

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ASCENTCARE DENTAL PRODUCTS, INC.,
Petitioner

v.

SOLMETEX, LLC
Patent Owner

Patent No. 11,744,686

Case No. IPR2025-01059

DECLARATION OF CHARLES A. GARRIS, JR., PH.D.

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I, Charles A. Garris, Jr., Ph.D., declare as follows:

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

2. I have been retained on behalf of Solmetex, LLC, (“Solmetex” or “Patent Owner”) as an independent expert consultant to provide this declaration concerning the technical subject matter relevant to U.S. Patent No. 11,744,686 (“the ‘686 patent”) in connection with an *inter partes* review (“IPR”) petition filed by Ascentcare Dental Products, Inc. (“Ascentcare” or “Petitioner”).

3. I am being compensated at my standard hourly rate of \$350 per hour for the time I spend on this matter. My compensation is not based on the content of my opinions or the resolution of this matter, and I have no other interest in this proceeding.

4. I understand that Solmetex is asserting the ‘686 Patent against Ascentcare in a related matter currently pending in the United States District Court for the Western District of Michigan (“the Michigan Litigation”).

5. In this declaration, I offer opinions relating to the ‘686 patent, claim construction, the references in the Petition, and the declaration submitted by Petitioner. The substance and bases of my opinions appear below.

I. BACKGROUND AND QUALIFICATIONS

6. In formulating my opinions, I have relied on my knowledge, training, and experience in the relevant field, which I will summarize briefly herein. In addition, Ex. 2027 is a true and correct copy of my current *curriculum vitae* (CV).

7. I received a Bachelor of Engineering in Marine Engineering from the State University of New York, Maritime College in 1965, a Master of Science Degree in Mechanical Engineering from the State University of New York at Stony Brook in 1968, and a Ph.D. in Mechanical Engineering from the State University of New York at Stony Brook in 1971. I also served as a post-doctoral research faculty in the Mechanical Engineering Department of the Massachusetts Institute of Technology.

8. I joined the faculty at The George Washington University in 1978 as an Associate Professor. I am currently a tenured full Professor of Mechanical & Aerospace Engineering in the Department of Mechanical and Aerospace Engineering. I have held this position since 1984. In 2003–2004 I served as the Interim Department Chair in the Department of Civil and Environmental Engineering.

9. I am a registered Professional Engineer in the Commonwealth of Virginia. I am also registered by the U.S. Patent and Trademark Office as a Patent

Agent. I was formerly licensed by the U.S. Coast Guard as a steam and diesel engineer certified to serve on vessels of unlimited horsepower.

10. I am a Fellow of the American Society of Mechanical Engineers, a Fellow of the National Academy of Inventors, an Associate Fellow of the American Institute of Aeronautics and Astronautics, a member of the Society of Automotive Engineers, a member of the American Society for Engineering Education, a member of Sigma Xi, and a member of Pi Tau Sigma.

11. I have been granted a number of patents on my own inventions in the areas of controls, energy conversion, fluid mechanics, refrigeration, fuel cells, and turbochargers and have led research groups at George Washington University developing my inventions. I am the sole named inventor on the following U.S. Patent Nos.: 4,875,623, 4,696,598, 5,647,221, 6,138,456, 6,434,943, 6,663,991, and 7,497,666. I received the 2006 Thomas A. Edison Award from the American Society of Mechanical Engineers in recognition of my inventions.

12. From approximately 1988 through 1991, on a consulting basis, I was Director of Engineering for Speakman Innovations, a subsidiary of Speakman Corporation. Speakman Corporation is a leading manufacturer of shower valves for the hotel industry. I developed a new shower control, called the “Ultra Valve” which would have computer control of a shower valve and digital input by the user through an interface. Since the unit was placed in the harsh shower environment,

protection of the electronic components from water spray was essential. The effort resulted in two U.S. patents where I was the sole inventor (U.S. Patent Nos. 4,875,623 and 4,969,598).

13. I teach courses at George Washington University in heat and mass transfer, fluid dynamics, and energy conversion. Energy conversion includes many types of engines, power plants, and systems in which filtration and trapping of impurities and particulate matter. In connection with my teaching of mechanical engineering courses at George Washington University, I frequently instruct students on topics involving filtration, sedimentation, and particulate-liquid separation. I have had many years of formal training on the concepts of power plant operation, and filtration and separation of particulates and fluids are a fundamental requirement.

14. I also have many years of experience designing medical devices, dental devices, and suction devices. For many years, I assisted my father, a dentist and prolific inventor, in developing novel dental apparatus for facilitating difficult fillings and extractions, dental X-ray apparatus, bridges and prosthetic dental devices, and the like. As a professor of mechanical engineering at GWU, I have occasionally worked with doctors at the GW Hospital to develop surgical instruments and designs and medical instrumentation for measuring blood flow. In the early 2000's, I worked with Dr. Lee Smith, MD, formerly Chair of Colon &

Rectal Surgery at GWU, on various projects including: (1) development of a colon encapsulation device to prevent the spread of cancer during colon cancer surgery; (2) development of an apparatus to improve the success rate of anal sphincteroplasty; and (3) endoscopic instruments for gall bladder surgery.

15. From my personal background, I come from a long line of dentists: my wife, my father, my grandfather, my great grandfather, and other family members have all been practicing dentists. Starting from early childhood, I helped my dentist family members in their operatories and labs and joined them in attending dental conventions. In fact, as a youth, I was encouraged to continue the family tradition and become a dentist. I spent many hours with my father discussing his methodologies and processes, including the use of saliva ejectors, and helped him to service his equipment. Although I did not follow the family tradition and did not formally study dentistry, I have always had a great interest in the dental processes and equipment and have acquired considerable knowledge of the profession and the technology. This also helps me understand the problems addressed by the '686 Patent and the references in this case.

II. MATERIALS CONSIDERED

16. In forming the opinions set forth herein, I have considered and relied upon my education, knowledge of the relevant field, and my experience. I have also reviewed and considered the '686 Patent (Ex. 1001), the '686 Patent's file

history (Ex. 1002 (part 1), Ex. 1020 (part 2), and Ex. 1021 (part 3)), and at least the following additional materials:

- Ascentcare’s Petition for *Inter Partes* Review of the ‘686 Patent (Paper 2);
- Declaration of Dr. Brian P. Black (Ex. 1003);
- U.S. Patent No. 8,029,280 (“Black,” Ex. 1005);
- Korean Patent No. 10-1082826 (“Park,” Ex. 1006);
- U.S. Patent No. 3,101,543 (“Baughan,” Ex. 1007);
- U.S. Patent No. 4,017,975 (“Johnson,” Ex. 1008);
- U.S. Patent Publication No. 2003/0134253 (“Hirsch,” Ex. 1012); and
- Prosecution History of U.S. Patent No. 8,911,232 (Ex. 1015).

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

III. LEGAL STANDARDS

18. In forming the opinions set forth herein, I have considered and relied upon my education, my work experience, my teaching experience, and my personal experience with the dental industry.

A. Claim Construction

19. I understand that claim construction is the process by which a court determines the scope and meaning of terms used in the claims of a patent. I understand that the goal of this process is to give claim terms the ordinary and

customary meaning they would have had to a person of ordinary skill in the art (“POSITA”) at the time of the invention, after reading the patent and its prosecution history.

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

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

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

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

B. Anticipation

24. I understand that anticipation analysis is a two-step process. The first step is to determine the meaning and scope of the asserted claims. Each claim must be viewed as a whole, and it is improper to ignore any element of the claim.

For a claim to be anticipated: (1) each and every claim element must be identically disclosed, either explicitly or inherently, in a single prior art reference; (2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim; and (3) the identical invention must be disclosed in the single prior art reference, in as complete detail as set forth in the claim. Where even one element is not disclosed in a reference, there is no anticipation.

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

26. I further understand that where a prior art reference fails to explicitly disclose a claim element, the prior art reference inherently discloses the claim element only if the prior art reference must necessarily include the undisclosed claim element. Inherency may not be established by probabilities or possibilities. The fact that an element may result from a given set of circumstances is not sufficient to prove inherency.

C. Obviousness

27. I understand that a patent claim is invalid under 35 U.S.C. § 103 as being obvious only if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time

the invention was made to a person of ordinary skill in that art. An obviousness analysis requires consideration of four factors: (1) scope and content of the prior art relied upon to challenge patentability; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) the objective evidence of non-obviousness, such as commercial success, unexpected results, the failure of others to achieve the results of the invention, a long-felt need which the invention fills, copying of the invention by competitors, praise for the invention, skepticism for the invention, or independent development.

28. I understand that a prior art reference is proper to use in an obviousness determination if the prior art reference is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met. First, a prior art reference is analogous art if it is from the same field of endeavor as the claimed invention, even if the prior art reference addresses a different problem and/or arrives at a different solution. Second, a prior art reference is analogous art if the prior art reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

29. I understand that it must be shown that one having ordinary skill in the art at the time of the invention would have had a reasonable expectation that a

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

30. I further understand that the law recognizes several guidelines that inform the obviousness analysis. First, I understand that a reconstructive hindsight approach to this analysis, i.e., the improper use of post-invention information to help perform the selection and combination, or the improper use of the listing of elements in a claim as a blueprint to identify selected portions of different prior art references in an attempt to show that the claim is obvious, is not permitted. Second, I understand that any prior art that specifically teaches away from the claimed subject matter, i.e., prior art that would lead a person of ordinary skill in the art to a specifically different solution than the claimed invention, points to non-obviousness, and conversely, that any prior art that contains any teaching, suggestion, or motivation to modify or combine such prior art reference(s) points to the obviousness of such a modification or combination. Third, while many

combinations of the prior art might be “obvious to try,” I understand that any obvious to try analysis will not render a patent invalid unless it is shown that the possible combinations are: (1) sufficiently small in number so as to be reasonable to conclude that the combination would have been selected; and (2) such that the combination would have been believed to be one that would produce predictable and well understood results. Fourth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references uses known methods or techniques that yield predictable results, then that factor also points to obviousness. Fifth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of known work in one field prompting variations of it for use in the same field or a different one based on design incentives or other market forces that yields predictable variations, then that factor also points to obviousness. Sixth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of routine optimization, then that factor also points to obviousness. Seventh, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of a substitution of one known prior art element for another known prior art element to yield predictable results, then that factor also points to obviousness.

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

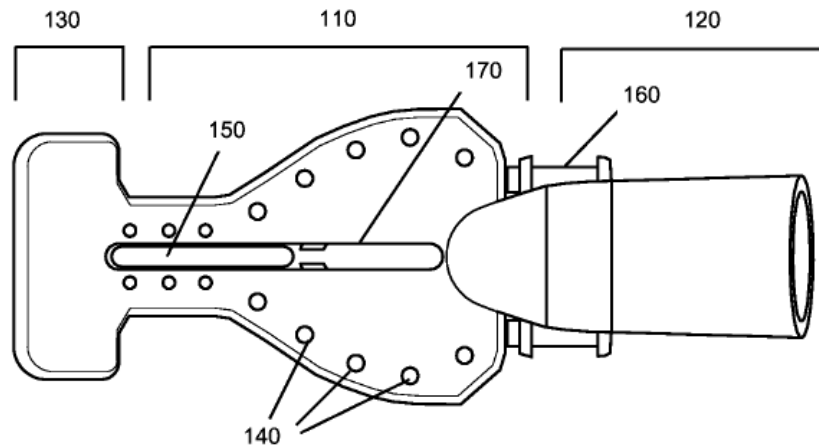
D. Dependent Claims

32. I understand that a dependent claim incorporates each and every limitation of the claim(s) from which it depends. Thus, my understanding is that if a prior art reference fails to anticipate an independent claim, then that prior art reference also necessarily fails to anticipate all of its dependent claims. Similarly, my understanding is that if a prior art reference or combination of prior art references fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all of its dependent claims.

IV. OVERVIEW OF THE ‘686 PATENT

33. The ‘686 Patent discloses and claims a dental appliance often referred to as a dental isolation mouthpiece. Ex. 1001 at 1:17-19. The background section of the ‘686 Patent explains that at the time of the invention, “[v]arious mouthpieces are currently used by dental health professionals, dental hygienists, and dental assistants.” Ex. 1001 at 1:23-25. Traditionally, dental procedures were (and often still are) performed by “a two-person team that comprises a dental professional and a dental assistant” and used “many different types of dental equipment and materials.” Ex. 1001 at 1:25-29. By using a two-person teams, the dental assistant can “assist the dental professional in coordinating the use of these multiple items of different equipment and materials.” Ex. 1001 at 1:37-40.

