

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

DECLARATION OF MICHAEL JOBIN

TABLE OF CONTENTS

I.	BACKGROUND AND QUALIFICATIONS	2
A.	Education	2
B.	Work Experience	2
C.	Patents.....	7
II.	MATERIALS CONSIDERED	9
III.	LEGAL STANDARDS	10
A.	Claim Construction.....	10
B.	Anticipation	12
C.	Obviousness.....	13
D.	Dependent Claims.....	16
IV.	OVERVIEW OF THE ‘217 PATENT	17
V.	PROSECUTION HISTORY OF THE ‘217 PATENT.....	27
VI.	LEVEL OF SKILL IN THE ART	31
VII.	SUMMARY OF REFERENCES IN THE PETITION	32
A.	Nguyen (Ex.....	33
B.	Black (Ex	33
C.	Hirsch (Ex.....	37
VIII.	CLAIM CONSTRUCTION	38
A.	“partially across the distance of the interior space” (claims 1-23).....	38
B.	Petitioner’s Constructions in the Parallel Litigation	39
IX.	OPINIONS ON GROUNDS IN THE PETITION	40
A.	Ground 1: Obviousness Based on Nguyen and Black (Claims 1-11 and 13-23) 40	
1.	Independent Claim 1.....	41
a.	Petitioner and Dr.....	44
b.	A POSITA Would Not Modify Nguyen to Increase Suction.....	49
c.	Nguyen is Not “Difficult” to Clean.....	59
d.	Petitioner and Dr.....	64

	Page
e. Petitioner and Dr.....	66
2. Independent Claim 17.....	68
3. Dependent Claims 2-11, 13-16, and 18-23.....	71
B. Ground 2: Obviousness Based on Nguyen, Black, and Hirsch (Dependent Claims 8 and 19)	72
C. Ground 3: Obviousness Based on Nguyen and Hirsch (Claims 17-23).....	73
1. Independent Claim 17.....	73
a. Limitation 17(c).....	73
b. Limitations 17(d) and 17(e).....	74
2. Dependent Claims 18-23	85
X. CONCLUSION.....	86

I, Michael Jobin, declare as follows:

1. I make this declaration based upon my own personal knowledge and, if called upon to testify, would testify competently to the matters stated herein.

2. I have been retained on behalf of Solmetex, LLC, (“Solmetex” or “Patent Owner”) as an independent expert consultant to provide this declaration concerning the technical subject matter relevant to U.S. Patent No. 11,826,217 (“the ‘217 patent”) in connection with an *inter partes* review (“IPR”) petition filed by Ascentcare Dental Products, Inc. (“Ascentcare” or “Petitioner”).

3. I am being compensated at my standard hourly rate of \$595 per hour for the time I spend on this matter. My compensation is not based on the content of my opinions or the resolution of this matter, and I have no other interest in this proceeding.

4. I understand that Solmetex is asserting the ‘217 Patent against Ascentcare in a related matter currently pending in the United States District Court for the Western District of Michigan (“the Parallel Litigation”).

5. In this declaration, I offer opinions relating to the ‘217 patent, claim construction, the references in the Petition, and the declaration submitted by Petitioner. The substance and bases of my opinions appear below.

I. BACKGROUND AND QUALIFICATIONS

6. In formulating my opinions, I have relied on my knowledge, training, and experience in the relevant field, which I will summarize briefly herein. In addition, Ex. 2021 is a true and correct copy of my current *curriculum vitae* (CV).

Education

7. I received two degrees from the University of Michigan in 1991, a Bachelor of Science, Engineering with a focus on mechanical engineering, and a Bachelor of Fine Arts, Industrial Design with a focus on product development, both cum laude. I was the recipient of the Kiefer Award for excellence in Industrial Design.

Work Experience

8. I have worked in various product development companies throughout my 33 year career, and have developed many products that demonstrate knowledge and experience with the subject matter relevant in this case. I provide below a summary of my work experience and relevant project examples.

9. After my undergraduate degrees, I was hired as a program manager by Design 4 Plastics, Inc. I leveraged my industrial design and engineering education to develop a wide range of products. My projects included a heavy emphasis on plastic part design (including injection molding, rotational molding, vacuum and pressure forming) and sheet metal fabrication (stamping, forming).

10. For NTI Surgical, I designed a custom sterilized impeller pump and tubing set for insufflation of the abdomen during laparoscopic surgery. I developed a cleaning and storage system for reusable tonometer tips, which are used to measure intraocular pressure.

11. For Coca-Cola, I developed a disposable valve for a bag-in-box syrup dispensing system using FDA grade materials.

12. Next, in 1996, I joined Proteus, Inc. as Senior Mechanical Engineer. There, I focused on product design and engineering of products for consumer, medical, and laboratory applications. For example, I developed a disposable cartridge for measuring blood coagulation characteristics prior to surgery.

13. For PUR, I developed a faucet mounted water filter with replaceable cartridge and a rotary actuated valve, and filtered water pitchers.

14. For Physiometrix, I developed an anesthesia monitor including flexible disposable electrodes for fitment to the head.

15. I founded Boston Innovation in 1998, focusing on developing precision fluidic dispensing instruments for pharmaceutical research applications that leveraged a novel pressure activated valve technology that I invented. In these instruments, sample fluid was stored in small sealed reservoirs, and precision low volumes dispensed by the translation of a needle and application of a rinse fluid and/or air pressure. *See, e.g.*, U.S. Pat. Nos. 6,085,773 and 6,706,538.

16. For Gillette, I designed a disposable, handheld shaving cream dispenser.

17. For Bard, I designed a handheld endoscopic device with integrated irrigation and suction.

18. In 2000, I joined Arthur D. Little, where I led mechanical engineering of a next-generation network storage product, integrating contributions of mechanical, software, hardware and industrial designers.

19. I founded MicroBioSciences in 2001. There, I invented and developed novel disposable fluid handling cartridges for high throughput screening in pharmaceutical research.

20. Later in 2001, I joined Altitude, Inc., a product development consulting firm, first as Engineering Manager, and then I was promoted to Director of Engineering in 2005. I performed design and engineering activities and led a team of designers and engineers to develop a wide range of consumer products, medical devices and instrumentation.

21. I developed a wide range of home humidifiers for Honeywell, Kaz and Vicks. These included water reservoirs with removable caps and elastomer valves.

22. I developed a water dispenser for PUR with chilled and heated water and dispensing valves. This included a refillable water reservoir with wide mouth threaded cap and valve for easy cleaning.

23. For Colgate, I developed a low-cost, low profile electric toothbrush in or around 2008. This toothbrush was the first commercially available toothbrush that ran on one AA battery (rather than multiple batteries).

24. For Exact Sciences, I designed a custom cylindrical sample collection and shipping vessel with large diameter threaded lid and elastomer gaskets.

25. I developed the first integrated ice shaving and blending frozen drink appliances for home use for Margaritaville. These products included a reservoir for ice, a robust motor and rotary ice shaving blade, a blender, and electronic controls.

26. I developed a wine preservation and dispensing system for home use. The product stored multiple wine bottles at the user-selected optimum temperature using thermoelectric chiller technology, and used valves and air pressure for dispensing, and vacuum for preservation.

27. I developed a handheld eye medication dispenser for Optimyst. This product included a custom disposable fluid reservoir and ultrasonic dispensing technology. *See* U.S. Pat. Nos. D597,206; 8,545,463; 8,012,136.

28. I developed a range of safety eyewear for UVEX. These included adjustable features leveraging advanced injection molding techniques such as in-mold assembly and plastic and elastomer materials. *See, e.g.*, U.S. Pat. Nos. 7,758,789; 7,246,901; 7,237,892; 7,210,777; 7,175,270.

29. In 2008 I founded Aston Technology Advisors, and continued with product development and consulting activities.

30. There I developed an instrument that uses sound to measure wind. This included a novel hydronic heating system for melting snow. *See* U.S. Pat. Nos. 8,958,269 and 9,279,821.

31. I developed a custom plastic and elastomer sterilizable probe for measuring blood oxygen inside the cheek (buccal mucosa) for Pendar Technologies. The probe was positioned in the mouth to press against the inside of the cheek.

32. I developed a custom, portable dispenser for hand sanitizer for use by health care professionals.

33. In 2012, I cofounded 908 Devices Inc. to develop portable chemical detection instrumentation based on mass spectroscopy. Here I have developed various instruments with applications in pharmaceutical research, forensics and hazardous material identification at the point of need. These instruments include complex fluid handling, fluidic and pneumatic connectors, custom vacuum pumps,

pressure regulators and pressure sensors. *See* U.S. Pat. Nos. D703,074; D703,075; 9,093,253; 9,502,226; 9,698,000; 9,978,574; 10,438,787.

34. At 908 Devices I developed reusable sensors and for bioprocessing applications designed to survive repeated autoclaving cycles. I also developed various single use sterilized tubing sets.

35. Throughout my professional career, I have designed products that have won various awards, including: Industrial Designers Society of America (IDSA) IDEA Awards, R&D 100, The Scientist Top 10 Innovations, and The Instrument Business Outlook Industrial Design Gold Award.

36. I have served as an expert in multiple cases. For example, in *Keurig, Inc. v. Kappos*, I was hired on behalf of the United States Patent & Trademark Office as an expert regarding technical concepts related to a USPTO Examiner's rejection of patent claims around Keurig's K-Cup coffee pods, including analysis of relevant prior art. Key issues included high volume manufacturing of thermoformed plastic pods, forming and assembly of filter baskets and fluid flow through the system under high pressure. Ultimately, the USPTO Examiner's rejection was affirmed on appeal.

Patents

37. I am a named inventor on nineteen issued utility patents and six issued design patents, which are listed below. These patents range in technologies from

consumer products to medical devices to instrumentation, and address technical issues like precision fluid handling, injection molding, and compact mass spectroscopy.

1. U.S. D932,046 Fluidic cartridge assembly
2. U.S. 10,438,787 Integrated mass spectrometry systems
3. U.S. 9,978,574 Sample collection in compact mass spectrometry systems
4. U.S. 9,698,000 Integrated mass spectrometry systems
5. U.S. 9,502,226 Sample collection in compact mass spectrometry systems
6. U.S. 9,279,821 Deicing system in sodar systems
7. U.S. 9,093,253 High pressure mass spectrometry systems and methods
8. U.S. 8,958,269 Transducer for phased array acoustic systems
9. U.S. D703,074 Handheld sensor
10. U.S. D703,075 Sensor device
11. U.S. 8,545,463 Ophthalmic fluid reservoir assembly for use with an ophthalmic fluid delivery device
12. U.S. 8,525,111 High pressure mass spectrometry systems and methods

- 13.U.S. 8,012,136 Ophthalmic fluid delivery device and method of operation
- 14.U.S. 7,758,789 Temple bar assembly for eyeglasses
- 15.U.S. D597,206 Ophthalmic misting device
- 16.U.S. 7,246,901 Adjustable length upper frame member for eyeglasses
- 17.U.S. 7,237,892 Temple bar with ball and socket hinge and method of making same
- 18.U.S. 7,210,777 Floating lens brow bar attachment for eyeglasses
- 19.U.S. 7,175,270 Flexible frame assembly for eyeglasses
- 20.U.S. D534,446 Handheld instrument
- 21.U.S. 7,080,904 One piece spectacle with temple pre-load
- 22.U.S. 6,706,538 Microvolume liquid dispensing array
- 23.U.S. 6,085,773 Automatic fluid switching valve
- 24.U.S. D425,979 Window fan
- 25.U.S. 5,794,897 Transmission line hanger, a method of attaching the hanger and the resulting assembly

II. MATERIALS CONSIDERED

38. In forming the opinions set forth herein, I have considered and relied upon my education, knowledge of the relevant field, and my experience. I have

also reviewed and considered the ‘217 Patent (Ex. 1001), the ‘217 Patent’s file history (Ex. 1002 (part 1), Ex. 1015 (part 2), and Ex. 1016 (part 3)), and at least the following additional materials:

- Ascentcare’s Petition for *Inter Partes* Review of the ‘217 Patent (Paper 2);
- Declaration of Dr. Brian P. Black (Ex. 1003);
- U.S. Patent No. 8,911,232 (“Nguyen,” Ex. 1005);
- U.S. Patent No. 9,532,858 (“Hirsch,” Ex. 1006);
- U.S. Patent No. 8,029,280 (“Black,” Ex. 1007);
- Chinese Patent No. 10-4490483 (Ex. 1017);
- Korean Patent No. 10-0654392 (“Kim,” Ex. 1018);
- U.S. Patent Publication No. 2017/0156832 (“Reyes,” Ex. 1019); and
- DryShield User Guide (Ex. 2019).

39. I also considered any materials cited in this declaration to the extent they are not expressly listed above.

III. LEGAL STANDARDS

40. In forming the opinions set forth herein, I have considered and relied upon my education, my work experience, and my personal experience designing medical devices.

A. Claim Construction

41. I understand that claim construction is the process by which a court determines the scope and meaning of terms used in the claims of a patent. I understand that the goal of this process is to give claim terms the ordinary and customary meaning they would have had to a person of ordinary skill in the art (“POSITA”) at the time of the invention, after reading the patent and its prosecution history.

42. I understand that the patent specification may reveal a special definition given to a claim term by the patentee that differs from the plain and ordinary meaning it would otherwise have to a POSITA. In such cases, I understand that the patentee’s definition usually controls.

43. I understand that the prosecution history of a patent can inform the meaning of some claim language and that the prosecution history must be considered when construing the claims.

44. I understand that the court may consider extrinsic evidence, such as dictionaries, treatises, and expert opinions, to understand the technology at issue and the way in which claim terms would be understood by a POSITA in the relevant timeframe.

45. I understand that a dependent claim incorporates each and every limitation of the claim or claims from which it depends.

Anticipation

46. I have been informed and understand that a patent claim may be unpatentable as “anticipated” under 35 U.S.C. § 102. I understand that anticipation analysis is a two-step process. The first step is to determine the meaning and scope of the asserted claims. Each claim must be viewed as a whole, and it is improper to ignore any element of the claim. For a claim to be anticipated: (1) each and every claim element must be identically disclosed, either explicitly or inherently, in a single prior art reference; (2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim; and (3) the identical invention must be disclosed in the single prior art reference, in as complete detail as set forth in the claim. Where even one element is not disclosed in a reference, there is no anticipation.

47. I understand that to serve as an anticipatory reference, the reference itself must be enabled, i.e., it must provide enough information so that a person of ordinary skill in the art can practice the subject matter of the reference without undue experimentation.

48. I further understand that where a prior art reference fails to explicitly disclose a claim element, the prior art reference inherently discloses the claim element only if the prior art reference must necessarily include the undisclosed claim element. Inherency may not be established by probabilities or possibilities.

