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
Issue Date: November 28, 2023
Title: DENTAL MOUTHPIECE

Inter Partes Review No. IPR2025-01065

DECLARATION OF DR. BRIAN P. BLACK IN SUPPORT OF PETITIONER'S PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,826,217

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1. Independent Claim 1....30

2. Claim 2: "The mouthpiece of claim 1, wherein the at least one connector includes at least one of a wall spanning

longitudinally in the main body portion in the interior space or a pillar." 49

3. Claim 3: "3. The mouthpiece of claim 1, further comprising a bridge structure that includes one or more protrusions protruding from the posterior wall within the interior space, wherein the protrusions include spaced crests and troughs." 50

4. Claim 4: "4. The mouthpiece of claim 3, wherein the protrusions vary in height and length."....51

5. Claim 5: "5. The mouthpiece of claim 1, wherein at least one of the anterior intervening wall and the posterior intervening wall includes a plurality of portions of varying heights relative to a longitudinal axis of the mouthpiece."....51

6. Claim 6: "6. The mouthpiece of claim 1, wherein the anterior intervening wall and the posterior intervening wall meet at a point where the suction connector meets the main body portion." 52

7. Claim 7: "7. The mouthpiece of claim 1, wherein the anterior intervening wall and the posterior intervening wall meet at a point where the main body portion meets the cheek retractor portion." 52

8. Claim 8: "8. The mouthpiece of claim 1, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient."....53

9. Claim 9: "9. The mouthpiece of claim 1, wherein the main body portion, the suction connector portion, and the cheek retractor portion are formed by injection-molding as one piece." 53

10. Claim 10: "10. The mouthpiece of claim 1, wherein a material that forms the main body portion, the suction connector portion, and the cheek retractor portion is a flexible, translucent, high heat-resistant, autoclavable silicone-based material."....54

11. Claim 11: "11. The mouthpiece of claim 1, wherein the posterior wall further includes a stability bar protruding from an interior surface of the posterior wall and along a longitudinal axis of the main body portion." 54

12. Claim 13: "13. The mouthpiece of claim 1, wherein the suction connector portion comprises a cutout corresponding to a protrusion on a vacuum adapter to provide an interlocking fit." 54

13. Claim 14: "14. The mouthpiece of claim 1, where in the suction connector portion connects to the vacuum suction source, wherein activation of the vacuum suction source provides suction of fluids from the interior space of the main body portion." 54

14. Claim 15: "15. The mouthpiece of claim 14, wherein the activation of the vacuum suction source draws fluids from an exterior of the main body portion into the interior space of the main body portion." 55

15. Claim 16: "16. The mouthpiece of claim 1, wherein the span of the anterior intervening wall extends from the edge of the anterior wall to at least a mid-point of the interior space between the anterior wall and the posterior wall." 55

16. Independent Claim 17 56

17. Claim 18: "18. The mouthpiece of claim 17, wherein the at least one intervening wall includes a plurality of portions of varying heights relative to a longitudinal axis of the mouthpiece." 58

18. Claim 19: "19. The mouthpiece of claim 17, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient." 59

19. Claim 20: "20. The mouthpiece of claim 17, wherein the main body portion, the suction connector portion, and the cheek retractor portion are formed by injection-molding as one piece." 59

20. Claim 21: "21. The mouthpiece of claim 17, wherein the suction connector portion comprises a cutout corresponding to a protrusion on a vacuum adapter to provide an interlocking fit." 59

21. Claim 22: "22. The mouthpiece of claim 17, where in the suction connector portion connects to the vacuum suction source, wherein activation of the vacuum suction source

provides suction of fluids from the interior space of the main body portion." 59

22. Claim 23: "23. The mouthpiece of claim 22, wherein the activation of the vacuum suction source further draws fluids from an exterior of the main body portion into the interior space of the main body portion." 60

C. Ground 2: Claims 8 and 19 are further obvious under 35 U.S.C. § 103 by Nguyen in view of Black and Hirsch. 60

1. Claim 8: "8. The mouthpiece of claim 1, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient." 60

2. Claim 19: "19. The mouthpiece of claim 17, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient." 61

D. Ground 3: Claims 17–23 are obvious under 35 U.S.C. § 103 by Nguyen in view of Hirsch. 61

1. Independent Claim 17 61

2. Claim 18: "18. The mouthpiece of claim 17, wherein the at least one intervening wall includes a plurality of portions of varying heights relative to a longitudinal axis of the mouthpiece." 73

3. Claim 19: "19. The mouthpiece of claim 17, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient." 73

4. Claim 20: "20. The mouthpiece of claim 17, wherein the main body portion, the suction connector portion, and the cheek retractor portion are formed by injection-molding as one piece." 74

5. Claim 21: "21. The mouthpiece of claim 17, wherein the suction connector portion comprises a cutout corresponding to a protrusion on a vacuum adapter to provide an interlocking fit." 74

6. Claim 22: "22. The mouthpiece of claim 17, where in the suction connector portion connects to the vacuum suction source, wherein activation of the vacuum suction source provides suction of fluids from the interior space of the main body portion." 74

7. Claim 23: "23. The mouthpiece of claim 22, wherein the activation of the vacuum suction source further draws fluids from an exterior of the main body portion into the interior space of the main body portion." 74

IX. Conclusion 75

I, Dr. Brian P. Black, offer this declaration in support of the Petition for *Inter Partes* Review of U.S. Patent No. 11,826,217 ("the '217 Patent"). I am over the age of 18, competent to make this declaration, and have personal knowledge of the facts set forth below. If called to testify, I could and would testify honestly, under oath, to the matters set forth herein.

I. INTRODUCTION

1. I am a general dentist, and I am also the inventor of a dental isolation mouthpiece sold under the name Mr. Thirsty. I disclosed the design of that dental isolation mouthpiece in a patent application filed in 2008, many years before Patent Owner filed a provisional application related to the '217 Patent. It is my understanding that one of my patents is being used as part of a ground to demonstrate invalidity of the '217 Patent.

2. I have read the '217 Patent, and I am aware of Patent Owner's single use dental isolation mouthpiece sold under the name "Dryshield" through my dental practice. I recognized the single use Dryshield product as an open-sided mouthpiece. I also recognized that Patent Owner previously sold an autoclavable mouthpiece almost identical to the mouthpiece disclosed in the '217 Patent, except that the autoclavable mouthpiece had sidewalls that fully enclose a central chamber of the mouthpiece. My patent is directed to an open-sided mouthpiece. Through private experimentation, I found that an open-sided mouthpiece performed better

with better suction properties than a closed-sided mouthpiece. The claims of the '217 Patent recite mouthpiece structure that I, and others, including the Patent Owner, disclosed long before May 2019, when Patent Owner filed its provisional application.

3. I am not an attorney, and I have not been asked to offer any legal opinions. I have been informed and understand the law to be applied for determining invalidity, which I explain in places below. I have applied the law told to me in developing my technical opinions in this Declaration.

II. BACKGROUND AND QUALIFICATIONS

A. Education and Work Experience

4. I received my dental degree (Doctor of Dental Surgery, "DDS") from Loma Linda University School of Dentistry (LLUSD) on May 28, 2000. I was born and raised in Southern California where I received my education, worked, and lived for 51 years. After I graduated from dental school, I successfully completed a one-year Advanced Education in General Dentistry (AEGD) residency through the United States Air Force (USAF) in the 82nd Dental Squadron at Sheppard Air Force Base in Wichita Falls, Texas on August 1, 2001. I then served as a staff dentist in the 95th Dental Wing at Edwards Air Force Base located in Edwards, California from September 10, 2001 to June 19, 2003. I received an honorable discharge from active duty in the USAF and returned to LLUSD as a clinical

instructor, eventually becoming the predoctoral clinic director and achieving a promotion to associate professor.

5. I subsequently resigned to pursue dental product development for a company I founded in 2007. Since then, I have also practiced as an associate dentist for a large dental group from 2009 - 2012. I then started my own dental practice, which I operated for almost ten years, growing it to over 4,000 active patients. I sold my practice on December 20, 2021 and moved to Washington state in January 2022.

6. Currently, I am employed as the lead dentist for a Native American tribe in Washington. As the lead dentist, I manage the daily operation of the tribe's dental clinic, which is one of several departments in the tribe's community health center.

7. I have a significant history and experience in the subject matter as evidenced in the attached curriculum vitae (EX1004).

B. **Experience Related to Isolation Mouthpieces**

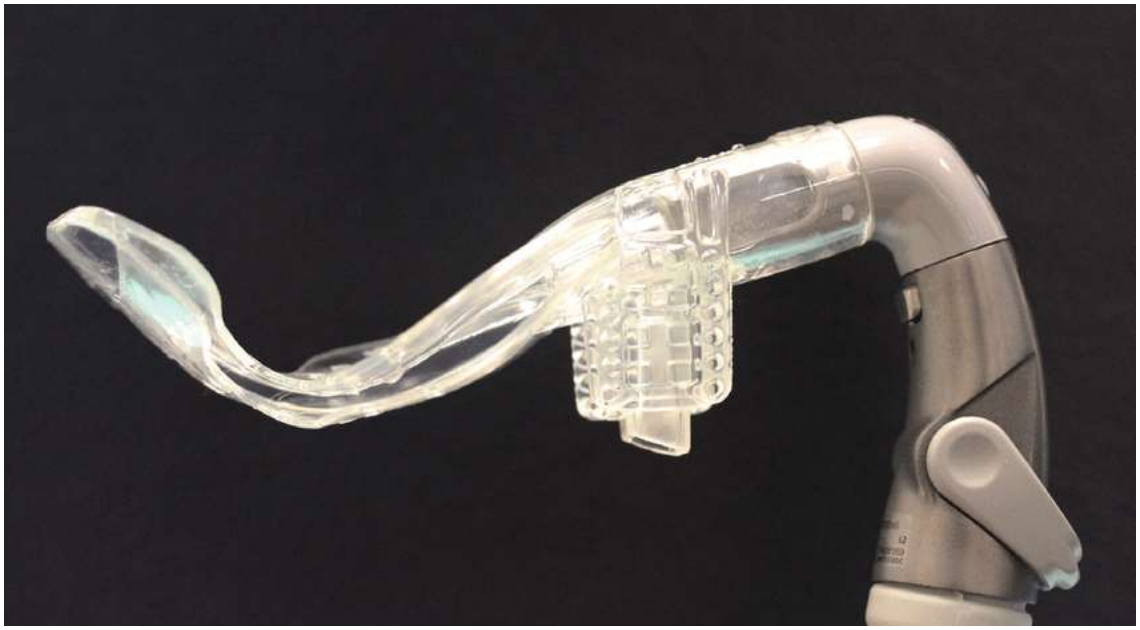
8. I resigned my faculty appointment at LLUSD in the Fall of 2008 to dedicate my full attention to Edge Medical Technologies, Inc., a company I founded in 2007 for the purpose of developing a competitive intraoral isolation device and, potentially, other dental products. I successfully developed and secured U.S. patents for “Mr. Thirsty,” an intraoral isolation device. By “intraoral isolation

device," I mean a device that the dentist or hygienist can use that holds a patient's mouth open like a bite block so the patient doesn't have to use his/her jaw muscles actively, while the device also suctions fluids away from the patient's throat so he/she does not choke on or swallow those fluids while the dentist or hygienist is working. As yet a further benefit, an intraoral isolation device retracts a patient's tongue and cheek tissue so that the tongue and the cheek tissue do not interfere with the dental procedure. The goals for such a device are: 1) for patients to be more comfortable during procedures, 2) for dentists and hygienists to have a clearer or drier working space, and 3) for dentists or hygienists to complete procedures in less time because normal disruptions are obviated, such as patients resting jaw muscles, breathing, coughing, or swallowing fluids or debris. Also, the continuous suction from the intraoral isolation device results in fewer interruptions because the dental assistant no longer must periodically insert the typical suction tube into the mouth to clear fluids.

9. During my service in the USAF, I first learned of an intraoral isolation device named "Isolite" through dental advertisements in trade publications. Isolite offered a method for helping dental patients keep their mouths open passively during dental procedures while simultaneously removing fluids and debris through suction (as previously described), but it also provided illumination in the mouth for the dentist or hygienist to have better visibility while working.

10. I subsequently attended the California Dental Association (CDA) Scientific Session (an annual dental education conference and trade show) in Anaheim, California, May 12-15, 2005 where I saw the Isolite device displayed and sold by the company Isolite Systems (now Zyris) at their booth. Looking at the device, I noticed that it had two parts: the first part was a flexible, translucent, somewhat figure-8 shaped "mouthpiece" which had, at one end, a bite block for the upper and lower teeth to rest on and keep the patient's mouth open passively. And, extending from the inside edge of the bite block, the mouthpiece had a wide shape that blocked the tongue, then narrowed to wrap behind the upper and lower molars, and then widened again into a smaller round end flap that pushed the cheek away.

The second component was an adapter that connected to a High-Volume Evacuation (HVE) hose. The second component was specially designed to house the lighting mechanism that illuminated the mouthpiece when in the patient's mouth. The adapter inserted into the bite block end of the mouthpiece.



11. An HVE hose typically connects to a 9 mm internal diameter opening (or larger) for a straight or slightly angled, plastic, disposable tube that is inserted into the patient's mouth for purpose of suctioning debris during dental procedures. Differently, the Isolite HVE adapter terminated with two smaller diameter suction channels, which results in decreased suction.

12. The Isolite mouthpiece was designed so that it had two upper and lower flaps separated by a thicker, longitudinal "spine" (imagine a butterfly whereby the body is the "spine" and the wings extending from it are the "flaps").