34. The inventors of the ‘686 Patent recognized “a need in the art for improved systems and methods of providing dental services in a more efficient, comfortable, and safe manner to the dental patient.” Ex. 1001, 1:41-43. The ‘686 Patent discloses “a mouthpiece that may be attached to a high-suction dental adapter for the purpose of assisting the dental staff during dental procedures through chair-side, hands-free suction, and isolation.” Ex. 1001 at 1:48-51. In one example, an isolation mouthpiece includes a main body portion 110, a suction connector portion 120, and a check retractor portion 130. Ex. 1001 at 3:24-26. FIG. 1B of the ‘686 Patent, which shows these features, is reproduced below:



Ex. 1001 at FIG. 1B

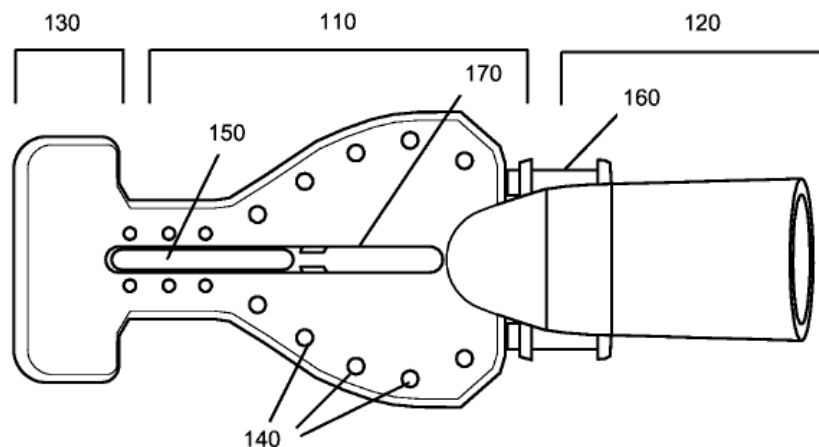
35. The main body portion 110 “may include an anterior wall facing the front of the mouth (e.g., the side with slit 170) and a posterior wall facing the back of the mouth.” Ex. 1001 at 3:45-48. According to the specification, the anterior and posterior walls “protect the back of the mouth (e.g., throat and airway) from falling debris.” Ex. 1001 at 3:60-63.

36. The specification details how the mouthpiece is used in dental procedure. “When placed in a patient’s mouth, the suction connector portion may protrude from one side of the patient’s mouth, while the main body portion 110 lies against the back of the patient’s mouth, and the cheek retractor portion 130 retracts the patient’s cheek on the opposite side of the patient’s mouth.” Ex. 1001 at 3:33-38. An illustration of how the mouthpiece fits into the patient’s mouth, which I understand is from Patent Owner’s literature for its commercial product, is shown below:



Ex. 2018

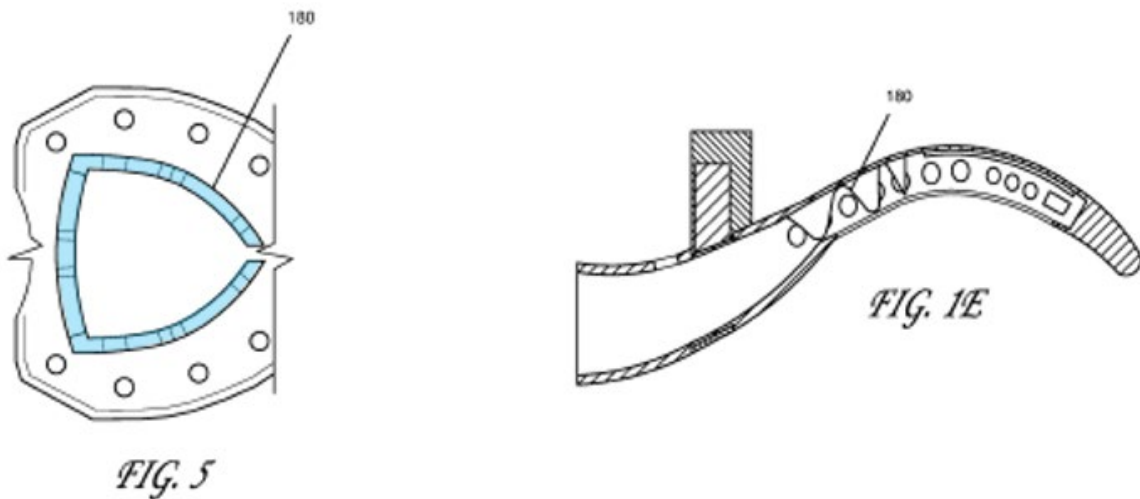
37. In order to allow for suctioning of fluids while positioned within the mouth during a dental procedure, the main body portion 110 includes perforations 140 that “assist in suctioning of water, saliva and debris from the oral cavity.” Ex. 1001 at 4:5-9. The open slit 170 may also assist in the suctioning “of water, saliva and debris.” Ex. 1001 at 4:41-47.



Ex. 1001 at FIG. 1B

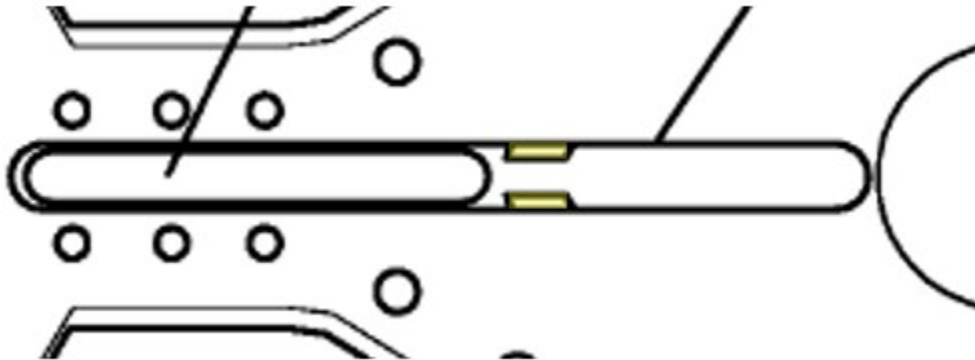
38. The specification acknowledges that given this particular design (including the presence of the open slit 170 in the anterior wall), when the suction force is applied to the mouthpiece during operation, opposing anterior and posterior surfaces of the main body 110 could collapse and limit or block the suctioning through the perforations 140. To avoid this, a bridge structure 180 is formed “on an interior surface [of the main body 110] to ensure that the anterior and posterior surfaces remain separated during suction.” Ex. 1001 at 4:48-51.

39. FIG. 5 shows a “close-up view of the bridge structure 180,” and FIG. 1E shows a cross-sectional view illustrating the bridge structure 180 formed on the interior surface of upper wall of the main body 110 and protruding toward the lower wall:



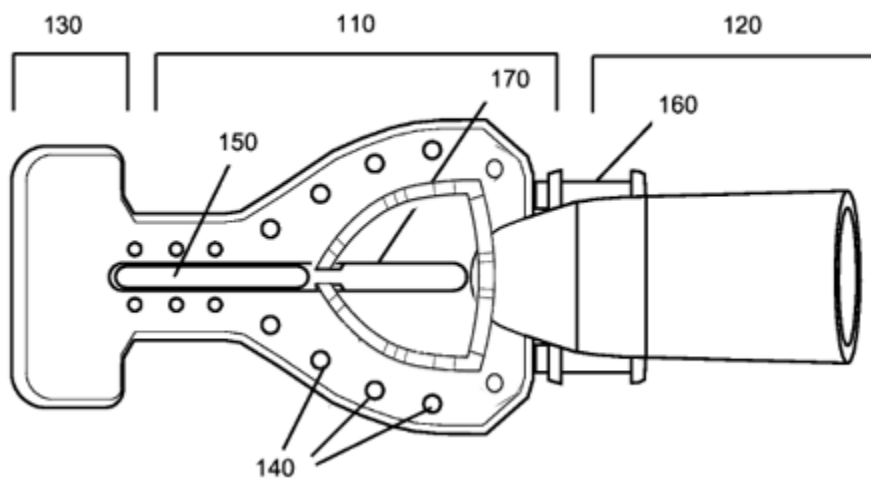
Ex. 1001 at FIGS. 5, 1E (annotated)

40. In FIG. 1A, a portion of the internal bridge structure is visible through the open slit 170, as shown by the highlighting below:



Ex. 1001 at FIG. 1B (excerpted and annotated)

41. In the image below, FIG. 5 is superimposed on top of FIG. 1B to show how the bridge structure 180 is positioned in the area of the slit 170 with portions of the bridge structure 180 near some of the perforations 140 that follow the edges of the main body 110.



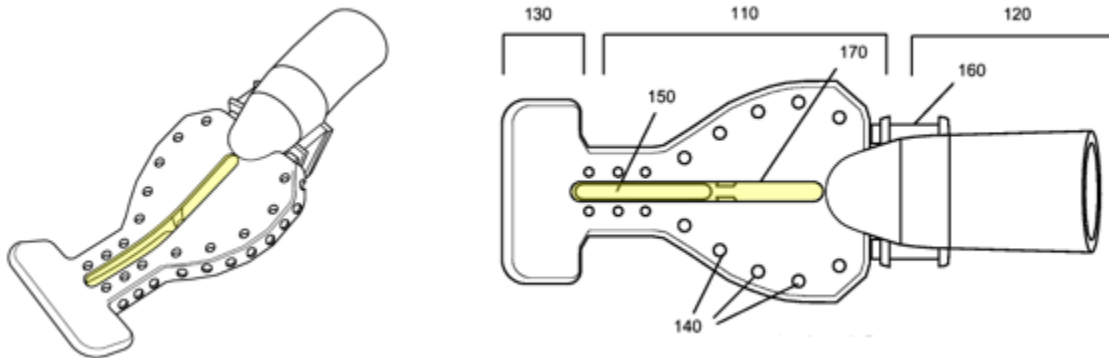
Ex. 1001 at FIGS. 1B and 5 (superimposed)

42. As shown the cross-sectional view illustrated in FIGS. 1E and 2E, the bridge structure 180 is “formed as a[] wave-like protrusion that generally corresponds to the distance between the anterior and posterior walls extending substantially (e.g., within 1 mm) the full distance at its crest and substantially flush to the surface at its trough.” Ex. 1001 at 4:54-59. Within the wave-like structure, “[t]he crests provide a plurality of contact points with the anterior wall to keep the anterior wall separated from the posterior wall during suction [while] the troughs provide gaps that allow for suction of air, fluids, and small debris through the bridge structure.” Ex. 1001 at 2:19-24. The geometry of the bridge structure 180 is important during use of the dental isolation mouthpiece because “[t]he gaps (or troughs) between the waves of the bridge structure 180 assist in the suction-driven transfer of water and saliva to the suction connector portion 120,” which is “configured to attach to a high-suction vacuum adapter and to assist in transferring water, saliva, and debris from the oral cavity to the external adapter for removal” from of the patient’s mouth during a dental procedure. Ex. 1001 at 5:1-7.

43. Because the wave-like protrusions are formed on the interior surface of only one wall (not both walls) of the main body 110, this provides an additional benefit in that both walls of the main body 110 can be pulled away from each other by hand to permit access into the interior space between the walls to facilitate cleaning. The ‘686 Patent teaches that the mouthpiece can be made of “a high heat-

resistant and autoclavable material” so that the “mouthpiece may be reusable.” Ex. 1001 at 1:60-62. Being “autoclavable” refers to the ability to be cleaned and sterilized for reuse in medical (e.g., dental) procedures.

44. The specification explains that in addition to allowing suctioning of materials therethrough, the open slit 170 also permits access into the interior space between the walls to “assist in cleaning and maintenance.” Ex. 1001 at 4:45-47.



Ex. 1001 at FIGS. 1A-1B (annotated)

The open slit 170 allows one to insert a cleaning brush in the interior of the main body 110 through the open slit 170 for cleaning or maintenance.

45. Since the wave-like protrusions of the bridge structure 180 are formed on the interior surface of one wall of the main body 110, this configuration provides additional flexibility to the mouthpiece. This is helpful when attempting to position the mouthpiece within the patient’s mouth for a dental procedure. If the bridge structure 180 were instead connected to the interior surfaces of both walls,

the main body 110 would be more rigid and more resistive of torsional forces when attempting to twist the mouthpiece into the proper position for a dental procedure.

46. To summarize, because the wave-like protrusions of the bridge structure 180 are formed on the interior surface of one wall of the main body 110, the main body 110 is more flexible and the walls can be pulled apart from each other to allow access into the interior space the main body 110 for maintenance or cleaning. Additionally, when suction forces are applied, the wave-like protrusions keep the two walls separated from each other by use of the contact points at the crests of the wave-like protrusions, while still permitting the suction of air, fluids, and small debris through the troughs between the crests of the wave-like protrusions. Ex. 1001 at 2:16-24.

