

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. 11,826,217

Case No. IPR2025-01065

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	OVERVIEW OF THE ‘217 PATENT	3
III.	SUMMARY OF PETITIONER’S REFERENCES	11
	A. Nguyen (EX1005) (Grounds 1-3)	11
	B. Black (EX1007) (Grounds 1-3).....	13
	C. Hirsch (EX1006) (Grounds 2-3)	16
IV.	LEVEL OF SKILL IN THE ART	18
V.	CLAIM CONSTRUCTION	18
	A. “partially across the distance of the interior space” (claims 1-23)	18
	B. Other District Court Constructions	19
VI.	PETITIONER FAILED TO MEET ITS BURDEN	20
	A. Ground 1: Alleged Obviousness Based on Nguyen and Black (Claims 1-11 and 13-23)	20
	1. Petitioner Failed to Meet its Burden for Claim 1	20
	a) Petitioner and Dr.....	22
	b) Petitioner Has Not Shown That a POSITA Would Have Been Motivated to Modify Nguyen.....	26
	i. A POSITA Would Not Have Been Motivated to Modify Nguyen to “Increase Suction”	26
	ii. A POSITA Would Not Have Been Motivated to Modify Nguyen for “Easier Cleaning”	35
	iii. Petitioner’s Proposed Modification Requires More Than Simply “Cutting” Nguyen Open	39
	c) Petitioner’s Duplication of Parts Argument is Conclusory and Unsupported	41
	2. Petitioner Failed to Meet its Burden for Claim 17	43
	a. Petitioner Failed to Meet its Burden for Limitations 17(d) and 17(e) for the Same Reasons as Claim 1	43
	b. Petitioner Ignores the “Within the Interior Space” Requirement in Limitation 17(c)	44
	3. Dependent Claims 2-11, 13-16, and 18-23	45

	Page
B. Ground 2: Alleged Obviousness Based on Nguyen, Black, and Hirsch (Claims 8 and 19)	46
C. Ground 3: Alleged Obviousness Based on Nguyen and Hirsch (Claims 17-23)	46
1. Petitioner Failed to Meet its Burden for Claim 17	46
a. Petitioner Again Ignores the “Within the Interior Space” Requirement in Limitation 17(c).....	47
b. A POSITA Would Not Have Modified Nguyen in View of Hirsch for Limitations 17(d) and 17(e)	47
i. A POSITA Would Not Have Been Motivated to Modify Nguyen to “Improve Suction”	48
ii. A POSITA Would Not Have Been Motivated to Modify Nguyen for Cleaning	50
2. Dependent Claims 18-23.....	52
VII. CONCLUSION.....	52

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Allergan, Inc. v. Sandoz Inc.</i> , 796 F.3d 1293 (Fed. Cir. 2015)	49
<i>Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.</i> , 876 F.3d 1350 (Fed. Cir. 2017)	49
<i>Arctic Cat Inc. v. Polaris Indus., Inc.</i> , 795 F. App'x 827 (Fed. Cir. 2019)	41
<i>Grain Processing Corp. v. Am. Maize-Prods. Co.</i> , 840 F.2d 902 (Fed. Cir. 1988)	32
<i>Henny Penny Corp. v. Frymaster LLC</i> , 938 F.3d 1324 (Fed. Cir. 2019)	41
<i>In re Fine</i> , 837 F.2d 1071 (Fed. Cir. 1988)	46, 52
<i>In re Fulton</i> , 391 F.3d 1195 (Fed. Cir. 2004)	41
<i>In re Kahn</i> , 441 F.3d 977 (Fed. Cir. 2006)	42, 50
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.</i> , 868 F.3d 1013, 1017 (Fed. Cir. 2017)	18, 19
<i>Orthopedic Equip. Co. v. United States</i> , 702 F.2d 1005 (Fed. Cir. 1983)	33
<i>Purdue Pharma L.P. v. Depomed, Inc.</i> , 643 F. App'x 960 (Fed. Cir. 2016)	32
<i>Winner Int'l Royalty Corp. v. Wang</i> ,	

202 F.3d 1340 (Fed. Cir. 2000)	41
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (PTAB Aug. 24, 2022).....	32
Regulations	
37 C.F.R. § 42.65	32

LISTING OF EXHIBITS

Exhibit No.	Description
2001	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Brief in Support of Motion to Stay, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 38 (Jul. 11, 2025)
2002	Declaration of Nathan P. Sportel in Support of Defendant/Counter-Plaintiff's Motion to Stay, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 39 (Jul. 11, 2025)
2003	U.S. Patent Publication No. 2014/0162209 ("Nguyen '209 Publication")
2004	U.S. Patent Publication No. 2014/0212841 ("Nguyen '841 Publication")
2005	U.S. Patent Publication No. 2014/0212838 ("Nguyen '838 Publication")
2006	U.S. Patent No. 9,358,086 ("Hirsch '086 Patent")
2007	U.S. Patent Publication No. 2015/0335409 ("Hirsch '409 Publication")
2008	U.S. Patent Publication No. 2009/0274991 ("Black Publication")
2009	U.S. Patent Publication No. 2018/0153637 ("Al-Shawi")
2010	U.S. Pat Pub. No. 2017/0156832 ("Reyes")
2011	First Case Management Order, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 20 (Apr. 22, 2025)

2012	Docket Navigator Statistics, Western District of Michigan
2013	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Invalidity Contentions Cover Pleading, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025
2014	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Invalidity Contentions Claim Chart for the '217 Patent, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025
2015	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Non-Infringement Contentions, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025
2016	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Stipulation of Invalidity Contentions, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV (W.D. Mich. Aug. 20, 2025)
2017	Zyris, Inc. Virtual Patent Marking, https://www.zyris.com/patents/ (last accessed Aug. 25, 2025)
2018	Plaintiff/Counter-Defendant Solmetex, LLC's Opposition to Ascentcare's Motion to Stay, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 41 (Jul. 25, 2025)
2019	DryShield User Guide (https://solmetex.com/wp-content/uploads/2023/10/dryshield_userguide_RevE_6x9_FINAL.pdf)
2020	Declaration of Michael Jobin
2021	<i>Curriculum vitae</i> of Michael Jobin
2022	Excerpt from the '217 Patent's Certified File History

2023	Agreed-Upon Constructions, Exhibit B to Solmetex, LLC's Opening Claim Construction Brief, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 62 (Oct. 10, 2025)
2024	Disputed Constructions, Exhibit C to Solmetex, LLC's Opening Claim Construction Brief, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 62 (Oct. 10, 2025)

Solmetex, LLC ("Patent Owner") submits this Preliminary Response under 37 C.F.R. § 42.207 to the Petition for *Inter Partes* Review ("Petition") of U.S. Patent No. 11,823,217 ("the '217 Patent"), filed by Ascentcare Dental Products, Inc. ("Petitioner" or "Ascentcare").¹

I. INTRODUCTION

Patent Owner respectfully requests that the Board deny institution because Petitioner has not shown any challenged claim of the '217 Patent is unpatentable in relation to any ground raised in the Petition. As an initial matter, each of the references relied upon the Petition (Nguyen, Black, and Hirsch) was considered during prosecution of the '217 Patent. In fact, Nguyen (the primary reference in Grounds 1-3) and Hirsch (the secondary reference in Ground 3) were applied in multiple rejections during prosecution and overcome.

Petitioner did not meet its burden for Grounds 1-2, which rely on Nguyen and Black, for at least three reasons. First, Petitioner and its expert, Dr. Black, who is Black's author, repeatedly mischaracterize Black's teachings. For example, Petitioner argues that Black teaches that an "open-sided" mouthpiece is

¹ The Board granted a good cause extension for this Preliminary Response due to a medical emergency. Paper 7; Paper 9. Patent Owner thanks the Board for its understanding.

advantageous over a “closed-sided” mouthpiece. Black does not disclose this. Instead, the cited portion of Black is merely comparing one of Black's embodiments against the others and does not support Petitioner's assertion. As another example, Dr. Black claims that Black teaches that prior art dental isolation mouthpieces, including Black, opted for an “open-sided” design because this was easier to clean than a “close-sided” design. But Black again does not support this assertion because Black is directed to a disposable mouthpiece and that is not cleaned.

Second, Petitioner failed to show that a POSITA would modify Nguyen to either (1) increase suction or (2) allow for easier cleaning. Regarding suction, Petitioner speculates that Nguyen's mouthpiece would bend due to forces from the patient's mouth tissue and that this would impede suction. But there would have to be significant bending of the mouthpiece to cause the flow restrictions Petitioner suggests, and the evidence shows that this does not occur. Regarding cleaning, Petitioner provides no evidence that one would modify Nguyen's autoclavable mouthpiece to make manual cleaning “easier,” especially because Nguyen already has an open slit specially designed for this very purpose.

Third, independent claims 1 and 17 both recite a “connector” that connects the anterior wall to the posterior wall. Claim 17 adds that the “connector” connects the anterior and posterior walls “within the interior space.” Petitioner and Dr. Black disregard this additional requirement in claim 17, and their analysis for claim 1

points to a structure on the *outside* (not the inside) of Nguyen's mouthpiece as the claimed "connector."

Petitioner did not meet its burden for Ground 3, which relies on Nguyen and Hirsch and the same alleged motivations to modify Nguyen as Ground 1, for at least the same reasons discussed above. Additionally, in Ground 3, Petitioner argues that a POSITA would have modified Nguyen to include "anti-collapse structure" at the edges because Hirsch teaches that the edges would otherwise collapse and form an undesirable seal. But Hirsch actually teaches the opposite: Hirsch intentionally creates this seal at the edges of the mouthpiece and certainly does not suggest adding an "anti-collapse structure" to prevent sealing. Hirsch therefore teaches away from Petitioner's proposed modification to Nguyen.

II. OVERVIEW OF THE '217 PATENT

The '217 Patent discloses and claims a dental appliance often referred to as a dental isolation mouthpiece. EX1001, 1:15-17; EX2020, ¶55. The specification acknowledges that at the time of the inventions, "[v]arious mouthpieces" were "used by dental health professional, dental hygienists, and dental assistants in the field of dentistry." EX1001, 1:21-25; EX2020, ¶56. Prior to such mouthpieces, dental patients were typically "treated by a two-person team (e.g., a dental professional and a dental assistant)" using different equipment, including "an intraoral mirror, a bite block, a slow speed suction ejector, a high speed suction ejector, gauzes, cotton rolls,

and dry angles.” EX1001, 1:23-30. The dental assistant's role was to assist “in coordinating the use of these multiple items of different equipment and materials.” EX1001, 1:35-38.

The inventors of the '217 Patent recognized “a need in the art for improved systems and methods of providing dental services in a more efficient, comfortable, and safe manner to the dental patient.” EX1001, 1:39-41; EX2020, ¶57. To that end, the '217 Patent discloses and claims various dental isolation mouthpieces. For example, FIG. 1 illustrates an exemplary mouthpiece including a main body portion 102, suction connector portion 108, cheek retractor portion 110, and bite block 101. EX1001, 2:52-65; EX2020, ¶57.