The fact that an element may result from a given set of circumstances is not sufficient to prove inherency.

Obviousness

49. I understand that a patent claim is invalid under 35 U.S.C. § 103 as being obvious only if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in that art. An obviousness analysis requires consideration of four factors: (1) scope and content of the prior art relied upon to challenge patentability; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) the objective evidence of non-obviousness, such as commercial success, unexpected results, the failure of others to achieve the results of the invention, a long-felt need which the invention fills, copying of the invention by competitors, praise for the invention, skepticism for the invention, or independent development.

50. I understand that a prior art reference is proper to use in an obviousness determination if the prior art reference is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met. First, a prior art reference is analogous art if it is from the same field of endeavor as the claimed invention, even if the prior

art reference addresses a different problem and/or arrives at a different solution.

Second, a prior art reference is analogous art if the prior art reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

51. I understand that it must be shown that one having ordinary skill in the art at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded. Furthermore, I understand that a claim may be obvious in view of a single prior art reference, without the need to combine references, if the elements of the claim that are not found in the reference can be supplied by the knowledge or common sense of one of ordinary skill in the relevant art. However, I understand that it is inappropriate to resolve obviousness issues by a retrospective analysis or hindsight reconstruction of the prior art and that the use of “hindsight reconstruction” is improper in analyzing the obviousness of a patent claim.

52. I further understand that the law recognizes several guidelines that inform the obviousness analysis. First, I understand that a reconstructive hindsight approach to this analysis, i.e., the improper use of post-invention information to help perform the selection and combination, or the improper use of the listing of elements in a claim as a blueprint to identify selected portions of different prior art references in an attempt to show that the claim is obvious, is not permitted.

Second, I understand that any prior art that specifically teaches away from the claimed subject matter, i.e., prior art that would lead a person of ordinary skill in the art to a specifically different solution than the claimed invention, points to non-obviousness, and conversely, that any prior art that contains any teaching, suggestion, or motivation to modify or combine such prior art reference(s) points to the obviousness of such a modification or combination. Third, while many combinations of the prior art might be “obvious to try,” I understand that any obvious to try analysis will not render a patent invalid unless it is shown that the possible combinations are: (1) sufficiently small in number so as to be reasonable to conclude that the combination would have been selected; and (2) such that the combination would have been believed to be one that would produce predictable and well understood results. Fourth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references uses known methods or techniques that yield predictable results, then that factor also points to obviousness. Fifth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of known work in one field prompting variations of it for use in the same field or a different one based on design incentives or other market forces that yields predictable variations, then that factor also points to obviousness. Sixth, I understand that if a claimed invention that arises from the modification or

combination of one or more prior art references is the result of routine optimization, then that factor also points to obviousness. Seventh, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of a substitution of one known prior art element for another known prior art element to yield predictable results, then that factor also points to obviousness.

53. I understand that each alleged prior art reference in a proposed obviousness combination must be evaluated in its entirety, i.e., including those portions that would argue against obviousness, and must be considered for everything that it teaches, not simply the described invention or a preferred embodiment. I understand that it is impermissible to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art, or to ignore portions of the reference that argue against obviousness. I also understand that all of the supposed prior art to be combined as proposed must also be evaluated as a whole and should be evaluated for what they teach in combination as well as separately.

Dependent Claims

54. I understand that a dependent claim incorporates each and every limitation of the claim(s) from which it depends. Thus, my understanding is that if

a prior art reference fails to anticipate an independent claim, then that prior art reference also necessarily fails to anticipate all of its dependent claims. Similarly, my understanding is that if a prior art reference or combination of prior art references fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all of its dependent claims.

IV. OVERVIEW OF THE ‘217 PATENT

55. The ‘217 Patent discloses and claims a dental appliance often referred to as a dental isolation mouthpiece. *See, e.g.*, Ex. 1001 at 1:15-17 (“the present invention relates to intraoral dental suction and isolation mouthpieces”).

56. The specification acknowledges that “[v]arious mouthpieces are currently used by dental health professional, dental hygienists, and dental assistants in the field of dentistry.” Ex. 1001 at 1:21-25. The specification also describes a typical dental treatment where a dental patient is 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.” Ex. 1001 at 1:23-30. Typically, the dental assistant assists “in coordinating the use of these multiple items of different equipment and materials.” Ex. 1001 at 1:35-38.

57. 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.” Ex. 1001 at 1:39-41. 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. Ex. 1001 at 2:52-65.

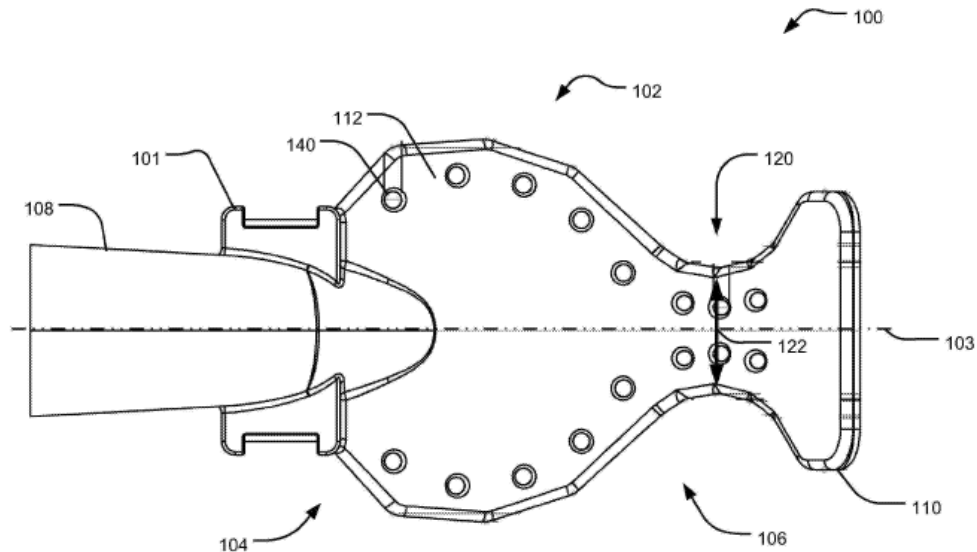
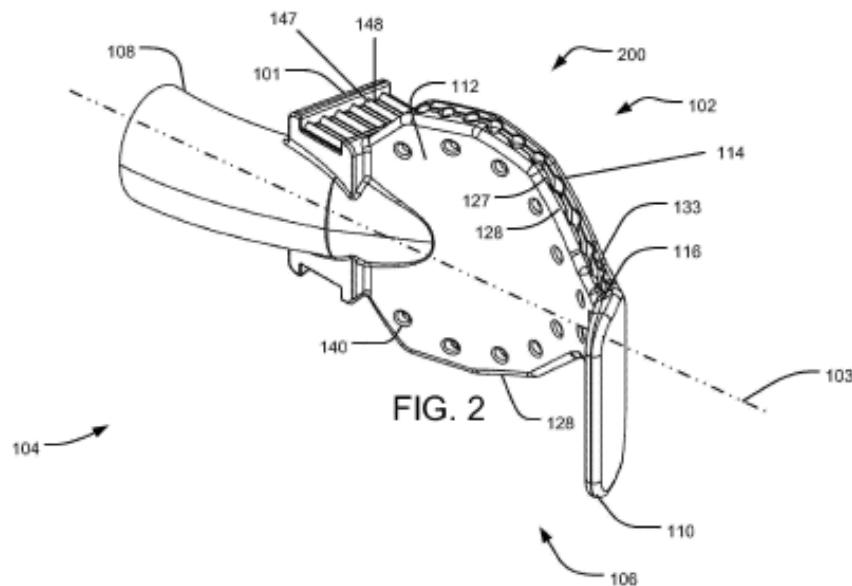


FIG. 1

Ex. 1001 at FIG. 1

58. FIG. 2 is an isometric view of the mouthpiece illustrated in FIG. 1. Ex. 1001 at 2:9-10. 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." Ex. 1001 at 3:24-28. "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." Ex. 1001 at 3:29-34.



59. 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." Ex. 1001 at 3:52-54. When placed in a patient's mouth, 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." Ex. 1001 at 3:54-57. The specification further explains that "[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." Ex. 1001 at 4:6-13.

60. As shown in the figures, the main body portion 102 can include opening on the anterior wall 112 and/or posterior wall 114 (shown with reference number 140 and referred to as perforations, slit, aperture, etc.) 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." Ex. 1001 at 4:14-20.

61. In addition to the posterior and anterior walls, the '217 Patent 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." Ex. 1001 at 6:20-24. 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." Ex. 1001 at 6:31-35. These crests and troughs "may provide further retraction, stability, support, and curvature to the mouthpiece 100." Ex. 1001 at 6:42-44. An example is shown below in FIG. 6:

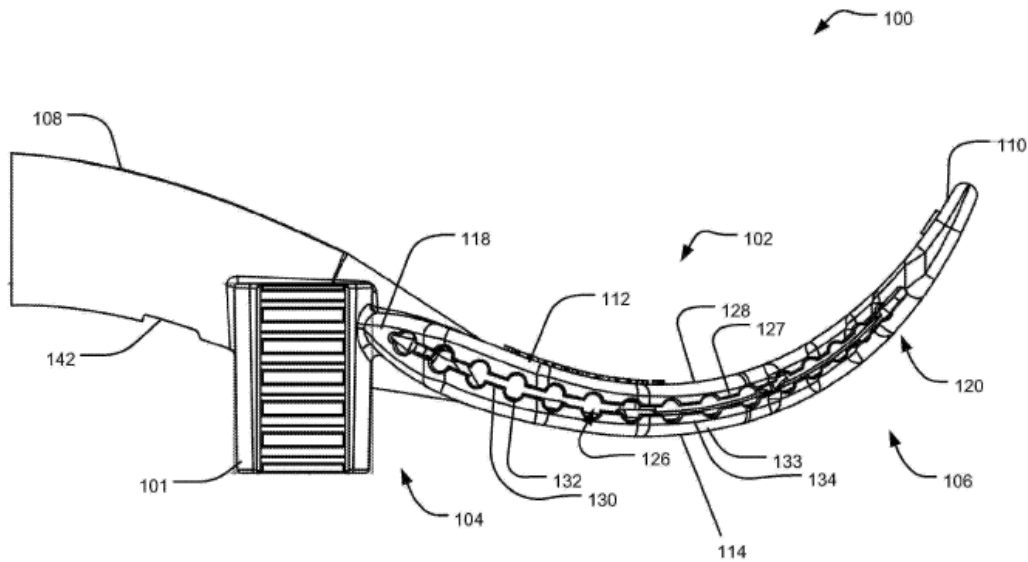


FIG. 6

Ex. 1001 at FIG. 6

62. The mouthpiece 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.” Ex. 1001 at 6:45-48. The posterior intervening wall 134 “may likewise exhibit ridges that are the same, a mirror image, or different from the anterior intervening wall 127.” Ex. 1001 at 6:48-50. An open mesh 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.” Ex. 1001 at 6:59-64.

63. FIG. 7 of the ‘217 Patent shows the anterior wall of the mouthpiece pulled away from a posterior wall of the mouthpiece.” Ex. 1001 at 7:8-10.

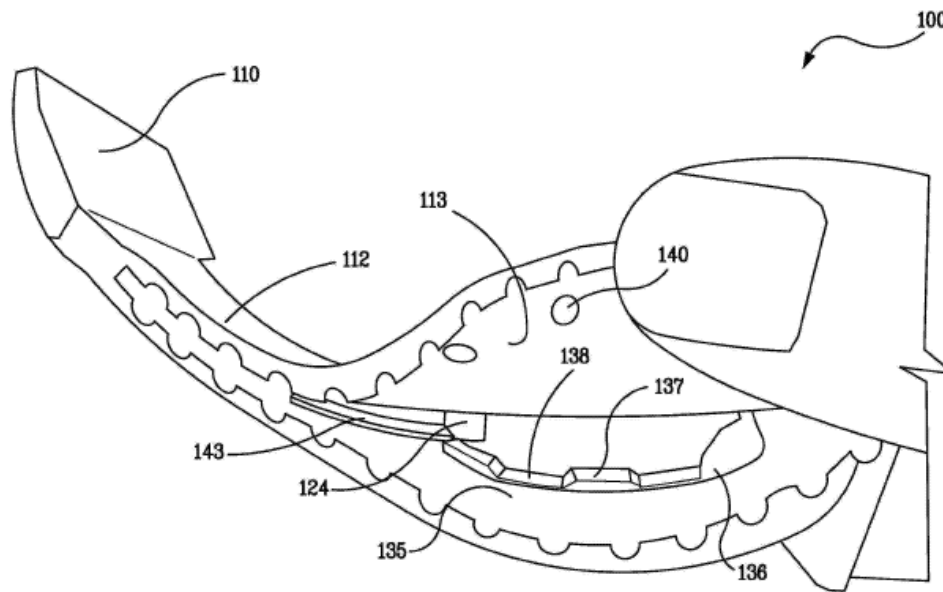


FIG. 7

Ex. 1001 at FIG. 7

64. The ‘217 Patent also describes a “connector” feature. For example, the “anterior wall 112 and the posterior wall 114 may be connected to each other ... by at least one connector 124.” Ex. 1001 at 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.” Ex. 1001 at 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.” Ex. 1001 at 8:24-27. An exemplary connector can be seen in FIGS. 4-5 (reproduced below) and FIG. 7:

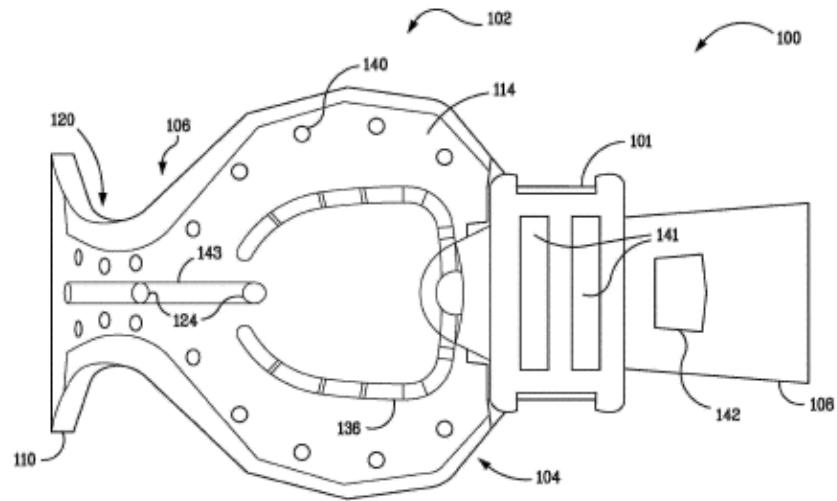


FIG. 4

Ex. 1001 at FIG. 4

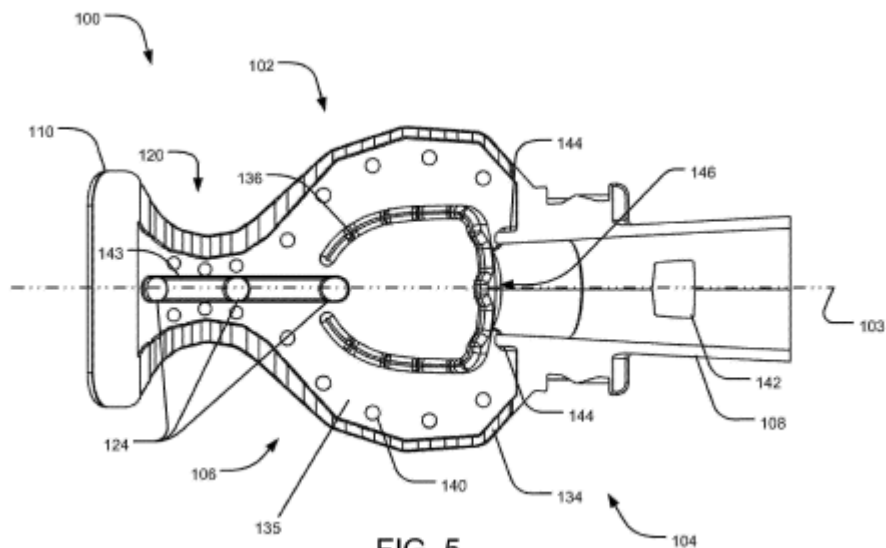


FIG. 5

Ex. 1001 at FIG. 5

65. The '217 Patent also describes a “bridge structure” feature. In one example, the bridge structure 136 protrudes “from the interior surface 135 in a wave shape with bridge crests 137 and bridge troughs 138.” Ex. 1001 at 5:6-20.

