

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ASCENTCARE DENTAL PRODUCTS, INC.  
*Petitioner*

v.

SOLMETEX, LLC  
*Patent Owner*

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

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Post-grant Review No. PGR2025-00058

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**DECLARATION OF DR. BRIAN P. BLACK IN SUPPORT OF  
PETITIONER'S PETITION FOR POST-GRANT REVIEW OF  
U.S. PATENT NO. 12,167,948**

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I, Dr. Brian P. Black, offer this declaration in support of the Petition for Post-grant Review of U.S. Patent No. 12,167,948 (“the ’948 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 that became U.S. Patent No. 8,029,280, years before Patent Owner filed a provisional application related to the ’948 Patent. It is my understanding that one of my patents is being used as part of a ground to demonstrate invalidity of the ’948 Patent.

2. I have read the ’948 Patent, and I am aware of Patent Owner’s dental isolation mouthpieces sold under the name “Dryshield” through my dental practice. I recognized one of the Dryshield products as an open-sided mouthpiece. I also recognized that Patent Owner previously sold a mouthpiece almost identical to the mouthpiece disclosed in the ’948 Patent, except that the older mouthpiece had sidewalls that fully enclose a central chamber of the mouthpiece. My patent (US 8,029,280) is directed to an open-sided mouthpiece. Through private experimentation before filing my patent application, I found that an open-sided

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mouthpiece performed better with better suction properties than a closed-sided mouthpiece. The claims of the '948 Patent recite a 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 obviousness, lack of written description support, and indefiniteness 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

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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

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U.S. patents (U.S. 8,029,280 and 8,292,620) 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

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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.

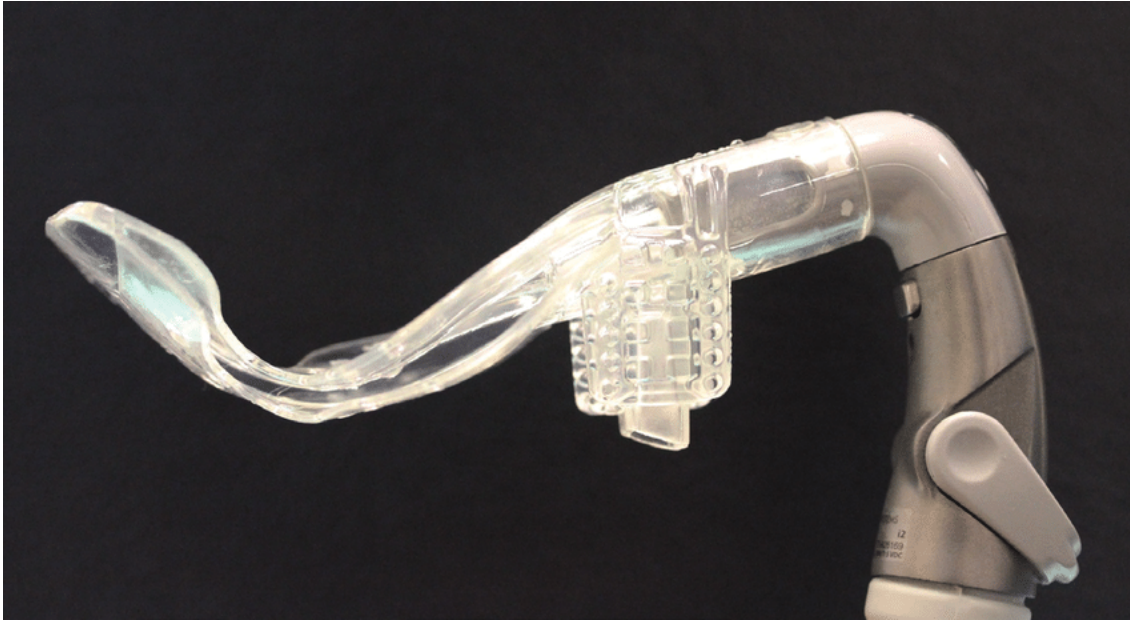


The second component was an adapter that connected to a High-Volume Evacuation (HVE) hose. The second component was specially designed to house

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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, rather than one larger diameter suction channel, resulting 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").

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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.

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17. So, in 2007, I started to develop an affordable, 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, such as EX1014 and EX1021 directed to the Isolite mouthpiece. 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 post-grant review of the ’948 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 ’948 Patent. I was also asked to opine on the validity of claims 1-31 (the “Challenged Claims”) of the ’948 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

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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:

<b>Ex #</b>	<b><u>Exhibit</u></b>
1001	U.S. Patent No. 12,167,948 (“the ’948 Patent”)
1002	Prosecution History of the ’948 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”)
1013	U.S. Patent No. 4,024,642
1014	U.S. Patent Application No. 2003/0134253
1015	Prosecution History of the ’948 Patent (part 2)
1017	Chinese Patent No. 10-4490483
1018	Korean Patent No. 10-0654392

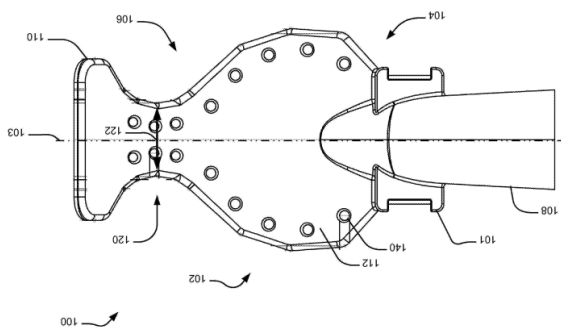
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1019	U.S. Patent Publication No. 2017/0156832
1021	U.S. Patent No. 6,974,321

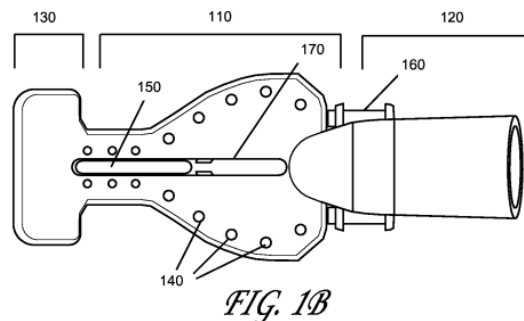
IV. **OVERVIEW OF THE PATENT AT ISSUE**

25. I have read and considered the '948 Patent, EX1001, filed on May 08, 2020, as well as its prosecution history. EX1002, EX1015. I have been told that the '948 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 '948 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 qualify as prior art based on the May 10, 2019 priority date, so it is irrelevant for my purposes whether the provisional application does or does not support all of the claim limitations of the '948 Patent.

26. It must be noted that all four mouthpieces I considered for this report (the '948 Patent, Nguyen, Hirsch, Black) have similar shapes and structure due to their function.



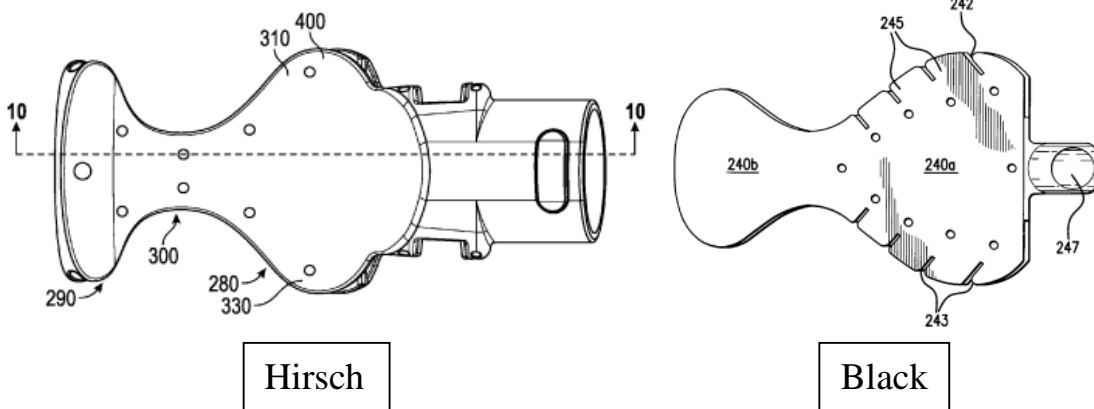
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Nguyen

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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 wall) and a posterior (back wall), and all mouthpieces are longitudinally symmetrical.

28. The '948 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 '948 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 '948 Patent and Nguyen both disclose that the main body portion has an anterior wall

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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 '948 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 '948 Patent. In contrast, Nguyen has a sidewall that connects to both of the anterior and posterior walls. EX1005, 3:37-45. Also, Nguyen has a series of circular holes while the '948 Patent uses crests and troughs. EX1001, 6:31-64; EX1005, 3:63-4:3.

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. 37. Each of these intervening walls included alternating crests and troughs. *Id.*

31. In the only rejection issued against the application that became the '948 Patent, the Examiner cited U.S. Pub. No. 2017/0056143 against most claims. EX1002, pp. 295-304. Nguyen was also cited against a couple dependent claims reciting subject matter related to a suction connector interlocking cutout and the

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use of flexible material. EX1002, pp. 305-306. The Examiner also indicated that the cheek retractor was allowable subject matter in that Office Action. EX1002, p. 306. Patent Owner accepted this allowable subject matter by amending the claims to include it, and the claims were allowed. EX1015, pp. 15-20 and 81.

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 '948 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 and in the same field

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as the '948 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 as of 2019 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 '948 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 '948 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

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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 well known in 2019.

38. Regarding rapidity, innovations in intraoral isolation devices have occurred with a moderate frequency in the past six decades. 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.

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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 post-grant review, claim terms in an unexpired patent are to be given their plain and ordinary meaning, as

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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 most terms (unless otherwise construed or discussed as indefinite), for the purposes of post-grant 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 '948 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 '948 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 '948 Patent because it is my opinion that

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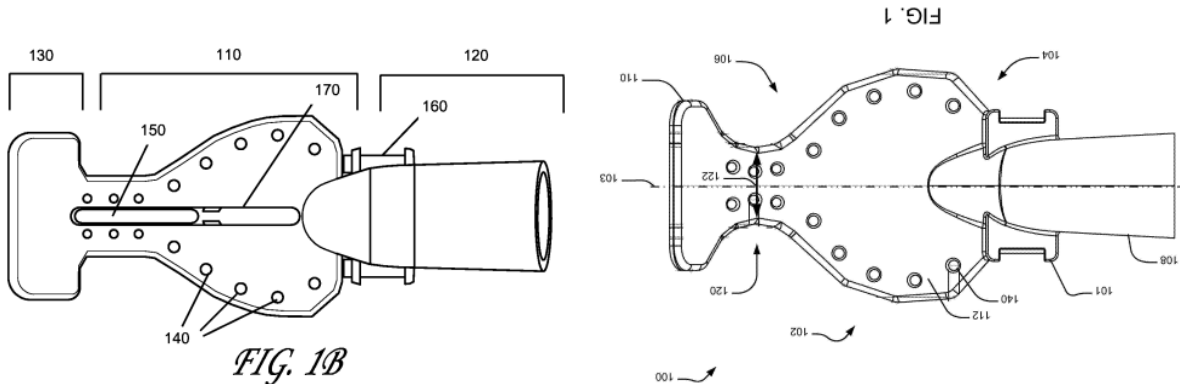
all of the claims are clearly invalid as obvious based on the prior art I have considered and my experience in the dental isolation mouthpiece field.

46. While many terms can be given their plain and ordinary meaning for the purposes of considering invalidity herein, there are some terms that are indefinite, which I explain below.

VII. **SUMMARY OF THE PRIOR ART**

A. **Nguyen**

47. Nguyen discloses a dental mouthpiece that is nearly identical to the dental mouthpiece of the '948 Patent. EX1005, FIG. 1B; EX1001, FIG. 1.



This is likely because Nguyen is an inventor of the Nguyen patent '948 Patent inventors on the '948 Patent. EX1001, (72); EX1005, (72). The dental mouthpiece in Nguyen, just like the '948 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

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and shape as one another. EX1005, 3:36-49, FIG. 1B, 1C. Nguyen teaches

sidewalls that connect to the anterior or posterior wall at the edges of the anterior

or posterior wall. EX1005, 3:36-49, FIG. 1A, 1D.

48. 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**

49. Black is one of my patents, and I invented the mouthpiece disclosed by Black. Black discloses a dental isolation mouthpiece with the same basic shape as the '948 Patent. EX1001, FIG. 1; EX1007, FIG. 23A.