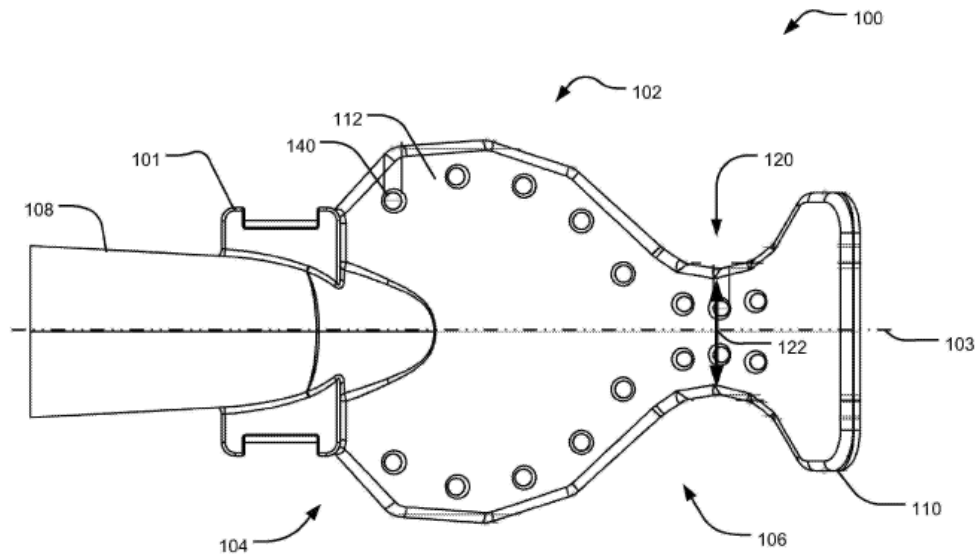
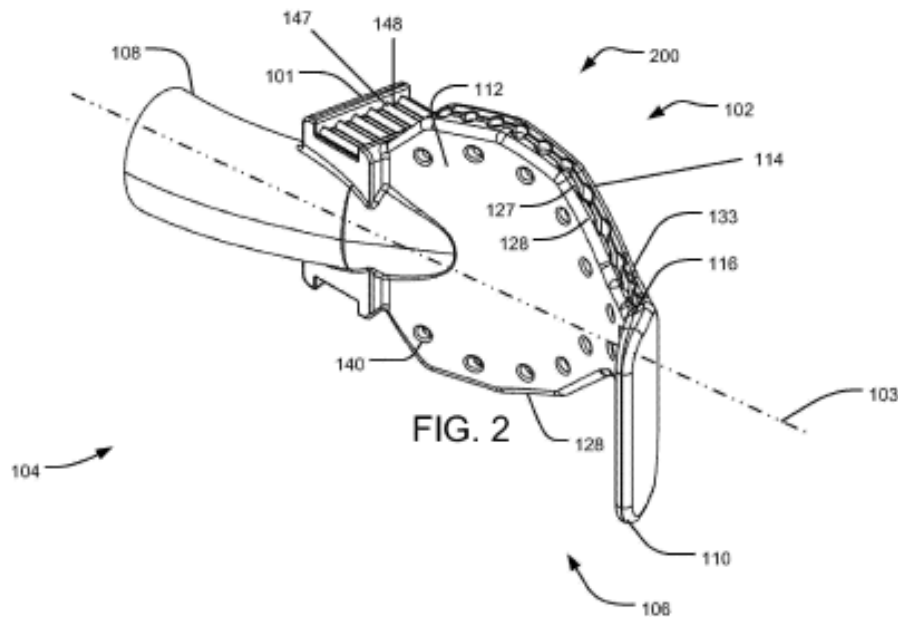


FIG. 1

EX1001, FIG. 1

As shown in FIG. 2, “the main body portion 102 may be shaped in a curve” and “[b]ecause the mouthpiece is made of a flexible and resilient material (e.g., thermoplastic elastomer), the mouthpiece 100 may be bent when placed in a patient’s mouth to conform to the shape of the mouth.” EX1001, 3:24-28.



EX1001, FIG. 2

“When properly positioned, the suction connector portion 108 may protrude from one side of the patient’s mouth, while the main body portion 102 lies against the back of the patient’s mouth, and the cheek retractor portion 110 presses against the patient’s cheek on the opposite side of the patient’s mouth.” EX1001, 3:29-34; EX2020, ¶58. The specification teaches that “[d]ifferently-sized mouthpieces may be provided for differently-sized mouths of adults and children” to ensure a proper fit. EX1001, 4:1-3; EX2020, ¶67.

The main body portion 102 may include “an anterior wall 112 on an inner part of the curve and a posterior wall 114 ... on an outer part of the curve.” EX1001, 3:52-54; EX2020, ¶59. In use, the anterior wall 112 “face[s] a front of the patient’s mouth” while the posterior wall 114 “face[s] a back of the patient’s mouth.” EX1001, 3:54-57; EX2020, ¶59. Additionally, “[w]hen 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, 4:6-13; EX2020, ¶59. The main body portion 102 may also include openings on the anterior wall 112 and/or posterior wall 114 to “allow for suction of air, fluids, and small debris from the patient’s mouth through the openings 140 and into the interior space 126, and into the suction connector portion 108 towards a suction source.” EX1001, 4:14-20; EX2020, ¶60.

The ‘217 Patent further discloses an anterior intervening wall 127 that “may extend from at least one edge 128 of the anterior wall 112 partially towards the posterior wall 114,” as shown below in FIG. 6. EX1001, 6:20-24; EX2020, ¶61.

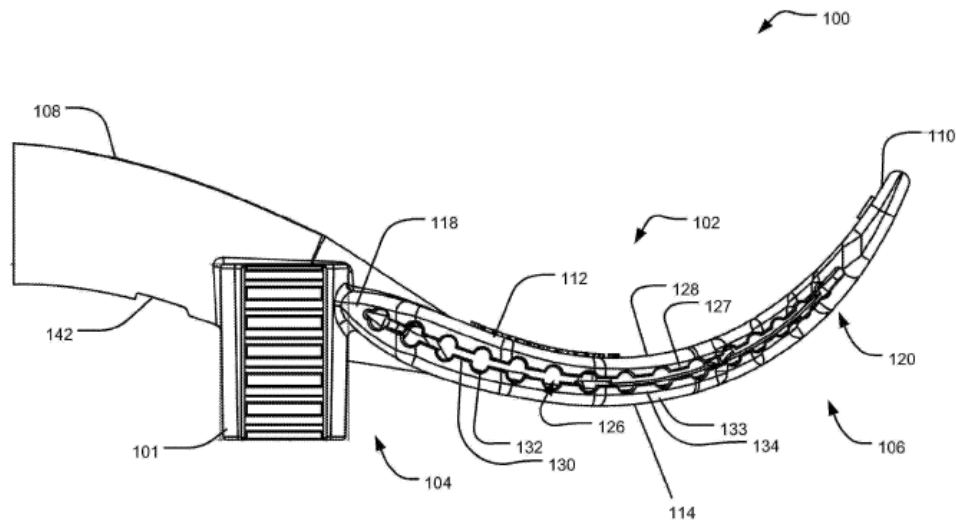


FIG. 6

EX1001, FIG. 6

The anterior intervening wall “may further be ridged in some embodiments,” for example, the anterior intervening wall 127 can include “an alternating crest 130 and trough 132.” EX1001, 6:31-35; EX2020, ¶61. These crests and troughs “may provide further retraction, stability, support, and curvature to the mouthpiece 100.” EX1001, 6:42-44; EX2020, ¶61.

The mouthpieces disclosed in the ‘217 Patent may also include a posterior intervening wall 134 “that extends from at least one edge 133 of the posterior wall 114 and partially extends toward the anterior wall 112.” EX1001, 6:45-48; EX2020, ¶62. The posterior intervening wall 134 “may likewise exhibit ridges that are the same, a mirror image, or different from the anterior intervening wall 127.” EX1001, 6:48-50; EX2020, ¶62. An open mesh configuration between the anterior and

posterior intervening walls “allows for suction of air, fluids, and small debris from the patient’s mouth, through the mesh into the interior space 126 and into the suction connector portion 108 towards a suction source.” EX1001, 6:59-64; EX2020, ¶62.

FIG. 7 of the ‘217 Patent shows the anterior wall of the mouthpiece pulled away from a posterior wall of the mouthpiece. EX1001, 7:8-10; EX2020, ¶63.

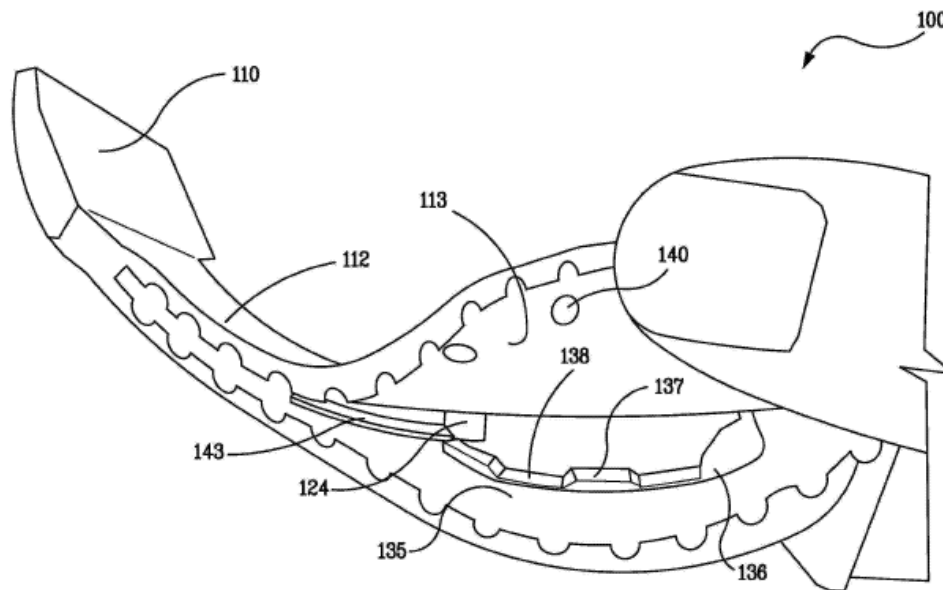


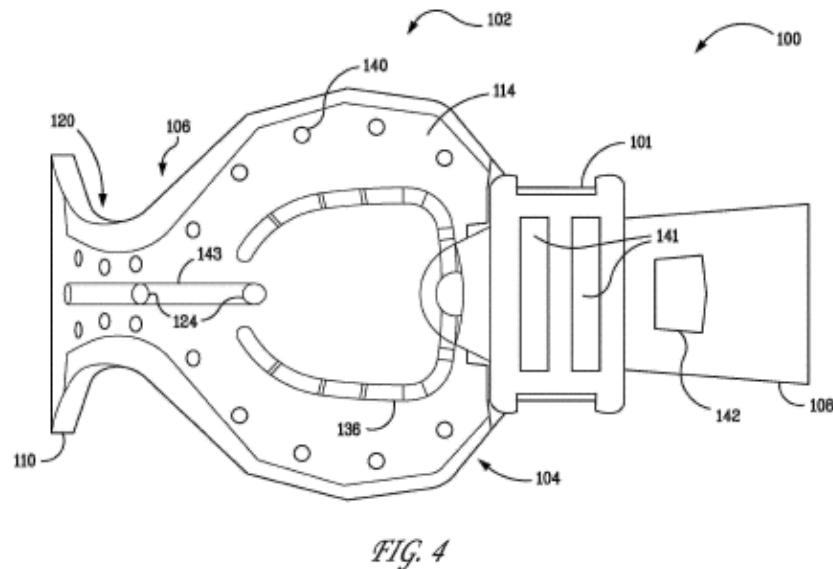
FIG. 7

EX1001, FIG. 7

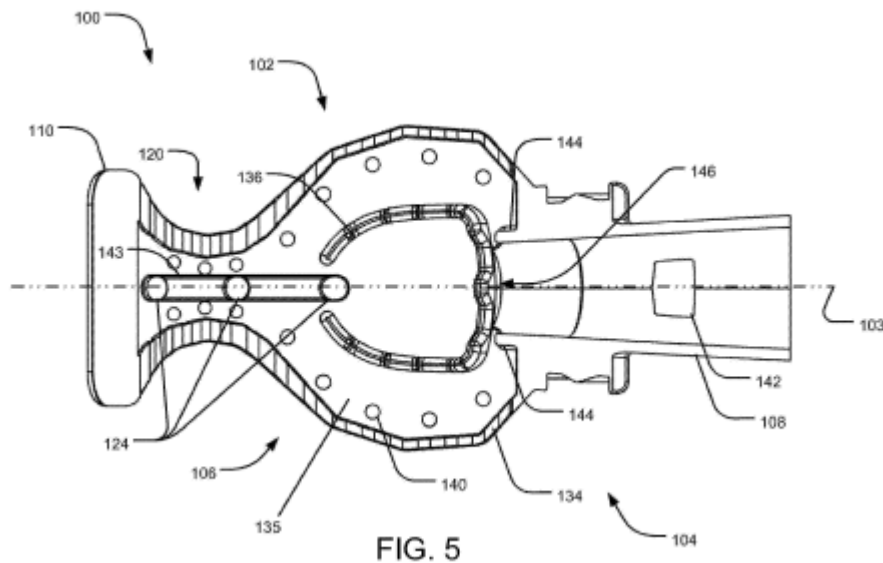
Thus, the mesh created by the ridged configuration at the edges of the anterior and posterior walls (through which the suctioning of fluids and debris occurs) can be opened, which the ‘217 Patent refers to as “open mesh” EX1001, 6:59-64.

