the mouthpiece. Instead, the patent specification describes the edges of the walls being connected at (1) the first end of the main body portion near the suction connector portion or (2) at the second end of the main body portion near the cheek retractor portion or at the cheek retractor portion. EX1001, 6:65-7:7. The patent specification only depicts embodiments where the edges of the first and second wall are **connected**. *See* EX1001, Figs. 3 and 6. Nowhere does the patent describe a mouthpiece where the edges of the first and second wall are unconnected in the main body portion, as claimed in independent claims 20 and 23. EX1003, ¶ 205. In fact, the patent disclosed a main body portion specifically connected at the edges of the first and second walls. Thus, the specification does not reasonably convey to a PHOSITA that the inventor had possession of either of these claimed elements and the respective claims are invalid. EX1003, ¶ 202-205

Independent claims 20 and 23 claim a mouthpiece with a **main body portion comprising:**

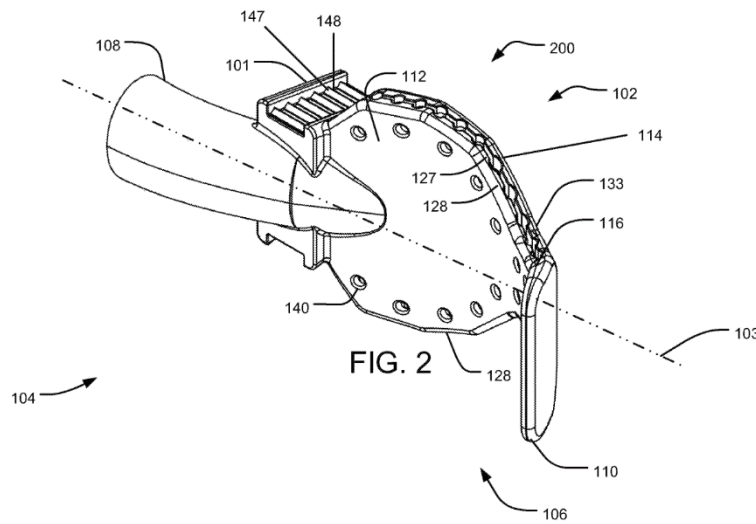
a first wall that includes two edges,

a second wall set at a distance from the first wall

wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall

wherein the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances partially across the distance between the first wall and the second wall, the **two edges of the first wall being unconnected to the second wall,**

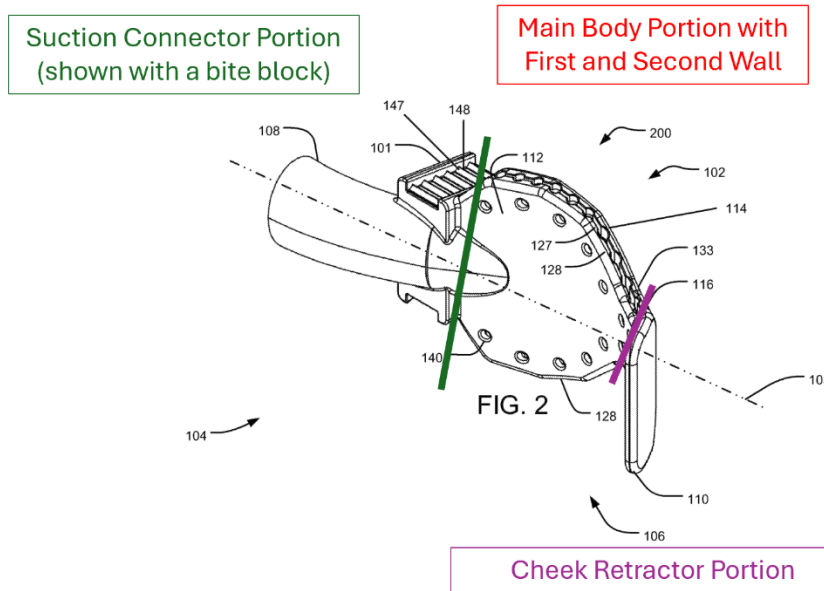
EX1001, 10:5-30, 10:37-61. These independent claims go on to claim other, independent sections from the main body portion, described as the suction connector portion and the cheek retractor portions. The '948 Patent describes a bite block 101 integrated into the suction connector portion, and not part of the main body portion. EX1001, 2:63-67.