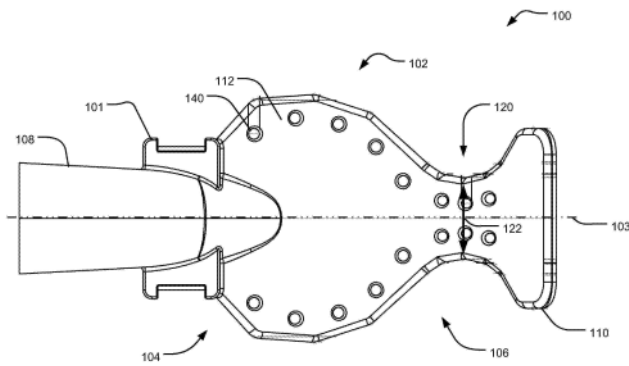


FIG. 1

'948 Patent

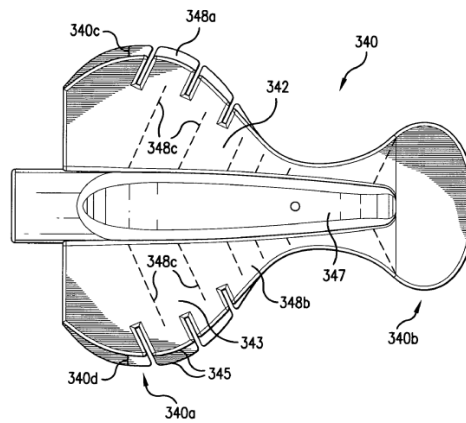


FIG. 23A

Black

As with the Isolite product first disclosed in 2001, Black discloses that the mouthpiece is open sided (with a wall formed near the suction connection tube).

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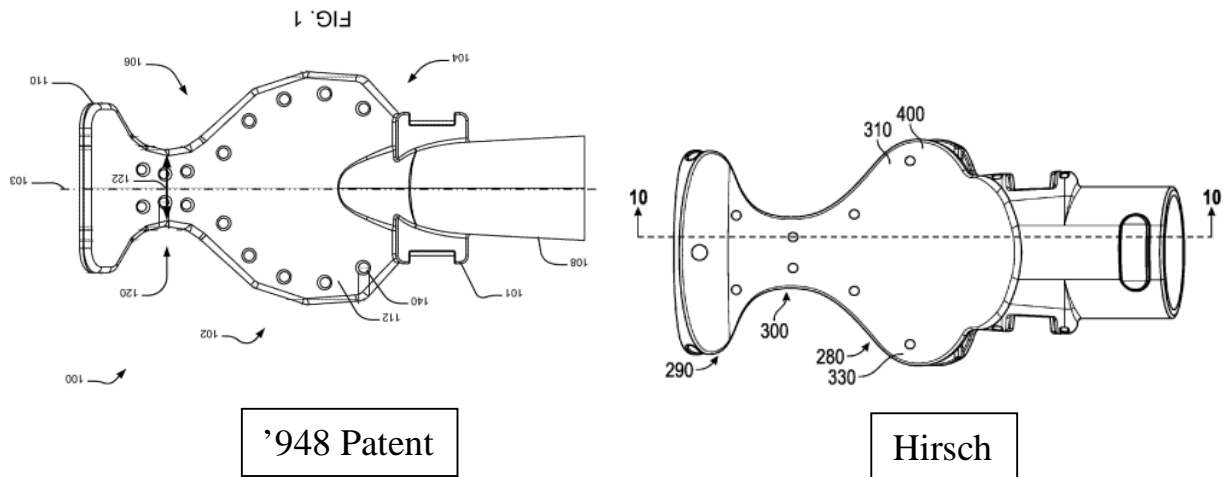
EX1007, 6:60-7:9, 14:34-15:20. Black goes on to explain that open sides

mouthpieces provide certain advantages, such as improved suction and greater

flexibility. EX1007, 17:47-54.

**C. Hirsch**

50. Hirsch discloses a dental isolation mouthpiece with the same basic shape as the '948 Patent. EX1001, FIG. 1; EX1006, FIG. 4.



As with both Isolite and Black, 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 grooves 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**

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51. 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.

52. 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).

53. 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.

54. 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.

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55. 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

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

56. 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.

57. 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.

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58. 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. Legal Principals of the Written Description Requirement**

59. I understand that 35 U.S.C. § 112, ¶ 1 requires that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....”

60. I understand that a claim satisfies the written description requirement if the specification clearly allows a POSA to recognize that the inventor invented what is claimed. In other words, the specification must reasonably convey to a POSA that the inventor had possession of the claimed invention as of its filing date. I understand that the test for written description requires an objective inquiry into the four corners of the specification from the perspective of a POSA. The written description requirement does not require disclosure of examples or an actual reduction to

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practice of the claimed invention. The specification, however, must show possession of the invention on its face, and evidence of reduction to practice outside the specification is not sufficient by itself to satisfy the written description requirement.

I understand that the level of detail required to satisfy the written description requirement depends on a number of factors such as the nature and scope of the claims, the complexity and predictability of the relevant technology, existing knowledge in the field, the extent and content of the prior art, and the maturity of the technology.

**C. Legal Principals of Indefiniteness**

61. I understand that 35 U.S.C. § 112, ¶ 2 requires that the “specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or joint inventor regards as the invention.” I understand that a patent is invalid for indefiniteness if its claim, read in light of the specification and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

62. It is my understanding that if an independent claim is found to be invalid under 35 U.S.C. § 112, its dependent claims would be invalid.

**D. Ground 1: Claims 1-14, 17-24, and 28 are obvious under 35 U.S.C. § 103 by Nguyen in view of Black.**

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63. It is my opinion that Nguyen in view of Black discloses all of the limitations of claims 1-14, 17-24, and 28.

1. **Independent Claim 1**

a. **Preamble/Limitation 1(a): “A mouthpiece comprising:”**

64. 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.

65. Even if the preamble is limiting, Nguyen discloses a mouthpiece.  
EX1005, Abstract, 6:2-3, FIG. 1A, 1D.

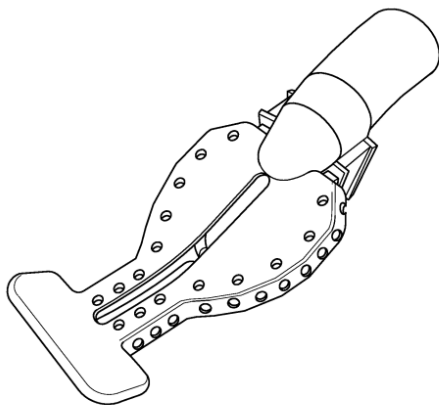
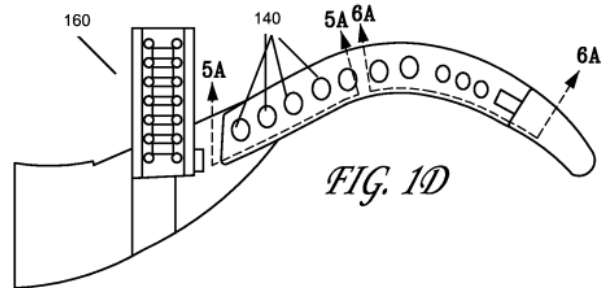


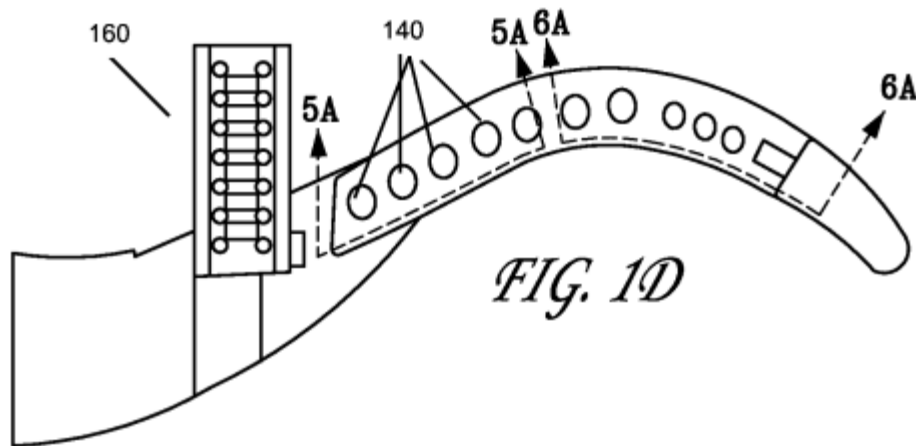
FIG. 1A



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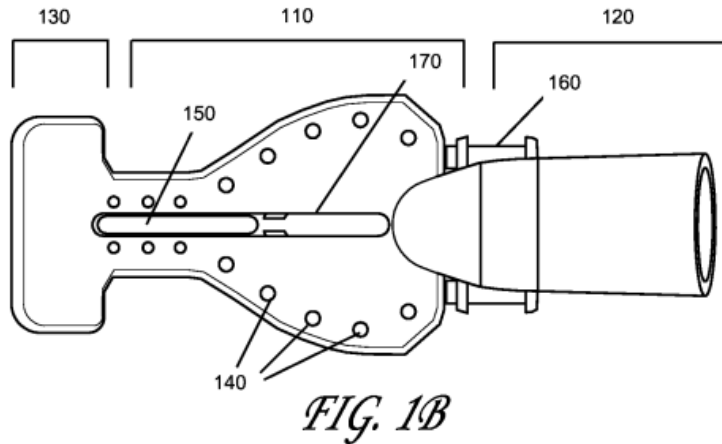
- b. **Limitation 1(b): “a main body comprising: a first wall that includes one or more edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall; and”**

66. Nguyen discloses a main body portion 110. EX1005, 6:4-6, FIG. 1D.



67. 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.

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68. Nguyen discloses an anterior wall and a posterior wall spaced apart at a distance from the anterior wall. EX1005, 3:36-54, 4:6-11, 1:58-60, FIGS. 1D-1E.

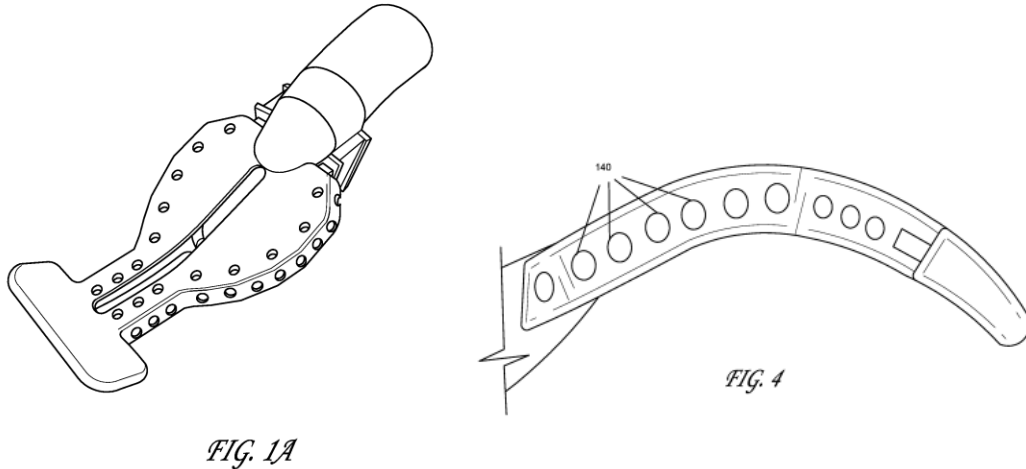
69. Nguyen discloses a “pocket” that is “at least partially enclosed” and that the pocket is an interior space, that is defined by the anterior wall and the posterior wall. EX1005, 1:58-60, 3:36-54.

- c. **Limitation 1(c): “at least one intervening wall that includes a span protruding from the one or more edges of the first wall, wherein the span is defined by a ridged edge that includes a plurality of ridges extending different distances at least partially across the distance between the first wall and the second wall;”**

70. It is my understanding that this claim limitation requires at least one intervening wall that extends 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.

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71. Nguyen discloses a superior wall and an inferior wall protruding from and extending along an edge of both the anterior and posterior walls. EX1005, 3:36-54, FIG. 1A, 3:63-4:3.



72. 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.

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

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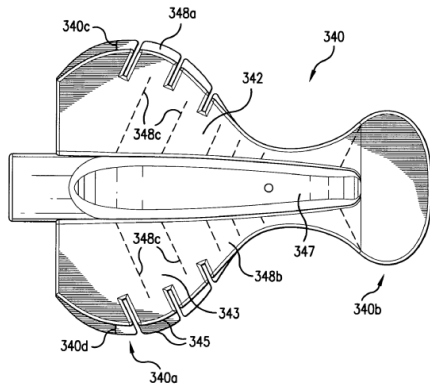


FIG. 23A

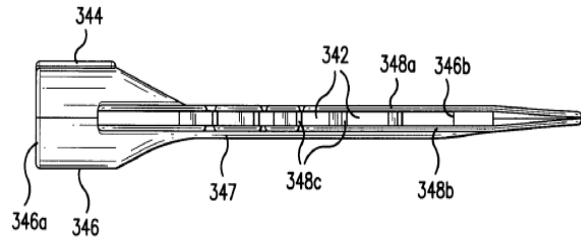


FIG. 23C

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).