The ‘217 Patent also discloses and claims a “connector” feature. EX2020, ¶64. For example, the “anterior wall 112 and the posterior wall 114 may be connected to each other ... by at least one connector 124.” EX1001, 4:55-57. The connector 124

may be used to “provide structural rigidity to the mouthpiece 100 and may be a pillar, column, wall, or the like.” *Id.*, 7:15-17. “In one example, the at least one connector 124 is a rib that extends from the main body portion 102, through the neck 120, and to the cheek retractor portion 110.” *Id.*, 8:24-27. An exemplary connector 124 can be seen in FIGS. 4-5 (reproduced below), as well as FIG. 7:



EX1001, FIG. 4



EX1001, FIG. 5

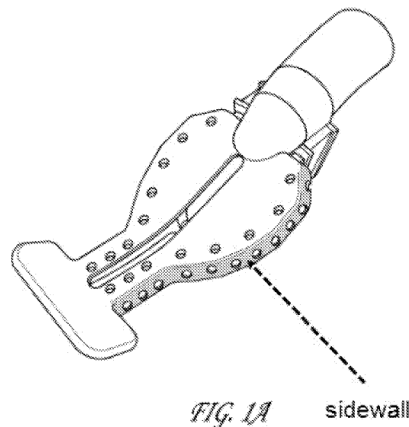
The '217 Patent further discloses a “bridge structure” feature, which is shown above in FIGS. 4-5, for example. EX2020, ¶65. In one embodiment, the bridge structure 136 protrudes “from the interior surface 135 in a wave shape with bridge crests 137 and bridge troughs 138.” EX1001, 5:6-20. When suction is applied, “[t]he bridge crests contact the anterior wall 112 during suction to keep the anterior wall 112 spaced away from the posterior wall 114 during suction, thereby preventing collapse of the anterior wall 112 of the posterior wall 114 into the interior space 126 so that debris and/or water can be evacuated through the interior space 126.” *Id.*, 5:32-38. “[T]he bridge troughs 138 provide gaps that allow for suction of air, fluids, and small debris through the bridge structure 136.” *Id.*, 5:38-40.

III. SUMMARY OF PETITIONER'S REFERENCES

A. Nguyen (EX1005) (Grounds 1-3)

Nguyen is directed to “intraoral dental suction and isolation mouthpieces” and lists two the same named inventors as the ‘217 Patent. EX1005, 1:16-17, Cover; EX1001, Cover. Nguyen and its corresponding publication (EX2003) were considered during prosecution of the ‘217 Patent. EX1015, 92-93. In fact, Nguyen or its corresponding publication was applied in at least three rejections during prosecution of the ‘217 Patent. *See* EX1015, 53-56, 262-77; EX1016, 237-39.

The Examiner found that Nguyen discloses (1) “a main body portion” including anterior and posterior walls; (2) “a suction connector portion”; (3) a “cheek retractor”; and (4) “a side wall . . . that extends along the edge of both the anterior and posterior wall.” *Id.*, 264-65 (rejection for claim 1); *see also id.*, 272 (same for claim 19). The Examiner annotated the “sidewall” Nguyen as shown below:



EX1015, 265 (annotating EX1005, FIG. 1A).

But the Examiner acknowledged that Nguyen did not disclose all limitations of the pending claims, including the “intervening wall” feature with “alternating crests and troughs”:

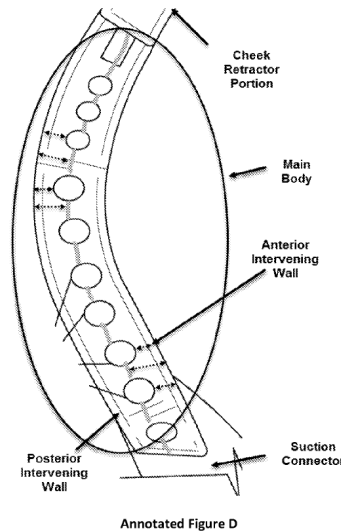
Nguyen is silent to the sidewall being made from an at least one anterior intervening wall extending along an edge of the anterior wall partially across the distance towards the posterior wall, and at least one posterior intervening wall extending along an edge of the posterior wall partially across the distance towards the anterior wall, the at least one anterior intervening wall and the at least one posterior intervening wall each having alternating crests and troughs.

EX1015, 265-66 (rejecting claim 1); *see also id.*, 272 (asserting the same for claim 19). For these limitations, the Examiner applied Al-Shawi (EX2009) and asserted that it discloses “suction conduits . . . formed by two half-walls (401, 402) having mating projections (422) . . . with interspaced flow channels form crest and trough shapes on the two mating half-walls (401, 402) that extend toward each other and abut each other to provide the flow channels within the device.” *Id.*, 266 (rejecting claim 1); *see also id.*, 272 (same for claim 19).

The Examiner then asserted that it would have been obvious to open Nguyen's sidewall and to create two abutting sidewalls with crests and troughs:

It would have been obvious to someone skilled in the art before the effective filing date to modify the single solid sidewall of Nguyen to be made from two abutting anterior and posterior sidewalls with complementary mating and abutting crests and troughs to form the flow channels as taught by Al-Shawi in order to use an alternative sidewall arrangement shown in the prior art which would yield predictable results of forming flow channels through a double walled suction device.

EX1015, 266 (claim 1); *id.*, 272 (same for claim 19). The Examiner illustrated how Nguyen's single sidewall would be modified to open it to create abutting anterior and posterior intervening walls with crests and troughs:



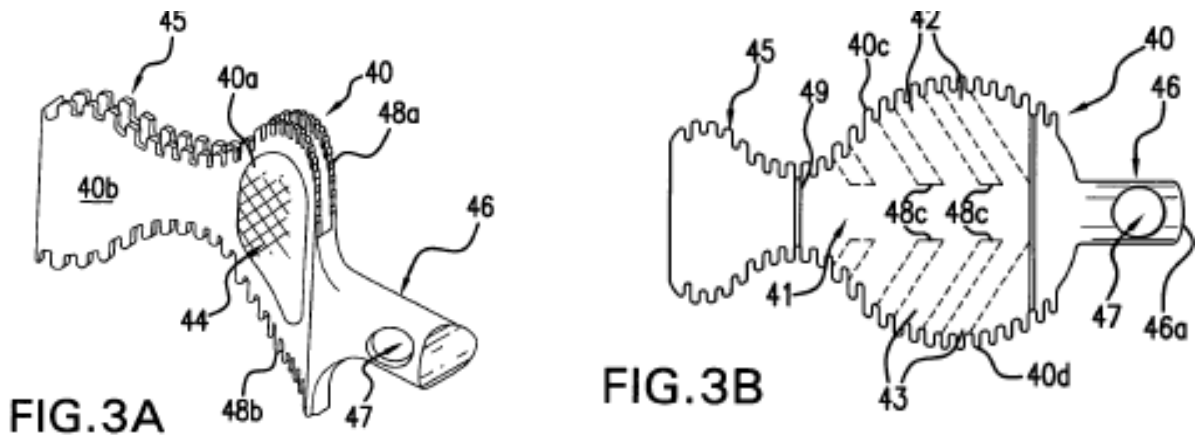
EX1015, 269 (annotating EX1005, FIG. 1D)

In response, Applicant argued, among other things, that “there is no motivation that would have led a person having ordinary skill in the art to combine the teachings of Al-Shawi with Nguyen to arrive at the claimed ‘dental mouthpiece.’” *Id.*, 195-96. The Examiner subsequently withdrew the § 103 rejections using Nguyen as the primary reference. EX1016, 239.

B. Black (EX1007) (Grounds 1-3)

Black (U.S. Pat. No. 8,029,280) and the corresponding publication (U.S. Pub. No. 2009/0274991, “Black Publication,” EX2008) were cited in an IDS and were considered by the Examiner during prosecution. EX1015, 92-93. 88.

Black describes multiple embodiments of an intraoral device including a tongue shield aspirator, a bite member, a bite grip, and an evacuation tube. EX1007, Abstract; EX2020, ¶88. In one embodiment, a tongue shield aspirator 40 includes “a first (posterior) layer 48a and a second (anterior) layer 48b which are connected to, but spaced apart from, one another by transverse walls 48c.” EX1007, 5:55-60; EX2020, ¶¶89-90. The transverse walls 48c (which are shown in dashed lines in FIG. 3B below) connect the first layer 48a to the second layer 48b. *Id.*



EX1007, FIGS. 3A-3B

In another embodiment, tongue shield aspirator 340 includes “a first (posterior) layer 348a and a second (anterior) layer 348b which are connected to, but spaced apart from, one another by transverse walls 348c (shown in phantom in FIG. 23A).” EX1007, 14:25-30; EX2020, ¶¶91-92. Like the prior embodiment, the transverse walls 348c are angled relative to the longitudinal (central) axis of the tongue shield aspirator 340, as shown below:

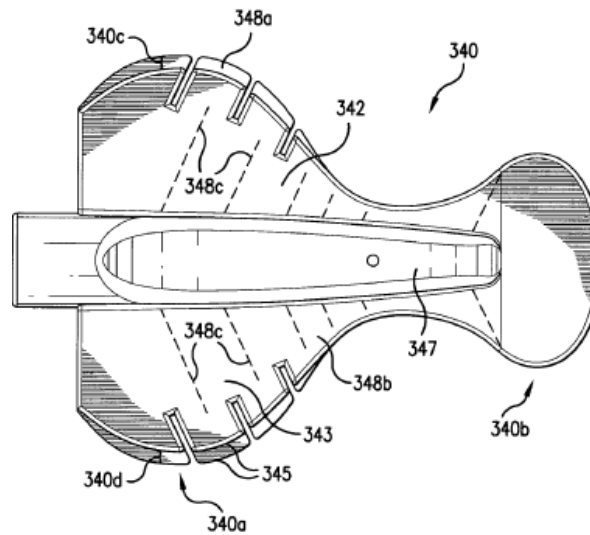


FIG. 23A

EX1007, FIG. 23A

FIG. 23C shows a side view of the tongue shield aspirator 340, including the transverse walls 348c connecting the first layer 348a and the second layer 348b, and the channels 342 between adjacent transverse walls 348c. EX2020, ¶93.

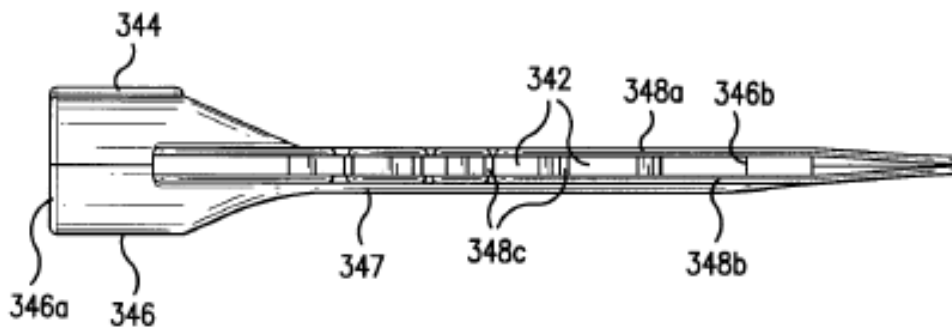
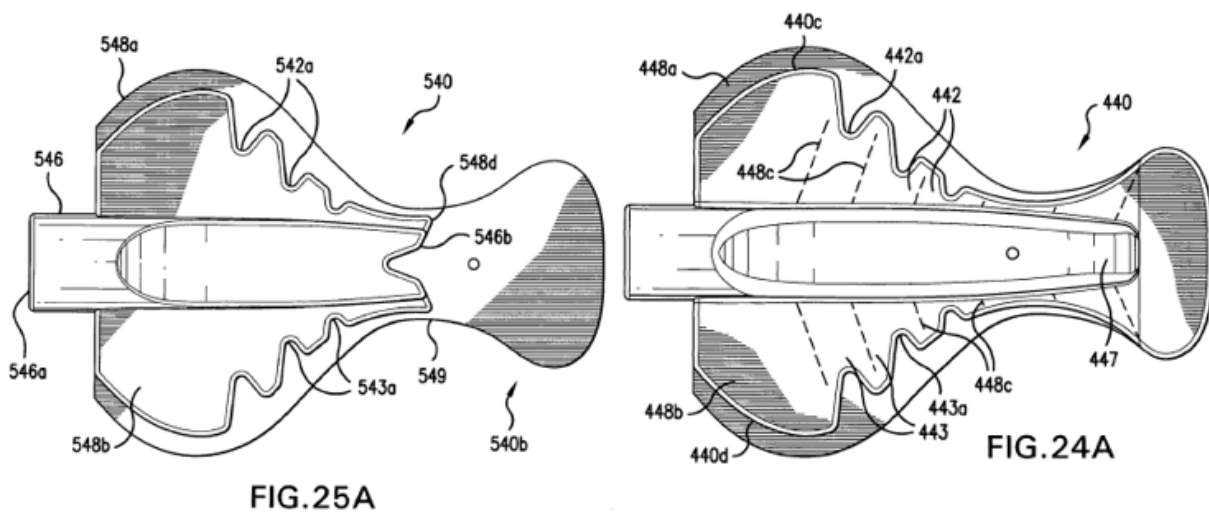


FIG. 23C

EX1007, FIG. 23C

Black discloses additional embodiments in FIGS. 24 and 25. EX2020, ¶94.