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 Sheet 2 of 10
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'948 Patent Figure 2: Angled Profile (Isometric View)

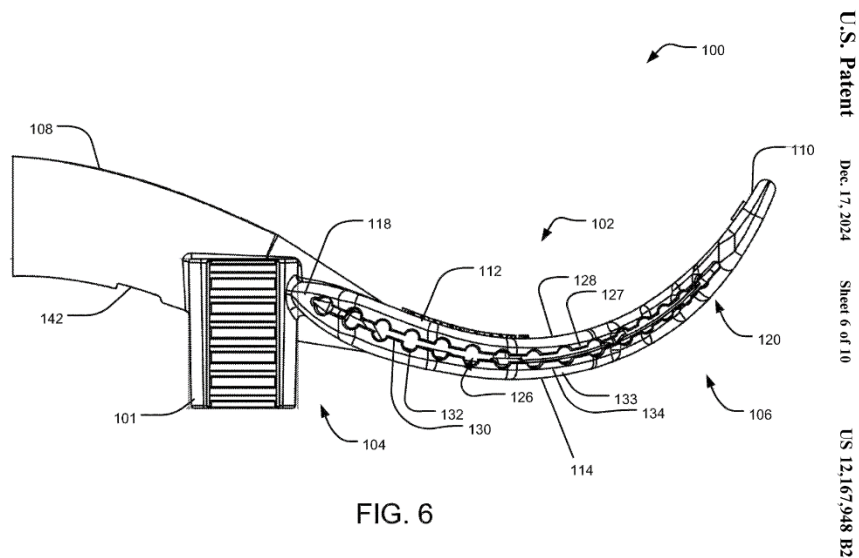
Figure 2 depicts an angled-side profile of an embodiment, illustrating the three sections (main body portion **102**, suction connector portion **108**, and cheek retractor portion **110**) as well as the first wall and second wall within the main body portion **102**. EX1003, ¶ 204.



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EX1001, Fig 2 (Modified): Isometric View with Portions Defined

Figure 6 depicts a side view of the mouthpiece showing the suction connector portion 108 (and bite block 101) on the left, the main body portion 102 in the center ending in the neck 120 on the right, and the cheek retractor portion 110 at the rightmost end. The specification describes connections of the edges of the first and second walls occurring at the superior and inferior walls. EX1001, 6:65-7:7; EX1003, ¶ 205. The superior and inferior walls are described as the portions that rest against the roof and floor of the mouth respectively, which would be the face of Figure 6 shown (or side-profile of the mouthpiece) for one wall (superior or inferior depending on insertion) and the opposite, hidden side (inferior or superior) for the other. EX1001, 4:41-45.



'948 Patent Figure 6: Side View of Mouthpiece

The specification refers to the first and second wall as the anterior and posterior walls. Further, the specification describes intervening walls as protrusions from the

first and second walls (anterior and posterior) out towards one another shown in Figure 6 as 127 and 134. The specification states the following regarding the potential connections for the first wall and second wall:

The anterior intervening wall 127 may join with the posterior intervening wall 134 at the superior wall 116 and the inferior wall 118 at near the suction connector portion 108 of the main body at the first end 104. The anterior intervening wall 127 may also join with the posterior intervening wall 134 at the superior wall 116 and the inferior wall 118 near the cheek retractor portion 110 at the second end 106. In some embodiments, the anterior intervening wall 127 may join with the posterior intervening wall 134 at the cheek retractor portion 110.