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

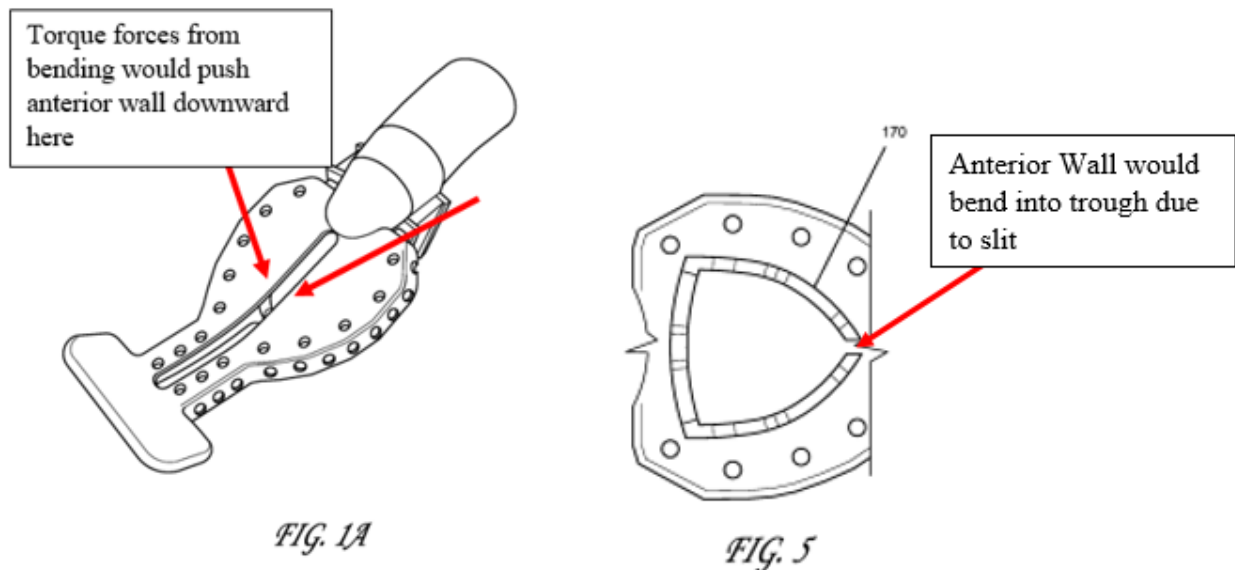
75. More specifically regarding improved suction, a POSA would know that Nguyen's dental mouthpiece would bend in a patient's mouth due to the roof of the mouth pressing down on the superior sidewall and the floor of the mouth pressing up on the inferior sidewall. EX1005, 3:29-31, 3:42-45; EX1007, 19:33-20:47. 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.

76. 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 phenomenon is known as the basic geometric constraint of bending layered materials. Thus, the

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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.*

77. 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.

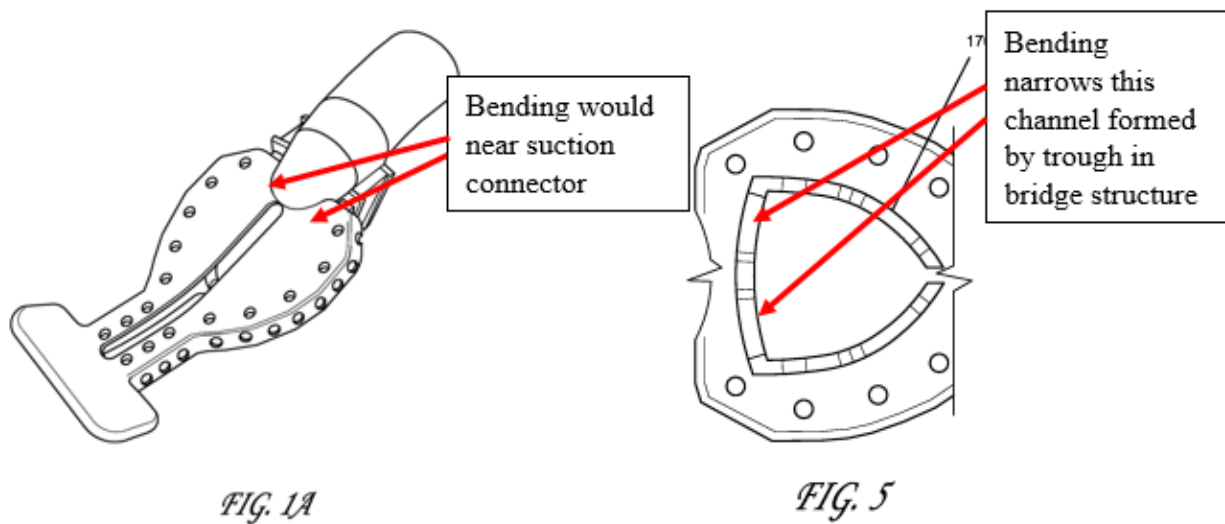


The bent anterior wall at the slit would decrease suction at the rectangular portion of the mouthpiece, an important place for suction because the dental operation occurs near the rectangular portion. EX1005, 2:10-16, 4:38-56; *see also* EX1013, 2:6-41, FIG. 2. A POSA would further recognize that the troughs of the bridge

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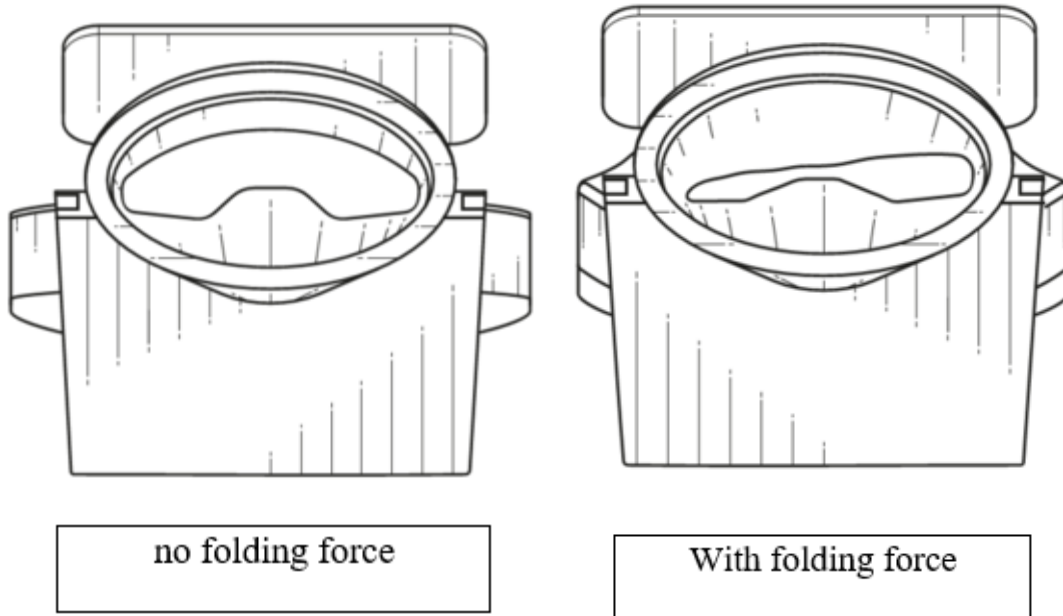
structure 180 are the locations for channel narrowing because there are no projections/crests of the bridge structure 180 providing a resistant force.

78. 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.*



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

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79. 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.

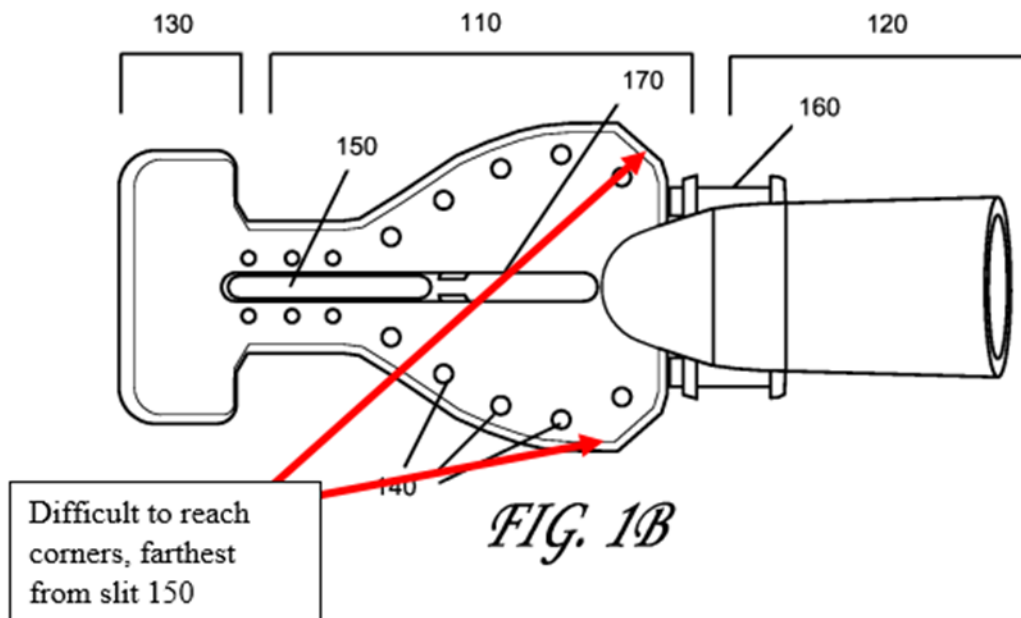
80. A POSA would also recognize that opening the sidewall of Nguyen would improve suction through the sides of the dental mouthpiece. Nguyen's mouthpiece can only provide suction through the holes 140 in the sidewall and not between the holes 140. EX1005, 3:63-4:3. In contrast, if the sidewalls of Nguyen were open, suction could occur all along the entire side. EX1007, 17:47-54.

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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.*

81. 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.



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

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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.

82. 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.

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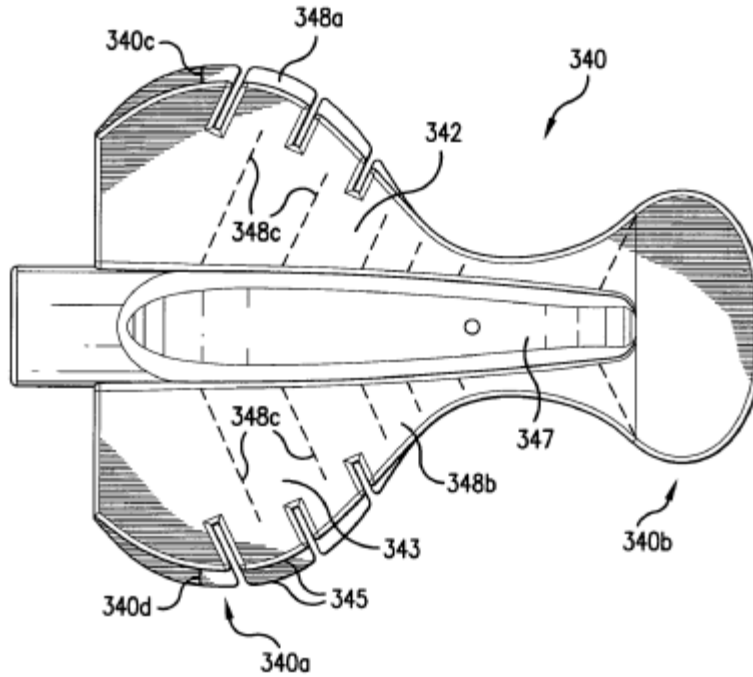
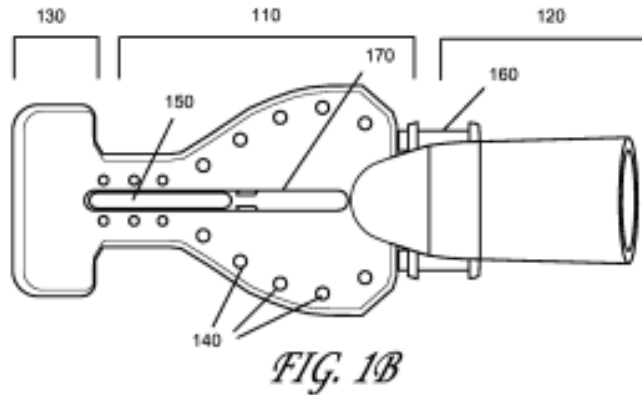


FIG. 23A

83. 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. Hirsch explains that mouthpieces without anti-collapse structure at the edges seal under suction. EX1006, 5:2-4, 4:4-6.

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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.

84. 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.

85. Essentially, an open-sided Nguyen would require a second "bridge structure" formed at the edges of the mouthpiece. The '948 Patent describes the intervening wall as having "alternating crests and troughs," which is exactly how Nguyen also describes the bridge structure 180. EX1001, 6:33-38; EX1005, 2:10-16. Thus, the intervening walls recited in the '948 Patent are essentially a second bridge structure formed at the edges of the mouthpiece. *Id.* Therefore, an

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intervening wall with alternating troughs and crests is a mere duplication of parts, which I am told is typically an obvious modification.

86. 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.

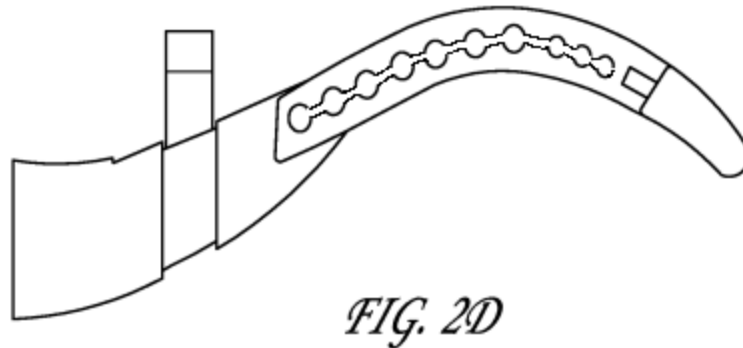
87. A POSA would recognize that the best way to cut open the sidewalls of Nguyen in view of Black is to cut the material between the perforations 140 formed in the sidewall of Nguyen. A POSA would choose to cut there for many reasons. First, cutting at the perforations requires cutting the least amount 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.