EX1007, FIGS. 24A and 25A

Black teaches that the tongue shield aspirators disclosed in the various embodiments “may be made of disposable material.” EX1007, 9:23-28; EX2020, ¶95. Black states that the bite member or evacuation tube are “re-usable (autoclavable),” but does not suggest that the tongue shield aspirators are reusable, autoclavable, or cleaned. EX1007, 9:50-52, 10:34-39, 19:35-38 (referring to bite member and evacuation tube, but not the tongue shield aspirator, as “[t]he autoclavable components of the device”); EX2020, ¶95.

C. Hirsch (EX1006) (Grounds 2-3)

Hirsch is a continuation of U.S. Patent No. 9,358,086 (“Hirsch ‘086 Patent”), which was published as U.S. Patent Publication No. 2015/0335409 (“Hirsch ‘409 Publication”), both of which were cited in an IDS and considered by the Examiner. EX2006; EX2007; EX1015, 92-93. Petitioner acknowledges that Hirsch (EX1006)

and the Hirsch '409 Publication are substantively the same when it admits that "Hirsch" was used in rejections during prosecution. Petition, 20-21; EX1016, 230-39, 340.

Hirsch describes "dental appliances for vacuum suction of the mouth of a dental patient for examination and/or operative purposes." EX1006, 1:13-15; EX2020, ¶96. Hirsch's mouthpiece is "disposable after each use." EX1006, 3:1-2. The mouthpiece is designed such that when suction is applied, the upper front flap 310 and the upper rear flap 320 "create a substantial seal along the upper edges 370, 380" except "for the V-shaped grooves 416." EX1006, 4:45-55; EX2020, ¶97. There is also a "seal along lower edges 390, 400." EX1006, 4:58-67.

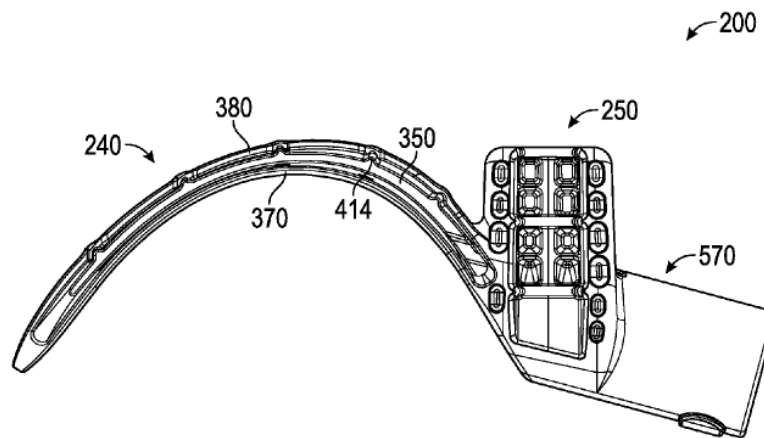


FIG. 9

EX1006, FIG. 9

IV. LEVEL OF SKILL IN THE ART

Petitioner proposes the following definition for a POSITA in relation to the '217 Patent:

a PHOSITA, at the time the '217 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.

Petition, 21. For purposes of this Preliminary Response, Patent Owner adopts Petitioner's proposed level of skill in the art. EX2020, ¶¶83-85.

V. CLAIM CONSTRUCTION

The Petition proposes one term for construction and states that "[u]nless otherwise addressed herein, the terms of the '217 Patent's claim are to be given their plain and ordinary meaning as understood by one of ordinary skill in the art." Petition, 21. For purposes of this Preliminary Response, the Board need not resolve any claim construction disputes from the Paralell Litigation to find that Petitioner failed to meet its burden. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

A. "partially across the distance of the interior space" (claims 1-23)

Petitioner argues that the phrase "partially across the distance of the interior space," which appears in independent claims 1 and 17, should be construed to mean

“only partly, and not entirely, across the distance of the interior space.” Petition, 22-23. Patent Owner applies Petitioner's proposed construction for purposes of this Preliminary Response. EX2020, ¶¶100-01; EX2023.

B. Other District Court Constructions

The parties have proposed the following constructions for claim 17 of the '217 in the Parallel Litigation:

Term/Phrase	Petitioner's Construction	Patent Owner's Construction
“main body portion”	The portion of the mouthpiece between, but not including, the cheek retractor portion and the suction connector and mouth prop, if present	Plain and ordinary meaning
“interior space”	A generally open and unobstructed space allowing for suction to flow throughout and having a similar shape as the shape of the anterior and posterior walls	Plain and ordinary meaning

EX2024, 8. While Patent Owner disagrees with Petitioner's proposed constructions, Patent Owner submits that the Board need not resolve these disputes to deny institution. *Nidec*, 868 F.3d at 1017; EX2020, ¶¶102-05.

VI. PETITIONER FAILED TO MEET ITS BURDEN

The Board should deny institution because Petitioner has not met its burden of showing a reasonable likelihood that any claim of the '217 Patent is unpatentable for any of the grounds in the Petition.

A. Ground 1: Alleged Obviousness Based on Nguyen and Black (Claims 1-11 and 13-23)

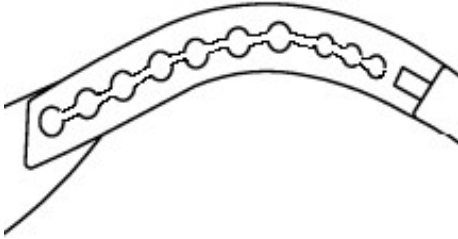
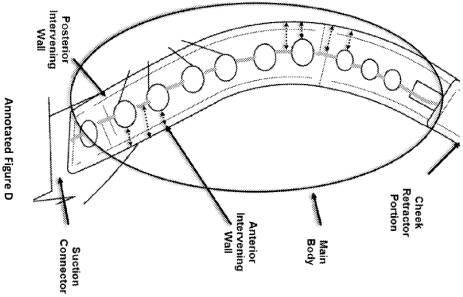
In Ground 1, Petitioner argues that claims 1-11 and 13-23 of the '217 Patent are obvious over Nguyen in view of Black. Petition, 28-53. For the reasons discussed below, Petitioner failed to meet its burden.

1. Petitioner Failed to Meet its Burden for Claim 1

Petitioner admits that Nguyen does not disclose “an anterior intervening wall” or “a posterior intervening wall” that extends “along an edge of the anterior[/posterior] wall” and “extends partially across the distance of the interior space towards the posterior[/anterior] wall” as recited in limitation 1(d). Petition, 33; EX2020, ¶¶108-09. Indeed, this is consistent with the Examiner's findings regarding Nguyen during prosecution. EX1015, 265-66, 272.

In an attempt to address this deficiency, Petitioner argues that “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.” Petition, 33. Petitioner's proposed modification in view of Black is nearly identical to the Examiner's proposal during prosecution “to

modify the single solid sidewall of Nguyen to be made from two abutting anterior and posterior sidewalls with complementary mating and abutting crests and troughs to form the flow channels.” EX1015, 266; EX2020, ¶¶110-11.

Petitioner's Proposed Modification to Nguyen	The Examiner's Proposed Modification to Nguyen
 Petition, 43 (modifying EX1005, FIG. 2D)	 EX1015, 269 (modifying EX1005, FIG. 2D)

In response to this rejection, the Applicant argued, among other things, that “there is no motivation that would have led a person having ordinary skill in the art to combine the teachings of Al-Shawi with Nguyen to arrive at the claimed ‘dental mouthpiece.’” EX1016, 195-96; EX2020, ¶112. The Examiner withdrew the rejection in the next Office Action and eventually allowed the claims over Nguyen and Black. EX1016, 237 (withdrawing Nguyen rejection), 337-42 (Notice of Allowance).

Nothing in the Petition warrants a different result from the Examiner's findings regarding Nguyen and Black during prosecution. Petitioner's reliance on Black is flawed because Petitioner and its expert mischaracterize Black's teachings.

Petitioner has also failed to show that a POSITA would have been motivated to modify Nguyen for “improved suction” or to make cleaning “easier.” Petitioner’s alternative “duplication of parts” fails because it is conclusory, unsupported, and does not address all of the limitations in claim 1 of the ‘217 Patent.

a) Petitioner and Dr. Black Mischaracterize Black’s Teachings

Petitioner and Dr. Black rely on alleged teachings in Black as purportedly providing motivation to modify Nguyen to arrive at the claimed inventions. *See* Petition, 33-42; EX1003, ¶¶69, 71-72, 77, 80-83. These arguments are flawed because they mischaracterize Black’s teachings, which do not support Petitioner’s contentions.

First, Petitioner argues that “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.” Petition, 33 (citing EX1007, 17:47-54). Dr. Black takes this argument a step further and claims that “[a]s I explain in my patent [Black], an open-sided mouthpiece provides advantages over a closed-sided dental mouthpiece, like Nguyen. For example, open-sided mouthpieces provide increased aspiration of fluid/debris and bend more easily to fit inside a patient’s mouth.” EX1003, ¶69 (citing EX1007, 17:47-54). Contrary to these suggestions, Black does *not* teach that “open-sided” mouthpieces have advantages over “closed-sided” mouthpiece. EX2020, ¶116.

The portion of Black cited by Petitioner and Dr. Black for this alleged teaching is reproduced in full below:

Thus, in the embodiment shown in FIGS. 25A-25D, the tongue shield aspirator 540 is open in the sense that, in addition to the upper and lower edges of the tongue shield, the distal end of the passageway is also open to, or in communication with, the patient's oral cavity. This provides various advantages, including enhanced fluid and debris aspiration, as well as facilitated bending at or around the transition section 549.

EX1007, 17:47-54. Here, Black is describing the embodiment shown in FIGS. 25A-25D, which differs from the other embodiments (e.g., the one shown in FIG. 24A) in that “the anterior layer 548b is longitudinally shorter than the posterior layer 548a.” EX1007, 17:29-38; EX2020, ¶¶117-18.

