

Patent No. 12,290,418
Petition for *Inter Partes* Review

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ASCENTCARE DENTAL PRODUCTS, INC.
Petitioner

v.

SOLMETEX, LLC
Patent Owner

Patent No. 12,290,418
Issue Date: June 18, 2024
Title: INTRAORAL DEVICE

Inter Partes Review No. IPR2025-01175

**DECLARATION OF DR. BRIAN P. BLACK IN SUPPORT OF
PETITIONER'S PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 12,290,418**

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I, Dr. Brian P. Black, offer this declaration in support of the Petition for *Inter Partes* Review of U.S. Patent No. 12,290,418 (“the ’418 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 ’418 Patent. It is my understanding that one of my patents is being used as part of a ground to demonstrate invalidity of the ’418 Patent.

2. I have read the ’418 Patent, and I am aware of Patent Owner’s dental isolation mouthpiece sold under the name “Dryshield” through my dental practice. I recognize the Dryshield autoclavable product as a mouthpiece lacking a central spine and having sidewalls that fully enclose a central chamber of the mouthpiece. My patent is directed to an open-sided tongue shield aspirator. EX1005, 22:18. Through private experimentation, I found that an open-sided mouthpiece demonstrated improved performance with better suction properties than a closed-

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sided mouthpiece, like the mouthpiece disclosed by the '418 Patent and the Dryshield autoclavable product.

3. I have been informed that Patent Owner now asserts that its patent covers open-sided mouthpieces and mouthpieces that include a central spine. In particular, Patent Owner asserts that at least some claims are not limited to mouthpieces having sidewalls connecting an anterior wall and a posterior wall to enclose an interior chamber of the mouthpiece. EX1011. It is my understanding that Patent Owner has even asserted that a “third wall”, as claimed in claim 1, could be met by a bite block. EX1011, p. 7. These new, much broader, constructions recite mouthpiece structure that I, and others, disclosed long before December 2012, when Patent Owner filed its provisional application. Moreover, these new, much broader, constructions contradict statements made to the Examiner during prosecution explaining the claimed apparatus. EX2022.

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

II. **BACKGROUND AND QUALIFICATIONS**

A. **Education and Work Experience**

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

6. 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.

7. 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

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dental clinic, which is one of several departments in the tribe's community health center.

8. 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

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

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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.

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

11. 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.

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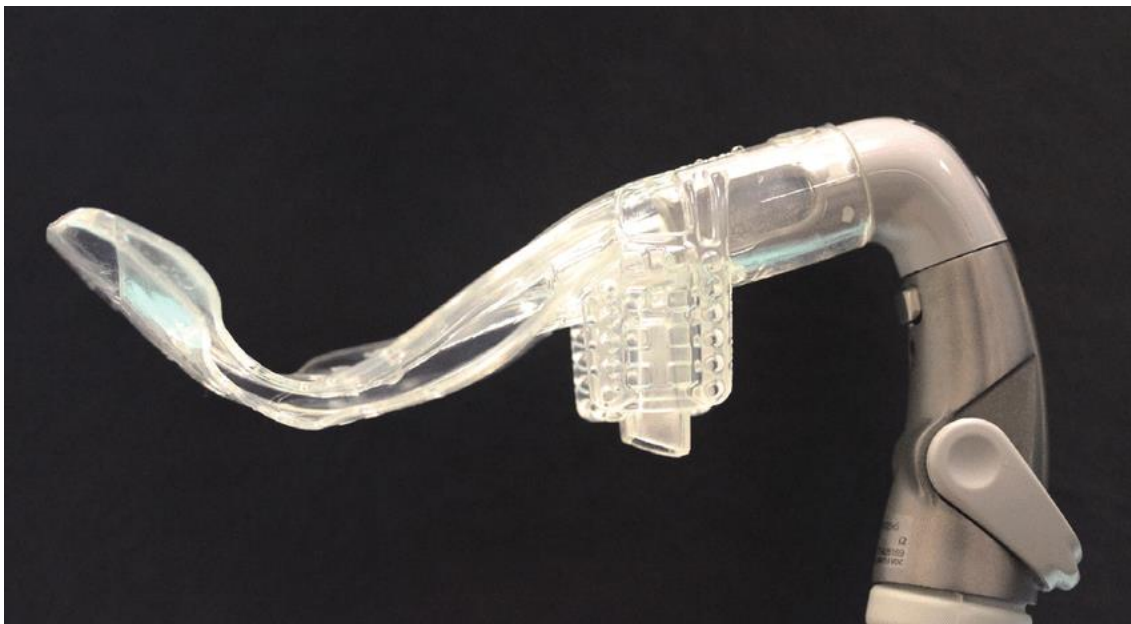
EX1003

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



12. 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.

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Differently, the Isolite HVE adapter terminated with two smaller diameter suction channels, rather than one larger diameter suction channel, resulting in decreased suction.

13. 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”).

14. 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.

15. 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.

16. 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.

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17. 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.

18. 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”.

19. I have been retained as an independent expert consultant by Ascentcare Dental Products, Inc. (“Petitioner”) in connection with a petition for *inter partes* review of the ’418 Patent (EX1001).

20. Specifically, I was asked to investigate and opine on the technology claimed in, and the patentability or unpatentability of certain claims of the ’418 Patent. I was also asked to opine on the validity of claims 1-25 and 27-30 (the “Challenged Claims”) of the ’418 Patent.

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21. 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.

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

23. 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.

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

III. **MATERIALS CONSIDERED**

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

Ex #	<u>Exhibit</u>
1001	U.S. Patent No. 12,290,418 (“the ’418 Patent”)
1002	Prosecution History of the ’418 Patent (part 1)

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1005	U.S. Patent No. 8,029,280 to Black (“Black”)
1006	Korean Patent No. 10-1082826 (“Park”)
1007	U.S. Patent No. 3,101,543 (“Baughan”)
1008	U.S. Patent No. 4,017,975 (“Johnson”)
1011	Solmetex Infringement Contentions
1012	U.S. Patent Application No. 2003/0134253 (“Hirsch”)
1013	Korean Patent No. 10-0654392
1014	U.S. Patent No. 8,911,232
1015	Prosecution History of U.S. Patent No. 8,911,232
1016	U.S. Patent No. 4,024,642
1017	U.S. Patent No. 1,731,322
1018	U.S. Patent No. 6,575,746
1019	U.S. Patent No. 9,532,858
1021	Chinese Patent Application Publication No. 200420094338.X (“Zheng”)
1022	Prosecution History Excerpt from U.S. Patent No. 11,589,969

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

26. I have read and considered the ’418 Patent, EX1001, filed on June 30, 2023, as well as its prosecution history. EX1002. I am told that the ’418 Patent is a continuation of U.S. Patent No. 8,911,232, and I have also considered the prosecution history of U.S. Patent No. 8,911,232 because I have been told that statements made in a related patent proceeding can impact the scope of other patents in the same patent family. EX1015. I have been told that the ’418 Patent has a priority date of December 7, 2012 for some claim features. It is my

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understanding that the provisional patent application may not support all claim limitations in the '418 Patent, but for the purposes of my review, this date was irrelevant because all the prior art I studied was published over a year before December 7, 2012.

27. It must be noted that all four mouthpieces I considered for this report (the '418 Patent, Hirsch, Park, Black) have similar shapes and structure due to their function.

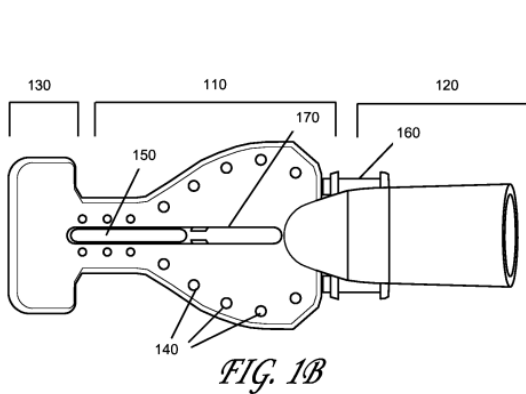
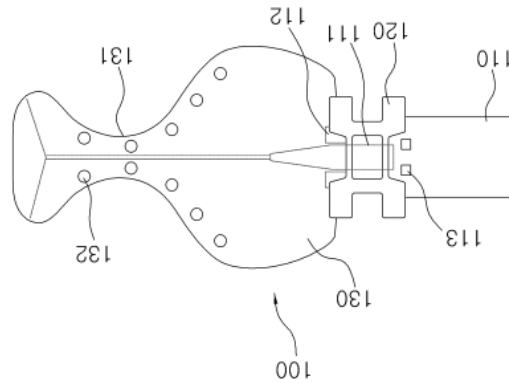


FIG. 18B

'418 Patent



Park

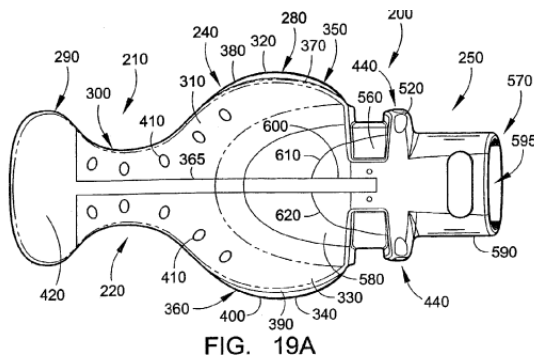
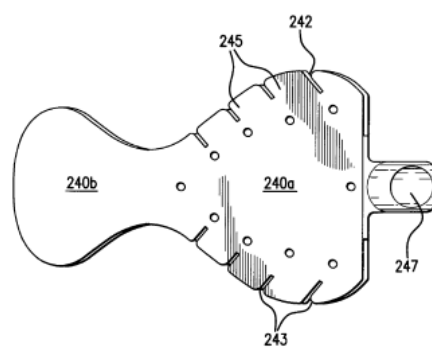


FIG. 19A
Hirsch



Black

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All four mouthpieces have a main larger body portion that blocks the tongue, then a narrower connecting portion that ends in a smaller cheek retractor end. On each mouthpiece, the larger body portion has an extension to connect to a suction hose. All of these devices have an anterior (front or first wall) and a posterior (back or second wall), and all mouthpieces are longitudinally symmetrical. Hence, none of these features of the '418 Patent are novel or unique.

28. The '418 Patent teaches a dental isolation mouthpiece with the same basic shape as my invention. My patent and the '418 Patent both teach a suction connector formed on one side of the mouthpiece, a removable 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. EX1001, FIG. 1B, 5:8-9, 5:28-39, 4:21-28, 3:16-22; EX1005, FIG. 23A, 14:1-20; 2:1-7.

29. The '418 Patent, just like my patent, discloses an anterior wall/layer and a posterior wall/layer formed parallel to each other. EX1001, 3:52-58, FIG. 1A. The '418 Patent further discloses a “bridge structure” 180, which is a plurality of projections extending upward from the posterior wall to ensure that the anterior wall remains separated from the posterior wall under suction. EX1001, 4:55-5:7. My patent includes the same basic idea, with my patent including a plurality of

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transverse walls that form channels and ensure that the anterior layer remains separated from the posterior layer. EX1005, 14:21-47

30. Indeed, the only real difference between my patent and the '418 Patent appears to be the existence of sidewalls in the '418 Patent, whereas my patent opted for open sides. EX1001, FIG. 1A, 1D; EX1005, FIG. 23C. However, at least one of the claims of the '418 Patent no longer requires sidewalls. For example, claim 1 merely requires a “third wall” formed somewhere along an edge of the “main body” (i.e., the tongue retractor part). EX1001, claim 1. Knowing that Patent Owner intends to read a third wall formed anywhere, and not limited to the sides or limited to the main body portion, my patent includes such a wall, which is formed near the suction connector. EX1011, p. 7; EX1005, e.g., FIG. 4C.

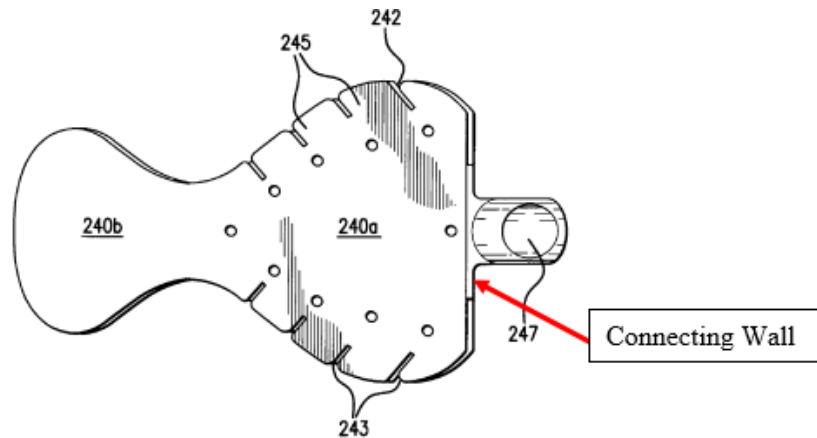


FIG.4C

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31. The '418 Patent discloses an enclosed space or “pocket”, and there exists a bridge structure 180 on the interior surface of the mouthpiece’s posterior wall. EX1001, 4:55-5:7.

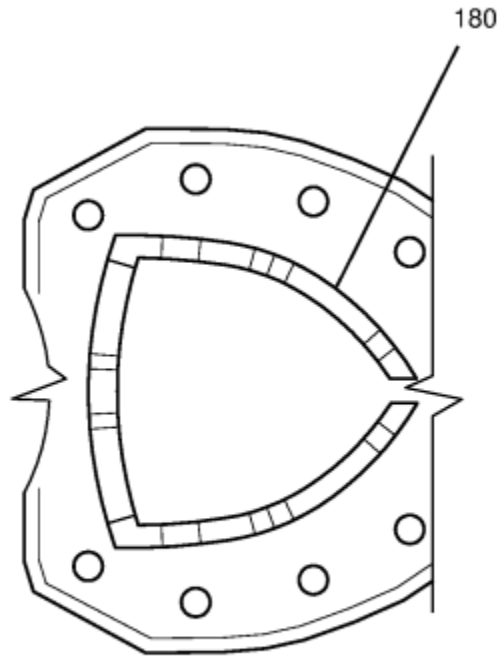
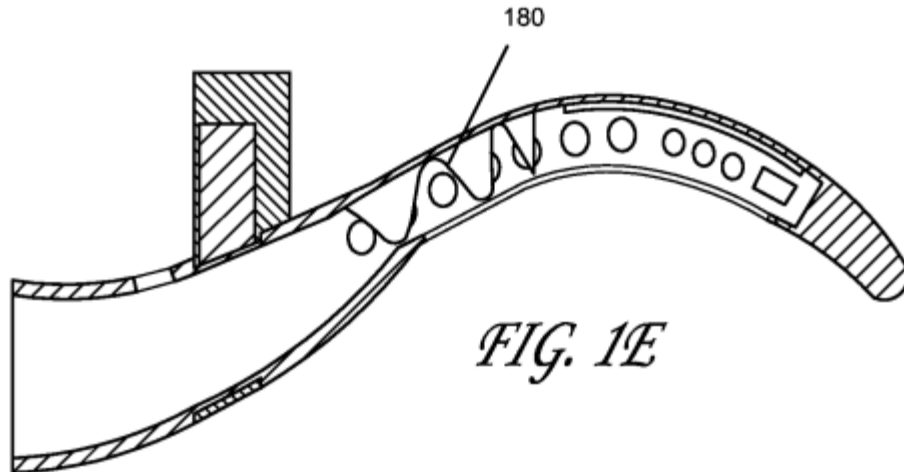


FIG. 5

The bridge 180 is, in fact, intermittent vertical extensions of the same material that comprises the interior surface of the second wall; these material extensions form the “crest” and the lack thereof forms the “trough” in this description, and the combination of crests and troughs form a “wave shape”. *Id.*

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The bridge prevents the interior of second (posterior) wall from completely collapsing into the interior (facing surface) of the opposing first (anterior) wall from suction pressure because the vertical extensions called “crests” from the interior surface of the second (posterior) wall stop the interior (facing) surface of the first (anterior) wall from collapsing upon the posterior wall, thereby blocking suction. Meanwhile, the “troughs” allow for suction pressure, and thereby fluid flow, to continue within and through mouthpiece to the connected suction hose.

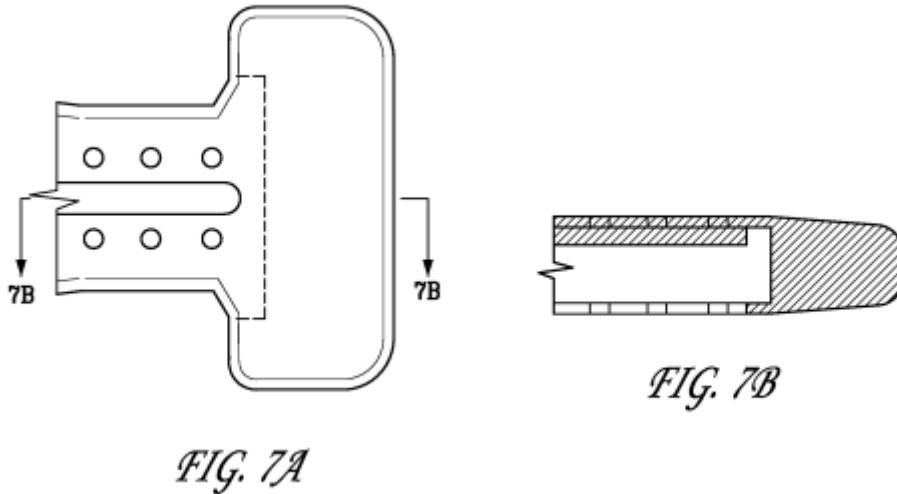
EX1001, 4:55-5:7.

32. The '418 Patent also attempts to claim features only illustrated in FIGS. 7A and 7B. Indeed, the specification does not describe FIGS. 7A and 7B in any meaningful way. EX1001, 5:22-27. Nevertheless, independent claim 9 and dependent claim 4 recite a cheek retractor having a first wall of a main body and a second wall of the main body “transitioning into and being connected in the cheek

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retractor portion to form the cheek retractor portion, wherein the first wall and the second wall are spaced apart from each other at a distance within the cheek retractor portion before being connected at the cheek retractor portion.”



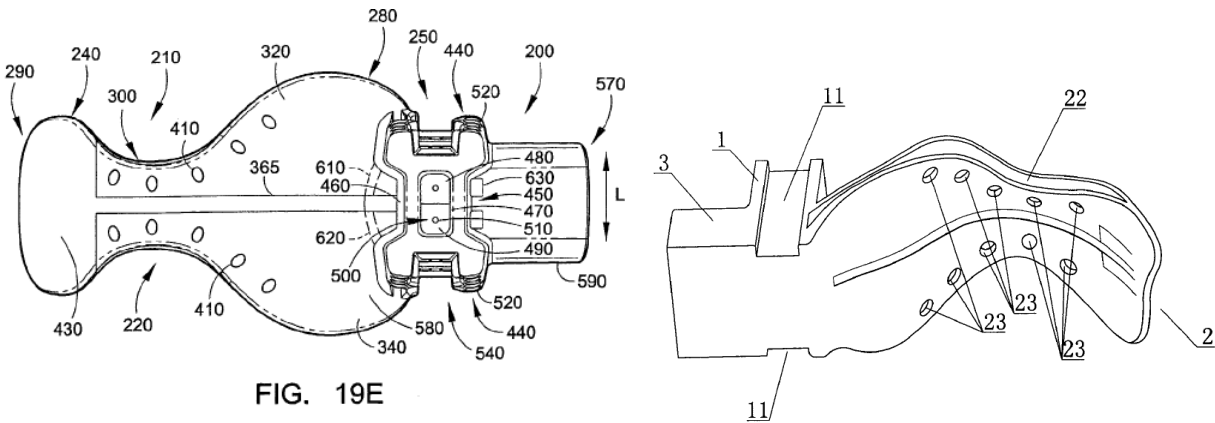
33. As I understand this limitation (to the extent it is understandable), there is a small part of the cheek retractor where the anterior wall and the posterior wall remain separated before the cheek retractor becomes solid. This limitation is confusing because I don't understand this concept of walls "transitioning". Finally, the claim limitation does not make much sense because the claim says that the walls are separated "for a distance within the cheek retractor portion" while also reciting that the first and second walls are "connected *at* the cheek retractor portion". These are two opposite ideas. How can something remain separated in part of the cheek retractor while also being connected "at" the cheek retractor portion. It can't be both.

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34. Regardless, Patent Owner has cited this patent against Petitioner's product, and the cheek retractor in Petitioner's product follows the prior art. As shown below, Petitioner's product includes a central spine, and the central spine spreads outward towards the tip of the cheek retractor. EX1011, p. 2.



This exactly matches other prior art designs, like Hirsch and Zheng. EX1012, FIG. 19; EX1021, FIG. 2.



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35. I reviewed the prosecution history leading up to the issuance of the '418 Patent as well as the prosecution history of related patents in the same family as the '418 Patent.

36. Beginning with the parent application, I note that the originally filed claims recited a sidewall. EX1015, p. 24. In fact, the claims are a bit more specific in explaining that the sidewall “define[s] an interior portion of the defined pocket”. *Id.* In other words, Patent Owner originally believed that his invention was directed to an enclosed pocket enclosed by an anterior wall, a posterior wall, and a sidewall. As I said above, that was also my understanding of the Dryshield product, particularly in how it differed from my invention.

37. I see that my patent was originally used to reject the claims of the parent application. EX1015, pp. 51-52. What is most interesting to me is that the Examiner agrees with me that the transverse walls 348c disclosed by Black (my patent) are “a bridge structure protruding from an interior surface of the posterior wall, the protruding structure comprising a plurality of spaced contact points that keep the anterior wall separated from the posterior wall during suction”. *Id.* The Examiner specifically said “Black discloses an intraoral suction device comprising a wave-shaped bridge structure 48c having formed therein the interior wall of the device 40 (FIG. 3B; paragraph 80). Note that the troughs between bridges/transverse walls 48c allow for communication with the suction source.”

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This finding by the Examiner is exactly the same position that I take below regarding why the “bridge structure” claimed in claim 1 is met by my invention. I also note that Patent Owner never refuted or disagreed with this position. EX1015, pp. 91-93.

38. My patent was again cited in the second office action against the claimed bridge structure. EX1015, pp. 109-111. Different than the first office action, the Examiner found that dependent claim 9 was now allowable, dependent claim 9 further reciting “that contact points of the bridge structure formed a wave shape with contact points at crests of the wave shape”. It is unclear why this subject matter was allowable over Black in the second office action, but not the first. Regardless, Patent Owner amended the independent claims to include the subject matter of allegedly allowable claim 9, and the Examiner allowed the application. EX1015, pp. 109-111, 130, 140.

39. Patent Owner filed a continuation application that was eventually allowed after 9 years, around the same time as two other continuation applications that were all filed on the same day (December 9, 2013). The application that became the '418 Patent is a child application of one of those three applications.

40. The first thing I should note is that the '418 Patent was filed with a Track One request. EX1002, pp. 13, 76. It is my understanding that Track One patent applications are examined much faster than other applications for a

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significant filing fee. It is also my understanding that Track One patents are allowed at a significantly higher rate than normal patent applications.

<https://www.uspto.gov/dashboard/patents/track-one.html>.

41. Nevertheless, the original claims no longer recited a sidewall, like the parent, and instead recited “a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall...” EX1002, pp. 23-29. The original claims also claimed “a plurality of crests of a wave-like structure...” *Id.* No prior art was ever asserted against these original claims. EX1002, pp. 113-115. Patent Owner addressing some § 112 rejections and received an allowance. EX1002, pp. 215-222, 260.

V. **LEVEL OF ORDINARY SKILL IN THE ART**

A. **Legal Principals**

42. 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.

