

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. 11,589,969

Case No. IPR2025-01020

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. 11,589,969 (“the ‘969 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 ‘969 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 ‘969 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. 2017 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 '969 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 '969 patent (Ex. 1001), the '969 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 ‘969 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.

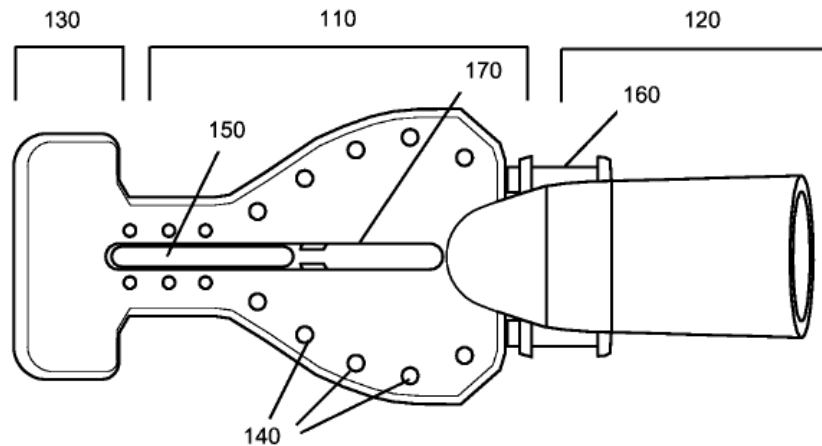
D. Dependent Claims

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 '969 PATENT

33. The '969 Patent discloses and claims a dental appliance often referred to as a dental isolation mouthpiece. Ex. 1001 at 1:16-18. The background section of the '969 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 1:20-22. 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 1:22-34. 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 1:34-37.

34. The inventors of the '969 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, 1:38-40. The '969 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 1:44-48. 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 3:19-25. FIG. 1B of the '969 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 3:44-47. According to the specification, the anterior and posterior walls “may serve to protect and separate the top of the mouth and the bottom of the mouth/tongue” and “protect the back of the mouth (e.g., throat and airway) from falling debris.” Ex. 1001 at 3:7-62.

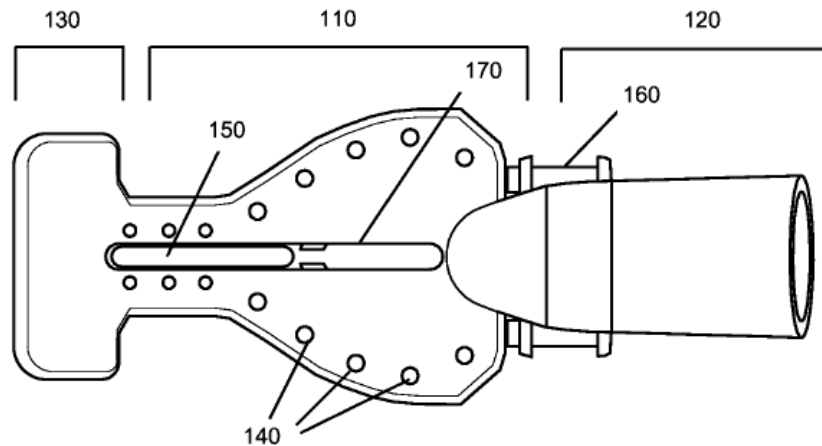
36. The specification details how the mouthpiece is used in dental procedure. “When placed in a patient’s mouth, the suction connector portion may protrude from one side of the patient’s mouth, while the main body portion 110 lies against the back of the patient’s mouth, and the cheek retractor portion 130 retracts the patient’s cheek on the opposite side of the patient’s mouth.” Ex. 1001 at 3:32-39. 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 4:4-8. The open slit 170 may also assist in the suctioning “of water, saliva and debris.” Ex. 1001 at 4:39-45.

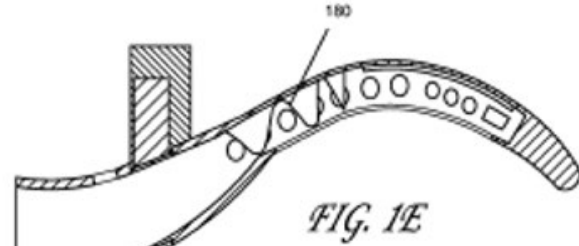
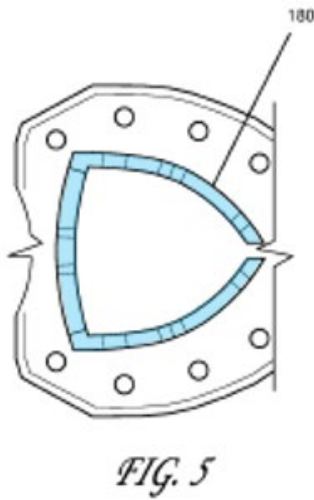


Ex. 1001 at FIG. 1B

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 4:46-49.

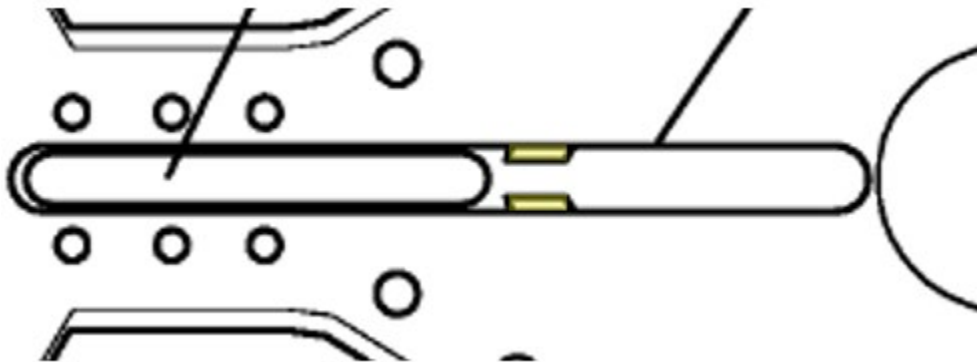
39. FIG. 5 shows a “close-up view of the bridge structure 180,” and FIG. 1E shows a cross-sectional view illustrating the bridge structure 180 formed on the interior surface of upper wall of the main body 110 and protruding toward the

lower wall:



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

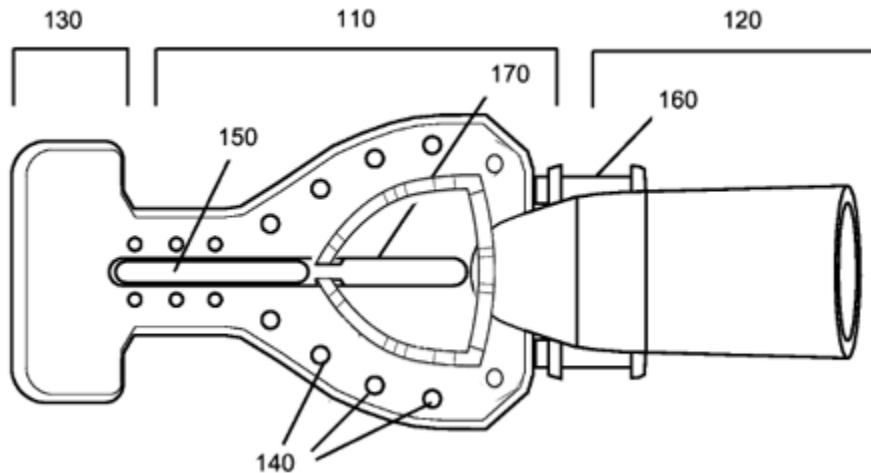
40. In FIG. 1A, a portion of the internal bridge structure is visible through the open slit 170, as shown by the highlighting below:



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.



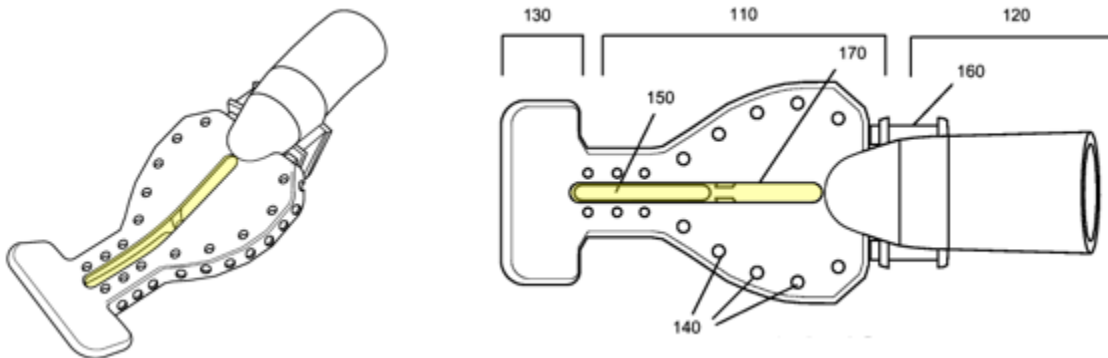
Ex. 1001 at FIGS. 1B and 5 (superimposed)

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 4:52-57. 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 2:16-22. 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 4:59-6, 5:1-5.

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 ‘969 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 1:57-59. 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 4:39-45.



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 2:16-22.

47. The independent claims of the '969 Patent are reproduced below with the identifiers used by Petitioner and Dr. Black for ease of reference:

48. Independent claim 1 recites:

1(a)	A dental mouthpiece comprising:
1(b)	a main body portion, configured as a pocket having a plurality of perforations in communication with an interior open space,
1(c)	the pocket having a first end that is narrower than a second end, the pocket is defined by:
1(d)	a first wall having a shape defined by an exterior edge, wherein the first wall includes an opening to the interior open space of the pocket,
1(e)	a second wall having a shape corresponding to the defined shape of the first wall, wherein an exterior edge of the second wall shape corresponds to the exterior edge of the first wall, and
1(f)	a side wall connecting the exterior edge of the first wall to the corresponding edge of the second wall;
1(g)	the second wall comprising a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall and extending a span between the first wall and the second wall, wherein the bridge structure is not attached to the first wall,

1(h)	wherein the plurality of protrusions of the bridge structure protrude from the interior surface of the second wall in a wave shape comprising one or more crests and one or more troughs and wherein the span between the first and the second wall is less than a width of the first and the second wall,
1(i)	wherein a shape of the interior open space of the pocket spans between the defined shape of the first wall and the corresponding shape of the second wall, and
1(j)	the pocket including a transition portion at the first end and that flexibly connects to a cheek retractor, wherein the plurality of perforations comprise one or more perforations at the transition portion.