When the mouthpiece is in use, “[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.” Ex. 1001 at 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.” Ex. 1001 at 5:38-40.

66. Regarding the interior of the mouthpiece, the specification explains that “[o]ther than the at least one connector 124, a stability bar 143, and a bridge structure 136, the interior space 126 is generally open and unobstructed, thereby allowing for suction to flow throughout the interior space 126.” Ex. 1001 at 6:8-12.

67. The ‘217 Patent also teaches that “[d]ifferently-sized mouthpieces may be provided for differently-sized mouths of adults and children.” Ex. 1001 at 4:1-3.

68. Independent claims 1 and 17 of the ‘217 Patent, which I understand are the challenged independent claims, are reproduced below with the identifiers used in the Petition and Dr. Black’s declaration for ease of reference:

69. Independent claim 1 recites:

1(a)	A dental mouthpiece formed in a curve, the dental mouthpiece comprising:
1(b)	a main body portion at a central part of the curve having a first end and a second end, the main body portion having an anterior wall inside the curve and a posterior wall outside the curve, the anterior wall and the posterior wall defining an interior space corresponding to a distance between the anterior wall and the posterior wall,
1(c)	at least one connector connecting the anterior wall to the posterior wall,
1(d)	an anterior intervening wall protruding from and extending along an edge of the anterior wall, the anterior intervening wall having a span that extends partially across the distance of the interior space towards the posterior wall, and a posterior intervening wall extending along an edge of the posterior wall partially across the distance towards the anterior wall, and
1(e)	wherein an edge of the span of the anterior intervening wall has alternating crests and troughs that extend different distances partially across the interior space towards the posterior intervening wall;

1(f)	a suction connector portion connected to the first end, the suction connector portion connecting the interior space to a vacuum suction source; and
1(g)	a cheek retractor portion connected to the second end.

70. Independent claim 17 recites:

17(a)	A dental mouthpiece comprising:
17(b)	a main body portion having a first end and a second end, the main body portion comprising: an anterior wall, a posterior wall spaced at a distance from the anterior wall, wherein an interior space corresponding to the distance between the anterior wall and the posterior wall is defined by the anterior wall and the posterior wall,
17(c)	at least one connector that connects the anterior wall to the posterior wall within the interior space,
17(d)	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, and

17(e)	wherein 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, and
17(f)	a neck extending from the second end of the main body portion, wherein a width of the neck is less than a width of the main body portion at the first end;
17(g)	a suction connector portion connected to the first end of the main body portion, the suction connector portion further configured to connect the interior space to a vacuum suction source; and
17(h)	a cheek retractor portion connected to the neck that extends from the second end of the main body portion, wherein the width of the neck is less than a width of the cheek retractor portion.

V. PROSECUTION HISTORY OF THE ‘217 PATENT

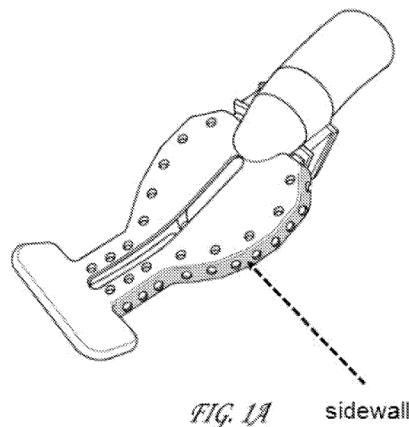
71. I understand that the application leading to the ‘217 Patent was filed on May 8, 2020 and claims priority to a provisional application filed on May 10, 2019. Ex. 1001 at Cover. The Patent Office issued three office actions during prosecution of the ‘217 Patent.

72. The Examiner issued a Non-Final Office Action on December 3, 2021. Ex. 1015 at 44-56. The Examiner rejected claims 1-3, 8-11, 13, 15-16, and

18-19 as anticipated by Reyes (Ex. 1019). *Id.* at 47. The Examiner also rejected claims 4-7, 12, 14, 17 and 20 as obvious over Reyes. *Id.* at 53.

73. The Applicant filed a response the first Office Action on March 2, 2022 and argued that Reyes does not disclose an “intervening wall” as claimed. Ex. 1015 at 228-37. The Applicant also explained this in a telephone interview with the Examiner held on March 4, 2022. *Id.* at 251-53.

74. The Examiner issued a Final Office Action on May 12, 2022. Ex. 1015, 262-77. The Examiner rejected claims 1, 3-5, 8, 10-14, 17-19, and 21-27 as obvious over Nguyen (Ex. 1005), Al-Shawi (Ex. 2009), and He (a Chinese reference). *Id.* at 264. 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.* at 264-65. The Examiner’s annotation of the “sidewall” in Nguyen is reproduced below:



Ex. 1015 at 265 (annotating Ex. 1005 at FIG. 1A).

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

Nugyen 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.

Ex. 1015 at 265-66.

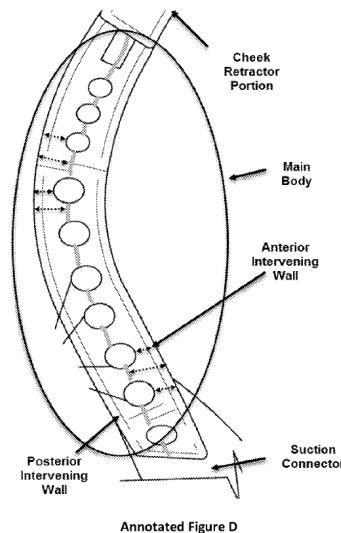
76. The Examiner then applied Al-Shawi (Ex. 2009) and asserted that it discloses “suction conduits . . . formed by two half-walls (401, 402) having mating projections (422) . . . with interspaced flow channels form crest and trough shapes on the two mating half-walls (401, 402) that extend toward each other and abut each other to provide the flow channels within the device.” *Id.* at 266. The Examiner also 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.

Ex. 1015 at 266.

77. The Examiner illustrated how Nguyen's single sidewall would be modified to create abutting anterior and posterior intervening walls with crests and troughs as shown below:



Ex. 1015 at 269 (annotating Ex. 1005 at FIG. 1D)

78. In response, Applicant argued against the combination of Nguyen and Al-Shawi, and in particular argued 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.* at 195-96.

79. The Examiner next issued a Non-Final Office Action on February 17, 2023. Ex. 1016 at 227-40. In this Office Action, the Examiner withdrew the prior rejection based on Nguyen. *Id.* at 239. Instead, the Examiner rejected claims 1, 3, 8, 10-13, 15, 18-19, 21-23, and 26-27 as anticipated by Hirsch. *Id.* at 230. The Examiner also rejected claims 4-5, 14, 17 and 24-25 as obvious over Hirsch and Nguyen. *Id.* at 237. The Examiner characterized Hirsch as “the best prior art.” *Id.* at 239.

80. Following this third Office Action, the Applicant conducted a telephone interview with the Examiner. Ex. 1016 at 247-53. The Applicant then filed a response with claim amendments relating to the “intervening wall” as discussed during the interview. *Id.* at 255-66.

81. On September 18, 2023, the Examiner issued a Notice of Allowance withdrawing the previous rejections and allowing the claims. Ex. 1016 at 337-42. In the statement of reasons for allowance, the Examiner again noted that “Hirsch ... was found to be the best art” and found that the “intervening wall” limitations in the independent claims made them “allowable when in combination with the other claimed limitation[s].” *Id.* at 340-41.

VI. LEVEL OF SKILL IN THE ART

82. I understand that the level of ordinary skill in the relevant art at the time of the invention is relevant to inquiries such as the meaning of claim terms,

the meaning of disclosures found in the prior art, and the reasons one of ordinary skill in the art may have for combining references.

83. I have reviewed the definition of the level of ordinary skill in the art proposed in the Petition, which is:

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 at 21.

84. For purposes of this declaration, I have been asked to apply Petitioner's proposed definition in my analysis. I reserve the right to identify a differing level of skill in the art for the '217 Patent should an IPR be instituted.

85. I was, as of at least May 10, 2019, and still am, a person of ordinary skill in the art through my education and experience under the definition Petitioner has proposed. I am also familiar with individuals having this level of skill in the relevant timeframe.

VII. SUMMARY OF REFERENCES IN THE PETITION

86. Below, I provide a summary of the references that are relied upon in Grounds 1-3 of the Petition.

A. Nguyen (Ex. 1005) (Grounds 1-3)

87. Nguyen is a patent that I understand is also assigned to Patent Owner. Nguyen lists Thien Nguyen and Tam Thanh Pham as inventors, both of whom are listed as inventors on the '217 Patent. Ex. 1001, Cover; Ex. 1005, Cover. I also understand that Nguyen is related to U.S. Patent No. 12,011,329, which is also challenged by Petitioner in IPR2025-01104.

Black (Ex. 1007) (Grounds 1-2)

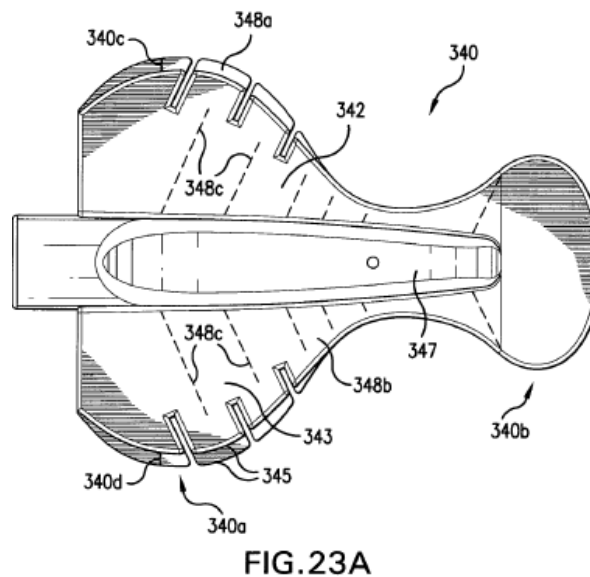
88. Black describes an intraoral device with a tongue shield aspirator, a bite member, a bite grip, and an evacuation tube. Ex. 1007, Abstract. Black discloses multiple embodiments.

89. In a first embodiment, Black describes a tongue shield aspirator 40 that 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.” Ex. 1007 at 5:55-60. The transverse walls 48c (which are shown in dashed lines in FIG. 3B below) connect the first layer 48a to the second layer 48b within the interior of the tongue shield aspirator 40 and are angled relative to the longitudinal (central) axis of the tongue shield aspirator 40.



FIG. 3B

91. In another embodiment, Black describes a tongue shield aspirator 340 including “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).” Ex. 1007 at 14:25-30. As in the first embodiment, these transverse walls 348c are angled relative to the longitudinal (central) axis of the tongue shield aspirator 340, as can be seen below in FIG. 23A.



Ex. 1007 at FIG. 23A

92. In the figure above, pairs of consecutive transverse walls 348c form the upper channels 342 and the lower channels 343 within the interior, like the first embodiment. Ex. 1007 at 14:33-37.

93. Black's figures do not include a side view of the embodiment in FIGS. 3A-B. However, FIG. 23C (which shows the other embodiment) shows a side view of the tongue shield aspirator 340 from FIGS. 23A, including the transverse walls 348c connecting the first layer 348a and the second layer 348b, and the channels 342 between adjacent transverse walls 348c.