EX1001, 6:65-7:7. In short, the first and second walls connect at the main body either near the first end (near the suction connector) and near the second end (the cheek retractor portion). The modified figure 6 below illustrates these potential connection points. EX1003, ¶¶ 208-209

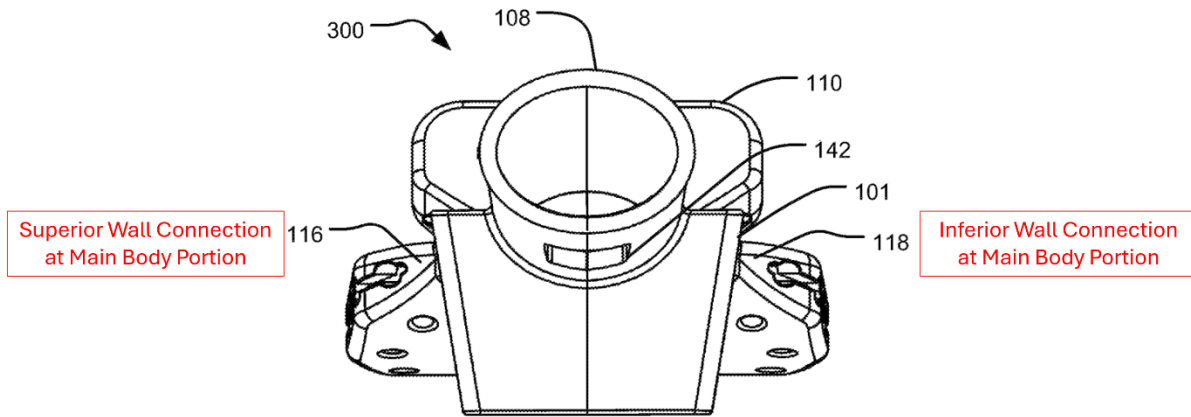


FIG. 3

Figure 3 (Modified): Rear View of Mouthpiece with Connections Identified

Nowhere does the specification describe or support a main body portion where the edges of the first and second walls are unconnected. The specification both depicts and describes the opposite. As a result, the specification does not reasonably convey to a PHOSITA that the inventor had possession of a mouthpiece with those claimed elements. EX1003, ¶ 210. Therefore, independent claims 20 and 23 lack adequate written description and are invalid under 35 U.S.C. § 112.

2. “[F]irst wall is configured at the two edges to have a ridged configuration with a plurality of ridges”

Independent claims 20 and 23 are invalid for a lack of adequate written description for a “first wall [] configured at the two edges to have a ridged configuration with a plurality of ridges.” The specification provides no support for a first wall with ridges. Instead, the specification describes separate, intervening walls with ridges that protrude out from the first or second walls. Nowhere does the

specification describe ridges on the first wall itself. Thus, the specification does not reasonably convey to a PHOSITA that the inventor had possession of either of these claimed elements and the respective claims are invalid. EX1003, ¶ 211.

Independent claims 20 and 23 claim a mouthpiece with a main body portion comprising:

a first wall that includes two edges,

a second wall set at a distance from the first wall

wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall

wherein **the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances partially across the distance between the first wall and the second wall**

EX1001, 10:5-30, 10:37-61. The specification, too, describes the ridges as not a part of the first wall, but rather that of an intervening wall protruding out from the first or second wall (also called anterior and posterior walls).

EX1001, 6:48-56 (“The posterior intervening wall 134 may likewise exhibit ridges that are the same, a mirror image, or different from the anterior

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intervening wall 127. In one example, the ridges of the anterior intervening wall 127, may be aligned with the ridges of the posterior intervening wall 134, as shown in FIG. 6. In combination, the anterior intervening wall 127 and the posterior intervening wall 134 and their respective aligned ridges may form an open mesh between the anterior wall 112 and the posterior wall 114.”). This lies in stark contrast to independent claim 1, claiming: “at least one intervening wall that includes a span protruding from the one or more edges of the first wall, wherein the span is defined by a ridged edge that includes a plurality of ridges.” United States Patent No. 11,826,217 (“the ’217 Patent”, EX1010), the patent from which the ’948 Patent continues, only claims mouthpieces with intervening walls. EX1010, 8:57-10:63. Claims 20-31, through independent claims 20 and 23 of the ’948 Patent, seek to impermissibly broaden the scope of its claim to mouthpieces beyond those that with intervening walls without sufficient disclosure in the specification. EX1015, pp. 18-20. Likely aware of this big departure from the specification, Applicant merely suggested that the amendments were supported by the “specification”, not any specific portion of the specification. EX1015, p. 23; EX1003, ¶¶ 212-214.