13. These flaps were paired (imagine the butterfly with two sets of wings of the same size and shape on each side of its body) and had a series of holes along the outer edges of each flap. When the flaps were pressed together in the mouth, suction would pull fluids through the holes and between the compressed flaps. The

spine had an added benefit: it allowed light to travel through it and illuminate the mouthpiece, thereby illuminating the patient's mouth where the dentist worked.

14. The Isolite mouthpiece is symmetrical so that it could be used on either side of the mouth by rotating it 180 degrees. In so doing, there exists “upper” and “lower” channels relative to the spine. EX1021.

15. I became interested in the Isolite mouthpiece while working at LLUSD. It is ideal for practitioners who do not have a dental assistant to help with fluid removal during procedures. Student dentists are not provided with dental assistants, so they work unaided. This presents a host of challenges for both the student and the patient.

16. After careful analysis of the Isolite system, I determined that there were three limiting factors: 1) high cost, 2) the advent of lightweight and affordable LED lighting for dental loupes (glasses that dentists and hygienists wear for magnified views of the teeth and gums), and 3) the lack of true HVE suction due to the Isolite HVE hose having two (upper and lower) smaller diameter suction channels that connected to the mouthpiece's upper and lower channels.

17. So, in 2007, I started to develop an affordable, disposable, unlighted, intraoral isolation dental mouthpiece that could insert directly into any standard HVE hose valve. In doing so, I reviewed prior intraoral isolation device designs. I also asked a law firm to review my concept and give an opinion on both

"patentability" and "non-infringement" of known patents. I received favorable opinions on both matters. Subsequently, I was awarded U.S. Patent Nos. 8,029,280 and 8,292,620 (the latter now abandoned). The patent for my intraoral isolation device is currently licensed to Zirc Dental Products, who manufactures, markets, and sells the device as "Mr. Thirsty".

18. I have been retained as an independent expert consultant by Ascentcare Dental Products, Inc. ("Petitioner") in connection with a petition for *inter partes* review of the '217 Patent (EX1001).

19. Specifically, I was asked to investigate and opine on the technology claimed in, and the patentability or unpatentability of certain claims of the '217 Patent. I was also asked to opine on the validity of claims 1–11 and 13–23 (the "Challenged Claims") of the '217 Patent.

20. Although I am being compensated for my services in this matter at my standard consulting rate of $650 per hour, my compensation is not contingent upon the opinions I render or the outcome of this proceeding. I have no financial interest in any of the parties, and I have no other interest in this proceeding.

21. This report is based on information currently available to me. I reserve the right to amend or supplement my analysis in this report and/or to respond to any additional submissions prepared by or on behalf of the Patent Owner. I also

reserve the right to amend or supplement my opinions based on further discovery and information provided in the case.

22. I reserve the right to create any additional summaries, tutorials, demonstrations, charts, drawings, tables, and/or animations that may be appropriate to supplement and demonstrate my opinions as necessary.

23. All of the opinions stated in this report are based on my own personal knowledge and professional judgment.

III. MATERIALS CONSIDERED

24. I have considered the following list of materials in formulating my opinions in this matter:

Ex #	Exhibit
1001	U.S. Patent No. 11,826,217 ("the '217 Patent")
1002	Prosecution History of the '217 Patent (part 1)
1005	U.S. Patent No. 8,911,232 to Nguyen ("Nguyen")
1006	U.S. Patent No. 9,532,858 ("Hirsch")
1007	U.S. Patent No. 8,029,280 ("Black")
1012	U.S. Patent Application Publication No. 2018/0153637
1013	U.S. Patent No. 4,024,642
1014	U.S. Patent Application No. 2003/0134253
1015	Prosecution History of the '217 Patent (part 2)
1016	Prosecution History of the '217 Patent (part 3)
1017	Chinese Patent No. 10-4490483

1018	Korean Patent No. 10-0654392
1019	U.S. Patent Publication No. 2017/0156832
1020	U.S. Patent No. 1,731,322
1021	U.S. Patent No. 6,974,321

IV. OVERVIEW OF THE PATENT AT ISSUE

25. I have read and considered the ’217 Patent, EX1001, filed on May 08, 2020, as well as its prosecution history. EX1002, EX1015, EX1016. I have been told that the ’217 Patent has a priority date of May 10, 2019 for some claim features. It is my understanding that the provisional patent application may not support all claim limitations in the ’217 Patent, but for the purposes of my review, I considered the May 10, 2019 date as the priority date. All of the references I reviewed and considered predate the May 10, 2019 date, so it is irrelevant for my purposes whether the provisional application does or does not support all of the claim limitations of the ’217 Patent.

26. It must be noted that all four mouthpieces I considered for this report (the ’217 Patent, Nguyen, Hirsch, Black) have similar shapes and structure due to their function.

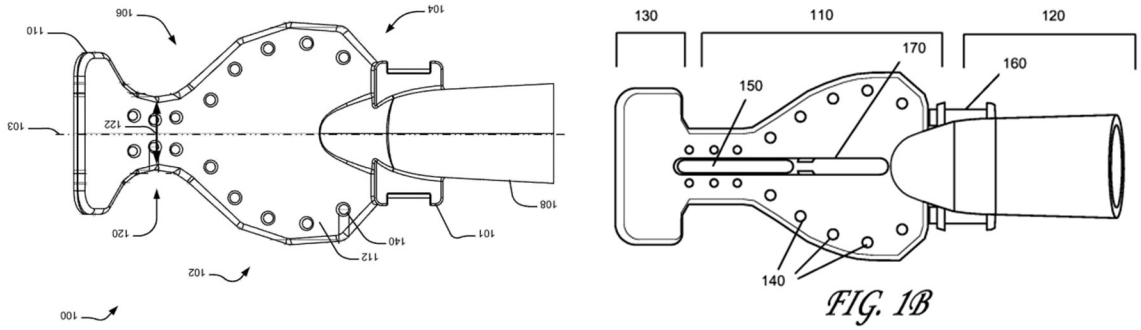
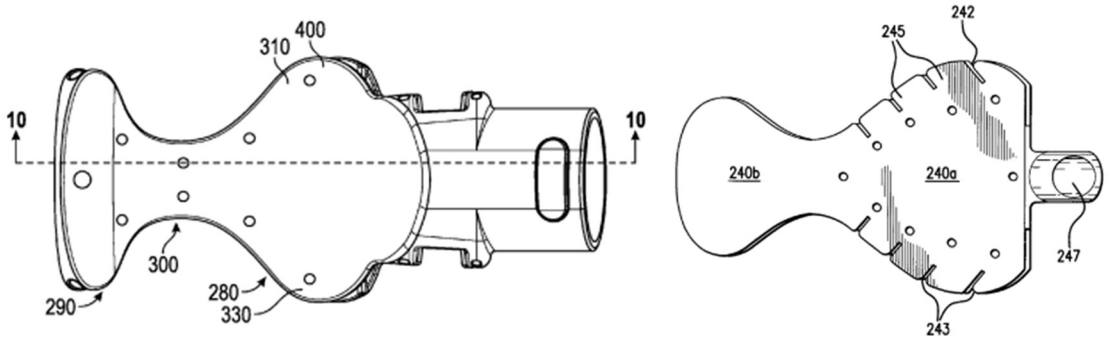


FIG. 1B



27. All four mouthpieces have a main larger body portion that blocks the tongue, then a narrower connecting portion that ends in a smaller cheek retractor end. On each mouthpiece, the larger body portion has an extension to connect to a suction hose. All of these devices have an anterior (front or first wall) and a posterior (back or second wall), and all mouthpieces are longitudinally symmetrical.

28. The ‘217 Patent teaches a dental isolation mouthpiece with the same basic shape as the dental isolation mouthpiece in U.S. Patent No. 8,911,232 to Nguyen (“Nguyen”), also owned by Patent Owner. EX1005. Nguyen and the ’217 Patent both teach a suction connector formed on one side of the mouthpiece, a bite

block formed near the suction connector end, a wider tongue suppression element, a narrow isthmus formed at an end of the mouthpiece opposite the suction connector, and a wider cheek retractor also connected to the isthmus. The '217 Patent and Nguyen both disclose that the main body portion has an anterior wall and a posterior wall having the same shape and size as the anterior wall, and they both disclose a bridge structure formed in the center of the main body portion that ensures that the anterior and posterior wall remain separated under suction.

29. Indeed, the only real difference between the '217 patent and Nguyen appears to be the existence of intervening walls that are connected to one of the anterior or posterior wall and extend toward the other of the anterior or exterior wall. EX1001, 6:20-64. Each of the intervening walls includes a plurality of crests and troughs. *Id.* This results in open sidewalls in the '217 Patent. In contrast, Nguyen has a sidewall that connects to both of the anterior and posterior walls. EX1005, 3:37-45.

30. The original claims recited a main body, a suction connector, and a cheek retractor, and that the main body included an anterior wall, a posterior wall, two intervening walls extending from one of the posterior or anterior wall toward the other of the anterior or posterior wall. EX1002, p. 33. Each of these intervening walls included alternating crests and troughs. *Id*.

31. At one point the Examiner rejected the claims in view of Nguyen (Patent Owner's earlier patent also directed to an isolation mouthpiece), He (CN104490483), and Al-Shawi (US 2018/0153637). EX1015, pp. 264-268. Patent Owner never even disputed any of the Examiner's findings about Nguyen, but instead argued that Al-Shawi is not analogous prior art because Al-Shawi describes a surgical gas shield device secured to an incision site at an area of the body, such as a breast, knee, neck, or arm, and not a dental mouthpiece. EX1012, ¶ 95; EX1016, p. 195-197. Applicant also argued that Al-Shawi failed to teach intervening walls formed at the edges of the surgical gas shield device. EX1016, p. 196. One of these arguments was convincing (unclear which) to the Examiner and after another round of prosecution, the claims were eventually allowed. EX1016, p. 335.

V. LEVEL OF ORDINARY SKILL IN THE ART

A. Legal Principals

32. I have been informed that patents are considered from the perspective of a person having ordinary skill in the art, and that this is a hypothetical person who is presumed to know the relevant prior art.

33. I have been informed that the following five factors inform the analysis for determining the level of ordinary skill in the art: (1) type of problems

encountered in the art; (2) prior art solutions to those problems; (3) rapidity which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. I apply these factors in the section below in providing my opinion as to the level of one having ordinary skill in the art.

B. Opinion as to the Level of a Person Having Ordinary Skill in the Art of the ’217 Patent

34. I have knowledge relevant to what a person having ordinary skill in the art (“POSA”) at the time of the invention would understand and do. Indeed, in 2019, I had invented a dental isolation mouthpiece similar to the ’217 Patent. By 2019, I had filed for, prosecuted, and received two patents related to my dental mouthpiece. Moreover, I designed and sold my product since 2008. Additionally, I am a dentist and had been working as a dentist for 19 years. I am able to read and understand the claims and specifications of the prior art and the ’217 Patent in the light that a POSA would read and understand them.

35. In my opinion, and applying the factors set forth above in paragraph 33, a person of ordinary skill in the art at the time of the filing of the ’217 Patent would be: a person having at least a degree in mechanical engineering or dentistry, with at least 2 years’ experience designing dental isolation mouthpieces. If a person has a higher level of education, such as a master’s degree, less work

experience could be acceptable, and vice versa. My opinion is based on the following analysis.

36. Regarding the types of problems encountered in the art, in 2007, I observed that the Isolite was an innovative approach to intraoral isolation because it had a mouthpiece that encompassed a vacuum (suction), a bite block, and a tongue and cheek retractor. However, the problem I observed was that it had a high cost, a light which was not necessary with the emerging market of lightweight, portable, wearable LED lighting, and the lack of true high-volume suction capability. As such, the types of problems encountered by the art included reducing unit cost and increasing suction capabilities of an isolation mouthpiece.

37. Prior art solutions for intraoral isolation date back to the advent of cotton rolls, which are used to block saliva flow or protect soft tissue when placed in the mouth during dental procedures. Other well-known solutions include cheek retractor shields like "dry-angles" and the rubber dam - a sheet of rubber/latex material that has a hole or series of holes punched through it to slide over a tooth or series of adjacent teeth, then held in place by an external frame and a retaining ring on the tooth. Of course, Nguyen, Hirsch, and Black were all prior art solutions in 2019, so combined bite blocks, isolation mouthpieces, cheek retractors, and suctioning devices were known in 2019.

38. Regarding rapidity, innovations in intraoral isolation devices have occurred with a moderate frequency in the past six decades, and especially the last three. Devices such as the "Erickson Vac-Ejector," "Svedopter," cotton rolls and cotton roll holders, disposable saliva ejectors and High Volume Evacuation (HVE) tips; "Dry Angles" and rubber dams all serve as suitable intra-oral isolation devices with various advantages and limitations. Isolation mouthpieces, like Isolite, also emerged around 2000, but the basic shape and structure of those mouthpieces has not changed in 20 years.

39. Regarding sophistication level, intraoral isolation devices can be designed using computer aided drafting (CAD) on programs such as SolidWorks and then transferred for a prototype manufacturing process using stereolithography (SLA). These technologies allow for inexpensive design and prototyping. Furthermore, modifications can be made quickly if beta testing the prototypes yields poor results. With modern injection molding machines, dental isolation products can be created with softer thermoplastic materials. Moreover, most isolation mouthpieces rely on conventional mechanical structure used in dental apparatuses for a long time, such as anti-collapse projections and molded walls.

40. Finally, regarding education level, some knowledge of mechanical engineering is probably required, but an understanding of intraoral anatomy is equally important.

41. In view of all these factors, it is my opinion that a POSA is someone with a degree in mechanical engineering or dentistry with at least two years of experience in designing dental isolation mouthpieces.