49. Independent claim 16 recites:

16(a)	A dental mouthpiece comprising:
16(b)	a cheek retractor;
16(c)	a main body portion having a first end connected to the cheek retractor, the main body portion configured as a pocket having a plurality of perforations in communication with an interior open space, the pocket is defined by:

16(d)	a first wall having a shape defined by an exterior edge, wherein the first wall includes an opening to the interior open space of the pocket,
16(e)	a second wall having a shape corresponding to the defined shape of the first wall, wherein an exterior edge of the second wall shape corresponds to the exterior edge of the first wall, and
16(f)	a side wall connecting the exterior edge of the first wall to the corresponding edge of the second wall;
16(g)	the second wall comprising a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall and extending a span between the first wall and the second wall, wherein the bridge structure is not attached to the first wall, wherein the plurality of protrusions of the bridge structure protrude from the interior surface of the second wall in a wave shape comprising one or more crests and one or more troughs;
16(h)	the pocket including a transition portion at the first end that flexibly connects to the cheek retractor;
16(i)	a suction connector portion connected to a second end of the main body portion, the suction connector configured to connect a vacuum source to the interior open space of the pocket within the main body portion.

50. Independent claim 19 recites:

19(a)	A dental mouthpiece comprising:
19(b)	a main body portion configured as a pocket at least partially enclosing an interior space, the pocket defined by:
19(c)	a first wall that includes one or more perforations in communication with the interior space of the pocket, the first wall having a shape defined by one or more edges along one or more sides;
19(d)	a second wall having a shape that corresponds to the shape of the first wall, the shape of the second wall defined by one or more corresponding edges along one or more corresponding sides,
19(e)	wherein the second wall includes a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall within the interior space of the pocket, 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, and
19(f)	a connecting wall that connects the one or more edges of the first wall to the one or more corresponding edges of the second wall across a span between the first wall and the second wall;

19(g)	a suction connector portion connected to a first end of the main body portion, the suction connector configured to connect a vacuum source to the interior space of the pocket; and
19(h)	a cheek retractor connected to a second end of the main body portion, wherein the second end is opposite the first end of the main body portion.

V. LEVEL OF SKILL IN THE ART

51. 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.

52. 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 28-29.

53. 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.

54. 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 am also familiar with individuals having this level of skill in the relevant timeframe.

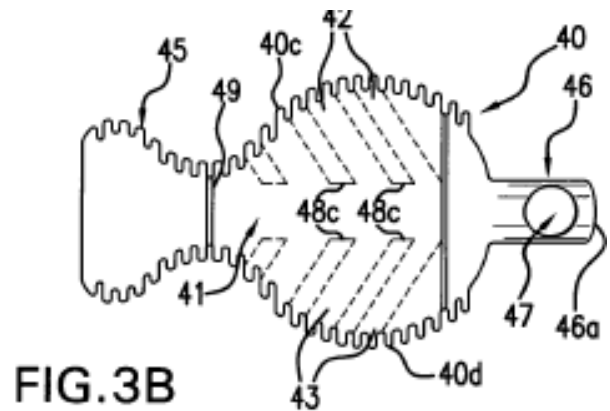
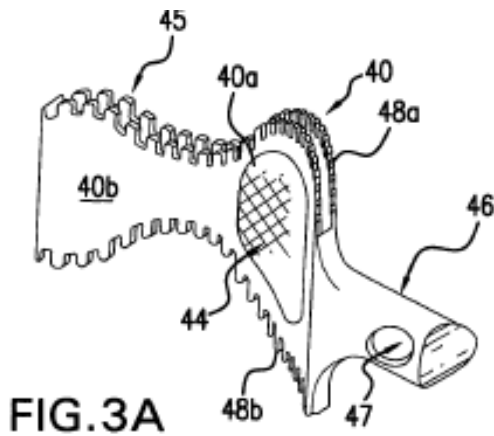
VI. SUMMARY OF REFERENCES IN THE PETITION

55. Below, I provide a summary of each of the references that are relied upon in the Petition.

A. Black (Ex. 1005)

56. 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.

57. 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

58. 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.

59. 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.

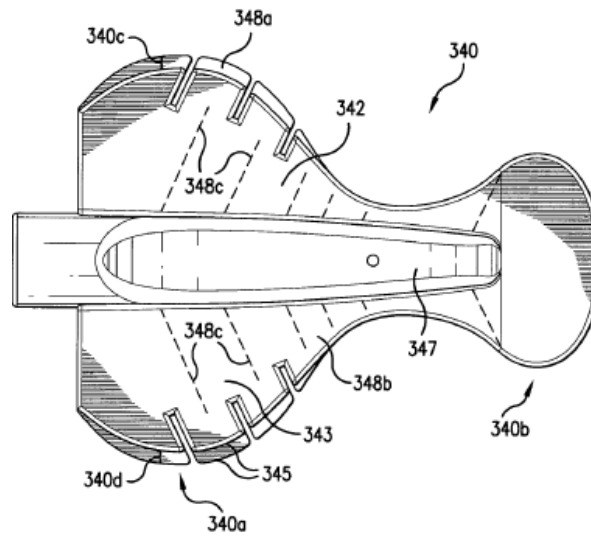


FIG. 23A

Ex. 1005 at FIG. 23A

60. 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.

61. 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.

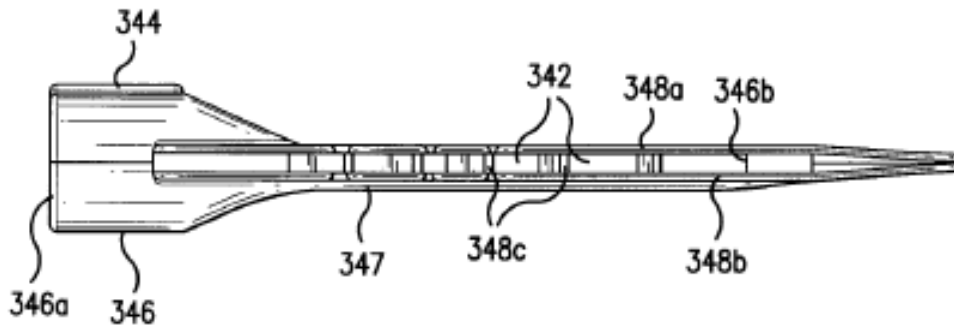


FIG. 23C

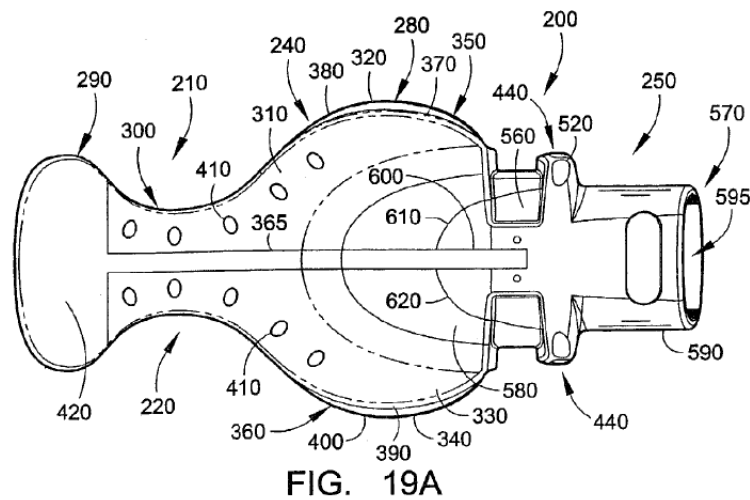
Ex. 1005 at FIG. 23C

B. Hirsch (Ex. 1012)

62. Hirsch '129 (Ex. 2005) is a continuation-in-part of the version of Hirsch (Ex. 1012) in the Petition. There are no material differences between Hirsch and Hirsch '129 because FIGS. 1-20 in Hirsch and Hirsch '129 are identical. Ex. 1012 at FIGS. 1-20; Ex. 2005 at FIGS. 1-20.

63. 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].

64. 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].

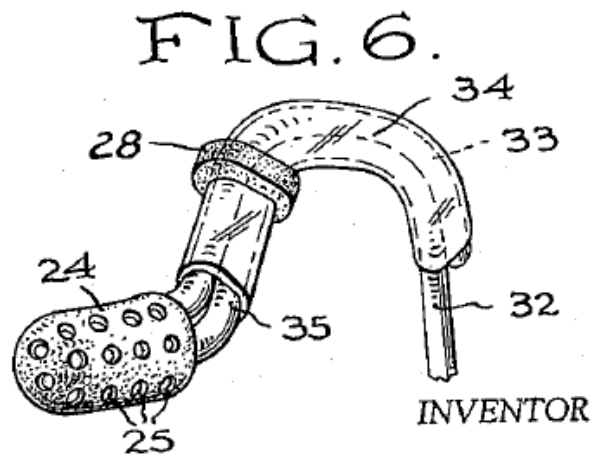


Ex. 1012 at FIG. 19A

C. Baughan (Ex. 1007)

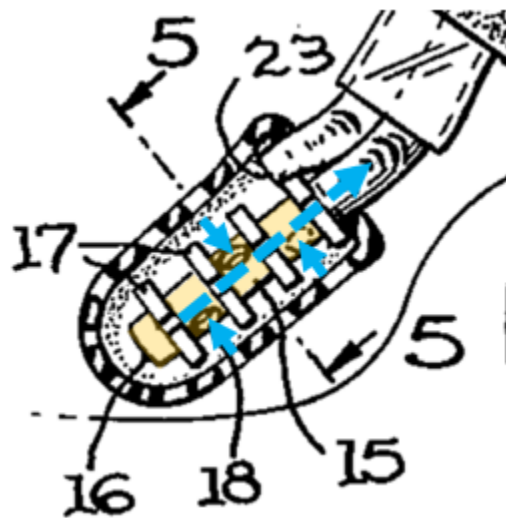
65. Baughan is directed to a different type of dental appliance than the '969 Patent: a dental saliva ejector with "suction relief means." Ex. 1007 at 1:6-7. The background section of the '969 Patent mentions high speed and low speed "suction ejector[s]" as being a different type of dental device than an isolation mouthpiece. Ex. 1001 at 1:24-29.