47. Independent claim 12 of the '686 Patent, which I understand is the only challenged independent claim, is reproduced below with the identifiers used by Petitioner and Dr. Black for ease of reference:

48. Independent claim 12 recites:

12(a)	A mouthpiece comprising:
12(b)	a main body having a first end opposite a second end, the first end wider than the second end, the main body comprising:

12(c)	a first wall having a plurality of first edges and extending from the first end to the second end,
12(d)	a second wall having a plurality of second edges and located at a distance from the first wall, the distance corresponding to a space between the first wall and the second wall, wherein the second wall also extends from the first end to the second end,
12(e)	a connecting wall that connects one of the first edges of the first wall to one of the second edges of the second wall across the distance between the first wall and the second wall; and
12(f)	a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall, the bridge structure extending through the interior space towards the first wall, wherein the bridge structure is not attached to the first wall,
12(g)	and wherein the plurality of protrusions of the bridge structure protrude in a wave shape comprising one or more crests and one or more troughs;
12(h)	a suction connector extending from the first end of the main body, wherein an evacuation conduit of the suction connector is in communication with the space between the first wall and the second wall, and wherein the suction connector includes a cutout shape

	configured to interlock with a corresponding protrusion shape of a vacuum adapter; and
12(i)	a cheek retractor at the second end of the main body.

V. LEVEL OF SKILL IN THE ART

49. I understand that the level of ordinary skill in the relevant art at the time of the invention is relevant to inquiries such as the meaning of claim terms, the meaning of disclosures found in the prior art, and the reasons one of ordinary skill in the art may have for combining references.

50. I have reviewed the definition of the level of ordinary skill in the art proposed in the Petition, which is: “a person with at least a B.S. degree in mechanical engineering or a related field with at least two years’ experience designing medical devices. Less work experience may be compensated by a higher level of education, such as a master’s degree, and vice versa.” Petition at 23.

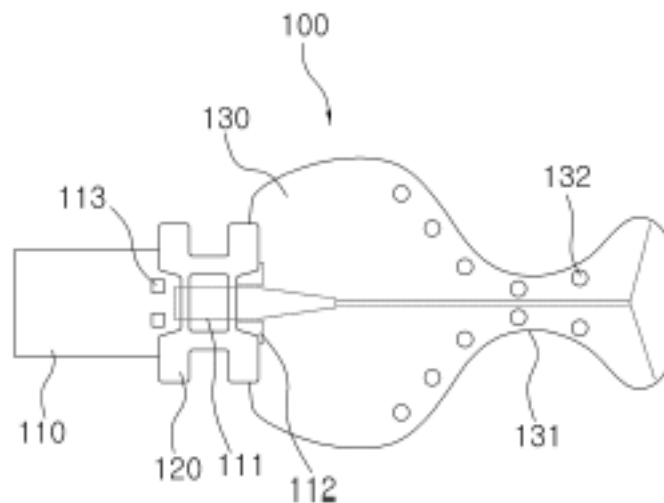
51. I have been asked to apply the proposed definition from the Petition for the hypothetical person of ordinary skill in the art in forming the opinions expressed in this declaration.

52. I was, as of at least December 2012, and still am, a person of ordinary skill in the art through my education and experience under Petitioner’s definition. I

VI. SUMMARY OF REFERENCES IN THE PETITION

A. Park (Ex. 1006) (Grounds 1-2)

Fig. 3

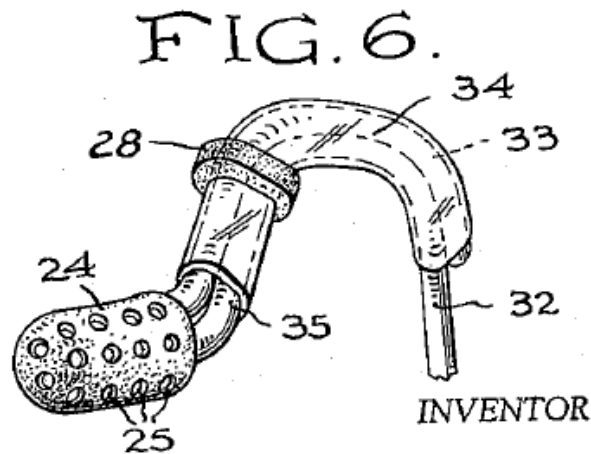


Ex. 1006 at FIG. 3

B. Baughan (Ex. 1007) (Grounds 1-2)

55. Baughan is directed to a different type of dental appliance than the ‘970 Patent: a dental saliva ejector with “suction relief means.” Ex. 1007 at 1:6-7. The background section of the ‘686 Patent mentions high speed and low speed “suction ejector[s]” as being a different type of dental device than an isolation mouthpiece. Ex. 1001 at 1:6-20.

56. Baughan’s dental saliva ejector is designed so that it “cannot traumatize or damage the mouth tissue by sucking the tissue into the suction orifices during the operation of the device for removing saliva from the mouth.” Ex. 1007 at 1:6-20.

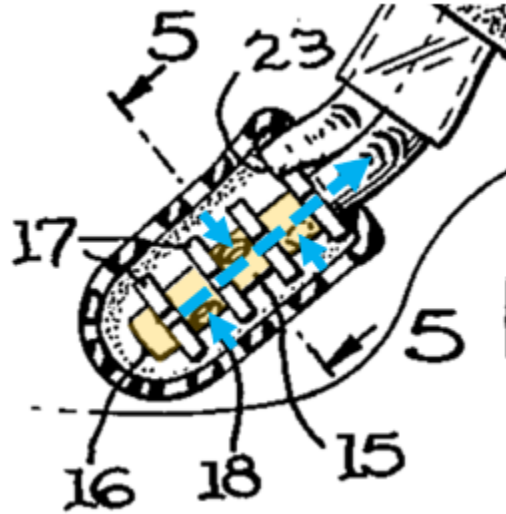


Ex. 1007 at FIG. 6

57. In Baughan, suction is applied via a terminal tube portion 15 with orifices 18, which in turn is surrounded by a series of circular discs 17 which

prevent the outer sleeve 24 from blocking the orifices 18 during operation. Ex.

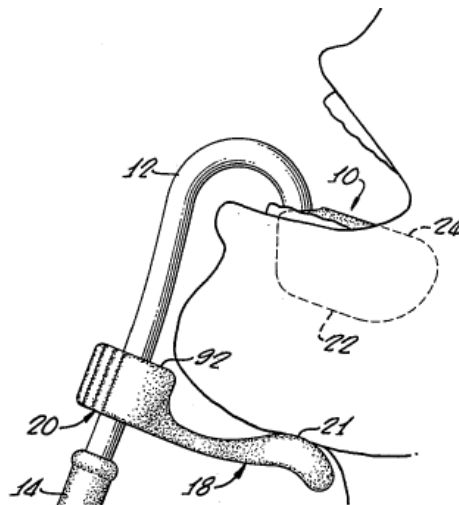
1007 at 3:36-48.



Ex. 1007, FIG 3 (excerpted and annotated)

C. Johnson (Ex. 1008) (Grounds 1-2)

58. Johnson describes a “saliva ejector capable of acting as a tongue guard” and “a chin holder . . . adapted for use with dental appliances, such as saliva ejectors.” Ex. 1008 at 1:6-11. An example is shown below:



Ex. 1008 at FIG. 1

D. Hirsch (Ex. 1012) (Ground 2)

59. Hirsch is generally directed to “dental appliances for illuminating and/or vacuum suction of the mouth of a dental patient for examination and/or operative purposes.” Ex. 1012 at ¶ [0002].

60. As shown in FIG. 19A, Hirsch includes two flaps 310 and 320. A central spine 365 located between those two flaps “may serve as a light pipe and a separator for an upper internal evacuation channel and a lower internal evacuation channel.” Ex. 1012 at ¶ [0078].

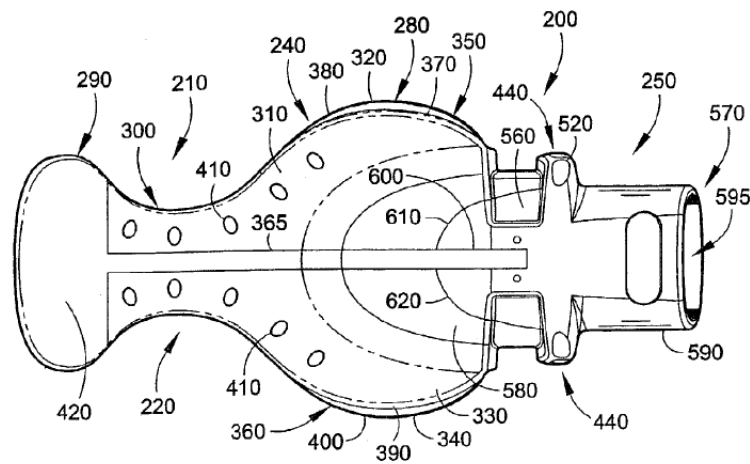


FIG. 19A

Ex. 1012 at FIG. 19A

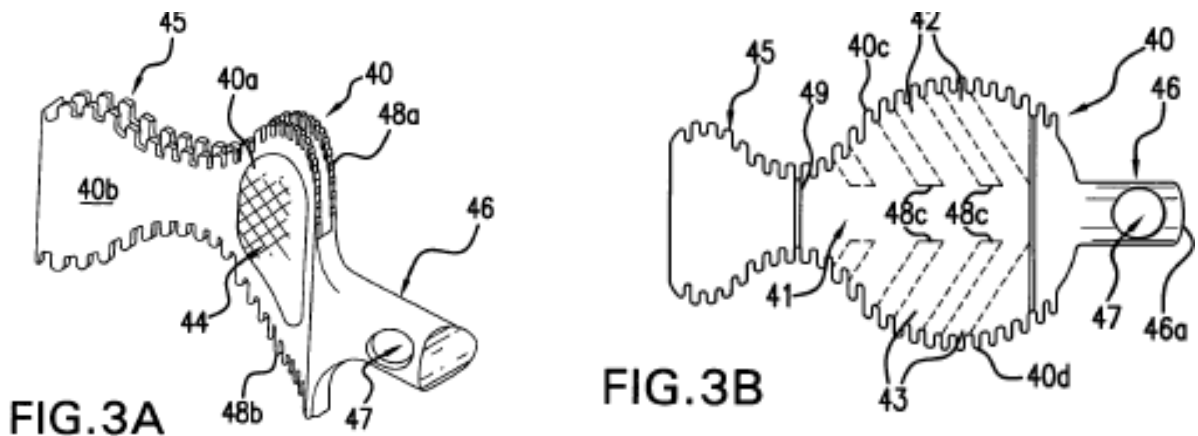
E. Black (Ex. 1005)

61. While Black is not part of Grounds 1-2 challenging the ‘686 Patent, the Petition says that Black “is highly relevant to the problems being solved in the

art.” Petition at 15-16. I also note that the Petition refers to Black in its discussion for Ground 1. *Id.* at 41-42. Thus, I briefly address Black below.

62. Black describes an intraoral device with, among other features, a tongue shield aspirator a bite member, a bite grip, and an evacuation tube. Ex. 1005, Abstract. Black discloses several distinct embodiments.

63. In a first embodiment, Black describes a tongue shield aspirator 40 that includes “a first (posterior) layer 48a and a second (anterior) layer 48b which are connected to, but spaced apart from, one another by transverse walls 48c.” Ex. 1005 at 5:55-60. These transverse walls 48c (which are shown in dashed lines in FIG. 3B below) connect the first layer 48a to the second layer 48b within the interior of the tongue shield aspirator 40 and are angled relative to the longitudinal (central) axis of the tongue shield aspirator 40.



Ex. 1005 at FIGS. 3A-3B

64. Black explains that “each set of two consecutive walls 48c that are disposed above the longitudinal lumen 41 forms an upper channel 42” while “[e]ach set of two consecutive walls 48c that are disposed below the longitudinal hollow lumen 41 forms a lower channel 42.” Ex. 1005 at 5:27-36.

65. In a second embodiment, Black describes a tongue shield aspirator 340 including “a first (posterior) layer 348a and a second (anterior) layer 348b which are connected to, but spaced apart from, one another by transverse walls 348c (shown in phantom in FIG. 23A).” Ex. 1005 at 14:25-30. As in the first embodiment, these transverse walls 348c are angled relative to the longitudinal (central) axis of the tongue shield aspirator 340, as can be seen below in FIG. 23A.