43. 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

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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 '418 Patent

44. 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 2012, I had invented a dental isolation mouthpiece extremely similar to the '418 Patent. By 2012, I had filed for, prosecuted, and received two patents related to my dental isolation mouthpiece. Moreover, I designed and sold my product since 2008. Additionally, I am a dentist and had been working as a dentist for 12 years by 2012. I am able to read and understand the claims and specifications of the prior art and the '418 Patent in the light that a POSA would read and understand them.

45. In my opinion, and applying the factors set forth above in paragraph 43, a person of ordinary skill in the art at the time of the filing of the '418 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.

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

47. 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, Hirsch, Park, and Black were all prior art solutions in 2012, so combined bite blocks, isolation mouthpieces, cheek retractors, and suctioning devices were known in 2012.

48. 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,

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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.

49. 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 disclosed at least as early as the 1960s.

50. Finally, regarding education level, some knowledge of mechanical engineering is probably required, but an understanding of intraoral anatomy is at least equally important. As such, hands-on dentistry or knowledge from those in the dentistry field cannot be substituted when trying to design dental apparatuses to be used by dentists.

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51. 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. Of course, more work experience could supplement a lowered educational level and vice versa.

VI. **CLAIM CONSTRUCTION**

A. **Legal Principals**

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

B. **Opinion on Claim Construction**

53. I believe that all terms, for the purposes of *inter partes* review, can be given their plain and ordinary meaning in view of the specification. Also, to the extent there is any dispute regarding claim scope, I am applying Patent Owner's implied construction in view of the infringement contentions supplied.

54. To the extent that the parties have disputes as to claim interpretation, they are irrelevant to the validity of the '418 Patent because it is my opinion that all of the claims are clearly invalid as anticipated or obvious based on the prior art I have considered and my experience in the dental isolation mouthpiece field.

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55. In Grounds 1 and 5, applying my patents to the independent claims, I apply all of Patent Owner’s implied claim constructions from its infringement contentions. For example, while I do not agree that significantly different sized walls can be “corresponding” under the claim language because walls of differing size would not be able to form an acceptable third wall that connects the “corresponding edges”, I nevertheless apply Patent Owner’s implied construction here. I note that Patent Owner asserts that Petitioner’s device, which has a much larger posterior wall than the anterior wall is “corresponding”. EX1011, p. 5. While I do not agree with this construction, I apply it in Ground 1 and 5 to show that Patent Owner’s constructions result in invalidity of at least claim 1. The same can be said of terms like “end” and “edge”. Patent Owner seems to conflate these words, despite using different terminology to define its invention. EX1011, p. 7. The same is true of “third wall”. *Id.*

56. Importantly, Grounds 2–4 and 6-8 show invalidity of ’418 Patent in view of either Petitioner’s or Patent Owner’s construction. So, again, claim construction is not an issue the Board must resolve to find invalidity.

VII. **SUMMARY OF THE PRIOR ART**

A. **Black**

57. Black is my patent, and I invented the mouthpiece disclosed by Black.

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58. In the Black mouthpiece, the intra-oral device is comprised of first and second layers (like “walls” or “flaps”) whereby these two layers (see column 22 line 28) are connected “by a plurality of walls such that the first and second layers are spaced apart from one another and define therebetween a single axial passageway, said passageway having a distal end that coincides with the second layer's distal edge and is open so as to be directly exposed to the patient's oral cavity at said distal end...” EX1005, 1:53-56.

59. Furthermore, in claim 16 (see EX1005, 23:34-45), these “plurality of walls including two walls disposed above the axial passageway so as to form an upper channel extending from the passageway towards the top edge of the second layer, and two walls disposed below the axial passageway so as to form a lower channel extending from the passageway towards the bottom edge of the second layer, wherein the upper channel provides fluid communication between the passageway and an upper portion of the patient's oral cavity, and the lower channel provides fluid communication between the passageway and a lower portion of the patient's oral cavity.” Moreover, in claim 21, the Black mouthpiece is described to have a “longitudinal stiffener” (EX1005, 23:66-67).

60. So, the Black mouthpiece has two layers (like Hirsch “flaps”) connected or “bridged” together by vertical extensions (identified as “transverse walls”) to prevent collapse of the two layers when suctioning fluids through the

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channels. EX1005, 5:36-44. In this case, this plurality of walls each physically connect one layer to the other as defined in the patent claims. *Id.* Also, the Black mouthpiece has a stiffener along the length of the mouthpiece to add rigidity to the device, which aids in preventing collapse during suction. EX1005, 19:4-18.

B. Park

61. Park discloses a “detachable oral illuminating device with a mouse [sic] prop” having a first and second wall joined by upper and lower continuous edge similar to the dental mouthpiece. EX1006, Abstract. Park also incorporates an LED light, which can be projected through a light guide that illuminates the mouthpiece while debris is suctioned through the first and second walls aided by a multiplicity of through holes. EX1006, Abstract, ¶¶ 28-31.

62. Park explains that “light guide that extends to project from the LED to the front of the fitting connection portion, guiding the light emitted from the LED to the mouse [sic] prop” and “at the center of the interior of the insertion port, a post fitting groove can be formed to accommodate the protruding light guide when the fitting connection portion is inserted, and suction ports can be formed on both sides of the post fitting groove to suck in foreign substances from the oral cavity.” EX1006, ¶¶ 13-14.

63. Park further explains that “multiple through holes (132) can be formed in the tongue traction portion (130)”. EX1006, ¶ 31. Finally, FIG. 2 and FIG. 6

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show “multiple through holes”(132) on the “tongue traction portion” (130) and a closed, continuous edge on the illustration. *Id.*

C. Baughan

64. Baughan describes an intra-oral isolation device that uses a saliva ejector, which attaches to a smaller diameter, lower volume suction hose typically found in dental offices. EX1007, 1:7-44. Baughan states that one of the objectives is to “provide a dental saliva ejector which is engineered on sound theoretical principles with relation to air flow dynamics and air turbulence produced by the specific arrangement, number and size of the suction orifices and other design factors embodied in the device.” EX1007, 1:26-31.

65. Continuing in the document, Baughan describes a device whereby radial discs surround a suction tube and in between the discs are vertical suction ports which intersect with the main suction tube (channel). EX1007, 2:19-35. This length of discs is covered by a perforated “sleeve” which cushion the patient's soft tissue. EX1007, 2:51-62. The Baughan patent description identifies the purpose for the sleeves and discs: “With suction applied to the main suction tube through the suction hose, the saliva which collects in the patient's mouth will be drawn inwardly through the apertures of the sleeves, and should these sleeves be drawn tightly about the discs, the saliva will always be free to pass through the notches of the disc and into the orifices which are also staggered circumferentially with

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relation to the notches. After passing through the orifices, the saliva will be drawn from the patient's mouth through the main suction tube. The discs prevent the flexible sleeve or boot from collapsing upon the terminal tube portion and closing the orifices thereof.” EX1007, 3:36-48.

66. So, in the Baughan design, the discs “assume vertical positions” (see EX1007, 4:6 like the “waves” in the bridge structure 180 in the ’418 Patent and are affixed to the suction tube. Within these vertical radial disks are notches similar to the “troughs” in the ’418 Patent mouthpiece bridge structure. EX1007, 2:32-35. The notches create a rigid support to allow for fluid to pass through to an open end of the suction tube even if the flexible sleeve is compressed from oral tissues. Also, the vertical radial discs extend from the interior portion of the device and are not physically connected to the outer member, which is the sleeve.

D. Johnson

67. Johnson describes a device of similar nature to Baughan in that a “saliva ejector is formed of a flattened body having upper and lower portions, a suction passage being formed in the body and a plurality of apertures communicating with the passage.” EX1008, 1:65-67. This saliva ejector device attaches to a suction hose typically found in dental offices. The plates are also “molded of a suitable rigid or semi-rigid plastic”. EX1008, 4:24-27.

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68. According to claim 1 of the Johnson patent, the device forms a “combined saliva ejector and tongue restraint adapted to be placed within the oral cavity between tongue and teeth, said ejector comprising, a flattened body having upper and lower portions, said body including, first and second plates in face to face contiguity, at least of said plates being formed with a recess extending along a surface thereof that faces the other of said plates to define a suction passage between said plates...said body being formed with a plurality of apertures communicating with said passage...” EX1008, 6:53-7:6.

69. Johnson also teaches multiple projections 81-86 formed on a flat surface of the saliva ejector. EX1008, 4:16-23, FIG. 3.

E. **Hirsch**

70. Hirsch discloses a mouthpiece with a central spine for added rigidity and anti-collapse support. EX1012, ¶ 78. This added rigidity helps in retracting cheek tissue because the added rigidity provides more memory force that pushes against cheek tissue based on position memory. *See* EX1005, 7:21-39. Thus, the spine assists in ensuring that the mouthpiece of Hirsch applies a proper amount of force to retract cheek tissue and prevent cheek tissue from interfering.

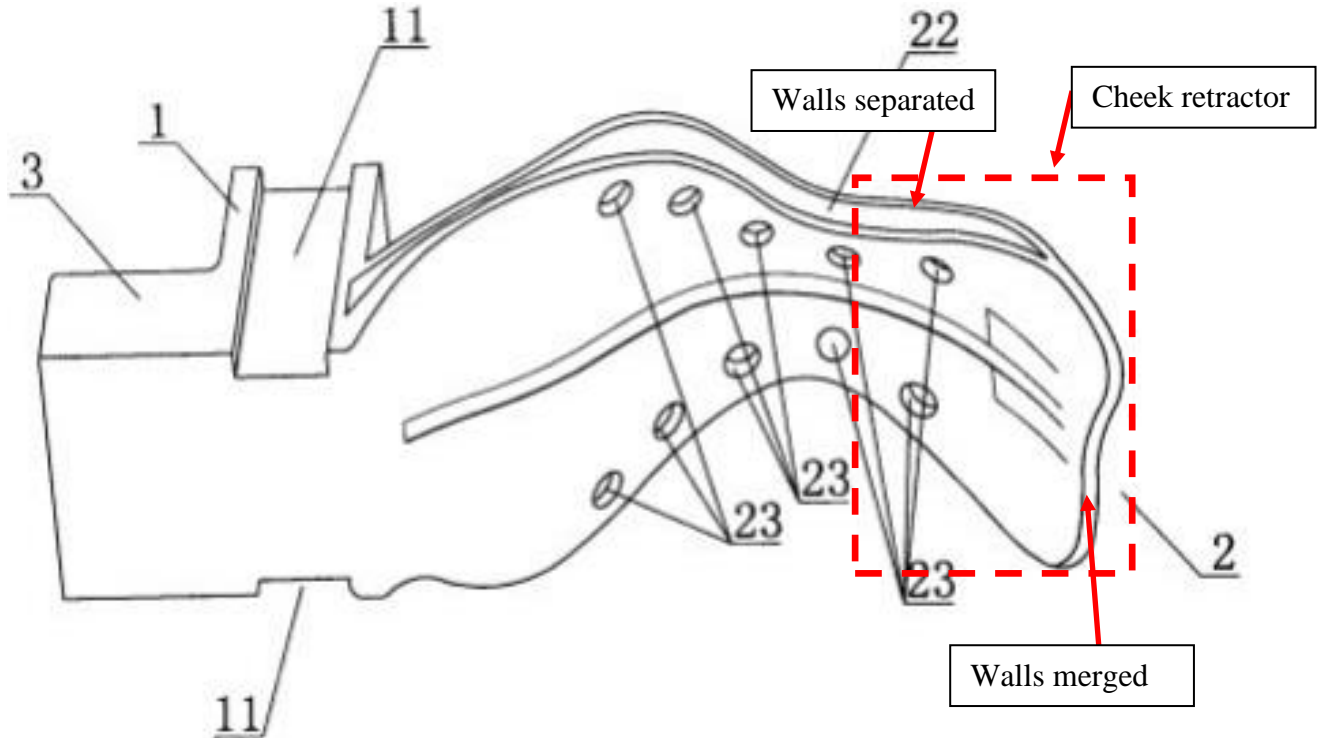
F. **Zheng**

71. Zheng teaches a mouthpiece similar in design to Hirsch with a cheek retractor (area in dashed) that connects the first wall and second wall part way

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through the cheek retractor, such that the first and second walls are separated for a short distance in the cheek retractor until they merge together part way through the cheek retractor. See EX 1021, FIG. 2 (annotated).



VIII. OPINION ON GROUNDS OF UNPATENTABILITY

A. Legal Principals of Obviousness

72. 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.”

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73. 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).

74. 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.

75. 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.

76. 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;

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- b. the substitution of one known element for another is likely to be obvious if it yields predictable results;
- c. the use of a known technique to improve similar items or methods in the same way is likely to be obvious if it yields predictable results;
- d. the application of a known technique to a prior art reference that is ready for improvement is likely obvious if it yields predictable results;
- e. any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed;
- f. a person of ordinary skill often will be able to fit the teachings of multiple references together like a puzzle; and
- g. the proper analysis of obviousness requires a determination of whether a person of ordinary skill in the art would have a “reasonable expectation of success” – not “absolute predictability” of success – in achieving the claimed invention by combining prior art references.

77. 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

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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.

78. 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.

79. 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.

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B. Ground 1: Claims 1–9, 11–17 and 19 are obvious under 35 U.S.C. 103 by Black and Hirsch.

80. It is my opinion that Black discloses all of the limitations of claims 1–9, 11–17 and 19. EX1005. It should be noted that there is significant overlap between many of the embodiments in Black, and elements described in prior embodiments are also incorporated into subsequently described embodiments. EX1005, 6:57-61 (“These, as well as many other features of the tongue shield aspirator 240 resemble those of the tongue shield aspirator 40 discussed immediately above.”); 14:2-5 (“The tongue shield aspirator 340 includes features that are similar to those described above in connection with the tongue shield aspirators 40, 240 shown in FIGS. 3 and 4.”). So, the teachings of earlier described embodiments do not necessarily require modification or a motivation to combine as they are already disclosed previously. To the extent an obviousness determination is necessary, I discuss this below.

1. Independent Claim 1

a. Preamble/Limitation 1(a): “An isolation mouthpiece for use with a suction system in a dental procedure, the isolation mouthpiece comprising:”

81. 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

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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 mouthpiece, use the mouthpiece with a suction system, and use the mouthpiece in a dental operation.

82. Even if the preamble is limiting, Black discloses an intra-oral device 300 that includes a bite member, a tongue shield aspirator, and an evacuation tube. EX1005, 11:54-60, 4:47-55, Abstract. My invention is a dental isolation system that includes a mouthpiece. The tongue shield aspirator 340 and the bite member together are a mouthpiece. The tongue shield aspirator connects to an HVE suction line and is used during a dental procedure. EX1005, 19:33-20:47.

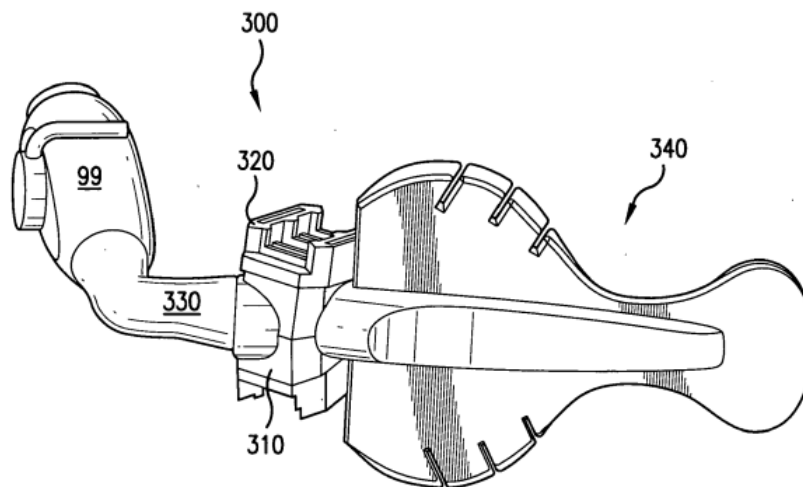


FIG. 18

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from the first end of the main body portion towards the second end of the main body portion,”

84. Black discloses that the first flap 340a (“main body portion”/”pocket”) includes a posterior layer 348a, which a POSA would consider a first wall. EX1005, 14:25-30. As shown in FIG. 23B, Black shows the posterior layer having a shape defined by multiple edges, and the posterior layer 348a extends from the first end to the second end.

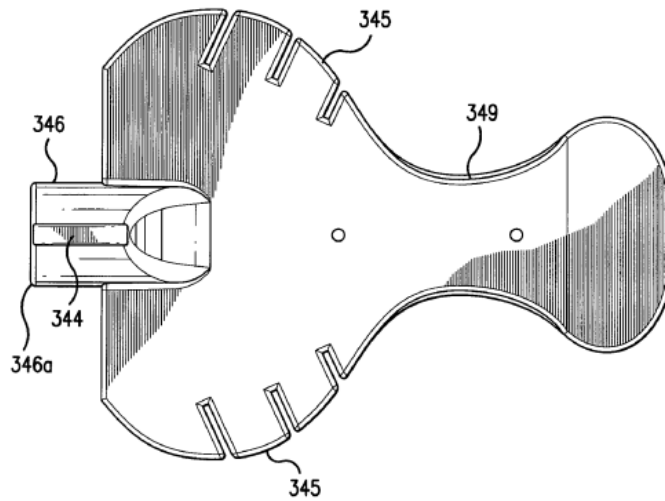


FIG.23B

- d. **Limitation 1(d): “a second wall having a second shape defined by third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a first plurality of perforations extending along a portion of the third edge, and a second plurality of perforations extending along a portion of the fourth edge,”**

85. Black discloses that the first flap 340a (“main body portion”/”pocket”) includes an anterior layer 348b, which a POSA would consider

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a second wall. EX1005, 14:25-30. As shown in FIG. 23A, Black shows the anterior layer having a shape defined by multiple edges, and the anterior layer 348a extends from the first end to the second end.

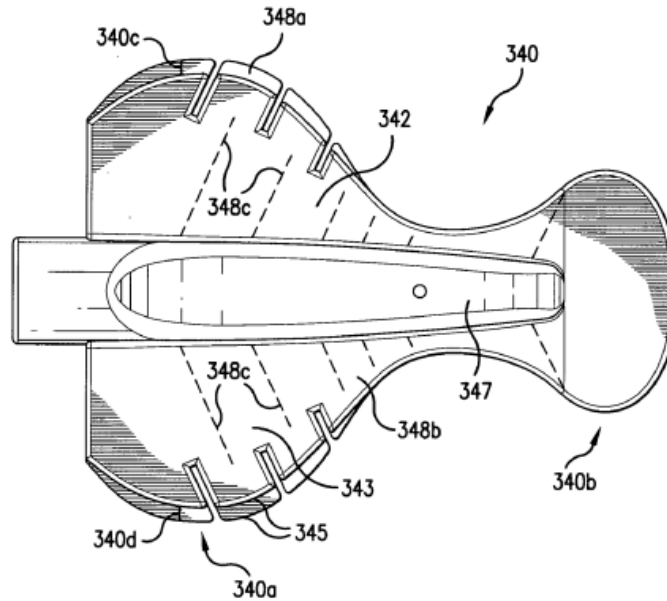


FIG. 23A

86. The tongue shield aspirator 340 includes two parallel walls: a posterior layer 348a and an anterior layer 348b spaced apart by transverse walls 348c. EX1005, 14:25-30. FIG. 23C of Black illustrates an interior area between the posterior layer 348a and the anterior layer 348b. Additionally, FIG. 23A of Black illustrates the channels 342, 343 created by the transverse walls 348c. EX1005, 14:30-63. The tongue shield aspirator 340 further includes a longitudinal lumen running down the center of the mouthpiece, which is fluidly connected to each channel 342, 343. EX1005, FIG. 3B, FIG. 23A, 14:21-25. Each of the lumen and

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the channels 342, 343 are interior spaces enclosed by the posterior layer 348a, the anterior layer 348b, and the transverse walls 348c.

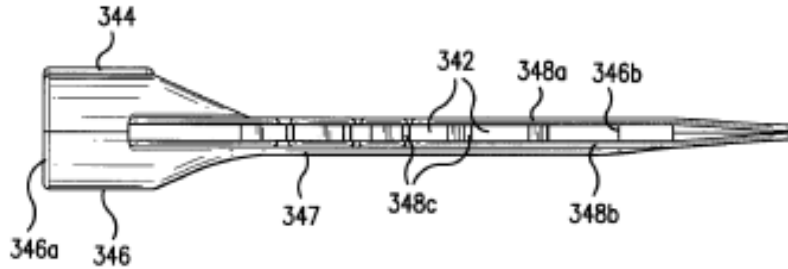


FIG. 23C

87. Black, in a separate embodiment, teaches a tongue shield aspirator with a plurality of holes (perforations) formed along superior and inferior edges of the anterior flap. The plurality of holes includes a first plurality of perforations formed adjacent to and extending along a portion of the first edge (holes on top half of first flap 240a) and a second plurality of perforations formed adjacent to and extending along a portion of the second edge (holes on bottom half of first flap 240b).

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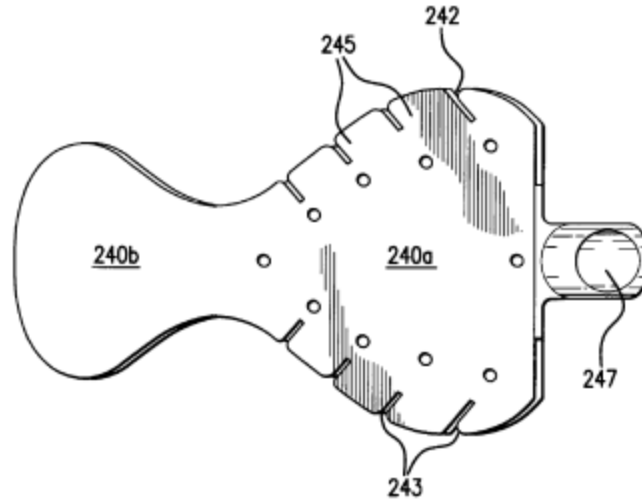


FIG. 4C

88. Although the publication Black does not specifically identify these circles in FIG 4C as holes, I am the author of Black, and I am the inventor of the tongue shield aspirator 340. I know these are perforations because I am the author of this reference. Yes, I envisioned the use of perforations when I filed the patent application. Perforations in dental isolation mouthpieces were well-known when I wrote my patent application. EX1012, FIG. 19A. I depicted perforations without describing them because these features were so common and well-understood. Nevertheless, these circles in FIG. 4C are meant to represent holes/perforations, and thus, Black teaches a first plurality of perforations formed adjacent to and extending along a portion of the first edge and a second plurality of perforations formed adjacent to and extending along a portion of the second edge.

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89. It would have been obvious to include the holes of the tongue shield aspirator 240 shown in FIG. 4C into the tongue shield aspirator 340 because these holes would have allowed suction through the anterior wall as well as through the sides of the tongue shield aspirator 340. Also, I envisioned cross-over between all the embodiments disclosed by my invention, which includes the use of holes on any of the embodiments. EX1005, 11:54-60, 14:1-5. I am informed by counsel that it does not require a leap of innovation to combine features from similar embodiments within the same reference. This is particularly true from my perspective, as I invented Black, and I did envision holes on any of the embodiments.