VI. CLAIM CONSTRUCTION

A. Legal Principals

42. I have been informed that in a proceeding for *inter partes* review, claim terms in an unexpired patent are to be given their plain and ordinary meaning, as understood by a person having ordinary skill in the art, in view of the patent's specification.

B. Opinion on Claim Construction

43. I believe that all terms, for the purposes of *inter partes* review, can be given their plain and ordinary meaning.

44. Although it is probably unnecessary to spell out, but the plain and ordinary meaning of "partially" is "not entirely". The specification consistently uses the term partially to mean "not entirely". EX1001, 6:20-48, FIGs. 2, 6. Even beyond describing the intervening walls, the '217 Patent uses "partially" to mean "not entirely," such as describing partial blockage of the suction connector by the bridge structure. EX1001, 8:28-39. With regard to the intervening walls, no description or figure ever discloses or suggests an intervening wall that can extend

across the full distance between the anterior and posterior wall. I bring this up only because Patent Owner has asserted the ’217 Patent against a mouthpiece that has a wall that spans the entirety of a distance between the walls, which disregards the plain and ordinary meaning and the specification’s use of “partially”.

45. To the extent that the parties have disputes as to claim interpretation, they are irrelevant to the validity of the ’217 Patent because it is my opinion that all of the claims are clearly invalid as obvious based on the prior art I have considered and my experience in the dental isolation mouthpiece field.

VII. SUMMARY OF THE PRIOR ART

A. Nguyen

46. Nguyen discloses a dental mouthpiece that is nearly identical to the dental mouthpiece of the ‘217 Patent. EX1005, FIG. 1B; EX1001, FIG. 1.

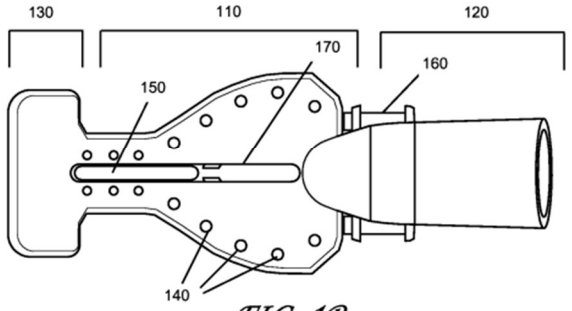


FIG. 1B

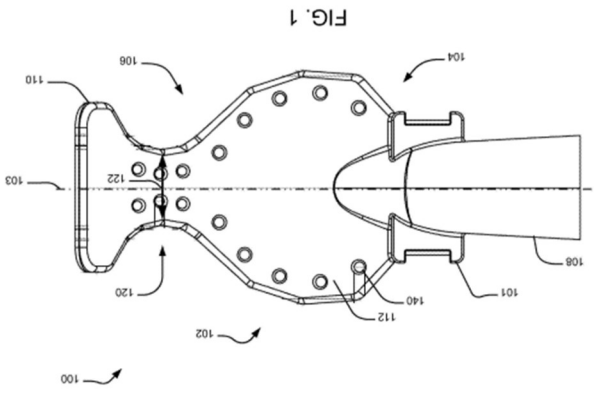


FIG. 1

This is likely because the two inventors of the Nguyen patent are also inventors on the ‘217 Patent. EX1001, (72); EX1005, (72). The dental mouthpiece in Nguyen,

just like the '217 Patent dental mouthpiece, has a suction connector, a main body portion, and a cheek retractor. EX1005, 3:15-17; EX1001, Abstract. In Nguyen, the main body portion has an anterior wall and a posterior wall that have the same size and shape as one another. EX1005, 3:37-49, FIG. 1B, 1C. Nguyen teaches sidewalls that connects to the anterior or posterior wall and the edges of the anterior or posterior wall. EX1005, 3:37-49, FIG. 1A, 1D.

47. Nguyen further discloses a bridge structure formed in the center of the main body portion that ensures that the anterior and posterior wall remain separated under suction. EX1005, 4:38-56. Nguyen also discloses a bite block that is formed around the suction connector. EX1005, 5:28-38.

B. **Black**

48. Black is my patent, and I invented the mouthpiece disclosed by Black. Black discloses a dental isolation mouthpiece with the same basic shape as the '217 Patent. EX1001, FIG. 1; EX1007, FIG. 23A.

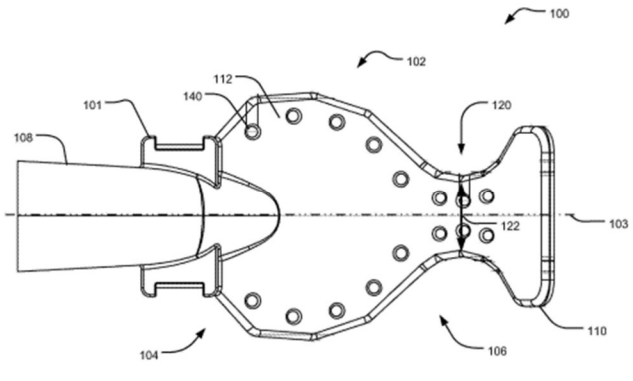


FIG. 1

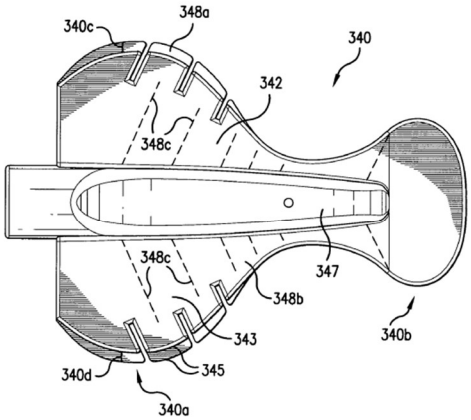
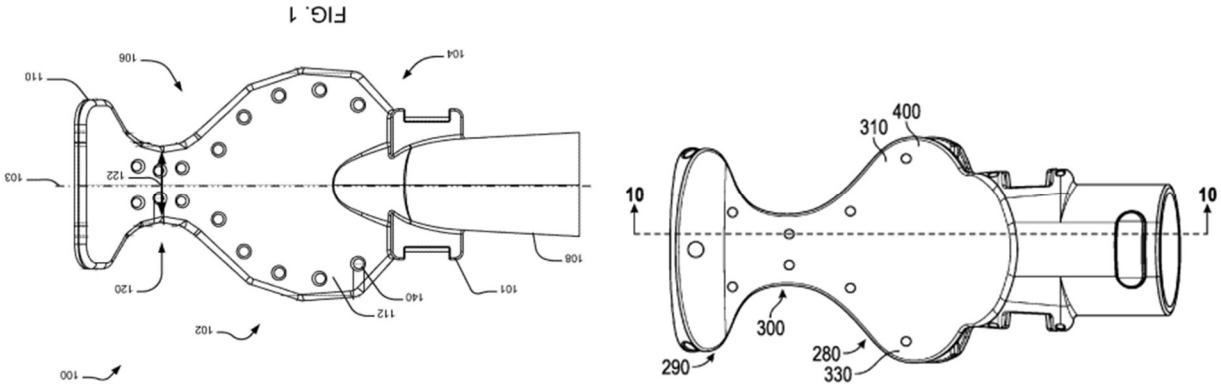


FIG.23A

Black discloses that the mouthpiece is open sided (and a sidewall formed near the suction connection tube). EX1007, 6:60-7:9, 14:34-15:20. Black goes on to explain that open sides mouthpieces provide certain advantages, such as improved suction and greater flexibility. EX1007, 17:47-54.

C. Hirsch

49. Hirsch discloses a dental isolation mouthpiece with the same basic shape as the '217 Patent. EX1001, FIG. 1; EX1006, FIG. 4.



The mouthpiece in Hirsch is open-sided and has a spine running longitudinally through the middle of the mouthpiece. EX1006, 3:17-21, 2:62-64. Hirsch discloses the basic concept that groves formed in walls of a dental mouthpiece wall can assist with suction at the grooves. EX1006, 3:17-24. Hirsch further discloses that the mouthpiece has an integral bite block. EX1006, 3:5-11.

VIII. OPINION ON GROUNDS OF UNPATENTABILITY

A. Legal Principals of Obviousness

50. I have been told that under 35 U.S.C. § 103(a), a patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102, if the differences between the subject matter sought to be patented 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 having ordinary skill in the art to which said subject matter pertains.

51. When considering the issues of obviousness, I have been told that I am to do the following:

a. determine the scope and content of the prior art;

b. ascertain the differences between the prior art and the claims at issue;

c. resolve the level of ordinary skill in the pertinent art; and

d. consider evidence of secondary indicia of non-obviousness (if available).

52. I have been told that the relevant time for considering whether a claim would have been obvious to a POSA is the time of alleged invention.

53. I have been told that a reference may be modified or combined with other references or with the POSA's own knowledge if the person would have found the modification or combination obvious. A POSA is presumed to know all relevant prior art, and the obviousness analysis may consider the inferences and creative steps that a POSA would employ.

54. In determining whether a prior art reference could have been combined with another prior art reference or other information known to a person having ordinary skill in the art, I have been told that the following principals may be considered

a. a combination of familiar elements according to known methods is likely to be obvious if it yields predictable results;
b. the substitution of one known element for another is likely to be obvious if it yields predictable results;
c. the use of a known technique to improve similar items or methods in the same way is likely to be obvious if it yields predictable results;
d. the application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results;
e. any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed;
f. a person of ordinary skill often will be able to fit the teachings of multiple references together like a puzzle; and
g. the proper analysis of obviousness requires a determination of whether a person of ordinary skill in the art would have a "reasonable

expectation of success" – not "absolute predictability" of success – in achieving the claimed invention by combining prior art references.

55. I have been told that whether a prior art reference renders a patent claim unpatentable as obvious is determined from the perspective of a POSA. Further, I have been told that while there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as filtered through the knowledge of one skilled in the art. I have also been told that the inferences and creative steps a POSA would employ are also relevant to the determination of obviousness.

56. I have been told that when a work is available in one field, design alternatives and other market forces can prompt variations of it, either in the same field or in another. If a POSA can implement a predictable variation and would see the benefit in doing so, that variation is likely to be obvious. In many fields, there may be little discussion of obviousness combinations, and in these fields market demand – not scientific literature – may drive design trends. When there is a design need or market pressure and there are a finite number of predictable solutions, a POSA has good reason to pursue those known options.

57. I have been told that there is no rigid rule that a reference or combination of references must contain a "teaching, suggestion, or motivation" to combine references. But I also have been told that the "teaching, suggestion, or motivation" test can be a useful guide in establishing a rationale for combining elements of the prior art. This test poses the question whether there is an express or implied teaching, suggestion, or motivation to combine prior art elements in a way that yields the claimed invention and avoids impermissible hindsight analysis.

B. Ground 1: Claims 1–23 are obvious under 35 U.S.C. § 103 by Nguyen in view of Black.

58. It is my opinion that Nguyen in view of Black discloses all of the limitations of claims 1–11 and 13–23.

1. Independent Claim 1

a. Preamble/Limitation 1(a): "A dental mouthpiece formed in a curve, the dental mouthpiece comprising:"

59. I have been informed by counsel that claim preambles are generally not a limitation when the content of the claimed preamble is an "intended use". I have been informed by counsel that preambles are generally statements of intended use when the body of a claim fully sets forth all the limitations of the claimed invention, and the preamble merely states the purpose or intended use of the invention. Here, the preamble merely states what the claimed mouthpiece is intended to do, i.e., be a dental isolation mouthpiece.

60. Even if the preamble is limiting, Nguyen discloses a dental mouthpiece formed on a curve. EX1005, Abstract, 6:2-3, FIG. 1A, 1D.

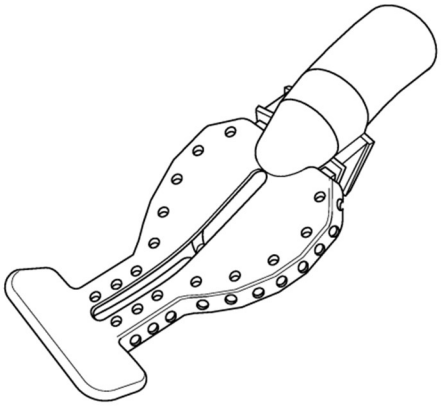


FIG. 1A

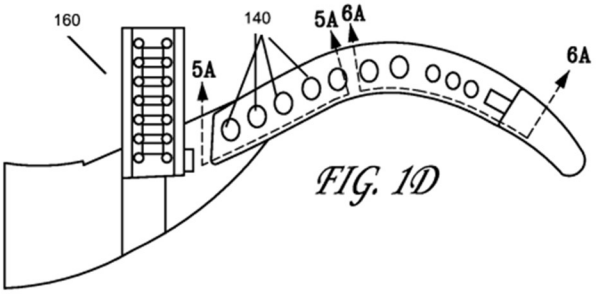


FIG. 1D

b. **Limitation 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,"**

61. Nguyen discloses a main body portion 110 that is formed at the central part of a curve. EX1005, 6:4-6.

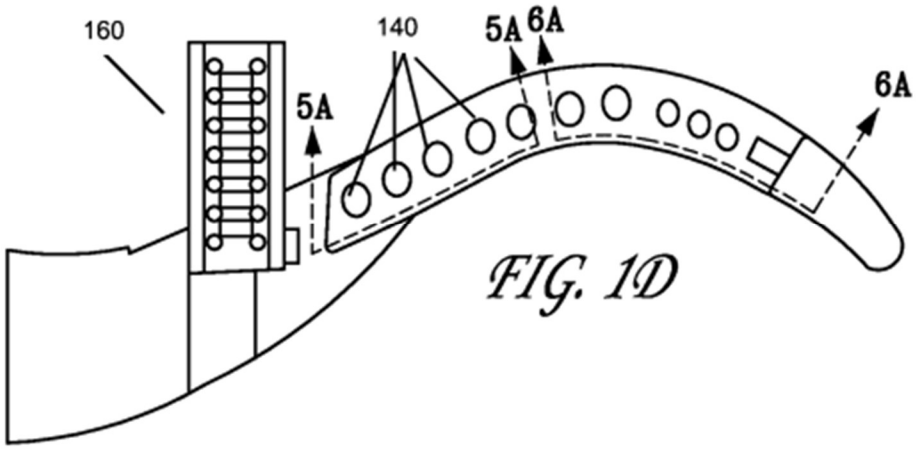


FIG. 1D

62. Nguyen discloses that the main body portion has a first end connected to a suction connector portion 120 and a second end connected to a cheek retractor 130. EX1005, FIG. 1B; 3:20-22.