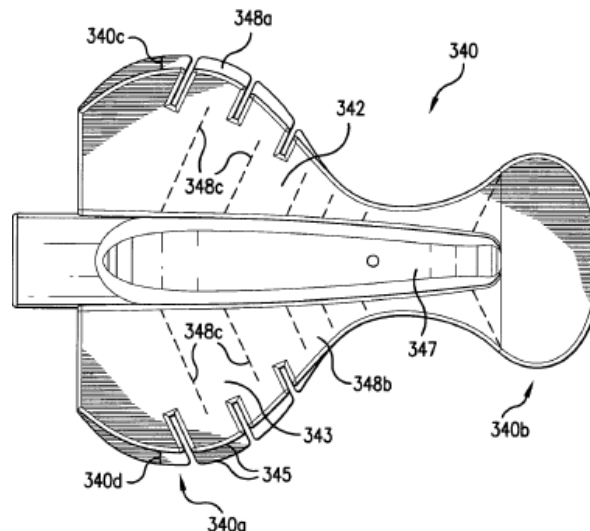


FIG. 23A

Ex. 1005 at FIG. 23A

66. In the figure above, pairs of consecutive transverse walls 348c form the upper channels 342 and the lower channels 343 within the interior, like the first embodiment. Ex. 1005 at 14:33-37.

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

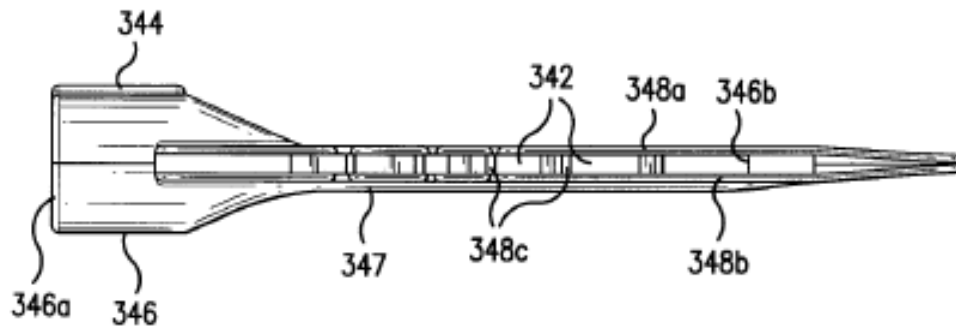


FIG. 23C

Ex. 1005 at FIG. 23C

VII. CLAIM CONSTRUCTION

68. I understand that Petitioner and Dr. Black did not expressly propose any terms or phrases from the ‘686 Patent for construction. Petition at 23-24; Ex. 1003 at ¶¶ 51-54.

A. The “bridge structure” limitation (claims 12-21)

69. Independent claim 12 of the ‘686 Patent recites: “a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall, the bridge structure extending through the interior space towards the first wall, wherein the bridge structure is not attached to the first wall, and wherein the plurality of protrusions of the bridge structure protrude in a wave shape comprising one or more crests and one or more troughs.” Ex. 1001 at 7:30-38.

70. I have been asked to offer my opinion regarding how a POSITA would understand these phrases in light of the specification and prosecution history of the ‘686 Patent. My opinions follow.

71. At the outset, I again note that Petitioner and Dr. Black do not expressly propose a claim construction for these phrases (or any of the terms appearing within the phrases). Petition at 23-24; Ex. 1003 at ¶¶ 51-54. However, in Ground 1, they both assert that rectangular protrusions meet the “wave shape” requirement in these phrases. Petition at 44-45; Ex. 1003 at ¶ 106.

72. I note that in connection with the related '969 Patent, which similarly claims "wherein the protrusions of the bridge structure protrude from the interior surface of the second wall toward the first wall in a wave shape comprising one or more crests and one or more troughs," Dr. Black asserted that "the claim's requirement that a bridge structure have a 'wave shape' in view of the specification merely means that you need spaced-apart projections with gaps therebetween." Ex. 2036 at ¶ 99.

73. I understand that Petitioner has also challenged U.S. Patent No. 12,290,418, which is related to the '686 Patent, in another IPR proceeding. There, Petitioner made the same argument that Dr. Black makes in his declaration regarding the meaning of this claim language:

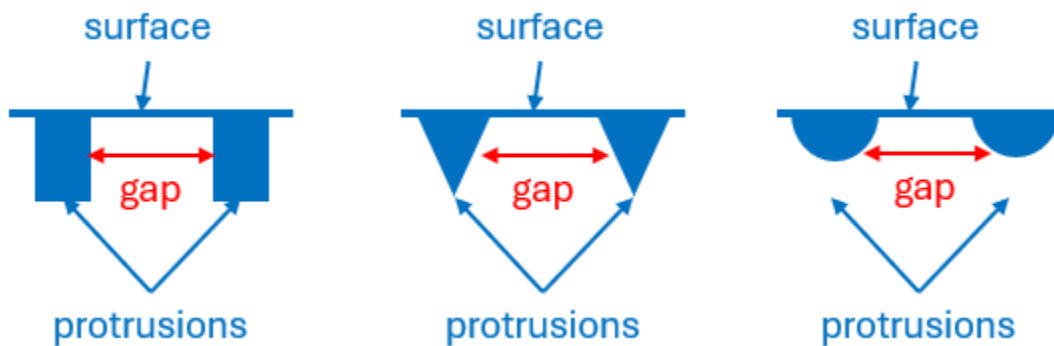
This limitation requires that the bridge structure has a plurality of "wave-like" protrusions. In light of the specification, **this merely means that the wave-like structure needs spaced-apart projections with gaps therebetween.** EX1001, 4:55-5:7, EX1003, 1 97. The resulting shape of any such bridge structure is necessarily a wave shape. EX1003, ¶ 97.

Ex. 2029 (emphasis added).

74. I disagree with Petitioner and Dr. Black's assertion that the claims merely require "spaced-apart projections with gaps therebetween." Instead, a POSITA would understand, in light of the plain and ordinary meaning of the claim language, the specification, and the prosecution history, that this phrase means the

plurality of protrusions of the bridge structure protrude from the interior surface of the second wall in an arrangement forming a pattern of curved surfaces between the one or more crests and the one or more troughs.

75. Starting with the claim language itself, claim 12 recites that the bridge structure “a plurality of protrusions integral with and protruding from an interior surface of the second wall.” It is necessarily the case that any plurality of protrusions (two or more) that are integral with and protrude from a given surface, regardless of their shape, will have a gap between each protrusion. These gaps define the separate protrusions. If there are no gaps, then there cannot be a plurality (two or more) protrusions. This is true regardless of how the protrusions are shaped (e.g., rectangular, triangular, semi-circular, etc.).



76. The claims of the ‘686 Patent require more than just a plurality of spaced-apart protrusions. They require that “he plurality of protrusions of the bridge structure protrude in a wave shape comprising one or more crests and one or

more troughs.” This language defines a specific shape or geometry for the protrusions that comprise the claimed bridge structure.

77. As noted above, Petitioner and Dr. Black take the position that this entire phrase merely requires “spaced-apart projections with gaps therebetween.” I disagree. A POSITA would not read the claims of the ‘686 Patent this way because doing so would strip the phrase “wave shape comprising one or more crests and one or more troughs” of any meaning since, as I noted above, any plurality of protrusions will necessarily have a gap between each protrusion. Stated another way, if Petitioner and Dr. Black’s interpretation is correct, then phrase “wave shape comprising one or more crests and one or more troughs” adds nothing to the claim and is superfluous.

78. The specification describes the “bridge structures” feature as follows:

The main body may further include an protruding bridge structure on the interior surface of the posterior wall. Such a bridge structure may protrude from the interior surface in a wave shape with crests and troughs. The crests provide a plurality of contact points with the anterior wall to keep the anterior wall separated from the posterior wall during suction. Meanwhile, the troughs provide gaps that allow for suction of air, fluids, and small debris through the bridge structure.

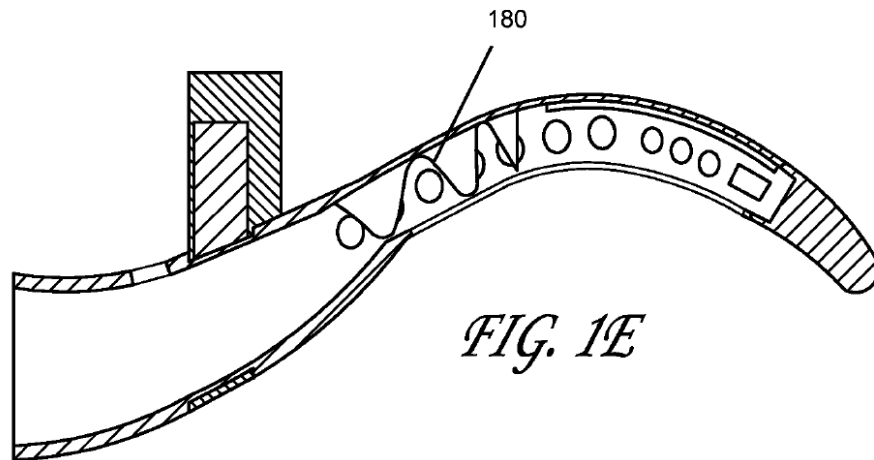
Ex 1001 at 2:16-24.

79. The specification also discloses:

Additionally, the main body of the mouthpiece may include a bridge structure 180 on an interior surface to ensure that the anterior and posterior surfaces remain separated during suction. FIG. 1E is a cross-sectional view of the mouthpiece in which the bridge structure 180 is illustrated. FIG. 5 is a close-up view of the bridge structure 180 without the surrounding walls of the main body portion. Such a bridge structure 180 may be formed as an wave-like protrusion that generally corresponds to the distance between the anterior and posterior walls extending substantially (e.g., within 1 mm) the full distance at its crest and substantially flush to the surface at its trough. In some embodiments, the bridge structure 180 may be centrally-located in the main body portion 110 of the mouthpiece. The gaps (or troughs) between the waves of the bridge structure 180 assist in the suction-driven transfer of water and saliva to the suction connector portion 120 and ultimately, into a central suction vacuum. In some embodiments, the bridge structure 180 may follow the shape of a logo (e.g., an arrowhead or shield).

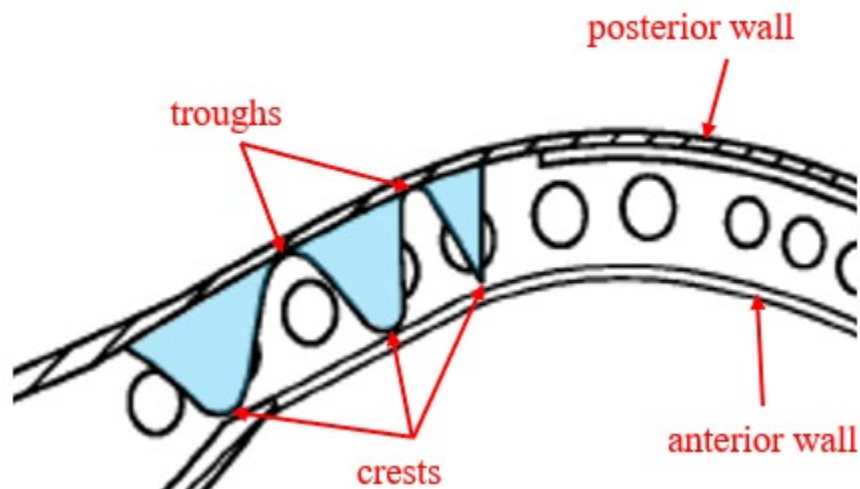
Ex. 1001 at 4:48-67.

80. A cross-sectional view of an exemplary bridge structure 180 with the plurality of protrusions is illustrated in FIG. 1E.



Ex. 1001 at FIG. 1E

A zoomed-in, annotated version of FIG. 1E is shown below illustrating the plurality of protrusions are integral with the interior surface of the posterior wall and protrude toward the anterior wall with crests and troughs in a wave-shaped pattern:

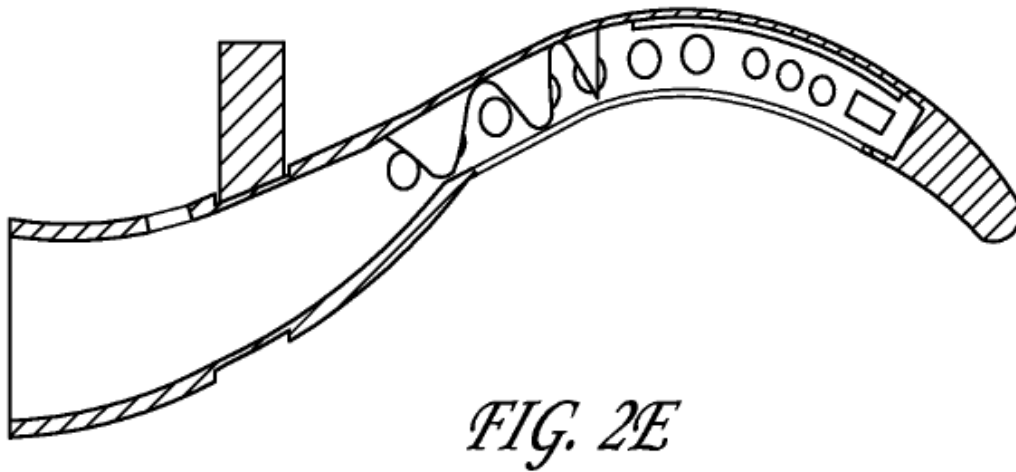


Ex. 1001 at FIG. 1E (excerpted and annotated)

As shown, the wave-shaped pattern has curved surfaces at locations between the crests and troughs.