90. Regardless, forming suction holes on both the anterior and posterior walls of a mouthpiece was well-known by 2012. Indeed, Hirsch teaches an intraoral device 200 including flaps 310, 320, 330, 340, which a POSA would consider a first or second wall. EX1012, ¶ 79. The flaps 310, 320, 330, 340 include evacuation holes 410 (perforations) extending along the edges of the flaps 310, 320, 330, 340, thus Hirsch teaches a plurality of perforations formed adjacent to and extending along a portion of the third edge, and a plurality of perforations formed adjacent to and extending along a portion of the fourth edge. *Id.*

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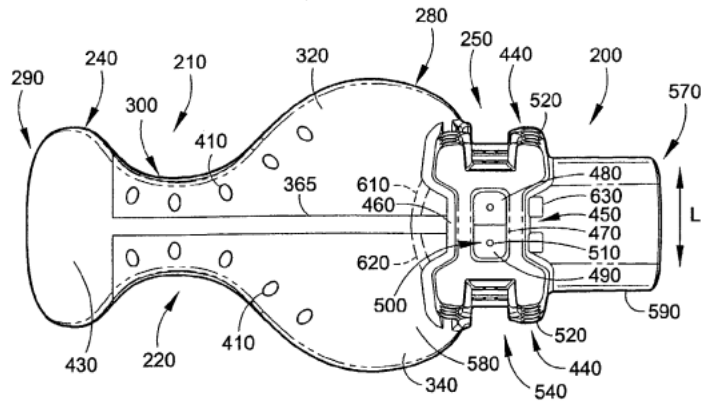


FIG. 19E

91. A POSA would have been motivated to modify the anterior or posterior layer 348a of Black to include the evacuation holes 410 to improve the suction through the tongue shield aspirator 340 and allow for suction through the anterior and/or posterior wall in case fluid escaped the barrier created by the tongue shield aspirator or pooled in the mouth in front of the tongue shield aspirator 340. EX1012, ¶ 71. Because both Hirsch and Black teach that holes can be formed in the anterior and posterior flap for suction purposes, a POSA would have expected success.

- e. **Limitation 1(e): “wherein a plurality of crests of a wave-like structure is formed on an interior surface of the second wall to provide contact points with the first wall, and a plurality of troughs of the wave-like structure provides gaps between adjacent ones of the plurality of crests for allowing the suctioning of fluid through the plurality of troughs;”**

92. The '418 Patent teaches a “bridge structure 180” that “ensures that the anterior and posterior surfaces remain separated under suction”. EX1001, 4:55-58.

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The '418 Patent describes the bridge structure 180 as having “crests” and “troughs”. EX1001, 4:60-5:5. The '418 Patent explains that the “troughs” are “gaps” between the projections formed on the inner surface of the posterior wall, and the gaps allow water and saliva to pass between the projections to be suctioned through the suction connector. *Id.* So, the “bridge structure 180” merely describes spaced-apart projections formed in the center part of the main body portion to ensure that the posterior wall and anterior wall do not collapse under suction. EX1001, 4:55-5:7.

93. Spaced apart protrusions to ensure that the posterior and anterior flaps remain separated is exactly what I described with the transverse walls 348c. EX1005, 14:21-47. The transverse walls 348c (crests/projections) are spaced apart to create channels 342, 343 to allow for suction of fluid and debris (troughs). A POSA would know that you cannot keep two flexible, parallel walls separated under suction unless there is some mechanical structure maintaining separation. Perpendicular projecting elements, like the wave-like structure and the transverse walls 348 of Black, are well-understood solutions to maintain separation of two parallel walls. EX1005, 14:21-47.

94. FIG. 3B also shows a wave-like structure having spaced apart protrusions, but from a top perspective.

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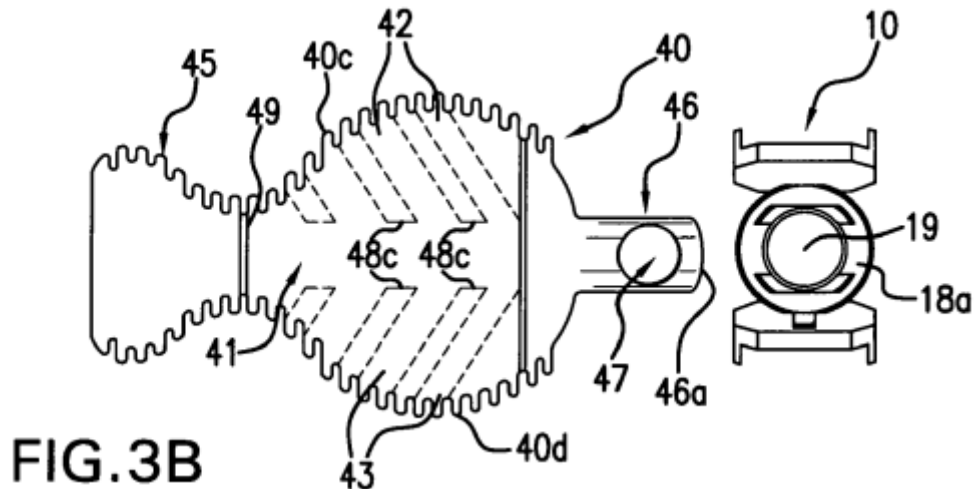


FIG. 3B actually further informs FIG. 23C. EX1005, 11:55-60, 14:2-5. These channels are formed extremely similarly as those in FIG. 23A, so I do not believe an obviousness analysis is required to rely on the teachings of FIG. 3B here.

95. Black teaches transverse walls 348c with channels 342, 343 formed therebetween. EX1005, 14:21-47. This is a wave-like structure, as claimed. The transverse walls 348c are projections, and the channels therebetween demonstrate that the transverse walls 348c are spaced apart. EX1005, 14:21-47. Just like the bridge structure 180, the transverse walls 348 allow for suction of fluid and debris through the channels 342 while keeping the anterior and posterior layers separated under suction. EX1005, 14:21-47.

96. The transverse walls 348c are connected to both the posterior layer and the anterior layer. EX1005, 14:21-47. Thus, the transverse walls 348c extend from an interior surface of the posterior flap toward the anterior flap. *Id.* Each wall

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is a protrusion, and FIGS. 23A and C, and FIG. 3B show a plurality of transverse walls. By connecting to the posterior wall, the transverse walls have contact points with the posterior wall.

97. Thus, the claim’s requirement that a structure be “wave-like” in view of the specification merely means that you need spaced-apart projections with gaps therebetween. EX1001, 4:55-5:5. The resulting shape is necessarily a wave shape. As you can see, in FIG. 23C, Black teaches a square wave shape formed by the channels 342 and the transverse walls 348c (i.e., the presence transverse walls 348c and the gaps therebetween that form the channels 342).

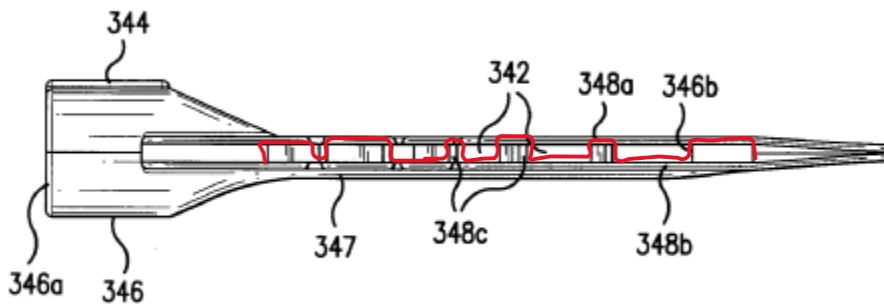


FIG. 23C

98. Thus, Black teaches a wave-like structure exactly as claimed in claim

1. I note that the Examiner agreed with me. EX1015, pp. 51-52.

- f. **Limitation 1(f): “and wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds in shape to the third edge of the second wall and the second edge of the first wall corresponds in shape to the fourth edge of the second wall; and wherein the first shape of the first wall**

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**corresponds to the second shape of the second wall,
 and”**

99. Black discloses that the first flap 340a (“main body portion”/“pocket”) includes an anterior layer 348b, which a POSA would consider a second wall. EX1005, 14:25-30. As shown in FIG. 23A, Black shows the anterior layer having a shape defined by a first edge on the upper side and a second edge on the lower side.

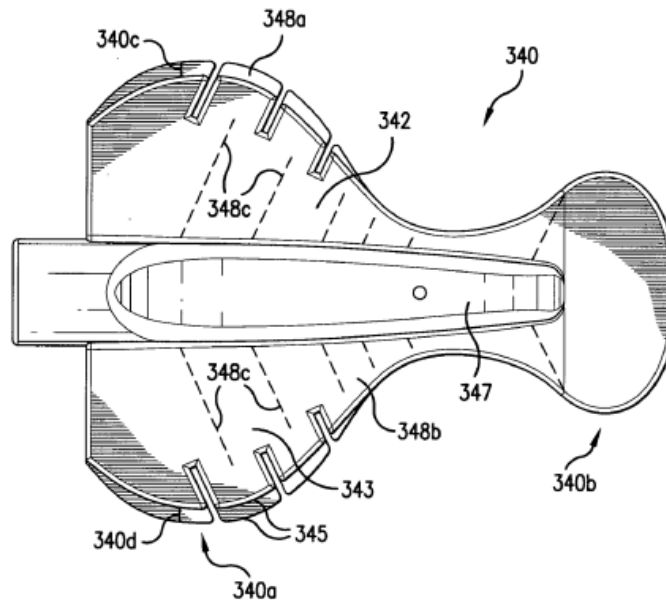


FIG. 23A

100. In the embodiment shown in FIG. 23A, the upper and lower edges of the anterior layer 348b are similar in size and shape to the upper and lower edges of the posterior layer 348a, respectively. Therefore, a POSA would understand that the anterior layer 348b (second wall) and the posterior layer 348a (first wall) are shaped such that the first (upper) edge of the first wall corresponds to the third

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(upper) edge of the second wall and the second (lower) edge of the first wall corresponds to the fourth (lower) edge of the second wall.

101. Nevertheless, in the embodiment shown in FIG. 23A, the posterior layer 348a is slightly bigger than the anterior layer 348b. EX1005, 15:57-63.

However, other embodiments in Black show identical shapes/sizes in the two flaps.

e.g., EX1005, FIG. 4C. So, to the extent Patent Owner argues that “the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall” means the two walls are identical in size and shape, I foresaw such an embodiment before the priority date of the '418 Patent. EX1005, FIG. 4C, *see also* FIGS. 1, 3B, 13.

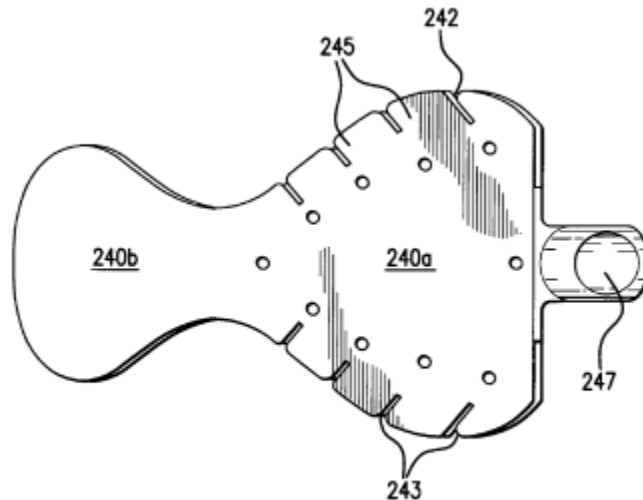


FIG.4C

102. It would have been obvious to make the make the anterior layer 348b identical in shape and size to the posterior layer 348a in view of any of FIGS. 1,

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3B, 4C, or 13. I have been informed by counsel that it does not require a leap of innovation to combine features different embodiments disclosed within the same patent specification. Indeed, it would have been obvious to a POSA to change the size of the posterior wall 348a to match the size and shape of the anterior wall 348a because changes in size are generally considered obvious, especially when I disclosed other embodiments showing identical anterior and posterior walls.

EX1005, FIGS. 1, 3B, 4C, 13.

103. Regardless, it appears that Patent Owner is construing “the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall” to mean something much broader than “identical in shape and size”. EX1011, pp. 4-5. Indeed, Petitioner’s mouthpiece has a posterior flap that is much wider than the anterior flap; and the difference in shape and size is more profound than what I depicted in FIG. 23A. *Id.* Under this implied construction from Patent Owner’s invalidity contentions, the posterior layer need to only generally resemble the anterior layer in size and shape to have the edges “correspond”. Clearly, either FIG. 4C or FIG. 23A shows an anterior layer that corresponds in shape to the posterior layer such that the edges of the posterior and anterior layers correspond to one another under this construction.

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- g. **Limitation 1(g): “a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall,”**

104. Black discloses that the first flap 340a (“main body portion”/“pocket”) includes a third wall. EX1005, FIG. 23A, *see also* FIGS. 19, 1, 3A, 4C, 24D.

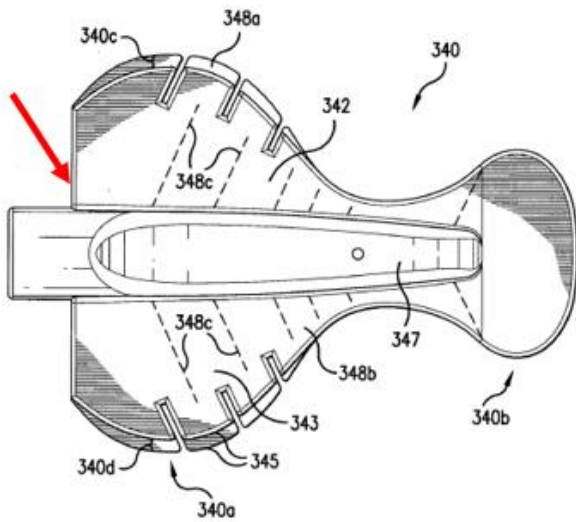


FIG. 23A

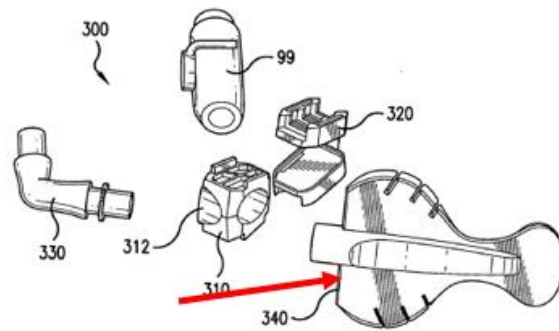


FIG. 19

Patent Owner may argue that FIGS. 18–19 and 23A–23C do not definitively show a third wall formed at the point I show above. But again, I wrote Black, and I know there is a third wall formed at that spot. I invented it. As further proof, many of the previous embodiments unequivocally showed such a third wall. EX1005, FIGS. 19, 1, 3A, 4C, 24D.

105. More specifically, many of the embodiments disclosed, including the tongue shield aspirator 240, include such a third wall formed near the “hollow neck

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246”, which is the suction port end of the tongue shield aspirator. As clearly shown in FIG. 4C, a wall connecting the posterior flap and the anterior flap is formed near the suction port. To the extent obviousness is necessary, it would have been obvious to include the third wall shown in FIG. 4C in the tongue shield aspirator 340 to provide additional structural integrity and more anti-collapse structure near the neck 346.

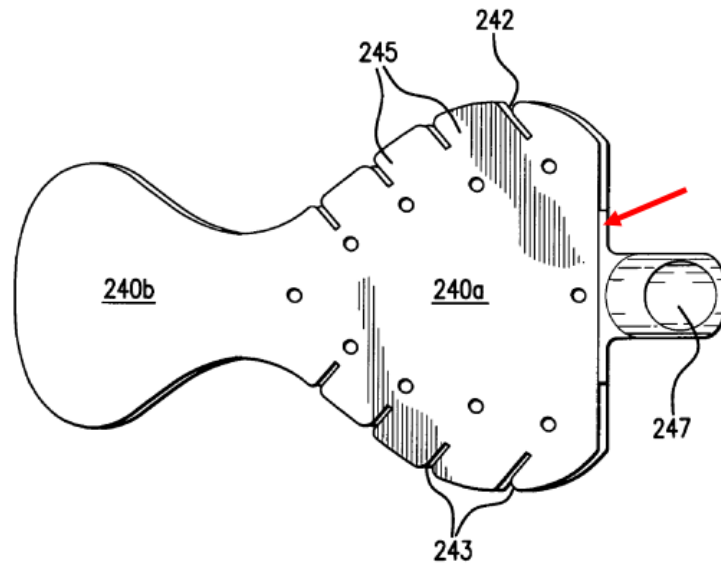


FIG.4C

106. Exactly as claimed, this wall connects an edge of the anterior wall to an edge of the posterior wall. Other embodiments show similar walls having differences in widths, including partially expanding along that end of the mouthpiece to extending across the entirety of the end.

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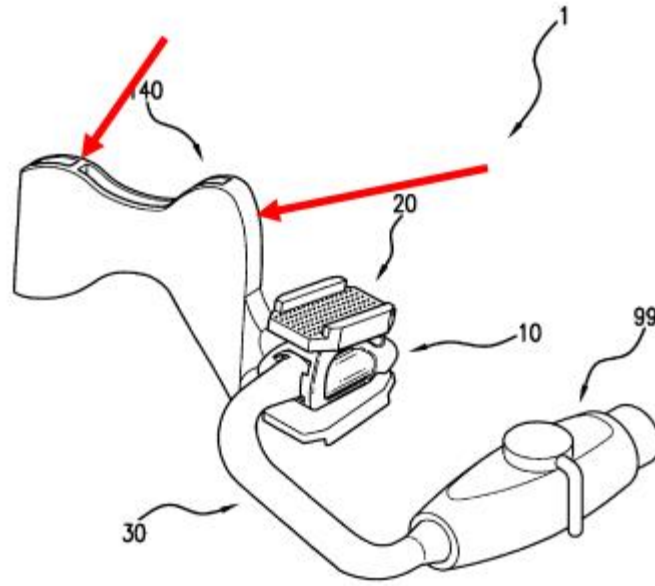


FIG. 1

Thus, if Patent Owner argues that the embodiment shown in FIG. 4C does not connect an entire “edge”, it would have been obvious to extend the wall across the entire hollow neck end, as such a change would just change the dimensions or proportions of the wall. I have been told by counsel that such changes are considered obvious in view of MPEP 2144.04.

107. It should be noted that I am again applying Patent Owner’s construction of “third wall” and “edge” (for claim 20). Patent Owner’s implied construction from its invalidity contentions shows a much broader construction. EX1011. For the sake of this Ground, I have applied Patent Owner’s construction to show that its construction results in invalid claims.

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- h. **Limitation 1(h):** “wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion, wherein a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width, and wherein the third width is greater than the fourth width;”

108. As shown in annotated FIG. 23A below, Black discloses that the two walls that make up the first flap 340a (“main body portion”/”pocket”), the anterior layer 348b and the posterior layer 348a, each define a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion and first widths are greater than the second widths.

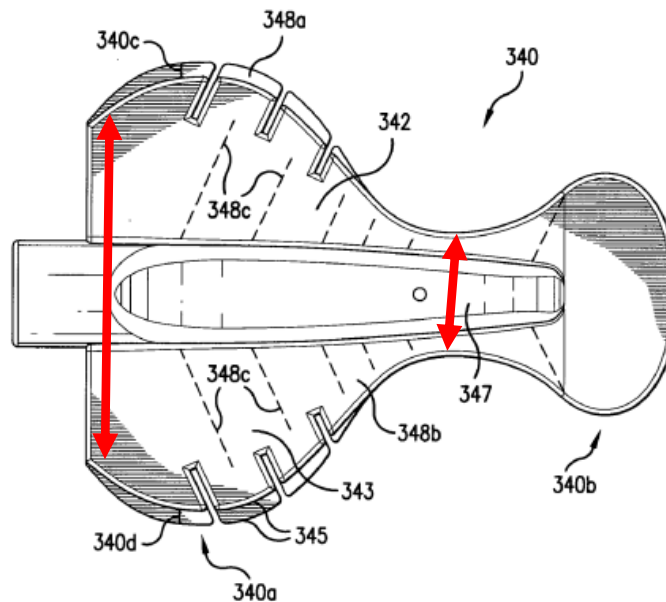


FIG.23A

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- i. **Limitation 1(i): “a suction connector portion extending from the first end of the main body portion, the suction connector portion including: a tubular conduit including an opening extending through the conduit and in fluid communication with the plurality of troughs of the wave-like structure, the opening being configured to receive a vacuum portion of the suction system therein, the tubular conduit further including a cutout configured to engage a protrusion on the suction system to aid in coupling the isolation mouthpiece to the suction system, and”**

109. Black discloses a hollow neck 346 that connects the tongue shield aspirator to an evacuation tube. EX1005, 15:21-51; 16:1-3, *see also* FIG. 24D.

The evacuation tube is a vacuum source (HVE valve), and the evacuation tube connects the vacuum source to the channels of the tongue shield aspirator.

EX1005, Abstract, 1:62-2:7, 10:18-33. Black teaches that the hollow neck 346 is formed on one end of the tongue shield aspirator 340. EX1005, FIG. 23C.

110. Black teaches that the suction connector includes a conduit through it that is in communication with the channels 342, 343 of the tongue shield aspirator 340. EX1005, 15:21-35.

111. As shown in FIGs. 23C and 24D, the neck includes a generally tubular conduit and an opening in fluid communication with the inner cavity of the mouthpiece.

112. Black teaches a “lock-and-key locking mechanism” to interlock the bite member 310 with an evacuation tube 330. EX1005, 13:16-67. Black explains

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EX1003

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that “the lock-and-key mechanism ensures that the evacuation tube [i.e., vacuum source] will not detach from the bite member during use...” EX1005, 13:57-59.

This configuration is exactly what is described by claim 1 of the '418 Patent, or at worst an obvious variant. EX1001, 5:42-46.

113. To the extent Patent Owner argues that Black fails to teach a locking mechanism of the suction connector, specifically, such an embodiment was well-known in the prior art. For example, Hirsch teaches a connection section 570 that extends from retractor 240 and attaches to vacuum-only adapter 230 to deliver suction to an intraoral device. EX1012, ¶ 89, FIG. 19E. The connection section 570 includes a tube 590 having slots 630 that retain corresponding retention bars on the vacuum-only adapter. EX1012, ¶ 90, FIG. 19E. This is a locking mechanism, in the form of a hole (*i.e.* cut out), formed on the suction connector of a mouthpiece and configured to receive corresponding protrusions from a vacuum adapter.

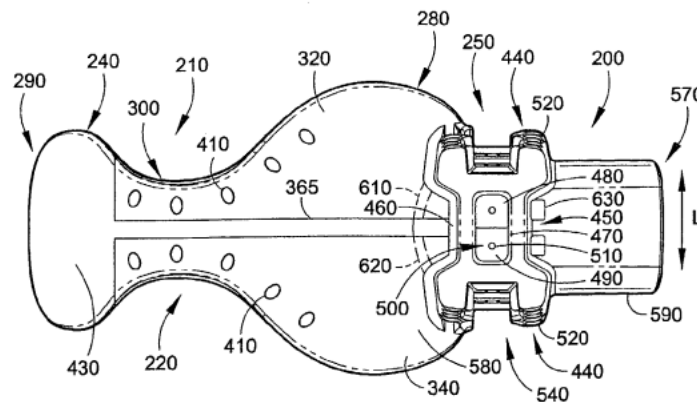


FIG. 19E

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114. It would have been obvious to a POSA to modify the neck 346 of Black to include the slots 630 of Hirsch to provide a secure connection between the mouthpiece and the vacuum source. EX1005, 16:1-7. Indeed, Black already understood that secure connection with the vacuum source was critical. EX1005, 13:57-59. Using holes formed on a suction connector to accept projections on the vacuum tube is simply an obvious variant of the lock-and-key mechanism taught by Black. I am told that where there are a finite number of predictable solutions, a POSA has good reason to pursue those known options.

- j. **Limitation 1(j): “a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second side each including a plurality of ridges; and”**

115. A POSA would understand this limitation to require a mouth prop, sometimes called a bite block, that has a smaller posterior surface (the surface that faces into the patient’s mouth when the mouthpiece is in use) than the larger, anterior surface (the surface that faces away the patient’s mouth when the mouthpiece is in use). It should be noted that almost all bite blocks are designed in this way because it follows the natural shape of the mouth when it is open, which is narrow at the back of the mouth and wider at the front of the mouth. This is because the jaw is a hinge, which any POSA would understand based on very basic dental anatomy.