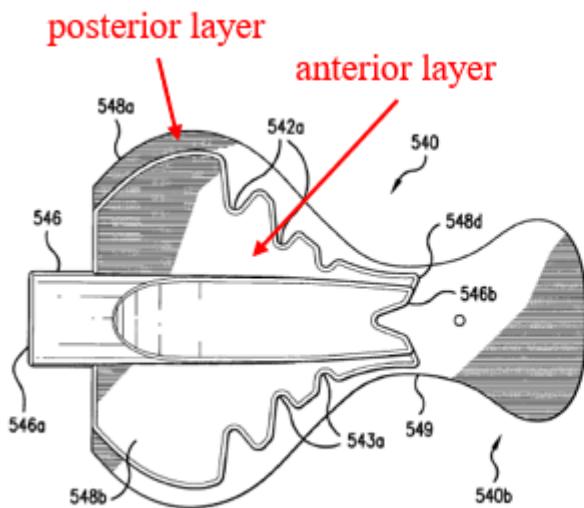


FIG. 25A

FIG. 25 Embodiment

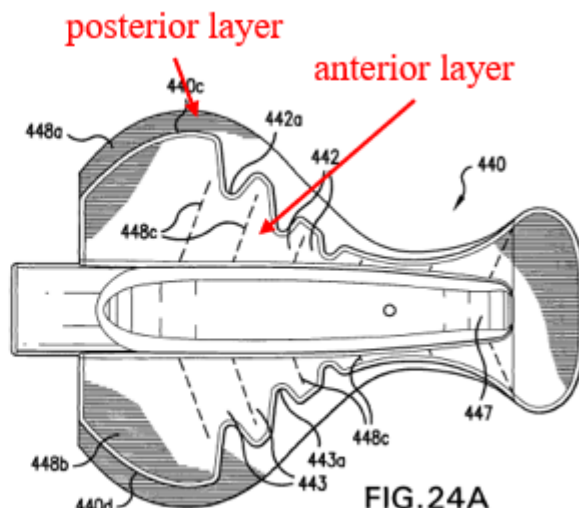
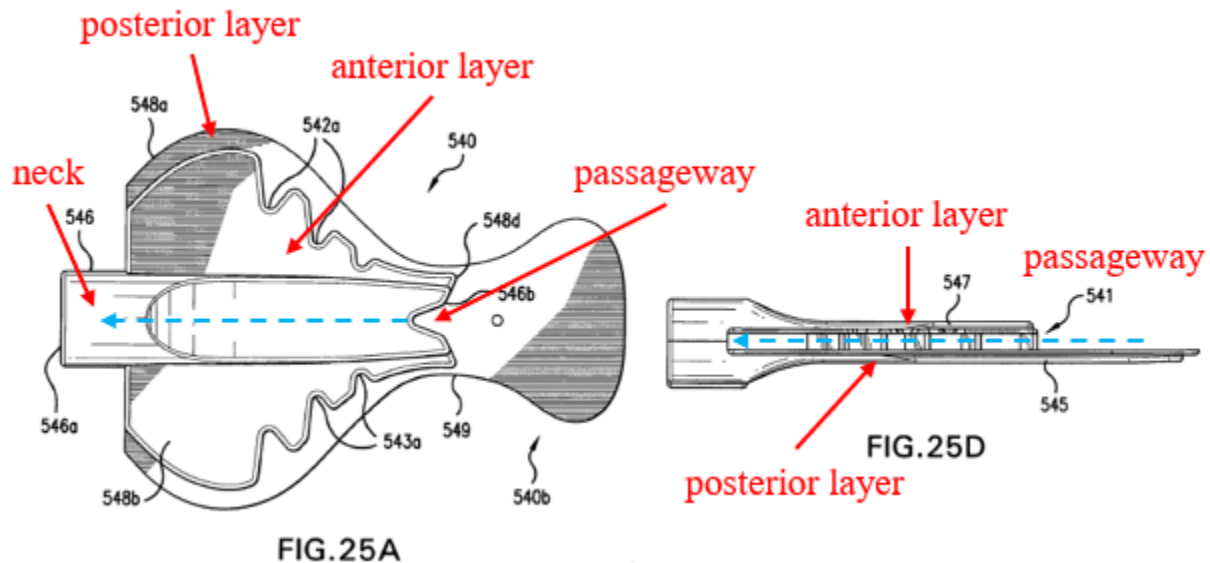


FIG. 24A

FIG. 24 Embodiment

The FIG. 25 embodiment includes “a hollow neck 546” with a passageway 541 that “extends from a distal end 546b, through the proximal flap 540a, and through the proximal end 546a of the neck 546.” EX1007, 17:39-44; EX2020, ¶119.

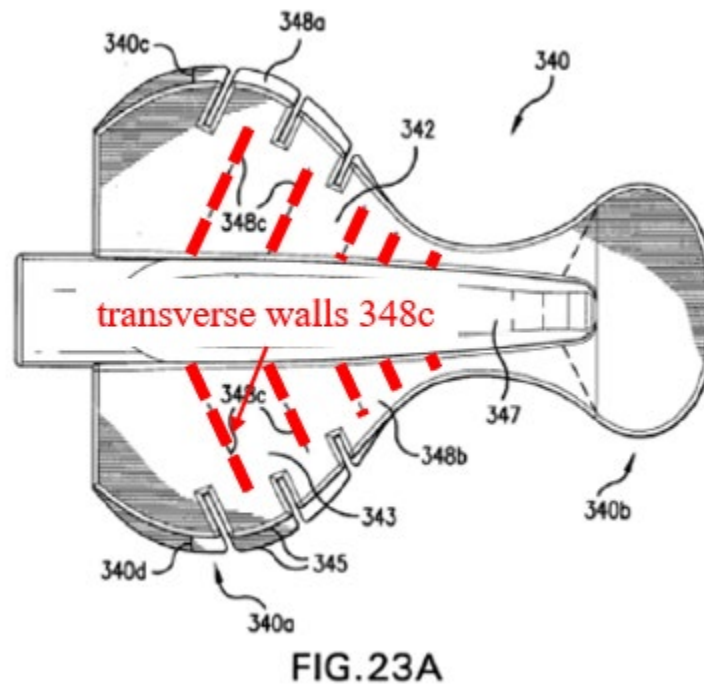


EX1007, FIGS. 25A and 25D (annotated)

Black's discussion of the FIG. 25 embodiment does **not** teach that “open-sided” mouthpieces have advantages over “closed-sided” mouthpieces. EX2020, ¶120. Rather, Black merely states that the alternative embodiment in FIG. 25 provides more suction and bending compared to the **other embodiments described in Black** (not compared to “closed-sided” mouthpieces) because it includes an additional passageway for fluid and debris aspiration. *Id.*; EX1007, 17:47-54.

Second, Petitioner claims that “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.” Petition, 40

(citing EX1007, 14:21-47, FIG. 23A; EX1003, ¶81). Dr. Black similarly asserts “Black teaches that anti-collapse structure is necessary at edges of the anterior wall.” EX1003, ¶81. Petitioner and Dr. Black are incorrect. As shown below in FIG. 23A of Black, the transverse walls 348c do **not** extend “all the way to the edge of the anterior flap 438b.” EX2020, ¶¶121-22.



EX1007, FIG. 23A (annotated)

Further, contrary to Dr. Black's suggestion, Black does not teach or suggest that the transverse walls 348c are “anti-collapse structure” or that structure is required at the edges to prevent collapse. EX2020, ¶123.

The Board should find that Petitioner failed to meet its burden because Ground 1 is premised on Black for allegedly teaching (1) that “open-sided” mouthpieces

have advantages over “closed-sided” mouthpieces and (2) an “anti-collapse structure” is required at the edges of an “open-sided” mouthpiece even though Black does not contain either teaching. Black simply does not support either of these contentions.

b) Petitioner Has Not Shown That a POSITA Would Have Been Motivated to Modify Nguyen

Petitioner offers two reasons why one would allegedly “open the sidewalls of Nguyen,” including (1) “to increase[] suction” and (2) “to make it easier to clean.” Petition, 33-34. As discussed below, Petitioner has not shown that a POSITA would have been motivated to modify Nguyen to arrive at the claimed inventions for either of these reasons.

i. A POSITA Would Not Have Been Motivated to Modify Nguyen to “Increase Suction”

Attempting to identify an alleged problem in Nguyen that would allegedly motivate a POSITA to modify the mouthpiece to “increase suction,” Petitioner argues that Nguyen’s mouthpiece “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.” Petition, 34 (citing EX1005, 3:29-31, 3:42-45; EX1007, 19:33-20:47; EX1003, ¶¶70-71). Petitioner also argues that “the force from the ridges of a patient’s gums on the rectangular portion of Nguyen would also cause additional bending/folding.” Petition, 34-35 (citing EX1005, 4:20-30; EX1007,

20:3-20; EX1003, ¶71; EX1005, 1:52-55, 2:2-5). Petitioner and Dr. Black speculate that this bending caused by mouth and gum tissue would impede suction and thereby motivate a POSITA to modify Nguyen to eliminate this issue. Petition, 35-38. These arguments are flawed for several reasons.

First, none of Petitioner's citations to Nguyen support its assertion that a POSITA would recognize that forces from patient's mouth/gum tissue would cause undesirable bending Nguyen's mouthpiece and impede suction. Petition, 34-35 (citing EX1005, 3:29-31, 3:42-25, 4:20-30, 1:52,55, 2:2-5); EX2020, ¶126. The fact that Nguyen describes the mouthpiece as "flexible" does not mean that mouth tissue causes enough bending when placed in the mouth to meaningfully block suction. EX2020, ¶126. Nguyen's references to bending relate to positioning the mouthpiece in the patient's mouth at the start of the procedure, not bending due to forces applied by the mouth once the mouthpiece is in position. EX1005, 2:2-5, 3:29-31; EX2020, ¶126. The illustration below shows how a dental mouthpiece like the one disclosed in Nguyen is bent so that it can be positioned in the mouth:

Placing Mouthpiece

1



Fold tail in towards the center of the mouthpiece.

2



Fold tail and outside edges together towards the center of the mouthpiece with one hand while using the other hand to control the bite block and DS1.

3



Slowly insert in the center of the mouth, lining up the bite block's anterior edge to distal of the canine (For kids, midline of the primary lateral).

4



Release the mouthpiece, allowing the tail and outside edges to fall back into its natural position.

EX2019, 15

Nguyen teaches that “[d]ifferently-sized mouthpieces may be provided for differently-sized mouths of adults and children,” so a POSITA would know that the type of bending problem described by Petitioner would not occur if the mouthpiece were appropriately sized. EX1005, 4:1-3; EX2020, ¶127. This is illustrated in Patent Owner's product literature for its DryShield product, which shows how to select the correct size mouthpiece for a patient:



Too small



Too big

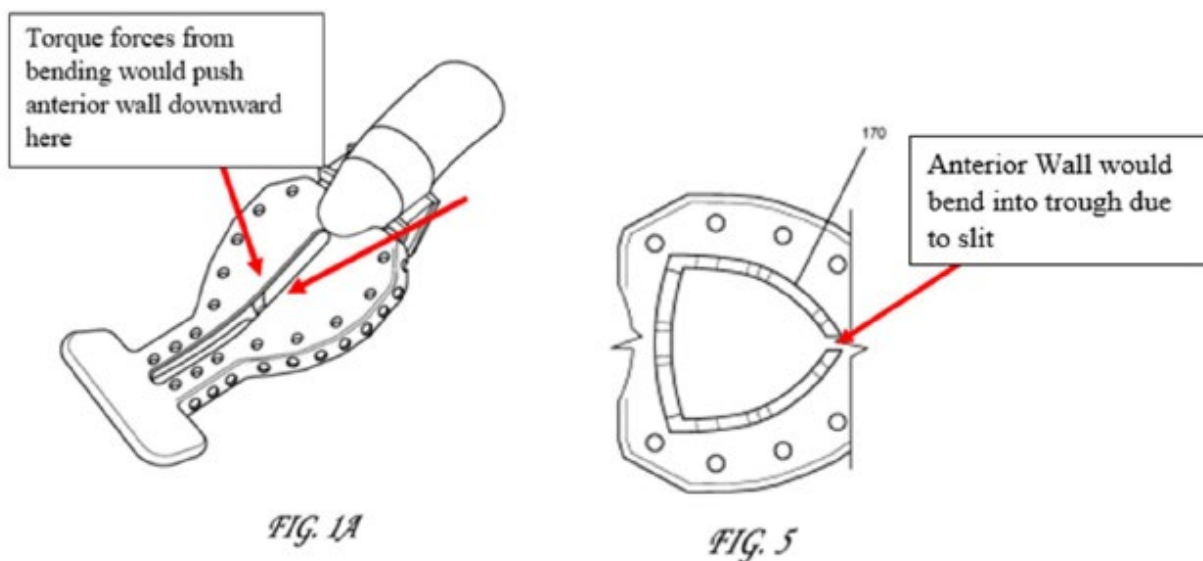


Correct fit

EX2019, 17

As shown above, the mouthpiece may exhibit the type of bending Petitioner describes due to the roof or floor of the mouth if it is too big for the patient's mouth. But if the mouthpiece is correctly sized for the patient, as taught by Nguyen, there would not be significant bending that would impede suction. EX2020, ¶¶128-29; EX1005, 4:1-3.

Speculating that bending of the mouthpiece would impede suction, Petitioner argues that “the anterior wall would first start to bend or crease at the slit 170” and this “would partially block on the channels (troughs) created by the bridge structure 180 and decrease suction.” Petition, 35-36.