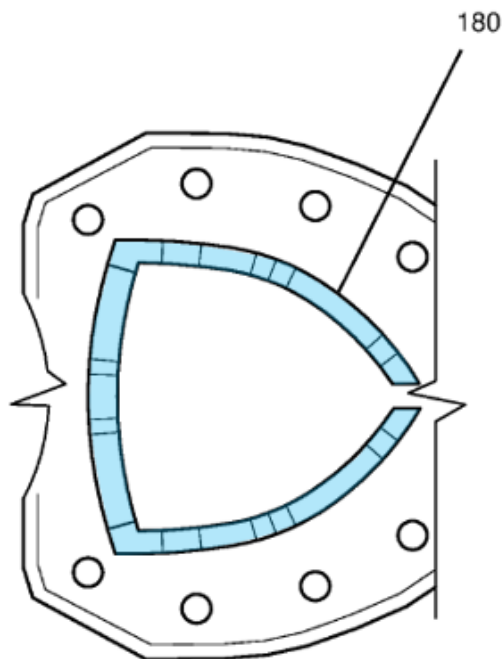
81. I note that in the bridge structure 180 shown in FIG. 1E, it appears in the drawing that the right protrusion of the three protrusions has less curvature between its crest and the adjacent trough. But that is merely because of the angle at which the drawing shows the bridge structure. Considering the bending of the legs of the bridge structure 180 as shown in FIG. 5, in the side view in FIG. 1E, the leg of the bridge structure 180 is either bending into or out of the page (depending on what side one is looking from), which is why the view of the right protrusion of the bridge structure in FIG. 1E appears to have little curvature. As such, a POSITA would understand that, if the viewing angle in FIG. 1E were changed to be more perpendicular to right protrusion, that right protrusion would look much more similar to the central protrusion and the left protrusion shown in FIG. 1E, which is consistent with “wave” shape description for the protrusions of the bridge structure in the specification. Ex. 1001 at 2:16-24, 4:48-67.

82. A cross-sectional view of the bridge structure 180 is also illustrated in FIG. 2E.



Ex. 1001 at FIG. 2E

83. A top view of the bridge structure is shown in FIG. 5 of the '686 Patent.

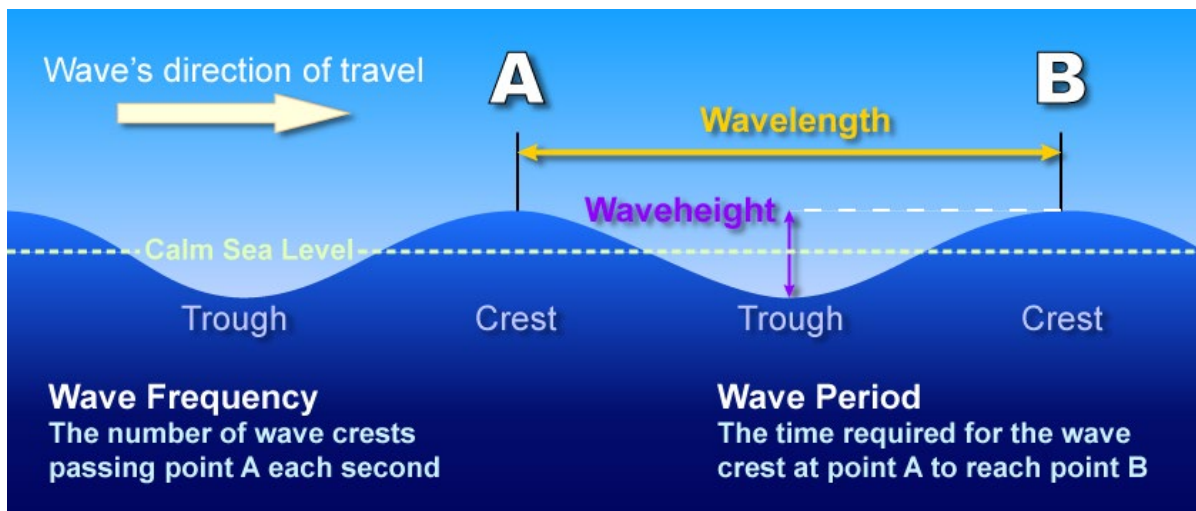


Ex. 1001 at FIG. 5 (annotated)

84. There is no example of a “bridge structure” in the specification or drawings of the ‘686 Patent that includes protrusions in a rectangular or square shape.

85. As noted above, the ‘686 Patent’s specification and claims use the word “wave” to describe the bridge structure. The most common mechanical “wave” that comes to mind is a wave on a body of water (e.g., a wave in the ocean). Waves have crests and troughs. The crest is the highest point of the wave, while the trough is at the lowest point. There is also at least some curvature between crests and troughs.

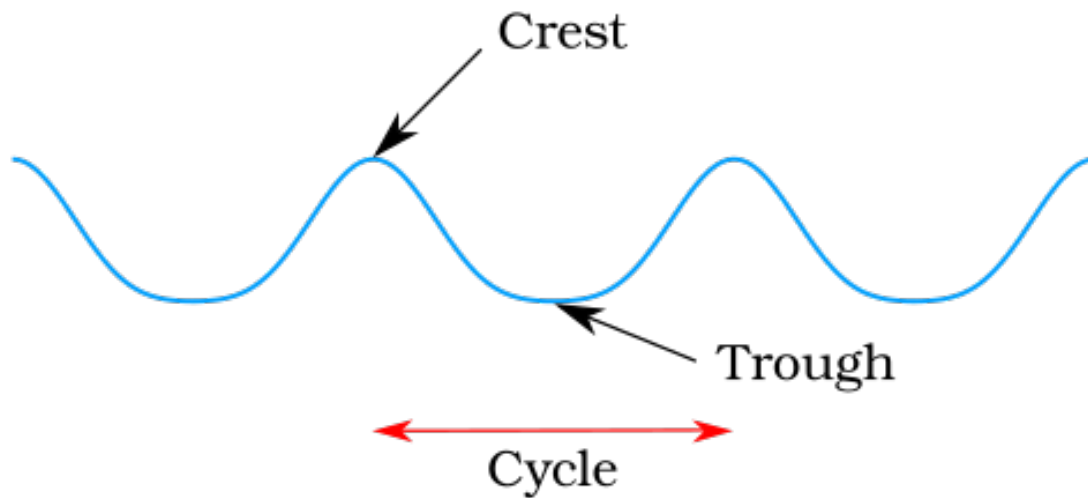
86. The graphic below illustrates a wave crest and a wave trough:¹



Below is another illustration of crests and troughs:²

¹ <https://www.noaa.gov/jetstream/ocean/waves/jetstream-max-anatomy-of-wave>.

² https://en.wikipedia.org/wiki/Crest_and_trough.



87. In the context of the specification, the crests are the points furthest away from the second wall that serve as contact points against the first wall during suction, while the troughs are the points nearest to the second wall that create the gaps between the crests that allow for the transfer of fluids during suction. Ex. 1001 at 2:18-23, 4:61-65 (referring “gaps (or troughs) between the waves”).

88. My opinions regarding the meaning of these claim terms to a POSITA is also consistent with dictionary definitions. The dictionary definition of “wave” is “a shape or outline having successive curves.” Ex. 2030 (Merriam-Webster Dictionary). The dictionary defines “crest” as “something suggesting a crest especially in being an upper prominence, edge, or limit, such as the top of a wave.” Ex. 2031 (Merriam-Webster Dictionary). The dictionary defines “trough” as “the minimum point of a complete cycle of a periodic function.” Ex. 2032 (Merriam-Webster Dictionary).

89. Putting all of this together, the claimed phrase requires that the plurality of protrusions of the bridge structure protrude from the interior surface of the second wall in an arrangement forming a pattern of curved surfaces between the one or more crests and the one or more troughs.

90. The prosecution history for the '686 Patent, the parent '232 Patent, and other related patents further confirm my opinions regarding the claim language.

91. During prosecution of the parent '232 Patent, the Examiner rejected the pending claims in a first office action either as anticipated by Rhoades or as obvious over Rhoades and Black. Ex. 1015 at 49-52. The then-pending dependent claims 9-10 in the application that were rejected based on Rhoades and Black claimed that the bridge structure has a “wave shape” similar to the challenged claims of the '686 Patent. These claims are reproduced below:

9. The mouthpiece of claim 8, wherein the bridge structure protrudes from the interior surface of the posterior wall in a wave shape, and wherein the contact points are at crests of the wave shape.

10. The mouthpiece of claim 9, wherein troughs of the wave shape are configured to allow suction through the bridge structure.

Id. at 25.

92. In the next office action, the Examiner rejected claims 1 and 8 as anticipated by Black, but found that dependent claims 9-10 were allowable over Black because:

the prior art fail to disclose or reasonably teach of a mouthpiece holding comprising, inter alia: a bridge structure protruding from an interior surface of a posterior wall *in a wave shape*, wherein the contact points are at *crests of the wave shape*.

Ex. 1015 at 109-11 (emphases added).

93. In response, Applicant amended the pending claims in the Parent ‘232 Patent but did *not* include the “wave shape” feature in those amended claims. Ex. 1015 at 124-31. The Applicant’s amendment to pending independent claim 1 relating to the “bridge structure” is reproduced below:

1. (currently amended) A dental mouthpiece composed of a bendable material, the dental mouthpiece formed in a curve and comprising:

a main body portion at a central part of the curve and comprising a defined pocket having an anterior wall inside the curve, a posterior wall outside the curve, and a side wall in between the anterior wall and the posterior wall, wherein the anterior wall, the posterior wall, and the side wall define an interior portion of the defined pocket, wherein the posterior wall comprises a bridge structure protruding from an interior surface of the posterior wall, the protruding bridge structure comprising a plurality of spaced contact points that keep the anterior wall separated from the posterior wall during suction, wherein the spaced contact points are at crests of the bridge structure, and wherein a plurality of troughs between the spaced contact points allow for suction through the bridge structure;

94. Notably, the claim was amended to recite that the bridge structure comprises “a plurality of spaced contact points that keep the anterior wall separated from the posterior wall during suction” and “a plurality of troughs between the spaced contact points allow for suction through the bridge structure.” Ex. 1015 at 124. This is similar to Petitioner and Dr. Black’s suggestion that the issued claims of the ‘686 Patent should be construed to merely require spaced-apart projections with gaps therebetween.

95. The Examiner issued a Notice of Allowance for the Parent ‘232 Patent after this amendment by the Applicant. However, the Examiner amended the claims to add the “wave shape” feature. Ex. 1015 at 145-48. The interview summary indicates that Hirsch and Black were discussed and specifically calls out the “wave shape” claim language. *Id.* at 147.

Issues Discussed	☐ 101	☐ 112	☒ 102	☒ 103	☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)					
Claim(s) discussed: <u>1 and 21-38.</u>					
Identification of prior art discussed: <u>Hirsch, Black.</u>					
Substance of Interview (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)					
<u>Proposed examiner's amendment to include the claim language "wave shape" in claim 1 and to correct claim dependency of claims 22-38 were dicussed and authorized by Applicant's counsel.</u>					

96. As shown below, the “wave shape” language was added to independent claim 1 to secure an allowance over Black. Ex. 1015 at 148.

1. (currently amended) A dental mouthpiece composed of a bendable material, the dental mouthpiece formed in a curve and comprising:

a main body portion at a central part of the curve and comprising a defined pocket having an anterior wall inside the curve, a posterior wall outside the curve, and a side wall in between the anterior wall and the posterior wall, wherein the anterior wall, the posterior wall, and the side wall define an interior portion of the defined pocket, wherein the posterior wall comprises a bridge structure protruding from an interior surface of the posterior wall in a wave shape, the protruding bridge structure comprising a plurality of spaced contact points that keep the anterior wall separated from the posterior wall during suction, wherein the spaced contact points are at crests of the wave shape bridge structure, and wherein a plurality of troughs of the wave shape between the spaced contact points allow for suction through the bridge structure;

97. The prosecution history of the ‘686 Patent further confirms this understanding of the “wave shape” requirement in the claims. During prosecution, the Examiner rejected the pending claims as anticipated by the Black reference. Ex. 1020 at 309-10. The Examiner found that Black discloses a “bridge structure 448c (shown as dashed lines 44c in Fig. 24A) ... wherein the protrusions of the bridge structure 448c protrude in a wave shape comprising one or more crests and one or more troughs (Figs. 24A and 26A).” *Id.* at 310.