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116. Black teaches a bite member 310 that has a top side 314 and a bottom side 316. According to Black, “the top side 314 and bottom side 316 of the bite member 310 lie in divergent planes, i.e., respective planes that diverge from one another at an acute angle so as to accommodate a patient's mouth in the open position.” EX1005, 11:61-12:9. In other words, the bite member of Black inwardly tapers from the anterior surface to the posterior surface when in use.

117. Black also teaches that the bite member includes a bite grip 320 having a plurality of ridges on each side of the bite grip 320. These ridges can be seen in FIG. 21A below.

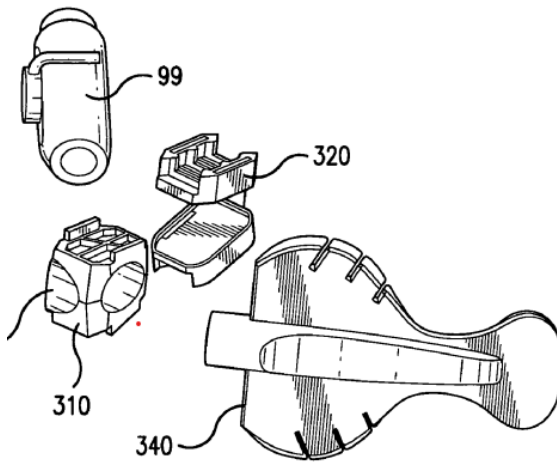


FIG. 19

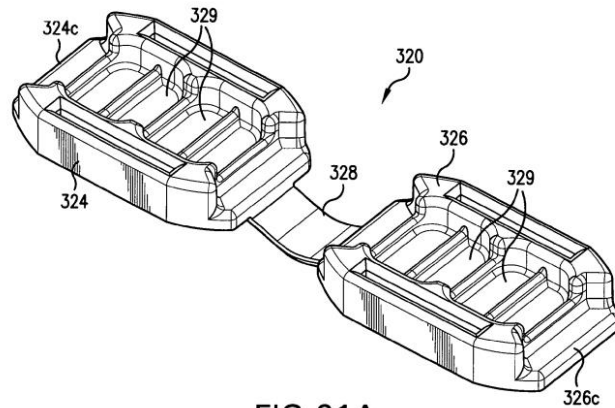


FIG. 21A

- k. **Limitation 1(k): “a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges.”**

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118. Black discloses a second flap 340b formed on an opposite side of the tongue shield aspirator 340 from the hollow neck 346. EX1005, 14:5-9, FIG. 23A. Black explains that the second flap 340b functions as a cheek retractor. *Id.* Black shows that the second flap 340b is connected to the narrower second end of the first flap 340a, and it expands outwardly away from the second end of the first flap 340a. Black shows the second flap (cheek retractor) as having rounded edges.

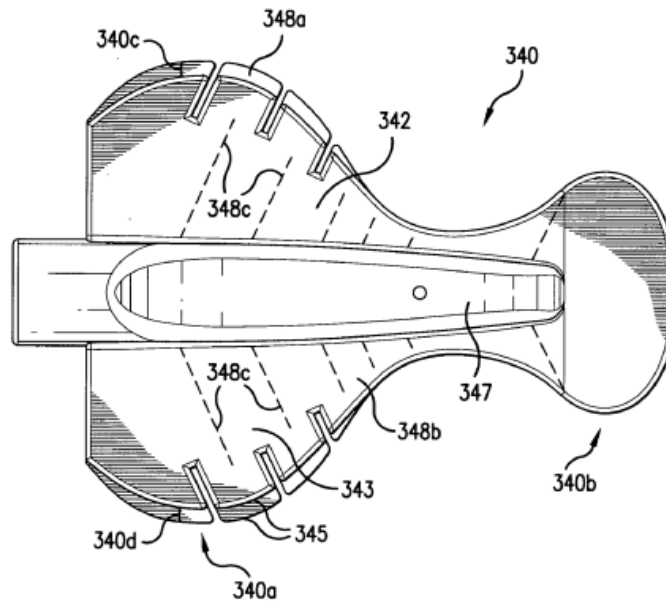


FIG. 23A

119. Thus, Black teaches each and every limitation of claim 1 alone.

2. **Claim 2: “2. The isolation mouthpiece of claim 1, wherein the first plurality of perforations includes five perforations and the second plurality of perforations include five perforations.”**

120. Black teaches, in FIG. 4C, that the first wall of the tongue shield aspirator 340 includes a first and second plurality of perforations that each include

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at least five perforations. As shown in annotated FIG. 4C below, the first plurality of perforations (along the upper edge) has five perforations and the second plurality of perforations (along the lower edge) has five perforations. The leftmost perforation, near the cheek retractor portion, counts as part of both the first and second plurality of perforations. As best as I can tell, nothing in this claim limitation requires the first and second pluralities of perforations to be completely separate from each other.

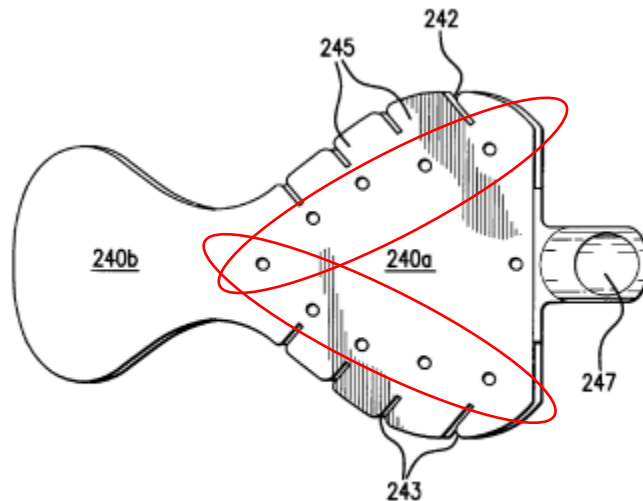


FIG. 4C

121. To the extent that Patent Owner argues that there cannot be any overlap between the first and second pluralities of perforations, it would have been obvious for a POSA to add more perforations to the first wall of the tongue shield aspirator 340 of Black, as such a change would just be a duplication of the parts (perforations). I have been told by counsel that such changes are considered

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obvious in view of MPEP 2144.04(VI)(B). A POSA would be motivated to add more perforations to the tongue shield aspirator of Black to improve suction.

EX1012, ¶ 71.

122. To the extent an express teaching in the prior art is required, Hirsch, in FIG. 19A, teaches an intraoral device 200 including flaps 310, 320, 330, 340 which a POSA would consider a second wall. EX1012, ¶ 79. The front flaps 310, 330 include evacuation holes 410 (perforations) extending along the edges of the front flaps 310, 330. *Id.* The evacuation holes 410 can be separated into a first plurality having five perforations along the edge of front flap 310 and a second plurality having five perforations along the edge of front flap 330.

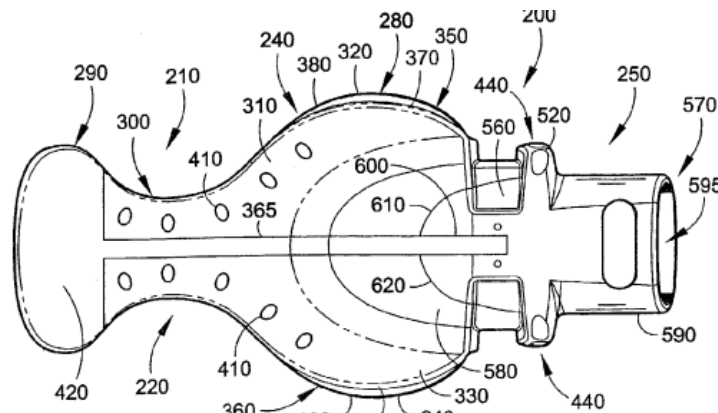


FIG. 19A

123. A POSA would have been motivated to modify the anterior layer 348b of Black in view of Hirsch to include more perforations to improve the suction through the tongue shield aspirator 340. EX1012, ¶ 71.

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3. **Claim 3: “3. The isolation mouthpiece of claim 2, wherein at least one of the first plurality of perforations and at least one of the second plurality of perforations are located adjacent to the second end and near the cheek retractor portion.”**

124. As discussed above, Hirsch teaches a first plurality of perforations and a second plurality of perforations formed in the second wall. *See* paragraphs 120–123.

125. Black as modified by Hirsch to include the perforations of Hirsch teaches that at least one of the first plurality of perforations and at least one of the second plurality of perforations are located adjacent to the second narrower end of the main body and near a portion of the first wall that is spaced apart from the second wall. *See* annotated FIG. 19E of Hirsch below.

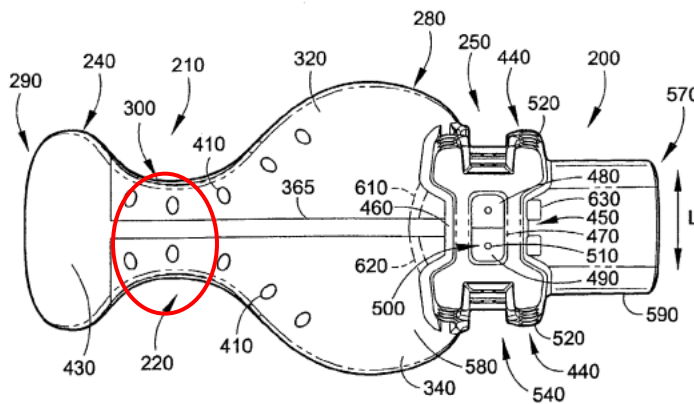


FIG. 19E

4. **Claim 4: “4. The isolation mouthpiece of claim 1, wherein the first wall and the second wall of the main body portion transition into and are connected in the cheek retractor portion to form the cheek retractor portion, the first wall and the second wall of the main body portion that transition into the cheek retractor portion are spaced apart from each other**

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EX1003

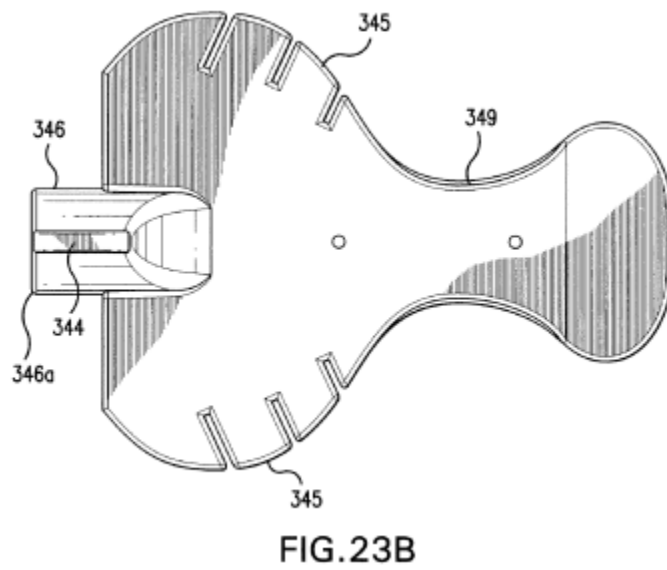
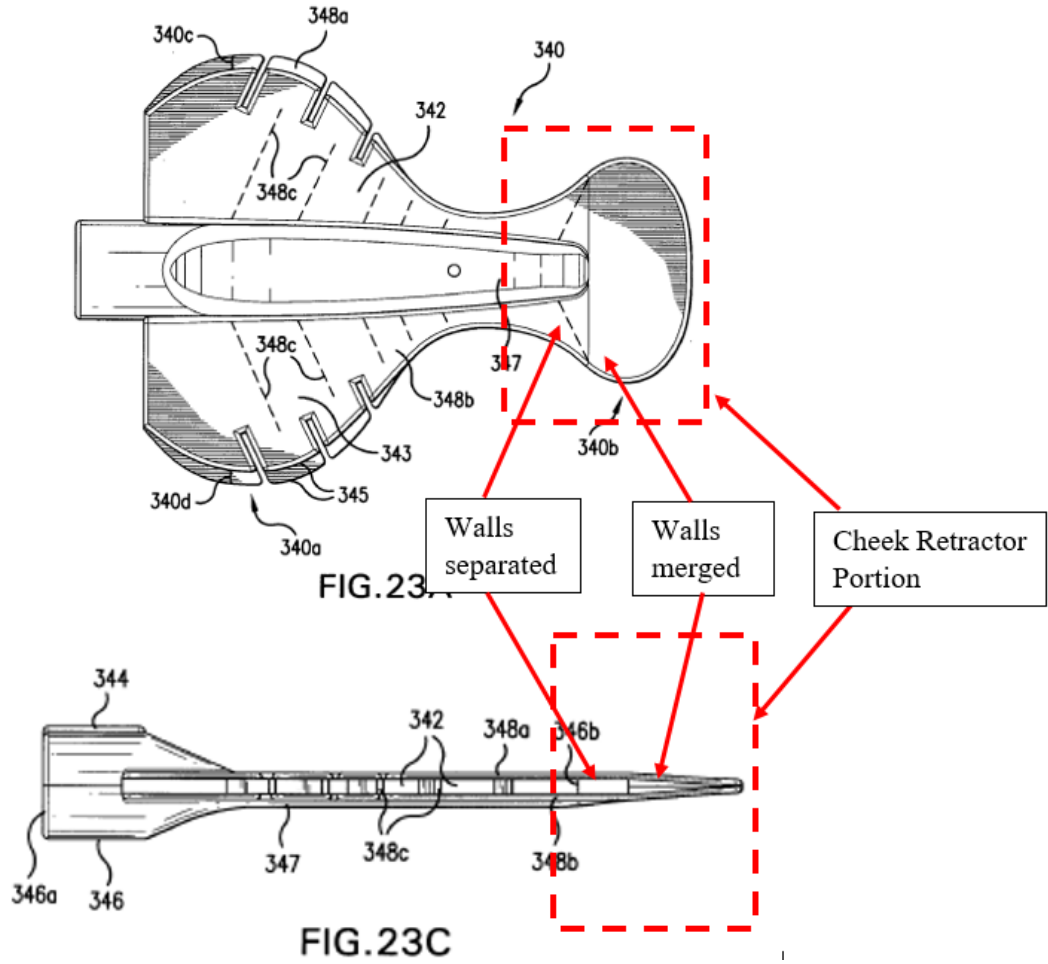
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for a distance within the cheek retractor portion before being connected to each other in the cheek retractor portion.”

126. Referring to FIG. 23C, Black shows that the anterior layer 348a and the posterior layer 348b transition into the second flap 340b (cheek retractor). The layers remain separated for a short distance after the narrowest portion of the isthmus (349) and then merge together to form the cheek retractor. As shown below, the cheek retractor portion (area in dashed) has the posterior layer 348a and the anterior layer 348b separated until they merge together part way through the dashed area.

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127. Exactly as I drew it above (again, I invented Black), Black describes the tongue shield aspirator 340 exactly as claimed: “In embodiments of the invention, the upper opening defined by the space between the top edges of the anterior and posterior layers, and the lower opening defined by the space between the bottom edges of the anterior and posterior layers may extend through the transition section 349 (as shown, e.g., in FIG. 23C) as well as at least a portion of the distal flap 340b.” EX1005, 15:14-20.

128. To the extent that Patent Owner argues that my dashed line definition of the “cheek retractor portion” is incorrect, I note that the specification defines the cheek retractor portion 130 as the part where the mouthpiece widens again after the narrow, “rectangular area”. EX1001, FIG. 1B. Indeed, the ’418 Patent specifically says that the narrow rectangular area is part of the “main body portion”. EX1001, 4:21-28, 5:22-27. Thus, defining the “cheek retractor portion” in Black as the point where the mouthpiece begins to widen again after the narrow isthmus 349 is entirely in-line with both the claim language (“a cheek-retractor portion connected to the narrower second end of the main body portion and expanding outwardly away from the second narrower end”) and the specification. Moreover, Black defines the transition section 349 as “the narrowest section of the tongue shield aspirator”. EX1005, 14:9-14.

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129. Regardless, an anterior wall and a posterior wall joining together midway through a cheek retractor portion is clearly taught by Black.

5. **Claim 5: “5. The isolation mouthpiece of claim 4, wherein at least one of the first plurality of perforations and at least one of the second plurality of perforations are located adjacent to the second end and near the cheek retractor portion.”**

130. See paragraph 124-125.

6. **Claim 6: “6. The isolation mouthpiece of claim 1, wherein the cutout has a shield shape.”**

131. See paragraphs 109-114.

132. Hirsch teaches that the slots 630 are generally rectangular. EX1012, FIG. 19E. It would have been obvious to a POSA to modify the rectangular slots 630 of Hirsch to have a shape of a shield logo, as such a change would just change the shape of the slots 630. I have been told by counsel that such changes in only shape are considered obvious in view of MPEP 2144.04(IV)(B).

7. **Claim 7: “7. The isolation mouthpiece of claim 1, wherein the cutout has a triangular shape.”**

133. See paragraphs 109-114.

134. Hirsch teaches that the slots 630 are generally rectangular. EX1012, FIG. 19E. It would have been obvious to a POSA to modify the rectangular slots 630 of Hirsch to have a triangular shape, as such a change would just change the

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shape of the slots 630. I have been told by counsel that such changes in only shape are considered obvious in view of MPEP 2144.04(IV)(B).

8. **Claim 8: “8. The isolation mouthpiece of claim 1, further including a stability bar located along a center aligned with a longitudinal axis of the first wall at least adjacent to the second end of the main body, at least one of the first plurality of perforations being positioned along one edge of the second wall and at least one of the second plurality of perforations being positioned along another edge of the second wall.”**

135. Black teaches a tongue shield aspirator 340 that includes a longitudinal stiffener 347 that prevents kinking when the tongue shield is flexed and/or bent for placement within the oral cavity. EX1005, 15:63-16:37, FIG. 23A. In other words, the stiffener 347 reinforces at least a portion of the main body, and in particular, reinforces the cheek retractor to help provide the necessary force to retract cheek tissue. The stiffener 347 corresponds to a thickened area of the main body and extends along a longitudinal axis of the main body. EX1005, FIG. 23A. In Black, stiffener 347 extends from an outer surface of the anterior layer 348b — not between the first and second walls.

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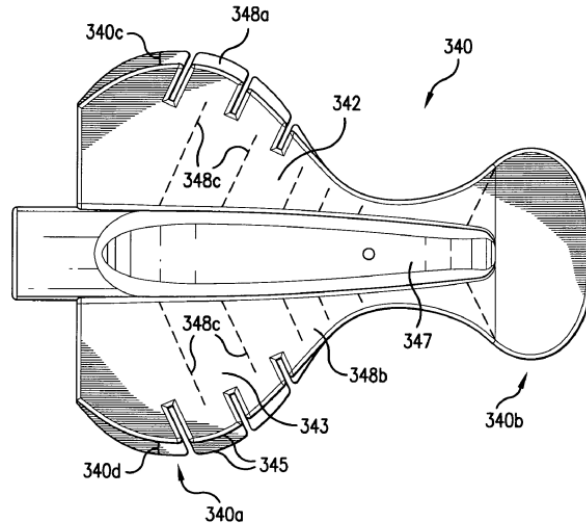


FIG. 23A

136. Hirsch illustrates a spine 365 running down the longitudinal axis of the mouthpiece and extending between the first wall and the second wall. EX1012, ¶ 78. The spine also provides reinforcement at the cheek retractor and helps retract cheek tissue.

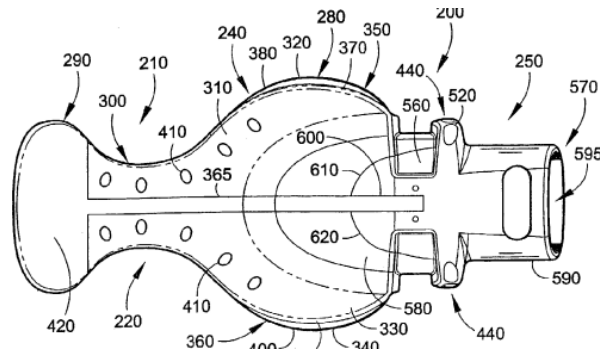


FIG. 19A

137. A POSA would have been motivated to include the spine of Hirsch in the tongue shield aspirator 340 of Black to increase rigidity of the tongue shield aspirator 340 to assist with retracting cheek tissue. EX1005, 15:63-67. The spine

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365 would provide added anti-collapse rigidity and also increased cheek retraction force to the tongue shield aspirator 340 of Black. A POSA would know that the spine could replace the transverse walls 348 comprising the longitudinal lumen running down the center of the mouthpiece and could strengthen those walls near the transition section 349 leading up to the second flap 340b (cheek retractor), thereby providing more rigidity and more cheek retraction force to push cheek tissue away from the dental procedure work area. EX1005, 14:1-20. In fact, including the spine 365 of Hirsch into the tongue shield aspirator 340 of Black could also simply be seen as moving the stiffener 347 to extend from an inner surface of the anterior layer 348b (where it would extend towards the posterior layer) and not an exterior surface.

138. Hirsch illustrates a spine 365 running down the center of the mouthpiece and extending between the first wall and the second wall. EX1012, ¶ 78. It is not clear what Patent Owner meant by the limitation that the stability bar is “at least adjacent to the second end of the main body.” As best as I can tell, Patent Owner means that the stability bar is present near the second end of the main body portion. As can be seen in FIG. 19A, the spine 365 extends through the second narrower end of the main body portion of the mouthpiece, thus fulfilling this limitation. It can also be seen in FIG. 19A that at least one of the first plurality of perforations is positioned on one side (the top side) of the spine and the at least one

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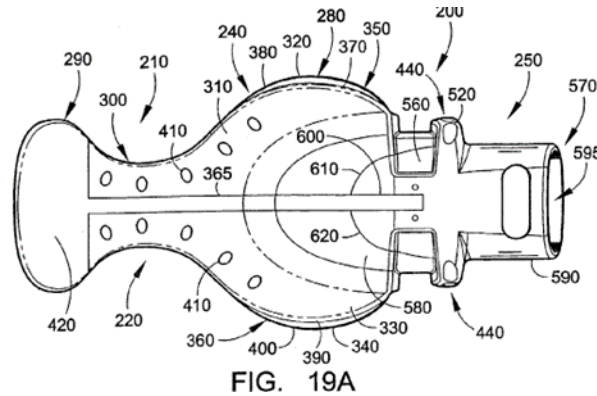
EX1003

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of the second plurality of perforations is positioned on another side (the bottom side) of the spine.



139. A POSA would have been motivated to include the spine of Hirsch into the tongue shield aspirator 340 of Black to increase rigidity of the tongue shield aspirator 340. The spine 365 would provide added anti-collapse rigidity throughout the center of the tongue shield aspirator 340 of Black.

9. **Claim 9: “9. The isolation mouthpiece of claim 8, wherein the stability bar extends upwardly from the second wall toward the first wall.”**

140. See paragraphs 135–139.

10. **Independent Claim 11**

a. **Preamble/Limitation 11(a): “An isolation mouthpiece for use with a suction system in a dental procedure, the isolation mouthpiece comprising:”**

141. See paragraphs 81–82.

b. **Limitation 11(b): “a main body portion having a first end and a second end, the main body portion including:”**

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142. See paragraph 83.