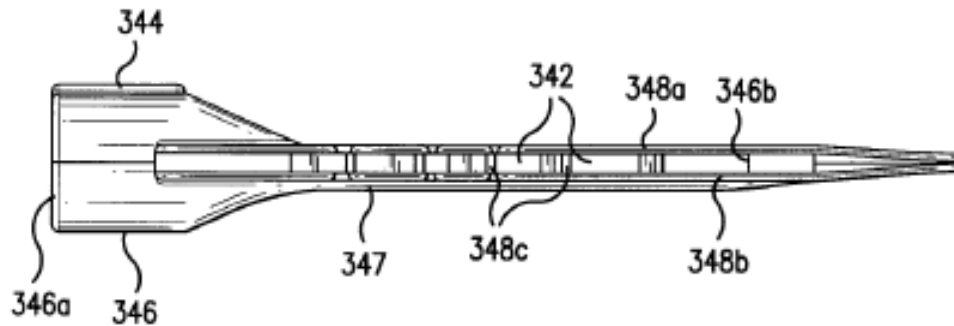
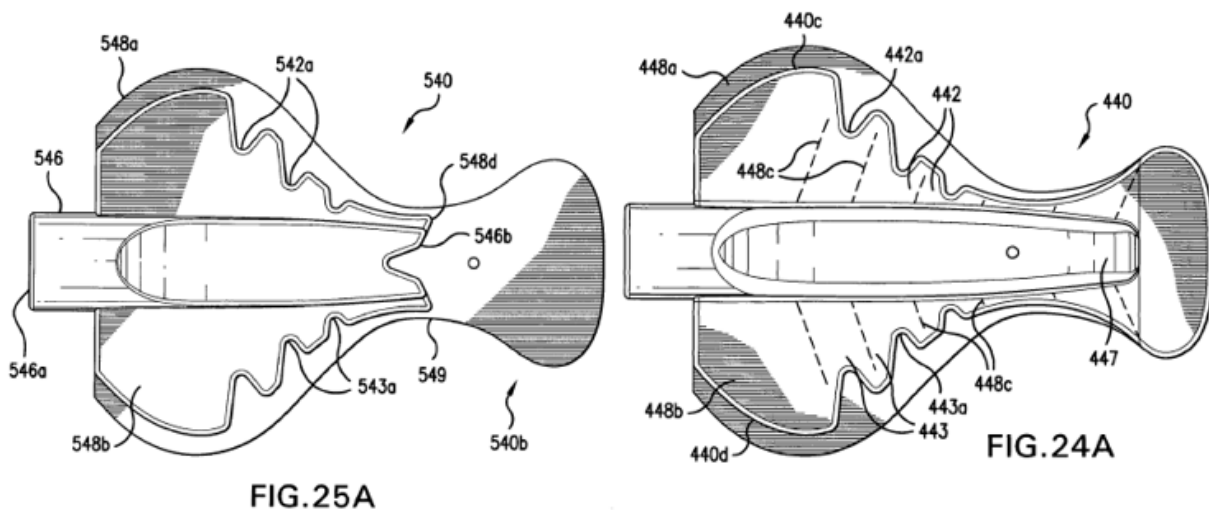


FIG. 23C

Ex. 1007 at FIG. 23C

94. Black discloses additional embodiments in FIGS. 24 and 25.



EX. 1007 at FIGS. 24A and 25A

95. Black teaches that the tongue shield aspirators disclosed in the various embodiments “may be made of disposable material.” Ex. 1007 at 9:23-28. Black indicates that the bite member or evacuation tube are “re-usable (autoclavable),” Black but never states that the tongue shield aspirators are reusable, autoclavable, or are otherwise cleaned. Ex. 1007, 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”).

Hirsch (Ex. 1006) (Ground 3)

96. Hirsch is generally directed to “dental appliances for vacuum suction of the mouth of a dental patient for examination and/or operative purposes.” Ex. 1006 at 1:13-15. Hirsch’s mouthpiece is “disposable after each use.” Ex. 1006 at 3:1-2.

97. Hirsch explains that when in use, 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.” Ex. 1006 at 4:45-55. There is also a “seal along lower edges 390, 400.” *Id.* at 4:58-67.

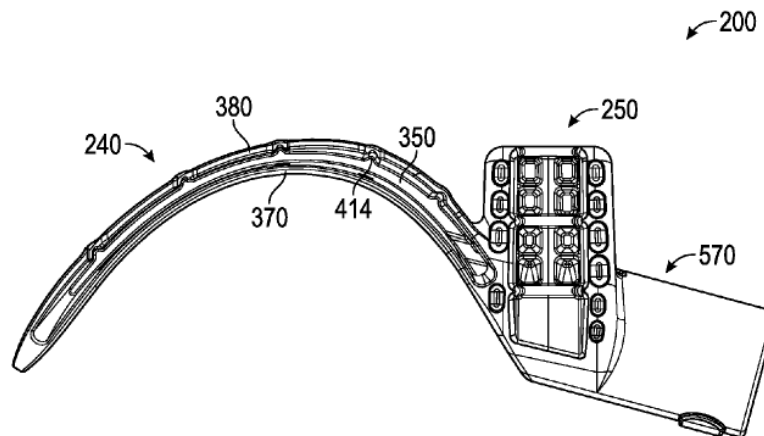


FIG. 9

Ex. 1006 at FIG. 9

VIII. CLAIM CONSTRUCTION

98. I understand that Petitioner and Dr. Black have proposed that one term/phrase in the ‘217 Patent be construed (which I address below) but otherwise contend that the remaining terms/phrases in the challenged claims of the ‘217 Patent do not require construction and can be afforded their plain and ordinary meanings. Petition at 21-24; Ex. 1003 at ¶¶ 43-45.

99. I am also informed and understand that Petitioner has proposed certain claim constructions for the ‘217 Patent in the Parallel Litigation.

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

100. Petitioner and Dr. Black assert that the phrase “partially across the distance of the interior space,” which appears in each of the independent claims,

should be construed as “only part, and not entirely, across the distance of the interior space.” Petition, 23; Ex. 1003 at ¶ 44.

101. For purposes of this declaration, I have been asked to apply Petitioner’s proposed construction for this phrase in my analysis of the grounds in the Petition.

B. Petitioner’s Constructions in the Parallel Litigation

102. I understand that the parties have proposed the following constructions for the term “main body portion” in claim 17 of the ‘217 Patent in the Parallel Litigation:

Patent Owner’s Construction	Petitioner’s Construction
Plain and ordinary meaning	The portion of the mouthpiece between, but not including, the cheek retractor portion and the suction connector and mouth prop, if present

103. I understand that the parties have proposed the following constructions for the term “interior space” in claim 17 of the ‘217 Patent in the Parallel Litigation:

Patent Owner’s Construction	Petitioner’s Construction
Plain and ordinary meaning	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
--	---

104. I note that these constructions relate to claim 17 because, as I understand it, claim 17 is the only asserted independent claim in the Parallel Litigation (i.e., independent claim 1 is not asserted). The same terms/phrases also appear in claim 1 of the '217 Patent.

105. My opinions regarding Grounds 1-3 as set forth in this declaration would not change regardless of which of the competing constructions noted above are adopted. I reserve the right to update my opinions should the district court or the Board issue claim constructions for these terms/phrases (or any other term or phrase in the '217 Patent).

IX. OPINIONS ON GROUNDS IN THE PETITION

106. The Petition and Dr. Black's declaration include three grounds challenging the validity of the '217 Patent. My opinions on each ground follow.

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

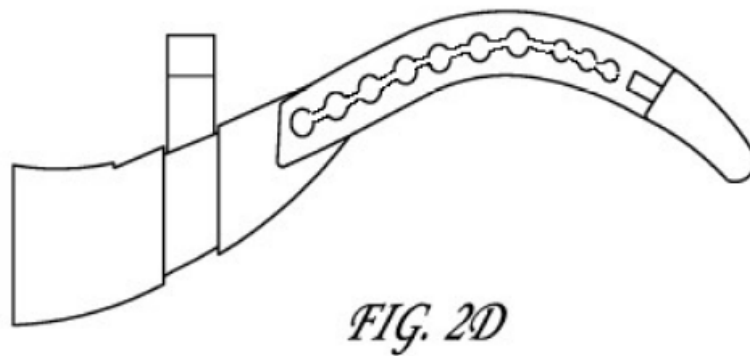
107. In Ground 1, Petitioner and Dr. Black assert that claims 1-11 and 13-23 of the '217 Patent are obvious over Nguyen in view of Black. Petition at 28-53; Ex. 1003 at ¶¶ 58-122. For at least the reasons discussed below, I disagree.

1. Independent Claim 1

108. Limitation 1(d) recites: “an anterior intervening wall protruding from and extending along an edge of the anterior wall, the anterior intervening wall having a span that extends partially across the distance of the interior space towards the posterior wall, and a posterior intervening wall extending along an edge of the posterior wall partially across the distance towards the anterior wall.”

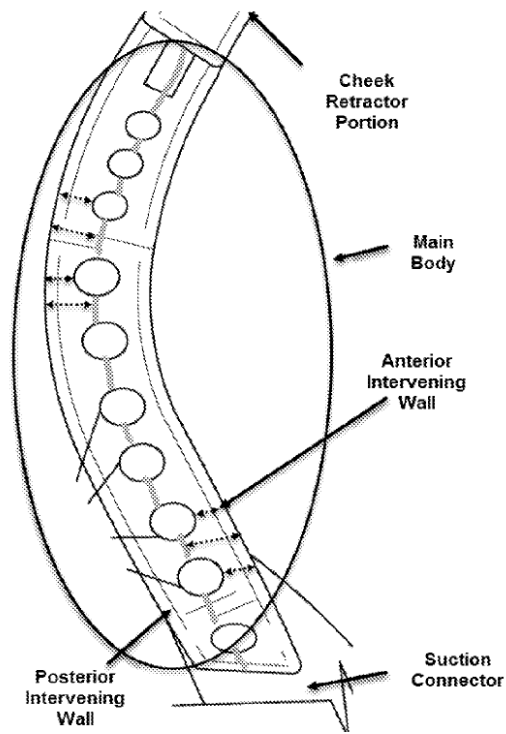
Limitation 1(f) adds: “wherein an edge of the span of the anterior intervening wall has alternating crests and troughs that extend different distances partially across the interior space towards the posterior intervening wall.”

109. Petitioner and Dr. Black concede that Nguyen does not disclose the claimed “intervening wall[s].” Petition at 33; Ex. 1003 at ¶ 68. Accordingly, Petitioner and Dr. Black propose modifying Nguyen in two ways. First, they propose “[c]utting open the sidewalls of Nguyen” and assert that this results in two intervening walls as claimed. Petition at 42-43; Ex. 1003 at ¶ 87. They show what the resulting modification to Nugyen would look like using the graphic reproduced below:



Petition, 43; Ex. 1003 at ¶ 87

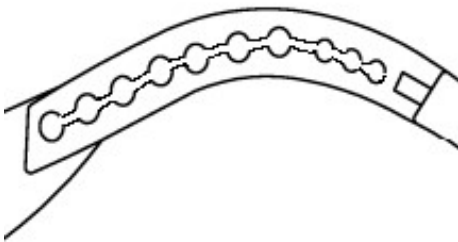
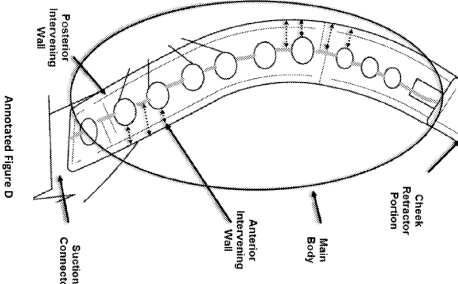
110. Before diving into a detailed analysis, I note that this proposed modification to Nguyen in view of Black is nearly identical to the obviousness rejection that the Applicant overcame during prosecution based on Nguyen and Al-Shawi. As discussed above, the Examiner had rejected broader pending claims as obvious based on Nguyen and argued that one would “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.” Ex. 1015 at 264-66. The Examiner even illustrated the proposed modification with the annotated drawing below:



Annotated Figure D

Ex. 1015 at 269

111. As shown below, Examiner's illustration of this modification is nearly identical to the illustration provided by Petitioner and Dr. Black:

Dr. Black's Proposed Modification to Nguyen	The Examiner's Proposed Modification to Nguyen
	

112. In response to this rejection, the Applicant argued 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.’” Ex. 1016 at 195-96. The Examiner subsequently withdrew the rejection in the next Office Action and eventually allowed the claims over Nguyen and Black, which was also considered during prosecution. *Id.* at 237 (third Office Action withdrawing Nguyen rejection), 337-42 (Notice of Allowance).

113. The second modification Petitioner and Dr. Black propose is duplicating Nguyen’s bridge structure at the edges of one of the anterior or posterior walls. Petition at 41-42; Ex. 1003 at ¶ 84.

114. For the reasons discussed below, I disagree with Petitioner and Dr. Black’s analysis and conclusions.

a. Petitioner and Dr. Black’s Contentions Regarding Black’s Teachings are Incorrect

115. Petitioner and Dr. Black rely on Black’s teachings as alleged motivation to modify Nguyen to arrive at the claimed inventions. However, as I discuss below, Petitioner and Dr. Black mischaracterizes Black’s teachings in multiple respects.

116. First, the Petition asserts 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 at 33 (citing Ex. 1007 at 17:47-54). Dr. Black takes Petitioner’s argument a next step further and asserts 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.” Ex. 1003 at ¶ 69 (citing Ex. 1007 at 17:47-54). I disagree.

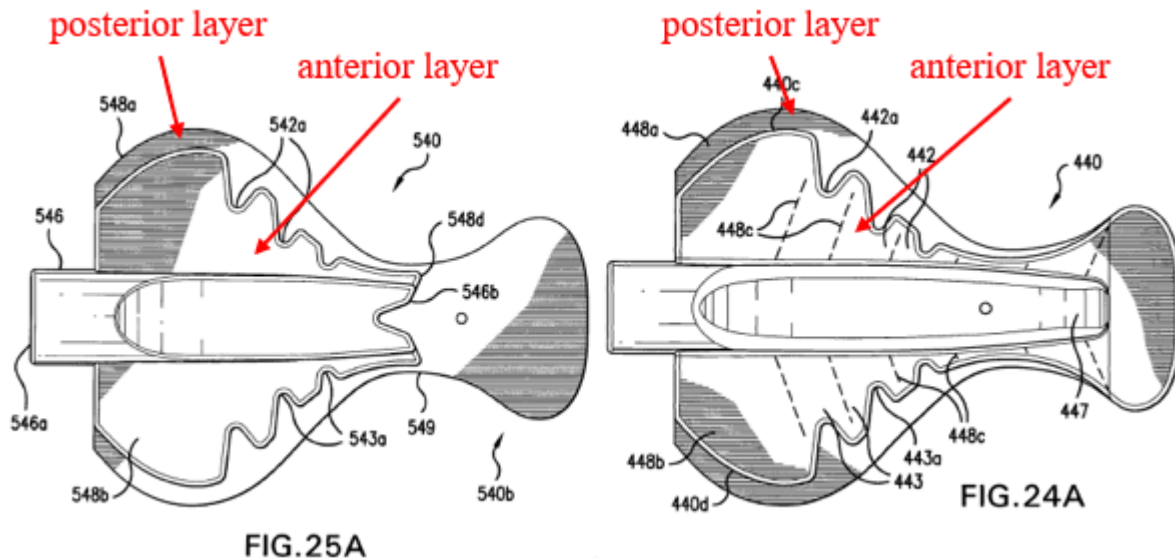
117. Contrary to Petitioner and Dr. Black’s assertions, Black does not teach that an “open-sided” mouthpiece provides advantages relative to a “closed-sided” mouthpiece. The portion of Black that is cited by Petitioner and Dr. Black for this premise is reproduced below:

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.