The main body 640 further comprises a bridge structure 448c (shown as dashed lines 448c in Fig. 24A) that includes a plurality of protrusions 448c integral with and protruding from an interior surface within the space between the first wall and the second wall, wherein the protrusions of the bridge structure 448c protrude in a wave shape comprising one or more crests and one or more troughs (Figs. 24A and 26A). Note that Fig. 26A shows the protrusions/walls 448c themselves being crests and channels 443 formed therebetween are troughs.

98. In response, the Applicant explained that “Black cannot teach ‘wherein the bridge structure is not attached [to] the first wall’ as claimed” and that “the walls 448c of Black are *rectangular columns* and *do not ‘protrude in a wave shape’* comprising one or more crests and one or more troughs’ that protrude from ‘an interior surface of the second wall’ as claimed.” Ex. 1020 at 369-70.

Moreover, the walls 448c of Black are rectangular columns and do not ‘protrude in a wave shape comprising one or more crests and one or more troughs’ that protrude from ‘an interior surface of the second wall’ as claimed. Thus, Black cannot teach ‘wherein the protrusions of the bridge

99. The Examiner withdrew the rejection based on Black after these arguments. Ex. 1020 at 384. This discussion shows that Patent Owner has been consistent in its interpretation of the “wave shape” requirement, including the fact that Black’s rectangular columns do not have a wave shape.

100. The prosecution history of the related ‘970 Patent further confirms this understanding of the “wave shape” requirement in the claims of the ‘686

Patent. I note that the ‘970 Patent was prosecuted in roughly the same timeframe as the ‘686 Patent. In an Office Action dated June 30, 2016, the Examiner applied the Black reference and asserted that it teaches a bridge structure as claimed in dependent claims. Ex. 2019 at 246.

8. **Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhoades in view of Black (2009/0274991).** Rhoades discloses the invention substantially as claimed except for a bridge structure comprising a plurality of protrusions and wave-shaped bridge structure. Black et al. 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. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rhoades by forming such bridge/transverse walls therein the interior of the intraoral device as taught by Black et al. in order to reinforce the device while still allowing effective suction.

101. In a response dated September 30, 2016, the Applicant made certain claim amendments. Independent claim 1 recited “wherein the bridge structure comprises a plurality of spaced apart protrusions.” Ex. 2019 at 307. I note that this is how Petitioner and Dr. Black appear to be interpreting the “wave shape” language in the issued claims of the ‘686 Patent. Dependent claim 15 recited that “the bridge structure defines a wave shape, and wherein the spaced protrusions are at crests of the wave shape.” *Id.* at 309. The Applicant argued against the rejection of the dependent claims directed to the “bridge structure” shape as follows:

Regarding claims 13-16, Applicants have cancelled claims 13-14, incorporating the subject matter therein into independent claim 1. The *Office Action* acknowledges that *Rhoades* fails to disclose a bridge structure as claimed. To remedy this deficiency, the *Office Action* relies on the teachings of *Black*, and in particular the internal walls (48c) that form channels 42 and 43 in the *Black* device. Applicants respectfully disagree and submit that the walls of *Black* do not provide a wave shape as claimed in dependent claims 15 and 16. Even assuming that the transverse walls of *Black* were considered to have a wave shape, claim 1 explicitly claims that the protrusions of the bridge structure are unattached to the anterior wall.

As shown above, the Applicant specifically argued that “the walls of Black do not provide a wave shape as claimed in dependent claims 15 and 16.” *Id.*

102. In an Office Action dated April 12, 2017, the examiner withdrew the prior rejections based on Black. Ex. 2019 at 391. The Examiner instead rejected the amended claims based on Hirsch but found that dependent claims 15-16, which recited that the bridge structure has a “wave shape” with “crests and “troughs” were allowable over Hirsch and Black. *Id.* at 387-90.

103. The above discussion from the prosecution history shows that the term “wave shape” requires more than a plurality of spaced apart protrusions, and that the “wave shape” feature was a key distinction between the claims and the Black reference.

VIII. OPINIONS ON GROUNDS IN THE PETITION

104. The Petition includes two grounds challenging the validity of the ‘686 Patent. I offer my opinions on each ground below.

A. Ground 1: Obviousness Based on Park, Baughan, and Johnson (Claims 12-15, 17-18, and 20-21)

105. I understand that in Ground 1, Petitioner and Dr. Black allege that claims 12-15, 17-18, and 20-21 of the ‘686 Patent are obvious over Park in view of Baughan and Johnson. Petition at 29-49; Ex. 1003 at ¶¶ 73-125. Claim 12 is the only independent claim. For at least the reasons discussed below, I disagree.

1. Limitation 12(g) – There is No “Wave Shape” in the Park-Baughan-Johnson Combination

106. As I discussed above, independent claim 12 recites “wherein the plurality of protrusions of the bridge structure protrude in a wave shape comprising one or more crests and one or more troughs.” Ex. 1001 at 7:35-38.

107. Petitioner and Dr. Black concede that Park does not expressly disclose a “bridge structure” as required in claim 12 of the ‘686 Patent. Petition at 37-45; Ex. 1003 at ¶¶ 94-107. For example, Petitioner concedes that “Park is silent regarding whether any structures are formed inside the interior chamber of the main body.” Petition at 37. Dr. Black similarly concedes that “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.” Ex. 1003 at

¶ 94. I agree that Park does not disclose a “bridge structure” as required in independent claim 12.

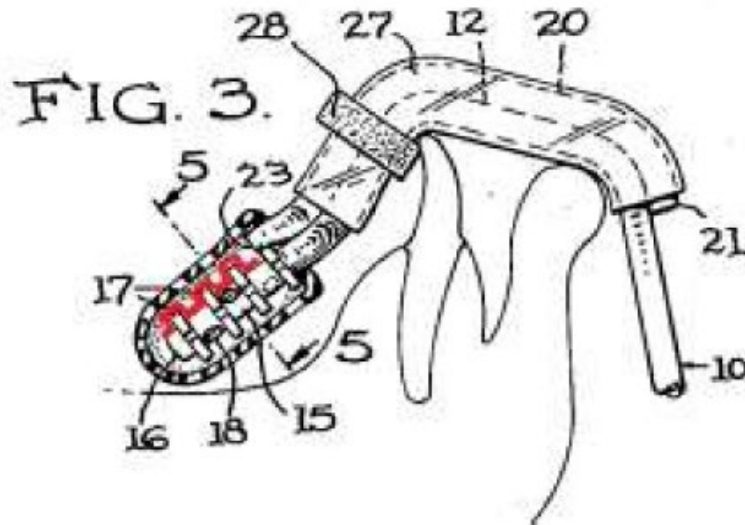
108. For element 12(g), which includes the “wave shape” feature, Petitioner argues that combining Park and Baughan meets this requirement because “Baughan teaches that the spaced-apart discs [17] result in a *square wave shape* having crests and troughs” and that “the notches 19 in the disc also form a *square wave shape*.” Petition at 44-45 (emphases added). Dr. Black similarly asserts that “a square wave shape is a wave-shape.” Ex. 1003 at ¶ 106.

109. As I discussed above, I disagree with Petitioner and Dr. Black’s assertion that a “square wave shape” meets the proper claim construction. Rather, as properly construed, the independent claims require that the plurality of protrusions of the bridge structure protrude from the interior surface of the second wall in an arrangement forming a pattern of curved surfaces between the one or more crests and the one or more troughs.

110. Even if one would have been motivated to combine Park, Baughan and/or Johnson (which I disagree with, for the reasons discussed below), Petitioner’s Park-Baughan-Johson combination does not disclose the “bridge structure” as properly construed. There are no curved surfaces in Baughan. Rather, as Petitioner and Dr. Black concede, Baughan discloses “that the spaced-apart discs [17] result in a *square wave shape* having crests and troughs” and that “the

notches 19 in the disc also form a *square wave shape*.” Petition at 44-45

(emphases added).



Ex. 1003 at ¶ 106 (annotating Ex. 1007 at FIG. 3)

111. In this regard, Baughan is similar to Black, which as I discussed above, was distinguished during prosecution because it lacks the claimed wave-shape. *Supra*, Section VII.A.

112. The Petition also argues that Baughan’s “notches 19 formed in each disc are described in the same way as the bridge structure of the ‘686 Patent” and that “the notches 19 in the disc also form a square wave shape.” Petition at 44-45. Petitioner shows this with the annotation below.



Petition at 45 (annotating Ex. 1007 at FIG. 5)

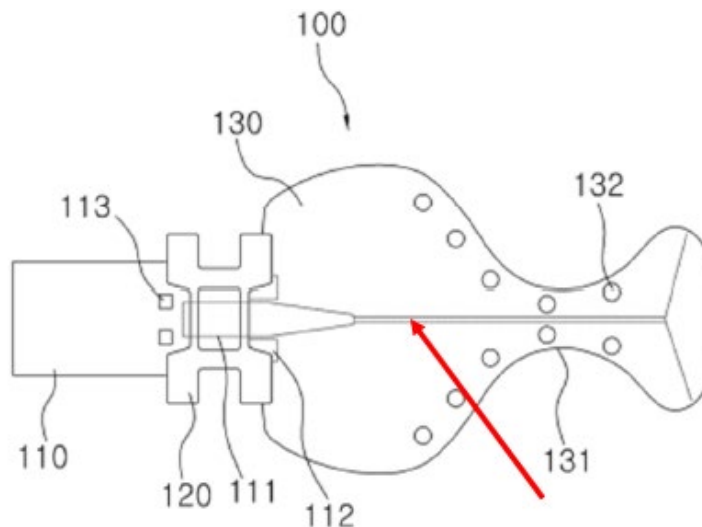
113. This appears to be an alternative theory for how the Park combination allegedly discloses a “wave shape.” Dr. Black similarly references the notches and asserts that they “follow a ‘wave shape’, just along the circumference of the disc. 17.” Ex. 1003 at ¶ 107. To the extent Petitioner and Dr. Black are relying on the notches 19 in FIG. 5 of Baughan as an alternative theory for how Baughan discloses the claimed wave-shape feature, I disagree because, once again, a “square” pattern does not meet the claim language as properly construed.

2. A POSITA Would Not Have Modified Park with Baughan or Johnson

114. Even if the Park-Baughan-Johnson combination meets all limitations of independent claim 12 (which it does not for at least the reason provided above), a POSITA would not have been motivated to modify Park with either Baughan or Johnson to arrive at the claimed invention.

115. As noted above, Petitioner and Dr. Black concede that Park does not expressly disclose any “bridge structure” feature. Dr. Black states that “Park also notes that its description omits that which is conventional, such as anti-collapse structure.” Ex. 1003 at ¶ 94. To the extent Dr. Black is asserting that “anti-collapse structures” were conventional in dental isolation mouthpieces prior to the ‘686 Patent, I disagree and note that Dr. Black presents no evidence or analysis showing that is the case.

116. Dr. Black identifies the feature show below with a red arrow and states that it “appears to be a light pipe extending through the mouth prop 100 . . . but it is unclear whether this is structural or simply something to assist with lighting.” Ex. 1003 at ¶ 94.



117. In his analysis, Dr. Black “assumes that there is a spine running down the symmetrical axis of the mouthpiece.” Ex. 1003 at ¶ 97. Later, he states that

“Park is not expressly clear whether there also exists a spine extending down the longitudinal axis of the mouth prop 100” and his “first impression was that the mouth prop 100 includes a spine, but it is equally possible that this line is reflective material to helps [sic] with light transmission.” Ex. 1003 at ¶ 126. Without conceding the correctness of his assumption, for this declaration, I will apply the same assumption as Dr. Black, i.e., the structure labeled with the arrow above is a spine running down the longitudinal axis of Park’s mouthpiece. Ex. 1003 at ¶ 97.

118. Dr. Black asserts that upon reviewing Park, “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.” Ex. 1003 at ¶ 96 (citing Ex. 1006 at ¶¶ 28, 42-43, 51; Ex. 1007 at ¶ 3:46-48). For at least the reasons discussed below, I disagree. There is nothing in Park or any other prior art in the Petition that would suggest to a POSITA that Park’s walls are likely to collapse during suction and therefore require modification, let alone a modification that results in the claimed inventions.

119. First, Dr. Black states that “[t]his is particularly true given how thin Park’s mouth prop 100 appears.” Ex. 1003 at ¶ 96. I disagree. Park does not provide any dimensions for the thickness of the various features of the mouth prop 100 or state that the figures are drawn to scale. *See* Ex. 1006. A POSITA would not be able to glean the relative thickness of the walls in Park from the figures, let

alone determine that the thickness of the walls is such that the mouthpiece is likely to collapse under suction. In its IPR Petition challenging the related '969 Patent, Petitioner admitted that "Park . . . is silent regarding the thickness of its various walls." Ex. 2022 at 74.