66. 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

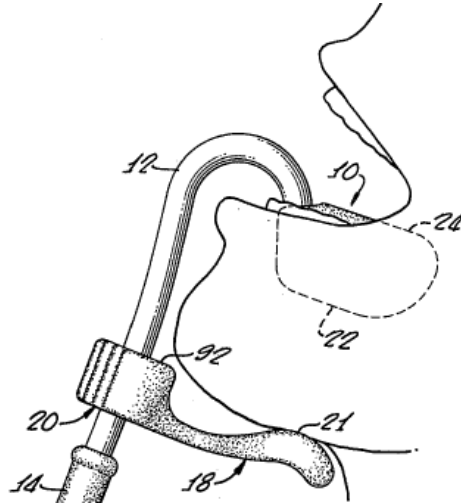
67. In Baughan, suction is applied via a terminal tube portion 15 with orifices 18, which in turn is surrounded by a series of circular discs 17 which prevent the outer sleeve 24 from blocking the orifices 18 during operation. Ex. 1007 at 3:36-48.



Ex. 1007, FIG 3 (excerpted and annotated)

D. Johnson (Ex. 1008)

68. 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:

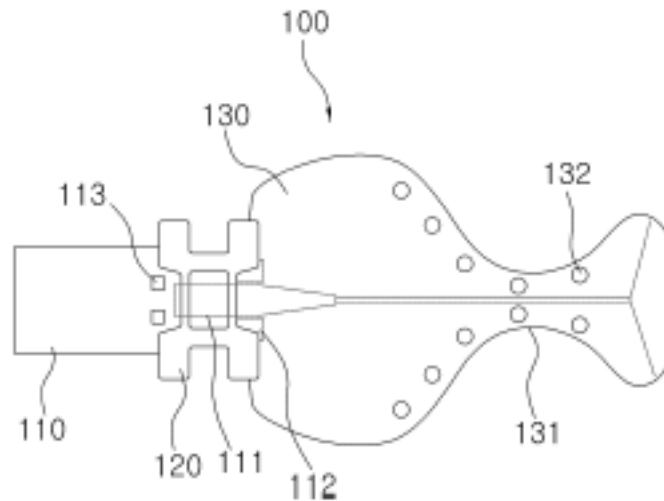


Ex. 1008 at FIG. 1

E. Park (Ex. 1006)

69. Park is a Korean patent reference that describes “a detachable oral illuminating device with a mouth prop that maintains the patient’s mouth in an open state, suppresses the movement of the tongue, allows for illumination and suction of foreign substance sin the oral cavity, and enables the sterilization of only the mouth prop.” Ex. 1006 at ¶ [0010].

Fig. 3



Ex. 1006 at FIG. 3

VII. CLAIM CONSTRUCTION

70. I understand that Petitioner and Dr. Black did not expressly propose any terms or phrases from the '969 Patent for construction. Petition at 29-30; Ex. 1003 at ¶¶ 52-55.

A. The “bridge structure” limitations (claims 1, 16 and 19)

71. Independent claim 19 of the '969 Patent recites: “the second wall includes a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall within the interior space of the pocket” where “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.” Ex. 1001 at 8:30-38. Independent claims 1 and 16 similarly recite: “the plurality of protrusions of the bridge structure

protrude from the interior surface of the second wall in a wave shape comprising one or more crests and one or more troughs.” Ex. 1001 at 6:27-36 (claim 1), 8:1-6 (claim 16).

72. 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 ‘969 Patent. My opinions follow.

73. 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 29-30; Ex. 1003 at ¶¶ 52-55. However, in Grounds 1-2, they both assert that rectangular protrusions meet the “wave shape” requirement in these phrases. Petition at 43-44, 65-66. Dr. Black asserts 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. 1003 at ¶ 99.

74. I understand that Petitioner has also challenged U.S. Patent No. 12,290,418, which is related to the ‘969 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:

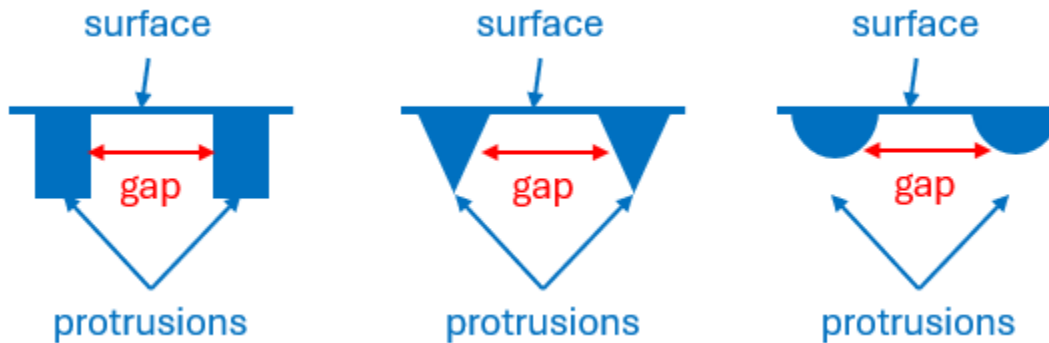
This limitation requires that the bridge structure has a plurality of "wave-like" protrusions. In light of the specification, **this merely means that the wave-like structure needs spaced-apart projections with**

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. 2019 (emphasis added).

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

76. Starting with the claim language itself, claim 19 recites that the bridge structure “includes 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.).



77. The claims of the '969 Patent require more than just a plurality of spaced-apart protrusions with gaps between them. The independent claims recite either that “the plurality of protrusions of the bridge structure protrude from the interior surface of the second wall in *a wave shape comprising one or more crests and one or more troughs*” (claims 1 and 16) or “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*” (claim 19). This language defines a specific shape or geometry for the protrusions that comprise the claimed bridge structure.

78. As noted above, Petitioner and Dr. Black take the position that this entire phrase merely requires “spaced-apart projections with gaps therebetween.” Ex. 1003 at ¶ 99. I disagree. A POSITA would not read the claims of the '969 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.

79. The specification states that the "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." Ex. 1001 at 2:39-48. The specification goes on to explain:

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.

Id. at 2:13-22.

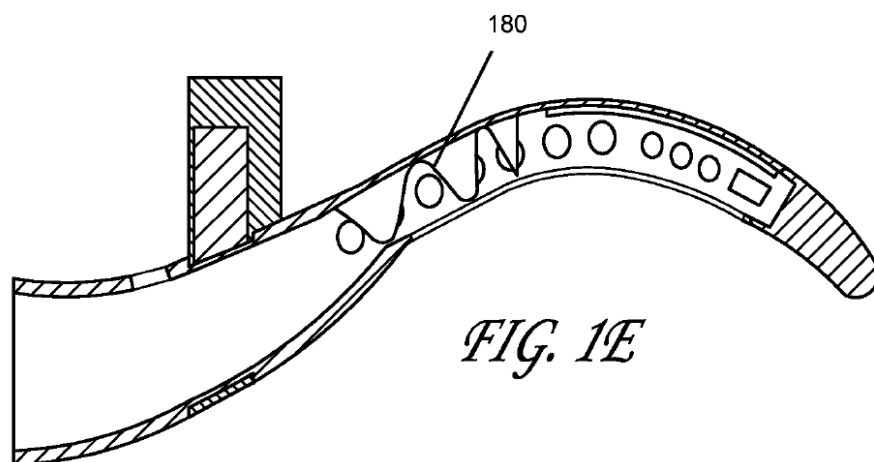
80. The specification also discloses:

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 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. 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).

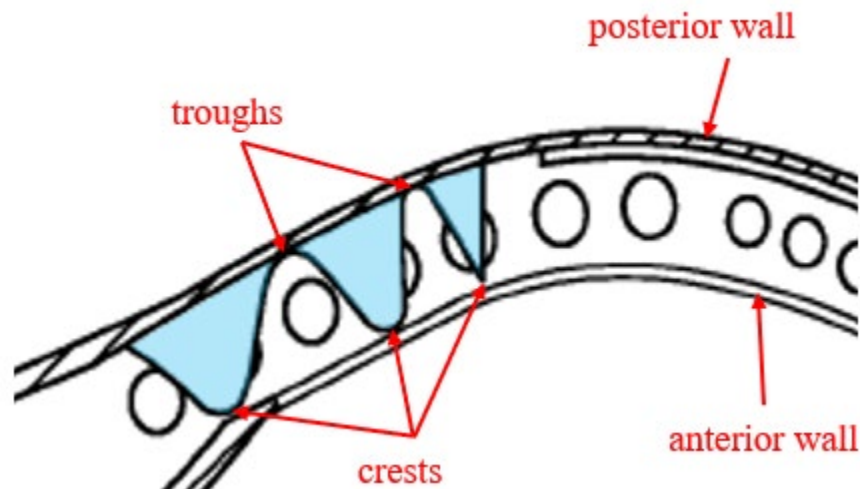
Ex. 1001 at 4:46-65.