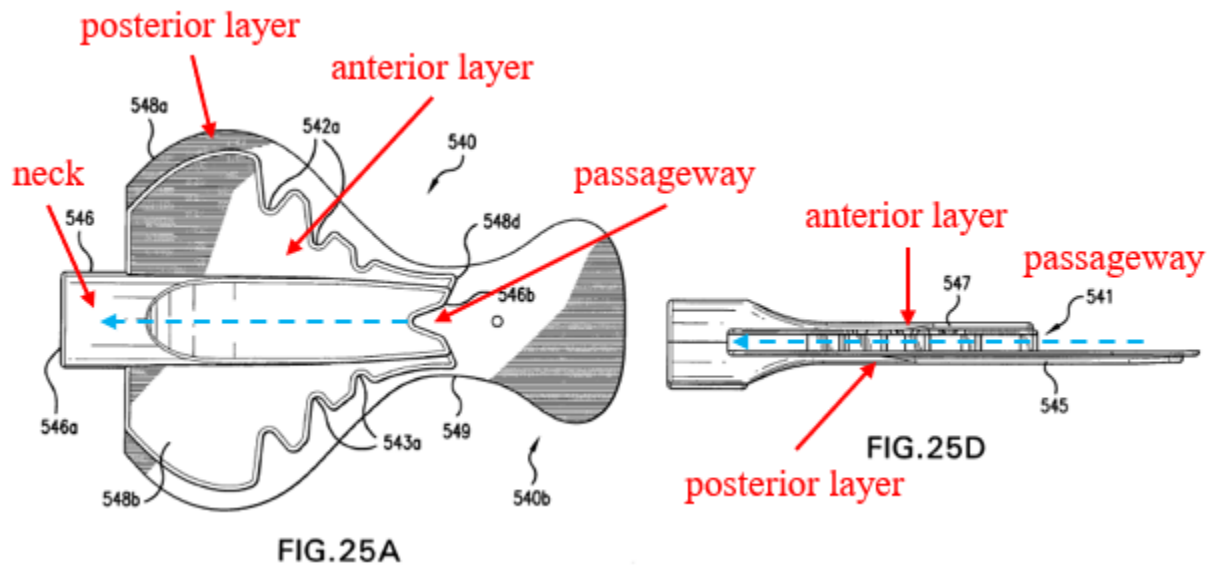
Ex. 1007 at 17:47-54.

118. Petitioner and Dr. Black do not address the surrounding context for these two sentences. This description relates to the embodiment shown in FIGS. 25A-25D. Black explains that this embodiment differs from the prior embodiments in that “the anterior layer 548b is longitudinally shorter than the posterior layer

548a.” Ex. 1007 at 17:29-38. For example, as shown below, the anterior layer 548b in the FIG. 25 embodiment (on the left) is shorter than the anterior layer 448b in the previous FIG. 24 embodiment on the (on the right).



119. Black’s 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.” Ex. 1007 at 17:39-44. The various components of the tongue shield aspirator in this embodiment are shown below:



Ex. 1007 at FIGS. 25A and 25D (annotated)

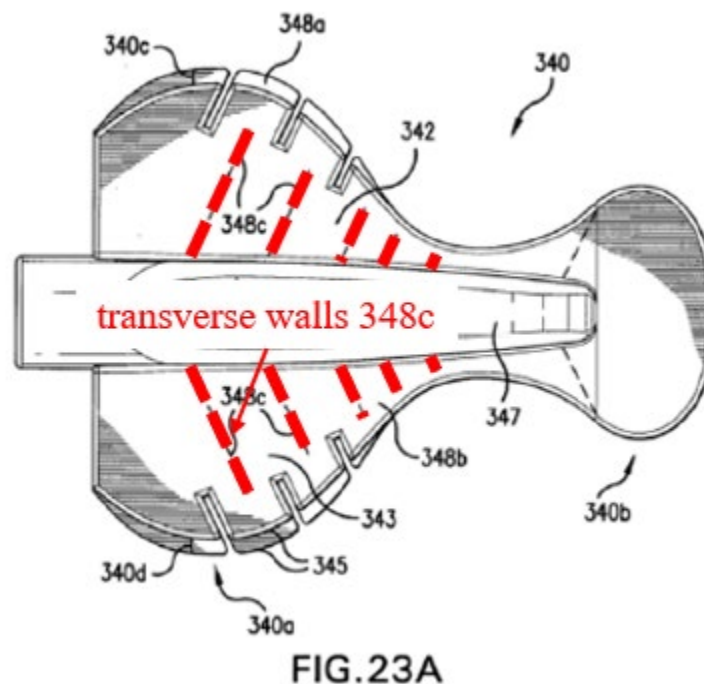
As shown above, there is a passageway through the middle or longitudinal axis of the aspirator in the FIG. 25A embodiment, which is made possible because the anterior layer 548b is shorter relative to the other embodiments. Ex. 1007 at 17:29-38.

120. Turning back to the portion of Black that Petitioner and Dr. Black rely on, when considering it in its fully context, it is clear that Black does not teach that “open-sided” mouthpieces have advantages over “closed-sided” mouthpieces. Rather, Black is explaining that the alternative embodiment shown in FIGS. 25A-D provides more suction and bending compared to the other embodiments in Black because it includes an additional passageway for fluid and debris aspiration. Ex. 1007 at 17:47-54.

121. Second, the Petition asserts 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 at 40 (citing Ex. 1007 at 14:21-47, FIG. 23A; Ex. 1003 at ¶ 81). Dr. Black similarly asserts “Black teaches that anti-collapse structure is necessary at edges of the anterior wall.” Ex. 1003 at ¶ 81. I disagree.

122. As shown below in FIG. 23A, Black’s transverse walls 348c do **not** extend “all the way to the edge of the anterior flap 438b” as asserted by Petitioner and Dr. Black:



EX1007, FIG. 23A (annotated)

123. Additionally, Black does not disclose that the purpose of the transverse walls 348c is to prevent the anterior and posterior walls from collapsing during suction. In fact, Black does not mention the possibility of the anterior and posterior walls collapsing during suction. Black does not expressly disclose “anti-collapse structure” and it does not disclose that the transverse walls 348c extend to the edges. I therefore disagree with Dr. Black’s claim that “Black teaches that anti-collapse structure is necessary at edges of the anterior wall.” Ex. 1003 at ¶ 81.

b. A POSITA Would Not Modify Nguyen to Increase Suction

124. Below, I address Petitioner and Dr. Black’s assertions regarding “improved suction.”

125. Dr. Black asserts that “a POSA would know that Nguyen’s dental mouthpiece would bend in a patient’s mouth due to the roof of the mouth pressing down on the super sidewall and the floor of the mouth pressing up on the inferior sidewall.” Ex. 1003 at ¶ 71. Dr. Black also asserts that “the patient’s gum ridges behind the molars would press down on the rectangular portion of Nguyen’s mouthpiece, causing additional bending/folding.” *Id.* Based on these forces from the mouth/gum, Dr. Black goes on to make a series of assertions regarding Nguyen’s walls bending/folding and how this is undesirable. *Id.* at ¶¶ 72-75. I disagree.

126. Regarding Dr. Black’s assertion that the roof and floor of the mouth would apply forces to Nguyen’s mouthpiece that would cause bending/folding, I first observe that none of Dr. Black’s citations to Nguyen or Black support this notion. Ex. 1003 at ¶ 71 (citing Ex. 1005 at 3:29-31, 3:42-25, 4:20-30, 1:52,55, 2:2-5; Ex. 1007 at 19:33-20:47, 20:3-20). Below I address each citation and show that it does not discuss the mouth applying a force that causes appreciable (let alone undesirable) bending:

- **Ex. 1005 at 3:29-31:** Nguyen states that “[t]he flexibility of the material used to form the mouthpiece allows for some bending when placed in the patient’s mouth.” Ex. 1005 at 3:29-31. This is simply referring to the fact that the dental professional needs to bend or fold the mouthpiece in order to initially place the mouthpiece in the patient’s mouth. This does not suggest to a POSITA that forces from the mouth floor and/or roof apply a force that causes undesirable bending of the mouthpiece when placed in the mouth during a dental procedure.
- **Ex. 1005 at 1:52-55:** Nguyen merely states that “the mouthpiece may be made of a material that is flexible, translucent, conducive to injection molding, high heat-resistant, and autoclavable.”
- **Ex. 1005 at 2:2-5:** similar to the citation at 3:29-31, Nguyen states “Because the mouthpiece is made of a flexible and resilient material (e.g., silicone),

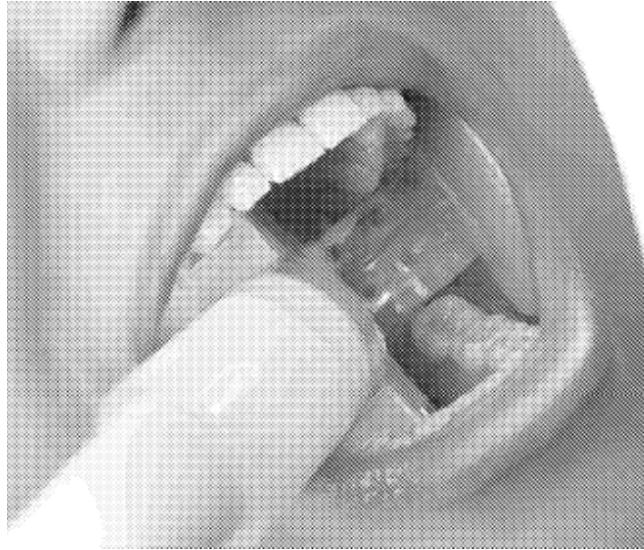
the mouthpiece may be bent when placed in a patient's mouth to conform to the shape of the mouth.” Again, this merely refers to bending the mouthpiece to initially position in the mouth, not the type of bending/folding that Dr. Black is referring to.

- **Ex. 1005 at 3:42-45:** Nguyen states that “[s]uperior may be used herein to refer to the side that rests against a roof of a patient’s mouth when placed therein, and inferior may be used to refer to the side that rests against the floor of the patient’s mouth.” Here, Nguyen is saying that the superior and inferior walls “rest[] against” a portion of the patient’s mouth. It does not say that there is an appreciable force that causes bending or folding of the mouthpiece.
- **Ex. 1005 at 4:20-30:** Nguyen discusses the reinforcing or stability bar 150 and states that this feature “may be located in the area where a positioned mouthpiece begins to wrap from the lingual side of the most posterior mandibular tooth, around the distal side of the most posterior tooth, and to anterior side of the most posterior mandibular tooth, thereby assisting in shaping the mouthpiece to the general intraoral shape of a patient's mouth.” Nguyen does not say that this portion of the mouth applies a force that is sufficient to cause undesirable bending or folding of the mouthpiece.

- **Ex. 1007 at 19:33-20:47:** here, Dr. Black cites over a column of text from Black but nowhere does Black discuss bending caused by vertical displacement from the mouth roof or floor.
- **Ex. 1007 at 20:3-20:** Black is discussing bending of the cheek retractor during insertion here, not bending due to forces from the roof and floor of the mouth when the mouthpiece is positioned in the mouth of the user.

127. Nguyen teaches that “[d]ifferently-sized mouthpieces may be provided for differently-sized mouths of adults and children.” Ex. 1005 at 4:1-3. A POSITA would know from this teaching that the mouthpiece can be appropriately sized so that the mouth floor/roof and gums would not apply the kind of force that would cause undesirable bending or folding of the mouthpiece suggested by Dr. Black.

128. My opinion on this point is consistent with Patent Owner’s product literature for its DryShield® product. I understand that a 2019 brochure for Patent Owner’s DryShield® product was cited in an Information Disclosure Statement and considered by the Examiner. Ex. 1015 at 35. I understand that Ex. 2022 is a copy of the submitted brochure. As can be seen in the image below, when placed in the mouthpiece, there is no noticeable bending or folding of the mouthpiece as suggested by Dr. Black.



EX2022

129. I understand that Ex. 2019 is a current brochure from Patent Owner that is available on its website at the following URL: https://solmetex.com/wp-content/uploads/2023/10/dryshield_userguide_RevE_6x9_FINAL.pdf. The brochure shows how to select the correct size mouthpiece for a patient:



Too small



Too big



Correct fit

EX2019, 17

In the middle, the mouthpiece is too big for the patient. As can be seen in the image, there is some of the bending/folding that Dr. Black describes in his declaration. However, as shown on the right side, when the correct fit is selected, there is minimal, if any, bending or folding of the mouthpiece, and certainly not any bending or folding that would meaningfully impede suction. Further, as can be seen on the right side of the photo, the gum ridges are not causing any bending or folding of the cheek retractor portion of the mouthpiece.

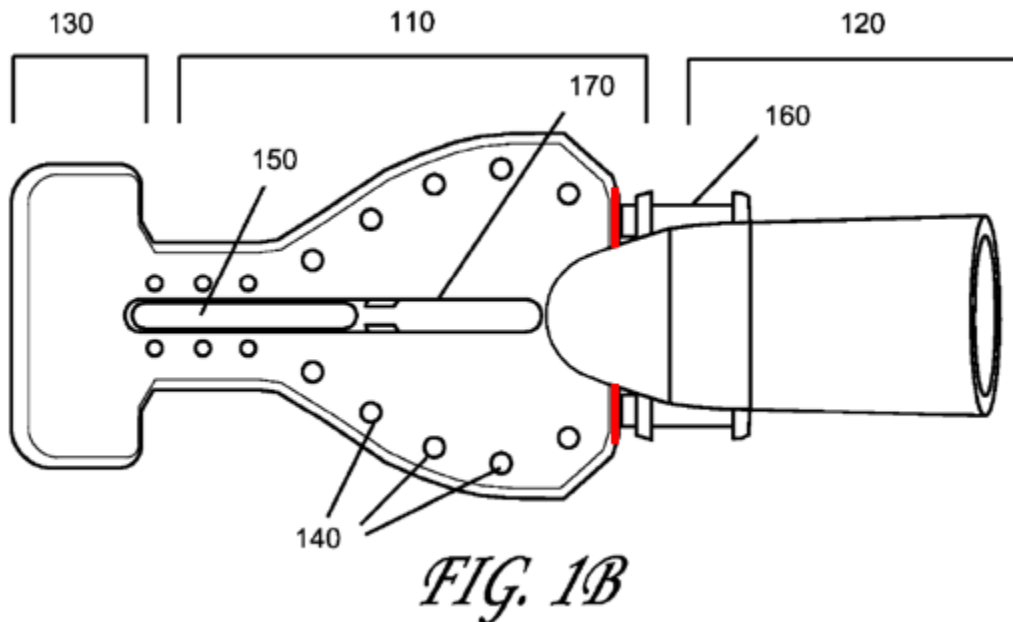
130. Dr. Black also asserts that Nguyen's anterior and posterior walls would "bend along different paths" but that "[w]ith connecting sidewalls, the geometry does not allow the anterior wall and the posterior wall to bend at different radiuses." Ex. 1003 at ¶ 72. In my view, Dr. Black overstates the impact of "sidewalls." Regardless of whether there are any sidewalls, the radii of the anterior and posterior walls are already different given that they are pre-curved.