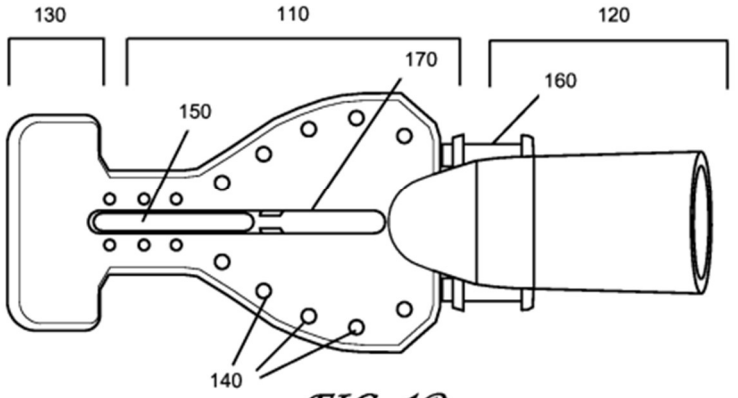


FIG. 1B

63. Nguyen discloses an anterior wall and a posterior wall spaced apart at a distance from the anterior wall. Nguyen discloses that the anterior wall is formed

inside the curve and the posterior wall is formed outside the curve. EX1005, 3:37-54, 4:6-11, 1:58-60, FIGS. 1D-1E.

64. Nguyen discloses a "pocket" that is "at least partially enclosed" and that the pocket is an interior space, that is defined by the anterior wall and the posterior wall. EX1005, 1:58-60, 3:36-54.

c. **Limitation 1(c): "at least one connector connecting the anterior wall to the posterior wall,"**

65. 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.

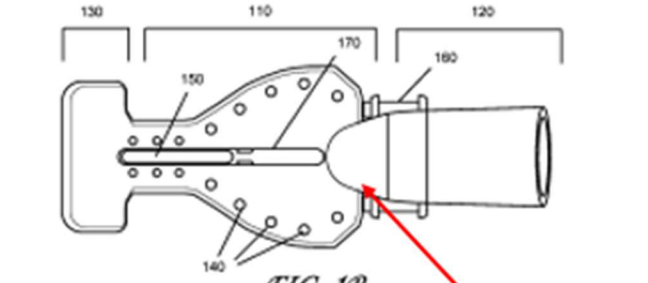


FIG. 1B

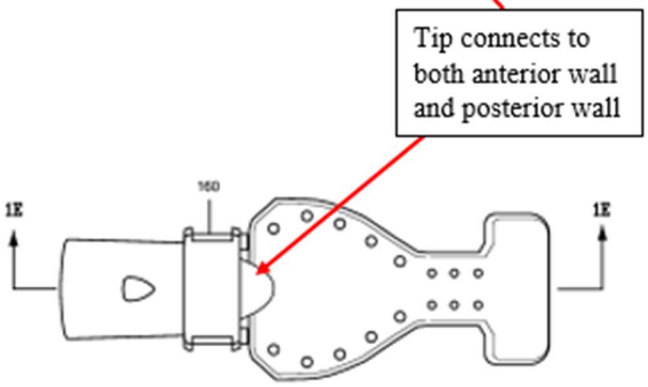


FIG. 1C

FIG. 1E confirms that this connection occurs between the anterior and posterior wall.

d. **Limitation 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,"**

66. It is my understanding that this claim limitation requires two intervening walls that each extend from one of an anterior wall or a posterior wall

only **partially** across the distance of the interior space towards the other of the anterior wall or posterior wall.

67. Nguyen discloses a superior wall and an inferior wall protruding from and extending along an edge of both the anterior and posterior walls. EX1005, 3:37-54, FIG. 1A, 3:63-4:3.

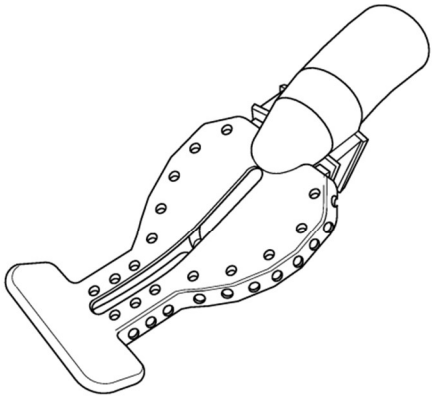


FIG. 1A

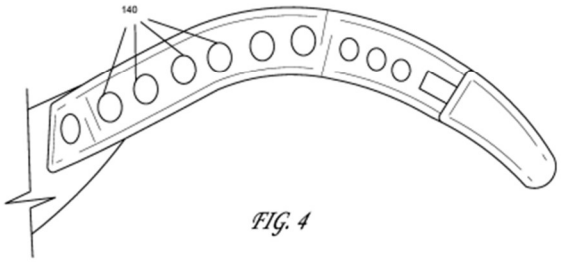


FIG. 4

68. Nguyen teaches that the sidewalls extend across the entirety of the distance between the anterior and posterior wall and connect to both the anterior wall and the posterior wall. *Id.* Thus, the sidewalls do not extend only partially across the distance. Nevertheless, it would have been obvious to a POSA to open the sidewalls of Nguyen in view of the teachings of my own patent (Black), thereby creating intervening walls that each extend only partially across the distance between the anterior and posterior walls.

69. My patent, Black, teaches an open-sided tongue shield aspirator (i.e., dental mouthpiece). EX1007, 17:47-54, 6:10-20, 5:60-63.

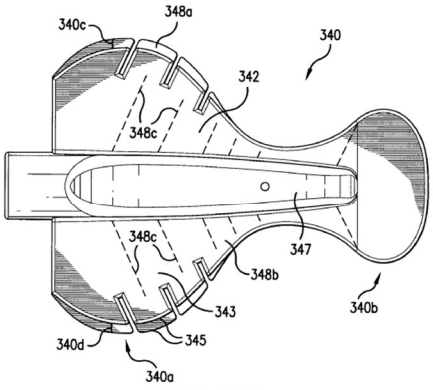


FIG.23A

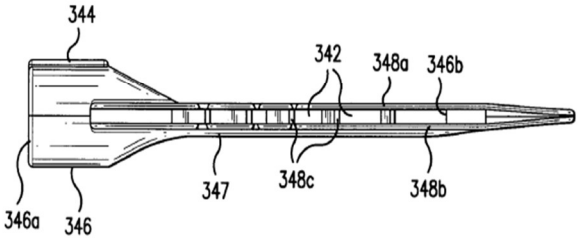


FIG.23C

As I explain in my patent, an open-sided dental 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. EX1007, 17:47-54. Knowing that open-sided mouthpieces provide advantages in suction, a POSA would be motivated to open the sidewalls of Nguyen to improve suction. *Id.* Also, a POSA would understand that an open-sided mouthpiece would be easier to clean. Opening the sidewalls of Nguyen would be applying a known technique (open sidewalls) to a known device ready for improvement (the dental mouthpiece of Nguyen) to yield predictable results (increasing the aspiration of fluid/debris through the mouthpiece and easier cleaning). Opening the sidewalls of Nguyen would also be using a known technique (open sidewalls) to improve similar mouthpieces (the dental mouthpiece

of Nguyen) in the same way (the mouthpiece of Nguyen would have increased suction and would be easier to clean).

70. I discuss each of the motivations for open sidewalls (improved suction and easier cleaning of the mouthpiece) in depth below.

71. More specifically regarding improved suction, 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 superior sidewall and the floor of the mouth pressing up on the inferior sidewall. EX1005, 3:29-31, 3:42-45; EX1007, 19:33-20:47. Additionally, the patient's gum ridges behind the molars would press down on the rectangular portion of Nguyen's mouthpiece, causing additional bending/folding. EX1005, 4:20-30; EX1007, 20:3-20. Indeed, the anterior and posterior walls of Nguyen comprise flexible material, making them susceptible to bending. EX1005, 1:52-55, 2:2-5.

72. A POSA would understand that when two parallel walls are connected at their edges and spaced apart, any bending force from mouth tissue would force the two walls to bend along different paths. The "outer" (posterior) wall would bend at a different radius than the "inner" anterior sheet. EX1005, FIG. 1A; EX1007, 20:3-20. With connecting sidewalls, the geometry does not allow the anterior wall and the posterior wall to bend at different radiuses. That is, one wall cannot slide or change its relative spacing, so the anterior wall will buckle from the

forces acted on it from the sidewalls. A POSA would know that is known as the basic geometric constraint of bending layered materials. Thus, the anterior wall (and the posterior wall) would receive a force from mouth tissue and an additional torque from the sidewalls due the connection between the anterior wall and posterior wall at the sidewalls due to the geometric constraint of bending layered materials. A POSA would understand that under these conditions, the anterior wall would bend towards the posterior wall at certain points. *Id*.

73. A POSA would recognize 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. EX1005, FIG. 1A.

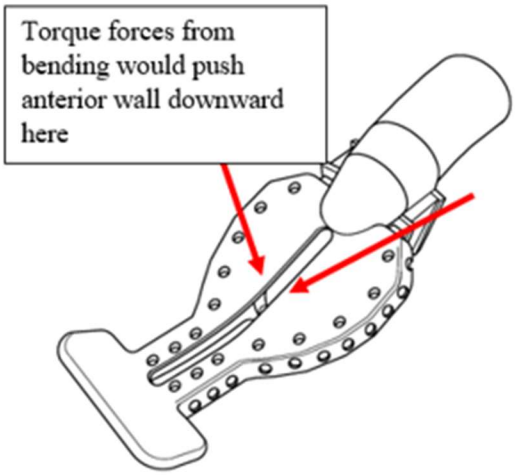


FIG. 1A

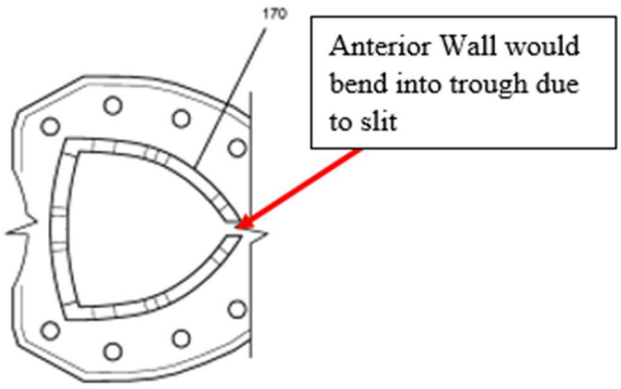


FIG. 5

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. EX1005, 2:10-16, 4:38-56; *see also* EX1013, 2:6-41, FIG. 2. A POSA would further recognize that the troughs of the bridge structure 180 are the locations for channel narrowing because there are no projections/crests of the bridge structure 180 providing a resistant force.

74. A POSA would recognize that the anterior wall would also bend where the anterior wall meets the suction connector. Nguyen teaches that the suction connector is made of a thicker material than the walls. EX1005, 4:57-63. A POSA would know 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.*