- c. **Limitation 11(c): “a first wall having a first shape defined by first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion,”**

143. See paragraph 84.

- d. **Limitation 11(d): “a second wall having a second shape defined by third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a first plurality of perforations extending along a portion of the third edge, and a second plurality of perforations extending along a portion of the fourth edge,”**

144. See paragraphs 85-91.

- e. **Limitation 11(e): “wherein a plurality of crests of a wave-like structure is formed on an interior surface of the second wall to provide contact points with the first wall, and a plurality of troughs of the wave-like structure provides gaps between adjacent ones of the plurality of crests for allowing the suctioning of fluid through the plurality of troughs, and”**

145. See paragraphs 92-98.

- f. **Limitation 11(f): “a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall,”**

146. See paragraphs 104-107.

- g. **Limitation 11(g): “wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion, wherein a portion of the**

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second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width, and wherein the third width is greater than the fourth width;”

147. See paragraph 108.

- h. **Limitation 11(h): “a suction connector portion extending from the first end of the main body portion, the suction connector portion including: a tubular conduit including an opening extending through the conduit and in fluid communication with the plurality of troughs of the wave-like structure, the opening being configured to receive a vacuum portion of the suction system therein, and”**

148. See paragraph 109–114.

- i. **Limitation 11(i): “a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second side each including a plurality of ridges; and”**

149. See paragraphs 115–117.

- j. **Limitation 11(j): “a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges, wherein the first wall and the second wall of the main body portion that transition into the cheek retractor portion are spaced apart from each other for a distance within the cheek retractor portion before being connected to each other in the cheek retractor portion.”**

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150. See paragraphs 126–129.

11. **Claim 12: “12. The isolation mouthpiece of claim 11, wherein the tubular conduit includes a cutout configured to engage a protrusion on the suction system to aid in coupling the isolation mouthpiece to the suction system.”**

151. See paragraphs 112-114.

12. **Claim 13: “13. The isolation mouthpiece of claim 11, wherein the first plurality of perforations includes five perforations and the second plurality of perforations include five perforations.”**

152. See paragraphs 120–123.

13. **Claim 14: “14. The isolation mouthpiece of claim 13, wherein the at least one of the first plurality of perforations and the at least one of the second plurality of perforations are located adjacent to the second end and near the cheek retractor portion.”**

153. See paragraphs 124–125.

14. **Claim 15: “15. The isolation mouthpiece of claim 11, wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds in shape to the third edge of the second wall and the second edge of the first wall corresponds in shape to the fourth edge of the second wall.”**

154. See paragraphs 99–103.

15. **Claim 16: “16. The isolation mouthpiece of claim 11, further including a stability bar located along a center aligned with a longitudinal axis of the first wall at least adjacent to the second end of the main body, at least one of the first plurality of perforations being positioned along one edge of the second wall and at least one of the second plurality of perforations being positioned along another edge of the second wall.”**

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155. See paragraphs 135–139.

16. **Claim 17: “17. The isolation mouthpiece of claim 16, wherein the stability bar extends upwardly from the second wall toward the first wall.”**

156. See paragraph 140.

17. **Claim 19: “19. The isolation mouthpiece of claim 11, wherein a wall thickness within the suction connector portion is greater than a wall thickness of the first wall or the second wall of the main body.”**

157. See paragraph 130.

C. **Ground 2: Claims 20-22 and 24-28 are obvious under 35 U.S.C. 103 by Park in view of Baughan and Johnson.**

158. It is my opinion that Park in view of Baughan and Johnson discloses all of the limitations of claims 20-22 and 24-28.

1. **Independent Claim 20**

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

159. 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

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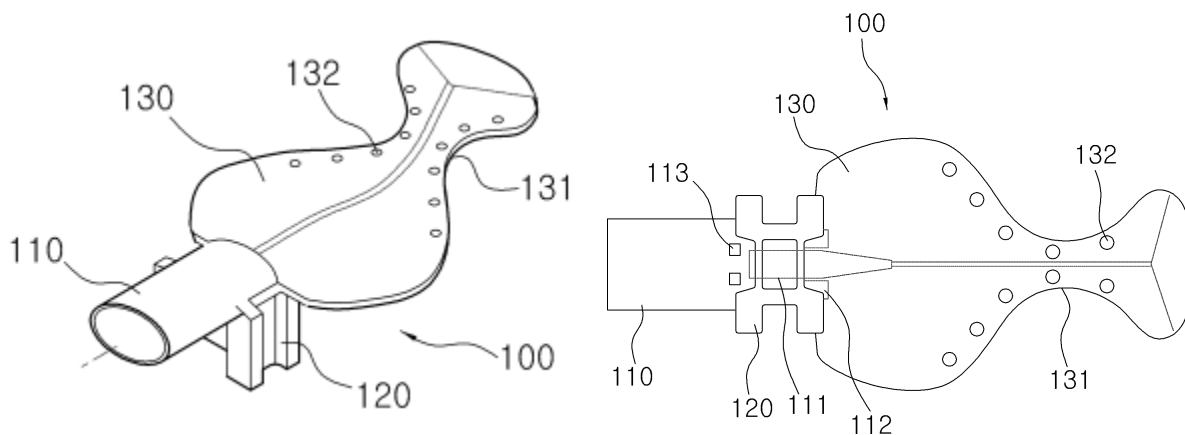
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intended to do, i.e., be a mouthpiece, use the mouthpiece with a suction system, and use the mouthpiece in a dental operation.

160. To the extent the preamble is limiting, Park discloses a mouth prop 100, which is a mouthpiece. EX1006, ¶¶ 25-26. Park teaches that the mouth prop 100 connects to a suction device during a dental procedure. EX1006, ¶¶ 42-43, 51.

- b. **Limitation 20(b): “a main body having a first end opposite a second end that is narrower than the first end, the main body comprising:”**

161. Park teaches a mouth prop 100 with the same general shape and configuration as the '418 Patent (and many others in this dental isolation mouthpiece field). EX1006, FIGS. 1-3. Park teaches a tongue retractor 130, which is the wider portion of the mouth prop 100 that fits in the patient's intraoral cavity. EX1006, ¶ 26. This retractor 130 is a main body portion.



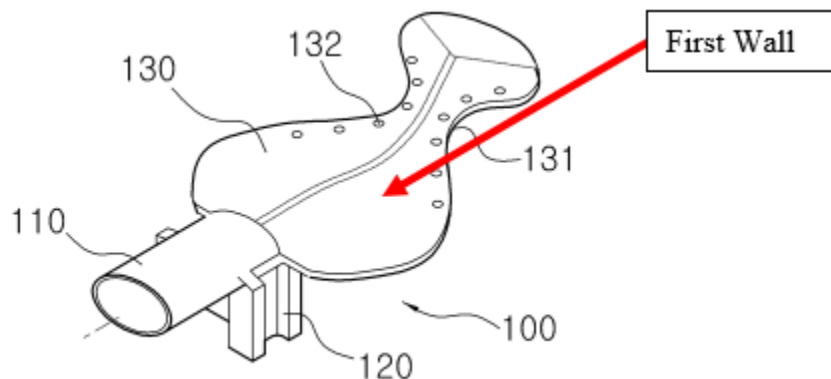
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162. Park shows that the tongue retractor 130 has a first end nearest to the insertion port 110 and a second end nearest the concave area 131, which is narrower than the first end. EX1006, FIG. 3.

- c. **Limitation 20(c): “a first wall that extends from the first end to the second end, wherein the first wall includes a plurality of first edges,”**

163. Park teaches a first wall that has a plurality of edges on the tongue retractor 130. EX1006, FIG. 2. A POSA would know that every wall (unless perfectly circular) would extend from a first end (near insertion port 110) to a second end (near concave portion 131). As shown in FIG. 2, Park shows the first wall of the tongue retractor 130 extending from a first end near the insertion port 110 to a second end near the concave portion 131.

164. The first wall is the anterior wall best seen by FIG. 2.

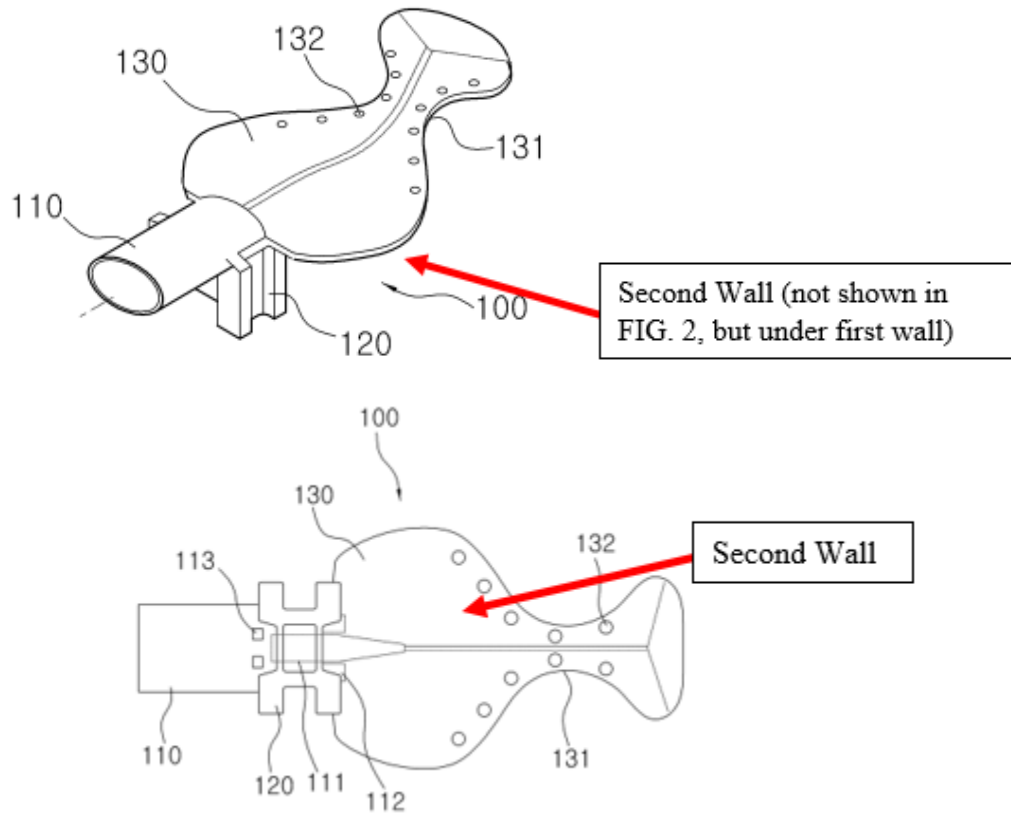


- d. **Limitation 20(d): “a second wall that extends from the first end to the second end, wherein the first wall and the second wall define an interior space therebetween, and wherein the second wall includes a plurality of second edges,”**

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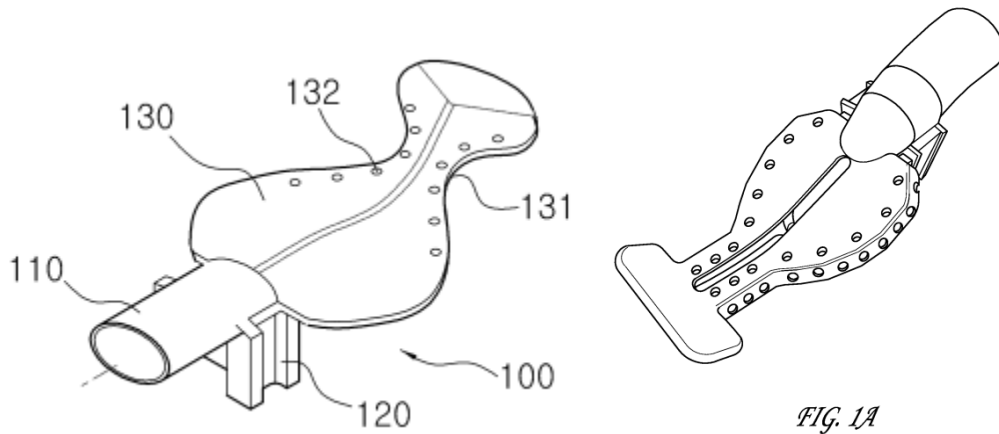
165. Park teaches a second wall identical in shape and size to the first wall. EX1006, FIGS. 2, 3. Since the second wall is identical to the first wall, it also has edges, extends from the first end to the second end, and is narrower at the second end (near concave portion 131) than the first end (near insertion port 110).

166. The second wall is the posterior wall best seen by FIG. 3.



167. Park also discloses an enclosed mouth prop 100 with four sides: a posterior wall, an anterior wall, and sidewalls connecting the posterior wall to the anterior wall along the sides and ends of the tongue retractor 130 and a concave portion 131, which is a similar design as the '418 Patent. EX1006, FIG. 2.

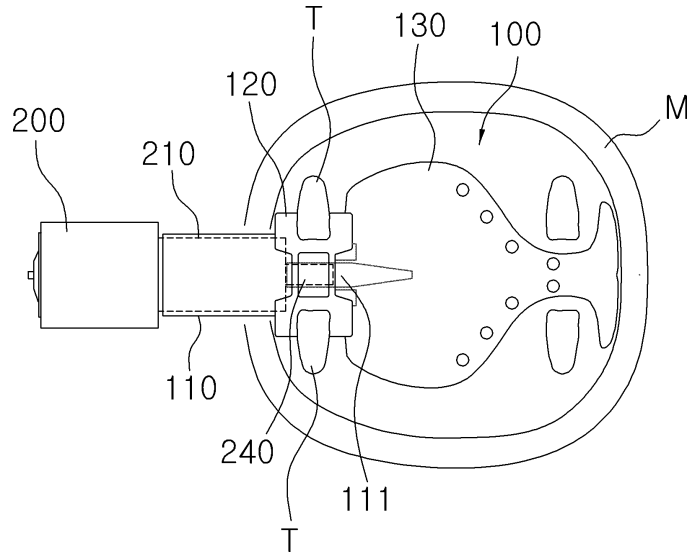
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168. Park clearly shows an enclosed mouth prop 100 with sidewalls in FIGS. 1-3. Patent Owner may argue that the mouth prop 100 of Park is too thin to have an interior space or that the mouth prop 100 of Park is just a single flap (i.e., one wall). However, a POSA would know that cannot possibly be the case because the mouth prop 100 of Park includes holes 132. EX1006, ¶ 31. Holes in a mouthpiece, like the one shown in Park, are formed for only one purpose: suction. This is particularly true considering that the holes are formed near the portion of the mouthpiece where a dental procedure would occur. EX1016, 2:13-20.

169. A POSA would know that dental mouthpieces having the well-known, and widely implemented, configuration of Park, Black, Hirsch, and the '418 Patent are positioned in a patient's mouth like this: the suction connector side (110 in Park) would extend out one side of the patient's mouth (say, left side), and the cheek retractor side would extend into the patient's opposite cheek (continuing my example, right cheek). Park shows this in FIG. 6.

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Once placed, it is the cheek retractor side where the operation (drilling, filling, sealing, etc.) occurs. EX1016, 2:13-20. The upper and lower ridges behind the patient's molars would engage Park's concave part 131, and the dentist would perform a dental procedure on a tooth or teeth on that side of the mouthpiece. EX1016, 2:13-20; EX1005, 21:35-46.

170. So, for example, if a patient had a cavity on his right, lower molar (tooth number, say 31), the doctor would insert the mouth prop 100 of Park such that the concave part 131 would fit between the patient's upper and lower ridges behind the patient's right molars while the patient's left molars would engage the bite block 120 of Park. In the example of a dental filling procedure, a dentist would constantly spray the teeth with water during the drilling process to keep the teeth from significantly rising in temperature due to the friction caused by drilling. EX1016, 1:6-10. A POSA would know that a significant rise in tooth temperature

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could damage the underlying nerve, which might require a root canal treatment to repair. The spraying water splashes due to ejection from an air/water syringe and from the drill. Not only water, but also tooth material or blood can spray from drilling and other dental operations. Thus, a POSA would know to place suction holes near the location of the dental operation as this location is where most of the fluid and debris is being generated, and which need to be removed from the patient's oral cavity, which is exactly where Park placed holes. EX1006, FIG. 6.

171. If the holes 132 were simply holes, unconnected from the suction ports 112, these holes would serve no actual purpose. In fact, they would allow fluid and debris to pass through and into the throat of a patient: the specific thing that Park seeks to avoid. EX1006, ¶ 12. A POSA would further know that allowing any fluid or debris down a patient's throat or airway would cause patient discomfort or serious risk and should be prevented. EX1019, 4:16-21. Moreover, if the suction ports 112 did not suction through an interior chamber of the mouth prop 100 fluidly connected to the holes 132, then the suction ports 112 would be extremely inefficient, basically tasked with aspirating the entire oral cavity. Also, the positioning of the suction ports 112 would be located in the worst possible location, furthest from the location where unwanted fluid would accumulate due to the dental procedure. A POSA would know that a suction port is most efficient when positioned immediately adjacent to the fluid that should be aspirated.

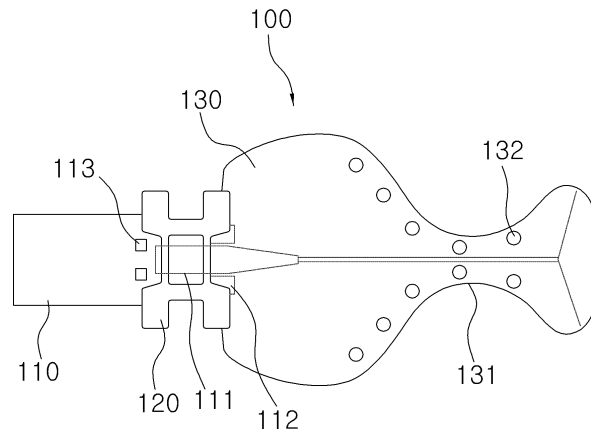
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EX1003

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172. Park teaches holes 132 that are formed on and near the concave area 131 (where the dental operation would occur). This positioning of the holes 132 is also far from the suction ports 112.



A POSA, knowing that suction is applied through the ports 112, would know that there is a fluid connection between the ports 112 and the holes 132 because the holes 132 must offer openings for suction of unwanted fluids, debris, etc. from the oral cavity. EX1006, ¶ 28. The only efficient fluid connection between the suction ports 112 and the holes 132 would be an interior cavity formed within the four walls of Park's mouth prop 100. Thus, a POSA looking at FIG. 2 would see the through holes 132 and the depicted sidewalls and know that there must be an interior chamber or space inside the mouth prop that provides a low-volume space that fluidly connects the holes 132 to the suction ports 112. This interior chamber or space is created due to the posterior wall being formed at a distance from the anterior wall. EX1006, FIG. 2.

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173. Additionally, I note that the specification of Park explains that the insertion port 110 extends into the tongue retractor 130, and only one side of the insertion port 110 is open. EX1006, FIG. 3, ¶¶ 27-28. If only one side of the insertion port 110 is open, then a POSA would understand that the other side is closed by the four walls of the tongue retractor 130. FIG. 3, which shows the suction ports 112 extending into the tongue retractor 130 further supports this conclusion.

174. Also, I note that the color of the lines representing the suction ports is slightly lighter than the lines denoting, for example, the edges of the mouth prop. A POSA would understand that this lighter shading indicates that these components are internal, and not completely visible from the exterior of the mouth prop 100. Or, they may be partially visible, since the mouth prop comprises clear silicone. EX1006, ¶ 32. I note that this difference in shading color was visible when I looked at Park on a computer screen. When I printed a copy of Park, the contrast was not easily detectable.

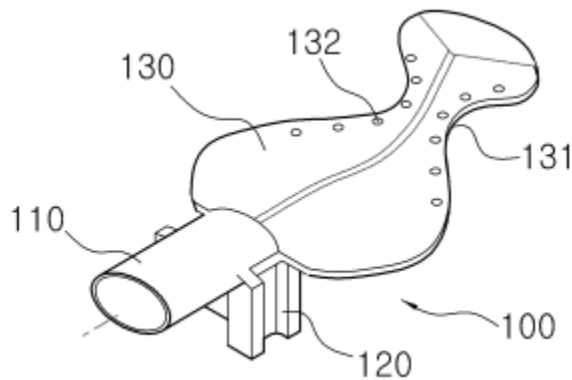
175. Furthermore, Park never mentions that suction can occur through the superior or inferior sides of the mouthpiece. In fact, looking at the mouth prop 100 in the figures, a POSA would know that suction only occurs at the holes 132.

176. The only logical reason why Park includes holes 132 is to provide inlets for suction, and the only way that the holes 132 can provide inlets for suction

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is to be fluidly connected to the suction ports 112, and the only way that the holes 132 can be efficiently fluidly connected to the suction ports 112 (i.e. no significant loss in suction) is through an interior chamber or space formed within the mouth prop 100. I have been informed by counsel that when a prior art reference clearly suggests a teaching to a POSA, then the prior art reference implicitly teaches that teaching. Here, a POSA would understand that Park, at worst, implicitly teaches a four-sided mouthpiece enclosing an interior space that fluidly connects the suction ports 112 to the holes 132.

177. Finally, to the extent Patent Owner argues that Park fails to teach sidewalls, a POSA would see that Park clearly depicts sidewalls in FIG. 2.



178. FIG. 2 shows a closed, continuous edge formed around the sides of the mouth prop 100. Indeed, the sidewall depicted even extends into the teeth support section 120 and the insertion port 110. The continuous wall shown extends

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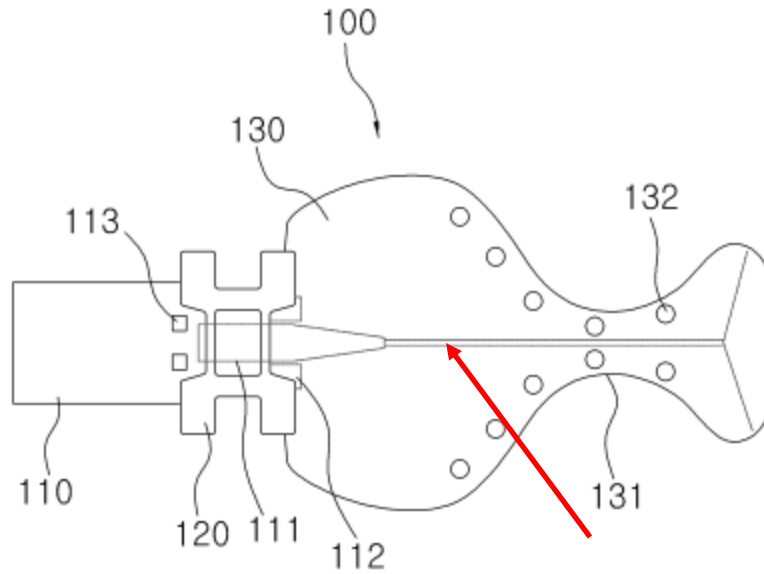
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from the sidewalls into the insertion port 110/teeth support section 120, thereby clearly depicting a continuous sidewall around the entire mouth prop 100.

- e. **Limitation 20(f): “wherein a plurality of crests is formed on an interior surface of the second wall to provide a plurality of contact points with the first wall, and wherein a plurality of troughs provide a plurality of gaps through which fluids can pass between the contact points, wherein the contact points are not attached to the first wall; and”**

179. Park is primarily focused on elements of the mouth prop related to lighting. EX1006. ¶¶ 1, 5-8. As such, Park fails to expressly describe or illustrate whether the mouth prop 100 includes any internal features that assist with suction or preventing collapse under suction. Park also notes that its description omits that which is conventional, such as anti-collapse structure. EX1006, ¶ 22. Park does illustrate what appears to be a light pipe extending through the mouth prop 100 (highlighted below), but it is unclear whether this is structural or simply something to assist with lighting.

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180. Nevertheless, Park does teach that suction occurs through the mouth prop 100 between the suction ports 112 and the holes 132. EX1006. ¶¶ 28, 43, 51. As explained above, a POSA would understand that a fluid connection exists through an interior chamber of the mouth prop 100 that exists between the suction ports 112 and the holes 132.