81. 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:



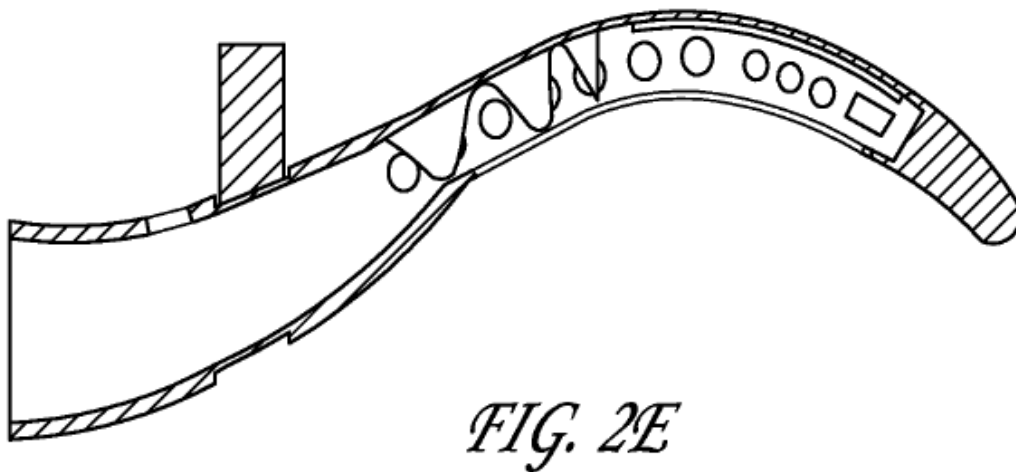
Ex. 1001 at FIG. 1E (excerpted and annotated)

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

82. 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

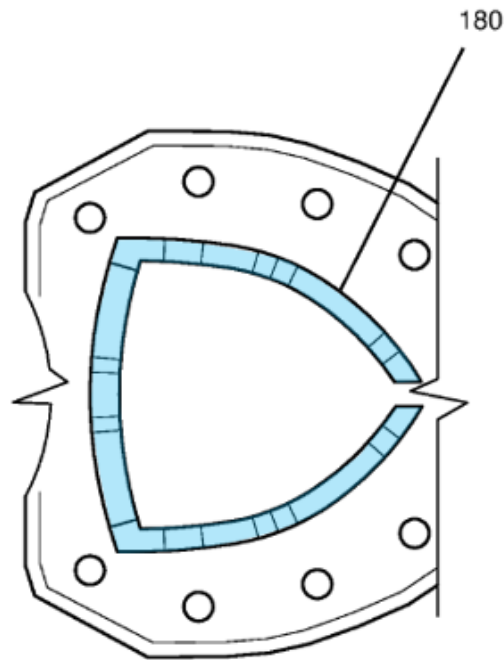
what side one is looking from), which is why the view of the right protrusion of the bridge structure in FIG. 1E appears to have little curvature. As such, a POSITA would understand that, if the viewing angle in FIG. 1E were changed to be more perpendicular to right protrusion, that right protrusion 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 2:13-22, 4:46-65.

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



Ex. 1001 at FIG. 2E

84. A top view of the bridge structure is shown in FIG. 5 of the ‘969 Patent.

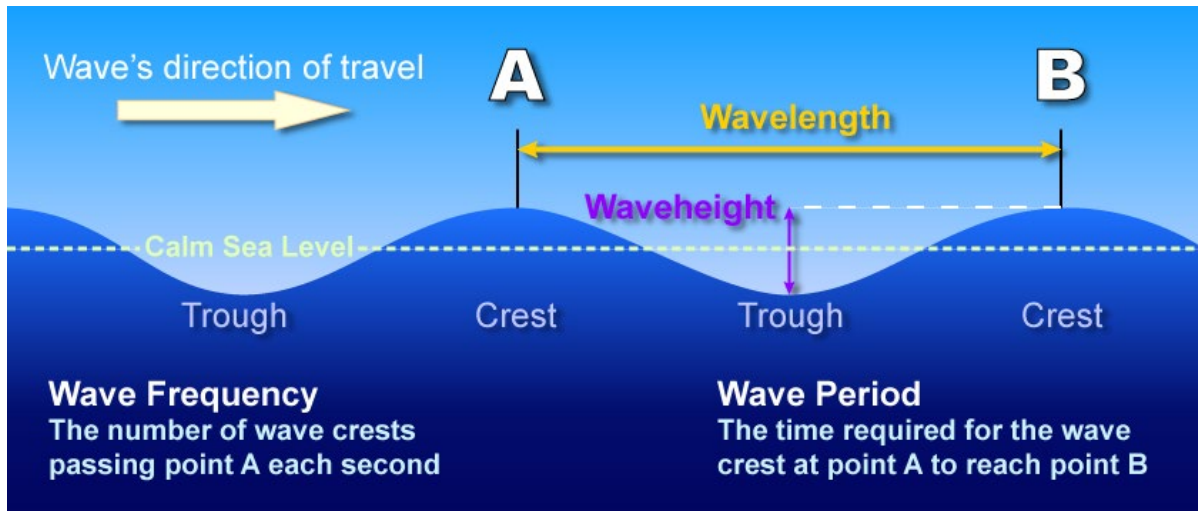


Ex. 1001 at FIG. 5 (annotated)

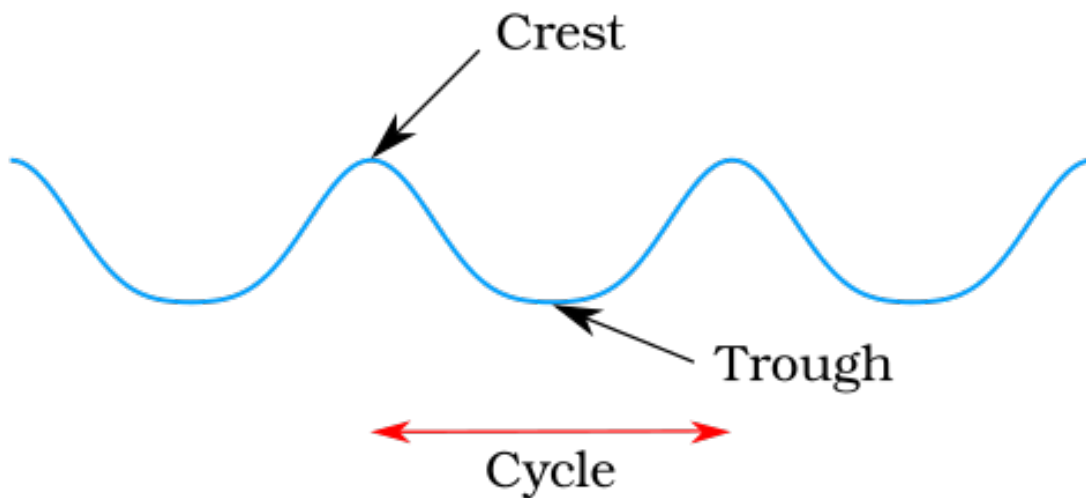
85. There is no example of a “bridge structure” in the specification or drawings of the ‘969 Patent that includes protrusions in a rectangular or square shape.

86. As noted above, the ‘969 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.

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



Below is another illustration of crests and troughs:²



88. In the context of the specification, the crests are the points away from the second wall that serve as contact points against the first wall during suction,

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

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

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 2:16-21, 4:59-63 (referring “gaps (or troughs) between the waves”).

89. My opinions regarding the meaning of these claim terms to a POSITA is also consistent with the dictionary definition for these claim terms. The dictionary definition of “wave” is “a shape or outline having successive curves.” Ex. 2020 (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. 2021 (Merriam-Webster Dictionary). The dictionary defines “trough” as “the minimum point of a complete cycle of a periodic function.” Ex. 2022 (Merriam-Webster Dictionary).

90. Putting all of this together, the claimed phrases require that the protrusions of the bridge structure protrude from the interior surface of the second wall toward the first wall in an arrangement forming a *pattern of curved surfaces* between the one or more crests and the one or more troughs.

91. The prosecution history for the ‘969 Patent and the parent ‘232 Patent further confirms my opinions regarding the claim language.

92. 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 ‘969 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.

93. 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).

94. 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;

95. 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 Dr. Black's assertion that the issued claims of the '969 Patent should be construed to merely require "spaced-apart projections with gaps therebetween." Ex. 1003 at ¶ 99.

96. 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	<input type="checkbox"/> 101	<input type="checkbox"/> 112	<input checked="" type="checkbox"/> 102	<input checked="" type="checkbox"/> 103	<input type="checkbox"/> 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 discussed and authorized by Applicant's counsel.</u>					

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

<p>1. (currently amended) A dental mouthpiece composed of a bendable material, the dental mouthpiece formed in a curve and comprising:</p> <p style="padding-left: 40px;">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 <u>in a wave shape</u>, 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 <u>wave shape bridge structure</u>, and wherein a plurality of troughs <u>of the wave shape</u> between the spaced contact points allow for suction through the bridge structure;</p>

98. The prosecution history of the ‘969 Patent further confirms this understanding of the “wave shape” language. There were several office actions

include which Black was discussed and the Examiner agreed that Black does not have a “wave shape” bridge structure.

99. First, in a Final Office Action issued on June 6, 2016, the Examiner found that “Black et al. discloses the invention substantially as claimed *except for a bridge structure.*” Ex. 1002 at 247.

5. **Claims 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. in view of Riddle (1,471,207).** Black et al. discloses the invention substantially as claimed except for a bridge structure. Riddle discloses a saliva ejector tube having a bridge structure protruding from an interior surface of a wall thereof and unattached to the opposite wall. The protruding bridge comprises a plurality of protrusions (waved wire) to keep the walls separated from one another during suction (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such bridge into Black et al.' device in order to prevent collapse when under suction pressure as explicitly taught by Riddle.

At the time, claims 9-10 recited the following:

9. (previously presented) The dental mouthpiece of claim 1 further comprising a bridge structure protruding from an interior surface of the posterior wall and unattached to the anterior wall, the protruding bridge structure comprising a plurality of protrusions collectively providing spaced contact points that keep the anterior wall separated from the posterior wall during suction.

10. (previously presented) The dental mouthpiece of claim 9, wherein the provided suction further draws fluids through spaces between the protrusions of the bridge structure towards the vacuum source.

Ex. 1002 at 225.

100. Second, in a Non-Final Office Action issued on November 7, 2016, the Examiner found that “Black et al in view of McKelvey discloses the invention substantially as claimed, *except the bridge structure.*” Ex. 1002 at 349-50.