88. 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

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



89. 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.

90. 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

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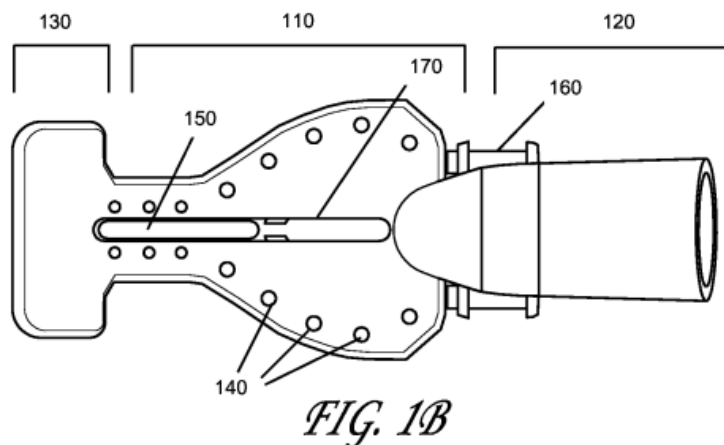
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as discussed above. Nguyen also discusses that the slit 170 may help provide suction so a POSA may decide to leave the slit 170 to aid in suction. Therefore, a POSA would know that the slit 170 could be removed in view of the open sidewalls or the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

91. 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.

- d. **Limitation 1(d): “a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and”**

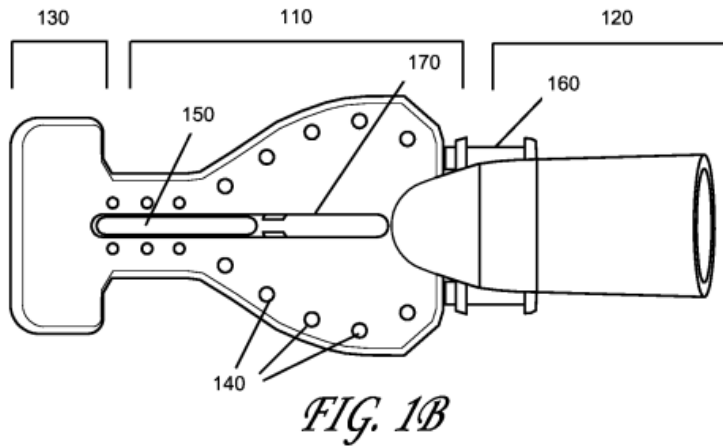
92. Nguyen discloses a suction connector portion 120 connected to the first end of the main body portion 110 that connects the interior space of the main body portion to a vacuum suction source. EX1005, 3:20-22, 4:57-63, 6:24-28.



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e. **Limitation 1(e): “a cheek retractor portion connected to the second end of the main body portion.”**

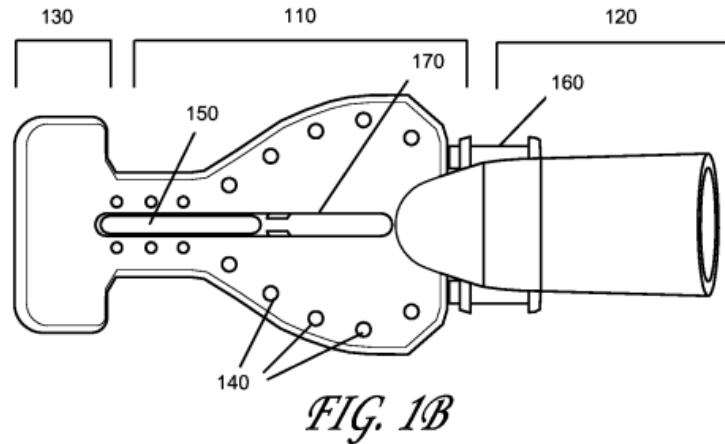
93. Nguyen discloses a cheek retractor portion 130 connected to the second end of the main body portion 110. EX1005, 3:20-22.



2. **Claim 2: “2. The mouthpiece of claim 1 wherein the main body portion further includes a neck that extends from the second end of the main body portion, the cheek retractor portion being connected to the neck of the main body portion, and wherein a width of the cheek retractor portion is greater than a width of the neck.”**

94. 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 cheek retractor 130.

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3. **Claim 3: “3. The mouthpiece of claim 1, wherein the first wall has a shape defined by the one or more edges, and wherein the second wall has a shape corresponding to the shape of the first wall.”**

95. Nguyen discloses that the anterior wall and posterior wall are identical in size and shape, thereby corresponding in shape. EX1005, 3:36-54, 3:67-4:1, FIG. 1A-1E. Also, the anterior and posterior walls are both defined by numerous edges in the polygonal shape of the illustrated, main body portion. *Id.*

4. **Claim 4: “4. The mouthpiece of claim 1, wherein the first wall has a shape that is different from a shape of the second wall.”**

96. As explained above in paragraph 95, Nguyen’s anterior wall is identical to the posterior wall in shape. *Id.* However, Black teaches an anterior wall having a smaller shape and size than a posterior wall. EX1007, FIG. 25A, 17:32-39. Black teaches that varying the sizes of the walls can result in enhanced fluid and debris aspiration from the patient’s cavity. EX1007, 17:66-18:7. Thus, after

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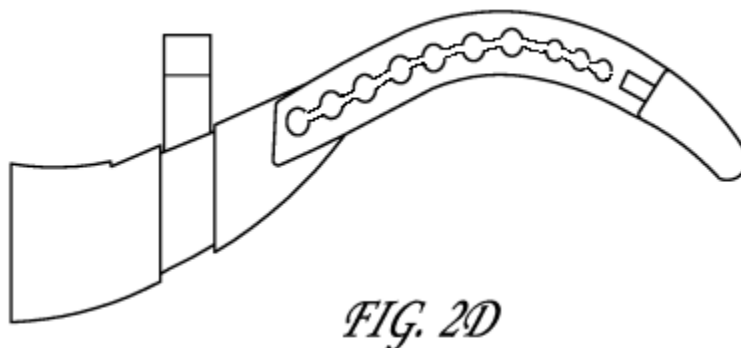
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modifying Nguyen in view of Black to open the sidewalls, a POSA would have been further motivated to change the shape of the anterior wall in view of Black to enhance fluid and debris aspiration from the patient's cavity.

97. Regardless of the above, I am informed by counsel that mere changes in shape are considered obvious design changes. So, claim 4 is obvious for multiple reasons.

5. **Claim 5: "5. The mouthpiece of claim 1, wherein the plurality of ridges includes alternating crests and troughs."**

98. 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. EX1005, FIG. 2D (annotated).



6. **Claim 6: "6. The mouthpiece of claim 5, wherein the alternating crests include at least one flat crest."**

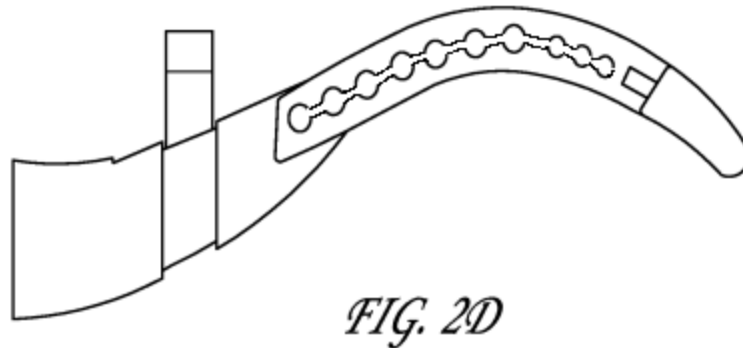
99. When the sidewall of Nguyen is cut open across the middle of the sidewall, anterior and posterior intervening walls are formed, which each have an

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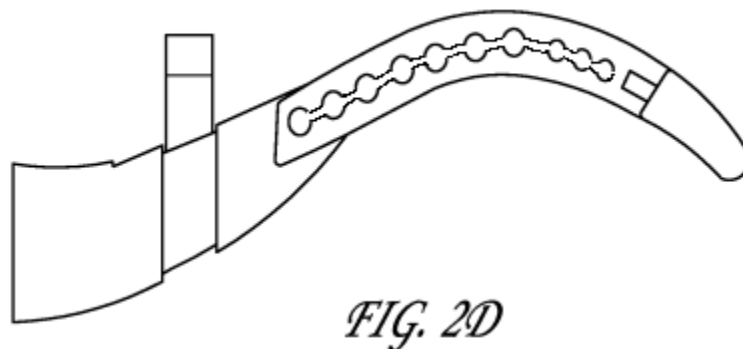
edge including alternating crests and troughs, and at least one of the crests is flat.

EX1005, FIG. 2D (annotated).



7. **Claim 7: “7. The mouthpiece of claim 5, wherein the alternating troughs include at least one semi-circular cutout trough.”**

100. 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, and at least one of the troughs is semi-circular. EX1005, FIG. 2D (annotated).



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8. **Claim 8: “8. The mouthpiece of claim 1, wherein the main body portion further includes one or more perforations in one or more of the first wall or the second wall, the perforations opening into the interior space.”**

101. Nguyen teaches perforations formed at inferior and superior sides on both the anterior wall and the posterior wall. EX1005, 3:63-67, FIG. 1B-1C. A POSA would know that these perforations are openings into the pocket.

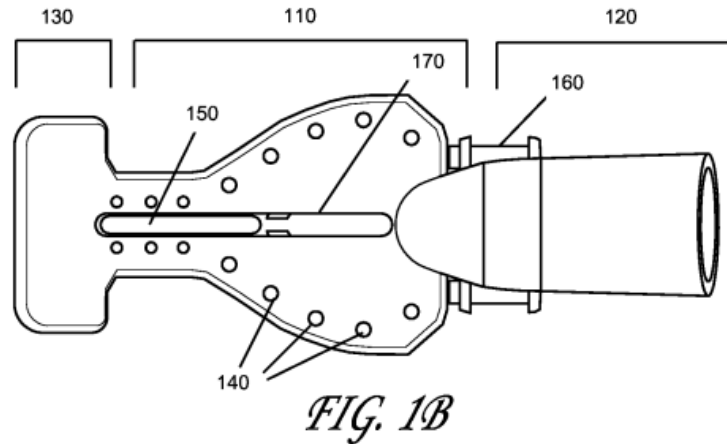
9. **Claim 9: “9. The mouthpiece of claim 8, wherein the perforations are located along a perimeter of one or more of the first wall or the second wall.”**

102. Nguyen teaches perforations formed at inferior and superior sides on both the anterior wall and the posterior wall. EX1005, 3:63-67, FIG. 1B-1C. A POSA would know that these perforations are openings into the pocket.

10. **Claim 10: “10. The mouthpiece of claim 8, wherein the main body portion further includes a neck that extends from the second end of the main body portion, and wherein the perforations are located along one or more sides of the neck.”**

103. Nguyen teaches a neck. See paragraph 94. As shown in FIG. 1B, some of the perforations 140 are formed on the rectangular portion of the main body near the stability bar 150.

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11. **Claim 11:** “11. The mouthpiece of claim 1, further comprising a bite block attached to an outside of the suction connector portion at the first end of the main body portion, wherein the bite block does not obstruct the opening into the interior space.”

104. Nguyen discloses a mouth prop 160 connected to the suction connector portion 120 (by using the strap 310). EX1005, 5:9-27, 4:65-5:2. Nguyen teaches that the strap wraps around the outside of the suction connector in a notch region. A POSA would understand that since the strap of the bite block wraps around the outside of the suction connector, the bite block would not obstruct any suction opening.

12. **Claim 12:** “12. The mouthpiece of claim 1, wherein the suction connector portion comprises a cutout in a shape corresponding to a shape of a protrusion of a vacuum adapter, the cutout configured to interlock with the protrusion of the vacuum adapter.”

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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.