120. Second, Dr. Black asserts that a POSITA "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.'" Ex. 1003 at ¶ 96 (quoting Ex. 1006 at ¶¶ 32, 34). I disagree. While Park refers to a "predetermined elasticity," Park does not specify any values for this elasticity. A POSITA would recognize the silicone material can have varying properties depending on what material is selected.

121. For example, Ex. 2033 is a typical silicone rubber selection guide that a POSITA might consult when constructing a device made from silicone. The guide shows that multiple silicone products are available with a wide range of properties in terms of hardness, density, tensile strength, elastic modulus, tear strength, and heat resistance (including sufficient heat resistance for an autoclavable part). A POSITA would know that a silicone material can be selected that is relatively flexible but strong enough to avoid collapsing when a suction force is applied in the application described by Park.

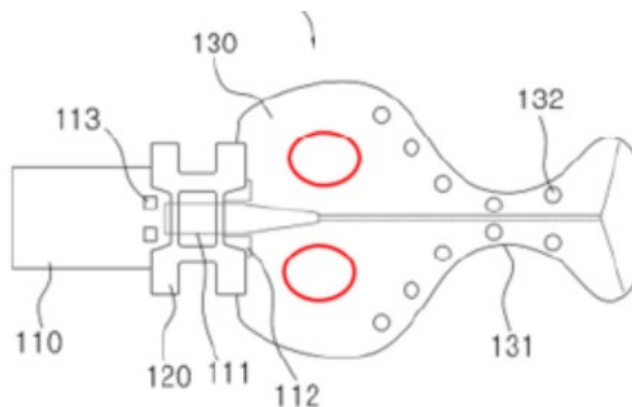
122. I note that in his declaration concerning the related ‘969 Patent, Dr. Black quotes the same sentence from Park regarding “elasticity” and states that “the elasticity would retract the cheek tissue,” and further that a POSITA “would understand that elasticity and ‘resiliency’ are essentially synonymous concepts when describing how an elastic device can retract cheek tissue.” Ex. 2036 at ¶ 155. This confirms that the silicone material used in Park is a resilient material and is not likely to collapse under suction.

123. Petitioner and Dr. Black’s analysis demonstrates that the silicone material used in Park provides at least some rigidity and is not inherently susceptible to collapsing during suction. For example, Dr. Black asserts that Park contains “sidewalls” and that these “sidewalls would assist with preventing collapse under suction.” Ex. 1003 at ¶ 96. To the extent Park has “sidewalls,” they would made of the same material as the rest of the mouthpiece, including the walls that Dr. Black asserts would “likely” collapse under suction given their material. Dr. Black agrees that Park’s mouthpiece is “formed in one piece.” Ex. 1003 at ¶ 119. Yet, according to Dr. Black, the “sidewalls” provide rigidity and resist collapse during suction despite the fact that they comprise the same silicone material that he says a POSITA would believe would collapse under suction. Ex. 1003 at ¶ 96.

124. As a further example, Dr. Black assumes that Park has a “spine” that runs down the longitudinal axis, and Dr. Black characterizes the spine as “anti-collapsing structure.” Ex. 1003 at ¶¶ 96-97. Again, the “spine” would be made of the same silicone materials as the walls.

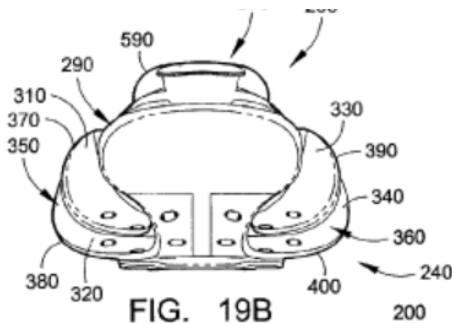
125. Each of these examples shows that, according to Petitioner and Dr. Black, Park already has rigid “anti-collapsing structure,” and that this structure comprises the same silicone material that Petitioner and Dr. Black characterize as being so flexible that the mouthpiece would “likely” collapse under suction. This is further evidence that a POSITA would not recognize any issue with collapsing under suction in Park that would motivate modifying Park with Baughan and/or Johnson.

126. As shown below, Dr. Black circles certain areas of Park’s mouthpiece in red and says that these are the areas most likely to collapse under suction. Ex. 1003 at ¶ 96.

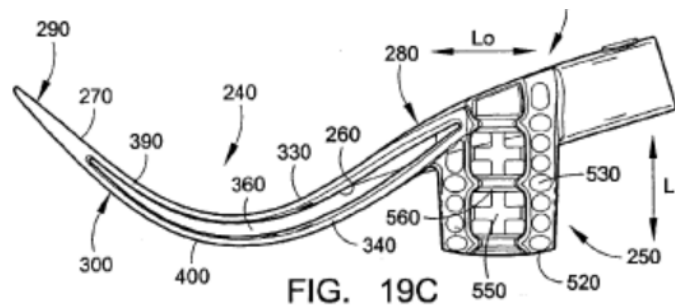


I disagree for at least the reasons discussed above – the mere fact that Park uses a “flexible” silicone material does not mean that these areas are likely to collapse under suction.

127. In connection with Ground 2, Petitioner and Dr. Black rely on the Hirsch reference. According to Petitioner and Dr. Black, the only difference between Park and Hirsch is that “Hirsch simply lacks a sidewall that Park discloses.” Ex. 1003 at ¶ 129; Petition at 51. As discussed above, Petitioner and Dr. Black concede that Park’s “sidewall” provides rigidity and constitutes “anti-collapse structure.” Ex. 1003 at ¶ 96 (“sidewalls would assist with preventing collapse under suction”). In at least one embodiment, Hirsch lacks a “sidewall.”



Ex. 1012 at FIG. 19B

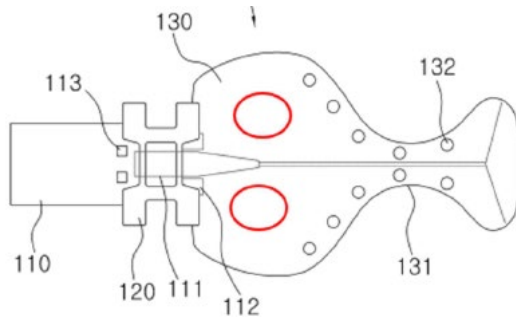


Ex. 1012 at FIG. 19C

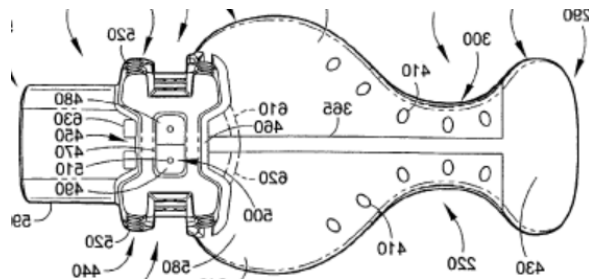
Like Park, Hirsch’s mouthpiece comprises a “translucent (e.g., transparent), flexible, soft, elastic, resilient, biocompatible thermoplastic elastomer.” Ex. 1012 at ¶ [0074].

128. If Petitioner and Dr. Black were correct that Park’s mouthpiece was “likely” to collapse under suction, then the same problem would apply at least

equally to Hirsch, especially because according to the Petition and Dr. Black, Hirsch “lacks a sidewall.” Ex. 1003 at ¶ 129. Yet, as shown below, there is no “anti-collapse” structure at the locations identified by Dr. Black as the “weak points” in Park that require reinforcement.



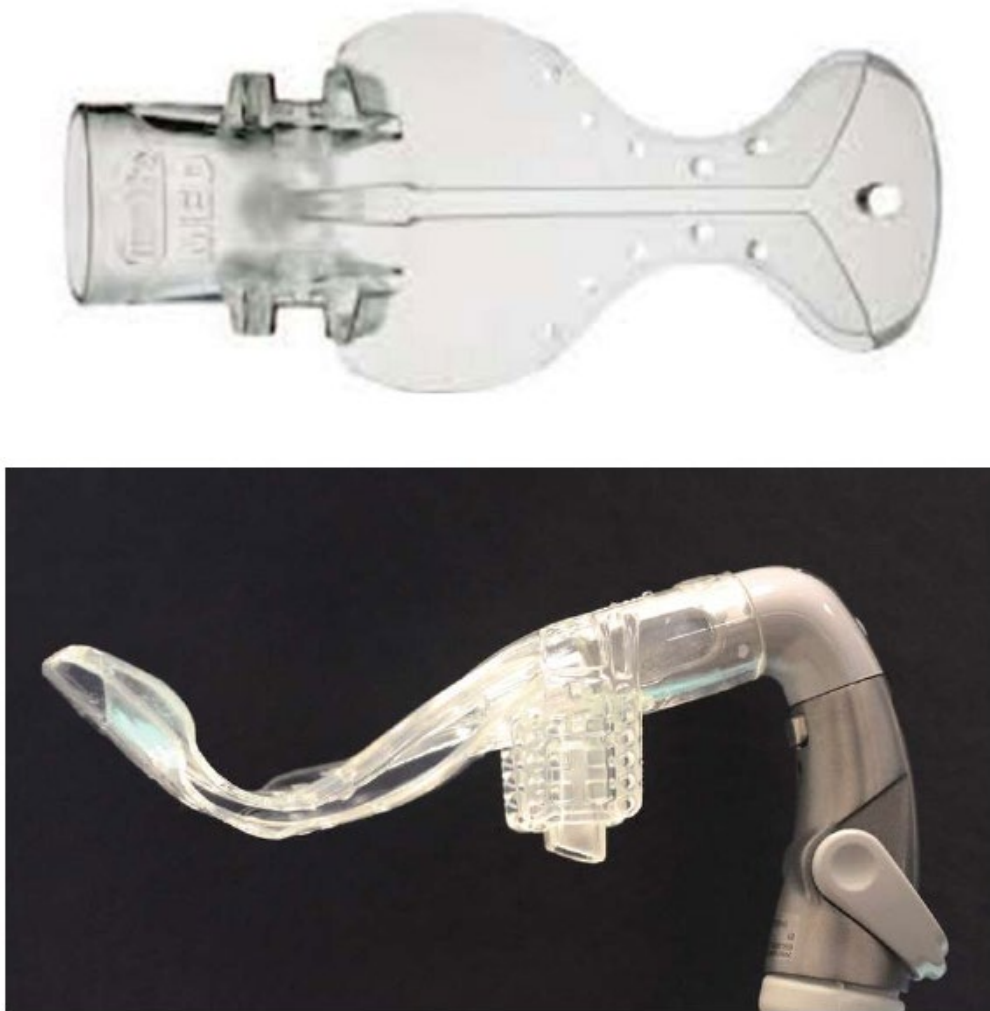
Ex. 1003 at ¶ 96



Ex. 1012 at FIG. 19E (rotated)

129. The fact that Hirsch does not contain “anti-collapse structure” at these locations reinforces the conclusion that Park does not suffer from a problem whereby its walls would collapse onto one another during suction in a way that blocks or impedes suction.

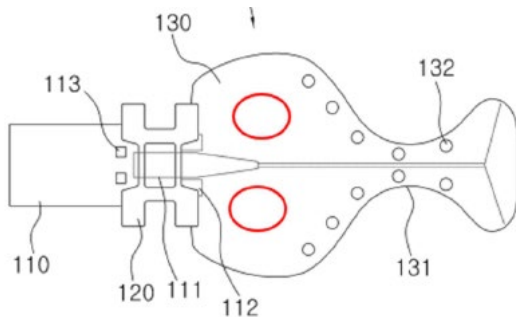
130. As another example, Dr. Black provides the photos below of a product called “Isolite” in his declaration:



Ex. 1003 at ¶ 11

131. Like the above embodiment from Hirsch, Isolite lacks a “sidewall.” It therefore follows that if Park is likely to collapse under suction, then problem would be equally applicable, if not more applicable, to the Isolite mouthpiece. Yet, like Hirsch, there are no anti-collapse structures at the locations identified by Dr. Black as requiring reinforcement in Park. This is clear because the material is transparent, and one can easily confirm that there is no structure at the locations in

the Isolite product corresponding to the circles Dr. Black draws on Park's mouthpiece.



Ex. 1003 at ¶ 96



Ex. 1003 at ¶ 11

132. The fact that Isolite does not contain “anti-collapse structure” at these locations reinforces the conclusion that Park does not suffer from a problem whereby its walls would collapse onto one another during suction in a way that blocks or impedes suction.

133. As noted above, Petitioner argues that unless Park is modified to include “anti-collapse” features, “collapsing *would occur* because Park teaches that the mouth prop comprises a flexible material, such as silicone.” Petition at 37 (emphasis added); Ex. 1003 at ¶ 96. Petitioner goes on to explain the consequences of this: “[i]f these areas collapse under suction, suction power would be significantly reduced or blocked entirely.” Petition at 38. Dr. Black states that “[e]ven 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.” Ex. 1003 at ¶ 98.