7. **Claims 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. in view of McKelvey as applied to claim 1 as detailed above, and further in view of Riddle (1,471,207).** Black et al. in view of McKelvey discloses the invention substantially as claimed except for a bridge structure. Riddle discloses a saliva ejector tube having a bridge structure protruding from an interior surface of a wall thereof and unattached to the opposite wall. The protruding bridge comprises a plurality of protrusions (waved wire) to keep the walls separated from one another during suction (Fig. 1). It would have been obvious to one having ordinary

At the time, claims 9-10 recited the following:

9. (previously presented) The dental mouthpiece of claim 1 further comprising a bridge structure protruding from an interior surface of the posterior wall and unattached to the anterior wall, the protruding bridge structure comprising a plurality of protrusions collectively providing spaced contact points that keep the anterior wall separated from the posterior wall during suction.

10. (previously presented) The dental mouthpiece of claim 9, wherein the provided suction further draws fluids through spaces between the protrusions of the bridge structure towards the vacuum source.

Ex. 1002 at 278.

101. Third, in a Final Office Action issued on January 16, 2018, the Examiner asserted that “Maycher/Black discloses the invention substantially as claimed except for a bridge structure.” Ex. 1020 at 18.

8. Claims 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Maycher et al. in view of Black et al., as applied to claim 21, and further in view of Riddle (1,471,207).

Maycher/Black discloses the invention substantially as claimed except for a bridge structure. Riddle discloses a saliva ejector tube having a bridge structure 5 protruding from an interior surface of a wall thereof and unattached to the opposite wall. The protruding bridge comprises a plurality of protrusions (waved wire) to keep the walls separated from one another during suction (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such bridge into Maycher/Black's device in order to prevent collapse when under suction pressure as explicitly taught by Riddle.

At that time, pending claims 9 and 10 recited:

9. (previously presented) The dental mouthpiece of claim 21 further comprising a bridge structure protruding from an interior surface of the posterior wall and unattached to the anterior wall, the protruding bridge structure comprising a plurality of protrusions collectively providing spaced contact points that keep the anterior wall separated from the posterior wall during suction.

10. (previously presented) The dental mouthpiece of claim 9, wherein suction provided at the suction connector within the interior of the pocket draws fluids through spaces between the protrusions of the bridge structure towards the suction connector.

Ex. 1002 at 477.

102. Fourth, in a Non-Final Office Action issued on October 5, 2018, the Examiner found that Black does not disclose the “bridge structure.” Ex. 1020 at 125-27.

5 **Claims 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Maycher et al. in view of Black et al., as applied to claim 21, and further in view of Riddle (1,471,207).** Maycher/Black discloses the invention substantially as claimed except for a bridge structure. Riddle discloses a saliva ejector tube having a bridge structure 5 protruding from an interior surface of a wall thereof and unattached to the opposite wall. The protruding bridge comprises a plurality of protrusions (waved wire) to keep the walls separated from one another during suction (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such bridge into Maycher/Black's device in order to prevent collapse when under suction pressure as explicitly taught by Riddle.

At that time, pending claims 9 and 10 recited:

9. (previously presented) The dental mouthpiece of claim 21 further comprising a bridge structure protruding from an interior surface of the posterior wall and unattached to the anterior wall, the protruding bridge structure comprising a plurality of protrusions collectively providing spaced contact points that keep the anterior wall separated from the posterior wall during suction.

10. (previously presented) The dental mouthpiece of claim 9, wherein suction provided at the suction connector within the interior of the pocket draws fluids through spaces between the protrusions of the bridge structure towards the suction connector.

Ex. 1020 at 65.

103. Fifth, in a Final Office Action issued on July 15, 2019, the Examiner found that Maycher and Black do not disclose the “bridge structure.” Ex. 1020 at 170-72.

5 Claims 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Maycher et al. in view of Black et al., as applied to claim 21, and further in view of Riddle (1,471,207).

Maycher/Black discloses the invention substantially as claimed except for a bridge structure. Riddle discloses a saliva ejector tube having a bridge structure 5 protruding from an interior surface of a wall thereof and unattached to the opposite wall. The protruding bridge comprises a plurality of protrusions (waved wire) to keep the walls separated from one another during suction (Fig. 1). It would have been obvious to one having ordinary skill in the art at the

Pending claims 9-10 recited:

9. (previously presented) The dental mouthpiece of claim 21 further comprising a bridge structure protruding from an interior surface of the posterior wall and unattached to the anterior wall, the protruding bridge structure comprising a plurality of protrusions collectively providing spaced contact points that keep the anterior wall separated from the posterior wall during suction.

10. (currently amended) The dental mouthpiece of claim 9, wherein suction provided at the suction connector within the interior open space of the pocket draws fluids through spaces between the protrusions of the bridge structure towards the suction connector.

Ex. 1020 at 147.

104. On January 21, 2021, the Applicant added new independent claim 23 (which eventually issued as independent claim 19 in the ‘969 Patent), which,

similar to the issued claims in the Parent '232 Patent, recited: “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.**” Ex. 1020 at 329. This new claim is reproduced in its entirety below:

23. (new) A dental mouthpiece comprising:
a main body portion configured as a pocket having an interior space, the pocket defined by:
a first wall that includes one or more perforations in communication with the interior space of the pocket, and
a second wall that includes a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall within the interior space of the pocket, 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, and
a suction connector portion connected to a first end of the main body portion, the suction connector configured to connect a vacuum source to the interior space of the pocket; and
a cheek retractor connected to a second end of the main body portion, wherein the second end is opposite the first end of the main body portion.

105. Pending claims 21 and 22 (which issued as independent claims 1 and 16, respectively) were similarly amended to include the “wave shape” claim language. Ex. 1020 at 326-28.

106. Despite the Examiner’s use of Black in the various rejections summarized above, the Examiner determined claim 23 was allowable over the prior art, including Black. Ex. 1021 at 296-301. The Examiner’s allowance of

claim 23 (now claim 19 in the '969 Patent) is consistent with the prior determinations in the Parent '232 Patent that Black does not disclose the claimed “bridge structure” because Black lacks the claimed “wave shape comprising one or more crests and one or more troughs.” Ex. 1015 at 109-11.

107. The Petition discusses a portion of the prosecution history of the '969 Patent suggests that the Examiner found the pending dependent claims directed to the bridge structure allowable over Black “likely because this version of dependent claim 9 specifically recited that the bridge structure protruding from an interior surface of the posterior wall is *unattached* to the anterior wall” and that “Black, on the other hand, specifically teaches that transverse walls 48c connect to *both* the anterior and posterior layers 48a, 48b.” Petition at 26. I agree that this is one distinction between independent claims 1 and 16 of the '969 Patent, but it is not the only distinction between Black and the challenged claims. As noted above, during prosecution of the parent '232 Patent, the addition of the “wave shape” language was critical to overcoming Black. There were two independent bases for overcoming Black during prosecution: (1) Black’s transverse walls cannot be a “bridge structure” but they are not “unattached” and (2) Black’s transverse walls do not have a “wave shape.” Each of the independent claims of the '969 Patent recite at least one of these features.

VIII. OPINIONS ON GROUNDS IN THE PETITION

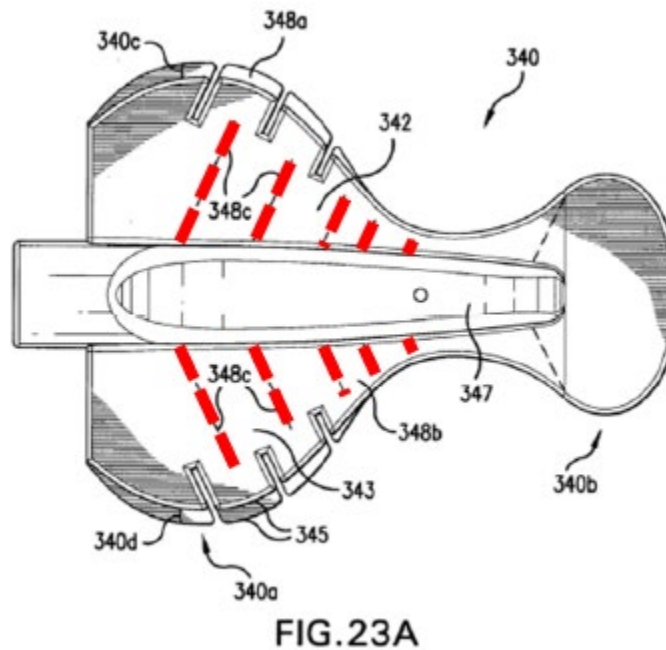
108. The Petition includes five grounds challenging the validity of the ‘969 Patent. I offer my opinions on each ground below.

A. Ground 1: Anticipation by Black (Independent Claim 19 Only)

109. I understand that in Ground 1, Petitioner and Dr. Black allege that claim 19 of the ‘969 Patent is anticipated by Black. Petition at 36-50; Ex. 1003 at ¶¶ 79-110. For at least the reasons discussed below, I disagree.

110. Limitation 19(e) recites: “wherein the second wall includes a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall within the interior space of the pocket, 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.”

111. For this limitation, Petitioner and Dr. Black cite aspects of two embodiments from the Black reference. Petition at 42-45; Ex. 1003 at ¶¶ 97-103. First, Petitioner and Dr. Black point to the embodiment in FIGS. 23A-C of Black, and specifically, the transverse walls 348a that are integral with the posterior flap 348a and the anterior flap 348b:



Ex. 1005 at FIG. 23A (annotated)

112. For the “wave shape” requirement within limitation 19(e), Petitioner and Dr. Black assert that Black’s “transverse walls 348c form crests in a wave shape and the channels 342 form troughs in a wave shape,” and that the annotated version of FIG. 23C below “illustrates the *square wave shape* formed by the presence of [sic] absence of the transverse walls.” Petition, 43-44 (emphasis added); Ex. 1003 at ¶ 99.