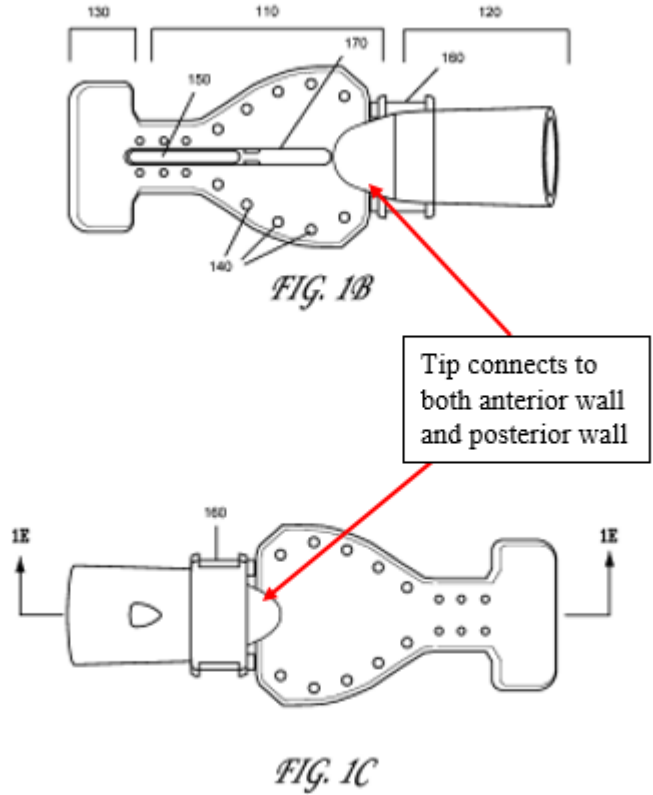
13. **Claim 13: “13. The mouthpiece of claim 1, wherein the suction connector portion includes an internal stop configured to assist with sliding an adapter to a predetermined depth.”**

106. Nguyen discloses that the suction connector 120 includes an internal stop exactly as claimed. EX1005, 4:63-65.

14. **Claim 14: “14. The mouthpiece of claim 1, further comprising at least one connector that connects the first wall to the second wall.”**

107. 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.

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15. **Claim 17: “17. The mouthpiece of claim 1, wherein the main body portion is formed of a flexible material that allows for the first wall to be pulled away from the second wall.”**

108. Nguyen discloses a mouthpiece formed of a flexible, translucent, high-heat resistant, autoclavable, silicone-based material. EX1005, Abstract. After opening the sidewalls in view of Black, a POSA would understand that the anterior wall could be pulled away from the posterior wall due to the anterior wall’s flexibility.

16. **Claim 18: “18. The mouthpiece of claim 1, wherein the main body portion is formed of a material that includes silicone, and wherein the material is at least translucent.”**

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

17. **Claim 19: “19. The mouthpiece of claim 1, further comprising a bridge structure that includes one or more protrusions protruding from an interior surface of one of the first wall or the second wall within the interior space.”**

110. Nguyen discloses a bridge structure 180 that is identical to the bridge structure in the ‘948 Patent. EX1005, 4:38-56.

18. **Independent Claim 20**

- a. **Preamble/Limitation 20(a): “A mouthpiece comprising:”**

111. As discussed above in paragraphs 64–65, Nguyen fully teaches this limitation.

- b. **Limitation 20(b): “a main body portion comprising: a first wall that includes two edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall;”**

112. As discussed above in paragraphs 66–69, Nguyen fully teaches this limitation.

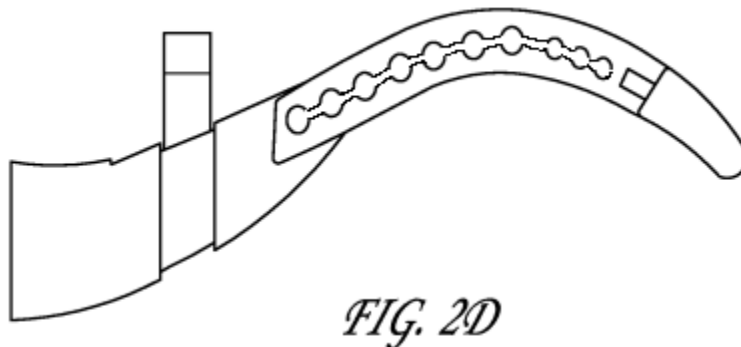
- c. **Limitation 20(c): “a first wall that includes one or more edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall; and”**

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113. As discussed above in paragraphs 70-91, Nguyen in view of Black fully teaches this limitation.

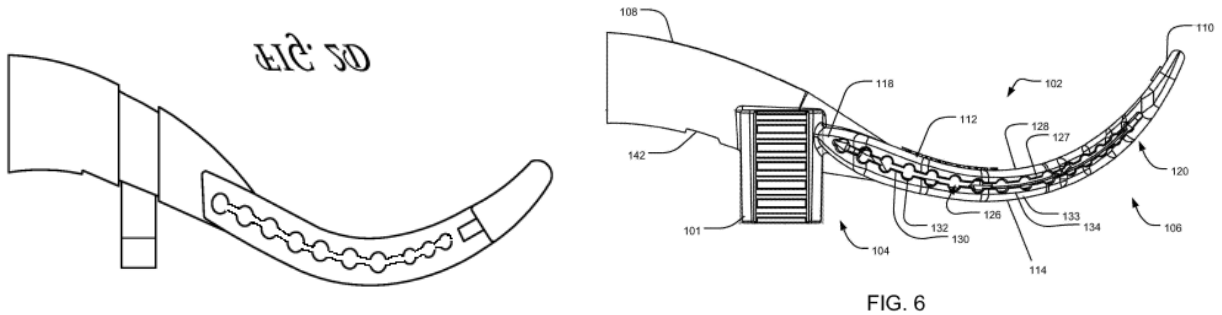
- d. **Limitation 20(d): “the two edges of the first wall being unconnected to the second wall, the plurality of ridges forming an open-meshed configuration between the first and second walls to allow for suction of fluids from a patient's mouth into the interior space between the first and second walls; and”**

114. After modifying Nguyen with Black to cut open the sidewalls, each of the two intervening walls formed from the cut would no longer be connected to each other. EX1005, FIG. 2D (annotated). Also, while the intervening walls are connected on the two ends after modification, that is the same as shown in the '948 Patent. The '948 specification does not support a completely separated first wall and second wall, so the result of Nguyen in view of Black results in the same thing shown and described by the specification of the '948 Patent, rendering the claim taught by the prior art.



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115. While I do not fully understand the term “open-meshed” (as discussed in further detail below), I will note that the '948 Patent describes the aligned ridges of FIG. 6 as an “open mesh”. EX1001, 6:50-64. Nguyen in view of Black looks very similar to FIG. 6.



116. So, the result of cutting open Nguyen’s sides apparently results in an “open meshed configuration.”

- e. **Limitation 20(e): “a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and”**

117. As discussed above in paragraph 92, Nguyen in view of Black fully teaches this limitation.

- f. **Limitation 20(f): “a cheek retractor portion connected to a second end of the main body portion.”**

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

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19. **Claim 21: “21. The mouthpiece of claim 20, wherein the cheek retractor portion is connected to a neck of the main body portion, wherein the neck extends from the second end of the main body portion.”**

119. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

20. **Claim 22: “22. The mouthpiece of claim 21, wherein a width of the cheek retractor portion is greater than a width of the neck.”**

120. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

21. **Independent Claim 23**

- a. **Preamble/Limitation 23(a): “A mouthpiece comprising:”**

121. As discussed above in paragraphs 64–65, Nguyen fully teaches this limitation.

- b. **Limitation 23(b): “a main body portion comprising: a first wall that includes two edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall;”**

122. As discussed above in paragraphs 66–69, Nguyen fully teaches this limitation.

- c. **Limitation 23(c): “wherein the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances**

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**partially across the distance between the first wall and the second wall,”**

123. As discussed above in paragraphs 70-91, Nguyen in view of Black fully teaches this limitation.

- d. **Limitation 23(d): “the two edges of the first wall being unconnected to the second wall, the plurality of ridges forming an open-meshed configuration between the first and second walls to allow for suction of fluids from a patient's mouth into the interior space between the first and second walls; and”**

124. As discussed above in paragraphs 114-116, Nguyen in view of Black fully teaches this limitation.

- e. **Limitation 23(e): “a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and”**

125. As discussed above in paragraph 92, Nguyen in view of Black fully teaches this limitation.

- f. **Limitation 23(f): “a neck that extends from the second end of the main body portion.”**

126. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

- 22. **Claim 24: “24. The mouthpiece of claim 23, wherein the main body portion further includes a plurality of perforations that open into the interior space, the plurality of perforations being located in the first wall and in the neck.”**

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127. As discussed above in paragraph 103, Nguyen fully teaches this limitation.

23. **Claim 28: “28. The mouthpiece of claim 23, wherein the main body portion is formed of a flexible material that allows for the first wall to be pulled away from the second wall.”**

128. As discussed above in paragraph 108, Nguyen fully teaches this limitation.

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

129. It is my opinion that Nguyen in view of Black and further in view of Hirsch discloses all of the limitations of claims 15-16, 25-27, and 29-31.

1. **Claim 15: “15. The mouthpiece of claim 14, wherein the connector includes a wall that extends within the interior space along a longitudinal axis of the main body portion.”**

130. The wall in the tip extends within the interior space along a longitudinal axis of the main body. EX1005, FIG. 1E. That said, Nguyen also discloses stability bar 150, also known as a reinforcing bar, formed in the neck. EX1005, 4:6-30. Nguyen teaches that the stability bar assists in “shaping the mouthpiece to the general intraoral shape of the patient’s mouth. EX1005, 4:28-30. However, a POSA would understand that this stability bar actually assists in providing additional resistance against a cheek and helps in retracting cheek tissue away from the teeth and working area of the dental procedure. EX1005, 3:29-35.

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Nguyen teaches that the stability bar is simply a thickened area. EX1005, 4:12-15, FIG. 6B. However, a POSA would understand that making the stability bar even thicker would further increase cheek retraction force, and the thickest you could make the stability bar would be to form it from the posterior wall all the way to the anterior wall. I understood this concept, which is why my mouthpiece includes a longitudinal stiffener, which I included to help with cheek retraction force. EX1007, 17:55-65.

131. Hirsch teaches a spine that provides rigidity for the cheek retractor. EX1006, 4:22-27, FIG. 14. The spine connects the anterior flaps to the posterior flaps. EX1006, 2:62-64, FIG. 14. Thus, it would have been obvious to replace the stability bar 150 with a spine connecting the anterior wall to the posterior wall in the rectangular portion of Nguyen to provide added rigidity in the neck and enhanced cheek retraction force. EX1005, 3:29-35. A POSA would have expected success because a POSA would know that a thickened spine would provide better cheek retraction abilities than a longitudinal stiffener or a thickened stability bar. The addition of the spine would close at least a portion of the slit 170 in Nguyen, but as explained above, the slit 170 is optional in view of the opened sides created in view of Black. See Paragraph 90.

2. **Claim 16: “16. The mouthpiece of claim 14, wherein the main body portion further includes a neck that extends from the second end of the main body portion, and wherein the**

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**connector extends through the neck at the second end of the main body portion.”**

132. As discussed above in paragraphs 130-131, Nguyen in view of Black and Hirsch teaches that the spine would replace the stability bar 150, which extends within the rectangular portion (neck) of Nguyen.

3. **Claim 25: “25. The mouthpiece of claim 23, further comprising a connector wall that connects the first wall to the second wall, the connector wall extending within the interior space along a longitudinal axis of the main body portion.”**

133. As discussed above in paragraphs 130-131, Nguyen in view of Black and Hirsch fully teaches this limitation.

4. **Claim 26: “26. The mouthpiece of claim 25, wherein the connector wall extends through the neck at the second end of the main body portion.”**

134. As discussed above in paragraph 132, Nguyen in view of Black and Hirsch fully teaches this limitation.

5. **Claim 27: “27. The mouthpiece of claim 26, wherein the main body portion is formed of a flexible material that allows for the two edges of the first wall to be pulled away from the second wall.”**

135. As discussed above in paragraph 108, Nguyen in view of Black and Hirsch fully teaches this limitation.

6. **Claim 29: “29. The mouthpiece of claim 28, further comprising a connector wall that connects the first wall to the second wall, the connector wall extending within the interior space along a longitudinal axis of the main body portion.”**

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136. As discussed above in paragraph 130-131, Nguyen in view of Black and Hirsch fully teaches this limitation.

7. **Claim 30: “30. The mouthpiece of claim 29, wherein the connector wall extends along the longitudinal axis along a portion of the main body portion.”**

137. As discussed above in paragraph 132, Nguyen in view of Black and Hirsch fully teaches this limitation.

8. **Claim 31: “31. The mouthpiece of claim 30, wherein the main body portion further includes a plurality of perforations that open into the interior space, the plurality of perforations being located in the first wall and in the neck.”**

138. As discussed above in paragraph 103, Nguyen in view of Black and Hirsch fully teaches this limitation.

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

139. It is my opinion that Nguyen in view of Hirsch discloses all of the limitations of claims 1-3 and 5-31.

1. **Independent Claim 1**

a. **Preamble/Limitation 1(a): “A mouthpiece comprising:”**

140. As discussed above in paragraphs 64–65, Nguyen fully teaches this limitation.

b. **Limitation 1(b): “a main body portion comprising: a first wall that includes one or more edges, a second wall set at a distance from the first wall, wherein the first**

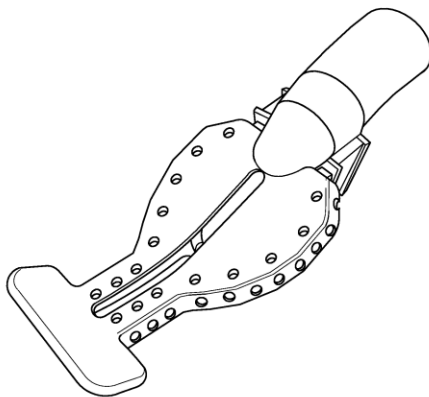
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**wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall; and”**

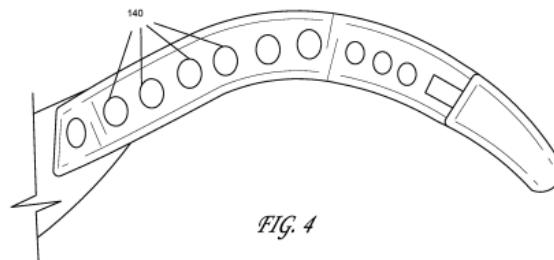
141. As discussed above in paragraphs 66–69, Nguyen fully teaches this limitation.