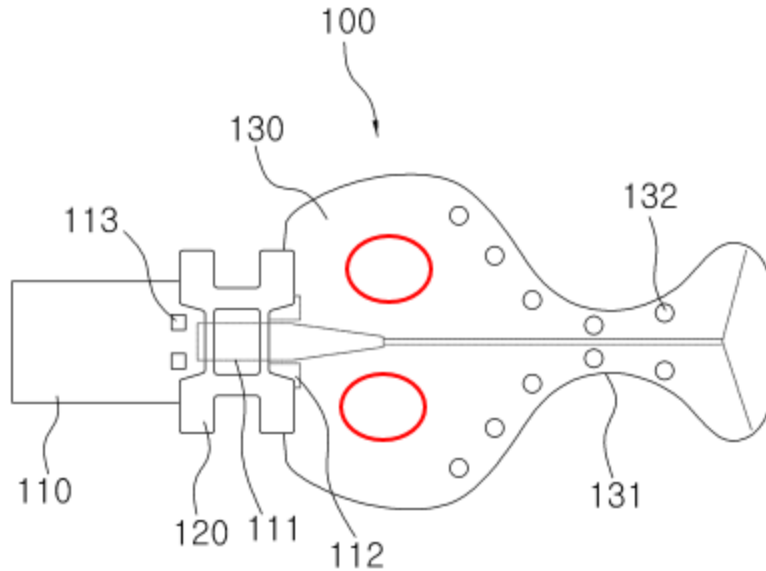
181. Knowing that suction pulls air and foreign substances through the holes and out the suction ports 112, a POSA would know that the anterior and posterior walls (first and second walls) are likely to collapse into each other due to the suction force applied by the external suction device 300. EX1006. ¶¶ 28, 42-43, 51; EX1007, 3:46-48. This is particularly true given how thin Park's mouth prop 100 appears and because the mouth prop is made of soft, flexible material.

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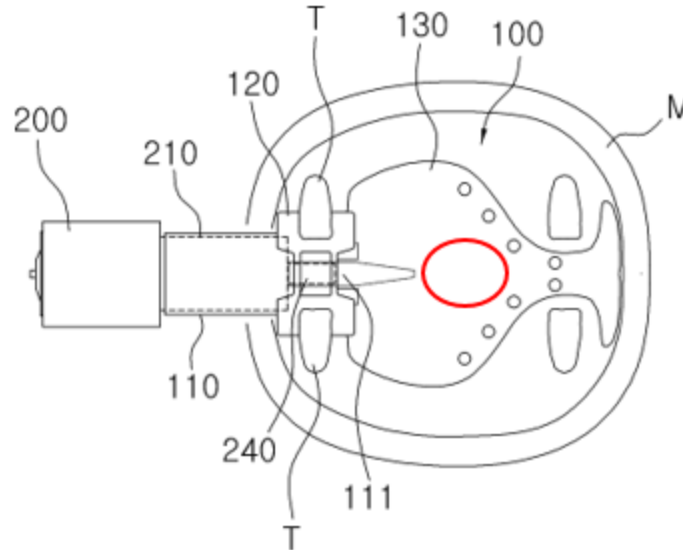
EX1006, ¶¶ 32, 34. A POSA would recognize this tendency to collapse because Park explains that the mouth prop 100 is made of silicone with “excellent tactile properties as well as a predetermined elasticity”. *Id.* Further still, a POSA would know that the mouth prop would tend to collapse at weak spots of the mouth prop because dental isolation mouthpieces must be folded into a patient’s mouth for insertion, and the roof and floor of a patient’s mouth would cause bending across the longitudinal axis of the mouthpiece. EX1005, 19:53-20:2, 20:15-20. The sidewalls would assist with preventing collapse under suction, but a POSA would know that there would still be weak points in the mouth prop 100 where collapse would occur under suction. A POSA would know that the locations most likely to collapse would be places furthest from anti-collapsing structure, such as sidewalls or a spine (if it exists). Looking at FIG. 3, a POSA would know that the two areas highlighted in red are most likely to collapse.

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182. The above assumes that there is a spine running down the symmetrical axis of the mouthpiece. If there were no spine, and the line depicted above is simply reflective material or the light for lighting purposes (a reasonable conclusion given that the line is not depicted in FIG. 6), then the weakest point would be in the center of the tongue retractor 130, which is highlighted in red below:

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183. Even if the areas identified above do not completely collapse, they may significantly narrow under suction due to the flexible nature of the mouth prop 100. EX1006, ¶ 32, 34. A POSA would recognize that a flexible, silicone mouth prop 100 would have weak spots that collapse or significantly narrow under suction, and a POSA would have been motivated to prevent complete collapse or significant narrowing at weak parts of the mouth prop using known anti-collapse structure. EX1007, 3:43-48. Indeed, preventing collapse would be applying a known technique (anti-collapse structure) to a known device ready for improvement (the mouth prop 100 of Park) to yield predictable results (preventing collapse at weak parts of the mouth prop 100 under suction).

184. Baughan teaches well-known anti-collapse structure in the form of outward projecting, spaced apart elements that provide a force opposite the suction

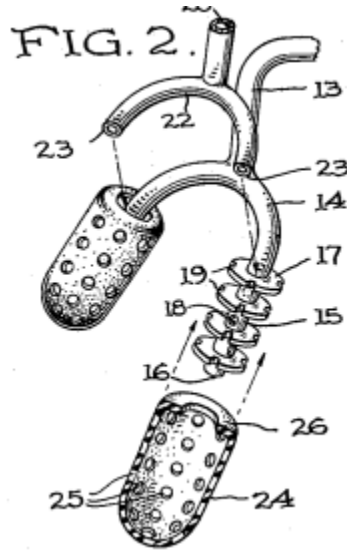
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force and still allow suction channels by spacing apart the elements. EX1007, 3:43-

48. Baughan teaches a suction tube 15 and a sleeve 24 to fits over the suction tube

15.

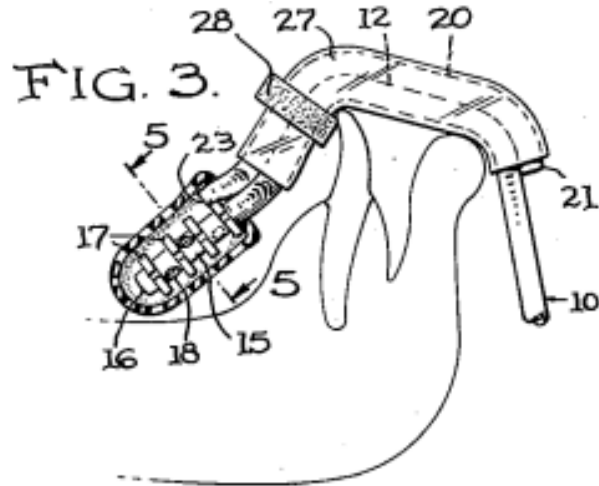


To prevent the flexible sleeve 24 from collapsing upon the tube 15, Baughan teaches three spaced-apart discs 17 that extend perpendicularly from the tube 15.

EX1007, 2:19-25, 2:51-55, 3:43-48. The discs 17 engage the sleeve and apply an anti-collapse force on the sleeve 24, thereby preventing its collapse under suction.

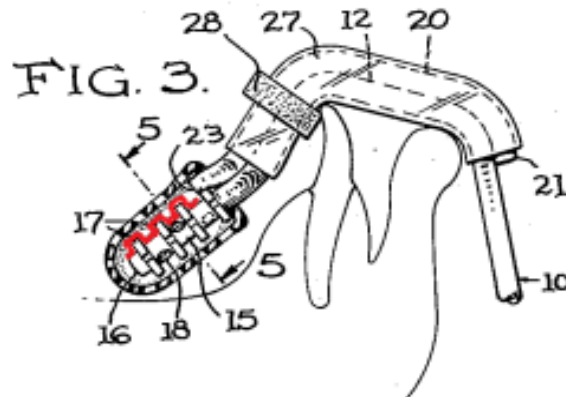
Id. The three discs are a plurality of protrusions protruding from an interior surface of the tube and extending a span between the tube 15 and the sleeve 24. EX1007, 2:19-25, 2:51-61.

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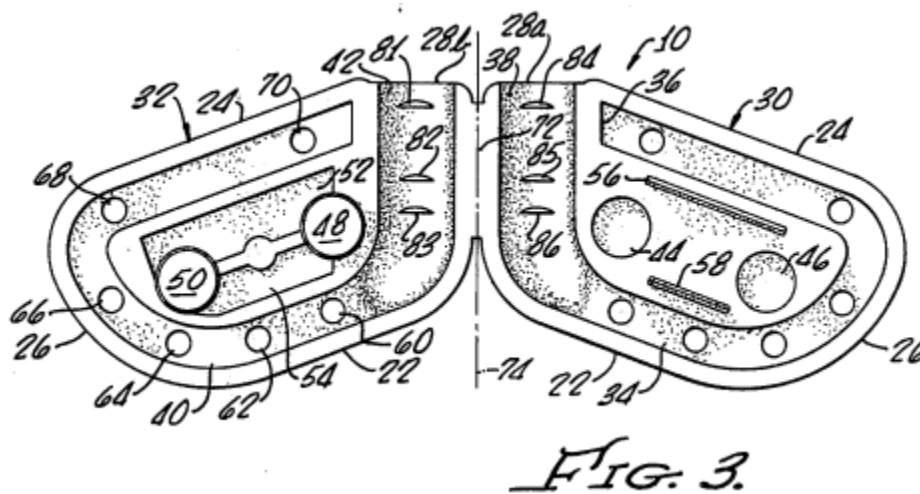
Thus, Baughan teaches a wave-like structure (discs 17) that includes a plurality (3) of protrusions protruding from an interior surface of the second wall (tube 15) and extending a span between the second wall (tube 15) and the first wall (sleeve 24), and the wave-like structure (discs 17) is not attached to the first wall (sleeve 24).

185. The spaced-apart discs 17 of Baughan protrude from a surface of the tube 15 in a wave shape with three crests (rings) and at least two troughs (space between rings). EX1007, FIG. 3 (annotated). A square wave shape is a wave-shape.



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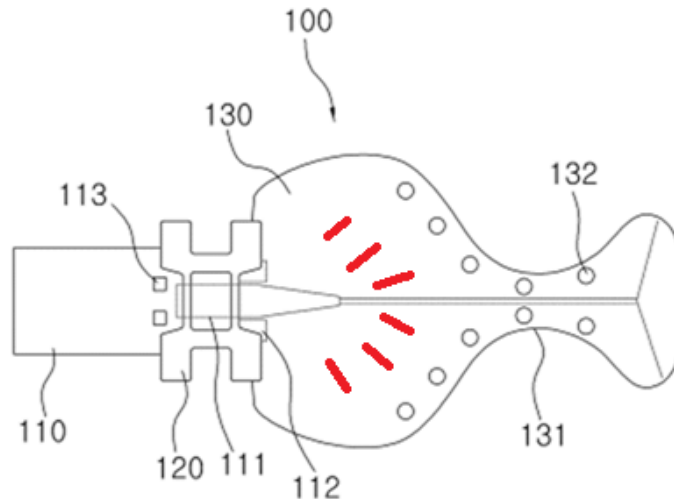
186. Baughan teaches an anti-collapse structure for a cylindrical, tube-shaped implementation. In this context, circular discs 17 make perfect sense. However, Baughan teaches that the discs are formed at a right angle to the tube 15. EX1007, 2:23-25. So, Baughan stands for the proposition that upward projecting elements at right angles to an underlying wall prevent collapse from a covering wall. EX1007, 2:19-25, 2:51-55, 3:43-48. Using only common sense, a POSA would know to convert the discs into basic flat projections for a non-tube implementation. Even though basic common sense is all that is required to apply the cylindrical anti-collapse structure to a flat anti-collapse structure, other prior art teach exactly how to form such projections. For example, Johnson shows how to form projections 81-86 on a flat surface 40 for dental application. EX1008, 4:16-23, FIG. 3.



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187. I should note that the discs 17 are essentially the exact same concept I taught in Black when I taught the transverse walls. The transverse walls were formed perpendicularly to the underlying wall, and prevented collapse under suction. EX1005, 5:54-59.

188. Applying the teachings of Baughan and Johnson, which are very old and clearly conventional (disclosed in the 1960s and 70s), a POSA could have easily included a plurality of spaced apart projections formed on the posterior wall of Park to prevent collapsing of the posterior and anterior wall under suction at the weakest points of the mouth prop 100, which is shown above in the tongue retractor 130. The result of adding projections to weak spots of Park would look like this:



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A POSA would know that the projections could be formed at any angle, including parallel to the lighting line running through the symmetrical axis of the mouthpiece. A POSA would further know that aligning the projections with the locations of the holes 132 would form a convergent flow, which would best allow for suction through the suction ports 112. EX1005, 8:21-39.

189. A POSA would have expected success in adding spaced-apart projections to the weak points of Park because these basic and conventional features were well-known to prevent collapse while still forming channels for suction between the projections. This is exactly what Baughan taught. EX1007, 2:19-25, 2:51-55, 3:43-48. Addition of spaced-apart projections to the weak spots of Park would have predictably prevented collapse or significant, restrictive narrowing of suction at weak points of the mouth prop 100 of Park while still forming suction channels between the formed projections. The combination of Baughan/Johnson to Park would be applying a known technique (anti-collapse structure) to a known device ready for improvement (the mouth prop 100 of Park) to yield predictable results (preventing collapse at weak parts of the mouth prop 100 under suction) or combining prior art elements (a mouth prop having an interior chamber) according to known methods (using spaced-apart projections to prevent collapse under suction) to yield predictable results (the projections would prevent collapse under suction and still allow for suction channels therebetween).

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EX1003

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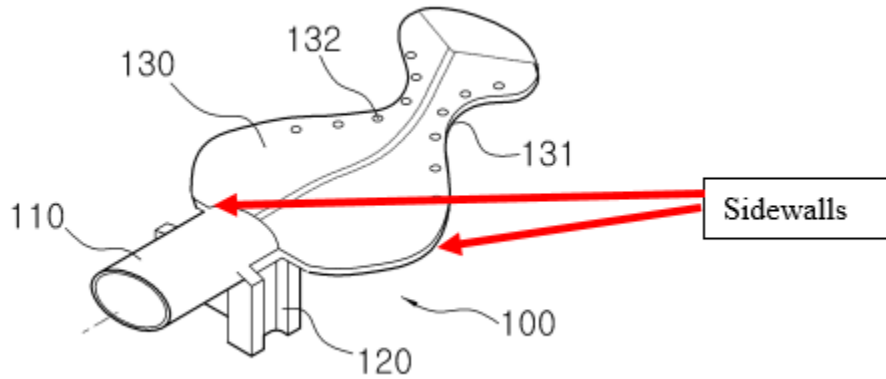
190. I mentioned above the projections could be formed on the posterior wall, but a POSA would know that the projections could be formed just as easily on the anterior wall. It makes no difference which wall receives the projections so long as the projections remain spaced apart and project toward the opposite wall. For example, a POSA would understand that the sleeve 24 of Baughan could just as easily include circular discs extending from the sleeve 24 and unconnected to the tube to serve the same function. Moreover, the size of the projections could be adjusted to ensure proper flow and anti-collapse, as I have been informed by counsel that changes in size/proportion are generally not patentable changes.

191. So, it would have been obvious to include an anti-collapse wave-like structure having a plurality of protrusions connected to a second wall and spanning toward the first wall in the mouth prop of Park in view of the basic and well-known teachings of Baughan and Johnson to predictably result in the mouth prop 100 having projections formed in weak spots shown above.

f. **Limitation 20(f): “a third wall that connects one of the first edges of the first wall to one of the second edges of the second wall; and”**

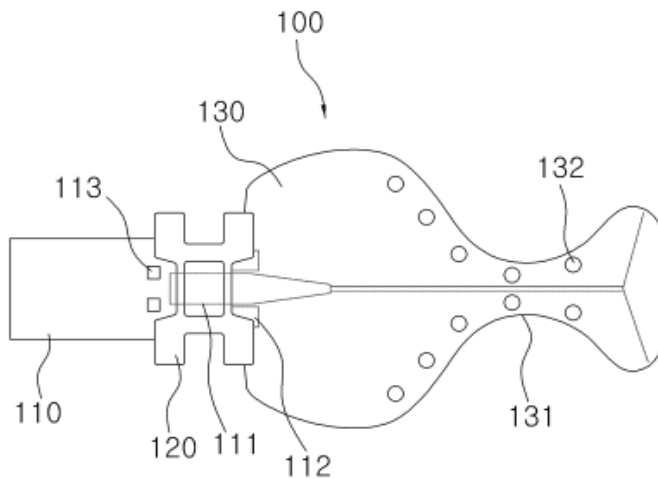
192. As explained above, Park shows a sidewall (“third wall”) that connects all edges of the anterior wall and the posterior wall. EX1006, FIG. 2.

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g. **Limitation 20(g): “a cheek retractor portion extending from the second end and connected to the first wall and the second wall of the main body.”**

193. Park teaches a concave section 131 (narrower second end) that connects to a cheek retractor, formed to the right of the concave section and expanding outwardly away from the second narrower end. EX1006, ¶ 31, FIGS. 1-3.



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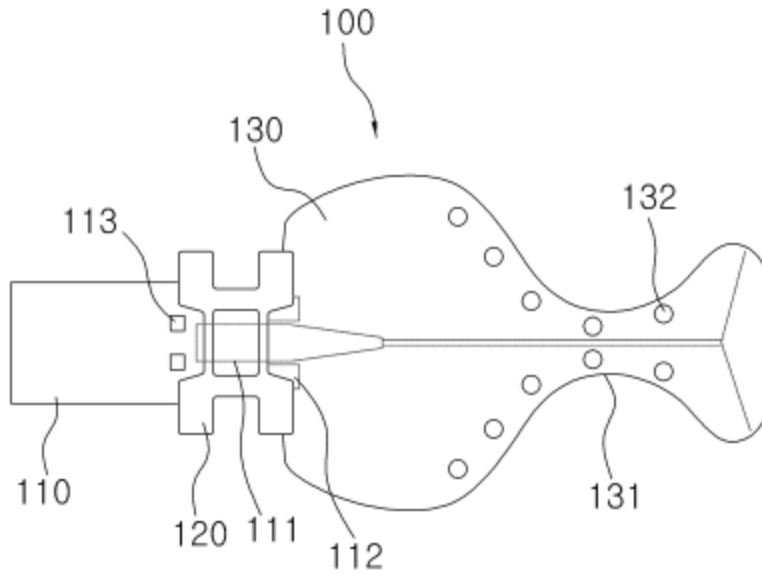
194. Thus, Park in view of Baughan and Johnson teaches each and every limitation of claim 1.

2. **Claim 21: “21. The mouthpiece of claim 20, further comprising a suction connector extending from the first end of the main body, wherein an evacuation conduit within the suction connector is in communication with the interior space between the first wall and the second wall.”**

195. Park teaches that an insertion port 110 connects the interior space, via suction ports 112, to a device body 200, and the device body 200 includes a suction line 260 that connects to an external suction device 300. EX1006, ¶¶ 26-27, 42. Park explains that the mouth prop 100 suctions fluids through the suction ports, which are connected to the holes 132 through the interior space of the mouth prop 100, which I explained above. EX1006, ¶¶ 31, 43. Park shows that the insertion port 110 extends from the first end of the main body portion. EX1006, Abstract.

196. Park teaches that the insertion port 110 is hollow, which means that the insertion port 100 has an evacuation conduit. EX1006, ¶ 27. Park further teaches that the insertion port has an open end, and that the insertion port 110 connects to suction ports 112 that are shown as extending into the tongue retractor 130. EX1006, ¶¶ 27-28. Thus, Park teaches exactly the suction connector described by this claim limitation.

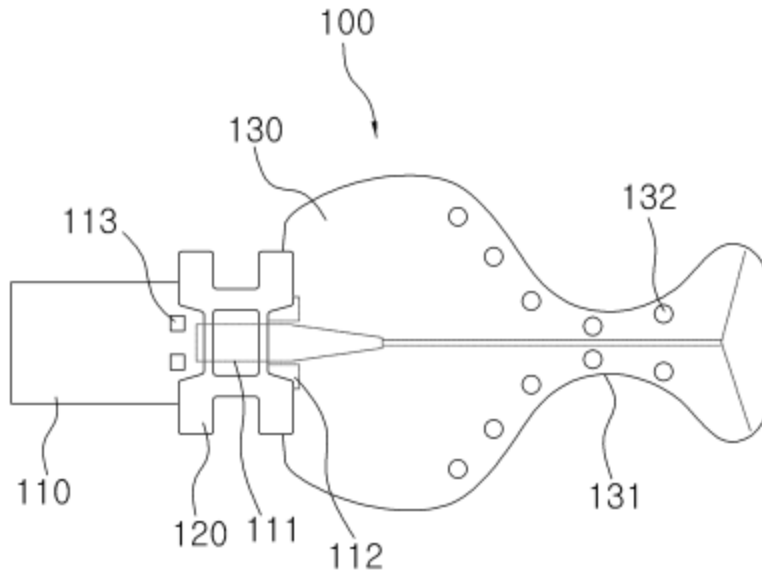
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3. **Claim 22: “22. The mouthpiece of claim 21, wherein the suction connector further includes a cutout configured to interlock with a corresponding protrusion of a vacuum adapter.”**

197. Park teaches a projection hole 113 formed such that a locking projection 211 formed on the vacuum adapter 200 can pass downward through it. EX1006, ¶ 35. A POSA would understand that these holes 113 for receiving a projection on the vacuum adapter 200 is an interlocking fit.

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4. **Claim 24: “24. The mouthpiece of claim 20, wherein a material used to form the main body is a flexible, translucent, high heat-resistant, autoclavable silicone-based material.”**

198. Park teaches a flexible, transparent, autoclavable, silicone material.

EX1006, ¶¶ 32, 49. A POSA would know that silicone is high heat-resistant because it is autoclavable.

5. **Claim 25: “25. The mouthpiece of claim 20, further comprising a mouth prop injection-molded in one piece.”**

199. Park teaches a mouth prop formed in one piece. EX1006, ¶ 32. Park explains that the mouth prop 100, as a whole, is detachable from the device body 200 and sterilized as one piece. EX1006, ¶ 53. Forming silicone is commonly performed using injection molding, and injection molding would have been a well-

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known option for a POSA. EX1008, 4:16-23, 5:20-22. Thus, a POSA would

understand that the entire mouth prop 100 is formed as one piece.

6. **Claim 26: “26. The mouthpiece of claim 25, wherein the mouth prop is connected to a suction connector.”**

200. Park teaches a tooth support section 120 (mouth prop) connected to the insertion port 110 and formed into one piece with the rest of the mouth prop 100. EX1006, ¶¶ 29, 32, 54, Abstract, FIG. 1-3.

7. **Claim 27: “27. The mouthpiece of claim 26, wherein at least one of the cheek retractor and the suction connector is integral with the main body.”**

201. Park teaches that the entire mouthpiece, which includes the tongue retractor 130, the insertion port 110, and the cheek retractor is formed into one piece. EX1006, ¶¶ 29, 32, 54, Abstract, FIG. 1-3.

8. **Claim 28: “28. The mouthpiece of claim 20, wherein the plurality of perforations are distributed along one or more of the second edges of the second wall.”**

202. Park teaches a plurality of holes distributed along edges of both the anterior and posterior wall. EX1006, ¶ 31, FIG. 1-3.

- D. **Ground 3: Claims 1–9, 11–17, and 23 are obvious under 35 U.S.C. 103 by Park in view of Baughan, Johnson, and Hirsch.**

203. It is my opinion that Park in view of Baughan, Johnson, and Black teaches all of the limitations of claims 1–9, 11–17, and 23.