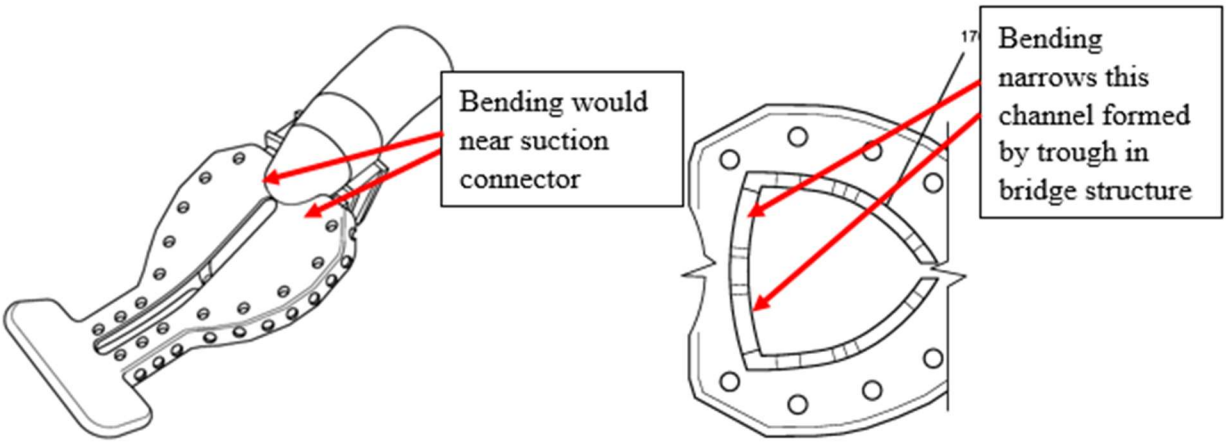
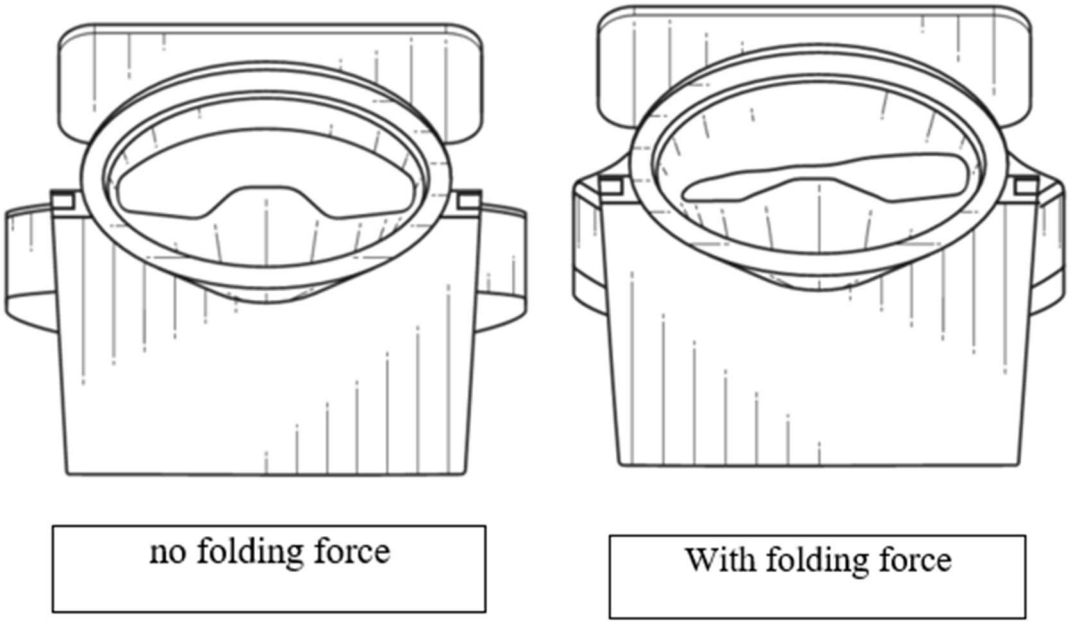


FIG. 1A FIG. 5

From a perspective down the suction connector tube, this channel narrowing would essentially look like this:



75. A POSA would also understand that opening the sidewalls would allow the anterior and posterior walls to bend at different radiuses because the anterior wall would not receive the posterior wall's folding force through the sidewalls in addition to any folding force it also received from the patient's mouth tissue. Instead, the anterior wall and the posterior wall could bend at different rates, independent of each other. As a result, the anterior wall would not block any important suction channels formed by the bridge structure 180.

76. A POSA would also recognize that opening the sidewall of Nguyen would improve suction through the sides of the dental mouthpiece.

77. Nguyen's mouthpiece can only provide suction through the holes 140 in the sidewall and not between the holes 140. EX1005, 3:63-4:3. In contrast, if the

sidewalls of Nguyen were open, suction could occur all along the entire side. EX1007, 17:47-54.

78. Opening the sidewalls would also have the added benefit of allowing for suction of larger pieces of debris that could not fit through the holes 140. *Id.*

79. Finally, regarding easier cleaning, Nguyen discloses that the mouthpiece is autoclavable and reusable. EX1005, 3:8-10. If a dental mouthpiece is going to be reused, it must be cleaned thoroughly between patients. EX1005, 4:34-37. Nguyen explains that cleaning occurs through the slit 170. *Id*. A POSA would recognize that trying to clean the inside of the mouthpiece of Nguyen through the slit 170 would not be easy. It 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.

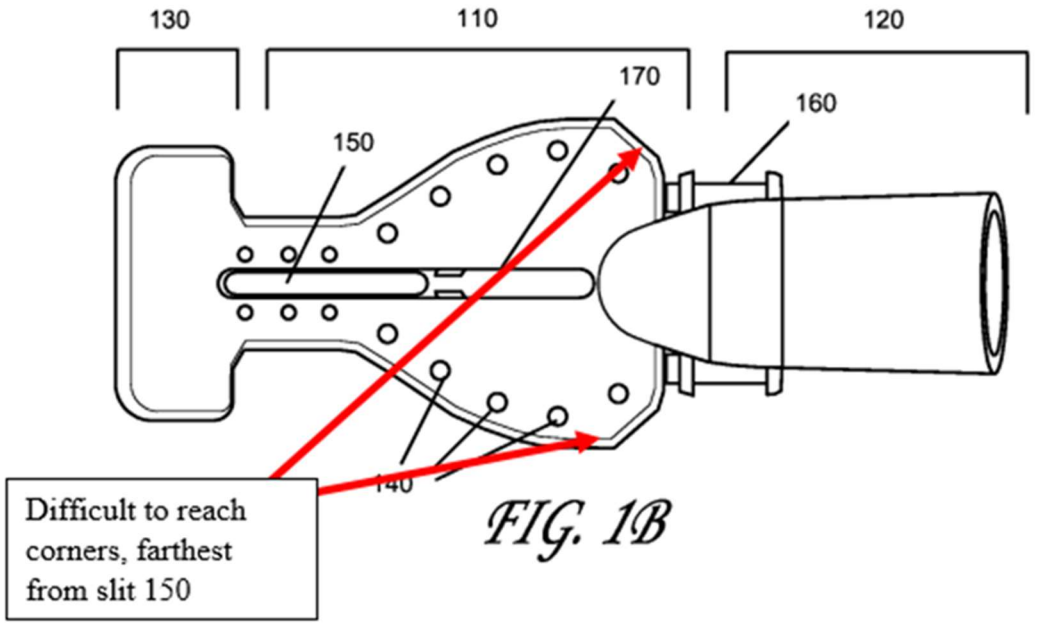


FIG. 1B

80. A POSA would know that opening the sidewalls of the mouthpiece of Nguyen would make the mouthpiece much easier to clean because a cleaning brush could be inserted through the open side of the mouthpiece to remove any bacteria or other debris. Inserting a cleaning brush through the open sides would be much easier than trying to fold the anterior wall of Nguyen at the slit 170 to insert the brush through the slit and try to get the brush into all of the internal corners of Nguyen's mouthpiece. EX1005, 4:34-37, FIG. 1B. Open sides eliminates any hard-to-reach corners. In fact, most prior art dental mouthpieces had open sides for at least this reason. EX1006, FIG. 2; EX1007, FIG. 23C, EX1017, FIG 4, EX1018, FIG. 1, EX1019, FIG. 3. Therefore, a POSA would be further motivated to open the sides of Nguyen in view of Black to make the mouthpiece easier to clean for reuse.

81. However, due to Nguyen's structure, a POSA would have been motivated to form open-sided, anti-collapse structure along the edges of Nguyen's mouthpiece in view of Black. My patent, Black, discloses a mouthpiece that has transverse walls 348c (shown in dashed lines below) that extend outwardly all the way to the edge of an anterior flap 348b. *See* also EX1007, 14:21-47, FIG. 23B. The transverse walls 348c are anti-collapse structure. EX1007, 14:21-47. Thus, Black teaches that anti-collapse structure is necessary at edges of the anterior wall.

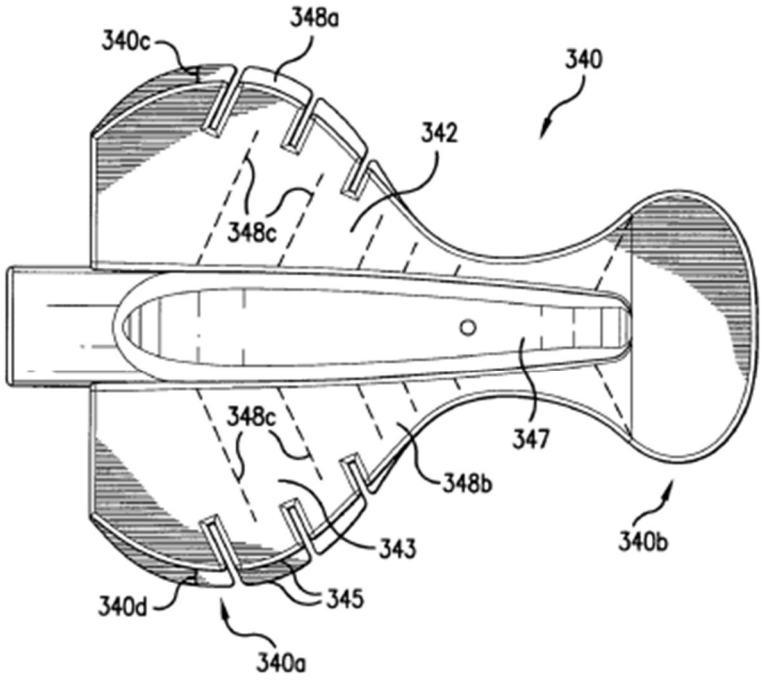


FIG.23A

82. Instead of transverse walls, Nguyen uses a bridge structure 180 and sidewalls to prevent collapse of the anterior and/or posterior walls under suction. EX1005, 2:10-16, 4:38-56. A POSA would know that completely removing the anti-collapse sidewalls of Nguyen would allow the anterior and/or posterior walls to collapse under suction near the edges of the mouthpiece, thereby blocking suction through the perforations 140 that are formed at the edges of the mouthpiece, elements that are critical to removing fluid from the patient's mouth. EX1005, 3:63-67.

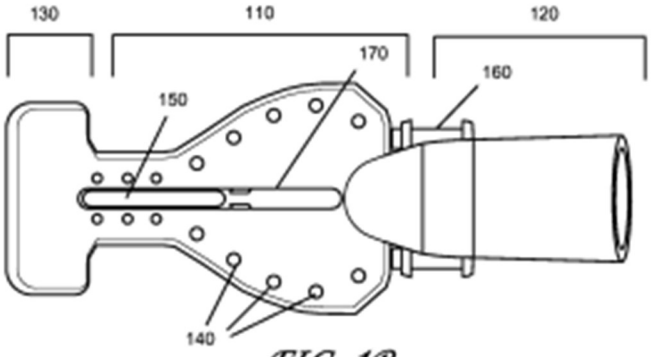


FIG. 1B

This would happen because the edges of the mouthpiece are too far from the bridge structure 180, such that the bridge structure's anti-collapse function would not extend to the edges of the mouthpiece. EX1005, FIG. 1B.

83. Therefore, 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. Black recognized this, which is why my transverse walls 348c extend all the way to the edges of the anterior wall. EX1007, FIG. 23A.

84. 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.

85. Alternatively, it would be immediately obvious to a POSA to simply cut open Nguyen's sidewalls to accomplish the goals stated above. Simply cutting open the sidewalls of Nguyen would open the sides and also create an anti-collapse structure at the edges of the mouthpiece. Even better, a POSA would know that such an elegant solution would not require a new mold to arrive at an open-sided mouthpiece; the existing mold of Nguyen could be reused with the additional step of cutting open the sidewalls.

86. A POSA would recognize 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. A POSA would choose to cut there for many reasons. First, cutting at the perforations requires cutting the least amount of material. Second, cutting at the perforations maximally reduces the chances of accidentally cutting or damaging the anterior or posterior walls of the mouthpiece, which would render the mouthpiece unusable.

87. Cutting open the sidewalls of Nguyen at the perforations would create semi-circular suction inlets. Simply cutting open the sidewalls of Nguyen at the perforations would result in an anterior and a posterior intervening wall, each

protruding partially across the distance toward the anterior wall. See annotated EX1005, FIG. 2D below.

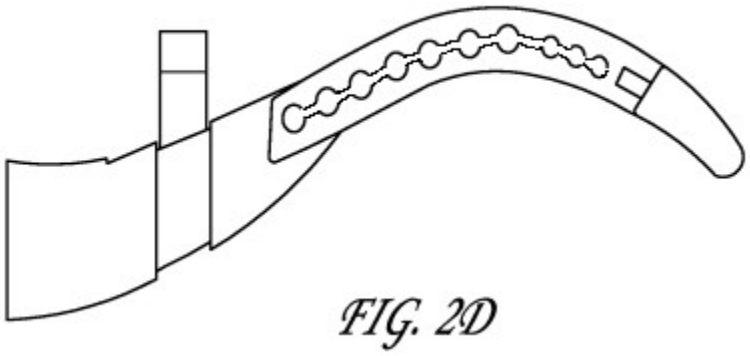


FIG. 2D

88. A POSA would expect success in cutting open the sidewalls of Nguyen because cutting open the sidewalls would be the easiest way to accomplish all of the above state goals (better suction, easier cleaning). Cutting open the sidewalls of Nguyen at the perforations in view of Black's teachings is an easy extra step to create a mouthpiece with open sides and would not require completely redesigning the mouthpiece. In fact, a POSA would not even need to change the injection mold of Nguyen; a POSA would simply need to perform one additional cutting step to create the open sided mouthpiece.

89. While I understand that the slit 170 is not a required feature of claim 1, I would like to note that if the sidewalls of Nguyen were opened, then the slit 170 would no longer be necessary. A POSA would know that removing the slit 170 could prevent the anterior wall from filling the troughs of the bridge structure 180

as discussed above. Nguyen also discusses that the slit 170 may help provide suction so a POSA may decide to leave the slit 170 to aid in suction. Therefore, a POSA would know that the slit 170 could be removed in view of the open sidewalls or the slit 170 could stay.

90. For all the reasons I discussed above, a POSA would be motivated to modify the mouthpiece of Nguyen in view of Black to cut open the sidewalls.

e. **Limitation 1(e): "and 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;"**

91. As shown below in annotated FIG. 2D, Nguyen as modified by Black to cut open the sidewalls results in two intervening walls extending partially across the distance between the anterior wall and the posterior wall. The simple cut across the middle of the original sidewall forms two intervening walls, each with an edge having alternating crests and troughs that extend different distances across the span. EX1005, FIG. 2D (annotated).