- c. **Limitation 1(c): “at least one intervening wall that includes a span protruding from the one or more edges of the first wall, wherein the span is defined by a ridged edge that includes a plurality of ridges extending different distances at least partially across the distance between the first wall and the second wall;”**

142. Nguyen discloses two walls (superior and inferior sidewalls) protruding from and extending along an edge of both the anterior and posterior walls. EX1005, 3:36-54, FIG. 1A, 3:63-4:3.



*FIG. 1A*



*FIG. 4*

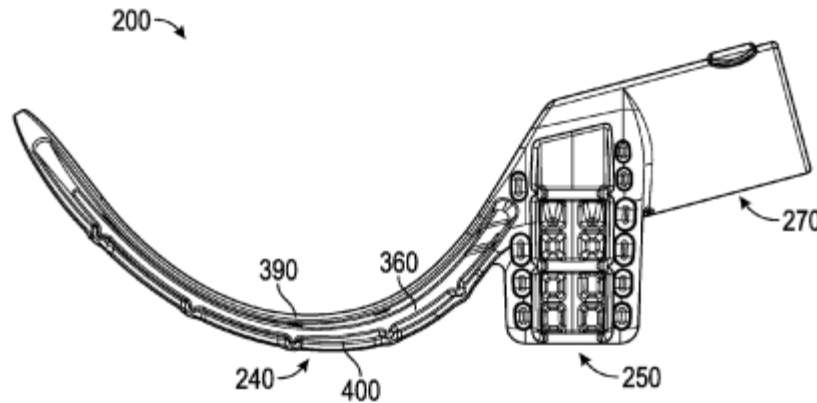
143. Nguyen teaches that the sidewalls extend across the entirety of the distance between the anterior and posterior wall and connect to both the anterior wall and the posterior wall. *Id.* Thus, the sidewalls do not extend only partially

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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.

144. 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**

145. 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.

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146. Additionally, an open-sided mouthpiece is easier to clean and offers improved suction. EX1005, 4:34-37; EX1006, 4:4-16. I discuss each of the motivations in depth below.

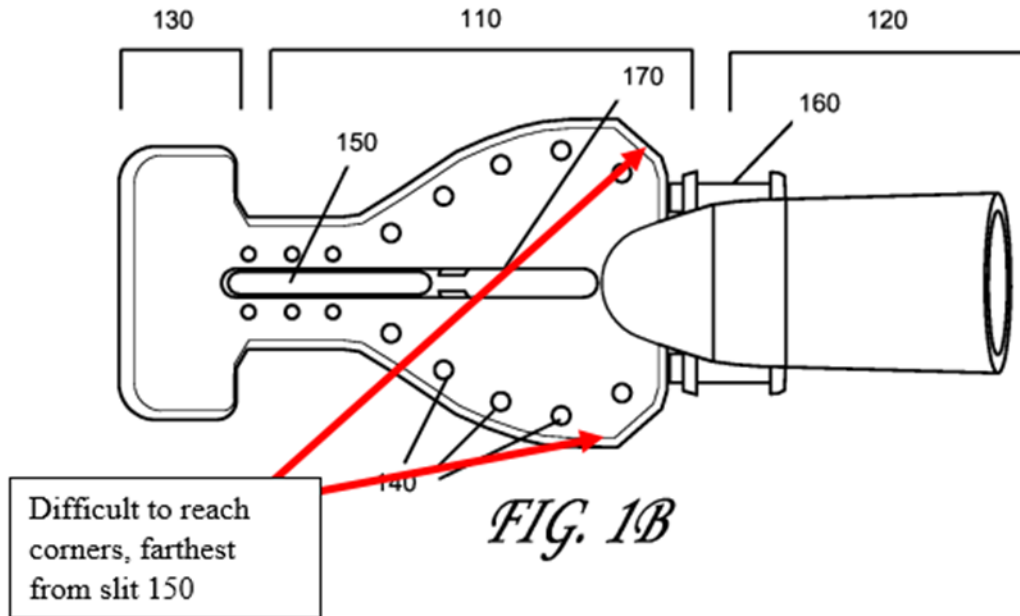
147. First, regarding improved suction, a POSA would know that Nguyen's dental mouthpiece would bend in a patient's mouth due to the roof of the mouth pressing down on the superior sidewall and the floor of the mouth pressing up on the inferior sidewall. EX1005, 3:29-31, 3:42-45; EX1006, 4:43-67. Additionally, 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. 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 75-79.

148. 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

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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.



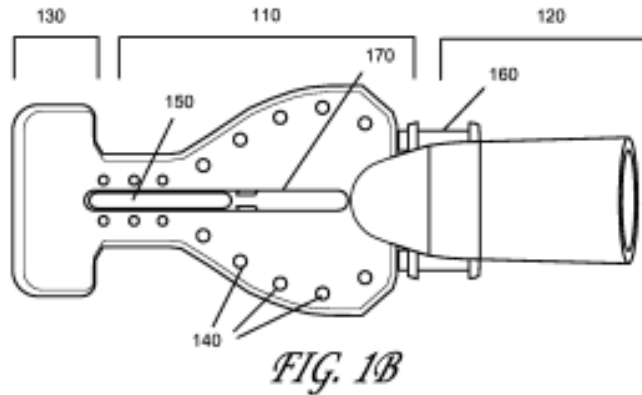
149. A POSA would know that opening the sidewalls of the mouthpiece of Nguyen would make the mouthpiece much easier to clean because a cleaning brush could be inserted through the open side of the mouthpiece to remove any bacteria or other debris. Inserting a cleaning brush through the open sides would 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,

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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.

150. 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, 4:4-6. 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.

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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.

151. 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, 4:4-6), 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.

152. Essentially, an open-sided Nguyen would require a second "bridge structure" formed at the edges of the mouthpiece. The '948 Patent describes the intervening wall as having "alternating crests and troughs," which is exactly how Nguyen also describes the bridge structure 180. EX1001, 6:33-38; EX1005, 2:10-16. Thus, the intervening walls recited in the '948 Patent are essentially a second bridge structure formed at the edges of the mouthpiece. *Id.* Therefore, an

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intervening wall with alternating troughs and crests is a mere duplication of parts, which I am told is typically an obvious modification.

153. 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 grooves at the edge of the span of the sidewall). See annotated EX1005, FIG. 1A and 1D.

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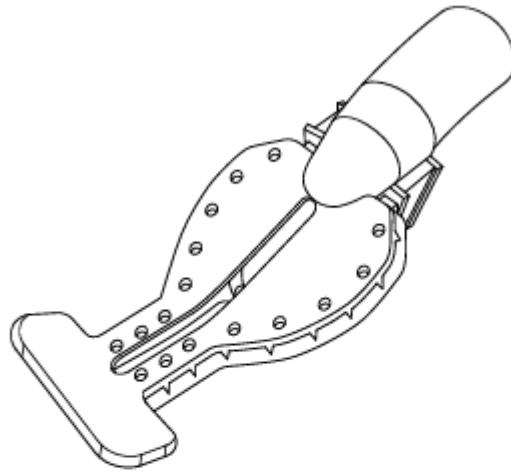


FIG. 1A

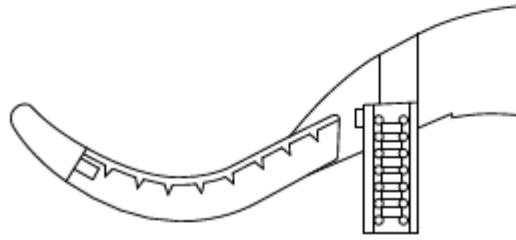


FIG. 1D

154. 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.

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

155. 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.

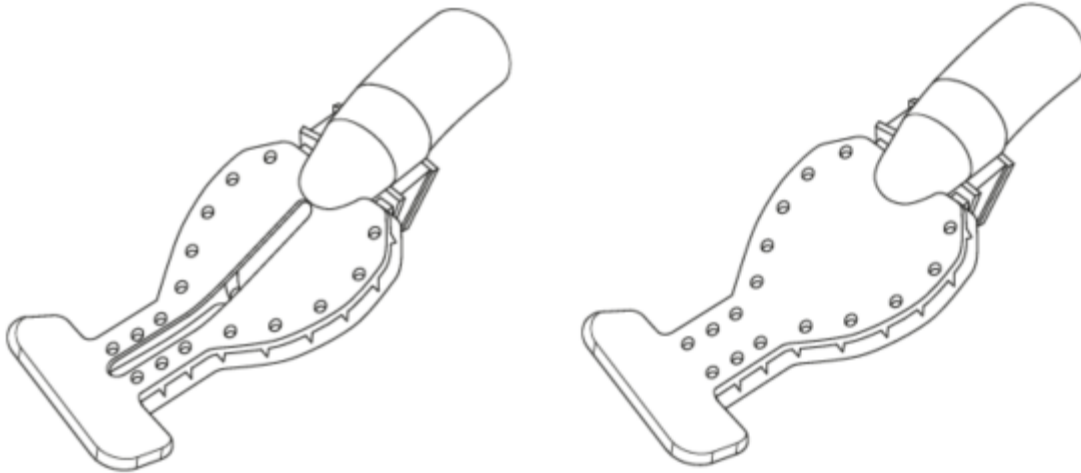
156. While I understand that the slit 170 is not a required feature of claim 1, I would like to note that if the sidewalls of Nguyen were opened, then the slit 170 would no longer be necessary. A POSA would know that removing the slit 170 could prevent the anterior wall from filling the troughs of the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

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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.



157. 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.

- d. **Limitation 1(d): “a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and”**

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

- e. **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.”**

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

2. **Claim 2: “2. The mouthpiece of claim 1 wherein the main body portion further includes a neck that extends from the second end of the main body portion, the cheek retractor portion being connected to the neck of the main body portion, and wherein a width of the cheek retractor portion is greater than a width of the neck.”**

160. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

3. **Claim 3: “3. The mouthpiece of claim 1, wherein the first wall has a shape defined by the one or more edges, and wherein the second wall has a shape corresponding to the shape of the first wall.”**

161. As discussed above in paragraph 95, Nguyen fully teaches this limitation.

4. **Claim 5: “5. The mouthpiece of claim 1, wherein the plurality of ridges includes alternating crests and troughs.”**

162. When the sidewall of Nguyen is replaced with the walls of Hirsch, an intervening wall is formed, which has an edge including alternating crests and troughs. EX1005, FIG. 2D (annotated).

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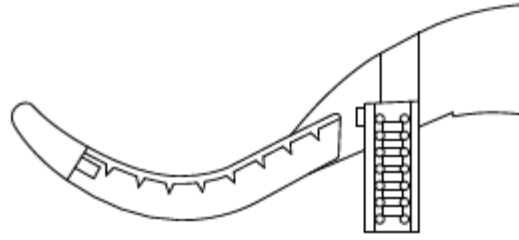


FIG. 1D

5. **Claim 6: “6. The mouthpiece of claim 5, wherein the alternating crests include at least one flat crest.”**

163. When the sidewall of Nguyen is replaced with the walls of Hirsch, an intervening wall is formed, which has an edge including alternating crests and troughs, and at least one of the crests is flat. EX1005, FIG. 2D (annotated).

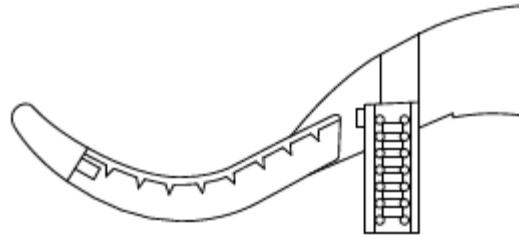


FIG. 1D

6. **Claim 7: “7. The mouthpiece of claim 5, wherein the alternating troughs include at least one semi-circular cutout trough.”**

164. When the sidewall of Nguyen is replaced with the walls of Hirsch, an intervening wall is formed, which has an edge including alternating crests and troughs, and at least one of the troughs is semi-circular. EX1005, FIG. 2D (annotated). While V-shaped grooves are illustrated, Hirsch explains that the V-

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shaped grooves may be substituted for U-shaped grooves, which would result in semi-circular grooves. EX1006, 3:56-60

7. **Claim 8: “8. The mouthpiece of claim 1, wherein the main body portion further includes one or more perforations in one or more of the first wall or the second wall, the perforations opening into the interior space.”**

165. As discussed above in paragraph 101, Nguyen fully teaches this limitation.

8. **Claim 9: “9. The mouthpiece of claim 8, wherein the perforations are located along a perimeter of one or more of the first wall or the second wall.”**

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

9. **Claim 10: “10. The mouthpiece of claim 8, wherein the main body portion further includes a neck that extends from the second end of the main body portion, and wherein the perforations are located along one or more sides of the neck.”**

167. As discussed above in paragraph 103, Nguyen fully teaches this limitation.

10. **Claim 11: “11. The mouthpiece of claim 1, further comprising a bite block attached to an outside of the suction connector portion at the first end of the main body portion, wherein the bite block does not obstruct the opening into the interior space.”**

168. As discussed above in paragraph 104, Nguyen fully teaches this limitation.

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11. **Claim 12: “12. The mouthpiece of claim 1, wherein the suction connector portion comprises a cutout in a shape corresponding to a shape of a protrusion of a vacuum adapter, the cutout configured to interlock with the protrusion of the vacuum adapter.”**

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

12. **Claim 13: “13. The mouthpiece of claim 1, wherein the suction connector portion includes an internal stop configured to assist with sliding an adapter to a predetermined depth.”**

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

13. **Claim 14: “14. The mouthpiece of claim 1, further comprising at least one connector that connects the first wall to the second wall.”**

171. As discussed above in paragraph 107 and 130-132, Nguyen fully teaches this limitation.

14. **Claim 15: “15. The mouthpiece of claim 14, wherein the connector includes a wall that extends within the interior space along a longitudinal axis of the main body portion.”**

172. As discussed above in paragraph 107 and 130-132, Nguyen fully teaches this limitation.

15. **Claim 16: “16. The mouthpiece of claim 14, wherein the main body portion further includes a neck that extends from the second end of the main body portion, and wherein the connector extends through the neck at the second end of the main body portion.”**

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173. As discussed above in paragraph 107 and 130-132, Nguyen fully teaches this limitation.