131. Dr. Black asserts that "one such bending point would be at the slit 170 (the weakest part of the anterior wall), thereby causing the anterior wall to fill a trough in the bridge structure 180 aligned with the slit." Ex. 1003 at ¶ 73. He then says that the "bent anterior wall at the slit would decrease suction at the rectangular portion of the mouthpiece, an important place for suction because the dental operation occurs near the rectangular portion." *Id.* I disagree for several reasons. One, there would have to be significant bending or folding of the mouthpiece for

the issues Dr. Black describes to occur. Two, as discussed above, the evidence cited by Dr. Black does not support the notion that the mouth/gums apply sufficient force to cause significantly bending and ignores that the mouthpiece would be properly sized for the patient. Three, even if there were some bending or buckling of the wall near the slit, any flow restriction introduced by such a buckling condition would be trivial. There are numerous alternate flow paths such as those provided by Nguyen's bridge structure as a whole. Stated another way, if, as Dr. Black concedes, the bridge structure in Nguyen prevents collapse of the walls during suction, they would also prevent collapse of the walls due to the buckling he describes.

132. Dr. Black asserts that a POSITA "would recognize that the anterior wall would also bend where the anterior wall meets the suction connector." Ex. 1003 at ¶ 74. Dr. Black acknowledges that "the suction connector is made of a thicker material than the wall," but nevertheless asserts that "this means the anterior wall would narrow or block suction channels formed at troughs of the bridge structure because the anterior wall is thinner, weaker, and more flexible than the suction connector walls." *Id.* I disagree. One, I disagree that the degree of bending or folding that would be required to cause the issue Dr. Black is describing would occur from forces from the mouth roof/floor or gums, as discussed above. Two, Dr. Black overlooks the fact in the exemplary embodiment shown in

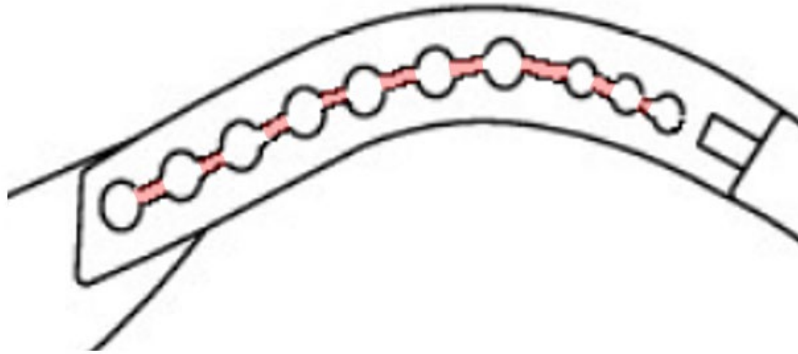
Nguyen's figures, there is additional material near the suction connector that would provide reinforcement (see, e.g., annotation below). Three, Dr. Black overlooks that Nguyen discloses that "[p]art of the base side of the arrowhead may be formed with thicker walls than the rest of the main body" and "[s]uch thickening may provide additional stability." Ex. 1005 at 3:59-62. The "base side" refers to the end of the mouthpiece near the suction connector.



Ex. 1005 at FIG. 1B (annotated)

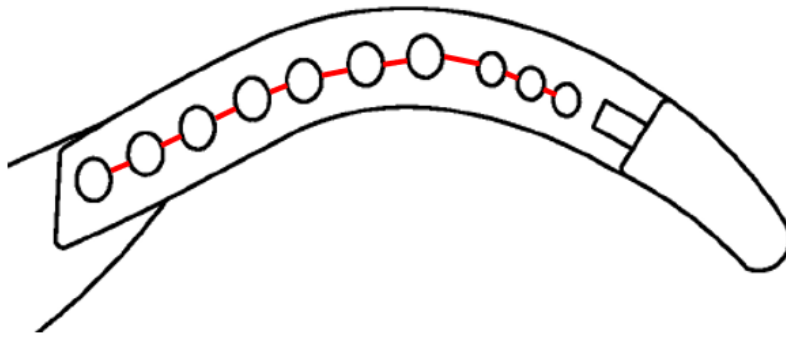
133. Dr. Black further asserts that "opening the sidewall of Nguyen would improve suction through the sides of the dental mouthpiece." Ex. 1003 at ¶ 76. Dr. Black goes on to say that "if the sidewalls of Nguyen were open, suction could occur all along the entire side" and that this "would also have the added benefit of allowing for suction of larger pieces of debris that could not fit through the holes

140.” *Id.* at ¶¶ 77-78. It appears that Dr. Black is referring to the additional open space created by cutting the material between the perforations 140 shown in Nguyen’s figures. I have annotated this space in red below:



Ex. 1003 at ¶ 87 (modifying Ex. 1005 at FIG. 2D) (red annotations added)

134. Later in his analysis, Dr. Black asserts that “there must also be a structure at the edges of the mouthpiece of Nguyen to prevent collapse under suction at the edges and at the perforations 140.” Ex. 1003 at ¶ 83. He says that “cutting open the sidewalls of Nguyen would open the sides and also create an anti-collapse structure at the edges of the mouthpiece.” *Id.* at ¶ 85. Thus, according to Dr. Black, modifying Nguyen as he proposes leads to anti-collapse structure at the edges of the mouthpiece. If that is true, then the crests would contact one another during suction to serve as anti-collapse structure. I have shown this visually using the graphic below:



EX1005, FIG. 2D) (excerpted and annotated)

135. If, as Dr. Black says, the geometry in his proposed modification leads to anti-collapse structure at the edges, then the geometry ends up being the same or similar to the original geometry prior to “cutting” Nguyen’s mouthpiece open when suction is applied. As such, the suction or flow through the mouthpiece would ultimately be the same or similar as prior to Dr. Black’s proposed modification to Nguyen. Accordingly, a POSITA would not make such a modification for purposes of increasing suction.

136. At the end of his discussion regarding limitation 1(d), Dr. Black states that “if the sidewalls of Nguyen were opened, then the slit 170 would no longer be necessary” and “removing the slit 170 could prevent the anterior wall from filling the troughs of the bridge structure 180 as discussed above.” Ex. 1003 at ¶ 89. In my view, this contradicts Dr. Black’s earlier opinions. On one hand, Dr. Black contends that Nguyen’s mouthpiece would bend when placed in the patient’s mouth such that the anterior wall would fill the troughs of the bridge structure

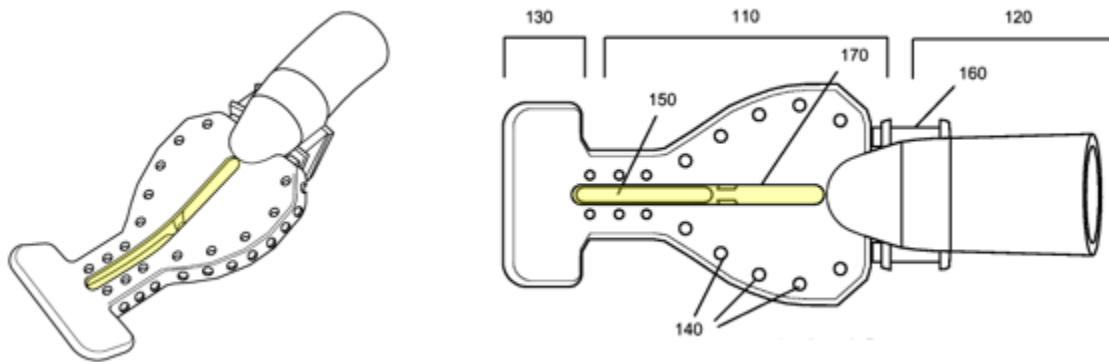
(which I disagree with) and therefore a POSITA would have been motivated to modify Nguyen in view of Black to avoid this problem. Yet on the other hand, even with the modification, Dr. Black indicates that the anterior wall may still fill the troughs of the bridge structure unless it is removed. If the latter point is true, then this is another reason why a POSITA would not have modified Nguyen in view of Black as Dr. Black suggests because doing so would not solve the supposed problem he identifies.

c. Nguyen is Not “Difficult” to Clean

137. Nugyen discloses that the mouthpieces it describes “may be made of a high heat-resistant and autoclavable material” and thus “may be reusable.” Ex. 1001 at 3:8-10. An autoclave is a device used to sterilize equipment (e.g., medical devices) using steam.

138. Dr. Black also asserts that it would have been obvious to modify Nguyen to make it “easier to clean.” Ex. 1003 at ¶¶ 69-70. Specifically, Dr. Black notes that Nguyen’s mouthpiece is autoclavable and reusable, but contends that “trying to clean inside of the mouthpiece of Nguyen through the slit 170 would not be easy” and “[i]t would be difficult for a dentist or hygienist to insert a cleaning brush through the slit 170, fold back the anterior wall, and reach the internal corners of the mouthpiece of Nguyen.” *Id.* at ¶ 79.

139. I disagree. Nothing in Nguyen would suggest to a POSITA that the mouthpiece is “difficult” to clean. As Dr. Black acknowledges, Nguyen expressly teaches that in addition to being autoclavable, manual cleaning and maintenance can occur by using slit 170, which may extend over approximately 2/3 of the main body on the anterior surface. Ex. 1005 at 4:31-37.



Ex. 10015 at FIG. 1A-1B (annotated)

140. A POSITA would readily understand that manual cleaning would be performed using a brush inserted through the slit 170. Because the mouthpiece is made of a flexible material, it can flex or stretch to accommodate the brush in the interior. 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.

141. The only specific reason Dr. Black gives for why cleaning would allegedly be difficult in Nguyen is that it would be difficult to reach the “internal corners of the mouthpiece.” Ex. 1003 at ¶ 79. I disagree. It would be simple and

straightforward for the user to insert the brush and clean the corners. One can easily use a brush with sufficient length to reach those corners through the slit 170. For example, the dental professional can use a toothbrush to easily manually clean or scrub the mouthpiece through the open slit 170.

142. Dr. Black asserts that a POSITA would modify Nguyen in view of Black's "open-sided" mouthpiece because "[o]pen sides eliminate any hard-to-reach corners" and "most prior art dental mouthpieces had open sides for at least this reason." Ex. 1003 at ¶ 80 (citing Ex. 1006, FIG. 2; Ex. 1007, FIG. 23C, Ex. 1017, FIG. 4, Ex. 1018, FIG. 1; Ex. 1019, FIG. 3). Here, Dr. Black cites figures from Hirsch (Ex. 1006), Black (Ex. 1007), an untranslated Chinese reference (Ex. 1017), Kim (Ex. 1018), and Reyes (Ex. 1019). While the figures may suggest that the mouthpieces are "open-sided" in the cited references, the figures do not support Dr. Black's assertion that the prior art had open sides for easier cleaning. In fact, as discussed below, none of these references disclose a reusable mouthpiece that requires cleaning.

143. Hirsch teaches that the mouthpiece described herein is "disposable after each use." Ex. 1006 at 3:1-2. Hirsch never mentions autoclaving the mouthpiece, cleaning the mouthpiece, or otherwise reusing the mouthpiece. Thus, Hirsch does not support Dr. Black's contention that the prior art used "open-sided" mouthpieces because they were easier to clean.

144. As noted above, Black describes a variety of tongue shield aspirators. Black teaches that these tongue shield aspirators “may be made of disposable material.” Ex. 1007 at 9:23-28. Black does not teach that the tongue shield aspirators are reusable. On the other hand, Black does mention that the bite member and evacuation tube components are “re-usable (autoclavable).” *Id.* at 9:50-52. In describing the various components of the device, Black refers to the bite member and evacuation tube as “[t]he autoclavable components of the device.” *Id.* at 19:35-38. The fact that Black describes some components as reusable but not the tongue shield aspirator reinforces that Black does not disclose or suggest cleaning the tongue shield aspirator for reuse. Thus, Black does not support Dr. Black’s contention that the prior art used “open-sided” mouthpieces because they were easier to clean.

145. Petitioner and Dr. Black did not provide an English translation of Ex. 1017 and therefore I cannot comment on it. I reserve the right to update my opinions should Petitioner provide a translation.

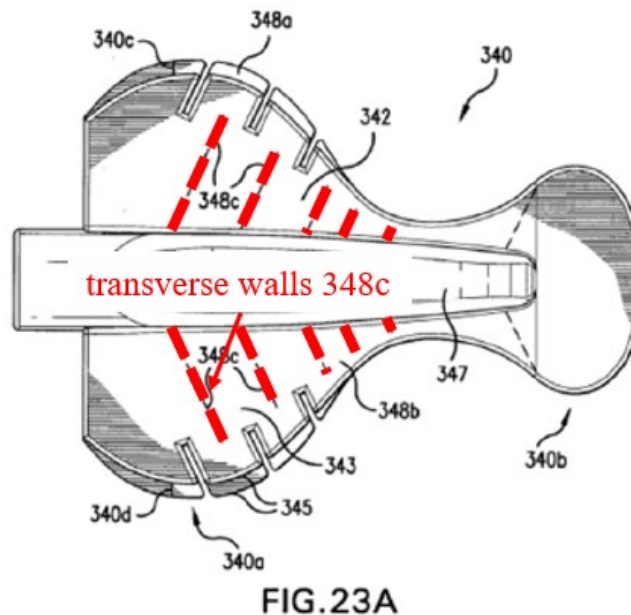
146. Kim is silent regarding whether the mouthpiece is reusable or cleaned. *See* Ex. 1018. Thus, Kim does not support Dr. Black’s contention that the prior art used “open-sided” mouthpieces because they were easier to clean.

147. Reyes teaches that its saliva ejector device is “disposable.” Ex. 1019 at Abstract, ¶¶ [0005], [0039]. There is no teaching or suggestion in Reyes that the

device is autoclavable, cleaned, or otherwise reused. Thus, Reyes does not support Dr. Black's contention that the prior art used "open-sided" mouthpieces because they were easier to clean.

148. As the discussion above demonstrates, Dr. Black does not cite any evidence that an "open-sided" mouthpiece was known to be easier to clean than a "closed-sided" mouthpiece.

149. Black further undermines Dr. Black's assertion that an "open-sided" mouthpiece like Black (assuming one had a reason to clean it even though it is disposable) would be "easier" to clean than Nguyen. In Black, there are ten total transverse walls 348c, as shown below in FIG. 23A.