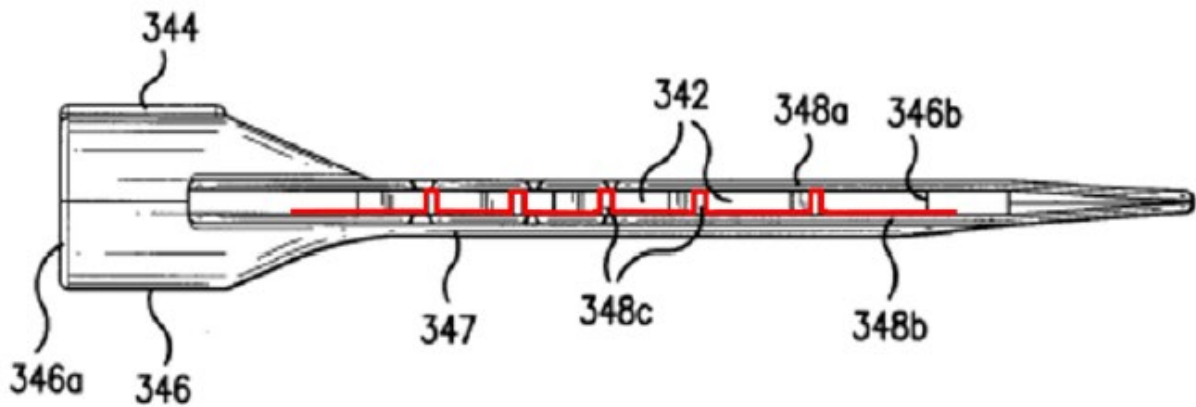


FIG.23C

Petition, 44 (annotating Ex. 1005 at FIG. 23C); Ex. 1003 at ¶ 99 (same)

113. Petitioner and Dr. Black’s annotated version of FIG. 23C can be misleading as the red lines outlining the alleged “square wave” are not “protrusions.” In my view, the image below is more accurate annotation of FIG. 23C:

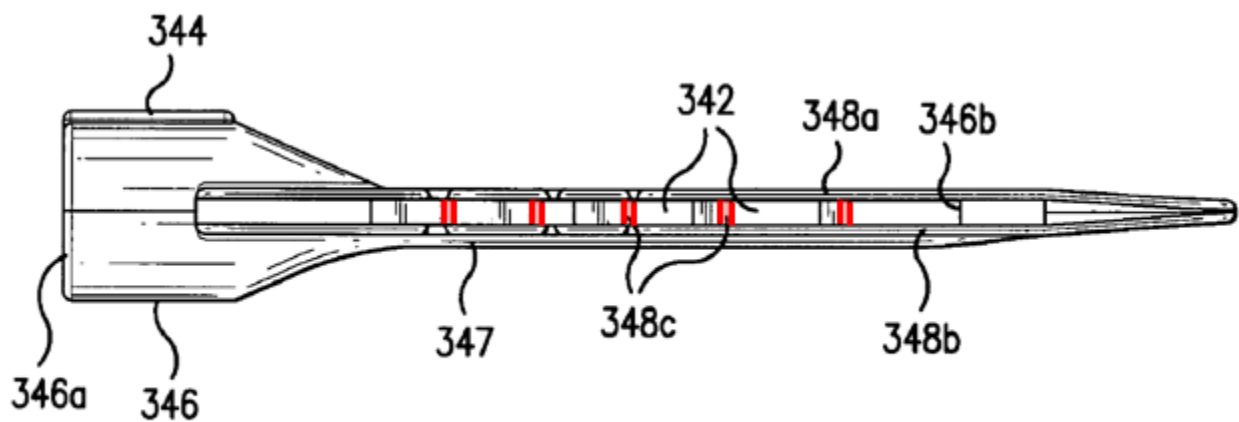


FIG.23C

114. Black expressly says that these are transverse walls 348c that are integral with both the posterior and anterior walls 348a and 348b. Ex. 1005 at

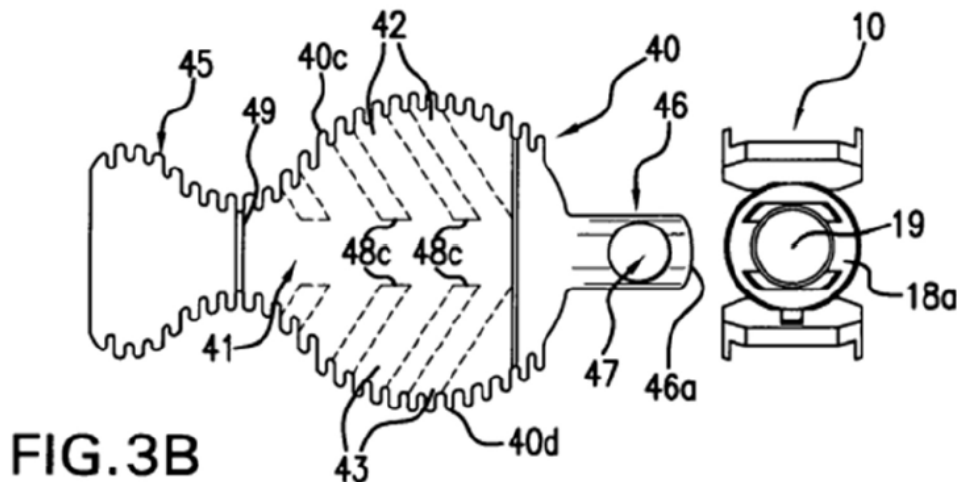
14:25-30. The '969 Patent makes clear that a "wall" and a "protrusion" are different things. Ex. 1001, 3:44-47 (describing the posterior and anterior walls), 4:53-55 (describing the "bridge structure" as a "wave-like protrusion . . . between the anterior and posterior walls). This is consistent with independent claim 19, which separately claims a "first wall," a "second wall," a the "connecting wall," then separately claims "protrusions" that protrude from the interior surface of the second wall towards the first wall. Ex. 1001 at 8:23-32.

115. Dr. Black opines 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" and that "[t]he resulting shape is necessarily a wave shape." Ex. 1003 at ¶ 99. Based on this broad interpretation of the claim language, Dr. Black opines that "Black teaches a square wave shape formed by the channels 342 and the transverse walls 348c (i.e., the presence [of – sic] transverse walls 348c and the gaps therebetween that form the channels 342)." *Id.* I disagree.

116. As discussed above, I disagree with Dr. Black's broad reading of the claim language, which renders the term "wave shape" superfluous, is inconsistent with the specification, and is inconsistent with the prosecution history of the '969 Patent and the parent '232 Patent. I therefore disagree that Black's alleged "square" shape is a "bridge structure" with a "wave shape comprising one or more

crests and one or more troughs” as required in claim 19 of the ‘969 Patent. Rather, this phrase requires that the protrusions of the bridge structure are arranged to form a pattern of curved surfaces between the one or more crests and the one or more troughs. By contrast, Black’s transverse walls 348c are all rectangular rather than “wave shaped,” and there are no “crests” that serve as contact points to the first wall during suction because Black’s transverse walls 348c are integral with both flaps 348a and 348b.

117. The Petition (but not Dr. Black) cites to FIG. 3B of Black and argues “[e]lements 42 and 43 illustrate the channels, or troughs, and element 48c illustrates the crests.” Petition at 44.



Ex. 1005 at FIG. 3B

118. I note that while the flaps have a wavy exterior edge, the transverse walls themselves, which is what Petitioner is saying is a “bridge structure,” do not.

In this figure, Petitioner is relying on elements 42 and 43 (alleged channels) and transverse walls 48c (alleged crests), which are not the “bridge structure” in claim 19 for the same reasons that the transverse walls 348c are not in the prior embodiment. Petition at 44-45.

119. Ground 1 contains several obviousness arguments, which I do not address here. None of those obviousness theories argue that it would have been obvious to modify Black to arrive at the claimed “bridge structure” under the proper claim construction.

120. For at least these reasons, I disagree with Petitioner and Dr. Black’s assertions that Black anticipates or renders obvious independent claim 19 of the ‘969 Patent.

B. Ground 2: Obviousness Based on Park, Baughan, and Johnson (Claims 1-4, 6-9, 11-12, 14, and 16-19)

121. I understand that in Ground 2, Petitioner and Dr. Black allege that claims 1-4, 6-9, 11-12, 14, and 16-19 of the ‘969 Patent are obvious over Park in view of Baughan and Johnson. Petition at 50-72; Ex. 1003 at ¶¶ 111-81. For at least the reasons discussed below, I disagree.

1. Limitations 1(h), 16(b), and 19(e) – There is No “Wave Shape” in the Park-Baughan-Johnson Combination

122. As I discussed above, independent claim 19 recites “the second wall includes a bridge structure that includes a plurality of protrusions integral with and

protruding from an interior surface of the second wall within the interior space of the pocket, 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.” Ex. 1001 at 8:30-38. Independent claims 1 and 16 include similar “bridge structure” limitations. *Id.* at 6:27-36 (claim 1), 8:1-6 (claim 16).

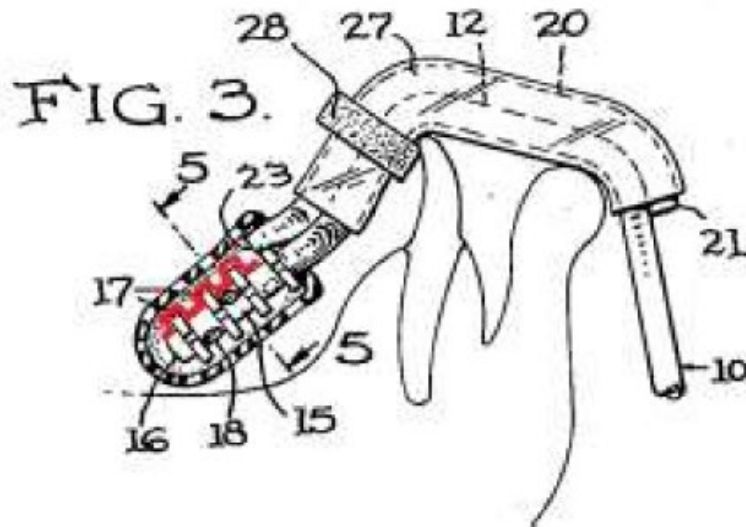
123. Petitioner and Dr. Black concede that Park does not expressly disclose a “bridge structure” as required in the independent claims of the ‘969 Patent. Petition at 57-65 (claim 1), 71 (claim 16), 72 (claim 19); Ex. 1003 at ¶¶ 131-42 (claim 1), 168 (claim 16), 178 (claim 19). For example, Petitioner concedes that “Park is silent regarding whether any structures are formed inside the interior chamber of the main body.” Petition at 58. 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 ¶ 131. I agree that Park does not disclose a “bridge structure” as required in the independent claims.