16. **Claim 17: “17. The mouthpiece of claim 1, wherein the main body portion is formed of a flexible material that allows for the first wall to be pulled away from the second wall.”**

174. As discussed above in paragraph 108, Nguyen fully teaches this limitation.

17. **Claim 18: “18. The mouthpiece of claim 1, wherein the main body portion is formed of a material that includes silicone, and wherein the material is at least translucent.”**

175. As discussed above in paragraph 109, Nguyen fully teaches this limitation.

18. **Claim 19: “19. The mouthpiece of claim 1, further comprising a bridge structure that includes one or more protrusions protruding from an interior surface of one of the first wall or the second wall within the interior space.”**

176. As discussed above in paragraph 110, Nguyen fully teaches this limitation.

19. **Independent Claim 20**

a. **Preamble/Limitation 20(a): “A mouthpiece comprising:”**

177. As discussed above in paragraphs 64–65, Nguyen fully teaches this limitation.

b. **Limitation 20(b): “a main body portion comprising: a first wall that includes two edges, a second wall set at a**

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**distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall;”**

178. As discussed above in paragraphs 66–69, Nguyen fully teaches this limitation.

- c. **Limitation 20(c): “a first wall that includes one or more edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall; and”**

179. As discussed above in paragraphs 142-157, Nguyen in view of Hirsch fully teaches this limitation.

- d. **Limitation 20(d): “the two edges of the first wall being unconnected to the second wall, the plurality of ridges forming an open-meshed configuration between the first and second walls to allow for suction of fluids from a patient's mouth into the interior space between the first and second walls; and”**

180. After modifying Nguyen with Hirsch to cut open the sidewalls, the intervening wall would not connect to the anterior wall. EX1005, FIG. 2D (annotated). Also, while the intervening walls are connected on the two ends after modification, the is the same as shown in the '948 Patent. The '948 specification does not support a completely separated first wall and second wall, so the result of Nguyen in view of Hirsch results in the essentially the same thing shown and

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described by the specification of the '948 Patent, rendering the claim taught by the prior art.

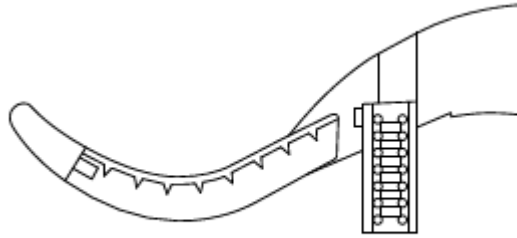


FIG. 1D

181. While I do not fully understand the term “open-meshed” (as discussed in further detail below), the claim explains that an open-meshed configuration allows “for suction of fluids from a patient's mouth into the interior space between the first and second walls”. Hirsch explains that the grooves allow for fluids to be suctioned. Thus, the grooved wall of Hirsch performs the same function as the “open-meshed configuration.” EX1006, 4:4-16.

- e. **Limitation 20(e): “a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and”**

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

- f. **Limitation 20(f): “a cheek retractor portion connected to a second end of the main body portion.”**

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

20. **Claim 21: “21. The mouthpiece of claim 20, wherein the cheek retractor portion is connected to a neck of the main body portion, wherein the neck extends from the second end of the main body portion.”**

184. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

21. **Claim 22: “22. The mouthpiece of claim 21, wherein a width of the cheek retractor portion is greater than a width of the neck.”**

185. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

22. **Independent Claim 23**

a. **Preamble/Limitation 23(a): “A mouthpiece comprising:”**

186. As discussed above in paragraphs 64–65, Nguyen fully teaches this limitation.

b. **Limitation 23(b): “a main body portion comprising: a first wall that includes two edges, a second wall set at a distance from the first wall, wherein the first wall and the second wall define an interior space that corresponds to the distance between the first wall and the second wall;”**

187. As discussed above in paragraphs 66–69, Nguyen fully teaches this limitation.

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- c. **Limitation 23(c): “wherein the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances partially across the distance between the first wall and the second wall,”**

188. As discussed above in paragraphs 142-157, Nguyen in view of Hirsch teaches this limitation.

- d. **Limitation 23(d): “the two edges of the first wall being unconnected to the second wall, the plurality of ridges forming an open-meshed configuration between the first and second walls to allow for suction of fluids from a patient's mouth into the interior space between the first and second walls; and”**

189. As discussed above in paragraphs 180-181, Nguyen in view of Hirsch fully teaches this limitation.

- e. **Limitation 23(e): “a suction connector portion extending from a first end of the main body portion, wherein the suction connector portion includes an evacuation conduit opening into the interior space of the main body portion; and”**

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

- f. **Limitation 23(f): “a neck that extends from the second end of the main body portion.”**

191. As discussed above in paragraph 94, Nguyen fully teaches this limitation.

- 23. **Claim 24: “24. The mouthpiece of claim 23, wherein the main body portion further includes a plurality of perforations that**

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**open into the interior space, the plurality of perforations being located in the first wall and in the neck.”**

192. As discussed above in paragraph 103, Nguyen fully teaches this limitation.

24. **Claim 25: “25. The mouthpiece of claim 23, further comprising a connector wall that connects the first wall to the second wall, the connector wall extending within the interior space along a longitudinal axis of the main body portion.”**

193. As discussed above in paragraphs 130-131, Nguyen in view of Hirsch fully teaches this limitation.

25. **Claim 26: “26. The mouthpiece of claim 25, wherein the connector wall extends through the neck at the second end of the main body portion.”**

194. As discussed above in paragraph 132, Nguyen in view of Hirsch fully teaches this limitation.

26. **Claim 27: “27. The mouthpiece of claim 26, wherein the main body portion is formed of a flexible material that allows for the two edges of the first wall to be pulled away from the second wall.”**

195. As discussed above in paragraph 108, Nguyen fully teaches this limitation.

27. **Claim 28: “28. The mouthpiece of claim 23, wherein the main body portion is formed of a flexible material that allows for the first wall to be pulled away from the second wall.”**

196. As discussed above in paragraph 108, Nguyen fully teaches this limitation.

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28. **Claim 29: “29. The mouthpiece of claim 28, further comprising a connector wall that connects the first wall to the second wall, the connector wall extending within the interior space along a longitudinal axis of the main body portion.”**

197. As discussed above in paragraph 130-131, Nguyen in view of Hirsch fully teaches this limitation.

29. **Claim 30: “30. The mouthpiece of claim 29, wherein the connector wall extends along the longitudinal axis along a portion of the main body portion.”**

198. As discussed above in paragraph 132, Nguyen in view of Hirsch fully teaches this limitation.

30. **Claim 31: “31. The mouthpiece of claim 30, wherein the main body portion further includes a plurality of perforations that open into the interior space, the plurality of perforations being located in the first wall and in the neck.”**

199. As discussed above in paragraph 103, Nguyen fully teaches this limitation.

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

200. It is my opinion that Nguyen in view of Black and further in view of Hirsch discloses all of the limitations of claims 15-16, 25-27, and 29-31.

1. **Claim 4: “15. The mouthpiece of claim 14, wherein the connector includes a wall that extends within the interior space along a longitudinal axis of the main body portion.”**

201. As discussed above in paragraphs 96-97, Nguyen as modified by Black fully teaches this limitation.

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

1. **No Support in the Specification for the Limitation “the two edges of the first wall being unconnected to the second wall ...”**

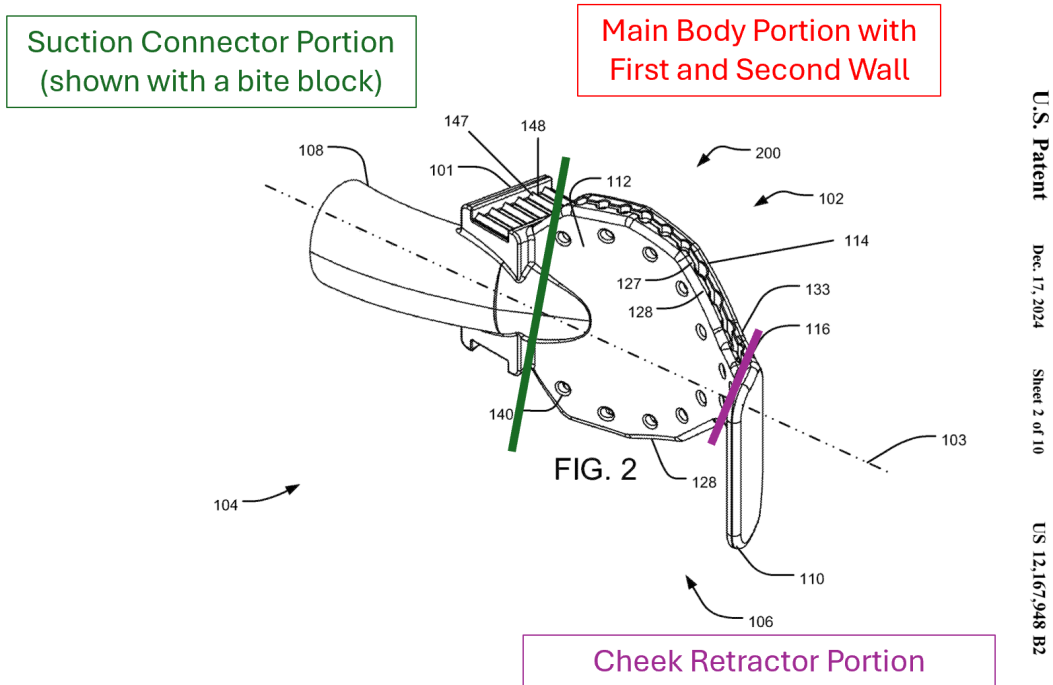
202. It is my opinion that the specification of the '948 Patent fails to provide adequate written support for Independent Claims 20 and 23 of the Patent, specifically for the two edges of a first wall being unconnected to a second wall in the main body portion of the mouthpiece.

203. The specification discloses the following regarding connections between the edges of the first wall and the edges of the second wall. EX1001, 6:65-7:7:

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

204. Figure 2 depicts an angled-side profile, described as an isometric view by the patent. Figure 2 shows the suction connector portion 108, the main body portion 102, and the cheek retractor portion 110.

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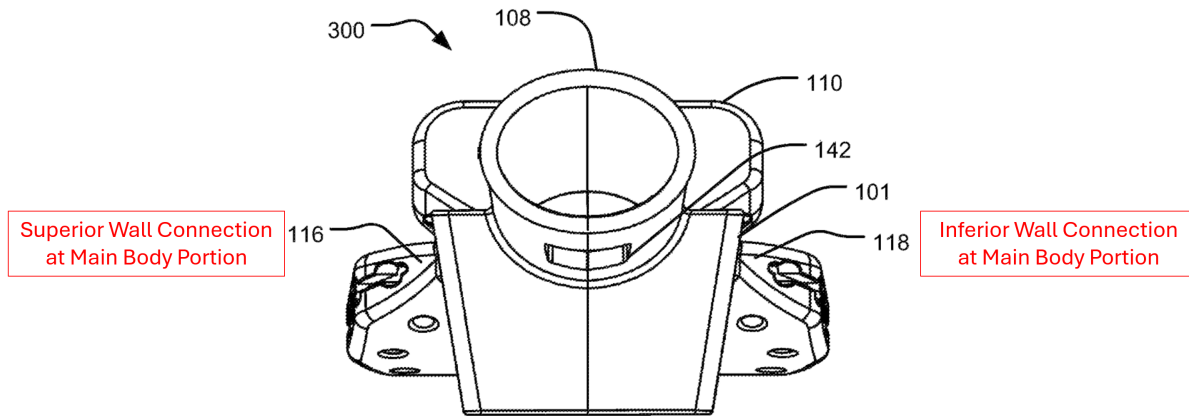
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**EX1001, Figure 2 (Modified)**

205. Independent claims 20 and 23 require that the edges of the first wall (also described as the anterior wall throughout the patent) be **unconnected** to the second wall (or posterior wall) in the main body portion depicted above. The embodiments in the patent, however, depict and teach the opposite. The patent describes connections at the superior and inferior walls, which are the walls within the main body portion and perpendicular to the first and second wall that represent the top and bottom of the device as shown in Figure 2 and more clearly in Figures 3 and 6.