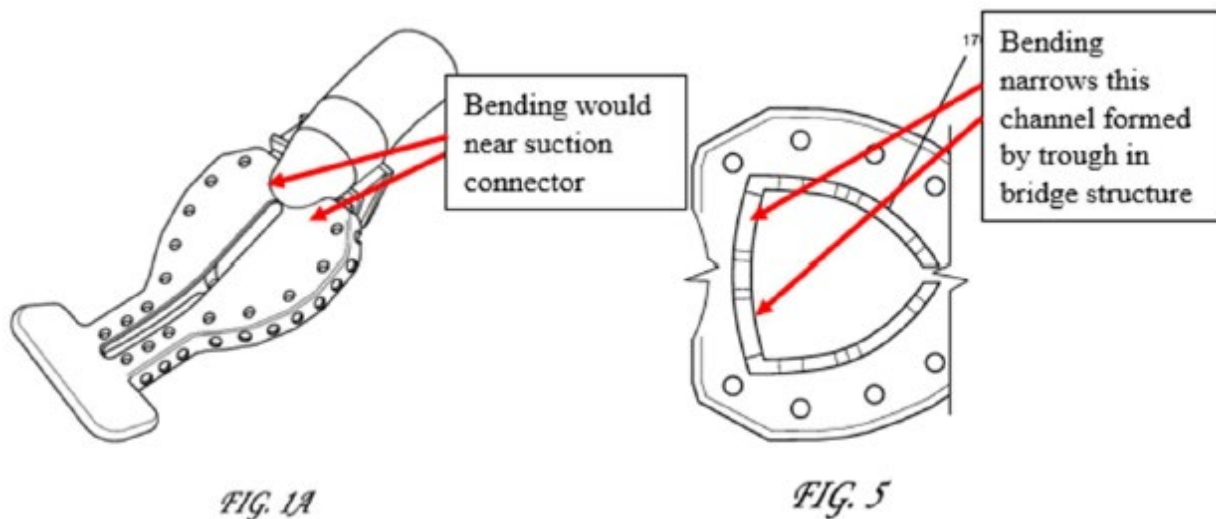


Petition, 36 (annotating EX1005, FIGS. 1A and 5)

However, significant bending would need to occur for there to be any significant blockage, and Petitioner provides no evidence that forces from the mouth/gums

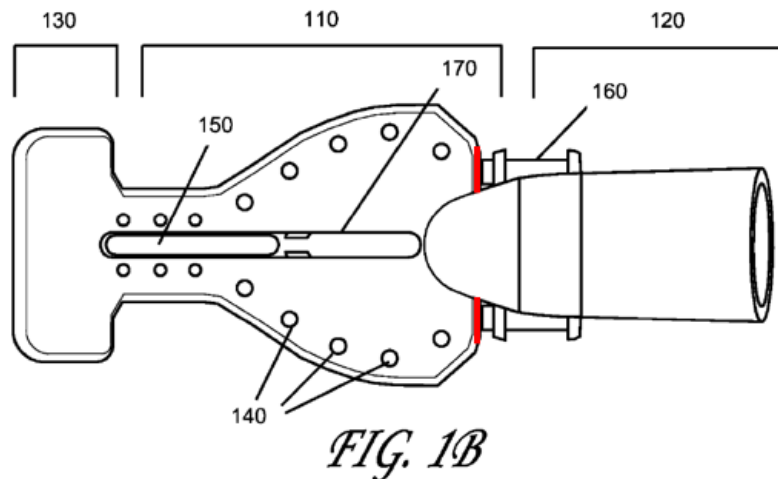
would cause significant bending. EX2020, ¶131. To the extent the mouth/gums do cause some bending, any reduction in suction would be trivial because there are alternate flow paths through the bridge structure. *Id.*

Petitioner also argues that bending would also occur “where the anterior wall meets the suction connector” because “the suction connector comprises a thicker material than the anterior wall, meaning the thinner, weaker, anterior wall would bend short of the suction connector.” Petition, 36.



Petition, 37

This argument ignores Nguyen's teachings that there is additional structure between the posterior and anterior walls near the suction connector, which would reinforce the mouthpiece. EX2020, ¶132.



EX1005, 1B (annotated)

Nguyen discloses that “[p]art of the base side of the arrowhead may be formed with thicker walls than the rest of the main body” and “[s]uch thickening may provide additional stability.” EX1005, 3:59-62; EX2020, ¶132. There is no evidence that significant bending would occur in this area of Nguyen’s mouthpiece.

Second, Black does not support Petitioner’s contentions that Nguyen’s mouthpiece would undesirably bend and block suction when positioned in the mouth (and therefore motivate a modification to Nguyen). Petition, 34-35 (citing EX1007, 19:33-20:47, 20:3-20). Petitioner first cites over a column of text from Black but does not discuss bending caused by vertical displacement from the mouth roof or floor. EX1007, 19:33-20:47; EX2020, ¶126. Petitioner’s other citation discusses bending of the cheek retractor during insertion, not bending due to forces from the roof and floor of the mouth when the mouthpiece is positioned. EX1007, 20:3-20;

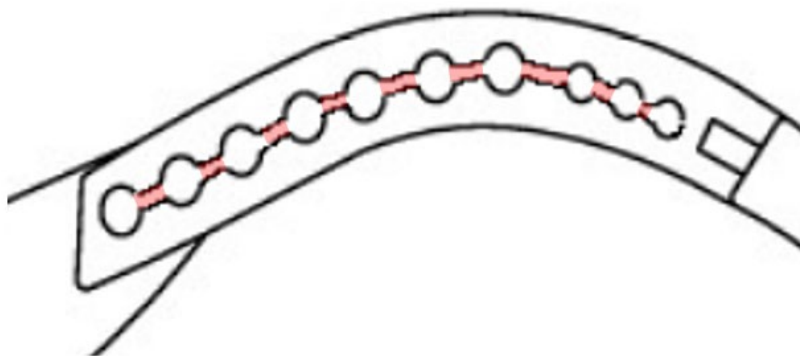
EX2020, ¶126. And like Nguyen, Black describes a “bite member” which “hold[s] the upper and lower jaws separate during dental procedures.” EX1007, 9:28-31.

Petitioner presents no evidence that Nguyen's mouthpiece would significantly bend when placed in the mouth and block suction other than Dr. Black's testimony. *See* Petition, 34-38. Dr. Black's testimony merely restates the contentions in the Petition and does not provide additional analysis or evidence. *Compare* Petition, 34-38 with EX1003, ¶¶71-74. The Board has held that such testimony is entitled to little or no weight. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15-17 (PTAB Aug. 24, 2022) (precedential) (testimony restating “the petitioner's arguments without any additional supporting evidence or reasoning” is accorded “little weight”); 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight”).

The Federal Circuit has held that the use of improper hindsight is apparent where, as here, the petitioner fails “to demonstrate ... that the problem was known in the art or that [the petitioner's] formulation of the problem was derived directly from the prior art, rather than from the challenged claims.” *Purdue Pharma L.P. v. Depomed, Inc.*, 643 F. App'x 960, 966 (Fed. Cir. 2016); *see also Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (“Care must be taken to avoid hindsight reconstruction by using ‘the patent in suit as a guide through

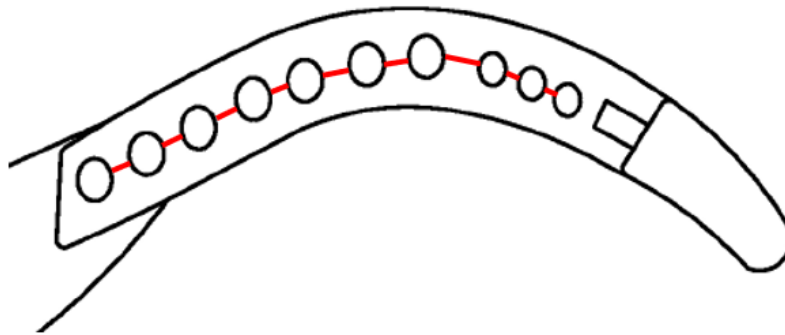
the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit”) (quoting *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983)). As demonstrated above, none of the prior art relied upon in the Petition suggests that the bending problem Petitioner relies on for motivation to combine occurs in Nguyen, which highlights the improper use of hindsight in Petitioner’s analysis.

Third, Petitioner argues that “[o]pening the sides [in Nguyen] would allow suction to occur in more places along the sides of the mouthpiece” and “also allow for the suction, and removal, of larger debris.” Petition, 38. Given that the proposed modification in Ground 1 involves “cutting the material formed between the sidewall perforations 140” (Petition, 42), the only location where suction may conceivably be increased is through the additional openings created by the cut between the circular perforations:



Petition, 43 (modifying EX1005, FIG. 2D) (red annotations added)

Yet Petitioner argues that “Nguyen would require some anti-collapse structure at the edges of the main body portion 110” and “[c]utting open the sidewalls would also create a projecting structure at the edges of the mouthpiece.” Petition, 41-42; EX1003, ¶85 (explaining that cutting open the sidewalls “create[s] an anti-collapse structure at the edges of the mouthpiece”). Petitioner also argues that this creates “an edge having alternating crests and troughs.” Petition, 44. Given Petitioner’s position that this feature constitutes “anti-collapse structure” when suction is applied, the crests on each intervening wall would contact one another. EX2020, ¶134.



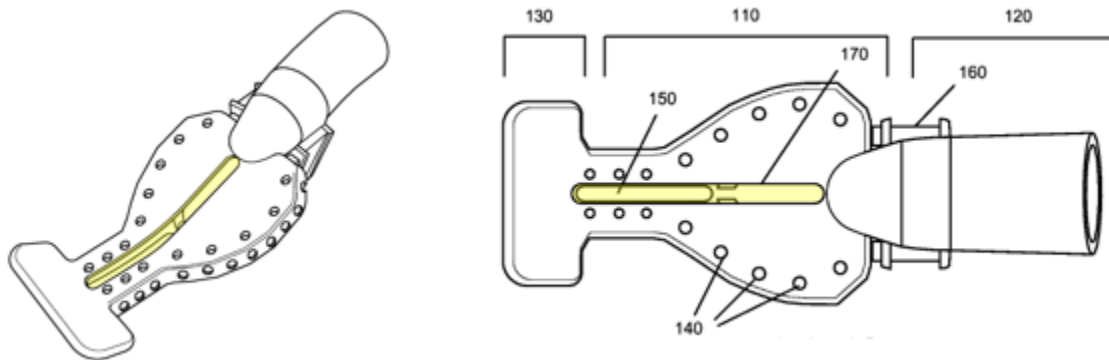
EX1005, FIG. 2D (excerpted and annotated)

Petitioner’s proposed modification therefore results in the same or a substantially similar amount of suction area through the perforations as unmodified Nguyen, which undermines Petitioner’s argument that the proposed combination would “improve” suction. EX2020, ¶135.

ii. A POSITA Would Not Have Been Motivated to Modify Nguyen for “Easier Cleaning”

Petitioner's other alleged motivation to modify Nguyen is that the proposed modification would “make it easier to clean and reuse the dental mouthpiece.” Petition, 38. This argument also fails.

Nguyen teaches that the mouthpieces disclosed therein “may be made of a high heat-resistant and autoclavable material” and thus “may be reusable.” EX1001, 3:8-10. An autoclavable material is a material that can be sterilized for reuse with multiple patients using steam. EX2020, ¶137. In addition to disclosing cleaning via an autoclave, Nguyen discloses an open slit 170 in the anterior wall that allows for manual “cleaning and maintenance.” EX1005, 4:31-37; EX2020, ¶139.



EX1001, FIG. 1A-1B (annotated)

Manual cleaning and maintenance could be performed, for example, using a brush inserted through the slit 170. EX2020, ¶140. Because the mouthpiece is made of a flexible material, it can flex or stretch to accommodate the brush within the interior.

Id. Moreover, because Nguyen's bridge structure 180 is only attached to one wall (but not both), one can easily move the brush throughout the interior of the mouthpiece for cleaning. *Id.* Petitioner's claim that Nguyen "would not be conducive to easy cleaning" because "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" ignores these teachings. Petition, 38-39.