124. For element 1(h), which recites 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 65 (emphases added). Dr. Black similarly asserts that “a square wave shape is a wave-shape.” Ex. 1003 at ¶ 143.

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

126. 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 concedes, 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 65 (emphases added).



Ex. 1003 at ¶ 143 (annotating Ex. 1007 at FIG. 3)

127. In this regard, Baughan is similar to Black, which I discussed above, lacks the claimed wave-shape. *Supra*, Section VIII.A.

128. 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 ‘969 Patent” and that “the notches 19 in the disc also form a square wave shape.” Petition at 65.

Petitioner shows this with the annotation below.



Petition at 66 (annotating Ex. 1007 at FIG. 5)

129. This appears to be an alternative theory for how Black allegedly discloses a “wave shape,” but I note that Dr. Black does not address it in his declaration. Ex. 1003 at ¶¶ 143-44. In any event, to the extent Petitioner is 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. In other words, to the extent this is meant to be an alternative theory, I disagree with it for the same reasons I already provided above with respect to Baughan’s discs 17.

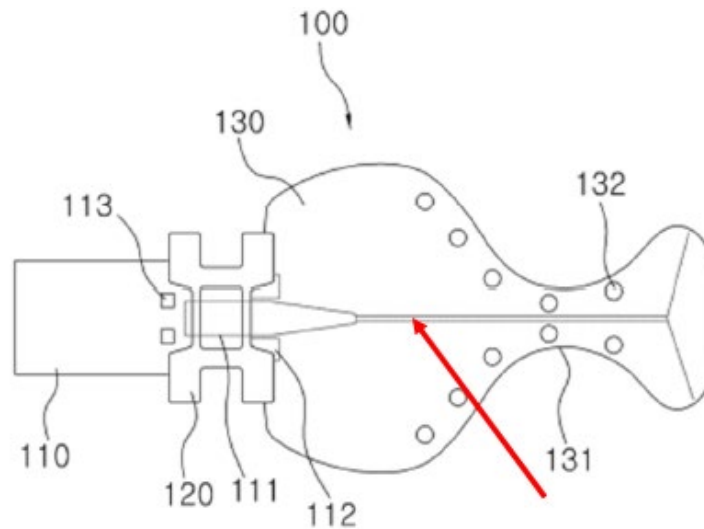
2. Limitations 1(g), 16(b), and 19(e) – a POSITA Would Not Have Modified Park with Baughan or Johnson

130. Even if the Park-Baughan-Johnson combination meets all limitations of the independent claims (which it does not), a POSITA would not have been motivated to modify Park with either Baughan or Johnson to arrive at the claimed invention.

131. 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 convention[al – sic], such as anti-collapse structure.” Ex. 1003 at ¶ 131. To the extent Dr. Black is asserting that “anti-collapse structures” were conventional in dental isolation mouthpieces prior

to the '969 Patent, I disagree and note that Dr. Black presents no evidence or analysis showing that is the case.

132. 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 ¶ 131.



133. In his analysis, Dr. Black “assumes that there is a spine running down the symmetrical axis of the mouthpiece.” Ex. 1003 at ¶ 134. 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 ¶ 182. 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 ¶ 134.

134. 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 ¶ 133 (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.

135. First, Dr. Black states that "[t]his is particularly true given how thin Park's mouth prop 100 appears." Ex. 1003 at ¶ 133. 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. The Petition admits that "Park . . . is silent regarding the thickness of its various walls." Petition at 74. Dr. Black similarly concedes that "[i]t is unclear whether the anterior and posterior walls of Park have different thicknesses." Ex. 1003 at ¶ 186.

136. 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 ¶ 133 (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.

137. For example, Ex. 2023 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.

138. I note that in analyzing dependent claim 9, which recites “wherein the cheek retractor has a surface that applies pressure when the dental mouthpiece is bent, wherein the pressure is based on resilience of a material from which the cheek retractor is formed,” 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. 1003 at ¶ 155. This confirms that the silicone material used in Park is a resilient material and is not likely to collapse under suction.

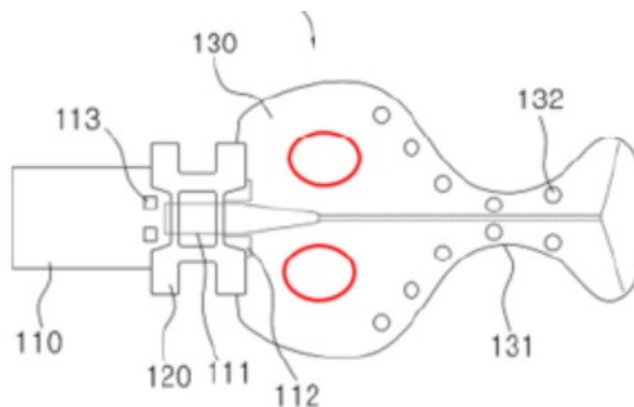
139. Petitioner and Dr. Black’s analysis demonstrates that the silicone material used in Park provides at least some rigidity and is not inherently susceptible to collapsing during suction. For example, Dr. Black asserts that Park contains “sidewalls” and that these “sidewalls would assist with preventing collapse under suction.” Ex. 1003 at ¶ 133. To the extent Park has “sidewalls,” they would be 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 ¶ 156. 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 ¶ 133.

140. As another example, Petitioner characterizes Park’s socket 111 and the insertion port 110 as “rigid structure[s].” Petition at 58. The socket 111 and the insertion port 110 are made of the same material as the walls that Petitioner and Dr. Black say would “likely” collapse under suction.

141. 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 ¶ 133. Again, the “spine” would be made of the same silicone materials as the walls.

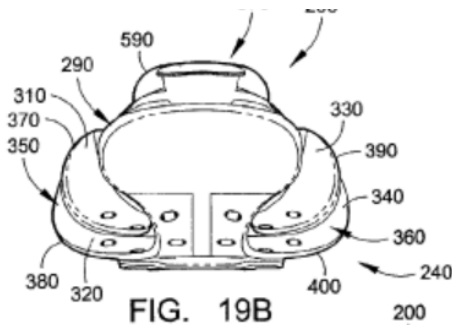
142. Each of these examples shows that, according to Petitioner and Dr. Black, Park already has rigid “anti-collapsing structure,” and that this structure comprises the same silicone material that Petitioner and Dr. Black characterize as being so flexible that the mouthpiece would “likely” collapse under 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.

143. 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 ¶ 133.

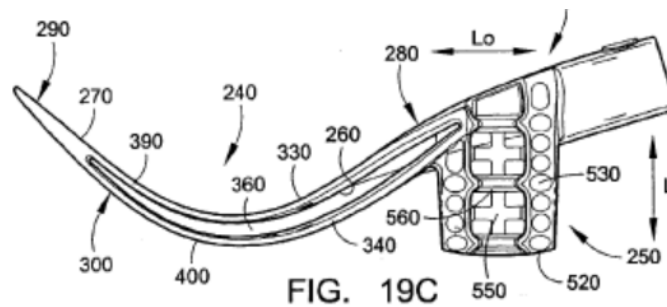


I disagree for at least the reasons discussed above – the mere fact that Park uses a “flexible” silicone material does not mean that these areas are likely to collapse under suction.

144. In connection with Ground 3, 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 ¶ 185; Petition at 74. As discussed above, Petitioner and Dr. Black concede that Park’s “sidewall” provides rigidity and constitutes “anti-collapse structure.” Ex. 1003 at ¶ 133 (“sidewalls would assist with preventing collapse under suction”). In at least one embodiment, Hirsch lacks a “sidewall.”



Ex. 1012 at FIG. 19B

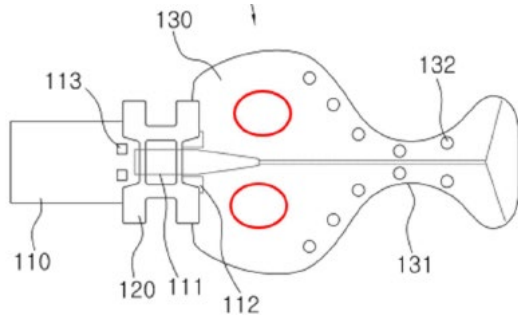


Ex. 1012 at FIG. 19C

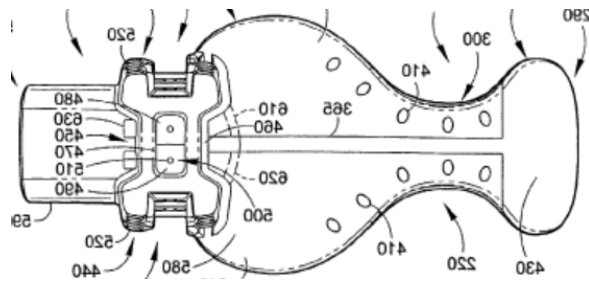
Like Park, Hirsch’s mouthpiece comprises a “translucent (e.g., transparent), flexible, soft, elastic, resilient, biocompatible thermoplastic elastomer.” Ex. 1012 at ¶ [0074].

145. 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 ¶ 185. 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.



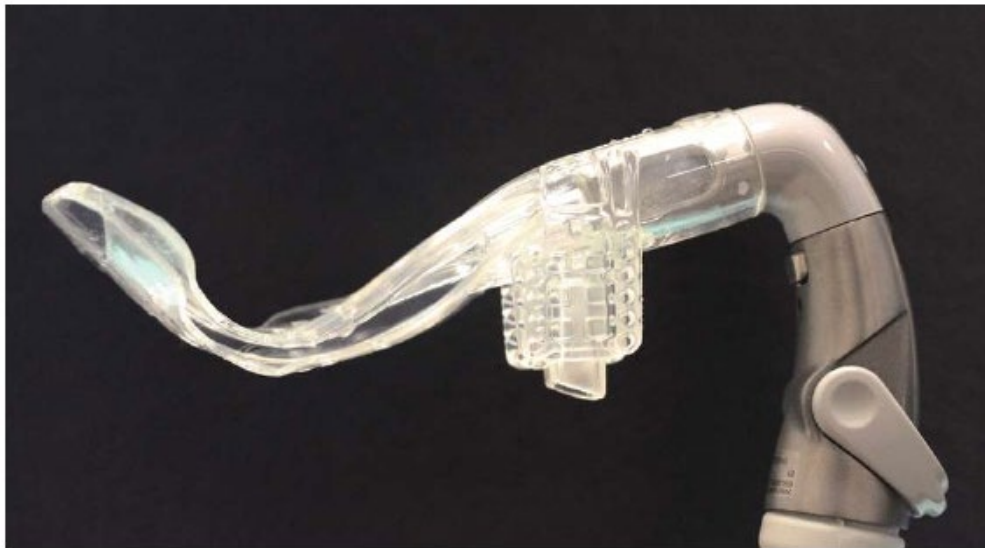
Ex. 1003 at ¶ 133



Ex. 1012 at FIG. 19E (rotated)

146. 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.