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206. Figure 3 depicts a rear view of the dental mouthpiece, with connections of the edges of the first and second walls within the main body portion shown at both the superior wall and inferior walls (116 and 118 respectively).



**FIG. 3**  
**EX1001, Figure 3**

207. Figure 3 depicts the connection described in the patent as the joining of the edges of the anterior and posterior walls (first and second walls) “near the suction connector portion 108 of the main body at the first end 104.” EX1001, 6:65-7:7. Nowhere does the patent depict an embodiment where the edges of the first and second walls are unconnected in the main body portion near the suction connector portion of the main body.

208. Figure 6 depicts a side view of the mouthpiece, with the edges of the first and second wall of the mouthpiece being connected at both ends of the mouthpiece in the main body portion.



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2. **No Support in the Specification for the Limitation “wherein the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges extending different distances partially across the distance between the first wall and the second wall ...”**

211. It is my opinion that the specification of the '948 Patent fails to provide adequate written support for Independent Claims 20 and 23 of the Patent, specifically for a first wall configured at the two edges to have a ridged configuration with a plurality of ridges.

212. The specification describes walls with a ridged configuration, however, these walls are the intervening walls 127 and 134 and not the first (or second) walls 112 and 114.

The posterior wall 114 may have a corresponding at least one posterior intervening wall 134 that extends from at least one edge 133 of the posterior wall 114 and partially extends towards the anterior wall 112. The posterior intervening wall 134 may likewise exhibit ridges that are the same, a mirror image, or different from the anterior intervening wall 127. In one example, the ridges of the anterior intervening wall 127 may be aligned with the ridges of the posterior intervening wall 134, as shown in FIG. 6 . In combination, the anterior intervening wall 127 and the posterior intervening wall 134 and their respective aligned ridges may form an open mesh between the anterior wall 112 and the posterior wall 114.

EX1001, 6:45-56.

213. The specification makes it clear that the first and second walls are different structures from the first and second intervening walls. EX1001, 6:20-22 (“[a]t least one anterior intervening wall 127 may extend from at least one edge 128

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of the anterior wall 112 partially towards the posterior wall 114.”) and 6:45-46 (“[t]he posterior wall 114 may have a corresponding at least one posterior intervening wall 134”).

214. This difference between a ridged first wall and intervening walls with ridges is further made clear through independent claim 1 of the '948 Patent, claiming “at least one intervening wall that includes a span protruding from the one or more edges of the first wall, where the span is defined **by a ridged edge that includes a plurality of ridges extending different distances at least partially across the distance between the first and second wall.**”

215. Figure 6 depicts the side of the mouthpiece. Figure 6 outlines distinct walls, the anterior wall 112 and posterior wall 114 (also referred to as first and second walls) spaced from one another, at least one anterior intervening wall 127, at least one posterior intervening wall 134, and the inferior wall 118 connecting the edges of the walls in the main body portion at both ends. For clarity, the anterior (first wall) 112 and posterior wall (second wall) 114 have been shaded blue. The anterior intervening wall 127 and posterior intervening wall 134 have been shaded green. The anterior and posterior intervening walls 127 and 134, not the anterior and posterior walls themselves 112 and 114, are described to include the ridged edge with a plurality of ridges extended distances across the distance between the anterior and posterior walls 112 and 114. This is shown by the green shading of the anterior

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intervening wall 127 and posterior intervening walls 134 protruding different distances towards one another and forming a gap between said intervening walls 127 and 134.

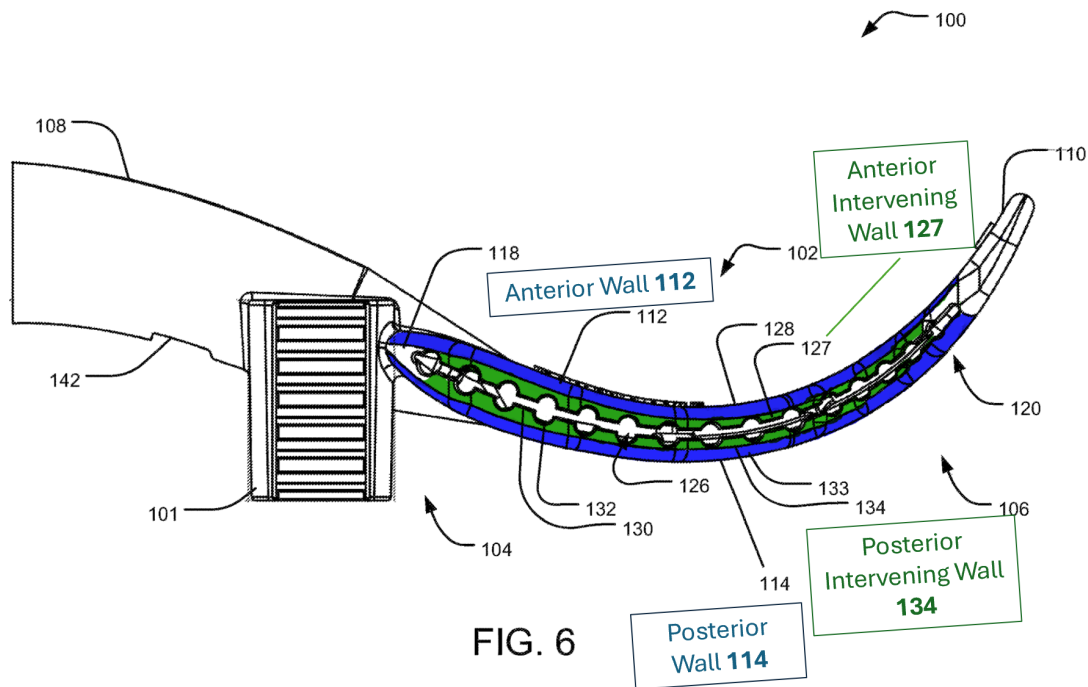


FIG. 6

**EX1001, Figure 6**

216. The patent specification fails to disclose and support a mouthpiece where the first wall is configured at the two edges to have a ridged configuration with a plurality of ridges. It is my opinion that independent claims 20 and 23, as well as their dependent claims 21-22 and 24-31, are invalid for lack of written description.

**I. Ground 6: Claims 20-31 are invalid under 35 U.S.C. § 112 for Indefiniteness**

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217. It is my opinion that the term “open-meshed configuration” in independent Claims 20 and 23 are indefinite. The specification fails to inform a POSA with reasonable certainty what is claimed by the term “open-meshed configuration”, let alone what a “mesh” or an “open mesh” is.

218. The specification describes an open mesh as what is formed between the intervening walls and allows for suction of fluids:

In one example, the ridges of the anterior intervening wall 127 may be aligned with the ridges of the posterior intervening wall 134, as shown in FIG. 6. In combination, the anterior intervening wall 127 and the posterior intervening wall 134 and their respective aligned ridges may form an open mesh between the anterior wall 112 and the posterior wall 114. Such open mesh may follow the edges 128, 133 of each of the anterior wall 112 and the posterior wall 114 from the first end 104 to the second end 106. The open mesh between the anterior intervening wall 127 and the posterior intervening wall 134 allows for suction of air, fluids, and small debris from patient's mouth, through the mesh into the interior space 126 and into the suction connector portion 108 towards a suction source.

EX1001, 6:50-64. There is no mention of an “open-meshed configuration” outside the independent claims.

219. Figure 7 is side view of the mouthpiece with an anterior wall of the mouthpiece 112 pulled away from a posterior wall of the mouthpiece 114. The “open-meshed configuration” is described as what “may” be formed between the ridges of the anterior and posterior walls. *Id.* On Figure 7, there is a series of gaps between the ridges both on the left side of the image where it is closed and also the

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series of gaps on the right side of the image where the anterior 112 and posterior wall 114 are pulled apart.

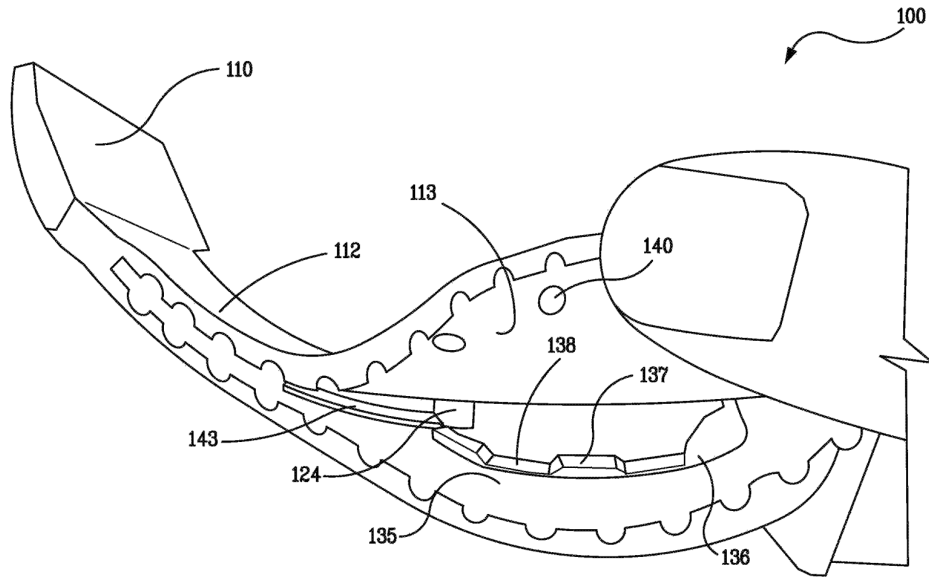


FIG. 7

**EX1001, Figure 7**

220. The terms “mesh”, “open mesh”, and “open-meshed configuration” are not specific terms of art in the field used by POSAs.

221. The plain and ordinary meaning of a “mesh” is some form of interconnected or interlaced structure. There is no such structure disclosed or depicted in the '948 Patent.

222. The plain and ordinary meaning of an “open mesh” is some form of interconnected or interlaced structure that “allows for suction of air, fluids, and small debris.” There is no such structure disclosed or depicted in the '948 Patent.

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223. The plain and ordinary meaning of an “open-meshed configuration” is a configuration that is some form of interconnected or interlaced structure that “allows for suction of air, fluids, and small debris.” There is no such structure disclosed or depicted in the ’948 Patent.

224. There is no explanation or description in the patent specification or file history regarding the meaning of the terms “mesh”, “open mesh”, or “open-mesh configuration” beyond the functional language that the structure “allows for suction of air, fluids, and small debris”. There are no interconnected elements, interlaced elements or crosshatch style patterns depicted in the embodiments of the patent that would commonly be understood to be a type of mesh. There is no “mesh” formed, “open mesh” formed, or “open-mesh configuration” depicted in the embodiments of the patent.

225. Instead, the patent depicts a series of disconnected gaps along the edge of the walls of the mouthpiece. *See* EX1001, Figures 2, 3, 6, 10, 11.

226. It is unclear to a POSA what the patentee claims as an “open-meshed configuration” and what constitutes a “mesh”, “open mesh”, or “open-meshed configuration” from a series of disconnected gaps.

227. The scope of these claims is therefore unclear, rendering independent claims 20 and 23, along with dependent claims 21-22, 24-31, invalid for indefiniteness.

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228. If the claim term “open-meshed” configuration is found to be not indefinite, then for the purposes of my prior art invalidity analysis, I will treat a mouthpiece with a series of gaps along the edges of the anterior and posterior walls to be an “open-meshed configuration”.

**J. Ground 7: Claim 18 is invalid under 35 U.S.C. § 112 for Indefiniteness**

229. It is my opinion that the term “at least translucent” in dependent claim 18 is indefinite. The specification fails to inform a POSA, with reasonable specificity, what the scope of the claim is.

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

231. The plain and ordinary meaning of translucent to a POSA is something that lets some but not all light pass. The specification fails to describe the purpose

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of the translucent property of the mouthpiece. It is unclear whether the desired embodiment is translucent to allow easier cleaning, to detect fluids during operation, to allow the dental practitioner to see through the mouthpiece, to block enough light to not distract the vision of the dental practitioner, to block light to further isolate the portion of the mouth being worked on, or some other reason.

232. The ability of light to pass through an object ranges from opaque (no light), to translucent (some light) to transparent (all light). When the claim requires the mouthpiece to be “at least translucent” it is unclear to a POSA whether that is claiming a mouthpiece that is translucent to opaque or a mouthpiece that is translucent to transparent.

233. The scope of the term is therefore unclear. It is my opinion that dependent claim 18 is invalid for indefiniteness.

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IX. CONCLUSION

234. For these reasons, it is my opinion that claims 1–31 of the '948 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 19<sup>th</sup> day of June, 2025.



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Dr. Brian P. Black.

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