Figure 6 depicts these intervening walls and their ridges as not part of the first or anterior wall, but rather that of the intervening walls. Figure 6

modified below depicts the first and second wall (anterior wall 112 and posterior wall 114) shaded in blue whereas the ridged, anterior and posterior intervening walls are shaded green. EX1003, ¶ 215.

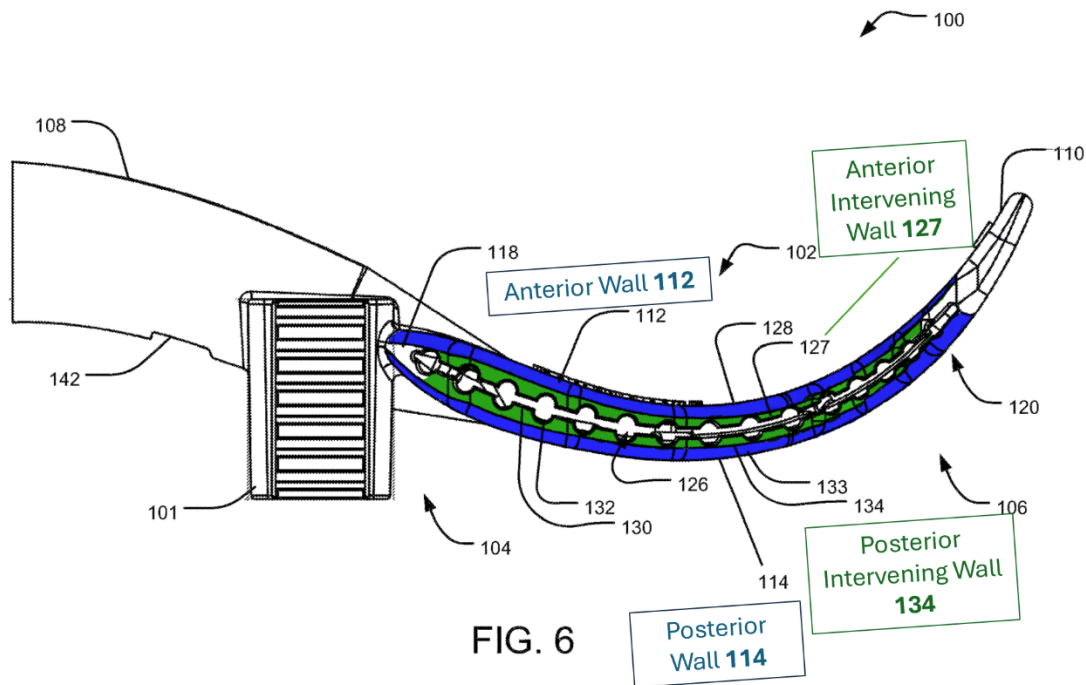


Figure 6 (Modified): Side View of Mouthpiece with Shading

The specification does not describe or even mention a first wall with ridges. The first mention is in independent claims 20 and 23. The specification only depicts and describes intervening walls with such ridges. As a result, the specification does not reasonably convey to a PHOSITA that the inventor had possession of a mouthpiece with those claimed elements. Therefore, independent claims 20 and 23 lack adequate written description and are invalid under 35 U.S.C. § 112. EX1003, ¶ 216.

F. **Ground 6: Claims 20-31 are Invalid as Indefinite under 35 U.S.C. § 112**

35 U.S.C. § 112 at ¶ 2 states:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

That is, “a patent is invalid for indefiniteness if its 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); EX1003, ¶¶ 61-62.

1. **“[O]pen-meshed configuration”**

Independent claims 20 and 23 are invalid for indefiniteness based on the term “open-meshed configuration.” EX1003, ¶ 217. The specification fails to inform a PHOSITA, with reasonable specificity, the scope of the claims, i.e. what is and is not a mesh, an open mesh, or an open-meshed configuration.