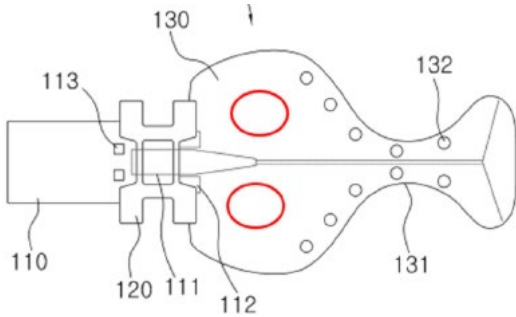
147. As another example, Dr. Black provides the photos below of a product called “Isolite” in his declaration:



Ex. 1003 at ¶ 11

148. 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 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 ¶ 133



Ex. 1003 at ¶ 11

149. 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. I also note that Dr. Black says that he evaluated the Isolite mouthpiece when developing his own patent application, but he did not report any issues with the flaps collapsing under suction in his declaration. Ex. 1003 at ¶¶ 10-18.

150. 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 58 (emphasis added). 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 59. 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 ¶ 135.

151. 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.

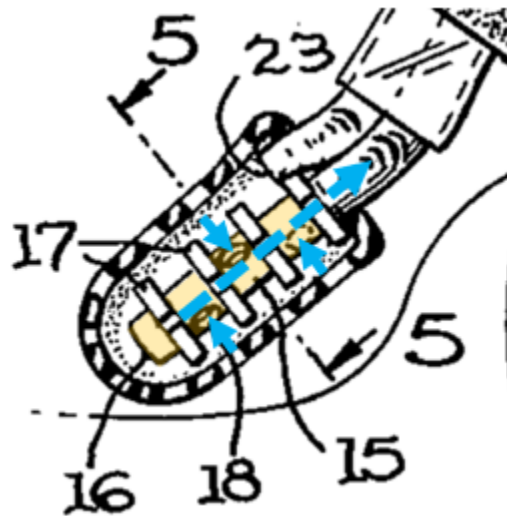
152. To the extent a POSITA were to believe that Park’s mouthpiece was likely to collapse under suction (which I disagree with), there would be other options available to a POSITA to address this problem as opposed to modifying Park’s mouthpiece to include a bridge structure. For instance, a POSITA would know if Park’s walls were too “thin,” as Dr. Black asserts, they could simply thicken the walls to reinforce them and increase rigidity. In fact, Dr. Black acknowledges this possibility in arguing that “it would have been obvious to make one of the walls [in Park] thicker” in order “to increase the rigidity of the mouth

prop 100.” Ex. 1003 at ¶ 186. 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.

153. 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.

154. Turning to the additional references relied upon in Ground 2, 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.

155. 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)

156. 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.

157. Petitioner acknowledges that Baughan uses “outward projecting discs” around the circumference of an inner cylindrical tube. Petition at 62. 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.*, 62. I disagree. The only reference Petitioner alleges teaches this feature is Johnson, which I discuss below.

158. 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 ¶ 137. This overlooks that each of the independent claims of the ‘969 Patent expressly requires that the protrusions are “integral with” the interior surface of the second wall.

159. 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.

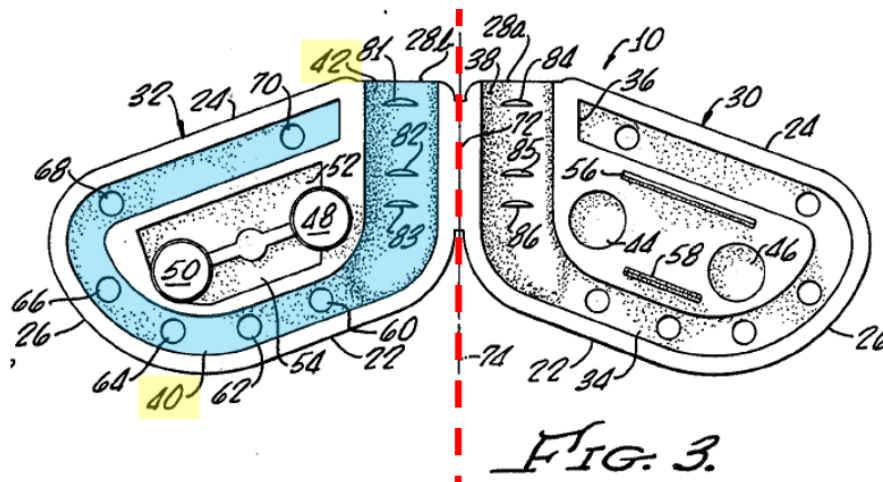
160. Again, the only other reference relied upon in Ground 2 is Johnson, which like Baughan, is not directed to a dental isolation mouthpiece. Petitioner and Dr. Black assert that Johnson “teaches that projections 81-86 are “formed on a flat surface.” Petition at 34; Ex. 1003 at ¶ 68. I disagree. Johnson’s projections are *not* formed on a flat surface; they are formed on a curved surface.

161. 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.

162. 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-*

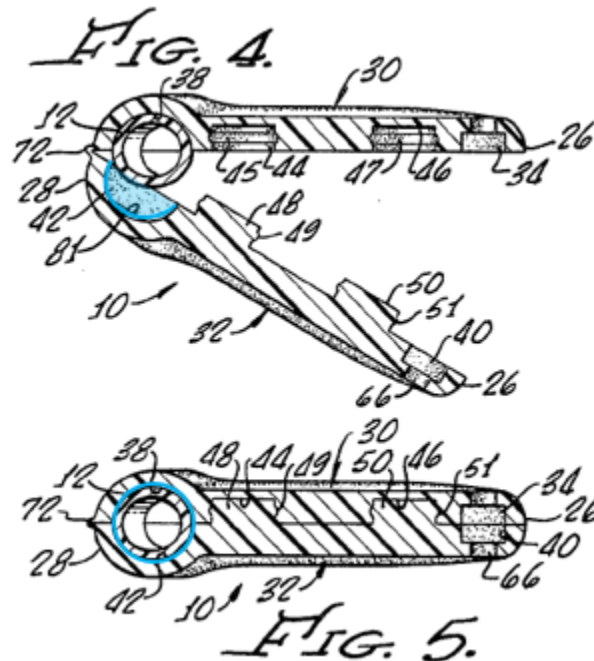
circular configuration to collectively define a circular cross-section vacuum tube receiving opening in the neck sections 28a and 28b of the neck 28 of the saliva ejector.” Ex. 1008 at 3:66-4:4 (emphasis added).

163. 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)

164. 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)

165. 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 ¶ 137. 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.

166. 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 ¶ 138. 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.

167. To this point, Dr. Black asserts that the transverse walls additionally “prevented collapse under suction.” Ex. 1003 at ¶ 138 (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.

C. Ground 3: Obviousness Based on Park, Baughan, Johnson, and Hirsch (Dependent Claim 10 Only)

168. In Ground 3, Petitioner and Dr. Black allege that dependent claim 10 of the ‘969 Patent is obvious based on Park, Baughan, Johnson, and Hirsch. Petition at 72-74; Ex. 1003 at ¶¶ 182-85. Specifically, they allege that it would have been obvious “to include the spine of Hirsch to the mouthpiece of Park.” *Id.* 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 3 for at least the same reasons I provided in connection with Ground 2.

D. Ground 4: Obviousness Based on Park, Baughan, Johnson, and Hirsch (Dependent Claims 13 and 15 Only)

169. In Ground 4, Petitioner and Dr. Black allege that dependent claims 13 and 15 of the '969 Patent are obvious based on Park, Baughan, Johnson, and Hirsch. Petition at 74-75; Ex. 1003 at ¶¶ 186-89.

170. For dependent claim 13, Petitioner and Dr. Black allege that it would have been obvious “to thicken the anterior wall of Park using the longitudinal stiffener taught by Black to prevent kinking when the mouth prop 100 was placed within an oral cavity.” Petition at 74-75; Ex. 1003 at ¶ 186. This proposed modification does not address the “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 conclusion for claim 13 in Ground 4 for at least the same reasons I provided in connection with Ground 2.

171. For dependent claim 15, Petitioner and Dr. Black allege that it would have been obvious to “include a corresponding groove/projection combination in the bite block to prevent rotation of the bite block in Park.” Petition at 75; Ex. 1003 at ¶ 189. This proposed modification does not address the “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 conclusion for claim 15 in Ground 4 for at least the same reasons I provided in connection with Ground 2.

E. Ground 5: Obviousness Based on Black and Hirsch (Independent Claim 19 Only)

172. In Ground 5, Petitioner and Dr. Black allege that independent claim 1 of the '969 Patent is obvious based Black and Hirsch. Petition at 76; Ex. 1003 at ¶ 190. Specifically, Petitioner and Dr. Black allege that if Black is found not to disclose “perforations” as claimed, then this feature would have been obvious over Hirsch. Petition at 76; Ex. 1003 at ¶ 190.

173. As I discussed above, Black fails to disclose the “bridge structure” in independent claim 19, and Petitioner and Dr. Black do not allege that Hirsch discloses this “bridge structure” in Ground 5. Petition at 76; Ex. 1003 at ¶ 190. Thus, I disagree with Petitioner and Dr. Black’s assertions in Ground 5 for at least the same reasons I provided above for Ground 1.

IX. CONCLUSION

174. 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 centered on a white rectangular background.

Date: September 18, 2025

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