1. **Independent Claim 1**

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- a. **Preamble/Limitation 1(a): “1. An isolation mouthpiece for use with a suction system in a dental procedure, the isolation mouthpiece comprising:”**

204. See paragraphs 159–160.

- b. **Limitation 1(b): “a main body portion having a first end and a second end, the main body portion including:”**

205. See paragraphs 161–162.

- c. **Limitation 1(c): “a first wall having a first shape defined by a first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion,”**

206. See paragraphs 163–164.

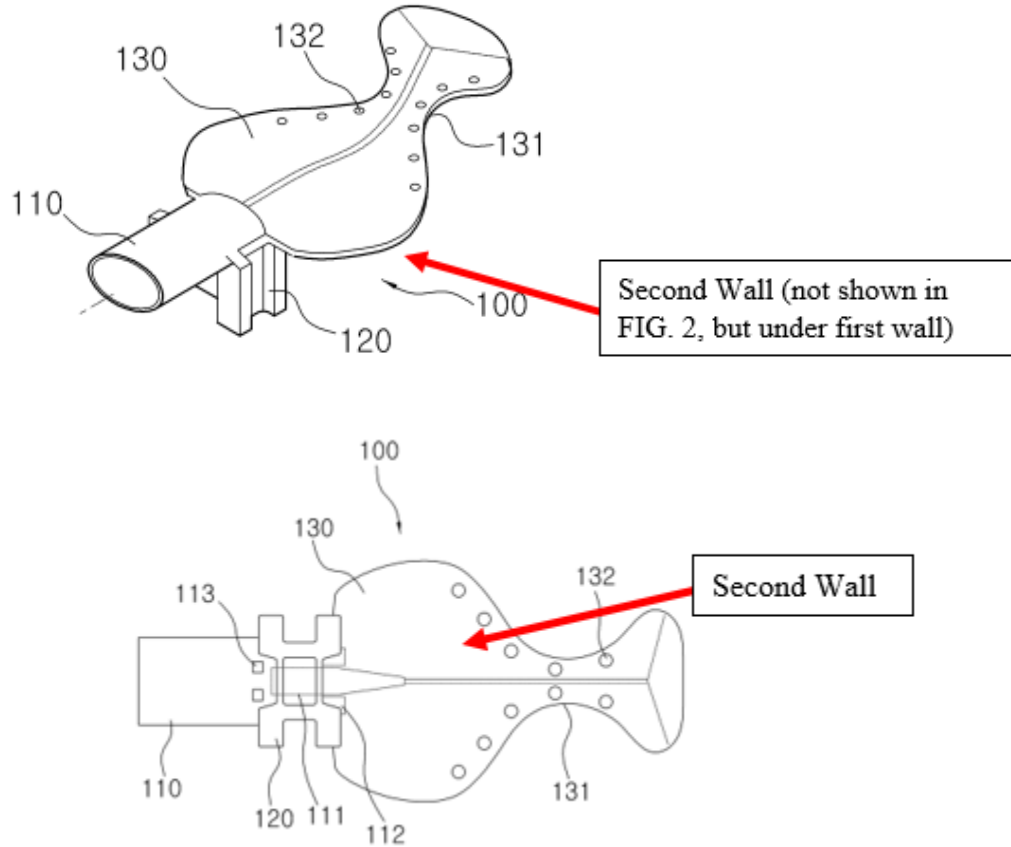
- d. **Limitation 1(d): “a second wall having a second shape defined by third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a first plurality of perforations extending along a portion of the third edge, and a second plurality of perforations extending along a portion of the fourth edge,”**

207. Park teaches a second wall identical in shape and size to the first wall.

EX1006, FIGS. 2, 3. Since the second wall is identical to the first wall, it also has edges, extends from the first end to the second end, and is narrower at the second end (near concave portion 131) than the first end (near insertion port 110).

208. The second wall is the posterior wall best seen by FIG. 3.

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209. Further, Park illustrates holes 132 formed in the posterior wall. EX1006, FIG 3. Thus, Park teaches a third plurality of perforations formed adjacent to and extending along a portion of the first edge of the posterior wall, and a second plurality of perforations formed adjacent to and extending along a portion of the fourth edge of the posterior wall. EX1006, ¶ 31, FIG 2. A POSA would understand that these holes 132 are perforations. *See also* Paragraphs 165–178.

- e. **Limitation 1(e): “wherein a plurality of crests of a wave-like structure is formed on an interior surface of the second wall to provide contact points with the first wall, and a plurality of troughs of the wave-like structure provides gaps between adjacent ones of the**

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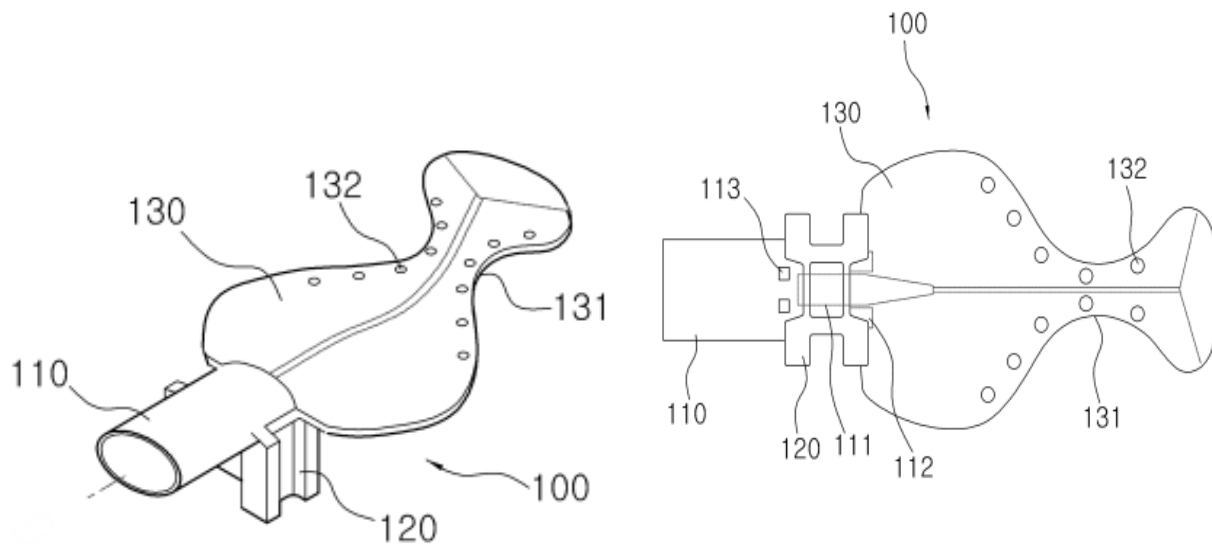
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plurality of crests for allowing the suctioning of fluid through the plurality of troughs;”

210. See paragraphs 179–191.

- f. **Limitation 1(f): “and wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds in shape to the third edge of the second wall and the second edge of the first wall corresponds in shape to the fourth edge of the second wall; and wherein the first shape of the first wall corresponds to the second shape of the second wall, and”**

211. Park illustrates that the anterior wall has the exact same size and shape as the posterior wall. EX1006, FIGS. 2-3. Therefore, Park teaches that the first wall and the second wall are shaped such that the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall.

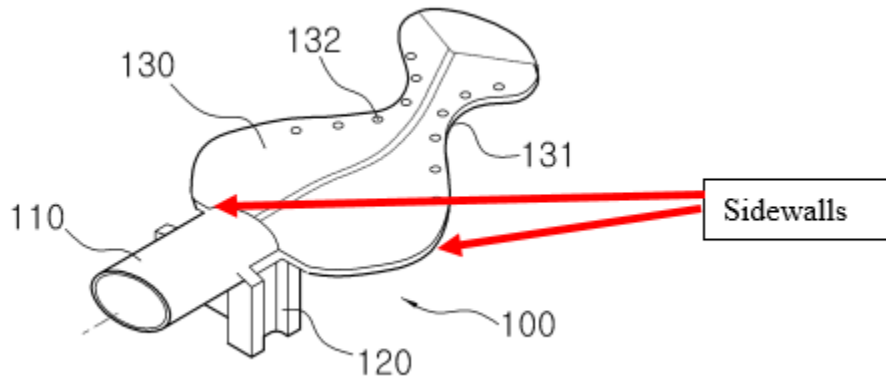


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- g. **Limitation 1(g): “a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall,”**

212. Park shows a sidewall that connects to the anterior wall and the posterior wall across the distance between these two walls. EX1006, FIG. 2.



213. As discussed in paragraphs 165–178, Park teaches that the first wall is spaced from the second wall to define an inner cavity.

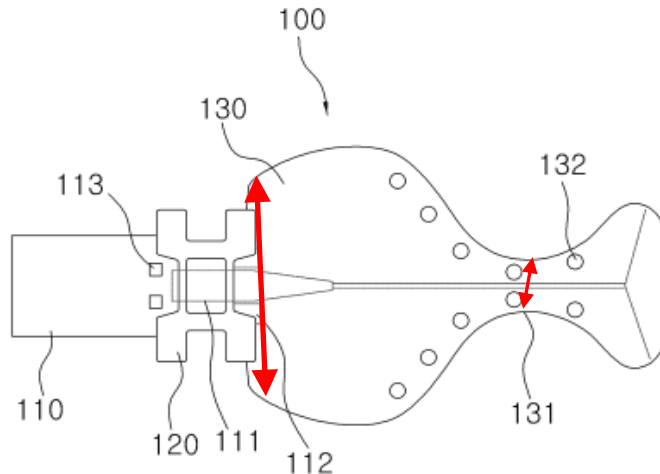
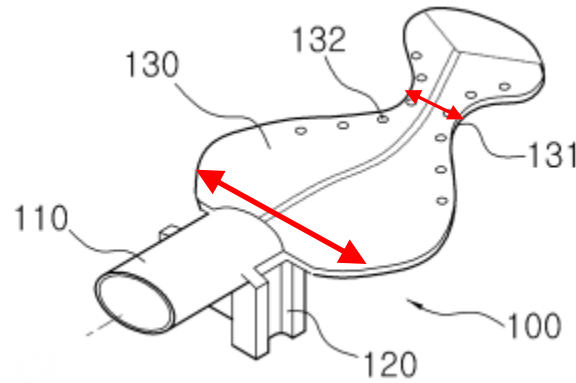
- h. **Limitation 1(h): “wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion, wherein a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width, and wherein the third width is greater than the fourth width;”**

214. Further, as shown in annotated FIGS. 2 and 3 below, Park teaches that (1) a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body

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portion; (2) a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion; (3) the first width is greater than the second width; and (4) the third width is greater than the fourth width.



- i. **Limitation 1(i):** “a suction connector portion extending from the first end of the main body portion, the suction connector portion including: a tubular conduit including an opening extending through the conduit and in fluid communication with the plurality of troughs of the wave-like structure, the opening being

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configured to receive a vacuum portion of the suction system therein, the tubular conduit further including a cutout configured to engage a protrusion on the suction system to aid in coupling the isolation mouthpiece to the suction system, and”

215. See paragraphs 195–196. After modified Park to have projections in view of Baughan and Johnson, the suction ports 112 and the insertion port 110 would be in fluid communication with all portions of the interior space, including the gaps between the formed anti-collapse projections.

- j. **Limitation 1(j): “a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second side each including a plurality of ridges; and”**

216. Park teaches a tooth support section 120 (mouth prop) with interlocking grooves formed on the upper and lower sides, allowing the patient's upper and lower teeth to interlock. EX1006, ¶ 29. Therefore, Park teaches a mouth prop including a first and second side that each include a plurality of ridges. It is unclear whether the first and second sides of the tooth support section 120 (mouth prop) of Park are tapered. Nevertheless, it would have been obvious to make the tooth support section 120 (mouth prop) tapered in view of Hirsch.

217. It should be noted that almost all bite blocks are designed in this way because it follows the natural shape of the mouth when it is open, which is smaller at the back of the mouth where the jaw hinges and wider at the front of the mouth

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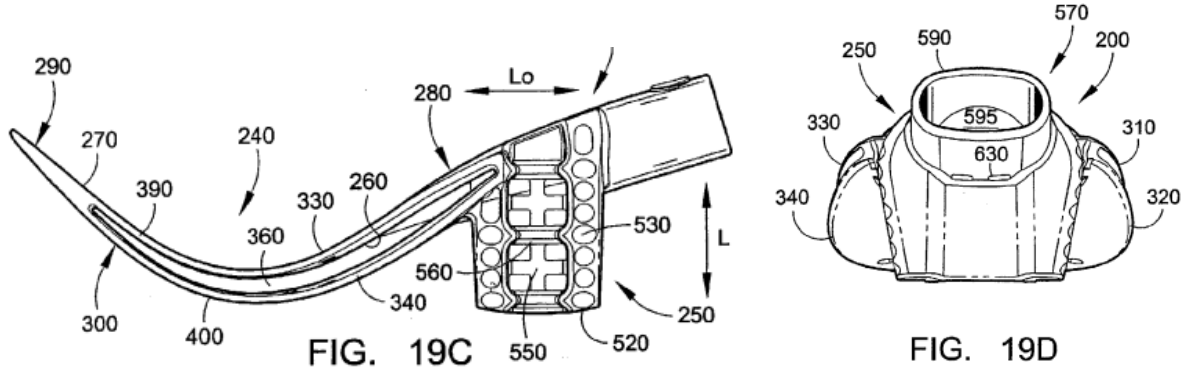
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— the upper and lower parts of the jaw forming a triangular shape when viewed from the side. EX1012, FIG. 19D. This is exactly why I designed the bite block of my own mouthpiece to be tapered. EX1005, FIGS. 1, 3C, 6C, 8, 15B, & 18.

218. Hirsch teaches a bite piece 250 that is tapered as best illustrated in FIG. 19D. EX1012, ¶ 84, FIG. 19D. In other words, the bite piece 250 of Hirsch inwardly tapers from the anterior surface to the posterior surface when in use. To a POSA, it would have been obvious to modify the tooth support section 120 to be tapered like the bite piece 250 of Hirsch because a tapered shape better accommodates a patient's mouth in the open position leading to increased patient comfort. EX1012, ¶¶ 85-88; *see also* EX1005, 11:61-12:9, 4:47-55.

219. Hirsch also teaches that the bite piece 250 includes tooth engaging ridges 520 and cross-shaped members 550 that “are biting surfaces that may be engaged by the bottom of the top teeth and the top of the bottom teeth to help keep the bite piece 250 in position.” EX1012, ¶ 88. It would have been further obvious to add this additional friction to keep the mouthpiece held in place by the teeth in view of the teachings of Hirsch.

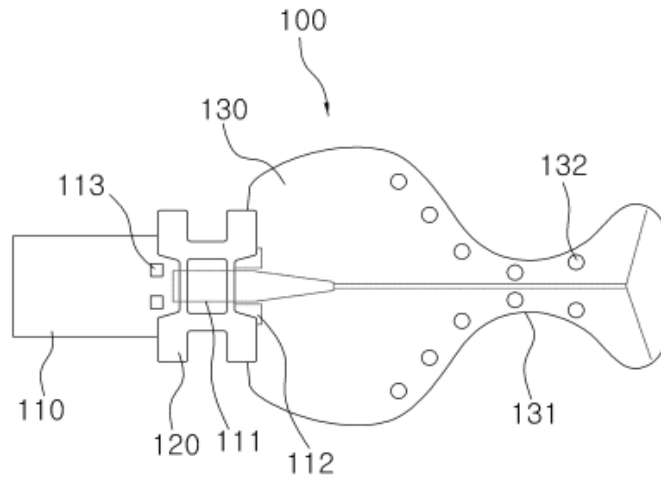
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- k. **Limitation 1(k): “a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges, wherein the first wall and the second wall of the main body portion that transition into the cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion.”**

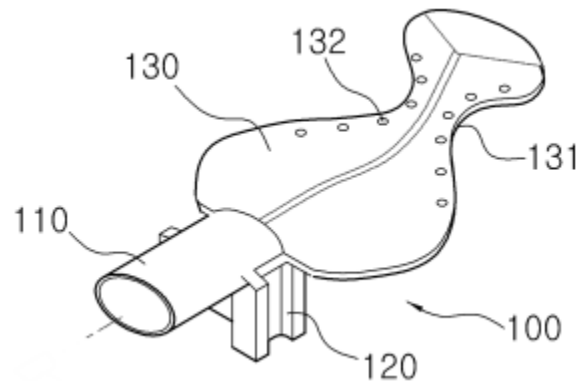
220. See paragraph 193. Additionally, Park teaches that the first and second ends of the cheek retractor each have rounded edges. EX1006, FIG. 3.

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2. **Claim 2: “2. The isolation mouthpiece of claim 1, wherein the first plurality of perforations includes five perforations and the second plurality of perforations include five perforations.”**

221. Park illustrates that the first and second pluralities of perforations each have at least 5 perforations. EX1006, FIG. 2. In fact, Park shows that the first and second pluralities of perforations each have 6 perforations.



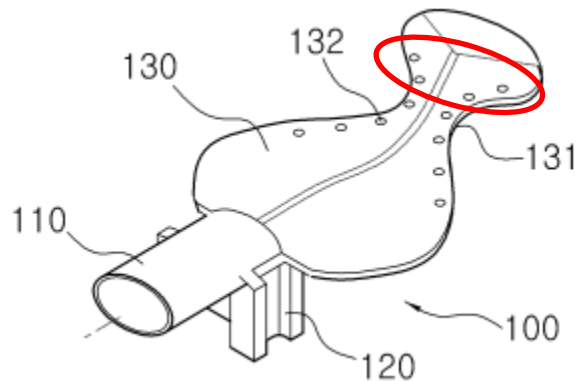
3. **Claim 3: “3. The isolation mouthpiece of claim 2, wherein at least one of the first plurality of perforations and at least one**

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of the second plurality of perforations are located adjacent to the second end and near the cheek retractor portion.”

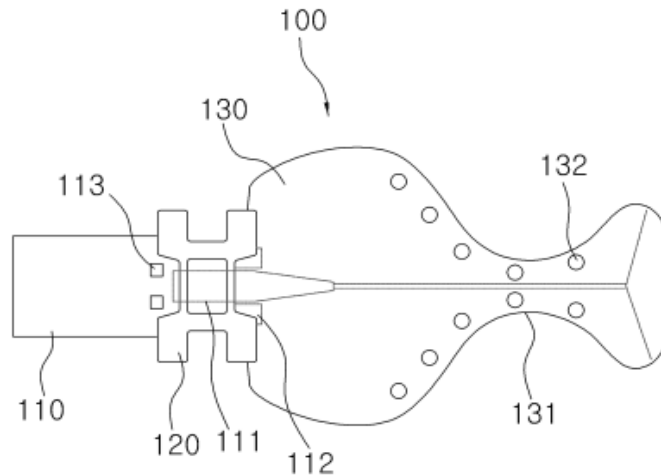
222. Park also illustrates that at least one of the first plurality of perforations and at least one of the second plurality of perforations that are located adjacent to the second narrower end of the main body are near a portion of the first wall that is spaced apart from the second wall. *See* annotated FIG. 2 below.



4. **Claim 4: “4. The isolation mouthpiece of claim 1, wherein the first wall and the second wall of the main body portion transition into and are connected in the cheek retractor portion to form the cheek retractor portion, the first wall and the second wall of the main body portion that transition into the cheek retractor portion are spaced apart from each other for a distance within the cheek retractor portion before being connected to each other in the cheek retractor portion.”**

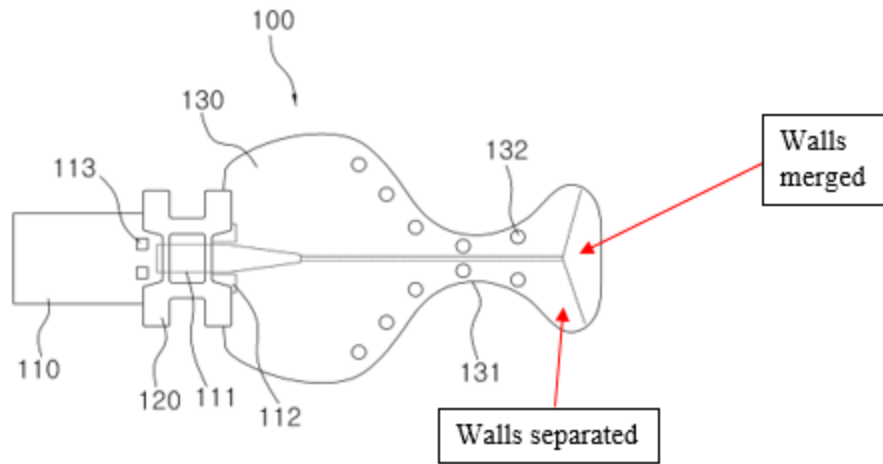
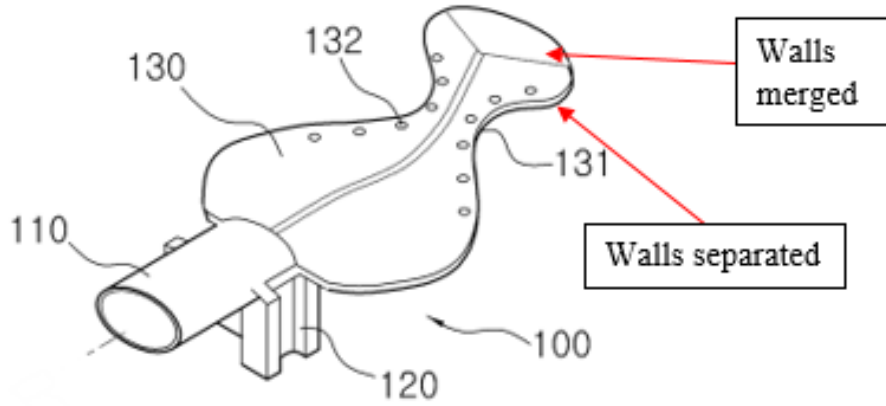
223. Park teaches a concave section 131 (narrower second end) that connects to a cheek retractor, formed to the right of the concave section and expanding outwardly away from the second narrower end. EX1006, ¶ 31, FIGS. 1-3.

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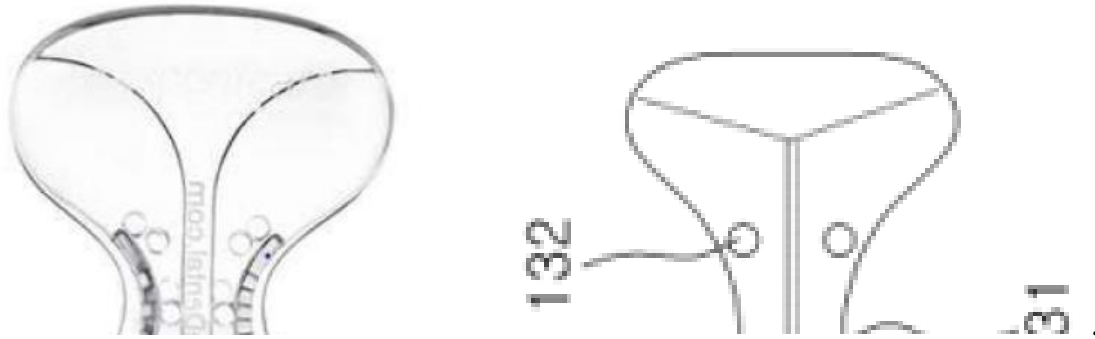
224. As discussed above, Park teaches that the first wall is separated from the second wall and connected to the second wall by a third wall. EX1006, FIG. 2. A POSA would understand that, in Park, the first wall is spaced apart from the second wall wherever a hole 132 is present. As shown in FIG. 2, a hole 132 is present right up until the two lines that form a “Y-shape” near the end of the mouth prop. Therefore, the first wall and the second wall of the main body portion of Park that transition into the cheek retractor portion are spaced apart from each other for a distance within the cheek retractor portion. Past the “Y-shaped” lines, the first wall connects to the second wall, such that they are no longer spaced apart.