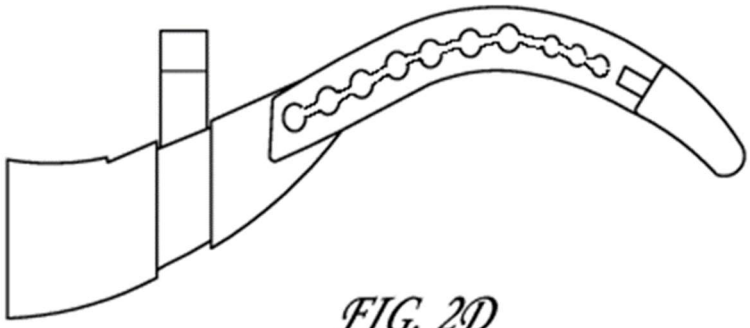


FIG. 2D

f. **Limitation 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"**

92. Nguyen discloses a suction connector portion 120 connected to the first end of the main body portion 110 that connects the interior space of the main body portion to a vacuum suction source. EX1005, 3:20-22, 4:57-63, 6:24-28.

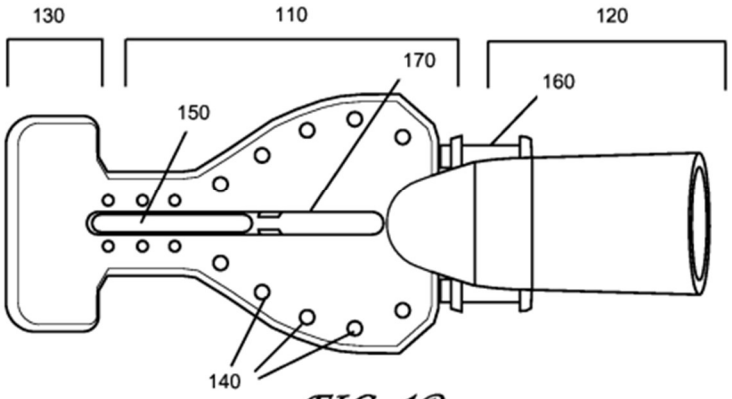


FIG. 1B

g. **Limitation 1(g): "a cheek retractor portion connected to the second end."**

93. Nguyen discloses a check retractor portion 130 connected to the second end of the main body portion 110. EX1005, 3:20-22.

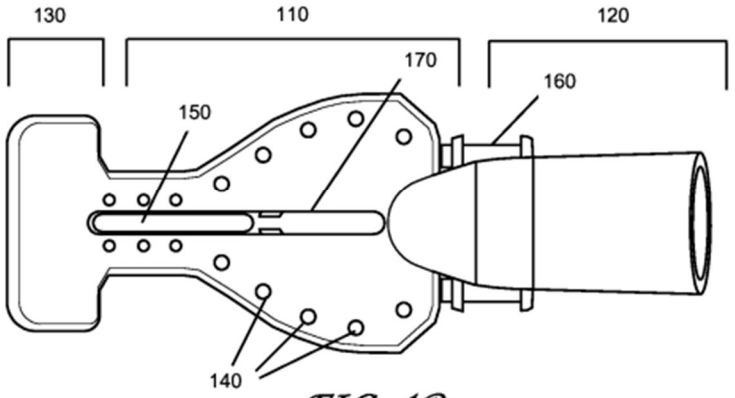


FIG. 1B

2. **Claim 2: "The mouthpiece of claim 1, wherein the at least one connector includes at least one of a wall spanning longitudinally in the main body portion in the interior space or a pillar."**

94. As shown in FIGS. 2A-2C, 2E, Nguyen discloses that the tip in front of the suction connector 120 includes at least one wall spanning longitudinally in the main body portion 110 in the interior space and connecting the anterior wall to the posterior wall. EX1005, FIGS. 2A-2C, 2E, 4:57-58.

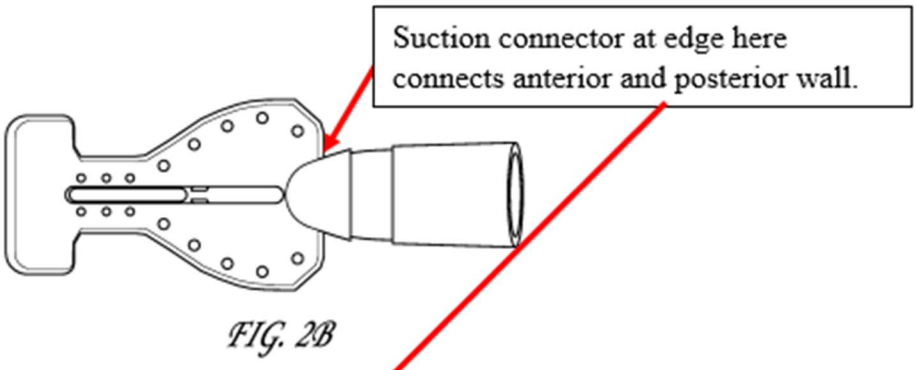


FIG. 2B

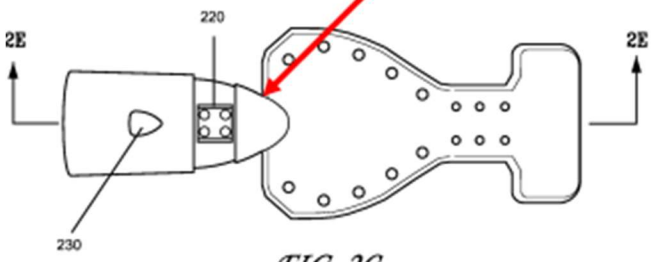


FIG. 2C

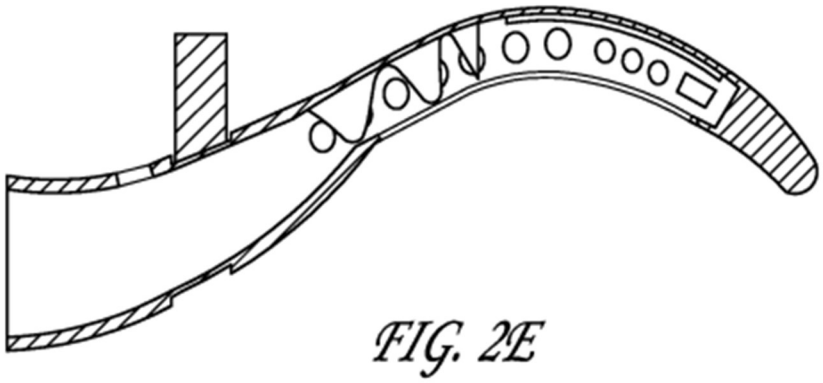


FIG. 2E

3. **Claim 3: "3. The mouthpiece of claim 1, further comprising a bridge structure that includes one or more protrusions protruding from the posterior wall within the interior space, wherein the protrusions include spaced crests and troughs."**

95. Nguyen discloses a bridge structure 180 that is identical to the bridge structure in the '217 Patent. EX1005, 4:38-56.

4. **Claim 4: "4. The mouthpiece of claim 3, wherein the protrusions vary in height and length."**

96. Nguyen discloses that the protrusions vary in height and length, as shown in FIGS. 2E and 5.

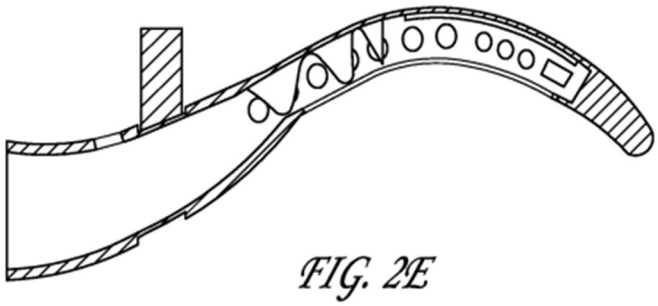


FIG. 2E

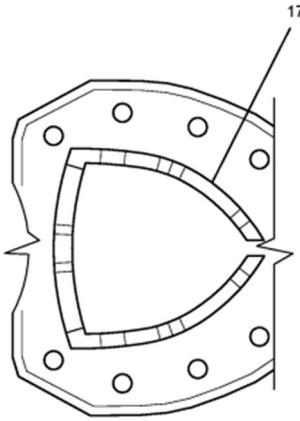


FIG. 5

5. **Claim 5: "5. The mouthpiece of claim 1, wherein at least one of the anterior intervening wall and the posterior intervening wall includes a plurality of portions of varying heights relative to a longitudinal axis of the mouthpiece."**

97. When the sidewall of Nguyen is cut open across the middle of the sidewall, anterior and posterior intervening walls are formed, which each have an edge including alternating crests and troughs that extend different distances across the span (portions of varying height). EX1005, FIG. 2D (annotated).

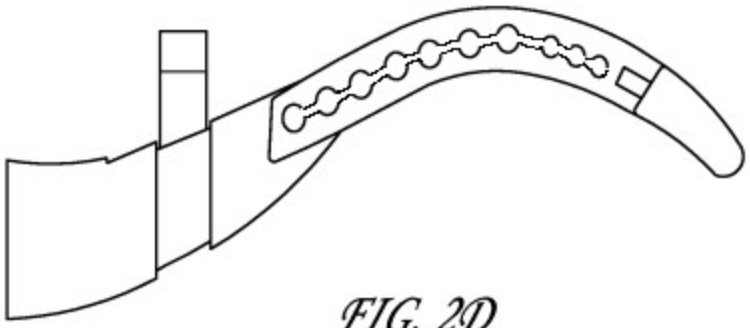


FIG. 2D

6. **Claim 6: "6. The mouthpiece of claim 1, wherein the anterior intervening wall and the posterior intervening wall meet at a point where the suction connector meets the main body portion."**

98. The anterior and posterior intervening walls of Nguyen formed by cutting open the sidewalls in view of Black would meet at the end of the cut. A POSA would not have been motivated to extend the cutting into the suction connector as a leak-free suction connector is necessary for efficient suction. Therefore, the anterior and posterior intervening walls would meet at the end of the main body near the suction connector portion.

7. **Claim 7: "7. The mouthpiece of claim 1, wherein the anterior intervening wall and the posterior intervening wall meet at a point where the main body portion meets the cheek retractor portion."**

99. The anterior and posterior intervening walls of Nguyen formed by cutting open the sidewalls in view of Black would meet at the end of the cut. A POSA would not have been motivated to extend the cutting into the cheek retractor

as that rigid material is necessary for retracting cheek tissue. Therefore, the anterior and posterior intervening walls would also meet at the end of the main body near the cheek retractor.

8. **Claim 8: "8. The mouthpiece of claim 1, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient."**

100. Nguyen discloses a mouth prop 160 integrated into the suction connector portion 120 (e.g., by using the strap 310) to provide crush-resistance during biting by a patient. EX1005, 5:9-28, 4:65-5:2.

101. I have been informed that even if the detachable mouth prop 160 is not considered "integrated to the suction connector", it would have been obvious to make the mouth prop integral, as making something integral is typically considered obvious. Here, I agree that changing a removable bite block to an integral one is an obvious design choice.

9. **Claim 9: "9. The mouthpiece of claim 1, wherein the main body portion, the suction connector portion, and the cheek retractor portion are formed by injection-molding as one piece."**

102. Nguyen discloses that all of the main body 110, the suction connector portion 120, and the cheek retractor 130 are formed in one piece by injection molding. EX1005, Abstract.

10. **Claim 10: "10. The mouthpiece of claim 1, wherein a material that forms the main body portion, the suction connector portion, and the cheek retractor portion is a flexible, translucent, high heat-resistant, autoclavable silicone-based material."**

103. Nguyen discloses a mouthpiece formed of a flexible, translucent, high-heat resistant, autoclavable, silicone-based material. EX1005, Abstract.

11. **Claim 11: "11. The mouthpiece of claim 1, wherein the posterior wall further includes a stability bar protruding from an interior surface of the posterior wall and along a longitudinal axis of the main body portion."**

104. Nguyen discloses a stability bar 150 that is the same as the stability bar in the '217 Patent. EX1005, 4:12-19.

12. **Claim 13: "13. The mouthpiece of claim 1, wherein the suction connector portion comprises a cutout corresponding to a protrusion on a vacuum adapter to provide an interlocking fit."**

105. Nguyen discloses that the suction connector 120 includes a cutout 230 that corresponds to a protrusion on a vacuum adaptor to provide an interlocking fit. EX1005, 5:22-57.

13. **Claim 14: "14. The mouthpiece of claim 1, where in the suction connector portion connects to the vacuum suction source, wherein activation of the vacuum suction source provides suction of fluids from the interior space of the main body portion."**

106. Nguyen discloses that the suction connector portion 120 connects to a vacuum source to provide suction of fluids from the interior space of the main body portion 110. EX1005, 4:57-63, 3:63-67.

14. **Claim 15: "15. The mouthpiece of claim 14, wherein the activation of the vacuum suction source draws fluids from an exterior of the main body portion into the interior space of the main body portion."**

107. Nguyen discloses that the suction connector portion 120 connects to a vacuum source to provide suction of fluids from an exterior of the main body portion 110 into the interior space of the main body portion 110. EX1005, 4:57-63, 3:63-67.

15. **Claim 16: "16. The mouthpiece of claim 1, wherein the span of the anterior intervening wall extends from the edge of the anterior wall to at least a mid-point of the interior space between the anterior wall and the posterior wall."**

108. As discussed above, the cut across the middle of the original sidewall of Nguyen forms anterior and posterior intervening walls, each with an edge having alternating crests and troughs. Nguyen as modified by Black discloses an anterior intervening wall that extends to at least a midpoint of the interior space. EX1005, FIG. 2D (annotated).