Independent claims 20 and 23 claim a first wall with ridges where “the plurality of ridges form[] **an open-meshed configuration** between the first and second walls to allow for suction of fluids from a patient’s mouth into the interior space between the first and second walls.” The specification states the following regarding an open mesh:

In combination, the anterior intervening wall 127 and the posterior intervening wall 134 and their respective aligned ridges may form an open mesh between the anterior wall 112 and the posterior wall 114. Such open mesh may follow the edges 128, 133 of each of the anterior wall 112 and the posterior wall 114 from the first end 104 to the second end 106. The open mesh between the anterior intervening wall 127 and the posterior intervening wall 134 allows for suction of air, fluids, and small debris from patient's mouth, through the mesh into the interior space 126 and into the suction connector portion 108 towards a suction source.

'948 Patent at 6:53-64; EX1003, ¶ 218. Essentially, the specification describes the open mesh as what is formed between the intervening walls. The mesh is defined in terms of its functionality, that is, something that “allows for suction of air, fluids and small debris.” The specification is otherwise silent regarding a mesh and open mesh and entirely silent regarding what an open-meshed configuration is. EX1003, ¶¶ 218-219.

Figure 7 depicts a side of the dental mouthpiece with an anterior wall of the mouthpiece 112 pulled away from a posterior wall of the mouthpiece 114. EX1003, ¶ 219.

mouthpiece for fluid suction. In Figure 7, is the open-meshed configuration “open” on both sides of the figure or only an “open-meshed configuration” when it’s “closed” on the left? It is unclear. EX1003, ¶¶ 224-226.

The specification is silent regarding what constitutes an open-meshed configuration between the walls. The scope of the claims is therefore unclear as to what the ’948 Patent claims, rendering Independent Claims 20 and 23 invalid for indefiniteness pursuant to 35 U.S.C. § 112. EX1003, ¶¶ 224-228.

G. Ground 7: Claim 18 is Invalid as Indefinite under 35 U.S.C. § 112

1. “[A]t least translucent”

Dependent claim 18 is invalid for lack of indefiniteness based on the term “at least translucent.” However, it is unclear how the modifier “at least” applies to the term “translucent”. EX1003, ¶¶ 229-230

The specification states that the mouthpiece may be made of material that is translucent. EX1001, 1:57-59 (“the mouthpiece may be made of material that flexible, translucent, conducive to injection molding, high heat-resistant, and autoclavable”), 2:49-53 (“the mouthpiece may be made of a material that is flexible, resilient, at least translucent, and conducive to injection molding”) and 3:21-24 (“the mouthpiece 100 may be made of a material that is flexible, resilient, translucent, and conducive to injection molding.”). EX1003, ¶ 230.

However, it is unclear whether the term “*at least translucent*” captures mouthpieces that span from translucent to transparent, translucent to opaque, or anywhere in between. The specification does not explain what impact the translucency of the mouthpiece has on the use of the device or its relevance. The specification only states that may be translucent. Is the purpose of the translucent property to allow enough light to pass through so the dental practitioner can see through the device or to block enough light to not distract the vision of the practitioner? What would be the desirable spectrum? It is unclear. EX1003, ¶¶ 231-233.

The specification fails to inform a PHOSITA, with reasonable specificity, the scope of the claim. Therefore, dependent claim 18 is invalid for indefiniteness.

X. **CONCLUSION**

Petitioner has demonstrated in this Petition that claims 1-31 of the '948 Patent are unpatentable. Petitioner, therefore, respectfully requests institution of a post-grant review of the '948 Patent and that claims 1-31 be canceled.

Respectfully submitted,

Dated: June 19, 2025

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CERTIFICATION

The Petition excluding the caption, Table of Contents, Table of Exhibits, Mandatory Notices under 37 C.F.R. § 42.8, and this Certification contains 10,967 words.

Respectfully submitted,

Dated: June 19, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on this the 19th day of June 2025, the foregoing Petition for post-grant review and all exhibits and other documents filed together with the Petition were served via Federal Express to the attorneys of record for the '948 Patent at the following address:

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