In an attempt to suggest that Nguyen's mouthpiece is more difficult to clean than an "open-sided" mouthpiece like Black, Dr. Black claims that "[o]pen sides eliminate any hard-to-reach corners" and "***most prior art dental mouthpieces had open sides for at least this reason.***" EX1003, ¶80 (citing EX1006, FIG. 2; EX1007, FIG. 23C, EX1017, FIG. 4, EX1018, FIG. 1; EX1019, FIG. 3).² Tellingly, Dr. Black only cites figures from these references to support his opinion. *Id.* That is because ***none*** of the references suggest that "open-sided" mouthpieces are easier to clean than a "closed-sided" mouthpiece. In fact, most of these references describe a disposable mouthpiece that requires no cleaning and therefore do not and cannot

² All emphasis in case and evidence quotations is added unless otherwise noted.

teach that an “open-sided” mouthpiece is easier to clean. Each reference cited by Dr. Black is addressed in turn below:

- **Hirsch (EX1006):** Hirsch discloses that its mouthpiece is “disposable after each use” and does not disclose or suggest that the mouthpiece can be cleaned and reused. EX1006, 3:1-2; EX2020, ¶143.
- **Black (EX1007):** As Dr. Black should know, Black teaches that the tongue shield aspirators “may be made of a disposable material.” EX1007, 9:23-28; EX2020, ¶144. While the bite member or evacuation tube are “re-usable (autoclavable),” Black never states that the mouthpiece is reusable or cleaned. EX1007, 9:50-52, 10:34-39, 19:35-38; EX2020, ¶144.
- **EX1017:** Petitioner does not provide an English translation,³ so this reference cannot support its argument that the prior art used “open-sided” mouthpieces because they were easier to clean. EX2020, ¶145.
- **Kim (EX1018):** Kim is silent regarding whether the mouthpiece is reusable. *See* EX2020, ¶146.

³ EX1017 does not comply with the Board’s rules for translations. 37 C.F.R. § 42.63(b); Petition, 13 n.1 (acknowledging that no translation was provided).

- **Reyes (EX1019):** Reyes discloses that its saliva ejector is “disposable” and never mentions cleaning or reusing it. EX1019, Abstract, ¶¶[0005], [0039]; EX2020, ¶147.

In short, Dr. Black's claim that the prior art used “open-sided” mouthpieces because they were easier to clean is belied by the very evidence that he purports to rely on.

If anything, Black's teachings demonstrate that an “open-sided” mouthpiece would be more difficult to clean than Nguyen. Assuming, *arguendo*, that one would have a reason to clean and reuse Black's mouthpiece even though Black teaches that it is disposable, manual cleaning would be far more difficult than in Nguyen. EX2020, ¶¶149-50. This is because one would need to insert a brush between each pair of transverse walls 348c, requiring multiple cleaning motions or operations. *Id.*

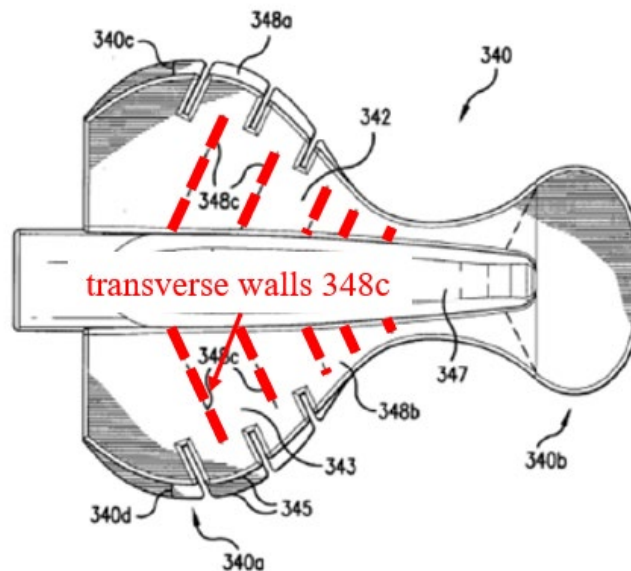


FIG. 23A

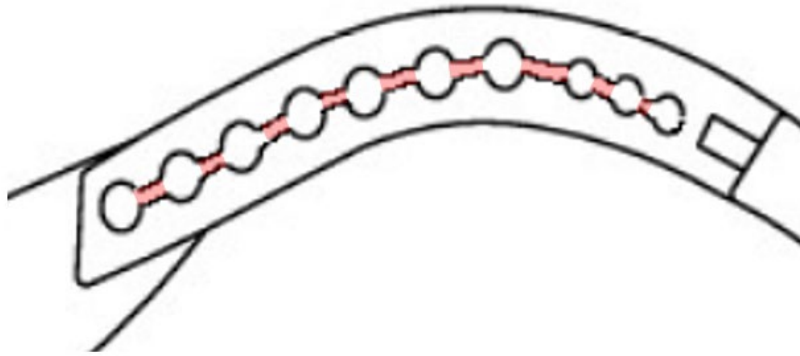
EX1007, FIG. 23A (annotated)

Thus, contrary to Petitioner and Dr. Black's suggestion, Black does not suggest that an "open-sided" mouthpiece is easier to clean – it shows the opposite.

iii. Petitioner's Proposed Modification Requires More Than Simply "Cutting" Nguyen Open

Petitioner argues that its proposed modification could be created "by simply cutting open the sidewalls" such that a POSITA "would not even need to create a new mold to arrive at the claims of the '217 Patent." Petition, 42. Specifically, Petitioner argues that "[b]y simply cutting Nguyen along the middle of the sidewalls, the result would be an anterior intervening wall and posterior intervening" as claimed." *Id.*, 43.

Petitioner and Dr. Black, however, do not explain how one would "cut" Nguyen's mouthpiece. Petition, 42-44. For example, Dr. Black does not explain what tool(s) would be used, how the mouthpiece would be held in place while the cutting occurred, or whether this process is automated or manual. EX1003, ¶¶85-86; EX2020, ¶152. To the extent Petitioner is suggesting that the "cut" would involve using scissors or a utility knife to open up the mouthpiece, Petitioner ignores the fact that its proposed modification requires the removal of some thickness of material (annotated in red below) rather than a thin slit. EX2020, ¶153.



Petition, 43 (modifying EX1005, FIG. 2D) (red annotations added)

The “cut” shown above could not be accomplished with a single pass from a pair of scissors or a knife and would require multiple cuts. EX2020, ¶153. For example, one would have to make at least 2 cuts between each pair of perforations, which requires at least 18 cutting operations on only one side of the mouthpiece, and 36 cutting operations if both sides were “cut.” *Id.*

Petitioner acknowledges the possibility that its proposed cutting operation may “accidentally damage[] the anterior or posterior wall, thereby creating a defective mouthpiece.” Petition, 42; EX1003, ¶86. Indeed, a POSITA would recognize that this cutting operation would carry the risk of additional manufacturing flaws or defects. EX2020, ¶154. The autoclavable mouthpieces described in Nguyen are medical grade devices, and a POSITA would recognize that adding an additional cutting operation would increase the risk of contamination or other issues that may make the mouthpiece unusable or unsafe. *Id.* Petitioner’s proposed modification would therefore be significantly more difficult to manufacture relative to Nguyen.

Id., ¶155. This is especially true if the modified mouthpiece were manufactured at scale: it would not be feasible to cut each mouthpiece on each side without significantly increasing the manufacturing time, cost, and complexity. *Id.*

These disadvantages introduced by Petitioner's proposed modification further weigh against any motivation to modify Nguyen to arrive at the claimed inventions. EX2020, ¶156; *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (in an obviousness analysis, the "benefits, both lost and gained, should be weighed against one another") (quoting *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349, n.8 (Fed. Cir. 2000)); *Arctic Cat Inc. v. Polaris Indus., Inc.*, 795 F. App'x 827, 833 (Fed. Cir. 2019) ("[t]he Board must weigh the benefits and drawbacks of the modification against each other, to determine whether there would be a motivation to combine"); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) ("the prior art as a whole must 'suggest the desirability' of the combination").

c) Petitioner's Duplication of Parts Argument is Conclusory and Unsupported

Petitioner also argues in the alternative that "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." Petition, 41-42 (citing EX1003, ¶84; MPEP 2144.04(VI)(B)). This argument fails to the same reasons discussed above. *Supra*, §VI.A.1.b.

Additionally, the argument is entirely conclusory and cites to the MPEP, which does not have the force of law. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“obviousness grounds cannot be sustained by mere conclusory statements”).

Dr. Black fares no better than the Petition. The entirety of Dr. Black's opinions on this issue are reproduced below:

Essentially, an open-sided Nguyen would require a second “bridge structure” formed at the edges of the mouthpiece. The '217 Patent describes the intervening wall as having “alternating crests and troughs,” which is exactly how Nguyen also describes the bridge structure 180. EX1001, 6:33-39; EX1005, 2:11-16. Thus, the intervening walls recited in the '217 Patent are essentially a second bridge structure formed at the edges of the mouthpiece. *Id.* Therefore, an intervening wall with alternating troughs and crests is a mere duplication of parts, which I am told is typically an obvious modification.

EX1003, ¶84. Dr. Black does not even opine that duplicating Nguyen's bridge structure would have been obvious; instead, he merely states his understanding that “a mere duplication of parts ... is typically an obvious modification.” *Id.*

Petitioner's duplication of parts argument is also flawed for another reason. Claim 1 recites *two* intervening walls: an anterior intervening wall and a posterior intervening wall. EX1001, 8:67-9:2, 9:4-7. Even if, *arguendo*, a POSITA were motivated to duplicate Nguyen's bridge structure at the edge of anterior wall as Petitioner proposes, Petitioner does not explain how the resulting mouthpiece would also have a posterior intervening wall as required in claim 1. Petition, 41-42;

EX2020, ¶159. In other words, even if one were to modify Nguyen as Petitioner suggests (which they would not do without the benefit of hindsight), it still would not meet the requirements of claim 1.

2. Petitioner Failed to Meet its Burden for Claim 17

For the reasons discussed below, Petitioner also failed to meet its burden for independent claim 17 of the '217 Patent.

a. Petitioner Failed to Meet its Burden for Limitations 17(d) and 17(e) for the Same Reasons as Claim 1

Limitation 17(d) recites “at least one intervening wall protruding from and extending along an edge of the anterior wall or the posterior wall, the at least one intervening wall having a span that extends partially across the distance of the interior space.” EX1001, 10:21-25. Limitation 17(e) adds that “an edge of the span of the at least one intervening wall has a plurality of alternating crests and troughs that extend different distances partially across the interior space.” *Id.*, 10:25-29.

For these limitations, Petitioner refers to its analysis for claim 1 without more. Petition, 51 (referring to Sections IX.A.1.d and IX.A.1.e); *see also* EX1003, ¶¶109-16 (referring to discussion for claim 1). Accordingly, Petitioner failed to meet its burden for these limitations for at least the same reasons provided above for claim 1, including because neither Nguyen nor Black discloses the claimed “intervening wall” and because a POSITA would not have modified Nguyen in view of Black as suggested by Petitioner. *Supra*, §VI.A.1; EX2020, ¶¶161-63.

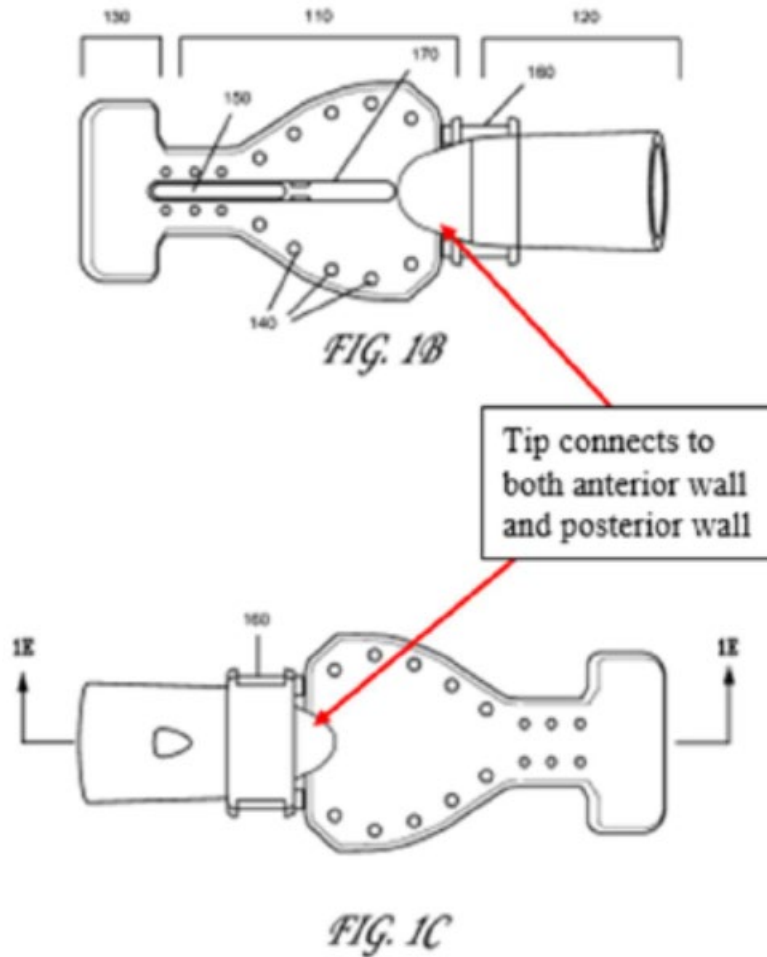
b. Petitioner Ignores the “Within the Interior Space” Requirement in Limitation 17(c)

Limitation 17(c) recites “at least one connector that connects the anterior wall to the posterior wall within the interior space.” EX1001, 10:19-20. For this limitation, the Petition refers to its discussion for limitation 1(c), which recites “at least one connector connecting the anterior wall to the posterior wall.” Petition, 51 (referring to Section IX.A.1.c); EX1001, 8:66-67.