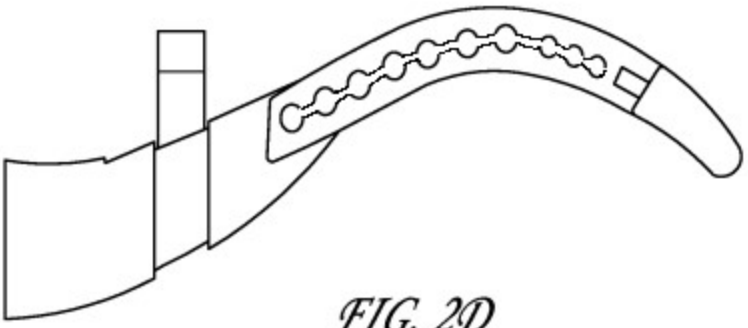


FIG. 2D

16. **Independent Claim 17**

a. **Preamble/Limitation 17(a): "A dental mouthpiece comprising:"**

109. As discussed above in paragraphs 59–60, Nguyen fully teaches this limitation.

b. **Limitation 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,"**

110. As discussed above in paragraphs 61–64, Nguyen fully teaches this limitation.

c. **Limitation 17(c): "at least one connector that connects the anterior wall to the posterior wall within the interior space,"**

111. As discussed above in paragraph 65, Nguyen fully teaches this limitation.

d. **Limitation 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,"**

112. As discussed above in paragraphs 66–90, Nguyen in view of Black fully teaches this limitation.

e. **Limitation 17(e): "and 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"**

113. As discussed above in paragraph 91, Nguyen in view of Black fully teaches this limitation.

f. **Limitation 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;"**

114. Nguyen discloses a neck (the rectangular portion) extending from the main body portion 110. EX1005, 4:4-11. As shown in FIG. 1B, for example, the rectangular portion is narrower than the main body portion 110 at the suction connector end 120.

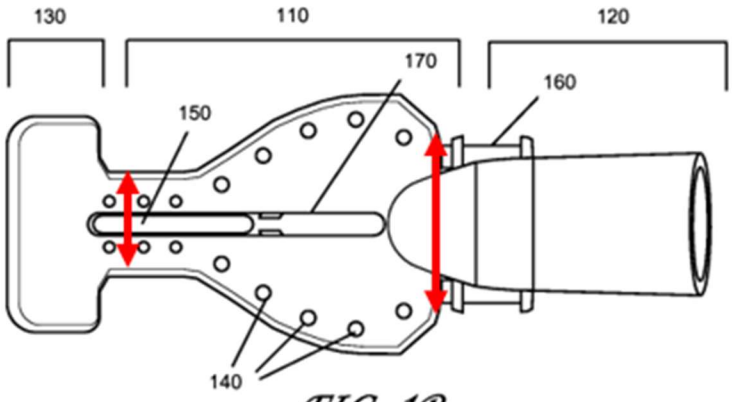


FIG. 1B

g. **Limitation 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"**

115. As discussed above in paragraph 92, Nguyen fully teaches this limitation.

h. **Limitation 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."**

116. As discussed above in paragraph 93, Nguyen fully teaches this limitation. As shown in FIG. 1B, the cheek retractor is wider than the neck.

17. **Claim 18: "18. The mouthpiece of claim 17, wherein the at least one intervening wall includes a plurality of portions of varying heights relative to a longitudinal axis of the mouthpiece."**

117. As discussed above in paragraph 97, Nguyen fully teaches this limitation.

18. **Claim 19: "19. The mouthpiece of claim 17, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient."**

118. As discussed above in paragraph 100, Nguyen fully teaches this limitation.

19. **Claim 20: "20. The mouthpiece of claim 17, wherein the main body portion, the suction connector portion, and the cheek retractor portion are formed by injection-molding as one piece."**

119. As discussed above in paragraph 102, Nguyen fully teaches this limitation.

20. **Claim 21: "21. The mouthpiece of claim 17, wherein the suction connector portion comprises a cutout corresponding to a protrusion on a vacuum adapter to provide an interlocking fit."**

120. As discussed above in paragraph 105, Nguyen fully teaches this limitation.

21. **Claim 22: "22. The mouthpiece of claim 17, where in the suction connector portion connects to the vacuum suction source, wherein activation of the vacuum suction source provides suction of fluids from the interior space of the main body portion."**

121. As discussed above in paragraph 106, Nguyen fully teaches this limitation.

22. **Claim 23: "23. The mouthpiece of claim 22, wherein the activation of the vacuum suction source further draws fluids from an exterior of the main body portion into the interior space of the main body portion."**

122. As discussed above in paragraph 107, Nguyen fully teaches this limitation.

C. **Ground 2: Claims 8 and 19 are further obvious under 35 U.S.C. § 103 by Nguyen in view of Black and Hirsch.**

123. It is my opinion that Nguyen in view of Black and further in view of Hirsch discloses all of the limitations of claims 8 and 19.

1. **Claim 8: "8. The mouthpiece of claim 1, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient."**

124. Nguyen discloses a mouth prop 160 integrated into the suction connector portion 120 (by using the strap 310) to provide crush-resistance during biting by a patient. EX1005, 5:9-28, 4:65-5:2. To the extent that the detachable mouth prop 160 is not considered "integrated to the suction connector", Hirsch discloses an integrated bite piece 250 that is integrated into a suction connector section 570. It would have been obvious to make the mouth prop 160 of Nguyen non-detachable so that the mouthpiece could be manufactured as one piece, which is recommended by both Hirsch and Nguyen. EX1005, 5:39-40; EX1006, 3:5-8. MPEP 2144.04(V)(B).

2. **Claim 19: "19. The mouthpiece of claim 17, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient."**

125. As discussed above in paragraph 124, Nguyen in view of Black and Hirsch fully teaches this limitation.

D. **Ground 3: Claims 17–23 are obvious under 35 U.S.C. § 103 by Nguyen in view of Hirsch.**

126. It is my opinion that Nguyen in view of Hirsch discloses all of the limitations of claims 17–23.

1. **Independent Claim 17**

a. **Preamble/Limitation 17(a): "A dental mouthpiece comprising:"**

127. As discussed above in paragraphs 59–60, Nguyen fully teaches this limitation.

b. **Limitation 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,"**

128. As discussed above in paragraphs 61–64, Nguyen fully teaches this limitation.

c. **Limitation 17(c): "at least one connector that connects the anterior wall to the posterior wall within the interior space,"**

129. As discussed above in paragraph 65, Nguyen fully teaches this limitation.

d. **Limitation 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,"**

130. Nguyen discloses two walls (superior and inferior sidewalls) protruding from and extending along an edge of both the anterior and posterior walls. EX1005, 3:37-54, FIG. 1A, 3:63-4:3.

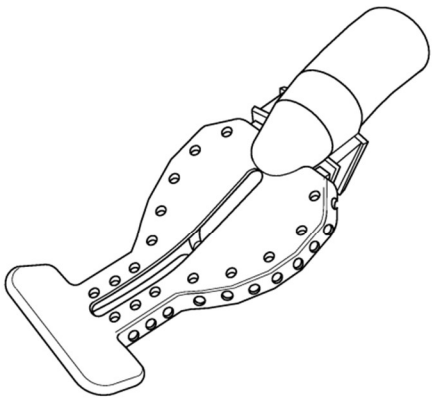


FIG. 1A

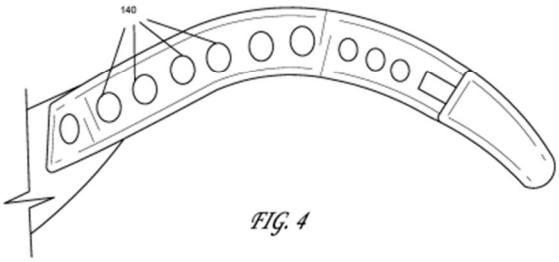


FIG. 4

131. Nguyen teaches that the sidewalls extend across the entirety of the distance between the anterior and posterior wall and connect to both the anterior wall and the posterior wall. *Id.* Thus, the sidewalls do not extend only partially across the distance. Nevertheless, it would have been obvious to a POSA to open the sidewalls of Nguyen in view of the teachings of Hirsch, thereby creating at

least one intervening wall that extends only partially across the distance between the anterior and posterior walls.

132. Hirsch discloses an intraoral device (dental mouthpiece) 200 that includes a tongue and cheek retractor 240 that has gaps 350, 360. EX1006, 3:17-21. Hirsch goes on to explain that the upper gap 350 engages the roof of the patient's mouth, the lower gap 360 engages the floor of the patient's mouth, and the mouth tissue bends the flaps 310, 320, 330, 340 forward. EX1006, 4:43-67.

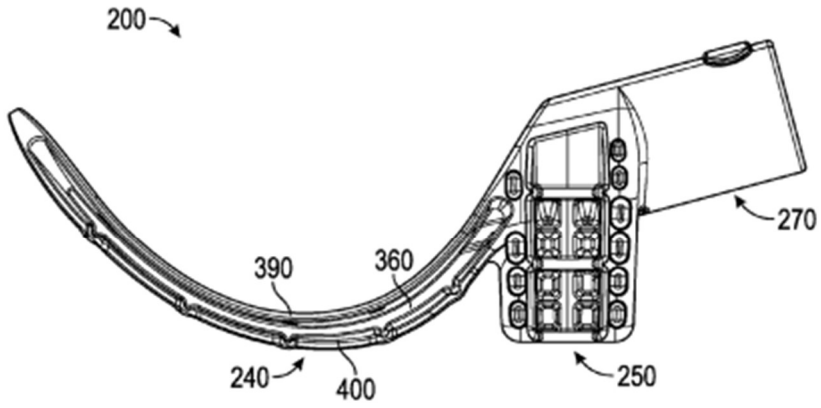


FIG. 6

133. As I discussed above, a POSA would know that a mouthpiece with open sides (like Hirsch's mouthpiece) would bend easier into a patient's mouth. EX1006, 4:43-67; *see also* EX1007, 17:47-54.

134. Additionally, an open-sided mouthpiece is easier to clean and offers improved suction. EX1005, 4:34-37; EX1006, 4:4-16.

135. I discuss each of the motivations in depth below.

136. First, regarding improved suction, 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 superior sidewall and the floor of the mouth pressing up on the inferior sidewall. EX1005, 3:29-31, 3:42-45; EX1006, 4:43-67. Additionally, the patient's gum ridges behind the molars would press down on the rectangular portion of Nguyen's mouthpiece, causing additional bending/folding. EX1005, 4:20-30; *see also* EX1007, 20:3-20. Indeed, the anterior and posterior walls of Nguyen comprise flexible material, making them susceptible to bending. EX1005, 1:52-55, 2:2-5.

137. A POSA would know that the sidewalls prevent the anterior wall from bending along an independent radius, leading to buckling by the anterior wall. EX1006, 4:43-67. I discussed the causes and results of mouth tissue pressure to the mouthpiece of Nguyen in-depth above in paragraphs 71-75.

138. Finally, regarding easier cleaning, Nguyen discloses that the mouthpiece is autoclavable and reusable. EX1005, 3:8-10. If a dental mouthpiece is going to be reused, it must be cleaned thoroughly between patients. EX1005, 4:34-37. Nguyen explains that cleaning occurs through the slit 170. *Id*. A POSA would recognize that trying to clean the inside of the mouthpiece of Nguyen through the slit 170 would not be easy. It 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.

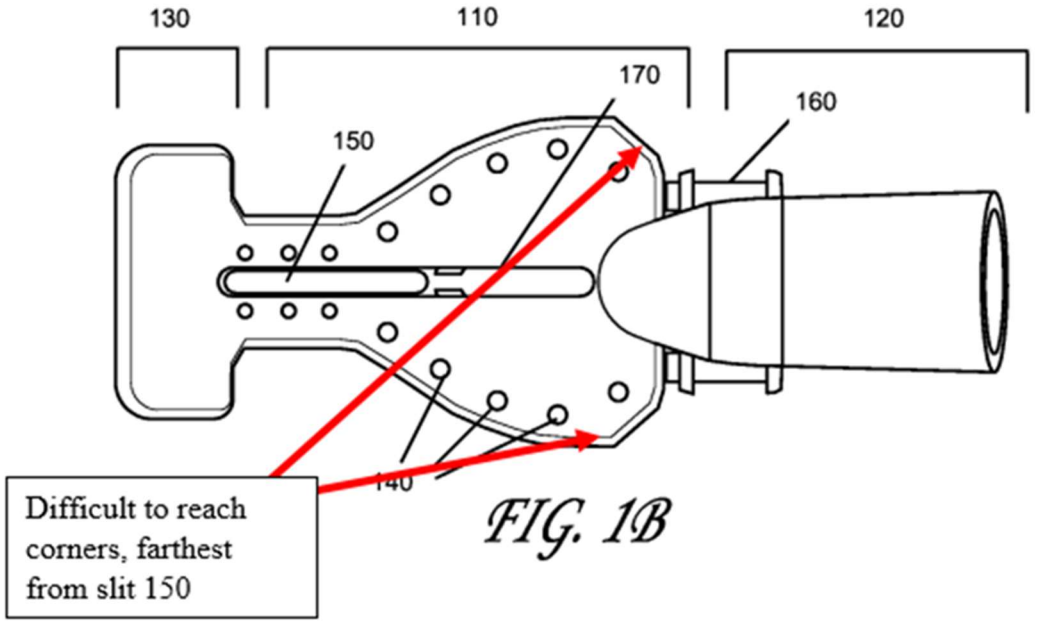


FIG. 1B

139. A POSA would know that opening the sidewalls of the mouthpiece of Nguyen would make the mouthpiece much easier to clean because a cleaning brush could be inserted through the open side of the mouthpiece to remove any bacteria or other debris. Inserting a cleaning brush through the open sides would be much easier than trying to fold the anterior wall of Nguyen at the slit 170 to insert the brush through the slit and try to get the brush into all of the internal corners of Nguyen's mouthpiece. EX1005, 4:34-37, FIG. 1B. Open sides eliminates any hard-to-reach corners. In fact, most prior art dental mouthpieces had open sides for at least this reason. EX1006, FIG. 2; EX1007, FIG. 23C, EX1017, FIG 4, EX1018, FIG. 1, EX1019, FIG. 3. Therefore, a POSA would be further motivated to open

the sides of Nguyen in view of Hirsch to make the mouthpiece easier to clean for reuse.