Ex. 1007 at FIG. 23A (annotated)

150. If one wanted to clean Black (and again, there is no indication that Black is reusable), they would have to insert a brush between each of the transverse walls. There would be at least 12 brush actions required to clean the mouthpiece. Further, the user would need to clean more than 20 internal corners, including those created by the transverse walls 348c. Thus, Black's "open-sided" mouthpiece would be more difficult to clean than Nguyen's mouthpiece.

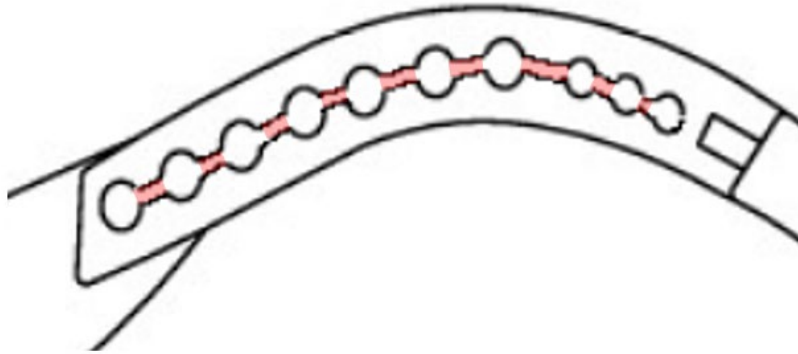
d. Petitioner and Dr. Black's Contentions Regarding the Manufacturing Process

151. Dr. Black asserts that the proposed modification to Nguyen "would not require a new mold to arrive at an open-sided mouthpiece" and "the existing mold of Nguyen could be reused with the additional step of cutting open the sidewalls." Ex. 1003 at ¶ 85. Dr. Black further asserts that "the best way to cut open the sidewalls of Nguyen in view of Black is to cut the material between the perforations 140 formed in the sidewall of Nguyen." *Id.* at ¶ 86. I disagree.

152. Dr. Black does not explain how one would "cut" through the perforations shown in Nguyen. Ex. 1003 at ¶¶ 85-86. 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.

153. Dr. Black's analysis suggests that the cutting process would be simple and involve using something like scissors or a utility knife to open up the mouthpiece. The problem is Petitioner and Dr. Black's proposed combination calls

for more than a thin slit down the side – it requires the removal of some thickness of material between the perforations:



Petition at 43 (modifying Ex. 1005 at FIG. 2D) (red annotations added)

The type of “cut” shown above could not be accomplished with a single pass of scissors or a knife and would require multiple cuts. For example, one would have to make two cuts between each pair of perforations. In the example above, that would involve at least 18 cutting operations on only one side of the mouthpiece, and 36 cutting operations if both sides were cut like this.

154. Dr. Black acknowledges the possibility that the cutting operation he proposes may accidentally cause damage to the rest of the mouthpiece and render the mouthpiece “unusable.” Ex. 1003 at ¶ 86. A POSITA would recognize that the cutting operation he proposes indeed would carry the risk of additional manufacturing flaws or defects. Further, the autoclavable mouthpieces described in Nguyen are medical grade devices because they are intended to be used in the mouth of a dental patient. A POSITA would recognize that adding an additional

cutting operation would increase the risk of contamination or other issues that would render the mouthpiece unusable for its intended purpose.

155. It would be significantly more difficult to manufacture the modified mouthpiece in the way Petitioner and Dr. Black propose relative to Nguyen. This is especially true if one considers manufacturing the mouthpiece at scale because it would not be feasible or practical to individually cut each of the mouthpieces on each side. This would significantly increase the manufacturing time, cost, and complexity.

156. In my view, these disadvantages associated with Petitioner and Dr. Black's proposed modification is further evidence that a POSITA would not have modified Nguyen as Petitioner and Dr. Black suggest without the use of hindsight (having seen the inventions in the '217 Patent).

e. Petitioner and Dr. Black's "Duplication of Parts" Theory

157. Petitioner and Dr. Black also assert 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 at 41-42; Ex. 1003 at ¶ 84. Because this is based on the same motivations previously discussed, I disagree with Petitioner

and Dr. Black's "duplication of parts" theory for at least the same reasons discussed above.

158. Additionally, the entirety of Dr. Black's opinions regarding this "duplication of parts" theory 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.

Ex. 1003 at ¶ 84. I note that Dr. Black also does not affirmatively say that duplicating Nguyen's bridge structure would have been obvious or why. Instead, Dr. Black states that he was "told" that "a mere duplication of parts ... is *typically* an obvious modification." *Id.* Dr. Black seems to acknowledge that a duplication of parts is not necessarily obvious but stops short of saying that this duplication would be. I reserve the right to respond if Petitioner or Dr. Black provide reasoning for their "duplication of parts" theory.

159. Petitioner and Dr. Black’s “duplication of parts” theory also fails to address all of the requirements of claim 1, which recites two intervening walls: an anterior intervening wall and a posterior intervening wall. Ex. 1001 at 8:67-9:2, 9:4-7. Even if one were to duplicate Nguyen’s bridge structure at the edge of anterior wall as Petitioner and Dr. Black propose, Petitioner and Dr. Black do not explain how the resulting mouthpiece would have a posterior intervening wall as well. Petition at 41-42; Ex. 1003 at ¶ 84. Duplicating Nguyen’s bridge structure at the end of the anterior wall would not meet the posterior intervening wall requirement of claim 1.

2. Independent Claim 17

160. Petitioner and Dr. Black also allege in Ground 1 that independent claim 17 of the ‘217 Patent is obvious over Nguyen and Black. Petition at 51-53; Ex. 1003 at ¶¶ 109-16. For the reasons discussed below, I disagree.

161. For limitations 17(a) – 17(e) and 17(g), the Petition simply refers back to its prior analysis of claim 1 without more. Petition at 51-53. Dr. Black does the same in his declaration. Ex. 1003 at ¶¶ 109-16.

162. 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.” Ex. 1001 at 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.* at 10:25-29.

163. At least because Petitioner and Dr. Black do not provide any additional analysis or discussion for limitations 17(d) and 17(e) beyond what they already provided for claim 1, I disagree for at least the same reasons discussed above.

164. Limitation 17(c) recites: “at least one connector that connects the anterior wall to the posterior wall within the interior space.” Ex. 1001 at 10:19-20. As noted above, Petitioner and Dr. Black do not provide any analysis for this limitation other than referring back to their analysis for claim 1. Petition at 56; Ex. 1003 at ¶ 111 (citing ¶ 65).

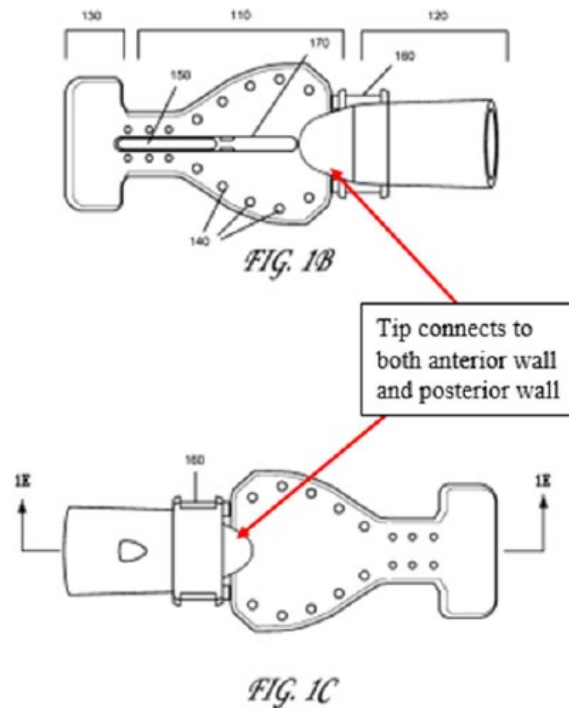
165. However, limitation 17(c) adds an additional limitation that Petitioner and Dr. Black fail to address. Limitation 1(c) recites “at least one connector connecting the anterior wall to the posterior wall.” Ex. 1001 at 8:66-67. By contrast, limitation 17(c) recites: “at least one connector that connects the anterior wall to the posterior wall **within the interior space.**” Ex. 1001 at 10:19-20.

Petitioner and Dr. Black do not address the “within the interior space” requirement in claim 17. Petition at 56; Ex. 1003 at ¶ 111.

166. Below is the entirety of Dr. Black’s analysis for limitation 1(c):

“Nguyen discloses that the anterior wall and posterior wall are connected by a front tip in front of the suction connector. EX1005, FIGS. 1B, 1C. Therefore, it is my opinion that the illustrated front tip is a connector connecting the anterior wall to the posterior wall.” Ex. 1003 at ¶ 65. Dr. Black also asserts “FIG. 1E confirms that

this connection occurs between the anterior and posterior wall” and provides the following annotations:



Ex. 1003 at ¶ 65

167. Dr. Black’s discussion does not address the “within the interior space” requirement in claim 17. The areas of the mouthpiece he points to with red arrows as the claimed “connector” are on the outside of the mouthpiece.

168. For at least these reasons, I disagree with Petitioner and Dr. Black’s conclusions for Ground 1 and independent claim 17 of the ‘217 Patent.

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

169. Petitioner and Dr. Black’s discussion of dependent claims 2-11, 13-16, and 18-23 of the ‘217 Patent focus on the additional limitations in those

dependent claims and does not address the deficiencies above with respect to the proposed Nguyen and Black combination. Petition at 46-50, 53; Ex. 1003 at ¶¶ 94-180, 117-22. Thus, I disagree with Petitioner and Dr. Black's conclusions for these dependent claims for at least the same reasons as independent claims 1 and 17 (from which all of these dependent claims depend).

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

170. In Ground 2, Petitioner and Dr. Black assert that dependent claims 8 and 19 of the '217 Patent are obvious of Nguyen, Black, and Hirsch. Petition at 53; Ex. 1003 at ¶¶ 123-25. Dependent claim 8 depends from independent claim 1, and dependent claim 19 depends from independent claim 17. Ex. 1001 at 9:42-44 (claim 8), 10:43-47 (claim 19).

171. Petitioner and Dr. Black's discussion of these dependent claims does not address the deficiencies I discussed above with respect to the proposed Nguyen and Black combination. Petition at 53; Ex. 1003 at ¶¶ 123-25. Thus, I disagree with Petitioner and Dr. Black's conclusions for these dependent claims for at least the same reasons as independent claims 1 and 17 (from which both of these dependent claims depend).

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

172. In Ground 3, Petitioner and Dr. Black assert that claim 17-23 of the ‘217 Patent are obvious over Nguyen in view of Hirsch. Petition at 54-64; Ex. 1003 at ¶¶ 126-57. For the reasons discussed below, I disagree.

1. Independent Claim 17

a. Limitation 17(c)

173. For limitation 17(c), which recites “at least one connector that connects the anterior wall to the posterior wall within the interior space,” Dr. Black refers back to his analysis for claim 1 without more. Ex. 1003 at ¶ 127 (“As discussed above in paragraph 65, Nguyen fully teaches this limitation”). As noted above, Petitioner and Dr. Black both fail to address the additional requirement in claim 17 that the connector connects the anterior and posterior wall “*within the interior space*.” Ex. 1001 at 10:19-20. Petitioner and Dr. Black do not rely on

Hirsch for this limitation. Thus, I disagree with Petitioner and Dr. Black for limitation 17(c) in Ground 3 for the same reasons I discussed above for Ground 1.

b. Limitations 17(d) and 17(e)

174. Much of Petitioner and Dr. Black’s analysis of these limitations in Ground 3 is the same as the analysis they already presented in Ground 1, except that Ground 3 uses Hirsch instead of Black.

175. The table below summarizes how Dr. Black’s opinions in Ground 3 are the same or at least substantively the same as the opinions he previously provided for Ground 1:

Ground 1	Ground 3
¶ 67	¶ 130
¶ 68	¶ 131
¶ 71	¶ 136
¶¶ 71-75	¶ 137
¶ 79	¶ 138
¶ 80	¶ 139
¶ 81	¶ 140
¶ 84	¶ 142
¶ 89	¶ 146

176. I disagree with Dr. Black's opinions in these paragraphs for at least the same reasons I provided for Ground 1. In particular, I disagree with Dr. Black's opinion that forces from the mouth/gum would apply forces to Nguyen's mouthpiece that would cause it to meaningfully bend or buckle such that suction is meaningfully affected.

177. Dr. Black asserts "a POSA would know that a mouthpiece with open sides (like Hirsch's mouthpiece) would bend easier into a patient's mouth." Ex. 1003 at ¶ 133 (citing Ex. 1006 at 4:43-67 and Ex. 1007 at 17:47-54). To the extent Dr. Black is asserting that Hirsch's mouthpiece is easier to bend and place in the patient's mouth than Nguyen's mouthpiece, I disagree. Nguyen teaches that the mouthpiece can bend so that it can be placed in the patient's mouth. Ex. 1005 at 3:29-35. There is no indication that there is any difficulty in doing so in Nguyen. Dr. Black's citations to Hirsch and Black do not support his contention. The cited portion of Hirsch discusses bending of the mouthpiece but does not suggest that Hirsch's design is more conducive to bending for placement in the mouth than Nguyen's mouthpiece. Ex. 1006 at 4:43-67. Similarly, the cited portion of Black relates to the FIG. 25, which as I discussed above, in no way suggests that an "open-sided" mouthpiece has benefits relative to a "close-sided" mouthpiece. Ex.

1007 at 17:47-54. Rather, Black is simply comparing the FIG. 25 embodiment to other disclosed embodiments.

178. With regard to “easier cleaning” of Nguyen, I disagree for the reasons I provided above for Ground 1 as Dr. Black’s arguments on this point are the same. Ex. 1003 at ¶¶ 134, 138-39. As I noted above, Hirsch does not suggest that an “open” mouthpiece is easier to clean than a “closed” mouthpiece. Hirsch’s mouthpiece is “disposable after each use” and never mentions cleaning. Ex. 1006 at 3:1-2. As such, Hirsch would not motivate a POSITA to “open” Nguyen for purposes of “easier cleaning” as suggested by Petitioner and Dr. Black.

179. Dr. Black asserts that “Hirsch lacks anti-collapse structure at the edges of its mouthpiece, and Hirsch discloses that collapse occurs at the edges, resulting in an undesirable ‘seal’ at the edges.” Ex. 1003 at ¶ 140 (citing Ex. 1006 at 4:43-5:8). I agree that “Hirsch lacks anti-collapse structure at the edges,” but otherwise disagree with Dr. Black. Hirsch does not teach or suggest that the seal at the edges is “undesirable.” To the contrary, Hirsch is intentional in creating this seal at the edges of the mouthpiece. In other words, Hirsch actually teaches that this is desirable, not “undesirable.”