Petitioner fails to address the additional requirement in claim 17 that the connector connects the anterior and posterior walls “*within the interior space*.” EX1001, 10:19-20; EX2020, ¶¶164-67. Dr. Black also ignores this additional requirement in claim 17. EX1003, ¶65. The entirety of Petitioner's analysis of limitation 1(c) is reproduced below:

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.

Petition, 31. Petitioner also provides the following annotated figures:



Petition, 32 (annotating EX1005, FIGS. 1B-1C)

Petitioner is pointing to the exterior of the tip on Nguyen's mouthpiece and does not identify a "connector" that is "within the interior space" as required by limitation 17(c). EX2020, ¶¶166-67. Thus, Petitioner failed to meet its burden for claim 17 for this additional reason.

3. Dependent Claims 2-11, 13-16, and 18-23

Petitioner's discussion of dependent claims 2-11, 13-16, and 18-23 focus on the additional limitations in these claims and does not address the deficiencies

discussed above in Petitioner's obviousness theories. Petition, 46-50, 53. Thus, Petitioner failed to meet its burden for these dependent claims for at least the same reasons as the independent claims from which they depend. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious"); EX2020, ¶169.

B. Ground 2: Alleged Obviousness Based on Nguyen, Black, and Hirsch (Claims 8 and 19)

In Ground 2, Petitioner argues that dependent claims 8 and 19 of the '217 Patent are obvious of Nguyen, Black, and Hirsch. Petition, 53. These dependent claims are not obvious over Nguyen and Black for at least the same reasons that independent claims 1 and 17 are not rendered obvious by Park. *Supra*, §VI.A; *Fine*, 837 F.2d at 1076; EX2020, ¶¶170-71. Accordingly, Petitioner failed to meet its burden for Ground 2 for at least the same reasons as Ground 1.

C. Ground 3: Alleged Obviousness Based on Nguyen and Hirsch (Claims 17-23)

In Ground 3, Petitioner argues that claims 17-23 of the '217 Patent are obvious over Nguyen in view of Hirsch. Petition, 54-64. For the reasons discussed below, Petitioner failed to meet its burden for Ground 3.

1. Petitioner Failed to Meet its Burden for Claim 17

a. Petitioner Again Ignores the “Within the Interior Space” Requirement in Limitation 17(c)

Petitioner does not rely on Hirsch for limitation 17(c). Petition, 51. Instead, Petitioner refers to its discussion for this limitation in Ground 1, which in turn refers to Petitioner's discussion for limitation 1(c). *Id.* (referring to Section IX.A.1.c). As discussed above, Petitioner never addresses the requirement in limitation 17(c) that the claimed “connector” connects the posterior and anterior walls “within the interior space.” *Supra*, §VI.A.2.b; EX2020, ¶173. Petitioner failed to meet its burden for claim 17 in Ground 3 for this reason alone.

b. A POSITA Would Not Have Modified Nguyen in View of Hirsch for Limitations 17(d) and 17(e)

As discussed above, Petitioner concedes that Nguyen does not disclose an intervening wall protruding from and extending along an edge of the anterior wall or the posterior wall as recited in claim 17. Petition, 54-55; *supra*, §VI.A.1. Petitioner's attempt to address this deficiency is similar to Ground 1 in that Petitioner argues “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.” Petition, 55. Petitioner's obviousness arguments fail for at least the same reasons discussed above for Ground 1. *Supra*, §VI.A.1; EX2020, ¶¶174-76. Nor does Hirsch address the deficiencies in Petitioner's analysis in Ground 1.

i. A POSITA Would Not Have Been Motivated to Modify Nguyen to “Improve Suction”

Just as it did in Ground 1, Petitioner argues that a POSITA “would have been motivated to open the sidewalls to improve suction through the mouthpiece” and states that “[t]he same rationale [as Ground 1] applies again here.” Petition, 55-56. That rationale fails for the reasons discussed above. *Supra*, §VI.A.1.b.i. Petitioner's additional assertions about Hirsch do not warrant a different outcome than iGround 1.

Petitioner's obviousness rationale in Ground 3 is, in part, predicated on its assertion if the inferior and superior walls shown in Nguyen's figures were removed, the anterior and posterior wall would “collapse under suction at the edges of the mouthpiece near the perforations, 140, which are critical to fluid removal.” Petition, 58. As an initial matter, Petitioner provides no evidence that suction through the perforations in the inferior and superior walls shown in Nguyen's figures is “critical” to Nguyen's functionality. *Id.*; EX2020, ¶181. Indeed, Nguyen describes these perforations as optional. EX1005, 3:36-4:3 (“the main body portion 110 of the mouthpiece **may include** a plurality of holes 140 distributed along the superior and inferior sides of the anterior and posterior walls to assist in suctioning of water, saliva and debris from the oral cavity” and that they may be included “[i]n **some** embodiments”).

Continuing, Petitioner argues that if Nguyen does not have the inferior and superior sidewalls shown in the figures, the anterior and posterior walls would collapse and “create the **undesirable seal** at the edges like Hirsch teaches.” Petition, 58 (citing EX1006, 4:43-67); *see also id.*, 61 (arguing that one would “avoid the **undesirable seal** taught by Hirsch”). While Hirsch does teach that the edges seal, it does not teach that this is “undesirable.” Hirsch **intentionally** creates a seal at the edges. EX2020, ¶179. For example, Hirsch teaches that “in a vacuum state the upper pocket opening and lower pocket opening are substantially **sealed closed** so that aspiration of fluids from the patient's mouth occurs through the evacuation holes in the front flaps and grooves, which become fluid inlets for drawing fluids through the channels, of the rear flaps.” EX1006, 1:50-56; *see also id.*, 2:13-18, 4:45-5:8; EX2020, ¶180. Thus, Hirsch actually teaches away from Petitioner's proposal to add structure at the edges to prevent a seal. *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017) (prior art teaches away when a POSITA “would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant”) (quoting *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015)).

Because Hirsch intentionally creates the seal at the edges, it necessarily does not disclose or suggest that the V-shaped grooves in the posterior wall constitute “anti-collapse” structure. EX2020, ¶186; Petition, 60 (acknowledging that the

grooves are on a posterior wall). Petitioner's conclusory assertion that it would be "common sense" to use this feature from Hirsch as an "anti-collapse structure at the edges" is unsupported and merely a hindsight reconstruction of the invention. Petition, 61; EX2020, ¶186; *Kahn*, 441 F.3d at 988 ("obviousness grounds cannot be sustained by mere conclusory statements").

For at least these reasons, a POSITA would not have been motivated to modify Nguyen in view of Hirsch to arrive at the claimed inventions.

ii. A POSITA Would Not Have Been Motivated to Modify Nguyen for Cleaning

Similar to Ground 1, Petitioner argues that a POSITA would "have also been motivated to open the sides of Nguyen to make it easier to clean and reuse the dental mouthpiece." Petition, 38-39. This rationale fails for the same reasons discussed above for Ground 1, and Petitioner's reliance on Hirsch in Ground 3 instead of Black does not change the result. *Supra*, §VI.A.1.b.ii. Hirsch would not have provided any motivation to modify Nguyen for "easier" cleaning because Hirsch does not disclose a reusable mouthpiece that requires cleaning. EX1006, 3:1-2; EX2020, ¶178.

Further, cleaning Petitioner's modified version of Nguyen would not be "easier" than using the open slit 170 that is already provided in Nguyen. EX2020, ¶188. The openings between the edge of Petitioner's new alleged intervening wall

and the V-shaped cutouts appear relatively small, making it difficult to insert a brush to clean the interior compared to using the slit 170 at the top. *Id.*

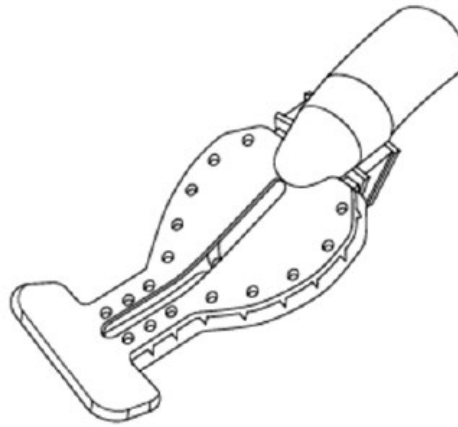


FIG. 1A

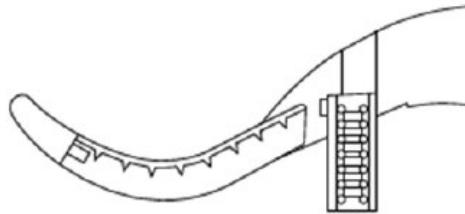


FIG. 1D

Petition, 60 (modifying EX1005, FIGS. 1A and 1D)

Petitioner also argues that Nguyen is difficult to clean because it has “difficult to reach corners,” whereas an “open-sided” mouthpiece would not. Petition, 57. As shown above, however, its proposed combination of Nguyen and Hirsch still has corners. EX2020, ¶189.

2. Dependent Claims 18-23

Dependent claims 18-23 are not obvious over Nguyen and Hirsch for at least the same reasons that independent claim 17 is not rendered obvious by Nguyen and Hirsch. *Supra*, §VI.C.1; *Fine*, 837 F.2d at 1076; EX2020, ¶194.

VII. CONCLUSION

For at least the foregoing reasons, the Petition should be denied as to each of the requested grounds. For brevity, Patent Owner may not have addressed all characterizations of the applied references and the challenged claims and reserves the right to do so should institution be granted. The absence of a response by Patent Owner to any of the positions presented in the Petition or the associated expert declaration is not a concession to those positions. The fact that Patent Owner's Preliminary Response has focused on particular arguments is not a concession that there are no other arguments for patentability of the challenged claims.

Respectfully submitted,

Dated: October 15, 2025

By: /s/ Angelo J. Christopher

Angelo J. Christopher
Reg. No. 81,594
NIXON PEABODY LLP
70 West Madison St., Suite 5200
Chicago, IL 60602-4378
Tel. 312-977-4391
Fax 844-450-2568

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Preliminary Response** was served on October 15, 2025, by email:

Nathan Sportel
Reg. No. 67,980
Miller Johnson
45 Ottawa Ave. SW, Suite 1100
Grand Rapids, MI 49503
(616) 831-1793 Tel
(616) 831-1701 Fax
sporteln@millerjohnson.com

Brandon Griffith
Reg. No. 74,934
Miller Johnson
500 Woodward Ave., Suite 2800
Detroit, MI 49503
(313) 672-6932 Tel
(313) 672-6951 Fax
griffithb@millerjohnson.com

Jacob Cowdrey
Reg. No. 81,803
Miller Johnson
45 Ottawa Ave. SW, Suite 1100
Grand Rapids, MI 49503
(616) 831-1864 Tel
(616) 831-1701 Fax
cowdreyj@millerjohnson.com

Counsel for Petitioner, Ascentcare Dental Products, Inc.

By: /s/ Angelo J. Christopher

Counsel for Patent Owner

CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the foregoing Patent Owner's Preliminary Response is produced using a 14-point Times New Roman font and contains approximately 8,891 words, which is less than the 14,000 total words permitted by the U.S. Patent Trial and Appeal Board rules. Counsel relies on the word count of the computer program used to prepare the response on October 15, 2025.

Dated: October 15, 2025

By: /s/ Angelo J. Christopher

Lead Counsel for Patent Owner