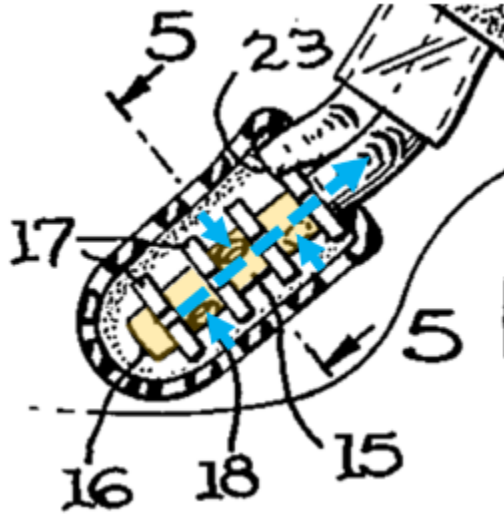
134. One of Park's objectives is to "form[] a suction line to expel foreign substances from the oral cavity" during dental procedures. Ex. 1006 at ¶ [0012]. If suction were blocked entirely, this would render Park's mouthpiece inoperable for its intended purpose. Similarly, even significantly reducing suction power would also render Park inoperable or at least highly ineffective at achieving its intended purpose. Nothing in Park would suggest to a POSITA that the mouthpiece disclosed therein is inoperable for its intended purpose. A POSITA would therefore know, contrary to Petitioner and Dr. Black's assertions, that Park does not collapse under suction because, according to Petitioner and Dr. Black, if it did, then it would not work in the first place.

135. To the extent a POSITA were to believe that Park's mouthpiece was likely to collapse under suction (which I disagree with), there would be other options available to a POSITA to address this problem as opposed to modifying Park's mouthpiece to include a bridge structure. For instance, a POSITA would know if Park's walls were too "thin," as Dr. Black asserts, they could simply thicken the walls to reinforce them and increase rigidity. As another example, if Park's material were too flexible and susceptible to collapse, a POSITA would know that they could easily select a stronger material that would more resistive to collapsing while still maintaining enough flexibility for use in a dental procedure.

136. A POSITA would recognize that both options described above would be far simpler and cheaper to implement in Park as opposed to adding a bridge structure as proposed by Petitioner and Dr. Black. Petitioner's proposed modification would require a far more complicated mold to create the mouthpiece with additional components than simply changing the material or thickening the walls. A POSITA would know that the mouthpiece in Park, which according to Dr. Black has an interior cavity, could be formed by injection molding with a single mold in a single molding process. This mold would include a structure to keep the walls separated and define the cavity. If a "bridge structure" were added to Park, the mold and/or the molding process would need to be modified to create the "bridge structure" that would only be attached to one wall and not the other. For example, the physical mold would need to be modified to include a more complicated geometry. As another example, this might require two separate molding processes to create the mouthpiece. This presents another potential point for failures or defects during manufacturing.

137. Turning to the additional references relied upon in Ground 1, Baughan is not directed to a dental isolation mouthpiece – it is directed to a saliva ejector. Ex. 1007 at 1:6-7. Thus, Baughan does not teach or suggest that a dental isolation mouthpiece like the one in Park would collapse under suction without adding an anti-collapse structure at the locations identified by Dr. Black.

138. Baughan is directed to a different problem and geometry than the alleged problem in Park. In Baughan, the discs 17 prevent the sleeve 24 from blocking the orifices 18 of the terminal tube portion 15, which are the source of suction. Ex. 1007 at 3:36-48.



Ex. 1007 at FIG 3 (excerpted and annotated)

139. Baughan's discs 17 are designed to prevent a moveable surface (the sleeve 24) from blocking holes providing suction from a fixed surface (the tube 15). By contrast, in Park, two surfaces are urged toward one another under suction rather than one surface being urged towards the source of suction.

140. Petitioner acknowledges that Baughan uses "outward projecting discs" around the circumference of an inner cylindrical tube. Petition at 41. Petitioner also acknowledges that Baughan's discs would need to be modified for use with Park and argues that "a PHOSITA using basic common sense, would

modify the discs for a tube-shaped embodiment to be projections for a flatter, non-tube embodiment.” *Id.* I disagree. The only reference Petitioner alleges teaches this feature is Johnson, which I discuss below.

141. Dr. Black asserts that “to the extent Patent Owner argues that the discs 17 of Baughan are not ‘integral with’ the interior surface of the second wall, Johnson” teaches this feature. Ex. 1003 at ¶ 100. This overlooks that independent claim 12 of the ‘686 Patent expressly requires that the protrusions are “integral with” the interior surface of the second wall.

142. In Baughan, the discs 17 are ***not*** integral with the surface that they “protrude” from. Baughan explains that “[t]he u-shaped tube portion 14 carries ***integral*** relatively short terminal tube extensions 15 having their lower ends 16 suitably closed, and carrying a plurality of longitudinally spaced circular flow rings or discs 17, suitably ***rigidly secured thereto*** in equidistantly spaced parallel relation and at right angles to the terminal tube portions 15.” Ex. 1007 at 2:19-25 (emphases added). Baughan therefore makes clear that the discs 17 are ***not*** integral with the terminal tube portions 15 – they are separate components that are coupled to the tube portion.

143. Again, the only other reference relied upon in Ground 1 is Johnson, which like Baughan, is not directed to a dental isolation mouthpiece. Petitioner and Dr. Black assert that Johnson “teaches that projections 81-86 are “formed on a flat

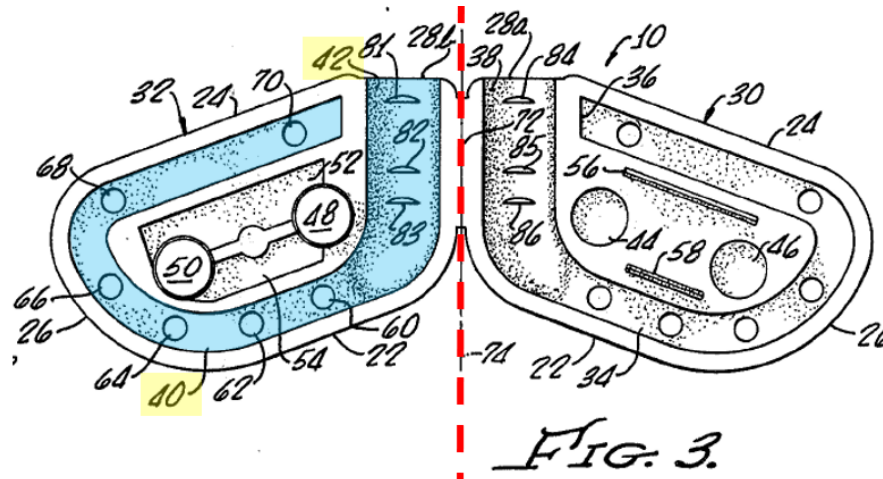
surface.” Petition at 33; Ex. 1003 at ¶ 100. I disagree. Johnson’s projections are *not* formed on a flat surface; they are formed on a curved surface.

144. Johnson explains: “[i]f deemed necessary or desirable, molded projections 81, 82, 83, 84, 86, 86 are formed on the interior surfaces of the neck sections 28a and 28b, having sharper corners or edges on their downwardly (as viewed in FIG. 3) facing edges in order to more firmly grasp the surface of the vacuum tube 12 and to better clamp the tube against inadvertent withdrawal from the cylindrical receiving opening.” Ex. 1008 at 4:16-23. There is no teaching or suggestion in Johnson that these projections serve the purpose of preventing two surfaces from collapsing onto one another. Instead, Johnson’s projections are used to grip or clamp the vacuum tube 12.

145. Johnson further explains that “[t]he grooves 38, 42, which communicate with the passage recesses 34, 40 of the respective plates 30, 32 are enlarged as compared to the passage recesses and each has a substantially *semi-circular* configuration to collectively define a circular cross-section vacuum tube receiving opening in the neck sections 28a and 28b of the neck 28 of the saliva ejector.” Ex. 1008 at 3:66-4:4 (emphasis added).

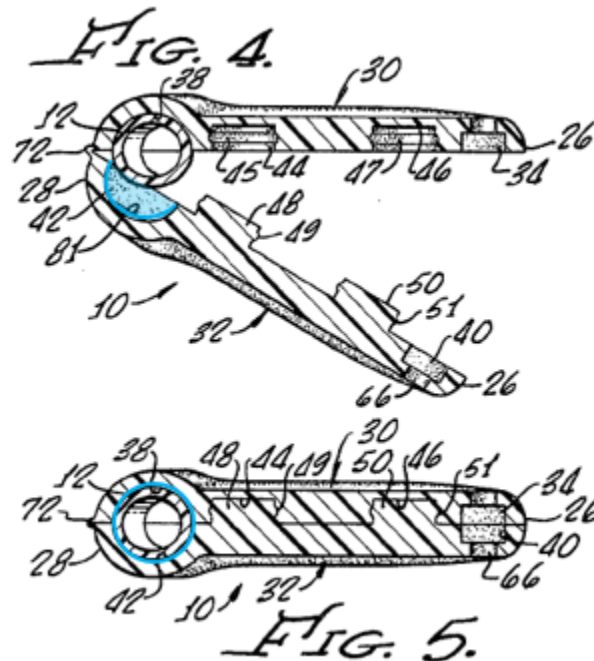
146. Johnson describes the feature shown with reference numeral 40 in FIG. 3 as follows: “recess 40 extend[s] from a closed end at the top rear edge of the plate forwardly along the edge of the plate, downwardly along the front edge

and rearwardly along the bottom edge where it terminates at groove 42 formed in the neck 28b of plate 32.” Ex. 1008 at 3:25-30. The plates 30 and 32 “pivot with respect to one another about a hinge axis (denoted by a line 74).” Ex. 1008 at 4:11-13.



Ex. 1008 at FIG. 3 (annotated)

147. As shown in FIGS. 4-5, when the plates 30 and 32 are closed, the recess 40 is not “flat” as asserted by Petitioner and Dr. Black – it is semicircular.



Ex. 1008 at FIGS. 4-5 (annotated)

148. Dr. Black further states that he is “informed by counsel that making something integral is simply an obvious design choice that cannot be the basis of a patentable invention.” Ex. 1003 at ¶ 100. I note that Dr. Black does not affirmatively say that making something integral is, in fact, “an obvious design choice.” To the extent that Dr. Black is asserting this, I disagree and reserve the right to supplement my opinions to the extent Petitioner and/or Dr. Black provide reasoning for why they believe this to be the case.

149. Dr. Black states that the discs 17 in Baughan “essentially the exact same concept I taught in Black when I taught transverse walls.” Ex. 1003 at ¶ 101. I disagree. The transverse walls in Black and not the “same concept” as the discs

17 in Baughan. As described above, the discs 17 go around the circumference of cylindrical tube 15, which contains orifices that apply suction, and prevent another generally cylindrical sleeve from collapsing onto the tube 15 and blocking the orifices. By contrast, the transverse walls in Black merely connect flaps together.

150. To this point, Dr. Black asserts that the transverse walls additionally “prevented collapse under suction.” Ex. 1003 at ¶ 101 (citing Ex. 1005 at 5:54-59). The cited portion of Black does not say that the transverse walls 48c were intended to prevent collapse under suction. Ex. 1005 at 5:54-59. Black does not expressly mention collapsing under suction as a problem or potential problem, let alone disclose that transverse walls are the solution.

3. Dependent Claims

151. Ground 1 challenges independent claim 12, which I discuss above, and also dependent claims 13-15, 17-19, and 20-21, which depend from independent claim 12. I note that Petitioner and Dr. Black’s analyses of these dependent claims rely on the same analysis and arguments for the “bridge structure” limitations that I discussed above. Petition at 46-49; Ex. 1003 at ¶¶ 114-25. I disagree with Petitioner and Dr. Black’s analyses of these dependent claims for at least the same reasons as independent claim 12.

B. Ground 2: Obviousness Based on Park, Baughan, Johnson, and Hirsch (Dependent Claims 16 and 19)

152. In Ground 2, Petitioner and Dr. Black allege that dependent claims 16 and 19 of the ‘686 Patent are obvious based on Park, Baughan, Johnson, and Hirsch. Petition at 49-51; Ex. 1003 at ¶¶ 126-31. Petitioner and Dr. Black do not rely on Hirsch for the claimed “bridge structure,” which as I discussed above, would not have been obvious in view of Park, Baughan, and Johnson. Thus, I disagree with Petitioner and Dr. Black’s conclusions in Ground 2 for these dependent claims for at least the same reasons I provided in connection with Ground 1.

IX. CONCLUSION

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

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

A handwritten signature in blue ink, appearing to read "C. Garris", is shown on a light blue background.

Date: September 28, 2025

Charles A. Garris, Jr., Ph.D.