180. For example, Hirsch teaches: “in a non-vacuum state the upper pocket opening and lower pocket opening are open and 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.” Ex. 1006 at 1:50-56. As another example, Hirsch teaches: “applying vacuum state to the intraoral device so that the upper pocket opening and lower pocket opening are substantially *sealed closed* and the grooves become fluid inlets for drawing fluids through the channels.” *Id.* at 2:13-18. Hirsch also teaches:

The upper roof of the mouth spans the upper gap 350 and pushes or bends the upper front flap 310 and the upper rear flap 320 forward to create a substantial seal along upper edges 370, 380, which are aligned with each other (excepted for the V-shaped grooves 416), creating a *substantially sealed upper internal evacuation channel 418* in the upper gap 350, but yet still in communication with the patient's mouth through the evacuation holes 410 in the front flaps 310, 330 and the rearwardly extending ridges 412/channels 414/V-shaped grooves 416 in the rear flaps 320, 340. Similarly, the lower front flap 330 and the lower rear flap 340 are configured to rest or flex against the lingual area of mouth or tongue to keep the tongue protected and retracted during use. The tongue and floor of the patient's mouth span the lower gap 360 and forms a substantially seal along lower edges 390, 400, which are aligned with each other (excepted for the V-shaped grooves 416), creating a *substantially sealed lower internal evacuation channel in the lower gap 360*, but yet still in communication with the patient's mouth through the

evacuation holes 410 in the front flaps 310, 330 and the rearwardly extending ridges 412/channels 414/V-shaped grooves 416 in the rear flaps 320, 340. Thus, in a non-vacuum state, the upper pocket opening 350 and lower pocket opening 360 are open and ***in a vacuum state the upper pocket opening 350 and lower pocket opening 360 are substantially sealed closed*** so that aspiration of fluids from the patient's mouth occurs through the evacuation holes 410 in the front flaps 310, 330 and the V-shaped grooves 416, which become fluid inlets for drawing fluids through the vertical channels 414, of the rear flaps 320, 340.

Id. at 4:45-5:8.

181. Dr. Black also asserts that “without anti-collapse structure at the edges, Nguyen would not be able to supply suction through the superior and inferior side, which Nguyen prioritizes.” Ex. 1003 at ¶ 140. I have seen no evidence that Nguyen “prioritizes” suction through the superior and inferior sides of the mouthpiece. In my view, a POSITA would understand that most of the suction is applied via the perforations in the anterior and posterior walls in the embodiments illustrated in Nguyen. Ex. 1005 at 3:36-67 (“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”). Indeed, Nguyen states that

superior and inferior walls may include holes “[i]n *some* embodiments,” which signals to a POSITA that these are optional. *Id.* at 3:67-4:3.

182. Dr. Black also asserts that “[k]nowing that a mouthpiece lacking anti-collapse structure formed at the edges would cause an undesirable seal in view of the teachings of Hirsch ... a POSA would recognize that there must also be a structure at the edges of the mouthpiece of Nugyen to prevent collapse under suction at the edges and at the perforations 140.” Ex. 1003 at ¶ 141. I disagree. As noted above, Hirsch does *not* teach that sealing at the edges is undesirable. Hirsch intentionally creates that seal. Thus, Hirsch does *not* teach or suggest that “there must also be a structure at the edges of the mouthpiece of Nugyen to prevent collapse under suction at the edges and at the perforations 140.” Ex. 1003 at ¶ 141. In fact, Hirsch teaches away from adding a structure to the edges. If a structure were added to the edges of Hirsch’s mouthpiece, then the edges would not seal, which is contrary to Hirsch’s teachings that the edges should seal when suction is applied. At a minimum, Hirsch’s teachings would discourage or dissuade a POSITA from adding an “anti-collapse” structure to the edges of the mouthpiece.

183. Similarly, Dr. Black asserts that “a POSA would also recognize that it is desirable to form anti-collapse structure at the edges of the mouthpiece to prevent collapse under suction.” Ex. 1003 at ¶ 143. However, as I noted above, Hirsch does not teach that “anti-collapse structure at the edges of the mouthpiece”

is desirable. In fact, as discussed above, Hirsch intentionally creates a seal at the edges and teaches away from preventing sealing at the edges.

184. Petitioner and Dr. Black show how they propose modifying Nugyen in view of Hirsch using the images below:

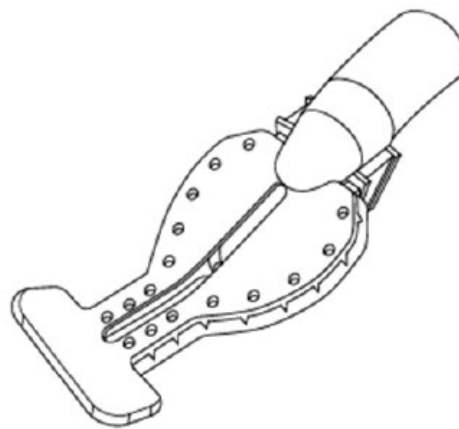


FIG. 1A

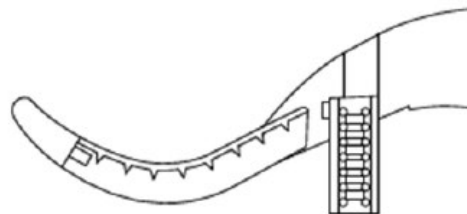
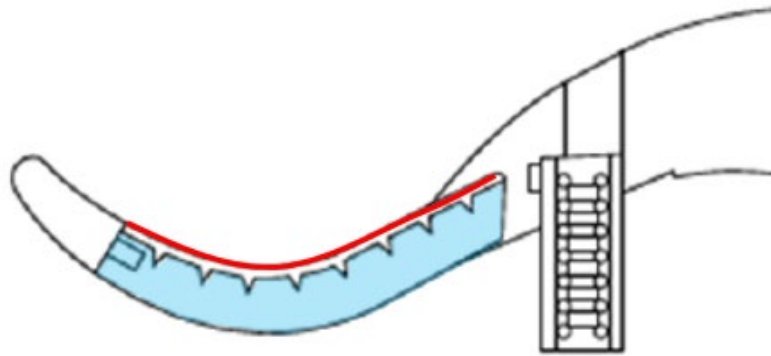


FIG. 1D

Ex. 1003 at ¶ 143

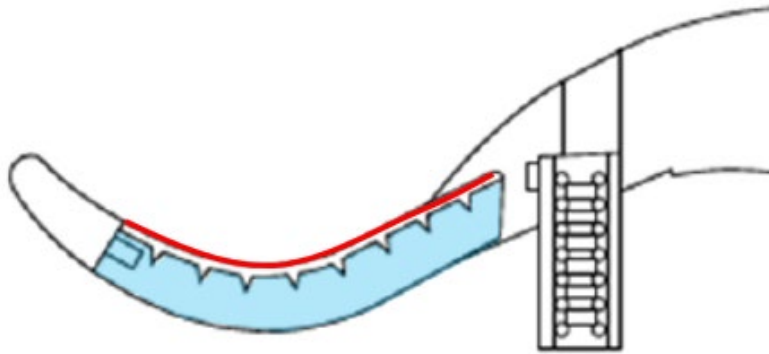
185. As an initial matter, I observe that this drawing of a hypothetical mouthpiece is incomplete and confusing because it does not show the anterior wall having any thickness from the side. Below, I have used color annotations to more clearly show where the anterior wall is relative to Petitioner and Dr. Black's alleged intervening wall:



186. In this proposed combination, Dr. Black says that a POSITA would “implement Hirsch’s wall with the V-shaped grooves to be anti-collapse structure at the edges of the mouthpiece by connecting this structure to only the posterior wall.” Ex. 1003 at ¶ 143. However, as Dr. Black acknowledges, the wall in Hirsch with the V-shaped grooves is a posterior wall. *Id.* at ¶ 145. To this point, Dr. Black asserts that it would be “common sense” to use Hirsch’s wall on the side of Nugyen. *Id.* I disagree. There is no teaching or suggestion in Hirsch that this structure can be used as a “sidewall.” Indeed, as I have discussed throughout this declaration, Hirsch is intentional about having any structures at the edges of the mouthpiece so that the edges can seal when suction is applied. Hirsch therefore teaches away from Dr. Black’s proposed modification.

187. In Ground 1, Petitioner and Dr. Black argue that modifying Nugyen in view of Black would “improve suction through the sides of the dental mouthpiece” and “if the sidewalls of Nugyen were open, suction could occur all along the entire side.” Ex. 1003 at ¶¶ 76-77. I note that Petitioner and Dr. Black do not make the

same assertion in Ground 3. That is because the proposed modification in view of Hirsch would have no better suction through the side than Nguyen, and likely worse suction given how small the V-shaped grooves appear.



188. Further, cleaning this modified version of Nguyen would not be “easier” than using the slit 170 that is already provided in Nguyen. The openings between the edge of the new alleged intervening wall and the V-shaped cutouts appear to be relatively small, making it difficult to insert a brush to clean the interior compared to using the slit 170 at the top. This scenario would also be less ergonomic than Nguyen. In Nguyen, one can grasp the entire mouthpiece (e.g., cup the mouthpiece in their palm) with one hand, and hold the brush in the other hand and clean through the slit 170. By contrast, cleaning through the side would be more difficult because the user’s other hand would apply pressure to the top and/or bottom of the mouthpiece to hold it in place and potentially impede the brush.

189. Further in regard to cleaning, Dr. Black asserts that in the proposed modification, “open sides of the mouthpiece would remove corners and crevices

where debris and germs can build up, thereby making it easier to clean. Ex. 1003 at ¶ 144. I disagree. As shown by Dr. Black’s drawings, there are still corners in the modified version of Nguyen’s mouthpiece.

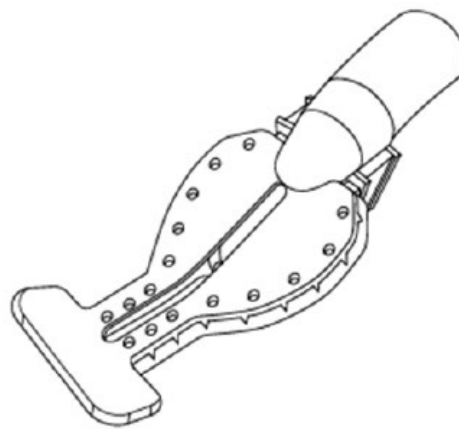


FIG. 1A

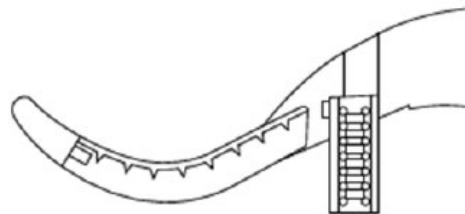


FIG. 1D

Ex. 1003 at ¶ 143

190. In Ground 1, Petitioner and Dr. Black discussed how the modified version of Nguyen in view of Black would be manufactured and noted that a new mold would not be required. *See, e.g.*, Ex. 1003 at ¶ 85. In Ground 3, Petitioner and Dr. Black do not expressly address how the modified version of Nguyen would be manufactured other than by stating that one would “implement Hirsch’s wall with the V-shaped grooves to be anti-collapse structure at the edges of the

mouthpiece by connecting this structure to only the posterior wall.” Ex. 1003 at ¶ 143. With the proposed Nguyen-Hirsch combination, in my view, a new mold would be needed. This is because one could not create the geometry shown by Dr. Black if they were starting from exactly what is shown in Nguyen’s drawings, e.g., the holes would have to be eliminated.

191. Additionally, Dr. Black asserts that Hirsch’s wall with V-shaped groove would be attached “to only the posterior wall” in Nguyen. Ex. 1003 at ¶ 143. But Dr. Black provides no reason for why a POSITA would attach Hirsch’s wall to the posterior wall as opposed to the anterior wall.

192. Dr. Black also argues, as he did in Ground 1, that “[e]ssentially, an open-sided Nguyen would require a second ‘bridge structure’ formed at the edges of the mouthpiece” and “an intervening wall with alternating troughs and crests is a mere duplication of parts, which I am told is typically an obvious modification.” Ex. 1003 at ¶ 142. I disagree for the same reasons discussed above in Ground 1 for this “duplication of parts” theory. I note that in Ground 3 Dr. Black again does not affirmatively opine that a “duplication of parts” is obvious, he merely states that he was told that such modifications are “typically” obvious. I reserve the right to supplement these opinions should Petitioner and/or Dr. Black provide reasoning why they believe a “duplication of parts” is obvious in this case.

193. At the end of this section, Dr. Black states that “if the sidewalls of Nguyen were opened, then the slit 170 would no longer be necessary” and “removing the slit 170 could prevent the anterior wall from filling the troughs of the bridge structure 180 as discussed above.” Ex. 1003 at ¶ 146. In my view, this contradicts Dr. Black’s earlier opinions. On one hand, Dr. Black contends that Nguyen’s mouthpiece would bend when placed in the patient’s mouth such that the anterior wall would fill the troughs of the bridge structure (which I disagree with) and therefore a POSITA would have been motivated to modify Nguyen in view of Hirsch to avoid this problem. Yet on the other hand, even with the modification, Dr. Black indicates that the anterior wall may still fill the troughs of the bridge structure unless it is removed. If the latter point is true, then this is another reason why a POSITA would not have modified Nguyen in view of Hirsch as Dr. Black suggests because doing so would not solve the supposed problem he identifies.

2. Dependent Claims 18-23

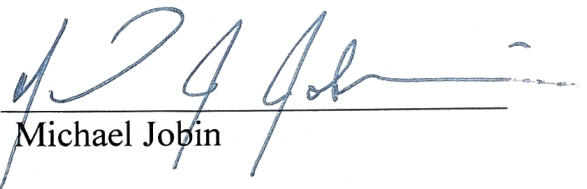
194. Petitioner and Dr. Black’s discussion of dependent claims 18-23 focus on the additional limitations of those claims and does not address any of the aforementioned deficiencies with respect to Nguyen and Hirsch in relation to claim 17. Petition at 63-64; Ex. 1003 at ¶¶ 152-57. Thus, I disagree with Dr. Black’s conclusions for these dependent claims for at least the same reasons as independent claim 1.

X. CONCLUSION

195. I reserve the right to modify or supplement my opinions, if necessary, based on further review and analysis of the evidence in this case, including review and analysis of information that may be provided to me subsequent to the date of this Declaration.

I declare that all statements made herein of my own knowledge are true and all statements made on information and believe are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: October 15, 2025



Michael Jobin