140. However, due to Nguyen's structure, a POSA would have been motivated to form open-sided, anti-collapse structure along the edges of Nguyen's mouthpiece in view of Hirsch. 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. EX1006, 4:43-5:8. This is because Hirsch lacks anti-collapse structure at the edges of the mouthpiece. *Id.* Thus, a POSA would know that simply removing the sidewalls of Nguyen in view of Hirsch would cause the anterior and/or posterior walls to collapse under suction near the edges of the mouthpiece, thereby blocking suction through the perforations 140 that are formed at the edges of the mouthpiece, elements that are critical to removing fluid from the patient's mouth. EX1005, 3:63-67; EX1006, 4:43-5:8. Additionally, without anti-collapse structure at the edges, Nguyen would not be able to apply suction through the superior and inferior side, which Nguyen prioritizes. EX1005, 3:63-4:3; EX1006, 4:43-67.

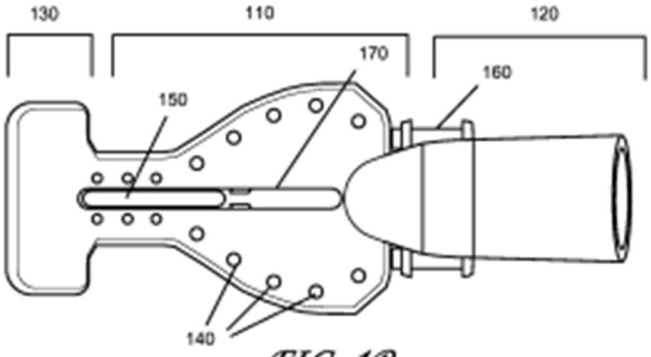


FIG. 1B

This would happen because the edges of the mouthpiece are too far from the bridge structure 180, such that the bridge structure's anti-collapse function would not extend to the edges of the mouthpiece. EX1005, FIG. 1B.

141. Knowing that a mouthpiece lacking anti-collapse structure formed at the edges would cause an undesirable seal in view of the teachings of Hirsch (EX1006, 4:43-5:8), a POSA would recognize 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.

142. 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.

143. Alternatively, 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, and the anti-collapse structure would still need some way to allow suction at the edges of the mouthpiece, which is one of Nguyen's goals. EX1005, 3:63-4:3. A POSA looking at Hirsch would see that Hirsch discloses a wall with V-shaped grooves 416 formed on the edge of the wall, and a POSA 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. EX1006: FIG. 8, 4:67-5:8. Modifying Nguyen in view of Hirsch would be a simple substitution of one known element (a sidewall connected to two walls) for another element (a wall having V-shaped grooves for suction formed at the edges of a wall) to obtain predictable results (a mouthpiece having a sidewall connected to only one of the walls and having V-shaped groves at the edge of the span of the sidewall). See annotated EX1005, FIG. 1A and 1D.

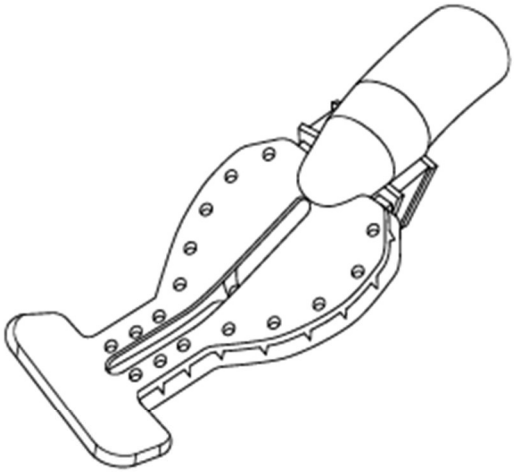


FIG. 1A

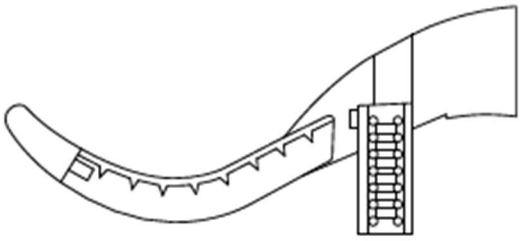


FIG. 1D

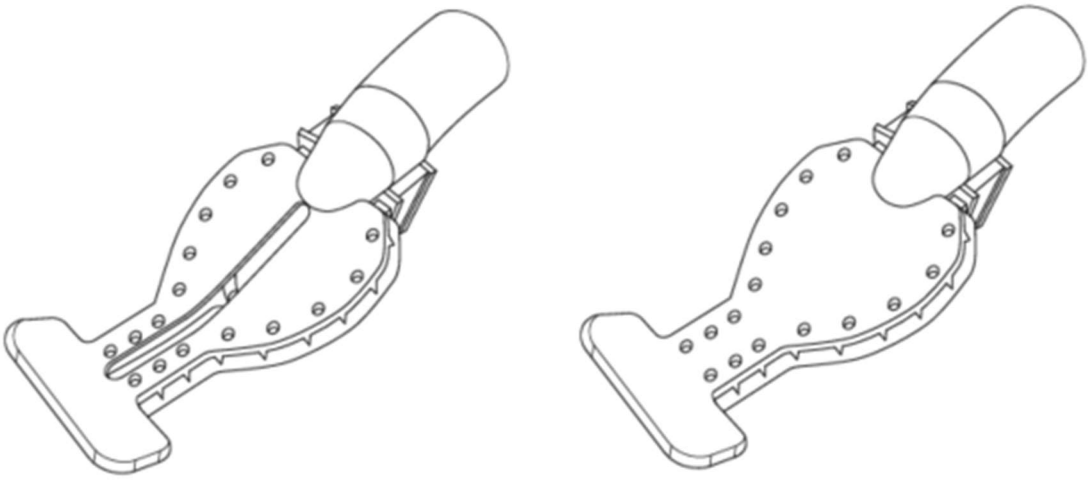
144. A POSA would expect success in modifying Nguyen as proposed above in view of Hirsch because doing so would accomplish all of the above stated goals (better suction, easier cleaning). First, Hirsch discloses that the V-shaped grooves 416 aid in suction. EX1006, 3:51-55, 4:4-16. Therefore, Nguyen as modified by Hirsch would allow for suction at the sides of the mouthpiece. EX1005, 3:63-4:3. Second, open sides on the mouthpiece would remove corners and crevices where debris and germs can build up, thereby making it easier to clean. Third, the wall with V-shaped grooves would act as projecting members (i.e.

anti-collapse structure) at the edges of the mouthpiece, which would assist in preventing collapse under suction.

145. Patent Owner may argue that a POSA would not be motivated to replace a sidewall with the wall with the V-shaped grooves 416 of Hirsch because Hirsch discloses that the V-shaped grooves 416 are located on a posterior flap. However, this argument would greatly diminish the level of common sense of a POSA. As I already described, a POSA would be motivated to keep at least anti-collapse member at the edges to prevent the edges of the mouthpiece. EX1006, 4:43-67; EX1005, 3:63-4:3. This is something Nguyen already formed in the middle of the mouthpiece in the bridge structure 180, and it would be obvious to duplicate a bridge structure at the edges. EX1005, 4:38-56. A POSA would also know that the edge anti-collapse structure must have some sort of inlet to allow fluid/debris through. EX1006, 3:51-55, 4:4-16. It would be immediately obvious to a POSA that the grooves (U- or V-shaped) 416 of Hirsch, which Hirsch describes as fluid inlets, would function the same on any wall.

146. While I understand that the slit 170 is not a required feature of claim 1, I would like to note that if the sidewalls of Nguyen were opened, then the slit 170 would no longer be necessary. A POSA would know that removing the slit 170 could prevent the anterior wall from filling the troughs of the bridge structure 180 as discussed above. Nguyen also discusses that the slit 170 may help provide

suction so a POSA may decide to leave the slit 170 to aid in suction. Therefore, a POSA would know that the slit 170 could be removed in view of the open sidewalls or the slit 170 could stay.



147. For all the reasons I discussed above, a POSA would be motivated to modify the mouthpiece of Nguyen in view of Hirsch to cut open the sidewalls.

e. **Limitation 17(e): "and 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"**

148. As shown below in annotated FIGS. 1A and 1D, Nguyen modified by Hirsch results in an intervening wall extending partially across the distance between the anterior wall and the posterior wall. The modified sidewall in view of Hirsch creates an edge having alternating crests and troughs that extend different distances across the span due to the V-shaped grooves 416 taught by Hirsch. EX1006, 3:51-55, 4:4-16; EX1005, FIGS. 1A and 1D (annotated).

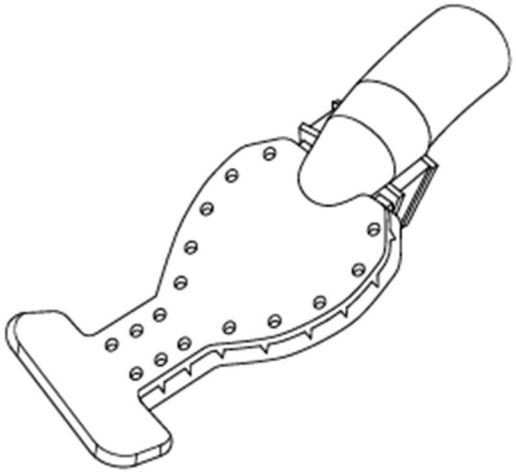


FIG. 1A

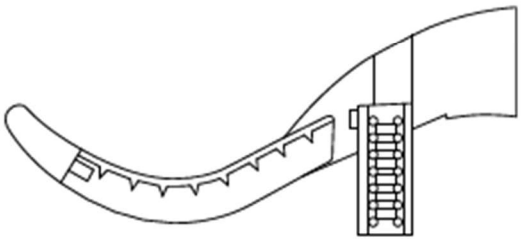


FIG. 1D

f. **Limitation 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;"**

149. As discussed above in paragraph 114, Nguyen fully teaches this limitation.

g. **Limitation 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"**

150. As discussed above in paragraph 92, Nguyen fully teaches this limitation.

h. **Limitation 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."**

151. As discussed above in paragraph 93, Nguyen fully teaches this limitation.

2. **Claim 18: "18. The mouthpiece of claim 17, wherein the at least one intervening wall includes a plurality of portions of varying heights relative to a longitudinal axis of the mouthpiece."**

152. The sidewall of Nguyen as modified by Hirsch would include a plurality of portions of varying heights relative to the longitudinal axis of the mouthpiece. The groove portions would have a different height at the bottom of the V-shape than the height of the groove portions at other parts of the V-shape.

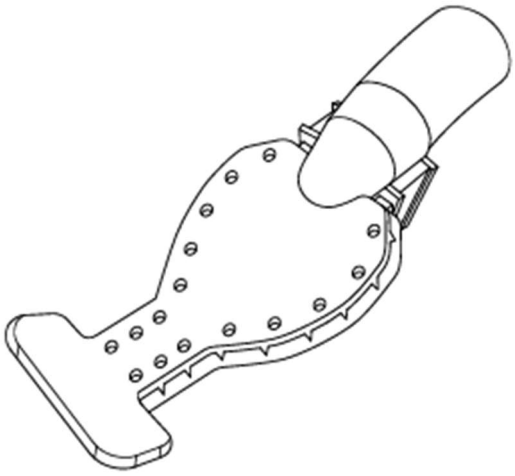


FIG. 1A

3. **Claim 19: "19. The mouthpiece of claim 17, further comprising a bite block integrated to the suction connector portion, wherein the bite block provides crush-resistance during biting by a patient."**

153. As discussed above in paragraph 124, Nguyen in view of Hirsch fully teaches this limitation.

4. **Claim 20: "20. The mouthpiece of claim 17, wherein the main body portion, the suction connector portion, and the cheek retractor portion are formed by injection-molding as one piece."**

154. As discussed above in paragraph 102, Nguyen fully teaches this limitation.

5. **Claim 21: "21. The mouthpiece of claim 17, wherein the suction connector portion comprises a cutout corresponding to a protrusion on a vacuum adapter to provide an interlocking fit."**

155. As discussed above in paragraph 105, Nguyen fully teaches this limitation.

6. **Claim 22: "22. The mouthpiece of claim 17, where in the suction connector portion connects to the vacuum suction source, wherein activation of the vacuum suction source provides suction of fluids from the interior space of the main body portion."**

156. As discussed above in paragraph 106, Nguyen fully teaches this limitation.

7. **Claim 23: "23. The mouthpiece of claim 22, wherein the activation of the vacuum suction source further draws fluids from an exterior of the main body portion into the interior space of the main body portion."**

157. As discussed above in paragraph 107, Nguyen fully teaches this limitation.

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IX. CONCLUSION

158. For these reasons, it is my opinion that claims 1–11 and 13–23 of the '217 Patent are unpatentable.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 5th day of June, 2025.

Dr. Brian P. Black.