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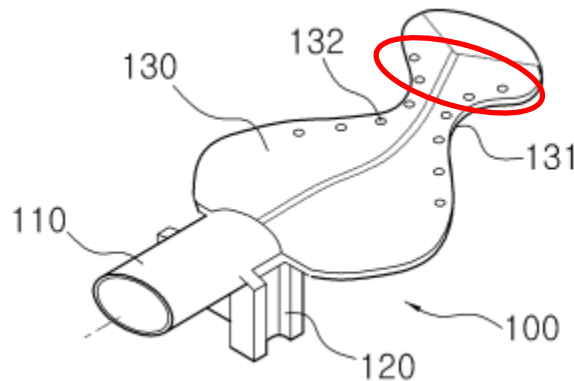
Of note: this design is almost identical in shape to the cheek retractor that Patent Owner appears to assert as infringing this limitation.

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5. **Claim 5: “5. The isolation mouthpiece of claim 4, wherein at least one of the first plurality of perforations and at least one of the second plurality of perforations are located adjacent to the second end and near the cheek retractor portion.”**

225. Park also illustrates that at least one of the first plurality of perforations and at least one of the second plurality of perforations that are located adjacent to the second narrower end of the main body. *See* annotated FIG. 2 below.



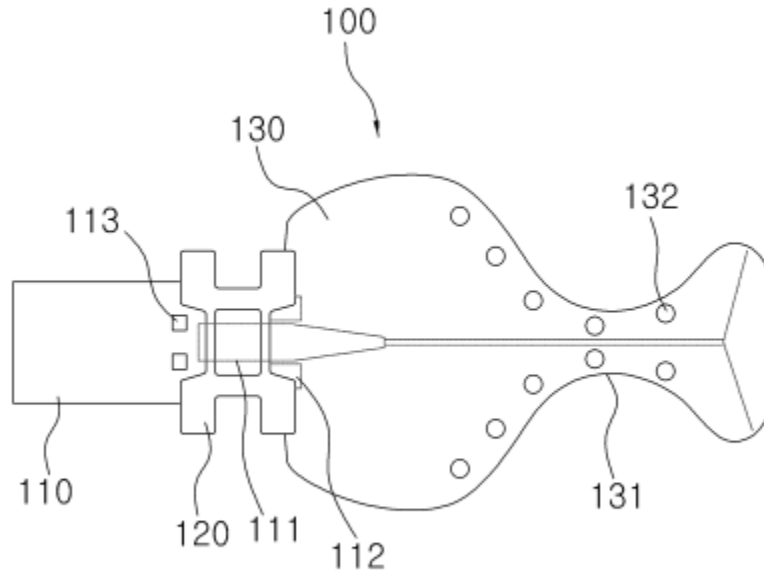
6. **Claim 6: “6. The isolation mouthpiece of claim 1, wherein the cutout has a shield shape.”**

226. Park teaches a projection hole 113 formed such that a locking projection 211 formed on the vacuum adapter 200 can pass downward through it.

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EX1006, ¶ 35. A POSA would understand that these holes 113 for receiving a projection on the vacuum adapter 200 is an interlocking fit.



227. Park teaches that the projection hole 113 is generally rectangular.

EX1006, FIG. 3. It would have been obvious to a POSA to modify the rectangular projection hole 113 of Park to have a shape of a shield logo, as such a change would just change the shape of the projection hole 113. I have been told by counsel that such changes are considered obvious in view of MPEP 2144.04(IV)(B).

7. **Claim 7: “7. The isolation mouthpiece of claim 1, wherein the cutout has a triangular shape.”**

228. Park teaches that the projection hole 113 is generally rectangular.

EX1006, FIG. 3. It would have been obvious to a POSA to modify the rectangular projection hole 113 of Park to have a triangular shape, as such a change would just

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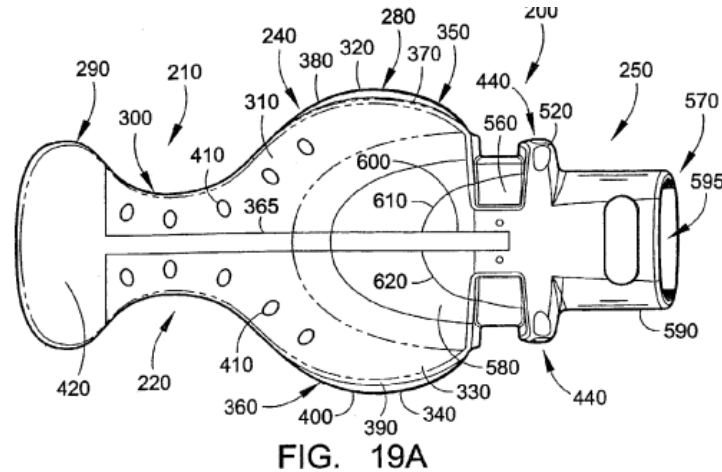
change the shape of the projection hole 113. I have been told by counsel that such changes are considered obvious in view of MPEP 2144.04(IV)(B).

8. **Claim 8: “8. The isolation mouthpiece of claim 1, further including a stability bar located along a center aligned with a longitudinal axis of the first wall at least adjacent to the second end of the main body, at least one of the first plurality of perforations being positioned along one edge of the second wall and at least one of the second plurality of perforations being positioned along another edge of the second wall.”**

229. Park incorporates an LED light, which can be projected through a light guide that illuminates the mouthpiece while debris is suctioned through the first and second walls aided by a multiplicity of through holes. EX1006, FIGS. 2-3. Park is not expressly clear whether there also exists a spine extending down the longitudinal axis of the mouth prop 100. My first impression was that the mouth prop 100 includes a spine, but it is equally possible that this line is reflective material to help with light transmission.

230. Regardless, spines in dental isolation mouthpieces were entirely conventional. In fact, the first dental isolation mouthpiece I ever saw in 2003 had such a spine. That device corresponded to the device disclosed in Hirsch. Hirsch illustrates a spine 365 running down the longitudinal axis of the mouthpiece.

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231. Hirsch teaches that the spine extends along a longitudinal axis of the main body between the anterior and posterior walls. EX1012, ¶ 78. Hirsch also teaches that the spine is a thickened area of the main body that extends between the anterior and posterior walls. *Id.* This spine assists with dispersing light into the intraoral cavity, just like the stated goal of Park. EX1006, Abstract; EX1012, ¶ 78. In addition to light transmission assistance, the spine 365 would reinforce the mouth prop of Park, particularly where upper and lower ridges, behind the molars, engage the concave portion 131 of Park to enhance cheek retraction.

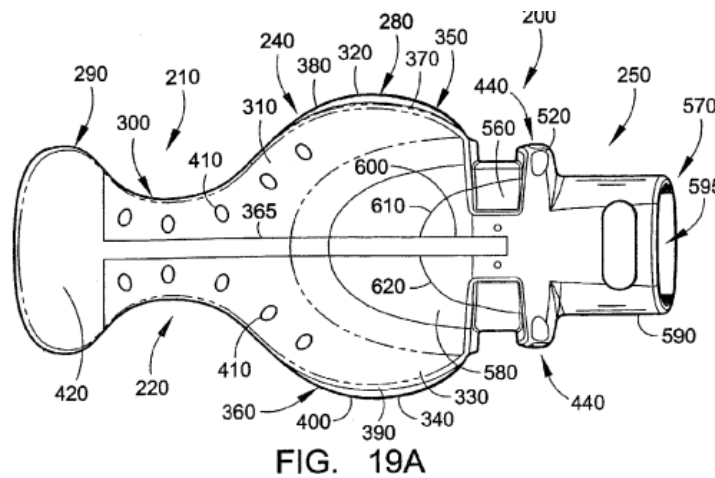
232. A POSA would have been motivated to include the spine of Hirsch into the mouth prop of Park (if Park doesn't already have a spine) to reinforce the mouth prop and help transmit light into the entire oral cavity. EX1006, Abstract; EX1012, ¶ 78. Because Hirsch and Park both discuss light transmission, a POSA would have expected success in using a spine to disperse light throughout the oral cavity. *Id.* Moreover, the designs of Park and Hirsch are very similar – Hirsch

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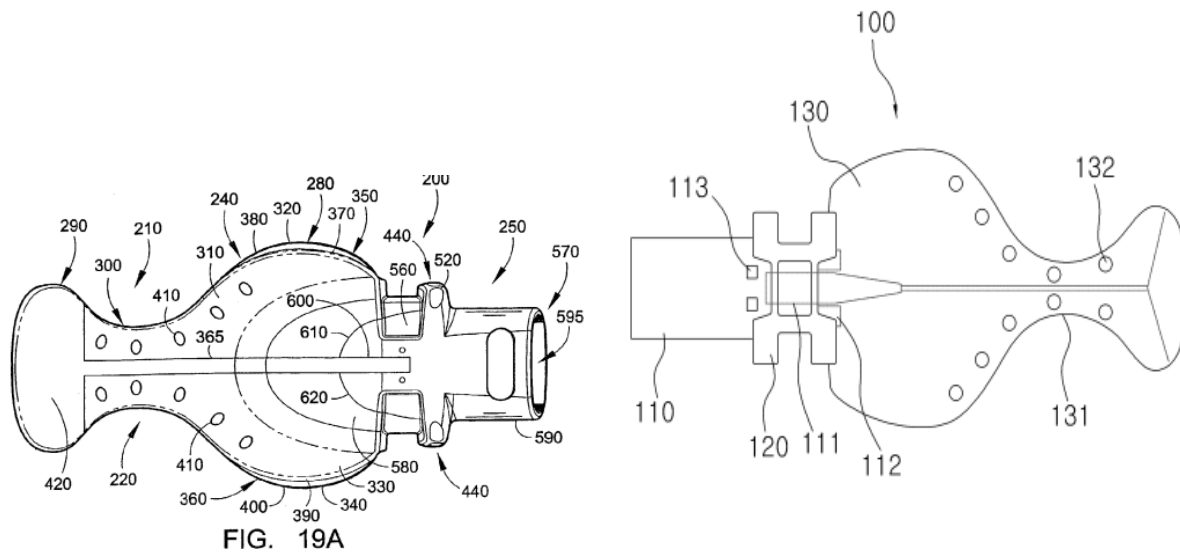
simply lacks a sidewall that Park discloses. Also, the spine 365 would provide added anti-collapse rigidity throughout the center of the mouth prop. Lastly, no additional modifications are required because Park already teaches a pair of suction ports 112 that are divided where the spine 365 would be formed.

233. Park in view of Hirsch teaches a stability bar located along a center of the first wall. Hirsch further discloses that the spine 365 is located along a center of the first wall at least adjacent to the second narrow end of the main body. EX 1012, FIG. 19A.



234. As shown in both Park and Hirsch, at least one of the first plurality of perforations is positioned on one side of the stability bar and the at least one of the second plurality of perforations is positioned on another side of the stability bar. EX 1012, FIG. 19A. EX 1006, FIG. 3.

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9. **Claim 9:** “9. The isolation mouthpiece of claim 8, wherein the stability bar extends upwardly from the second wall toward the first wall.”

235. See paragraphs 229-234.

10. **Independent Claim 11**

- a. **Preamble/Limitation 11(a):** “An isolation mouthpiece for use with a suction system in a dental procedure, the mouthpiece comprising:”

236. See paragraph 204.

- b. **Limitation 11(b):** “a main body portion having a first end and a second end, the main body portion including:”

237. See paragraph 205.

- c. **Limitation 11(c):** “a first wall having a first shape defined by first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion,”

238. See paragraph 206.

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- d. **Limitation 11(d): “a second wall having a second shape defined by third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a first plurality of perforations extending along a portion of the third edge, and a second plurality of perforations extending along a portion of the fourth edge,”**

239. See paragraphs 207-209.

- e. **Limitation 11(e): “wherein a plurality of crests of a wave-like structure is formed on an interior surface of the second wall to provide contact points with the first wall, and a plurality of troughs of the wave-like structure provides gaps between adjacent ones of the plurality of crests for allowing the suctioning of fluid through the plurality of troughs, and”**

240. See paragraph 210.

- f. **Limitation 11(f): “a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall, ”**

241. See paragraph 212-213.

- g. **Limitation 11(g): “wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion, wherein a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width, and wherein the third width is greater than the fourth width;”**

242. See paragraph 214.

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- h. **Limitation 11(h): “a suction connector portion extending from the first end of the main body portion, the suction connector portion including: a tubular conduit including an opening extending through the conduit and in fluid communication with the plurality of troughs of the wave-like structure, the opening being configured to receive a vacuum portion of the suction system therein, and”**

243. See paragraph 215.

- i. **Limitation 11(i): “a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second side each including a plurality of ridges; and”**

244. See paragraph 216-219.

- j. **Limitation 11(j): “a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges, wherein the first wall and the second wall of the main body portion that transition into the cheek retractor portion are spaced apart from each other for a distance within the cheek retractor portion before being connected to each other in the cheek retractor portion.”**

245. See paragraphs 223-224.

- 11. **Claim 12: “12. The isolation mouthpiece of claim 11, wherein the tubular conduit includes a cutout configured to engage a protrusion on the suction system to aid in coupling the isolation mouthpiece to the suction system.”**

246. See paragraph 215.

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12. **Claim 13:** “13. The isolation mouthpiece of claim 11, wherein the first plurality of perforations includes five perforations and the second plurality of perforations include five perforations.”

247. See paragraph 221.

13. **Claim 14:** “14. The isolation mouthpiece of claim 13, wherein the at least one of the first plurality of perforations and the at least one of the second plurality of perforations are located adjacent to the second end and near the cheek retractor portion.”

248. See paragraph 222.

14. **Claim 15:** “15. The isolation mouthpiece of claim 11, wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds in shape to the third edge of the second wall and the second edge of the first wall corresponds in shape to the fourth edge of the second wall.”

249. See paragraph 211.

15. **Claim 16:** “16. The isolation mouthpiece of claim 11, further including a stability bar located along a center aligned with a longitudinal axis of the first wall at least adjacent to the second end of the main body, at least one of the first plurality of perforations being positioned along one edge of the second wall and at least one of the second plurality of perforations being positioned along another edge of the second wall.”

250. See paragraphs 229-234.

16. **Claim 17:** “17. The isolation mouthpiece of claim 16, wherein the stability bar extends upwardly from the second wall toward the first wall.”

251. See paragraph 235.

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17. **Claim 23: “23. The mouthpiece of claim 20, further comprising a stability bar corresponding to a thickened area of the main body, the stability bar extending along a longitudinal axis of the main body between the first wall and the second wall, wherein a thickness of the stability bar reinforces at least a portion of the main body.”**

252. See paragraphs 229-234.

E. **Ground 4: Claims 7, 21–25, and 27–29 are obvious under 35 U.S.C. 103 by Park in view of Baughan, Johnson, Hirsch and Black.**

253. It is my opinion that Park in view of Baughan, Johnson, and Hirsch teaches all of the limitations of claims 7, 21–25, and 27–29.

1. **Claim 7: “7. The mouthpiece of claim 1, further comprising a stability bar corresponding to a thickened area of the main body, the stability bar extending along a longitudinal axis of the main body between the first wall and the second wall, wherein a thickness of the stability bar reinforces at least a portion of the main body.”**

254. It is unclear whether the suction connector and the first or second wall of Park have different thicknesses. Nevertheless, it would have been obvious to make the suction connector thicker than the first or second wall of Park in view of Black. Black teaches a tongue shield aspirator 440 having an anterior layer 448a (first wall) and a posterior layer 448b (second wall) and a neck 446 (suction connector). EX1005, 16:15-49. As shown in FIG. 24D, the thickness of the neck 446 (suction connector) is far thicker than the thickness of the anterior and posterior layers 448a, 448b.

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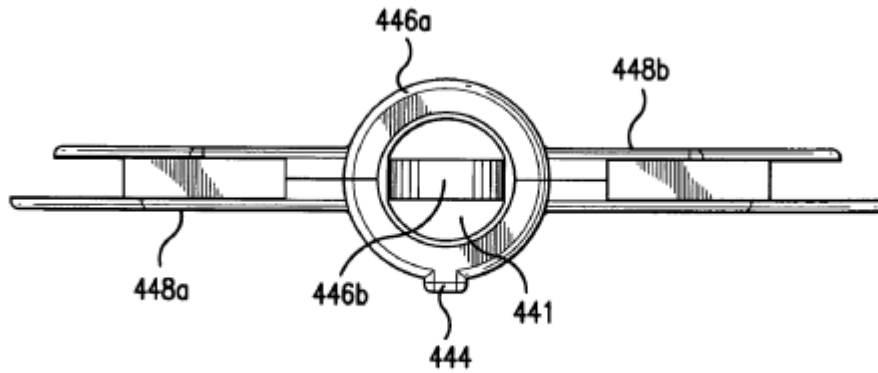


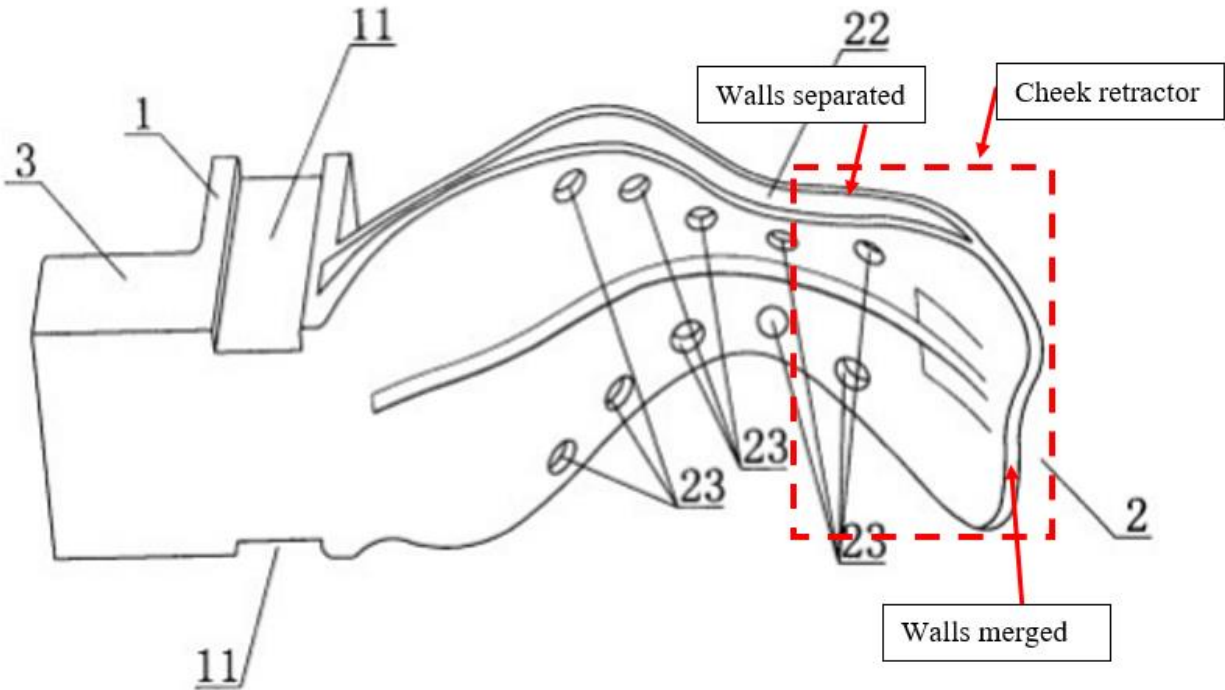
FIG. 24D

255. To a POSA, it would have been obvious to modify the neck 346 to have the thicker walls of neck 446 shown in FIG. 24D because the neck forms a connection with an evacuation tube. This connection should be strong and unlikely to break. Moreover, the neck is not inside the patient's mouth, so there is less of a patient comfort need in making the neck 346 soft. EX1005, 4:47-55.

F. Ground 5: Claims 1–9, 11–17 and 19 are obvious under 35 U.S.C. 103 in view of Black, Hirsch, and Zheng.

256. To the extent that the Board does not agree that Black teaches two walls that are separated for a short distance in the cheek retractor before merging together to form the cheek retractor, it would have been obvious to modify the mouthpiece to do so in view of Zheng. EX1021, FIG. 2. It would be obvious to do so to improve suction near the cheek retractor.

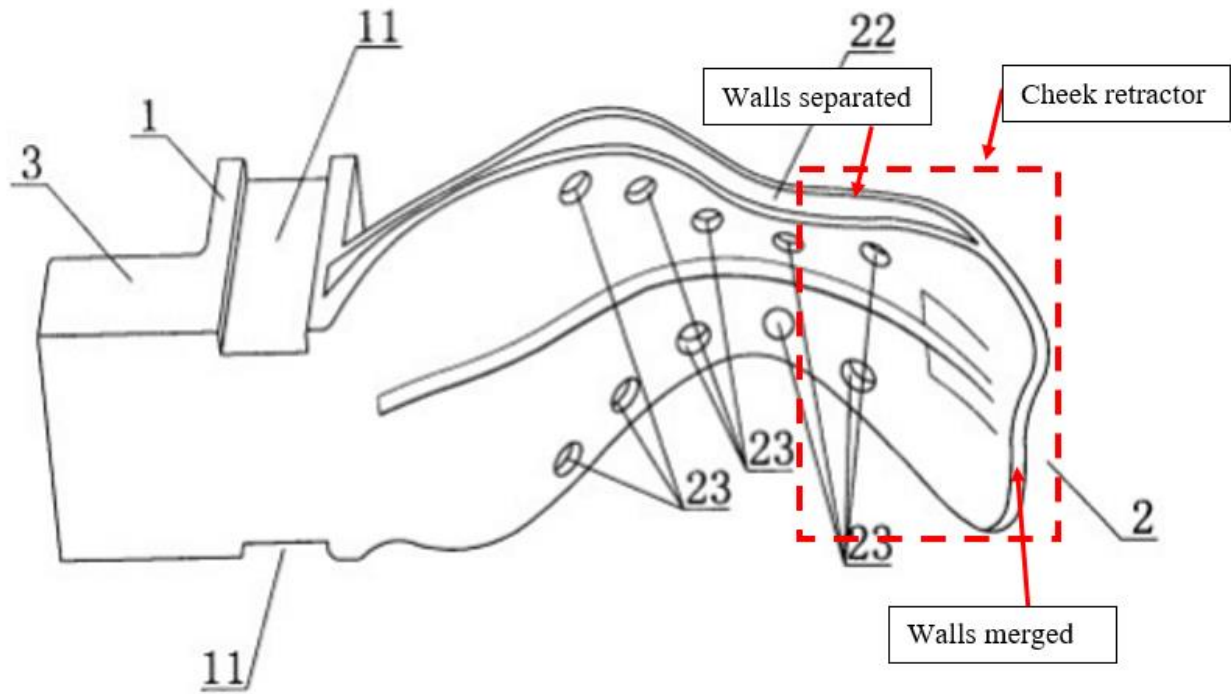
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G. **Grounds 8, 9, and 10: Claims 20–22 and 24–28 are obvious under 35 U.S.C. 103 in view of Park, Baughan, Johnson, and Zheng. Claims 1–9, 11–17, and 20–28 are obvious under 35 U.S.C. 103 in view of Park, Baughan, Johnson, Hirsch, and Zheng. Claim 19 is obvious under 35 U.S.C. 103 in view of Park, Baughan, Johnson, Hirsch, Black, and Zheng.**

257. To the extent that the Board does not agree that Park teaches two walls that are separated for a short distance in the cheek retractor before merging together to form the cheek retractor, it would have been obvious to modify the mouthpiece to do so in view of Zheng. EX1021, FIG. 2. It would be obvious to do so to improve suction near the cheek retractor.

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IX. **CONCLUSION**

258. For these reasons, it is my opinion that claims 1–9, 11–17 and 19–28 of the '418 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 23rd day of June, 2025.



Dr. Brian P. Black.

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